

Study on the barriers to effective development and implementation of national policies on antimicrobial resistance

Final Report



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Acronyms and abbreviations

ABS	Antihiatic Stowardship
AGENAS	Antibiotic Stewardship National Agency for Regional Health Services (Portugal)
AGES	
AGES	Austrian Agency for Health and Food Safety Agency for Medicines and Health Products (Spain)
AMR	Antimicrobial resistance
AMRIC	Antimicrobial Resistance and Infection Control (Ireland)
AMS	Antimicrobial stewardship
AURES	Austrian Report on Antimicrobial Resistance
BTSF	Better Training for Safer Food
BulSTAR	Bulgarian Surveillance Tracking Antimicrobial Resistance
CDC	Centers for Disease Control and Prevention (United States)
CDPC	Centre for Disease Prevention and Control (Latvia)
CEPI	Coalition for Epidemic Preparedness Innovations
CHO	Community Healthcare Organisations (Ireland)
COM	European Commission
CPD	Continuing Professional Development
CPR	C-reactive protein
DANMAP	Danish Integrated Antimicrobial Resistance Monitoring and Research Programme
DG SANTE	Directorate-General for Health and Food Safety
DSAM	Danish College of General Practitioners
EARSS	European Antimicrobial Resistance Surveillance System
EAAD	European Antibiotic Awareness Day
ECDC	European Centre for Disease Prevention and Control
EEA	European Economic Area
EFSA	European Food Safety Authority
EMA	European Medicines Agency
EARS-Net	European Antimicrobial Resistance Surveillance Network
ESAC-Net	European Surveillance of Antimicrobial Consumption Network
ESCMID	European Society of Clinical Microbiology and Infectious Diseases
ESVAC	European Surveillance of Veterinary Antimicrobial Consumption
EU	European Union
EU-JAMRAI	European Union Joint Action on Antimicrobial Resistance and Healthcare- Associated Infections
EUR	Euro
EURGen-Net	European Antimicrobial Resistance Genes Surveillance Network
EWRS	Early Warning and Response System
EXPH	Expert Panel on Effective Ways of Investing in Health
FAO	Food and Agriculture Organization of the United Nations
GAP-AMR	Global action plan on antimicrobial resistance
GARDP	Global Antibiotic Research and Development Partnership
GLASS	Global Antimicrobial Resistance and Use Surveillance System
Glem	Groupe local d'évaluation médicale (Belgium)
GMS	General medical services
GP	General practitioner
HaDEA	European Health and Digital Executive Agency
HERA	Health Emergency and Response Authority
HAI	Healthcare-associated infection
HALT	European Point Prevalence Survey of HAIs and antimicrobial use in European
	LTCFs
HIQA	Health Information and Quality Authority (Ireland)
HOST	Hospital Outbreak Support Team (Belgium)
HSE	Health Service Executive (Ireland)
	Infection Control and Antibiotic Committees (Hungary)
ICD ID	Infection Control Department (Malta) Infectious disease
IPC	Infection prevention and control
ICT	Information and communications technology
	7

IT JPIAMR KPI LTCF MDRO MMP MRSA NAC NAP NICE OECD OIE PAPA QSI RCGP REACT-EU RIVM RMPS RRF RTI SEFAC SSTI Svebar TAFTAR TFEU TAFTAR TFEU TACSS UICF UNEP	Information technology Joint Programming Initiative on Antimicrobial Resistance Key Performance Indicator Long-term care facility Multidrug-resistant organism Medicines management programme Meticillin-resistant <i>Staphylococcus aureus</i> National antimicrobial susceptibility committee National antimicrobial susceptibility committee National action plan National Institute for Care and Clinical Excellence (UK) Organisation for Economic Co-operation and Development <i>Office International des Epizooties</i> (former WOAH) Antibiotic prescription support programme (Portugal) Quality and safety indicators Royal College of General Practitioners (UK) Recovery Assistance for Cohesion and the Territories of Europe National Institute for Public Health and the Environment (Netherlands) Register of Medicinal Products Statistics (Denmark) Recovery and resilience facility Respiratory tract infection Spanish Society of Family and Community Pharmacy Skin and soft tissue infection <i>Svensk bevakning av antibiotikaresistens</i> (Sweden) Transatlantic Taskforce on Antimicrobial Resistance (TATFAR) Treaty on the Functioning of the European Union Tripartite AMR country self-assessment survey Universal Infection Control Framework (EU-JAMRAI) United Nations Environment Programme
UTI	Urinary tract infection
WAAW	World Antimicrobial Awareness Week
WHO	World Health Organization
WOAH	World Organisation for Animal Health
ZZZS	National health insurance fund (Slovakia)

Country abbreviations

AT	Austria	IS	Iceland
BE	Belgium	IT	Italy
BG	Bulgaria	LT	Lithuania
CY	Cyprus	LU	Luxembourg
CZ	Czechia	LV	Latvia
DE	Germany	MT	Malta
DK	Denmark	NL	Netherlands
EE	Estonia	NO	Norway
EL	Greece	PL	Poland
ES	Spain	PT	Portugal
FI	Finland	RO	Romania
FR	France	SE	Sweden
HR	Croatia	SI	Slovenia
HU	Hungary	SK	Slovakia
IE	Ireland		

Abstract

The present study focuses on the barriers to the effective implementation of policies against antimicrobial resistance (AMR) in the European Union (EU) Member States, Norway and Iceland. It provides input to support the EU's overall goal to combat AMR by improving the development and implementation of One Health national action plans (NAPs) which, in turn, shall contain effective measures in infection prevention and control and prudent use of antimicrobials. The research was conducted under the following study areas: development and implementation of One Health NAPs, infection prevention and control (IPC) measures in hospitals and long-term care facilities (LTCFs); and antimicrobial stewardship measures (AMS) in hospitals, LTCFs, primary care and pharmacies.

The research revealed some common problems across all countries, such as insufficient funding to deliver on the measures foreseen in the NAPs, the shortages of qualified staff at all levels of care, the lack of measures targeting LTCFs specifically, the limited involvement of pharmacies in AMS, and the disruptions caused by the COVID-19 pandemic in the health sector. The barriers affect each country differently but they are nevertheless common to all, independently of their size and socio-economic situation. Other barriers identified include: limited political focus and awareness of the challenges brought by AMR; lack of operational plans for delivering on the NAPs; lack of harmonised indicators for monitoring the implementation of plans; limited coverage of AMR, AMS and IPC in education and training; and limited public awareness of AMR.

Résumé

La présente étude porte sur les obstacles à une mise en œuvre efficace des politiques de lutte contre la résistance aux antimicrobiens dans les États membres de l'Union européenne (UE), en Norvège et en Islande. Elle soutient l'objectif global de l'UE de lutte contre la résistance aux antimicrobiens, en améliorant le développement et la mise en œuvre des plans d'action nationaux (PAN) fondés sur le principe « Une seule santé » qui contiennent, à leur tour, des mesures efficaces de prévention et de lutte contre les infections et d'utilisation prudente des antimicrobiens. La présente recherche a été menée dans les domaines d'étude suivants : développement et mise en œuvre des plans d'action nationaux fondés sur le principe « Une seule santé », mesures de prévention et de lutte contre les infections dans les hôpitaux et les établissements de soins de longue durée et mesures de promotion du bon usage des antimicrobiens dans les hôpitaux, les établissements de soins de longue durée, dans le cadre des soins primaires et dans les pharmacies.

L'étude a révélé des problèmes communs à tous les pays, tels qu'un financement insuffisant pour la mise en œuvre des mesures prévues dans les plans d'action nationaux, la pénurie de personnel qualifié à tous les niveaux de soins, l'absence de mesures ciblant principalement les établissements de soins de longue durée, la participation limitée des pharmacies aux mesures de promotion du bon usage des antimicrobiens et les perturbations causées par la pandémie de COVID-19 dans le secteur de la santé. Ces obstacles affectent chaque pays différemment, mais tous les pays, sans condition de taille et de situation économique, doivent tout de même y faire face. Parmi les autres obstacles identifiés, on retrouve : un intérêt politique et une connaissance limités des défis engendrés par la résistance aux antimicrobiens ; l'absence de plans opérationnels pour la mise en œuvre des plans d'action nationaux ; le manque d'indicateurs harmonisés en matière de suivi de la mise en œuvre des plans ; une attention limitée accordée à la résistance aux antimicrobiens, aux mesures de promotion du bon usage des antimicrobiens et à la prévention et à la lutte contre les infections au sein de l'éducation et de la formation et une sensibilisation faible de l'opinion publique à la résistance aux antimicrobiens.

Executive summary

Context

It is estimated that each year in the European Union/European Economic Area (EU/EEA), over 670 000 infections are due to bacteria resistant to antibiotics¹, which result in approximately 35 000 deaths. Some bacteria have developed resistance to multiple drugs.²

Inappropriate or unnecessary use of antibiotics in humans and animals are highly prevalent in the emergence of antimicrobial resistance (AMR). Globally, human antibiotic consumption is rising. Recent estimates show that at least 1.27 million deaths per year are currently directly attributable to AMR. AMR worsens health outcomes for patients and may lead to health complications and in some cases even death. It is projected that if AMR is not curbed by 2050 it might rise to 10 million deaths per year, becoming a more common cause of death than cancer. AMR also results in higher costs to the healthcare system associated with longer hospital stays and more costly treatments due to the use of more expensive drugs.

The European Commission supports efforts at international level being led by the United Nations and has long been at the forefront in the fight against AMR in Europe. The first Community strategy against AMR was adopted in 2001. Ten years later, the first EU One Health³ Action Plan against AMR was developed. In 2017, the Commission adopted a renewed Action Plan, which guides current EU actions in AMR. The plan is structured along three pillars: (1) making the EU a best-practice region; (2) boosting research, development, and innovation; and (3) shaping the global agenda. In 2019, the Council of the European Union adopted conclusions on the next steps towards making the EU a best-practice region in combatting AMR.

The present study aims at supporting the preparation of future policy initiatives on AMR and the implementation of the EU One Health Action Plan against AMR. It provides a detailed analysis of the existing barriers faced by 29 countries (EU Member States, Norway and Iceland) to the development and effective implementation of:

- national One Health action plans to address AMR (Study Area 1)
- effective infection prevention and control measures in human health (Study Area 2)
- effective antimicrobial stewardship measures in human health (Study Areas 3 and 4)

The study covers the barriers existing at institutional/ policy level, including financial barriers; the barriers existing at clinical level (e.g., in relation to clinical guidelines/practices); and at behavioural level (e.g., behaviours and practices of healthcare professionals, patients, etc.). The study also identifies ways to overcome the barriers, and good practices.

Methodology

The study included the following data collection activities:

• literature review;

¹ ECDC and WHO. 2022. Antimicrobial resistance surveillance in Europe 2022 – 2020 data. Available at <u>https://www.ecdc.europa.eu/sites/default/files/documents/ECDC-WHO-AMR-report.pdf</u>

² European Centre for Disease Prevention and Control. Assessing the health burden of infections with antibiotic-resistant bacteria in the EU/EEA, 2016-2020. Stockholm: ECDC; 2022. Available at <u>https://www.ecdc.europa.eu/sites/default/files/documents/Health-burden-infections-antibiotic-resistant-bacteria.pdf</u>

³ The "One Health" approach recognises that the health and well-being of humans, animals and ecosystems are interconnected. It applies a coordinated, collaborative, multidisciplinary, and cross-sectorial approach to address potential or existing risks that originate at the animal-human-ecosystem interfaces.

- in-depth interviews with stakeholders at EU and national level;
- targeted surveys of relevant groups of stakeholders; and
- a virtual workshop with stakeholders.

The study engaged a total of 473 stakeholders through the consultation activities.

The study's results have the following limitations:

- the amount and quality of evidence is variable across countries and study areas;
- the inventory of barriers to effective AMR policies is non-exhaustive;
- an assessment of the magnitude of the barriers in the different countries was beyond the scope of the study;
- the focus is on measures that can be put in place at EU level to help Member States address the barriers; other measures can and should be taken by Member States themselves since health is a national competence.

Findings

National One Health Action Plans

NAPs are in place (or are in the process of being reviewed/updated) in 28 of the 29 study countries), with most following a One Health approach. However, the implementation of the NAPs across Europe is very diverse. Moreover, many NAPs focus on the human and animal health sectors and tend to leave out or not cover the environmental dimension sufficiently.

There are barriers to the development of NAPs at the policy and institutional level, such as a limited political focus on developing, updating or approving the NAPs; deficiencies in the design of the NAPs (in particular, plans stay at a strategic level and are not translated into concrete operational plans); lack of or insufficiently developed monitoring systems to track progress on the implementation of the NAPs; and limited funds to allocate to the drafting of NAPs.

Institutional and policy barriers have also affected the implementation of NAPs. These include the lack of or insufficient inter-ministerial government structures to support NAPs implementation and cross-sectoral coordination of measures; and lack of dedicated funding for the implementation of NAPs. In terms of clinical barriers, the data needed for a systematic monitoring and surveillance of AMR and antimicrobial consumption present gaps, heterogeneity and fragmentation. As expected, the COVID-19 pandemic caused disruption, reprioritisation, and delays in the implementation of NAPs.

Within the scope of EU competence in health, the study suggests areas for EU action to help the Member States in overcoming the identified barriers, as follows:

Issue	Proposed supporting measures
Overcome deficiencies in the design of NAPs, reinforce the One Health approach and support NAPs implementation	Provide guidance and a support structure for the development/ renewal and implementation of NAPs.
Overcome issues related to	Promote the establishment at national level of One Health
limited cross-sectoral collaboration	structures or cooperation mechanisms on AMR.
Overcome issues related to insufficient dedicated funding	Provide specific (co)funding and signpost existing EU financial instruments that could be used in fighting AMR.
Overcome issues related to limited monitoring of the implementation of NAPs	Support Member States in monitoring progress in the implementation of NAPs by defining a harmonised list of indicators.

Improve Member States' surveillance systems	Support extension, frequency and further harmonisation of data collection methodologies and indicators on AMR and human and veterinary antibiotic consumption, as well as monitoring data on zoonoses and food and waterborne diseases.
Support Members States in implementing their NAPs	Promote peer support, expert exchanges and twinnings, while encouraging follow-up on findings from country visits and EU- funded projects. Support the provision of training activities.

The study also identified examples of good practices in the development and implementation of One Health NAPs:

Area	Country/ies	Good practice
Cross-sectoral exchange of progress and good practices	Ireland	Conference bringing together stakeholders from all sectors participating in the NAP (human and animal health and the environment). The conference goal was to share progress and exchange knowledge and good practices between sectors.
	Denmark	The National Antibiotic Council organised the collection of good, concrete experiences with initiatives involving healthcare workers, educators, doctors, nurses, and others. The efforts are presented in a catalogue "20 ways to use fewer antibiotics".
	France	The PROMISE project is a One Health professional meta-network on antibiotic resistance, which brings together 21 national networks and over 40 academic partners.
Evidence of political support for combating AMR	Portugal	AMR and infection control were designated as a Priority Public Health problem.
	Ireland	The Antimicrobial Resistance and Infection Control Division (AMRIC) was created to give policy direction and strong guidance and leadership to the AMR agenda.
	France	A high-level AMR leader position has been created within the Ministry of Health to coordinate actions across the One Health sectors.
Dedicated AMR teams at sub- national/local level	Lithuania	AMR management teams, established in 10 regions in 2015, conduct awareness-raising campaigns on antibiotic use and antibiotic resistance for public healthcare professionals, the general public, educational institutions, veterinarians and animal farmers.
Support to the implementation of the NAP	Italy	The SPiNCAR project supported the implementation of the Italian NAP to combat AMR by identifying and agreeing on national standards to drive prevention, management, and control of AMR at community and hospital level.
EU-funded components of NAP and bilateral support	Sweden and Latvia	In the framework of the EU Structural Reform Support Programme, an expert mission of the Swedish Board of Agriculture and the Public Health Agency of Sweden worked with their Latvian counterparts from the Ministry of Health and the Ministry of Agriculture to share

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		knowledge and provide training to trainers and
		training toolkits.
	Norway,	The Norwegian Institute of Public Health
	Romania and	cooperated as a project partner with Czechia
	Czechia	(Antibiotic Resistance Prevention Project to
		stop the rise in antibiotic consumption in the
		community) and Romania (development of the
		NAP, three guides and a methodology for
		reporting infections associated with medical
		assistance).
Systems for improved	Denmark	The Danish Integrated Antimicrobial Resistance
surveillance and monitoring	2 01110111	Monitoring and Research Programme
across the One Health sectors		(DANMAP) is a successful model for One
		Health integrated surveillance. It was
		established by the Danish Ministry of Food,
		Agriculture and Fisheries and the Danish
		Ministry of Health in 1995. The monitoring of
		antimicrobial resistance is based on three
		categories of bacteria: Human and animal
		pathogens, zoonotic bacteria, and indicator
		bacteria.
	Portugal	The quality index (PPCIRA-IQ) was created as
		a programme monitoring tool. The index uses
		several monitoring indicators to support
		benchmarking, which also create an incentive-
		mechanism for compliance by healthcare
		institutions. The index is created by obtaining
		data and indicators, per hospital institution, on
		hospital consumption of antibiotics, AMR, and
		HAIs. The PPCIRA-IQ is composed of the
		following variables: antimicrobial consumption;
		antimicrobial resistance; IPC practices; and
		epidemiological surveillance.
	Czechia	The introduction of innovative software for
	02001110	electronic (automated) data processing and
		transmission is one of the objectives of the NAP.
		In this context, scientists from the Veterinary
		Research Institute ⁴ are working closely with
		institutions such as the Institute for State
		Control of Veterinary Biopreparations and
		Medicines ⁵ to develop an application to
		digitalise veterinary records.
		As part of the NAP, an annual evaluation of the
		results of the National AMR Monitoring
		Programme for Veterinary Pathogens was
		carried out between 2016 and 2021.
		The NAP has an objective to establish a
		framework for monitoring AMR-resistant
		bacterial strains in soil, and possibly other parts
		of the environment, as well as residues of
		pharmaceutical substances used in livestock
		farming, which incur environmental risks. The
		NAP also proposes the incorporation of AMR

⁴ See: <u>https://www.vri.cz/en/900-2/</u>

⁵ See: <u>https://www.uskvbl.cz/en</u>

	monitoring issues into the soil-monitoring programme in Czechia. A series of reports ⁶ have been prepared addressing this objective, which include the optimisation of the methodology and determination of enrofloxacin residues in the required matrices (medicated water, treated broiler litter, soil with treated animal litter and soil with enrofloxacin enriched litter).
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Infection prevention and control measures in hospitals and long-term care facilities

The stakeholder consultation showed that, in general, IPC guidelines and legislation were generally developed at the national or regional level in the study countries, and that healthcare facilities develop their IPC programmes and measures based on these guidelines. Common measures in place include the established multidisciplinary technical group for surveillance of healthcare-associated infections (HAIs) and IPC monitoring and the existence of a strategic plan for HAI surveillance and for monitoring of IPC indicators.

In relation to hospitals, an important research finding is that, while there is legislation making IPC mandatory in most countries, this is not fully implemented and few countries have, for example, defined the composition of IPC teams. The monitoring of compliance of IPC programmes however is very diverse across hospitals, as well as annual reporting of indicators. There are countries where hospitals report about HAIs annually, but routine reporting of cases of multidrug-resistant organisms (MDROs) is variable across countries. Finally, it was noted that across study countries, IPC measures in hospitals are often perceived as an issue of hygiene and not necessaily related to a more comprehensive approach towards patient safety.

The situation is even more heterogeneous across the study countries when looking at longterm care facilities. Generally, the responsibility for LTCFs sits across different authorities (welfare, labour, pension, family and social policy). There is also variability regarding the definition of LTCFs. In this context, IPC is usually limited to some basic hygiene requirements, seasonal vaccination and disinfection of medical devices. In addition, there are no measures addressing AMR specifically, although LTCFs have been identified as important reservoirs of MDROs. Several guidelines to implement measures to prevent the transmission of MDROs have been reported, however they focus mainly on the hospital setting, not in LTCFs.

At institutional and policy level, the barriers affecting the development and implementation of IPC measures in hospitals include a weak monitoring or auditing of healthcare facilities by national authorities to ensure compliance of existing national IPC guidelines and/or legislation; and a lack of harmonised indicators for monitoring and evaluating IPC measures. There are also technological or methodological barriers, which include limitations in the methodologies or information systems in place at national or facility level to collect, process and use surveillance data. Clinical barriers include the variability of IPC practices across hospitals relating to hospital management approaches towards productivity and patient safety; limited testing capacity to detect and control cases of infection; and suboptimal interaction and/or information exchange between IPC practitioners and laboratories. Across the study countries, the research identified some behavioural issues leading to a low adherence to IPC practices: shortages of staff, especially of motivated and qualified staff; limited awareness or understanding of IPC as essential to patient safety; and limited financial resources. Limited coverage of AMR and IPC in the undergraduate

⁶ See: <u>https://eagri.cz/public/web/file/691658/Zprava_AMR_2021_FINAL_s_tit.pdf</u>

education of healthcare professionals was also signalled as a behavioural barrier in hospitals.

In long-term care facilities, an important institutional or policy barrier impacting on the implementation of IPC measures is the variable governance of long-term care. Depending on the countries' organisation of their health and social care systems, long-term care may be a national, regional, or local competence, may fall under the scope of health, social services or both, and may be provided by public or private organisations or at home. Other institutional barriers include the lack of or limited implementation of dedicated IPC programmes or operational plans for LTCFs; and no systematic surveillance of HAIs in LTCFs. Clinical barriers include the old and poor infrastructure of LTCFs. Long-term care suffers from both a general shortage of staff and, in particular, of staff with qualifications in IPC, especially of nurses. Lack of or limited dedicated financial resources for the implementation of IPC measures also affect LTCFs. In terms of behavioural barriers, adherence to IPC programmes and guidelines is significantly lower than in hospitals.

the proposed areas for EU action to help the Member States in overcoming the identified barriers are outlined in the table below:

Issue	Proposed supporting measures	
Strengthen IPC in LTCFs	Ensure that the development and implementation of IPC	
	measures in LTCFs features as a priority in Member States	
	new/updated NAPs.	
Develop and update national	Promote the timely revision and update of national IPC guidelines.	
IPC policies in Member	Continue developing and promoting the ECDC's directory of	
States	online resources for prevention and control of AMR and HAIs. Define, with the support of experts, a set of common outcome	
	indicators and guidelines for the monitoring and evaluation of IPC	
	measures in hospitals and LTCFs.	
	Promote the integration of IPC-related key performance indicators	
	(KPIs) to healthcare facilities' decisions on funding and staff	
	performance assessments, for example through the identification	
	and dissemination of good practices in this area.	
Address structural barriers	Advise Member States on existing EU sources of (co)-funding.	
(e.g., lack of funding and	Use existing and future EU funds to support IPC/patient safety	
skilled human resources)	efforts in Member States.	
	Promote IPC mainstreaming in Member States' undergraduate,	
	postgraduate, and vocational education and training programmes.	
	Continue funding, delivering and promoting training opportunities on IPC (and AMR more generally) targeting national policy-	
	makers and healthcare professionals.	
Enhance awareness of the	Continue delivering public awareness campaigns aimed at	
importance of IPC measures	establishing a culture of patient safety.	
to combat AMR in Europe	5 1 ,	
Exchange good practice and	Create or support existing fora for the sharing of good practices in	
learning between Member	IPC.	
States	Promote/ fund the establishment of IPC networks at national level.	
Strengthen surveillance and	Develop a framework for strengthening epidemiological	
research	surveillance across the EU, especially surveillance of MDROs.	
	(Co-)fund IPC research activities.	

As in the previous study area, the research identified examples of good practices in relation to IPC measures:

Area	Country/ies	Measure
Mainstreaming patient safety	Ireland	The prevention of HAIs is part of the patient
approaches		safety programme of the Health Service
		Executive (HSE). In addition, the NAP

[1	
		established a back-to-basics approach focusing on hand hygiene, standard precautions and the prevention of infections associated with medical devices. There is also a dedicated team (AMRIC Team) that provides leadership for AMR and IPC in the health sector by developing and publishing clinical guidance for patient and client care (in collaboration with stakeholders); providing education, training, and resources to implement this guidance; and providing specialist advice and support to services.
Functioning of multidisciplinary IPC teams	Malta	The main hospital in the country launched a hospital wide AMR Strategy in 2010. It also has a multidisciplinary Infection Control Department (ICD) with dedicated resources, support from the local authorities, and an effective infrastructure for surveillance. The Department coordinates all activities related to the prevention and control of HAIs in the hospital.
Networks of hospitals/ professionals for strengthening IPC	Belgium	The Hospital Outbreak Support Team (HOST) pilot projects were established in 2021 in the framework of the implementation of the NAP and in the context of the COVID-19 pandemic. The HOST pilot projects are aimed at strengthening IPC and AMS in hospitals, LTCFs and primary care through the establishment of networks of hospitals at regional level. The projects are developed through two complementary axes: on the one hand, a local- regional approach based on cooperation between hospitals, and on the other hand, a cross-cutting approach where the expertise of hospitals is made available to both residential facilities and other healthcare providers.
Integration of IPC into construction and renovation of acute hospital structures	Ireland	The HSE has produced guidance addressing the role of IPC in renovations and construction of acute hospitals. There are also building standards for new primary care centres that include IPC related concerns, including material choice, space, and design of sinks, among other requirements.
Strengthening IPC in LTCFs with the support of EU funding	Estonia	Since 2020, the supervision of residential LTCFs is organised by the Social Insurance Fund in cooperation with the Health Board and the State Agency of Medicines. The Social Insurance Fund uses contracted infection commissioners to monitor and advise, with the aid of funds from the European Commission's Recovery Assistance for Cohesion and the Territories of Europe (REACT-EU) programme.
Hand hygiene campaigning	Denmark	The Copenhagen Municipality's home care has developed a 'Monday kit' with tools for nail care, which is handed out to employees to focus their attention on preventing the spread of infection. The 'Monday kit' contains nail cleaners, acetone, cotton pads, nail clippers and a safety pin for jewellery and watches. This is to create a better understanding of the importance of

	sufficient hand hygiene to avoid the spread of
	infections.

Antimicrobial stewardship measures in hospitals and long-term care facilities

Antimicrobial stewardship in hospitals is covered in most of the countries' NAPs on AMR. However, to date there has been limited monitoring of the extent of the implementation of AMS measures as part of the NAPs.

While there are examples of local AMS committees that have been set-up in hospitals, the availability of AMS teams or staff with AMS specialists is generally limited across the study countries, even when their set-up is specified in national or regional action plans.

AMS measures in LTCFs are in a very early stage of development in most of the study countries or do not exist at all. As in the area of IPC, the development and implementation of AMS is challenged by the large number of LTCFs and the heterogeneity of their governance and administration. When AMS measures are implemented, they tend to depend on the proactivity and commitment of individual GPs or nurses, without national/ facility coordination. Data from the European Point Prevalence Survey of HAIs and antimicrobial use in European LTCFs (HALT-3) showed that 28.5% of the surveyed LTCFs did not have any of the ten specified antimicrobial stewardship elements in place.

In terms of barriers affecting the development and implementation of AMS measures in hospitals, these include the limited political focus on AMS, which is often not considered a priority; lack of national AMS strategies or operational plans for hospitals; lack of dedicated funds for AMS measures in hospitals; difficulties in implementing AMS measures and harmonising prescription practices within and between hospitals.

There are also technological/ methodological barriers including the absence of integrated information systems and data on prescriptions of antimicrobials. Paper-based prescribing in hospitals inhibits the easy monitoring of antimicrobial prescriptions in several countries. Another important barrier are the logistical delays in receiving laboratory results. Clinical barriers include the absence of evidence-based guidelines for the treatment of common infections, either because they do not exist at all or they are not known by health professionals; shortages of specialised staff; and the limited education and training of health professionals in AMS. There are also supply shortages and limited availability of narrow-spectrum antimicrobials. Finally, an important behavioural barrier is the pressure from patients to medical doctors to be prescribed antibiotics.

Institutional and policy barriers to effective AMS in LTCFs include the lack of AMS regulations covering these types of facilities, coupled with the fact that generally they are not included in NAPs or national AMS strategies. This results in the limited development of AMS programmes or operational plans addressing LTCFs, and the lack of, or inadequate, monitoring mechanisms. Clinical barriers include the lack of specialised staff in LTCFs and the fact that usually residents are treated by off-site GPs. Staff in LTCFs have diverse educational backgrounds, topped with general shortages of GPs and nurses across many of the study countries.

Issue	Proposed supporting measures
Developing and updating	Encourage Member States to include AMS programmes and
national AMS policies in	goals in their One Health National Action Plans and/or their
Member States	related national policies and strategies.
	Support Member States in prioritising AMS measures.
	Facilitate collaboration and sharing of good practices among EU
	Member States.

The proposed areas for EU action to help Member States in overcoming barriers to effective AMS in hospitals and long-term care facilities are outlined in the table below:

Addressing structural barriers	Advise Member States on the possibility of using several sources
such as the lack of funding	of EU funding for addressing structural barriers affecting the
and skilled human resources	implementation of AMS in hospitals and LTCFs.
	Promote training and specialisation in AMS among health
	professionals, including medical and non-medical staff.
Providing further support in	Continue developing and promoting the ECDC's directory on
the implementation of AMS	Antimicrobial Stewardship. ⁷
measures	Establish a set of indicators for monitoring AMS in hospitals and
	LTCFs at EU level.
Enhancing awareness of the	Work closely with Member States to support specific awareness
importance of AMS measures	campaigns aimed at enhancing the importance of AMS.
to combat AMR	
Strengthening research in	Foster research in AMS to show its effectiveness.
Member States	

The study also identifies examples of good practices in the implementation of AMS measures in hospitals and LTCFs:

Area	Country/ies	Measure
Implementation and monitoring of the impact of AMS practices in hospitals	Netherlands	The National and regional antibiotic guidelines in the Netherlands have been published and monitored by the Dutch Working Party on Antibiotic Policy (SWAB). Based on the SWAB guidance, regional antibiotic working groups have developed regional guidelines on antibiotic prescriptions tailored to the needs of their hospitals. The advantage of the approach is that patients are being treated similarly even if they are transferred to other hospitals within the region. At the same time, the regional approach divides the work and makes it easier
	Czechia	to ensure that the guidelines are up-to-date. The University Hospital Olomouc monitored the work of the hospital's antibiotic centre and presented the outcomes of the activity over a period of 10 years (2010-2019). ⁸ The data suggest low rates of bacterial resistance at the hospital, because of comprehensive antimicrobial stewardship measures implemented.
	Croatia	The General Hospital Koprivnica implemented a cohort study to rationalise the use of last line antibiotics. The study was designed to address the growing number of antibiotics reserve consumption. The results presented a reduction of duration of hospitalisation of patients in the intervention period by nearly 40%.
	Sweden	AMS ward rounds led by infectious disease (ID) specialists who give advice on antibiotic

⁷ See: <u>https://www.ecdc.europa.eu/en/publications-data/directory-guidance-prevention-and-control/prudent-use-antibiotics/antimicrobial</u>

⁸ Kolar, M.; Htoutou Sedlakova, M.; Urbanek, K.; Mlynarcik, P.; Roderova, M.; Hricova, K.; Mezerova, K.; Kucova, P.; Zapletalova, J.; Fiserova, K.; et al. Implementation of Antibiotic Stewardship in a University Hospital Setting. Antibiotics 2021, 10, 93. <u>https://doi.org/10.3390/antibiotics10010093</u>

		treatment are standard practice in Swedish
		intensive care units, oncology, haematology,
		and other highly specialised units that cater for
		patients who are at high risk for complicated infections.
	Denmark	The OptiCAP project in Denmark includes
		several interventions in selected hospital
		departments where attempts have been made
		to reduce unnecessarily long antibiotic
		treatment of patients with pneumonia.
AMS support to health and care	France, Italy,	France: AMS hotline
professionals	Sweden,	Portugal: Antibiotic prescription support
	Denmark	programme (PAPA)
		Italy: Ad-hoc repository of validated good
		practices.
		Sweden: Local Strama (strategic programme
		against antibiotic resistance) groups and
		network meetings
		Denmark: Regional working group advising on
		antibiotic policy.
		Ireland: Online repository of resources for
		residential care facilities and nursing homes
Development of AMS	Slovenia	Small Red Guidebooks for prescribing of
guidelines and		antibiotics in hospitals and primary care
recommendations		settings, published in 2002 and 2007, have
		been transferred to a computer application and
	Latio	a mobile app, called Quiba.
	Latvia	The Children's University Hospital developed
		recommendations for the use of antimicrobials
		in surgical prophylaxis with the aim of reducing
		the risks of surgical site infection.
		The Pauls Stradiņš Clinical University Hospital also developed its own internal
		also developed its own internal recommendations for the responsible use of
		antimicrobials. The guidelines describe when
		antimicrobial therapy should be used, the principles of rational choice of agents, and the
		conditions that should be assessed before
		prescribing antibiotics.
	Denmark	The Region of Central Jutland developed and
	Donnark	implemented prescription packages in
		hospitals. These compile the standardised
		operating procedures related to prescription to
		make it easier to follow the approved guidelines
		for the use of antibiotics.
Surveillance systems	Sweden	Svebar is a national surveillance system for
		cumulative antimicrobial susceptibility data in
		which 22 out of 26 clinical microbiology
		laboratories participate. The information
		collected covers around 90% of the Swedish
		population and allows for early detection and
		subsequent appropriate AMS efforts.
Training on AMS	Germany	Several AMS trainings are provided by the
		German Medical Association, the German
		Society for Infectiology and the German Society
		for Hospital Hygiene.
L		

Antimicrobial stewardship measures in primary care and pharmacies

Primary care GPs/family physicians and community pharmacies are often the first point of contact with the healthcare system. GPs also function as the 'gate-keeper' of the system in many of the study countries, requiring referral for access to secondary and other care. The volume of antimicrobials prescribed in primary care is high compared to secondary care in most countries. Thus, these healthcare professionals have an important role in managing symptoms of infection, enhancing patients' knowledge of the adequate use of antibiotics, and shaping patients' behaviours.

Across the study countries, there is variability in quality of surveillance for community antimicrobial consumption and appropriate use of antibiotics, and in terms of opportunities for feedback and learning for primary care doctors. In community pharmacy, while most countries have legislation to prevent over the counter sales of antibiotics, enforcement of such legislation is variable.

There are several institutional and policy barriers to the development and implementation of AMS measures in primary care. Primary care is generally omitted in NAPs or is mentioned briefly. There is also limited awareness of NAPs by primary care professionals and a lack of a regulatory framework on AMS. There is insufficient dedicated funding to develop and/or implement AMS measures in primary care and insufficient or inadequate monitoring or auditing of prescribing and dispensing practices by national or regional authorities. Clinical barriers include the lack of primary care specific guidelines for management of infections and limited awareness of GPs of national and international guidelines on antimicrobials use. This results in heavy reliance on clinical experience for antimicrobial treatment (empirical prescribing), which is reinforced by the absence of or limited evidence-informed diagnostic (testing). There are also several human resources and staffing issues affecting AMS that are multifaceted and often occur simultaneously (lack of specialised staff and lack of education and training on AMS, time constraints, ageing doctors). There are also some important behavioural barriers, such as limited interaction and/or communication between the different stakeholders involved in the implementation of AMS in primary care, including pharmacies and laboratories, in addition to complex systems of competences between multiple authorities. There are low levels of awareness and health literacy associated with antibiotic use and antimicrobial resistance among the public, even if it has been improving across the EU. As with hospital doctors, this translates into increased pressure from patients to be prescribed antibiotics, which is coupled with the fear from GPs of leaving patients untreated and developing infectious complications. There is also low adherence from patients to treatments as indicated by their doctors.

In relation to pharmacies, institutional and policy barriers include the limited or absence of explicit mention of community pharmacies in NAPs and the lack (in some countries) of a pharmacy policy or strategy around medicines use or optimisation. There are also market-related barriers such as shortages and outages of narrow-spectrum antibiotics; an inadequate pricing policy of antimicrobials that does not limit access to or prevent excessive consumption of antibiotics and over-packaging of antibiotics in the market. The research also found limited or lack of clarity on the role of pharmacies in combating AMR and lack of training in this area. Behavioural barriers also affect AMS in pharmacies. Despite legislation, dispensation of antibiotics without a prescriptions is common in some study countries.

The proposed areas for EU action to help Member States in overcoming barriers to effective AMS in primary care and pharmacies are outlined in the table below:

Issue	Proposed supporting measures
Effective monitoring of	Support the adoption or enhancement of auditing and feedback
antimicrobials prescriptions	mechanisms on the prescription of antimicrobials by primary care
and consumption in primary	doctors.
care	

Strongthoning AMS in	Decommand provide guidenes and manitar that One Health
Strengthening AMS in primary care and pharmacies	Recommend, provide guidance and monitor that One Health NAPs, and/or their related national policies and strategies, include
	AMS programmes.
	Promote existing AMS guidelines and support the creation of new
	ones.
	Support Member States in exploring ways to leverage quality
	prescribing through reimbursement models for healthcare
	providers.
Addressing structural	Advise Member States on the possibility of using several sources
barriers, such as lack of	of EU funding for addressing structural barriers affecting the
funding and skilled human	implementation of AMS in primary care and pharmacies.
resources)	(Co-)develop training modules/ materials and provide support for
	the improvement of the training of primary care health
	professionals and pharmacists on AMS.
Raising awareness and	Support Member States (through the provision of technical
understanding of AMS	support and/or guidance, or developing a "model campaign" with
among the public	materials, templates, etc.) to reinforce communication campaigns
	to improve awareness and health literacy of citizens.
Exchanging good practices	Exchange of good practices in establishing processes for auditing
and learning between	prescriptions.
Member States	Exchange of good practices in increasing the use of laboratory
	testing and the use of point-of-care diagnostic tests by primary
	care providers.
	Promote the development of networks of pharmacists.
	Improve cooperation and knowledge exchange between
	community pharmacists and hospitals/hospital pharmacists.
Strengthening monitoring of	Establish a set of indicators, guidance and recommendation for
prescribing and dispensing	monitoring of antimicrobials prescribing and dispensing. Foster AMS research.
practices and research on AMS	
AMS	Support for research and development of new/rapid diagnostic tests and alternative treatments to antibiotics.
Overeeming market berriere	
Overcoming market barriers	Recommend authorisation for pharmacists to alter the packaging
affecting access to medicinal products, mostly in	to dispense only the prescribed amount of an antimicrobial. Work with the European Medicines Agency (EMA) to understand
products, mostly in community pharmacies (but	the value of biosimilar agents in the long term to mitigate drug
also at hospital level):	outages and shortages.
	Develop together with Member States a list of antimicrobials that
	should be stocked in public pharmacies.
	Should be stocked in public phannacles.

The research also identified examples of good practices in the implementation of AMS measures in primary care and pharmacies:

Area			Country/ies	Measure
Monitoring prescription ar	-	antibiotics pensation	Denmark	Pharmacists are obliged to register all the medications that they sell and are monitored if the sales exceed the expectations. Information on all prescription drugs sold in Denmark has been recorded in the Register of Medicinal Products Statistics (RMPS), maintained by the Danish Medicines Agency. RMPS provides individual-level information on dispensed prescriptions for the entire nation. A national tool -Ordiprax- has been developed to allow Danish physicians to have an electronic overview of their prescribing practices and

		antibiotic prescriptions, as well as the ability to
		compare them to those of other physicians.
	Ireland	The national surveillance for community
		antimicrobial consumption has been in place
		since 2003. Data is based on pharmacy
		wholesale data, rather than on individual
		prescriptions, and covers 95% of community
		antimicrobial consumption in the country.
	Sweden	The national IT capability ('Primärvårdskvalitet')
		extracts data from patients' electronic medical
		records for the close monitoring of antibiotic
		prescribing and dispensing, as well as antibiotic
		resistance, in primary care nationwide.
		The National Prescribed Drug Register
		5 5
		(<i>'Läkemedelsregisret'</i>), established in 2005,
		provides a foundation for official statistics about
		prescribed drugs in Sweden. Using personal
		identification numbers, it contains all prescribed
		drugs dispensed at pharmacies.
	Netherlands	The SABEL project (Reflective Information
		Antibiotics First Line, Spiegelinformatie
		Antibotica Eerstelijn) aimed at providing general
		practitioners benchmarking information on how
		their prescribing behaviour compares to other
		GPs at a regional and a national level.
New ways of collaborative	Sweden	The Strama model from Sweden is led by County
work on AMS, peer education		Medical Officers for Communicable Diseases
and collaboration		Control in every county.
	Belgium	Local quality circles (groupe local d'évaluation
	-	médicale - Glem) to discuss and improve
		antibiotic prescribing behaviour allows
		healthcare professionals to learn from one
		another and identify areas for improvement in
		their prescribing practices.
	Croatia	The Croatian Health Insurance Fund decided to
		finance peer review meetings where healthcare
		professionals educate each other.
	Ireland	A Pharmacist Antimicrobial Stewardship
	noiana	Network (PAMS-net) was launched in August
		2022. It is a network of pharmacists that aims to
		support pharmacists to work towards the
		common goal of promoting responsible use of
		antimicrobials.
Mait and any preservations	Soverel	
Wait-and-see prescriptions	Several	These are implemented in Belgium, Croatia,
	countries	Cyprus, Denmark, Germany, Hungary, Ireland,
		Italy, Luxembourg, Malta, the Netherlands, and
		Sweden. Studies in Denmark have shown that
		this measure reduces the consumption of
		antibiotics in general practice. Doctors dispense
		a normal prescription that is instructed not to be
		redeemed unless the symptoms remain
		unchanged for a predetermined time period.
Point-of-care tests	Denmark	These are rapid testing methods that are being
		developed for use in general practice. They
		developed for use in general practice. They would assist physicians in making quick

		decisions on antibiotic prescription, helping to prevent unnecessary prescription.
Therapeutic decision supporting tools	Ireland	The Green/Red Antibiotic Quality Improvement Initiative for Community Prescribers was developed in 2019 as a mouse-mat that aims to help community prescribers with antibiotic decision-making at the point of prescribing.
	France	The ANTIBIOCLIC app is a tool to aid therapeutic decision-making of first line physicians. It aims to support rational antibiotic therapy in primary care.
Online learning resources	Sweden and France	There are a number of e-learning resources aimed at various groups of stakeholders, from the general public to healthcare providers in Sweden and France.
Awareness raising campaigns	Sweden	The National Antibiotics Forum is held every year in conjunction with the European Antibiotic Awareness Day (EAAD) on 18 November.
	Romania	Public information campaign for raising awareness on the consumption of antibiotics without a medical prescription was launched in 2018 at the initiative of a network of private pharmacies.

Conclusions

The study reveals problems common to all countries, such as insufficient funding to deliver on the measures foreseen in the NAPs, the shortages of qualified staff at all levels of care, the lack of measures targeting LTCFs specifically, the limited involvement of pharmacies in AMS, and the disruptions caused by the COVID-19 pandemic in the health sector. The barriers affect each country differently but they are nevertheless common to all, indepedently of their size and socio-economic situation.

Other barriers identified include: limited political focus and awareness of the challenges brought by AMR; lack of operational plans for delivering on the NAPs; lack of harmonised indicators for monitoring the implementation of plans; limited coverage of AMR, AMS and IPC in education and training; limited public awareness of AMR.

Résumé analytique

Contexte

On estime que, chaque année, au sein de l'Union européenne/de l'Espace économique européen (UE/EEE) plus de 670 000 infections sont causées par les bactéries résistantes aux antibiotiques⁹, ce qui provoque la mort d'environ 35 000 personnes. Certaines bactéries ont développé une résistance à plusieurs médicaments.¹⁰

⁹ ECDC et OMS. 2022. Rapport sur la surveillance de la résistance aux antimicrobiens en Europe 2022 – données de 2020 (Antimicrobial resistance surveillance in Europe 2022 – 2020 data). Disponible à l'adresse <u>https://www.ecdc.europa.eu/sites/default/files/documents/ECDC-WHO-AMR-report.pdf</u>

¹⁰ Centre européen de prévention et de contrôle des maladies. Étude sur le fardeau sanitaire : impact des infections à bactéries résistantes aux antibiotiques au sein de l'UE/de l'EEE 2016-2020 (Assessing the health burden of infections with

L'utilisation inappropriée ou inutile d'antibiotiques chez l'homme ou l'animal est une cause très commune de l'apparition de la résistance aux antimicrobiens. A l'échelle mondiale, la consommation d'antibiotiques chez l'homme est à la hausse. Il ressort d'estimations récentes qu'au moins 1,27 millions de décès par an sont, à l'heure actuelle, directement causés par la résistance aux antimicrobiens. La résistance aux antimicrobiens aggrave les conditions de santé des patients et peut entraîner des complications et, dans certains cas, la mort. Si la résistance aux antimicrobiens n'est pas freinée d'ici 2050, on prévoit que le nombre de décès liés à la résistance aux antimicrobiens pourrait atteindre 10 millions par an, au point qu'elle devienne une cause de mortalité plus importante que le cancer. La résistance aux antimicrobiens entraîne aussi des coûts plus élevés pour le système de santé, dus à des séjours hospitaliers plus longs et à des traitements coûteux à cause de l'utilisation de médicaments plus onéreux.

La Commission européenne soutient les efforts engagés au niveau international par les Nations unies et figure depuis longtemps au tout premier rang de la lutte contre la résistance aux antimicrobiens en Europe. La première stratégie communautaire de lutte contre la résistance aux antimicrobiens a été adoptée en 2001. Dix ans plus tard, le premier plan d'action de l'UE pour combattre la résistance aux antimicrobiens fondé sur le principe « Une seule santé »¹¹ a été développé. En 2017 la Commission a adopté un plan d'action révisé, qui sert de guide aux actions actuellement menées par l'UE dans le domaine de la résistance aux antimicrobiens. Le plan s'articule autour de trois piliers : (1) faire de l'UE un exemple en matière de bonnes pratiques ; (2) encourager la recherche, le développement et l'innovation ; et (3) définir le programme mondial. En 2019 le Conseil de l'Union européenne a adopté des conclusions sur les prochaines étapes nécessaires pour faire de l'UE un exemple en matière de bonnes pratiques dans le domaine de la lutte contre la résistance aux antimicrobiens.

La présente étude vise à soutenir l'élaboration des initiatives politiques futures en matière de résistance aux antimicrobiens et la mise en œuvre des plans d'action de l'UE « Une seule santé » de lutte contre la résistance aux antimicrobiens. Elle présente une analyse détaillée des obstacles existants, auxquels font face 29 pays (les États membres de l'UE, la Norvège et l'Islande), au développement et à la mise en œuvre efficace de :

- plans d'action nationaux « Une seule santé » afin de combattre la résistance aux antimicrobiens (domaine d'étude 1)
- mesures efficaces de prévention et lutte contre les infections en santé humaine (domaine d'étude 2)
- mesures efficaces de promotion du bon usage des antimicrobiens en santé humaine (domaines d'étude 3 et 4)

La présente étude porte sur les obstacles existants au niveau institutionnel/politique, y compris les obstacles financiers, les obstacles existants d'ordre clinique (liés, par exemple, à des lignes directrices/pratiques cliniques) et d'ordre comportemental (par exemple, les comportements et les pratiques des professionnels de la santé, des patients, etc.). L'étude permet également de trouver des moyens de surmonter les obstacles et d'identifier les bonnes pratiques.

Méthodologie

La présente étude a inclus les activités de collecte des données suivantes :

antibiotic-resistant bacteria in the EU/EEA, 2016-2020). Stockholm : ECDC ; 2022. Disponible à l'adresse <u>https://www.ecdc.europa.eu/sites/default/files/documents/Health-burden-infections-antibiotic-resistant-bacteria.pdf</u>

¹¹L'approche « Une seule santé » consiste à reconnaître que la santé et le bien-être des humains, des animaux et des écosystèmes sont étroitement liés. Cette approche est coordonnée, collaborative, pluridisciplinaire et intersectorielle et vise à prévenir des risques potentiels ou existants qui résultent des interfaces entre l'animal, l'homme et les écosystèmes.

- une analyse documentaire ;
- des entretiens approfondis avec les parties prenantes aux niveaux européen et national ;
- des enquêtes ciblées auprès des groupes de parties prenantes pertinents; et un
- atelier virtuel avec les parties prenantes.

En tout, 473 parties prenantes ont participé aux activités de consultation prévues par la présente étude.

Les résultats de l'étude comportent les limites suivantes :

- la quantité et la qualité des éléments probants sont variables d'un pays à l'autre et d'un domaine d'étude à l'autre ;
- l'inventaire des obstacles qui entravent la mise en œuvre efficace des politiques de lutte contre la résistance aux antimicrobiens n'est pas exhaustif ;
- l'évaluation de l'ampleur des obstacles dans les différents pays dépassait le cadre de la présente étude ;
- l'accent est mis sur les mesures qui peuvent être mises en place au niveau européen afin d'aider les États membres à supprimer les obstacles ; les États membres peuvent et doivent mettre en place d'autres mesures au niveau national, le secteur de la santé relevant du niveau national.

Résultats

Plans d'action nationaux fondés sur le principe « Une seule santé »

Les plans d'action nationaux ont été mis en place (ou sont en cours de révision/mise à jour) dans 28 des 29 pays participant à l'étude, la plupart ayant adopté l'approche « Une seule santé ». Toutefois, la mise en œuvre des plans d'action nationaux en Europe est très variée. En outre, de nombreux plans d'action nationaux sont axés sur les secteurs de la santé humaine et animale et ont tendance à ignorer ou à ne pas approfondir suffisamment les aspects environnementaux.

Il existe des obstacles qui entravent le développement des plans d'action nationaux aux niveaux politique et institutionnel, tels qu'un intérêt politique limité pour le développement, la mise à jour ou l'approbation des plans d'action nationaux ; des lacunes dans l'élaboration de plans d'action nationaux (les plans se limitent notamment au niveau stratégique et ne se traduisent pas par des plans opérationnels concrets) ; des systèmes de suivi absents ou insuffisamment développés visant à mesurer les progrès réalisés dans la mise en œuvre des plans d'action nationaux et des fonds limités destinés à l'élaboration de plans d'action nationaux.

Les obstacles d'ordre institutionnel et politique ont également eu une incidence sur la mise en œuvre des plans d'action nationaux. Il s'agit notamment de l'absence ou insuffisance de structures gouvernementales interministérielles visant à favoriser la mise en œuvre des plans d'action nationaux et d'une coordination intersectorielle et l'absence de fonds destinés à la mise en œuvre des plans d'action nationaux. En termes d'obstacles cliniques, on a observé des lacunes, ainsi qu'une hétérogénéité et une fragmentation des données nécessaires à un suivi et à une surveillance systématique de la résistance aux antimicrobiens et de la consommation d'antimicrobiens. Comme on pouvait s'y attendre, la pandémie de COVID-19 a occasionné des perturbations, une réorientation des priorités et des retards dans la mise en œuvre des plans d'action nationaux.

Dans les limites des compétences européennes en matière de santé, la présente étude suggère à l'Union européenne de mener des actions visant à aider les États membres à surmonter les obstacles identifiés comme suit :

Enjeu	Mesures d'aide proposées
Combler les lacunes dans l'élaboration de plans d'action nationaux, renforcer l'approche « Une seule santé » et favoriser la mise en œuvre des plans d'action nationaux	Fournir des orientations et une structure de soutien au développement/renouvellement et à la mise en œuvre des plans d'action nationaux
Surmonter les problèmes liés à une coordination intersectorielle limitée	Promouvoir la création, au niveau national, de structures fondées sur le principe « Une seule santé » ou de mécanismes de coopération en matière de résistance aux antimicrobiens
Surmonter les problèmes liés à un financement insuffisant prévu à cet effet	Offrir un (co)financement spécifique et indiquer les instruments financiers existants de l'UE, qui pourraient servir à la lutte contre la résistance aux antimicrobiens
Surmonter les problèmes liés au suivi limité de la mise en œuvre des plans d'action nationaux	Aider les États membres à suivre les progrès réalisés dans la mise en œuvre des plans d'action nationaux en définissant une liste harmonisée d'indicateurs
Améliorer les systèmes de surveillance des États membres	Favoriser l'extension, la fréquence ainsi qu'une meilleure harmonisation des méthodes de collecte de données et des indicateurs en matière de résistance aux antimicrobiens et de consommation d'antibiotiques chez l'homme et l'animal et favoriser le suivi des données sur les zoonoses et les maladies d'origine alimentaire et hydrique
Aider les États membres à mettre en œuvre leurs plans d'action nationaux	Promouvoir le soutien par les pairs, les échanges d'experts et les jumelages, en encourageant le suivi des résultats des visites dans les pays et des projets financés par l'UE. Soutenir la mise au point d'activités de formation.

La présente étude a également identifié des exemples de bonne pratique en matière de développement et mise en œuvre des plans d'action nationaux fondés sur le principe « Une seule santé » :

Domaine	Pays	Bonne pratique
Échange intersectoriel de progrès et de bonnes pratiques	Irlande	Des conférences réunissant les parties prenantes de tous les secteurs, qui participent au plan d'action national (santé humaine et animale et l'environnement). La conférence visait à faire part des progrès réalisés et échanger les connaissances et les bonnes pratiques entre secteurs.
	Danemark	Le Comité national sur les antibiotiques (National Antibiotic Council) a organisé la collecte d'expériences positives et concrètes par le biais d'initiatives auxquelles le personnel sanitaire, les éducateurs, les médecins, les infirmières, etc. ont participé. Les résultats de cette démarche sont rassemblés dans le catalogue « 20 ways to use fewer antibiotics » (20 astuces pour réduire la consommation d'antibiotiques).
	France	Le projet PROMISE est un méta-réseau professionnel fondé sur le principe « Une seule santé » sur la résistance aux antibiotiques, qui réunit 21 réseaux nationaux et plus de 40 partenaires universitaires.

<u> </u>		
Éléments de preuve du soutien	Portugal	La résistance aux antimicrobiens et la lutte
politique à la lutte contre la		contre les infections ont été identifiées comme
résistance aux antimicrobiens		des problèmes prioritaires de santé publique.
	Irlande	L'unité Résistance aux antimicrobiens et lutte
		contre les infections (Antimicrobial Resistance
		and Infection Control Division, AMRIC) a été
		créée afin de donner des directives politiques,
		une direction et un encadrement fermes à la
		politique de résistance aux antimicrobiens.
	France	Un poste de haut niveau en matière de
		résistance aux antibiotiques a été créé au sein
		du Ministère de la santé afin de coordonner les
		activités des secteurs « Une seule santé ».
Équipes dédiées à la	Lituanie	Des équipes de gestion de la résistance aux
résistance aux antimicrobiens		antimicrobiens, mises sur pied dans 10 régions
opérant au niveau		en 2015, mènent des campagnes de
infranational/local		sensibilisation à l'utilisation des antibiotiques et
		à la résistance aux antibiotiques auprès des
		professionnels de la santé publique, du grand
		public, des établissements d'enseignement, des
		vétérinaires et des éleveurs.
Soutien à la mise en œuvre du	Italie	Le projet SPiNCAR a soutenu la mise en œuvre
plan d'action national		du plan d'action national italien de lutte contre la
		résistance aux antimicrobiens, en identifiant et
		mettant au point des normes nationales ayant
		pour but de favoriser la prévention, la gestion et
		le contrôle de la résistance aux antimicrobiens
		aux niveaux des collectivités et des hôpitaux.
Éléments du plan d'action	Suède et	Dans le cadre du programme d'appui à la
national financés par l'UE et	Lettonie	réforme structurelle de l'UE, une mission
appui bilatéral		d'experts de l'Office suédois de l'agriculture et
-		d'experts de l'Office suédois de l'agriculture et de l'agence de santé publique de la Suède a
-		d'experts de l'Office suédois de l'agriculture et de l'agence de santé publique de la Suède a collaboré avec leurs homologues lettons du
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-		d'experts de l'Office suédois de l'agriculture et de l'agence de santé publique de la Suède a collaboré avec leurs homologues lettons du Ministère de la santé et du Ministère de l'agriculture afin de partager les connaissances
-	Norvège,	d'experts de l'Office suédois de l'agriculture et de l'agence de santé publique de la Suède a collaboré avec leurs homologues lettons du Ministère de la santé et du Ministère de l'agriculture afin de partager les connaissances et offrir une formation destinée aux formateurs
		d'experts de l'Office suédois de l'agriculture et de l'agence de santé publique de la Suède a collaboré avec leurs homologues lettons du Ministère de la santé et du Ministère de l'agriculture afin de partager les connaissances et offrir une formation destinée aux formateurs et des « boîtes à outils » pour la formation.
	Norvège,	d'experts de l'Office suédois de l'agriculture et de l'agence de santé publique de la Suède a collaboré avec leurs homologues lettons du Ministère de la santé et du Ministère de l'agriculture afin de partager les connaissances et offrir une formation destinée aux formateurs et des « boîtes à outils » pour la formation. L'Institut norvégien de santé publique a coopéré
	Norvège, Roumanie et	d'experts de l'Office suédois de l'agriculture et de l'agence de santé publique de la Suède a collaboré avec leurs homologues lettons du Ministère de la santé et du Ministère de l'agriculture afin de partager les connaissances et offrir une formation destinée aux formateurs et des « boîtes à outils » pour la formation. L'Institut norvégien de santé publique a coopéré en tant que partenaire de projets avec la
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	Norvège, Roumanie et	d'experts de l'Office suédois de l'agriculture et de l'agence de santé publique de la Suède a collaboré avec leurs homologues lettons du Ministère de la santé et du Ministère de l'agriculture afin de partager les connaissances et offrir une formation destinée aux formateurs et des « boîtes à outils » pour la formation. L'Institut norvégien de santé publique a coopéré en tant que partenaire de projets avec la Tchéquie (projet de prévention de la résistance aux antibiotiques ayant pour but de freiner la consommation des antibiotiques au sein de la collectivité) et la Roumanie (développement du plan d'action national, trois guides et une méthodologie pour présenter des rapports sur les infections associées aux soins).
appui bilatéral Systèmes pour améliorer la	Norvège, Roumanie et	d'experts de l'Office suédois de l'agriculture et de l'agence de santé publique de la Suède a collaboré avec leurs homologues lettons du Ministère de la santé et du Ministère de l'agriculture afin de partager les connaissances et offrir une formation destinée aux formateurs et des « boîtes à outils » pour la formation. L'Institut norvégien de santé publique a coopéré en tant que partenaire de projets avec la Tchéquie (projet de prévention de la résistance aux antibiotiques ayant pour but de freiner la consommation des antibiotiques au sein de la collectivité) et la Roumanie (développement du plan d'action national, trois guides et une méthodologie pour présenter des rapports sur les infections associées aux soins). Le Programme intégré danois de surveillance et
appui bilatéral Systèmes pour améliorer la surveillance et le suivi dans les	Norvège, Roumanie et Tchéquie	d'experts de l'Office suédois de l'agriculture et de l'agence de santé publique de la Suède a collaboré avec leurs homologues lettons du Ministère de la santé et du Ministère de l'agriculture afin de partager les connaissances et offrir une formation destinée aux formateurs et des « boîtes à outils » pour la formation. L'Institut norvégien de santé publique a coopéré en tant que partenaire de projets avec la Tchéquie (projet de prévention de la résistance aux antibiotiques ayant pour but de freiner la consommation des antibiotiques au sein de la collectivité) et la Roumanie (développement du plan d'action national, trois guides et une méthodologie pour présenter des rapports sur les infections associées aux soins).
appui bilatéral Systèmes pour améliorer la	Norvège, Roumanie et Tchéquie	d'experts de l'Office suédois de l'agriculture et de l'agence de santé publique de la Suède a collaboré avec leurs homologues lettons du Ministère de la santé et du Ministère de l'agriculture afin de partager les connaissances et offrir une formation destinée aux formateurs et des « boîtes à outils » pour la formation. L'Institut norvégien de santé publique a coopéré en tant que partenaire de projets avec la Tchéquie (projet de prévention de la résistance aux antibiotiques ayant pour but de freiner la consommation des antibiotiques au sein de la collectivité) et la Roumanie (développement du plan d'action national, trois guides et une méthodologie pour présenter des rapports sur les infections associées aux soins). Le Programme intégré danois de surveillance et de recherche sur la résistance aux agents antimicrobiens (Danish Integrated Antimicrobial
appui bilatéral Systèmes pour améliorer la surveillance et le suivi dans les	Norvège, Roumanie et Tchéquie	d'experts de l'Office suédois de l'agriculture et de l'agence de santé publique de la Suède a collaboré avec leurs homologues lettons du Ministère de la santé et du Ministère de l'agriculture afin de partager les connaissances et offrir une formation destinée aux formateurs et des « boîtes à outils » pour la formation. L'Institut norvégien de santé publique a coopéré en tant que partenaire de projets avec la Tchéquie (projet de prévention de la résistance aux antibiotiques ayant pour but de freiner la consommation des antibiotiques au sein de la collectivité) et la Roumanie (développement du plan d'action national, trois guides et une méthodologie pour présenter des rapports sur les infections associées aux soins). Le Programme intégré danois de surveillance et de recherche sur la résistance aux agents antimicrobiens (Danish Integrated Antimicrobial Resistance Monitoring and Research
appui bilatéral Systèmes pour améliorer la surveillance et le suivi dans les	Norvège, Roumanie et Tchéquie	d'experts de l'Office suédois de l'agriculture et de l'agence de santé publique de la Suède a collaboré avec leurs homologues lettons du Ministère de la santé et du Ministère de l'agriculture afin de partager les connaissances et offrir une formation destinée aux formateurs et des « boîtes à outils » pour la formation. L'Institut norvégien de santé publique a coopéré en tant que partenaire de projets avec la Tchéquie (projet de prévention de la résistance aux antibiotiques ayant pour but de freiner la consommation des antibiotiques au sein de la collectivité) et la Roumanie (développement du plan d'action national, trois guides et une méthodologie pour présenter des rapports sur les infections associées aux soins). Le Programme intégré danois de surveillance et de recherche sur la résistance aux agents antimicrobiens (Danish Integrated Antimicrobial Resistance Monitoring and Research Programme, DANMAP) est un modèle efficace
appui bilatéral Systèmes pour améliorer la surveillance et le suivi dans les	Norvège, Roumanie et Tchéquie	d'experts de l'Office suédois de l'agriculture et de l'agence de santé publique de la Suède a collaboré avec leurs homologues lettons du Ministère de la santé et du Ministère de l'agriculture afin de partager les connaissances et offrir une formation destinée aux formateurs et des « boîtes à outils » pour la formation. L'Institut norvégien de santé publique a coopéré en tant que partenaire de projets avec la Tchéquie (projet de prévention de la résistance aux antibiotiques ayant pour but de freiner la consommation des antibiotiques au sein de la collectivité) et la Roumanie (développement du plan d'action national, trois guides et une méthodologie pour présenter des rapports sur les infections associées aux soins). Le Programme intégré danois de surveillance et de recherche sur la résistance aux agents antimicrobiens (Danish Integrated Antimicrobial Resistance Monitoring and Research Programme, DANMAP) est un modèle efficace en ce qui concerne la surveillance intégrée
appui bilatéral Systèmes pour améliorer la surveillance et le suivi dans les	Norvège, Roumanie et Tchéquie	d'experts de l'Office suédois de l'agriculture et de l'agence de santé publique de la Suède a collaboré avec leurs homologues lettons du Ministère de la santé et du Ministère de l'agriculture afin de partager les connaissances et offrir une formation destinée aux formateurs et des « boîtes à outils » pour la formation. L'Institut norvégien de santé publique a coopéré en tant que partenaire de projets avec la Tchéquie (projet de prévention de la résistance aux antibiotiques ayant pour but de freiner la consommation des antibiotiques au sein de la collectivité) et la Roumanie (développement du plan d'action national, trois guides et une méthodologie pour présenter des rapports sur les infections associées aux soins). Le Programme intégré danois de surveillance et de recherche sur la résistance aux agents antimicrobiens (Danish Integrated Antimicrobial Resistance Monitoring and Research Programme, DANMAP) est un modèle efficace en ce qui concerne la surveillance intégrée fondée sur le principe « Une seule santé ». Il a
appui bilatéral Systèmes pour améliorer la surveillance et le suivi dans les	Norvège, Roumanie et Tchéquie	d'experts de l'Office suédois de l'agriculture et de l'agence de santé publique de la Suède a collaboré avec leurs homologues lettons du Ministère de la santé et du Ministère de l'agriculture afin de partager les connaissances et offrir une formation destinée aux formateurs et des « boîtes à outils » pour la formation. L'Institut norvégien de santé publique a coopéré en tant que partenaire de projets avec la Tchéquie (projet de prévention de la résistance aux antibiotiques ayant pour but de freiner la consommation des antibiotiques au sein de la collectivité) et la Roumanie (développement du plan d'action national, trois guides et une méthodologie pour présenter des rapports sur les infections associées aux soins). Le Programme intégré danois de surveillance et de recherche sur la résistance aux agents antimicrobiens (Danish Integrated Antimicrobial Resistance Monitoring and Research Programme, DANMAP) est un modèle efficace en ce qui concerne la surveillance intégrée fondée sur le principe « Une seule santé ». Il a été mis en place en 1995 par le Ministère danois
appui bilatéral Systèmes pour améliorer la surveillance et le suivi dans les	Norvège, Roumanie et Tchéquie	d'experts de l'Office suédois de l'agriculture et de l'agence de santé publique de la Suède a collaboré avec leurs homologues lettons du Ministère de la santé et du Ministère de l'agriculture afin de partager les connaissances et offrir une formation destinée aux formateurs et des « boîtes à outils » pour la formation. L'Institut norvégien de santé publique a coopéré en tant que partenaire de projets avec la Tchéquie (projet de prévention de la résistance aux antibiotiques ayant pour but de freiner la consommation des antibiotiques au sein de la collectivité) et la Roumanie (développement du plan d'action national, trois guides et une méthodologie pour présenter des rapports sur les infections associées aux soins). Le Programme intégré danois de surveillance et de recherche sur la résistance aux agents antimicrobiens (Danish Integrated Antimicrobial Resistance Monitoring and Research Programme, DANMAP) est un modèle efficace en ce qui concerne la surveillance intégrée fondée sur le principe « Une seule santé ». Il a

	résistance aux antimicrobiens repose sur trois catégories de bactéries : agents pathogènes pour l'homme et l'animal, agents zoonotiques et bactéries indicatrices.
Portugal	L'indice de qualité (PPCIRA-IQ) a été créé en tant qu'outil de suivi du programme. Cet indice utilise plusieurs indicateurs de suivi afin d'encourager une évaluation comparative, ce qui constitue également une incitation pour les établissements de soins à être conforme. L'indice est calculé avec les données et indicateurs, obtenus dans chaque établissement hospitalier en matière de consommation des antibiotiques au sein de l'hôpital, de résistance aux antimicrobiens et d'infections associées aux soins. L'indice PPCIRA-IQ se compose des variables suivantes : consommation d'antimicrobiens, résistance aux antimicrobiens, pratiques de prévention des infections et surveillance épidémiologique.
Tchéquie	L'un des objectifs du plan d'action national est d'introduire un logiciel innovant pour le traitement et la transmission électroniques (automatisés) des données. Dans ce contexte, les chercheurs de l'Institut de recherche vétérinaire ¹² travaillent en étroite collaboration avec des institutions, telles que l'Institut pour le contrôle public des bio-préparations et des médicaments vétérinaires ¹³ , afin de développer une application ayant pour but de numériser les registres vétérinaires. Dans le cadre du plan, une évaluation annuelle des résultats du programme national de suivi de la résistance aux antimicrobiens pour les agents pathogènes d'importance vétérinaire a été réalisée entre 2016 et 2021. Le plan d'action national vise à instaurer un cadre pour le suivi des souches bactériennes résistantes aux antimicrobiens dans le sol, et possiblement dans d'autres milieux de l'environnement, ainsi que des résidus des substances pharmaceutiques utilisées dans les élevages, qui présentent des risques pour l'environnement. Le plan d'action national prévoit également l'intégration des questions liées au suivi de la résistance aux antimicrobiens dans le programme de surveillance des sols en Tchéquie. Plusieurs rapports ¹⁴ traitant de cet objectif ont été élaborés, y compris l'optimisation de la méthode et la détermination des résidus d'enrofloxacine

¹² Plus d'informations sont disponibles à l'adresse : <u>https://www.vri.cz/en/900-2/</u>

¹³ Plus d'informations sont disponibles à l'adresse : <u>https://www.uskvbl.cz/en</u>

 ¹⁴
 Plus
 d'informations
 sont
 disponibles
 à
 l'adresse :

 <u>https://eagri.cz/public/web/file/691658/Zprava_AMR_2021_FINAL_s_tit.pdf</u>
 I'adresse :
 itadresse :
 itadresse :

dans les matrices nécessaires (eau
médicamenteuse, litière de volaille traitée, sol
avec litière pour animaux traitée et sol avec
litière enrichie avec enrofloxacine).

Mesures de prévention et de lutte contre les infections dans les hôpitaux et dans les établissements de soins de longue durée

La consultation des parties prenantes a montré que, en règle générale, les lignes directrices et la législation en matière de prévention et lutte contre les infections étaient généralement développées dans les pays de l'étude aux niveaux national ou régional et que les établissements de soins se basent sur ces lignes directrices pour développer les programmes et les mesures de prévention et lutte contre les infections. Parmi les mesures communes mises en place figurent la création d'un groupe technique pluridisciplinaire pour la surveillance des infections associées aux soins et le suivi de la prévention et lutte contre les infections, ainsi que pour l'existence d'un plan stratégique de surveillance des infections associées infections de prévention et lutte contre les infections.

En ce qui concerne les hôpitaux, une conclusion importante de la recherche est que, bien qu'il existe dans la plupart des pays une législation rendant obligatoire la prévention et la lutte contre les infections, elle n'est pas pleinement appliquée et, à titre d'exemple, peu de pays ont défini la composition de leurs équipes pour la prévention et la lutte contre les infections. Le contrôle du respect des programmes de prévention et lutte contre les infections, ainsi que les rapports annuels sur les indicateurs, sont cependant très variables d'un hôpital à l'autre. Dans certains pays, les hôpitaux rédigent un rapport annuel sur les infections associées aux soins, mais les rapports systématiques sur les cas d'organismes multirésistants varient d'un pays à l'autre. Pour terminer, on a pu constater que les mesures de prévention et lutte contre les infections dans les hôpitaux des pays de l'étude sont souvent perçues comme un problème d'hygiène et ne sont pas nécessairement liées à une démarche plus globale en matière de sécurité des patients.

La situation est encore plus hétérogène dans les pays de l'étude si on considère les établissements de soins de longue durée. En règle générale, la responsabilité des établissements de soins de longue durée incombe à plusieurs autorités (sécurité sociale, politique du travail, politique des retraites, politique familiale et politique sociale). La définition même des établissements de soins de longue durée est tout aussi variable. Dans ce contexte, les mesures de prévention et de lutte contre les infections se limitent à des règles d'hygiène de base, à la vaccination saisonnière et à la désinfection des dispositifs médicaux. En outre, aucune mesure n'est en place concernant spécifiquement la résistance aux antimicrobiens, même si les établissements de soins de longue durée ont été indiqués comme étant des réservoirs importants d'organismes multirésistants. Plusieurs lignes directrices pour la mise en œuvre des mesures destinées à prévenir la transmission des organismes multirésistants ont été signalées, mais elles portent principalement sur le milieu hospitalier et non sur les établissements de soins de longue durée.

Aux niveaux institutionnel et politique, les obstacles qui entravent le développement et la mise en œuvre des mesures de prévention et de lutte contre les infections dans les hôpitaux incluent un contrôle ou une vérification insuffisants des établissements de soins de la part des autorités nationales afin d'assurer la conformité aux lignes directrices et/ou à la législation nationales en matière de prévention et de lutte contre les infections, et le manque d'indicateurs harmonisés en matière de suivi et évaluation des mesures de prévention et de lutte contre les infections. Il existe également des obstacles d'ordre technologique ou méthodologique, y compris des limites dans les méthodes ou les systèmes d'information mis en place au niveau national ou de chaque établissement afin de collecter, traiter et utiliser les données de surveillance. Les obstacles cliniques incluent la variabilité des pratiques de prévention et de lutte contre les infections dans les hôpitaux en termes de méthodes de gestion de la productivité et de la sécurité des patients des hôpitaux;

capacités limitées de dépistage afin de détecter et contrôler les cas d'infection et une interaction et/ou des échanges d'informations sous-optimales entre les praticiens affectés à la prévention et la lutte contre les infections et les laboratoires. La recherche a détecté parmi les pays participant à l'étude certains problèmes liés au comportement ayant pour conséquence un faible niveau d'adoption des pratiques de prévention et de lutte contre les infections, tels que : pénuries de personnel, notamment de personnel motivé et qualifié ; manque de sensibilisation ou compréhension de la prévention et de la lutte contre les infections en tant que facteurs essentiels de la sécurité des patients et des ressources financières limitées. L'attention limitée accordée à la résistance aux antimicrobiens et aux mesures de prévention et de lutte contre les infections au niveau de l'éducation de premier cycle des professionnels de la santé a également été qualifiée d'obstacle comportemental dans les hôpitaux.

Dans les établissements de soins de longue durée, un obstacle important d'ordre institutionnel ou politique qui affecte la mise en œuvre des mesures de prévention et de lutte contre les infections est la gouvernance variable des soins de longue durée. Selon l'organisation des systèmes de santé et de protection sociale des pays, les soins de longue durée peuvent relever de la compétence nationale, régionale ou locale, peuvent être compris dans le champ d'application de la santé, des services sociaux ou des deux et peuvent être fournis par des organisations publiques ou privées ou à domicile. Parmi les autres obstacles d'ordre institutionnel figurent la mise en œuvre absente ou limitée des programmes dédiés à la prévention et à la lutte contre les infections ou des plans opérationnels pour les établissements de soins de longue durée et le manque d'une surveillance systématique des infections associées aux soins dans les établissements de soins de longue durée. Les obstacles d'ordre clinique incluent les infrastructures vieilles et médiocres des établissements de soins de longue durée. La pénurie générale de personnel et, notamment, de personnel qualifié dans le domaine de la prévention et de la lutte contre les infections, en particulier les infirmières, nuisent aux soins de longue durée. Les ressources financières consacrées à la mise en œuvre des mesures de prévention et de lutte contre les infections qui sont absentes ou limitées affectent également les établissements de soins de longue durée. En termes d'obstacles comportementaux, l'adoption des programmes et des lignes directrices en matière de prévention et de lutte contre les infections est sensiblement inférieure à celle dans les hôpitaux.

Enjeu	Mesures d'aide proposées
Renforcer la prévention et la	S'assurer que le développement et la mise en œuvre des mesures
lutte contre les infections	de prévention et de lutte contre les infections dans les
dans les établissements de	établissements de soins de longue durée sont bien considérés
soins de longue durée	comme une priorité dans les plans d'action nationaux
	nouveaux/mis à jour des États membres.
Développer et mettre à jour	Promouvoir la révision et la mise à jour en temps utile des lignes
des politiques nationales en	directrices nationales en matière de prévention et de lutte contre
matière de prévention et de	les infections.
lutte contre les infections	Poursuivre le développement et la promotion du répertoire des
dans les États membres	ressources en ligne pour la prévention et le suivi de la résistance
	aux antimicrobiens et des infections associées aux soins de l'ECDC.
	Avec l'appui d'experts, définir un ensemble d'indicateurs de
	résultats et de lignes directrices communs ayant pour but de
	suivre et évaluer les mesures de prévention et de lutte contre les
	infections dans les hôpitaux et dans les établissements de soins
	de longue durée.
	Promouvoir l'intégration des indicateurs de performance liés à la
	prévention et à la lutte contre les infections dans les décisions

Les actions de la part de l'Union européenne qui pourraient aider les États membres à surmonter les obstacles identifiés sont indiquées dans le tableau ci-dessous :

	prises au sein des établissements de soins en matière de financement et évaluation du rendement du personnel, par exemple en identifiant et diffusant les bonnes pratiques dans ce domaine.
Surmonter les obstacles d'ordre structurel (par ex. manque de financement et de ressources humaines qualifiées)	Indiquer les sources de (co)financement existantes provenant de l'Union européenne aux États membres. Utiliser les fonds existants et futurs provenant de l'Union européenne pour améliorer la prévention et la lutte contre les infections/ la sécurité des patients dans les États membres. Promouvoir l'intégration de la prévention et de la lutte contre les infections dans les programmes d'études de premier cycle et des cycles supérieurs et dans les programmes d'enseignement et de formation professionnelle des États membres. Continuer à financer, fournir et promouvoir les possibilités de formation en matière de prévention et de lutte contre les infections (et de manière plus générale la résistance aux antimicrobiens) visant les décideurs politiques nationaux et les professionnels de la santé.
Sensibiliser à l'importance des mesures de prévention et de lutte contre les infections afin de combattre la résistance aux antimicrobiens en Europe	Continuer à organiser des campagnes de sensibilisation du public visant à faire de la sécurité des patients un principe dominant.
Échanger les bonnes pratiques et les connaissances entre les États membres	Créer des forums ou soutenir les forums existants visant à partager les bonnes pratiques en matière de prévention et de lutte contre les infections. Promouvoir/financer la mise en place de réseaux pour la prévention et la lutte contre les infections au niveau national.
Renforcer la surveillance et la recherche	Développer un cadre de renforcement de la surveillance épidémiologique parmi l'UE, visant notamment la surveillance des organismes multirésistants. (Co)financer les activités de recherche en matière de prévention et de lutte contre les infections.

Comme c'était le cas du domaine d'étude précédent, la recherche a identifié des exemples de bonne pratique en matière de mesures de prévention et de lutte contre les infections :

Domaine	Pays	Mesure
Domaine Pleine intégration des approches ayant pour but la sécurité des patients	Pays Irlande	La prévention des infections associées aux soins fait partie du programme pour la sécurité des patients du bureau pour la santé et la sécurité (Health Service Executive, HSE). En outre, le plan d'action national a mis en place une approche basée sur les principes fondamentaux, qui porte sur l'hygiène des mains, sur les précautions de base et sur la
		prévention des infections liées aux dispositifs médicaux. Il existe également une équipe spécialisée (l'équipe AMRIC) qui fixe le cap en ce qui concerne la résistance aux antimicrobiens et la prévention et la lutte contre les infections dans le secteur de la santé, en rédigeant et publiant des lignes directrices cliniques sur les soins des patients et des clients (en collaboration avec les parties prenantes), en fournissant des opportunités

		d'enseignement et de formation et des
		ressources pour mettre en œuvre ces lignes
		directrices, et en offrant des avis spécialisés et
		du soutien aux services.
Fonctionnement des équipes pluridisciplinaires pour la prévention et la lutte contre les infections	Malta	L'hôpital principal du pays a lancé une stratégie de lutte contre la résistance aux antimicrobiens au sein de l'hôpital en 2010. Elle comprend également un département pluridisciplinaire de lutte contre les infections (ICD) disposant de ressources spécifiques, du
		soutien de la part des autorités locales et d'infrastructures de surveillance efficaces. Ce département coordonne toutes les activités liées à la prévention et à la lutte contre les infections associées aux soins dans l'hôpital.
Réseaux d'hôpitaux/professionnels visant à renforcer la prévention et la lutte contre les infections	Belgique	Les projets-pilotes appelés « Hospital Outbreak Support Team » (HOST) ont été mis sur pied en 2021 dans le cadre de la mise en œuvre du plan d'action national et dans le contexte de la pandémie de COVID-19. Les projets-pilotes HOST visent à renforcer la prévention et la lutte contre les infections ainsi que les mesures de promotion du bon usage des antimicrobiens dans les hôpitaux, dans les établissements de soins de longue durée et dans le cadre des soins primaires en mettant en place des réseaux d'hôpitaux au niveau régional. Ces projets se déclinent sur deux axes complémentaires : d'une part une approche locale-régionale fondée sur la coopération entre hôpitaux et, d'autre part, une approche transversale qui permet de mettre les compétences des hôpitaux à la disposition des établissements résidentiels et des autres
Intégration des mesures de prévention et de lutte contre les infections dans la construction et la rénovation des structures des hôpitaux de soins de courte durée	Irlande	prestataires de soins. Le bureau HSE a élaboré des lignes directrices sur le rôle de la prévention et de la lutte contre les infections dans les rénovations et les constructions d'hôpitaux de soins de courte durée. Il existe également des normes de construction pour les nouveaux centres de soins primaires, qui incluent des questions liées à la prévention et à la lutte contre les infections, y compris, entre autres, le choix du matériel, de l'espace, le style des éviers.
Renforcement de la prévention et de la lutte contre les infections dans les établissements de soins de longue durée avec le soutien des fonds de l'UE	Estonie	Depuis 2020, l'Institut d'assurance sociale, en collaboration avec le conseil de santé et l'agence nationale des médicaments, organise la supervision des établissements de soins de longue durée résidentiels. L'Institut d'assurance sociale emploie des commissaires spécialisés en infections qui surveillent et donnent des avis, avec le soutien des fonds du programme de la Commission européenne de soutien à la reprise en faveur de la cohésion et des territoires de l'Europe (REACT-EU).

mains municipalité de Copenhague kit appelé « Monday kit » av le soin des ongles, qui e employés avec le but de foca sur la prévention de la infections. Le « Monday nettoyant pour les ongles, disques de coton, des cou épingle de sûreté pour le montres. Cela a pour but l'importance d'une hygiè suffisante afin de prévenir la infections.

Mesures de promotion du bon usage des antimicrobiens dans les hôpitaux et dans les établissements de soins de longue durée

La promotion du bon usage des antimicrobiens dans les hôpitaux est couverte par les plans d'action nationaux en matière de résistance aux antimicrobiens de la plupart des pays. Toutefois, à ce jour le degré de mise en œuvre des mesures de prévention et de lutte contre les infections dans le cadre des plans d'action nationaux n'est suivi que de façon limitée.

Bien que des exemples de comités locaux spécialisés en prévention et lutte contre les infections ont été mis en place dans les hôpitaux, la disponibilité d'équipes spécialisées en prévention et lutte contre les infections ou de personnel incluant des spécialistes en prévention et lutte contre les infections est généralement limitée dans les pays de l'étude, même si leur mise en place est prévue par les plans d'action nationaux ou régionaux.

Les mesures de prévention et de lutte contre les infections dans les établissements de soins de longue durée sont soit encore à un stade très précoce de leur développement soit inexistantes dans la plupart des pays de l'étude. Comme c'est le cas pour les mesures de prévention et de lutte contre les infections, le développement et la mise en œuvre des mesures de promotion du bon usage des antimicrobiens sont entravés par le grand nombre d'établissements de soins de longue durée et par leur gouvernance et administration hétérogènes. Lorsque les mesures de promotion du bon usage des antimicrobiens des antimicrobiens sont mises en place, elles dépendent généralement de l'initiative et de l'engagement personnels des médecins traitants ou des infirmières, sans aucune coordination aux niveaux national/de chaque établissement. Les données de l'étude européenne de prévalence ponctuelle des infections associées aux soins et de l'utilisation des antimicrobiens dans les établissements de soins de longue durée européens (HALT-3) ont montré que 28,5 % des établissements de soins de longue durée consultés n'avaient mis en place aucune des dix mesures de promotion du bon usage des antimicrobiens spécifiées.

Les obstacles qui entravent le développement et la mise en œuvre des mesures de promotion du bon usage des antimicrobiens dans les hôpitaux incluent un intérêt politique limité pour les mesures de promotion du bon usage des antimicrobiens, qui ne sont souvent pas considérées comme une priorité ; l'absence de stratégies ou plans opérationnels nationaux en matière de promotion du bon usage des antimicrobiens pour les hôpitaux ; l'absence de fonds destinés aux mesures de promotion du bon usage des antimicrobiens dans les hôpitaux ; des difficultés de mise en œuvre des mesures de promotion du bon usage des antimicrobiens dans les hôpitaux ; des difficultés de mise en œuvre des mesures de promotion du bon usage des antimicrobiens et des difficultés à harmoniser les habitudes en matière de pratiques de prescription au sein de et entre les hôpitaux.

Il existe également des obstacles d'ordre technologique/ méthodologique, y compris l'absence de systèmes d'information intégrés et de données sur la prescription d'antimicrobiens. Les prescriptions sous forme papier dans les hôpitaux ne favorisent pas le suivi des prescriptions d'antimicrobiens dans plusieurs pays. Un autre obstacle important est constitué par les retards logistiques dans la réception des résultats de laboratoires. Les obstacles d'ordre clinique incluent le manque de lignes directrices, fondées sur des éléments probants, concernant les traitements contre les infections courantes, soit parce qu'elles n'existent pas, soit parce que les professionnels de la santé ne les connaissent pas ; des pénuries de personnel spécialisé et une éducation et une formation des professionnels de la santé en matière de mesures de promotion du bon usage des antimicrobiens limitées. Il existe également une pénurie dans l'approvisionnement et une disponibilité limitée d'antimicrobiens à spectre étroit. Pour conclure, un obstacle important d'ordre comportemental est constitué par les pressions exercées par les patients qui veulent que les médecins leur prescrivent des antibiotiques.

Les obstacles d'ordre institutionnel et politique empêchant une mise en œuvre efficace des mesures de promotion du bon usage des antimicrobiens dans les établissements de soins de longue durée incluent le manque de réglementations sur la promotion du bon usage des antimicrobiens relatives à ce type d'établissement et le fait que ces mesures ne font généralement pas partie de plans d'action nationaux ou de stratégies nationales en matière de promotion du bon usage des antimicrobiens. Il en résulte un développement limité des programmes ou plans opérationnels en matière de promotion du bon usage des antimicrobiens de longue durée et des mécanismes de suivi absents ou insuffisants. Parmi les obstacles d'ordre clinique figurent le manque de personnel spécialisé dans les établissements de soins de longue durée et le fait que les résidents de ces établissements sont généralement traités par des médecins traitants qui ne sont pas sur place. Les employés des établissements de soins de longue durée et médecins traitants et infirmières dans la plupart des pays de l'étude.

Les actions de la part de l'Union européenne qui pourraient aider les États membres à surmonter les obstacles empêchant une mise en œuvre efficace des mesures de promotion du bon usage des antimicrobiens dans les hôpitaux et dans les établissements de soins de longue durée sont indiquées dans le tableau ci-dessous :

Enjeu	Mesures d'aide proposées
Développer et mettre à jour des politiques nationales en matière de promotion du bon usage des antimicrobiens dans les États membres	Encourager les États membres à inclure les programmes et les objectifs concernant la promotion du bon usage des antimicrobiens dans leurs plans d'action nationaux « Une seule santé » et/ou dans leurs politiques et stratégies nationales correspondantes. Aider les États membres à donner la priorité aux mesures de promotion du bon usage des antimicrobiens. Favoriser la collaboration et le partage de bonnes pratiques entre les États membres.
Surmonter les obstacles d'ordre structurel, tels que le manque de financement et de ressources humaines qualifiées	Indiquer aux États membres qu'il existe plusieurs sources de financement provenant de l'Union européenne ayant pour but de surmonter les obstacles d'ordre structurel qui entravent la mise en œuvre des mesures de promotion du bon usage des antimicrobiens dans les hôpitaux et les établissements de soins de longue durée. Promouvoir la formation et la spécialisation dans la promotion du bon usage des antimicrobiens parmi les professionnels de la santé, y compris le personnel soignant et non soignant.
Soutenir davantage la mise	Continuer à développer et promouvoir le répertoire sur la
en œuvre des mesures de	politique de bon usage des antimicrobiens de l'ECDC. ¹⁵
promotion du bon usage des	Établir un ensemble d'indicateurs ayant pour but de contrôler les
antimicrobiens	mesures de promotion du bon usage des antimicrobiens dans les

¹⁵ Plus d'informations sont disponibles à l'adresse : <u>https://www.ecdc.europa.eu/en/publications-data/directory-guidance-prevention-and-control/prudent-use-antibiotics/antimicrobial</u>

	hôpitaux et les établissements de soins de longue durée au niveau européen.	
Sensibiliser à l'importance des mesures de promotion du bon usage des antimicrobiens afin de combattre la résistance aux antimicrobiens		
Renforcer la recherche dans les États membres	Stimuler la recherche en matière de promotion du bon usage des antimicrobiens afin d'en démontrer l'efficacité.	

La présente étude a également identifié des exemples de bonne pratique en matière de mise en œuvre des mesures de promotion du bon usage des antimicrobiens dans les hôpitaux et les établissements de soins de longue durée :

Domaine	Pays	Mesure
Mise en œuvre et suivi de l'impact des pratiques de promotion du bon usage des antimicrobiens dans les hôpitaux	Pays-Bas	Les lignes directrices nationales et régionales concernant les antibiotiques dans les Pays-Bas ont été publiées et suivies par le Groupe de travail néerlandais sur la politique en matière d'antibiotiques (SWAB). En fonction des lignes directrices du SWAB, les groupes de travail régionaux sur les antibiotiques ont établi des lignes directrices régionales en matière de prescriptions d'antibiotiques adaptées aux besoins des hôpitaux. L'avantage d'une telle approche réside dans le fait que les patients sont traités de la même façon, même s'ils sont transférés dans d'autres hôpitaux de la région. En même temps, l'approche régionale répartit le travail et permet de garantir la mise à jour des lignes directrices.
	Tchéquie	L'hôpital universitaire Olomouc a suivi les travaux du centre sur les antibiotiques de l'hôpital et a publié les résultats des activités menées sur une période de dix ans (2010- 2019). ¹⁶ Les données indiquent des taux faibles de résistance bactérienne dans l'hôpital en raison de la mise en œuvre des mesures générales de promotion du bon usage des antimicrobiens.
	Croatie	L'hôpital général de Koprivnica a effectué une étude de cohorte afin de rationaliser l'utilisation des antibiotiques de dernier recours. L'étude visait à traiter la question de la consommation croissante des antibiotiques de réserve. Les résultats ont montré une baisse de presque 40 % de la durée d'hospitalisation des patients au cours de la période d'intervention.
	Suède	Les visites des malades dans le cadre de la promotion du bon usage des antimicrobiens guidées par des spécialistes des maladies

¹⁶ Kolar, M.; Htoutou Sedlakova, M.; Urbanek, K.; Mlynarcik, P.; Roderova, M.; Hricova, K.; Mezerova, K.; Kucova, P.; Zapletalova, J.; Fiserova, K.; et al. Implementation of Antibiotic Stewardship in a University Hospital Setting. Antibiotics 2021, 10, 93. <u>https://doi.org/10.3390/antibiotics10010093</u>

		infectieuses, qui donnent des conseils sur le
		traitement antibiotique, constituent une
		pratique courante dans les services suédois de
		soins intensifs, dans le service d'oncologie,
		d'hématologie et dans les autres services
		hautement spécialisés qui traitent les patients
		fortement exposés au risque de contracter des
	Danemark	infections compliquées.
	Danemark	Le projet OptiCAP au Danemark prévoit plusieurs activités dans les départements
		d'hôpitaux sélectionnés, visant à réduire les
		traitements antibiotiques inutilement longs pour
		les patients souffrant de pneumonie.
Soutien en matière de	France, Italie,	France : Ligne téléphonique d'urgence pour la
promotion du bon usage des	Suède,	promotion du bon usage des antimicrobiens
antimicrobiens pour les	Danemark	Portugal : Programme de soutien en matière de
professionnels de la santé et de		prescription des antibiotiques (PAPA)
soins		Italie : Répertoire ad hoc des bonnes pratiques
		validées
		Suède : Groupes locaux sur le programme stratégique de lutte contre la résistance aux
		antibiotiques (Strama) et réunions des réseaux
		Danemark : Groupe de travail régional sur la
		politique en matière d'antibiotiques
		Irlande : Répertoire en ligne des ressources
		pour les établissements résidentiels de soins et
		les maisons de soins
Développement de lignes	Slovénie	Les petits guides rouges sur la prescription des
directrices et recommandations		antibiotiques dans les hôpitaux et dans le cadre
en matière de promotion du bon		des soins primaires, publiés en 2002 et en
usage des antimicrobiens		2007, ont été transférés dans une application pour ordinateurs et une application mobile
		appelée Quiba.
	Lettonie	L'hôpital universitaire de pédiatrie a élaboré
		des recommandations sur l'utilisation des
		antimicrobiens pour la prophylaxie chirurgicale
		avec le but de réduire les risques d'infections
		sur le site opératoire.
		L'hôpital clinique universitaire Pauls Stradiņš a
		également formulé ses propres
		recommandations à portée interne visant à promouvoir une utilisation responsable des
		antimicrobiens. Ces lignes directrices décrivent
		les conditions d'utilisation du traitement
		antimicrobien, les principes du choix rationnel
		des agents, et les conditions que l'on doit
		évaluer avant de prescrire des antibiotiques.
	Danemark	La région du Jutland central a développé et mis
		en place des paquets sur les prescriptions dans
		les hôpitaux. Ces paquets rassemblent les
		procédures opératoires standardisées
		associées aux prescriptions afin de permettre de suivre plus aisément les lignes directrices
		approuvées en matière d'utilisation des
		antibiotiques.

Systèmes de surveillance	Suède	Svebar est un système national de surveillance des données cumulatives concernant la sensibilité aux agents antimicrobiens, auquel 22 sur 26 laboratoires de microbiologie clinique participent. Les données collectées représentent autour de 90 % de la population suédoise et permettent une détection précoce et la définition des mesures appropriées en matière de promotion du bon usage des antimicrobiens.
Formation en matière de promotion du bon usage des antimicrobiens	Allemagne	Plusieurs formations en matière de promotion du bon usage des antimicrobiens ont été organisées par l'Association médicale allemande, la Société allemande de pathologie infectieuse et la Société allemande d'hygiène hospitalière.

Mesures de promotion du bon usage des antimicrobiens dans le cadre des soins primaires et dans les pharmacies

Les médecins traitants de soins primaires/médecins de famille et les pharmacies communales sont souvent le premier point de contact du public avec le système de santé. Les médecins traitants constituent également le « point d'entrée » du système dans plusieurs pays de l'étude, les soins secondaires et les autres soins nécessitant d'un système de prise en charge. La quantité d'antimicrobiens prescrits au sein de soins primaires est élevée comparée aux soins secondaires dans la plupart des pays. Les professionnels de la santé jouent, donc, un rôle important dans la gestion des symptômes associés à une infection, dans le renforcement des connaissances des patients sur une utilisation appropriée des antibiotiques et dans le changement des comportements des patients.

La qualité de la surveillance de la consommation d'antimicrobiens et de l'utilisation appropriée des antibiotiques par la collectivité, ainsi que les opportunités de retour d'informations et d'apprentissage pour les médecins de soins primaires, varient d'un pays de l'étude à l'autre. L'application de cette législation est variable dans les pharmacies communales, bien que la plupart de pays disposent de législations visant à prévenir la vente d'antibiotiques « en vente libre ».

Il y a plusieurs obstacles d'ordre institutionnel et politique qui entravent le développement et la mise en œuvre des mesures de promotion du bon usage des antimicrobiens dans le cadre des soins primaires. Les soins primaires sont généralement omis dans les plans d'action nationaux, ou mentionnés brièvement. En plus, les professionnels de soins primaires ne connaissent les plans d'action nationaux que de façon limitée et il n'existe pas de cadre réglementaire dans le domaine de la promotion du bon usage des antimicrobiens. Les fonds prévus pour le développement et/ou la mise en œuvre des mesures de promotion du bon usage des antimicrobiens dans le cadre des soins primaires ne sont pas suffisants et le suivi ou la vérification des pratiques de prescription et de délivrance de la part des autorités nationales ou régionales est insuffisant ou inadéquat. Parmi les obstacles d'ordre clinique figurent le manque de lignes directrices spécifiques aux soins primaires sur la gestion d'infections et une connaissance insuffisante des lignes directrices nationales et internationales sur l'utilisation des antimicrobiens de la part des médecins traitants. Il en résulte une forte dépendance envers l'expérience clinique pour le traitement antimicrobien (prescription empirique), ce qui s'ajoute à des diagnostics fondés sur des éléments probants qui sont absents ou limités (prescription documentée). Il existe également plusieurs problèmes complexes de ressources humaines et de personnel ayant une incidence sur la promotion du bon usage des antimicrobiens qui se produisent souvent en même temps (manque de personnel spécialisé et manque d'éducation et formation en matière de promotion du bon usage des antimicrobiens, contraintes de temps et vieillissement des médecins). Il y a aussi d'importants obstacles d'ordre comportemental. Les échanges et/ou la communication entre les différentes parties prenantes participant à la mise en œuvre des mesures de promotion du bon usage des antimicrobiens dans le cadre des soins primaires, y compris les pharmacies et les laboratoires, sont limités et le système de partage des compétences parmi les multiples autorités est complexe. Le niveau de sensibilisation du public et les connaissances en matière d'utilisation des antibiotiques et de résistance aux antimicrobiens sont faibles, même s'il y a eu des progrès au niveau européen. En ce qui concerne les médecins hospitaliers, cela se traduit par des pressions accrues exercées par les patients qui veulent qu'on leur prescrive des antibiotiques, ce qui s'ajoute au fait que les médecins traitants craignent que leurs patients ne soient pas traités et développent des complications infectieuses. En outre, les patients ne respectent que faiblement les traitements prescrits par leurs médecins.

En termes de pharmacies, les obstacles d'ordre institutionnel et politique incluent des mentions explicites absentes ou limitées des pharmacies communales dans les plans d'action nationaux et le manque, dans certains pays, d'une politique ou stratégie au sein des pharmacies en matière d'utilisation et optimisation des médicaments. Il existe également des obstacles d'ordre commercial, tels que la pénurie et l'indisponibilité d'antibiotiques à spectre étroit ; une politique tarifaire des antimicrobiens inadéquate, qui ne limite pas l'accès aux antibiotiques ou ne prévient pas une consommation d'antibiotiques excessive et l'excès d'emballage des antibiotiques sur le marché. La recherche a également montré un manque de clarté ou une clarté limitée quant au rôle des pharmacies dans la lutte contre la résistance aux antimicrobiens et un manque de formation dans ce domaine. Les obstacles d'ordre comportemental ont également une incidence sur les mesures de promotion du bon usage des antimicrobiens dans les pharmacies. En dépit de la législation, il est commun dans certains pays de l'étude de délivrer des antibiotiques sans prescription.

Les actions de la part de l'Union européenne qui pourraient aider les États membres à surmonter les obstacles empêchant une mise en œuvre efficace des mesures de promotion du bon usage des antimicrobiens dans le cadre des soins primaires et dans les pharmacies sont indiquées dans le tableau ci-dessous :

Enjeu	Mesures d'aide proposées
Effectuer un suivi efficace des prescriptions et de la consommation des antimicrobiens dans le cadre des soins primaires	Soutenir l'adoption ou l'amélioration des mécanismes de vérification et de retour d'informations en matière de prescription des antimicrobiens de la part des médecins de soins primaires.
Renforcer la promotion du bon usage des antimicrobiens dans le cadre des soins primaires et dans les pharmacies	Recommander, guider et contrôler à ce que les plans d'action nationaux suivant le principe « Une seule santé » et/ou les politiques et stratégies nationales en la matière incluent les programmes de promotion du bon usage des antimicrobiens. Promouvoir les lignes directrices existantes en matière de promotion du bon usage des antimicrobiens et appuyer l'élaboration de nouvelles lignes directrices. Aider les États membres à chercher de nouveaux moyens d'améliorer la qualité des prescriptions par le biais de modèles de remboursement pour les prestataires de santé.
Surmonter les obstacles d'ordre structurel, tels que le manque de financement et de ressources humaines qualifiées	Indiquer aux États membres qu'il existe plusieurs sources de financement provenant de l'Union européenne ayant pour but de surmonter les obstacles d'ordre structurel qui entravent la mise en œuvre des mesures de promotion du bon usage des antimicrobiens dans le cadre des soins primaires et dans les pharmacies.

Accroître la sensibilisation et	(Co)développer des modules et du matériel de formation et soutenir l'amélioration de la formation des professionnels de la santé dans le cadre des soins primaires et des pharmaciens en matière de promotion du bon usage des antimicrobiens.
la connaissance du public à l'égard de la promotion du bon usage des antimicrobiens	Aider les États membres (en fournissant du soutien et/ou de l'assistance techniques, ou en développant une campagne à titre de modèle avec le matériel, les formulaires-types, etc.) à renforcer les campagnes de communication afin d'accroître la sensibilisation et les connaissances médicales des citoyens.
Échanger les bonnes pratiques et connaissances entre les États membres	Échanger les bonnes pratiques pour l'élaboration de procédures visant à vérifier les prescriptions. Échanger les bonnes pratiques pour augmenter l'utilisation des analyses en laboratoire et des tests de diagnostic sur le lieu des soins de la part de prestataires de soins primaires. Promouvoir le développement de réseaux de pharmaciens. Améliorer la coopération et l'échange de connaissances entre les pharmacies communales et les hôpitaux/les pharmacies hospitalières.
Renforcer le suivi des pratiques de prescription et de délivrance et la recherche en matière de promotion du bon usage des antimicrobiens.	Établir un ensemble d'indicateurs, de lignes directrices et de recommandations visant à contrôler la prescription et la délivrance des antimicrobiens. Stimuler la recherche en matière de promotion du bon usage des antimicrobiens. Soutenir la recherche et le développement de tests de diagnostic nouveaux/rapides et de traitements alternatifs aux antibiotiques.
Surmonter les obstacles d'ordre commercial empêchant l'accès aux médicaments, spécialement dans les pharmacies communales (mais aussi dans les hôpitaux) :	Recommander que les pharmaciens aient l'autorisation de modifier l'emballage pour ne délivrer que la quantité prescrite d'antibiotique. Collaborer avec l'Agence européenne des médicaments (EMEA) afin de comprendre dans quelle mesure les médicaments biosimilaires peuvent réduire l'indisponibilité et les pénuries de médicaments à long terme. Développer avec les États membres une liste d'antimicrobiens qui doit être conservée dans les pharmacies publiques.

La recherche a également identifié des exemples de bonne pratique en matière de mise en œuvre des mesures de promotion du bon usage des antimicrobiens dans le cadre des soins primaires et dans les pharmacies :

Domaine	Pays	Mesure
Suivi de la prescription et de la délivrance des antibiotiques	Danemark	Les pharmaciens sont tenus d'enregistrer tous les médicaments qu'ils vendent et ils sont surveillés si les ventes réalisées surpassent les attentes. Les informations concernant les médicaments sur prescription vendus au Danemark ont été enregistrées dans le registre des statistiques sur les médicaments (RMPS), tenu par l'Agence danoise des médicaments. Le RMPS offre des données individuelles sur les prescriptions délivrées dans toute la nation. Un outil national appelé Ordiprax a été développé afin de permettre aux médecins danois d'avoir une vue d'ensemble sur support numérique de leurs pratiques de prescription et des prescriptions des antibiotiques, et de les comparer avec celles d'autres médecins.

		· · · ·
	Irlande	Le système national de surveillance de consommation des antimicrobiens au sein de la collectivité a été mis en place depuis 2003. Les données se basent sur les données en gros des pharmacies, plutôt que sur les prescriptions individuelles, et représentent 95 % de la consommation des antimicrobiens au sein de la collectivité dans le pays.
	Suède	La capacité nationale en matière de technologie de l'information (« Primärvårdskvalitet ») extrait des données des dossiers médicaux électroniques des patients afin de suivre de près la prescription et la délivrance des antibiotiques, ainsi que la résistance aux antibiotiques, dans le cadre des soins primaires au niveau national. Le registre national des médicaments prescrits (« Läkemedelsregisret' »), mis en place en 2005, sert de base aux statistiques officielles en matière de prescription de médicaments en Suède. Il utilise les numéros d'identification personnels et contient tous les médicaments prescrits délivrés dans les pharmacies.
	Pays-Bas	Le projet SABEL (Informations réfléchies sur les antibiotiques de première intention, <i>Spiegelinformatie Antibotica Eerstelijn</i>) vise à offrir aux médecins généralistes des informations de référence sur leurs comportements de prescription et à les comparer avec les comportements de prescriptions d'autres médecins généralistes aux niveaux régional et national.
Nouveaux moyens de travail collaboratif en matière de promotion du bon usage des antimicrobiens, d'éducation	Suède	Le modèle Strama de Suède est guidé par les agents médicaux des comtés pour le contrôle des maladies transmissibles dans chaque comté.
par les pairs et de collaboration	Belgique	Les groupes locaux d'évaluation médicale (GLEM) ayant pour but de débattre et améliorer les pratiques de prescription des antibiotiques permettent aux professionnels de la santé d'apprendre les uns des autres et d'identifier les points à améliorer dans leurs pratiques de prescription.
	Croatie	La caisse maladie croate a décidé de financer l'organisation des réunions entre pairs où les professionnels de la santé se renseignent mutuellement.
	Irlande	Un réseau de pharmaciens pour la promotion du bon usage des antimicrobiens (PAMS-net) a été établi en août 2022. Il s'agit d'un réseau visant à aider les pharmaciens à atteindre l'objectif commun d'une promotion de l'utilisation responsable des antimicrobiens.
Prescriptions « wait and see »	Plusieurs pays	Ces prescriptions sont utilisées en Belgique, en Croatie, à Chypre, au Danemark, en Allemagne, en Hongrie, en Irlande, en Italie, au Luxembourg, à Malte, aux Pays-Bas et en Suède. Des études

		au Danemark ont montré que cette mesure permet de réduire la consommation des antibiotiques dans la médecine générale. Les médecins délivrent une prescription normale qui ne peut pas être présentée à moins que les symptômes ne demeurent inchangés pendant une période prédéterminée.
Tests sur le lieu des soins	Danemark	Il s'agit de méthodes d'analyse rapide qui ont été développées afin d'être utilisées en médecine générale. Elles permettent aux médecins de prendre des décisions rapides en matière de prescription des antibiotiques, aidant à éviter les prescriptions inutiles.
Outils pour les décisions thérapeutiques	Irlande	L'initiative vert/rouge pour l'amélioration de la qualité des antibiotiques pour les prescripteurs de proximité a été adoptée en 2019 en tant que base pour aider les prescripteurs de proximité dans leur prise de décision en matière de prescription des antibiotiques.
	France	L'application ANTIBIOCLIC est un outil qui aide les médecins de première ligne dans leur prise de décision thérapeutique. Elle vise à favoriser une thérapie rationnelle d'antibiotiques dans le cadre des soins primaires.
Ressources pédagogiques en ligne	Suède et France	Il existe plusieurs ressources d'apprentissage en ligne visant plusieurs groupes de parties prenantes, du grand public aux prestataires de la santé en Suède et en France.
Campagnes de sensibilisation	Suède	Le Forum national en matière d'antibiotiques est organisé tous les ans en parallèle avec la Journée européenne de sensibilisation à l'usage des antibiotiques le 18 novembre.
	Roumanie	La campagne de sensibilisation de l'opinion publique en matière de consommation d'antibiotiques sans prescription médicale a été lancée en 2018 à l'initiative d'un réseau de pharmacies privées.

Conclusions

La présente étude révèle des problèmes communs à tous les pays, tels qu'un financement inadéquat pour la mise en œuvre des mesures prévues dans les plans d'action nationaux, la pénurie de personnel qualifié à tous les niveaux de soins, l'absence de mesures visant principalement les établissements de soins de longue durée, la participation limitée des pharmacies aux mesures de promotion du bon usage des antimicrobiens et les perturbations causées par la pandémie de COVID-19 dans le secteur de la santé. Ces obstacles affectent chaque pays différemment, mais tous les pays, sans condition de taille et de situation économique, y font face.

Parmi les autres obstacles identifiés, on retrouve : un intérêt politique et une connaissance limités des défis engendrés par la résistance aux antimicrobiens ; l'absence de plans opérationnels pour la mise en œuvre des plans d'action nationaux ; le manque d'indicateurs harmonisés en matière de suivi de la mise en œuvre des plans ; une attention limitée accordée à la résistance aux antimicrobiens, aux mesures de promotion du bon usage des antimicrobiens et à la prévention et à la lutte contre les infections au sein de l'éducation et

de la formation et une sensibilisation faible de l'opinion publique à la résistance aux antimicrobiens.

1. Introduction

This document constitutes the final report of the "Study on the barriers to effective development and implementation of national policies on antimicrobial resistance" (Service contract HaDEA SC 2021 P1 02). The content of the report is structured as follows:

Section	Content and purpose
Context to the study	The problem of antimicrobial resistance in Europe and across the globe, international initiatives for combatting AMR, the EU policy context.
Methodology	Summary of the methodological approach, results of the consultation activities, and study limitations.
Findings	Summary of cross-cutting findings emerging from the country-level research, covering all study areas and focusing on state of play, barriers and possible measures for the EU.
Conclusions	Main conclusions from the study.
Annexes	Annex 1: Glossary
	Annex 2: Study questions
	Annex 3: Key indicators on the development and implementation of national action plans, infection prevention and control, and antimicrobial stewardship measures across study countries
	Annex 4: Bibliography

Table 1: Structure of the report

2. Policy context of the study

2.1. The problem of antimicrobial resistance

Antimicrobial resistance (AMR) develops when microbes become resistant to antimicrobial agents including antibiotics. As a result, antibiotics, which are commonly used in human and veterinary medicine to treat a wide variety of infectious diseases, are no longer effective in killing or stopping the growth of bacteria. It is estimated that each year in the European Union/European Economic Area (EU/EEA), over 670 000 infections are due to bacteria resistant to antibiotics¹⁷, which result in approximately 35 000 deaths. Some bacteria have

¹⁷ ECDC and WHO. 2022. Antimicrobial resistance surveillance in Europe 2022 – 2020 data. Available at <u>https://www.ecdc.europa.eu/sites/default/files/documents/ECDC-WHO-AMR-report.pdf</u>

developed resistance to multiple drugs.¹⁸ Already in 2020, more than half (54%) of the *Escherichia coli* (commonly known as *E. coli*) isolates reported to EARS-Net were resistant to at least one of the antimicrobial groups under regular surveillance (i.e. aminopenicillins, fluoroquinolones, third-generation cephalosporins, aminoglycosides and carbapenems).¹⁹ Resistance to last-line antibiotics has also been identified as an area of major concern and a threat to patient safety.²⁰ Alarming levels of resistance are reported in all countries around the world, irrespective of their wealth status. Some common diseases are becoming untreatable, and the level of risk involved in carrying out lifesaving medical procedures is of increasing concern. In Europe, healthcare associated infections (HAIs) remain the highest burden compared to all other infectious diseases including HIV, tuberculosis, and influenza.²¹

Humans can acquire resistant bacteria from direct contact with animals, contaminated surfaces, as well as through food consumption. But scientific evidence confirms the link between antibiotics consumption and the development of AMR, which is viewed as one of the main drivers of the problem.²² Inappropriate or unnecessary use of antibiotics in humans and animals are highly prevalent in the emergence of AMR. In the 2022 Special Eurobarometer Report on AMR, 50% of respondents were aware that antibiotics are ineffective against viruses.²³ While this a move in the right direction, from 43% as measured in 2018, it also shows that there is still room to raise awareness given that half of the European population is unaware of this fact. Other positive developments include the reduction in food-producing animals' consumption of antibiotics²⁴, as well as the EU ban on the use of antibiotics as growth promoters in feed.²⁵ Moreover, the overall sales of veterinary antibiotics in European countries fell by more than 34%, between 2011 and 2018.²⁶ The Surveillance Veterinary Antimicrobial annual European of Consumption (ESVAC) report shows that, in the 25 EEU/EEA countries that provided sales data for all years, aggregated sales of veterinary antibiotics fell by 46.5% from 2011 to 2021, which was the lowest value ever reported.

Globally, however, human antibiotic consumption is still rising. Research by Klein et al. shows that the global use of antibiotics increased by 65% between 2000 and 2015, mainly due to an overconsumption in developing countries because of rising incomes.²⁷ At the start

²³ Special Eurobarometer 522 "Antimicrobial resistance", 2022. Available from: <u>https://europa.eu/eurobarometer/surveys/detail/2632</u>

¹⁸ European Centre for Disease Prevention and Control. Assessing the health burden of infections with antibiotic-resistant bacteria in the EU/EEA, 2016-2020. Stockholm: ECDC; 2022. Available at <u>https://www.ecdc.europa.eu/sites/default/files/documents/Health-burden-infections-antibiotic-resistant-bacteria.pdf</u>

¹⁹ WHO Regional Office for Europe/European Centre for Disease Prevention and Control. Antimicrobial resistance surveillance in Europe 2022 – 2020 data. Copenhagen: WHO Regional Office for Europe; 2022. Available from: https://www.ecdc.europa.eu/sites/default/files/documents/Joint-WHO-ECDC-AMR-report-2022.pdf

²⁰ ECDC and WHO. 2022. Antimicrobial resistance surveillance in Europe 2022 – 2020 data. Available at <u>https://www.ecdc.europa.eu/sites/default/files/documents/ECDC-WHO-AMR-report.pdf</u>

²¹ See: <u>https://www.ecdc.europa.eu/en/news-events/estimated-burden-healthcare-associated-infections-higher-other-infectious-diseases-such</u>

²² ECDC, EMA and EFSA. 2021. Third joint inter-agency report on integrated analysis of consumption of antimicrobial agents and occurrence of antimicrobial resistance in bacteria from humans and food-producing animals in the EU/EEA, JIACRA III. 2016–2018. Available at https://www.ecdc.europa.eu/sites/default/files/documents/JIACRA-III-Antimicrobial-Consumptionand-Resistance-in-Bacteria-from-Humans-and-Animals.pdf

²⁴ ECDC, EMA and EFSA. 2021. Third joint inter-agency report on integrated analysis of consumption of antimicrobial agents and occurrence of antimicrobial resistance in bacteria from humans and food-producing animals in the EU/EEA, JIACRA III. 2016–2018. Available at <u>https://www.ecdc.europa.eu/sites/default/files/documents/JIACRA-III-Antimicrobial-Consumptionand-Resistance-in-Bacteria-from-Humans-and-Animals.pdf</u>

²⁵ See: <u>https://ec.europa.eu/commission/presscorner/detail/en/IP_05_1687</u>

²⁶ EMA. Annual Report 2020. Available at <u>https://www.ema.europa.eu/en/annual-report-2020/antimicrobial-resistance-0.html</u> Last accessed on 8 March 2022.

²⁷ Klein, Eili Y., et al. "Global increase and geographic convergence in antibiotic consumption between 2000 and 2015." Proceedings of the National Academy of Sciences 115.15 (2018).

of the COVID-19 pandemic (in 2020), there were noticeable reductions in the consumption of antibiotics in Europe. Yet by 2021, the EU/EEA population-weighted means for total consumption and community consumption of antibiotics had stabilised, confirmed by the latest ECDC report on antimicrobial consumption in the EU/EEA.²⁰ Only one country reported an increase in total consumption between 2019 and 2020 (Bulgaria), but over half of countries reported increases between 2020 and 2021. However, 2021 consumption rates remained below 2019 rates for almost all countries. The report also confirms an increase in the ratio between 'broad' and 'narrow' spectrum antibacterials for systemic use in the community sector. In the hospital sector, the increase in the use of 'broad' spectrum antibacterials, as a proportion of all antibacterials, also accelerated during 2019–2021. While the hospital sector had unprecedented decreases in EU/EEA mean consumption during 2020 and 2021, there were large increases in consumption of broad-spectrum and last-line antibiotics.

One consequence of rising AMR is worse health outcomes for patients, including health complications and in some cases even death. For example, due to AMR, it might take longer to identify appropriate and effective antibiotic therapy while, simultaneously, the condition of the patient deteriorates. Another major problem is secondary infection because of surgery, injection, or ventilation in hospitals with drug-resistant bacteria (such as methicillin-resistant *Staphylococcus aureus* (MRSA)). At its worst, without effective antibiotics, the treatment of bacterial diseases, as well as some medical procedures such as organ transplants, cancer chemotherapy and intensive care, could no longer be possible.

It is projected that if AMR is not curbed by 2050, deaths might rise to 10 million per year, becoming a more common cause of death than cancer, as shown in Table 2.²⁰ New estimates from a study published in 2022 looking at AMR across 204 countries and territories show that at least 1.27 million deaths per year are currently directly attributable to AMR.³⁰

Antimicrobial Resistance	10 million
Cancer	8.2 million
Diabetes	1.5 million
Diarrheal Disease	1.4 million
Road Traffic Accidents	1.2 million
Measles	130,000
Cholera	100,000–120,000
Tetanus	60,000

Table 2: Global mortality rates by 2050 by condition

Source: Dadgostar, Porooshat. "Antimicrobial resistance: implications and costs." Infection and drug resistance 12 (2019).

²⁸ European Centre for Disease Prevention and Control. Antimicrobial consumption in the EU/EEA (ESAC-Net) - Annual Epidemiological Report 2020. Stockholm: ECDC; 2021. Available from: <u>https://www.ecdc.europa.eu/en/publications-</u> <u>data/surveillance-antimicrobial-consumption-europe-2020</u>

²⁹ EMA. European medicines agencies network strategy to 2025. p. 12. Available from: <u>https://www.ema.europa.eu/en/documents/report/european-union-medicines-agencies-network-strategy-2025-protecting-</u> public-health-time-rapid-change en.pdf

³⁰ Antimicrobial Resistance Collaborators. "Global burden of bacterial antimicrobial resistance in 2019: a systematic analysis" The Lancet Vol 399, issue 10325, P629-655 (2022). Available from: <u>https://www.thelancet.com/action/showPdf?pii=S0140-6736%2821%2902724-0</u>

Another consequence of AMR is higher costs to the healthcare system, associated with longer hospital stays and more costly treatments due to the use of more expensive drugs. One estimate puts the extra healthcare costs for treating infections due to multi-drug resistant bacteria in the EU each year at EUR 1.5 billion.³¹ According to other studies, it is projected that AMR could cost from \$300 billion to more than \$1 trillion annually by 2050 worldwide.³² High costs associated with expensive and intensive treatments and increases in resource utilisation are the direct monetary effects of AMR on healthcare.

In addition, the World Bank suggests that failure to contain AMR could result in substantial losses to the global economy between now and 2050. If left unchecked, in an optimistic scenario of comparatively low impacts, AMR will likely reduce annual global GDP by 1.1 percent by 2050. In a high-AMR-impact scenario, by 2050, drug-resistant infections may cut annual global GDP by 3.8 percent³³.

No country is safe in the 'High-AMR' scenario, but low-income countries would be disproportionately hit the hardest. Investment in limiting this high-risk scenario can bring significant rewards. The World Bank argues that 'putting funds into AMR control is likely to be among the highest-yield investments that countries and partners can make today'. AMR investments of 0.2 trillion USD will bring cumulative benefits of between 10 and 27 trillion USD. While middle and high-income countries stand to reap the largest economic reward from containing AMR (in absolute and per capita terms), AMR cannot be addressed in isolation. AMR requires global mobilisation, with wealthier countries at the forefront of actions.³⁴

The fight against AMR requires a concerted effort globally and from all sectors concerned. One Health is the integrative effort of multiple disciplines working locally, nationally, regionally, and globally to attain optimal health for people, animals, and the environment. One Health recognises that the health and well-being of humans, animals and ecosystems are interconnected. Achieving the concept of One Health involves applying a coordinated, collaborative, multidisciplinary, and cross-sectorial approach to address potential or existing risks that originate at the animal-human-ecosystem interfaces. According to OECD. investing just EUR 1.5 per capita per year in a policy package to tackle AMR is effective and cost-saving, avoiding 27 000 deaths and saving EUR 1.4 billion each year in EU/EEA countries.³⁵ The policy package to tackle AMR more effectively should include improving hygiene in health facilities, adopting antimicrobial stewardship (AMS) programmes, increasing reliance on rapid diagnostic tests, delaying antibiotic prescriptions and raising public awareness. Other effective cost-saving interventions recommended by ECDC include antimicrobial stewardship programmes that promote the use of forgotten older antibiotics and scale up electronic prescribing, infection prevention and control (IPC) initiatives that involve education, training and feedback to healthcare workers, enhanced biosecurity and farm management measures such as animal vaccination and improved breeding, housing and nutrition.

³¹ European Commission. EU Action on Antimicrobial Resistance. Available from: <u>https://health.ec.europa.eu/antimicrobial-resistance/eu-action-antimicrobial-resistance_en</u>.

³² Chokshi A, Sifri Z, Cennimo D, Horng H. Global Contributors to Antibiotic Resistance. J Glob Infect Dis. 2019;11(1):36–42. doi: 10.4103/jgid_jgid_jgid_jgid_jgid_18 and Drug-resistant infections a threat to our economic future; 2017. Available from: www.worldbank.org. Accessed September 16, 2019, cited in Dadgostar P. Antimicrobial Resistance: Implications and Costs. Infect Drug Resist. 2019 Dec 20;12:3903-3910. doi: 10.2147/IDR.S234610. PMID: 31908502; PMCID: PMC6929930.

³³ Adeyi, O. O., et al. "Final Report Drug-Resistant Infections: A Threat to Our Economic Future." The World Bank: Washington, DC, USA (2017): 17. Available from: <u>https://documents.worldbank.org/en/publication/documents-reports/documentdetail/323311493396993758/final-report</u>

³⁴ Ibid.

³⁵ OECD. Briefing note on Antimicrobial Resistance in the EU/EEA: A One Health Response. 2022. Available from: <u>https://www.oecd.org/health/Antimicrobial-Resistance-in-the-EU-EEA-A-One-Health-Response-March-2022.pdf</u>.

2.2. Action at international level

AMR poses a global threat to the achievement of the Sustainable Development Goals linked to health, poverty, food security and the environment. In response to this threat, the WHO adopted a global action plan on antimicrobial resistance (GAP-AMR) in May 2015.³⁶ The 68th World Health Assembly endorsed the plan, which was developed in collaboration with the Food and Agriculture Organization of the United Nations (FAO) and the World Organisation for Animal Health (WOAH, founded as *Office International des Epizooties* (OIE)).³⁷

These three organisations are referred to as "the Tripartite". Heads of state further endorsed the plan during the United Nations General Assembly in October 2016. The GAP provides countries with a broad framework on how to tackle AMR, which focuses on five strategic objectives to:

- improve awareness and understanding of antimicrobial resistance through effective communication, education and training;
- strengthen the knowledge and evidence base through surveillance and research;
- reduce the incidence of infection through effective sanitation, hygiene and infection prevention measures;
- optimise the use of antimicrobial medicines in human and animal health;
- develop the economic case for sustainable investment that takes account of the needs of all countries; and
- increase investment in new medicines, diagnostic tools, vaccines, and other interventions.

The WHO GAP-AMR provided guidance that countries should aim to have an AMR National Action Plan in place within two years. In addition, the Tripartite has established a joint secretariat, hosted by WHO, to drive multi-stakeholder engagement in AMR.³⁸ The key governance structures agreed include the Global Leaders Group on AMR, which began its work in November 2020, the Independent Panel on Evidence for Action against AMR, and the Multi-Stakeholder Partnership Platform, which are currently being established.

The United Nations Environment Programme (UNEP) has joined up with the Tripartite to form the Quadripartite. The Quadripartite coordinates global activities to address health risks to animal-human-ecosystems, promoting the One Health Approach as the guiding frame for national responses to AMR.³⁹

As a key part of its approach to GAP-AMR monitoring and evaluation, the Tripartite set up the Tripartite AMR country self-assessment survey (TrACSS)⁴⁰, which is jointly administered by members of the Quadripartite. Since 2016, this annual survey has been monitoring the

³⁶ WHO. Monitoring global progress on antimicrobial resistance: tripartite AMR country self-assessment survey (TrACSS) 2019–2020. Global analysis report, 2021. Available from: <u>https://www.who.int/publications/i/item/monitoring-global-progress-on-antimicrobial-resistance-tripartite-amr-country-self-assessment-survey-(tracss)-2019-2020</u>

³⁷ Expert Panel on Effective Ways of Investing in Health (EXPH), Managing antimicrobial resistance across the health system, 2022. Available from: <u>https://health.ec.europa.eu/publications/managing-antimicrobial-resistance-across-health-system_en</u>

³⁸ WHO. Monitoring global progress on antimicrobial resistance: tripartite AMR country self-assessment survey (TrACSS) 2019–2020. Global analysis report, 2021. Available from: <u>https://www.who.int/publications/i/item/monitoring-global-progress-on-antimicrobial-resistance-tripartite-amr-country-self-assessment-survey-(tracss)-2019-2020</u>

³⁹ Expert Panel on Effective Ways of Investing in Health (EXPH), Managing antimicrobial resistance across the health system, 2022. Available from: <u>https://health.ec.europa.eu/publications/managing-antimicrobial-resistance-across-health-system_en</u>

⁴⁰ Tripartite AMR Country Self-Assessment Survey (TrACSS) 2020-2021. Available from: <u>https://www.who.int/publications/m/item/tripartite-amr-country-self-assessment-survey-(tracss)-2020-2021</u>

implementation of AMR national action plans. National authorities conduct a selfassessment of actions in relevant sectors, identifying progress on a series of topics. Each country is asked to submit a combined official response, which has been validated by all sectors involved and summarises national progress. The responses are structured according to the first four WHO-GAP objectives. In the 2022 survey, it was possible to generate country reports for the 166 countries (163 countries in 2021) that participated in 2022 TrACSS questionnaire. According to the latest published TrACSS report (covering 2019-2020), survey results confirmed an increase in the number of countries reaching nationwide implementation of several indicators, including the number of countries with: national action plans; functional multisectoral working groups on AMR; and with nationwide implementation of national infection prevention and control programmes, aligned with the WHO Guidelines on Core Components for IPC.⁴¹

In addition to the above initiatives, the Transatlantic Taskforce on Antimicrobial Resistance (TATFAR) was created in 2009 to address the urgent threat of antimicrobial resistance (AMR).⁴² TATFAR's technical experts from the Commission and other European Institutions, including the European Centre for Disease Prevention and Control (ECDC), the European Medicines Agency (EMA) and the European Food Safety Authority (EFSA) cooperate closely with the governments and relevant specialised agencies of the USA, Canada, Norway and the UK to share best practices to strengthen domestic and global efforts.⁴³ The US Centers for Disease Control and Prevention (CDC) serve as the secretariat for TATFAR, providing administrative support and maintaining the website for the Taskforce. There are four key focal areas:

- appropriate antimicrobial use in human and veterinary medicine;
- surveillance and prevention of AMR;
- strategies to improve financial incentives, access, research, and development of antimicrobial drugs, diagnostics, and alternatives; and
- cross-cutting actions to improve awareness and disseminate information from TATFAR.

In the autumn of 2021, TATFAR revised its work plan and identified 18 actions for continued collaboration through to 2026.

Other selected international initiatives against AMR are presented in the table below:

Title	Description
ReAct ⁴⁴	Created in 2005, ReAct is one of the first international independent networks to articulate the complex nature of antibiotic resistance and its drivers. ReAct was initiated with the goal of becoming a global catalyst, advocating and stimulating for global engagement on antibiotic resistance and has region specific networks (Africa, Asia Pacific, Europe, Latin America, North America).
The Joint Programming Initiative on	The JPIAMR is an international collaborative platform engaging 29 nations and the European Commission to curb antimicrobial resistance. The JPIAMR, established in 2011, coordinates national-research funding

Table 3: Examples of other international initiatives against AMR

⁴¹ WHO. Monitoring global progress on antimicrobial resistance: tripartite AMR country self-assessment survey (TrACSS) 2019–2020. Global analysis report (2021)

⁴² See: <u>https://www.cdc.gov/drugresistance/tatfar/index.html</u>

⁴³ See: <u>https://health.ec.europa.eu/antimicrobial-resistance/action-global-level_en</u>

⁴⁴ See: https://www.reactgroup.org/

Title	Description
AMR (JPIAMR) ⁴⁵	and supports collaborative action for filling AMR-knowledge gaps with a One Health perspective.
World Antimicrobial Awareness Week (WAAW) ⁴⁶	Established 2015, WAAW is a global campaign that aims to raise awareness of antimicrobial resistance worldwide and encourage best practices among the general public, health workers and policy makers to slow the development and spread of drug-resistant infections. The WAAW was previously called World <i>Antibiotic</i> Awareness Week. Since 2020, it has been called World <i>Antimicrobial</i> Awareness Week, to reflect the broadened scope of the WAAW to include all antimicrobials.
The Global Antimicrobial Resistance and Use Surveillance System (GLASS) ⁴⁷	The WHO launched the GLASS in 2015 to continue filling knowledge gaps and to inform strategies at all levels. GLASS was designed to progressively incorporate data from surveillance of AMR in humans and surveillance of the use of antimicrobial medicines, as well as AMR in the food chain and in the environment. GLASS provides a standardised approach to the collection, analysis, interpretation and sharing of data by countries, territories, and areas, and monitors the status of existing and new national surveillance systems, with emphasis on representativeness and the quality of data collection.
Global Antibiotic Research and Development Partnership (GARDP) ⁴⁸	GARDP is a not-for-profit global partnership developing treatments for drug-resistant infections that pose the greatest threat to health. Created in 2016, GARDP works across sectors to ensure equitable access to treatments and promote their responsible use.
Global Research and Development priority setting for AMR ⁴⁹	In 2017, to guide research and development into new antimicrobials, diagnostics, and vaccines, WHO developed the WHO priority-pathogens list. On an annual basis, WHO reviews the pre-clinical and clinical antibacterial pipelines to see how the pipeline is progressing with respect to the WHO priority-pathogens list.
International Centre for Antimicrobial Resistance Solutions (ICARS) ⁵⁰	ICARS (convened in 2018, and independent since 2021) is a platform for generating, assessing, and using evidence to support the development and implementation of cost-effective and context-specific solutions to mitigate antimicrobial resistance in low- and middle-income countries (LMICs).

⁴⁵ See: <u>https://www.jpiamr.eu/</u>

⁴⁶ See: <u>https://www.who.int/campaigns/world-antimicrobial-awareness-week</u>

⁴⁷ See: <u>https://www.who.int/news-room/fact-sheets/detail/antimicrobial-resistance</u>

⁴⁸ Ibid.

⁴⁹ Ibid.

⁵⁰ See: <u>https://icars-global.org/</u>

Title	Description
The Global AMR R&D Hub ⁵¹	The Global AMR R&D Hub was launched in May 2018, following a call from G20 Leaders, to address challenges and improve coordination and collaboration in global AMR research and development, using a One Health approach. It is a global partnership currently consisting of 17 countries, the European Commission and two philanthropic foundations.
The Global Leaders Group on Antimicrobial Resistance ⁵²	The Global Leaders Group on Antimicrobial Resistance was established in November 2020 following the recommendation of the Interagency Coordination Group (IACG) on Antimicrobial Resistance to strengthen global political momentum and leadership on AMR. The group performs an independent global advisory and advocacy role and works to maintain urgency, public support, political momentum, and visibility of the AMR challenge on the global health and development agenda.

2.3. Action at EU level

The EU has long been at the forefront in the fight against AMR, which reflects the size of the issue and its impact on public health, healthcare-system sustainability, the wider economy, and global-health security.

As early as 1997, a meeting of EU chief medical officers agreed that 'inappropriate use of antimicrobial agents was an important factor and were concerned that effective mechanisms to limit the emerging problem may not yet be in place'⁵³. In 1998, they set up a conference on "The Microbial Threat" in Copenhagen that presented a series of recommendations urging for prioritisation of this issue, which was qualified as a 'major European and global problem'.⁵⁴ The European Commission established the European Antimicrobial Resistance Surveillance System (EARSS), now known as EARS-Net, as a direct response. The table below presents surveillance networks, hosted by EU Agencies, working on AMR:

Surveillance Network	EU Agency
European Antimicrobial Resistance Surveillance Network (EARS-Net)	ECDC
European Surveillance of Antimicrobial Consumption Network (ESAC-Net)	ECDC
European Surveillance of Veterinary Antimicrobial Consumption (ESVAC)	EMA
Network for Zoonoses Monitoring Data	EFSA

⁵¹ See: <u>https://globalamrhub.org/</u>

⁵² See: <u>https://www.amrleaders.org/</u>

⁵³ Weinberg, J. "From the editors: European Union conference on the microbial threat." Weekly releases (1997–2007) 2.36 (1998): 1161.

⁵⁴ Copenhagen Recommendations. Report from the Invitational EU Conference on the Microbial Threat, (1998). <u>http://strama.se/wp-content/uploads/2016/04/Kopenhamnsmotet_1998.pdf</u>

Food- and Waterborne Diseases and Zoonoses Network (FWD- Net) ECDC

In 2001, the Commission adopted a Community strategy against AMR, which identified the importance of tackling AMR and called for EU action on surveillance, research, prevention, and international cooperation.⁵⁵ The 2006 ban⁵⁶ on the use of antimicrobials for growth promotion was a natural continuation of this policy, and a final step in the phasing out of antibiotic use for non-medicinal purposes.

The first EU One Health Action Plan against AMR (hereafter referred to as the AMR Action Plan) was developed in 2011. It proposed a holistic approach, in line with the "One Health" initiative⁵⁷, and contained 12 actions for implementation across EU Member States. It also identified seven areas where measures were most needed. This policy was reinforced with the 2011 Commission action plan, notable for its One Health approach, addressing AMR in both humans and animals. The 2016 evaluation of the AMR Action Plan confirmed its added value as a symbol of political commitment, which stimulated several actions in the Member States. The AMR Action Plan also provided a framework to guide and coordinate international AMR activities on monitoring, surveillance and R&D.

In 2017, the Commission adopted a renewed AMR Action Plan, which became the central document that currently guides EU strategy and action in AMR. The key objectives of the renewed plan are to preserve the possibility of effective treatment of infections, reduce the emergence and spread of AMR, and increase the development and availability of new effective antimicrobials. These objectives are structured along three pillars: (1) making the EU a best-practice region; (2) boosting research, development, and innovation; and (3) shaping the global agenda.

Further major initiatives adopted by the Commission include, *inter alia*, the "Guidelines on the prudent use of antimicrobials in veterinary medicine"⁵⁹ (2015), the "EU guidelines on the prudent use of antimicrobials in human medicine"⁵⁹ (2017) and, notably, the 2020 "A pharmaceutical Strategy for Europe",⁶⁰ which addresses the required investment for unmet needs, including the development of novel antimicrobials or alternatives. The Pharmaceutical Strategy includes interventions related to AMR. Pull-incentive models are being examined, and pilots launched, to (1) incentivise innovation, (2) keep existing and new antibiotics on the market, and (3) maintain manufacturing capacity and stockpiles in the EU. In addition, measures to restrict and optimise the use of antimicrobial medicines are included in the review of the pharmaceutical legislation.⁶¹

The Commission chairs and coordinates the EU AMR One Health Network. The network is composed of experts in human, animal and plant health from EU Member States, scientific agencies, and the Commission. The network serves as a platform for the exchange of information and best practice, and for discussion on policy options. Network membership

⁵⁵ Communication from the Commission on a Community Strategy against antimicrobial resistance, COM(2001)333. Available from: <u>https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=celex:52001DC0333</u>

⁵⁶ Communication from the Commission to the European Parliament and the Council on the Action plan against the rising threats from Antimicrobial Resistance, 15 November 2011, COM (2011) 748. Available from: <u>https://ec.europa.eu/health/system/files/2020-01/communication amr 2011 748 en 0.pdf</u>

⁵⁷ Ibid.

⁵⁸ Guidelines for the prudent use of antimicrobials in veterinary medicine. OJ 2015/C 299/04 <u>https://ec.europa.eu/health/document/download/190841e8-5975-4390-a304-908c259592ab_en</u>

⁵⁹ EU Guidelines for the prudent use of antimicrobials in human health. C/2017/4326 OJ C 212, 1.7.2017, p. 1–12. <u>https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:52017XC0701(01)</u>

⁶⁰ Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions Pharmaceutical Strategy for Europe, COM/2020/761 final. Available from: <u>https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:52020DC0761</u>

⁶¹ For more information on the proposed reform of the EU pharmaceutical legislation, please refer to: <u>https://health.ec.europa.eu/medicinal-products/pharmaceutical-strategy-europe/reform-eu-pharmaceutical-legislation_en</u>

was renewed and extended in 2022.⁶² Meanwhile, the Health Security Committee (HSC), set up in 2001 at the request of EU Health Ministers as an informal advisory group on health security at European level, and also provides a platform for discussion on actions against AMR in the human health sector. The HSC is mandated to reinforce the coordination and sharing of best practice and information on national prevention, preparedness, and response actions. Member States also consult one another within the Committee with a view to coordinating national responses to serious cross border threats to health.⁶³

Through various instruments and programmes, the Commission is funding actions to support national efforts in Member States. Notable initiatives include the Joint Action on Antimicrobial Resistance and Healthcare-Associated Infections (EU-JAMRAI), which involved the competent authorities of EU Member States and ran from 2017 until February 2021. A new Joint Action under EU4Health is in preparation, with a larger available budget of EUR 50 million than the previous one, and will be operational in 2024.⁶⁴ The Joint Action, which brings together the EU Member States and Norway, Iceland and Ukraine, will support competent authorities' implementation of a range of policies and measures to tackle AMR in a One Health approach, such as strengthening National Action Plans (NAPs); improving surveillance; upgrading infection prevention and control measures; fostering the prudent use of antimicrobials; and rolling out awareness-raising campaigns.

The Commission also funds research on AMR, including on the development of new approaches, treatments, and medicines to address microbial infections. Horizon 2020 and Horizon Europe have funded numerous initiatives contributing to the fight against AMR. A search on the CORDIS database for 'antimicrobial' and 'resistance' under both programmes yields 1 852 results. The Horizon-Europe partnership on One Health Anti-Microbial Resistance is expected to start in 2025.⁶⁵ Meanwhile this year, Horizon Europe, which includes projects on animal vaccine development and on animal welfare, will launch its planned partnership on Animal Health and Welfare.⁶⁶ The partnership includes targeting antimicrobial use and resistance in livestock within its priorities. One of its aims is to generate knowledge and develop products and services to improve the prevention and control of diseases. The total indicative EU contribution for the full duration of the partnership is EUR 180 million.

On 25 June 2019, the Council of the European Union adopted conclusions on the next steps towards making the EU a best-practice region in combatting AMR (2019/C 214/01). The conclusions call upon the Member States and the Commission to pursue several policy priorities. The present study on barriers to the effective implementation of AMR policies and measures is a response to the Council conclusions and seeks to address these issues.

The Council conclusions underline the importance of regular meetings of the EU AMR One Health Network, as part of the implementation of the EU Action Plan on AMR. The conclusions also call for increased cooperation and solidarity between the Member States, and the sharing of best practices and expertise, to support the implementation of NAPs as well as infection prevention and control and antimicrobial stewardship programmes relating to human health, food, animal health, environment, research and other relevant sectors.

The 2019 Strategic Approach to Pharmaceuticals in the Environment includes several actions which contribute to the objectives of the AMR Action Plan, to tackling the problem of AMR, and to honouring international commitments. As a strong global actor, the EU can

⁶² See: <u>https://ec.europa.eu/transparency/expert-groups-register/screen/expert-groups/consult?lang=en&groupID=3853</u>

⁶³ See: <u>https://health.ec.europa.eu/health-security-and-infectious-diseases/preparedness-and-response/health-security-committee-hsc_en</u>

⁶⁴ See: <u>https://ec.europa.eu/commission/presscorner/detail/en/qanda_23_1845</u>

⁶⁵ See: <u>https://ec.europa.eu/info/funding-tenders/opportunities/portal/screen/opportunities</u>

⁶⁶ See: <u>https://agriculture.ec.europa.eu/news/combatting-antimicrobial-resistance-farms-thanks-cap-support-2023-04-26_en</u>

encourage wide cooperation.⁶⁷ The Zero Pollution Action Plan (2021), in particular the upcoming revision of the Urban Wastewater Treatment Directive, addresses some of the consequences of increased AMR on the environment in the list of water pollutants under the Water Framework Directive and the Integrated Nutrient Management Action Plan.

In 2020, the COVID-19 pandemic disrupted the world's healthcare systems. The pandemic also led to the introduction of several EU and national initiatives, under the banner of the European Health Union, which support addressing AMR, and should boost work in this field in the coming years.⁶⁸ One of these initiatives is the Regulation on serious cross-border threats to health, which was adopted in December 2022 and covers AMR in human health.⁶⁹ The implementation of the Regulation through subsequent Commission acts will strengthen EU action on AMR on human health by improving surveillance, detection, prevention, and coordination among the Member States. In addition, AMR is included in the top three priority threats of the newly-created Health Emergency and Response Authority (HERA), which will implement actions to promote the development and availability of medical countermeasures relevant to AMR.⁷⁰ Moreover, the revision of the mandates of the ECDC and the EMA strengthen their responsibilities relating to the surveillance and monitoring of AMR.⁷¹

Since the start of the pandemic, the Commission has implemented a range of other initiatives (not linked to COVID-19) to address AMR. Initiatives include the publication of an Overview report of Member States' One Health National Action Plans against Antimicrobial Resistance,⁷² and the introduction of regulatory measures under the Animal Health Law for certain animal diseases in April 2021.⁷³

In May 2020, the Commission adopted the Farm to Fork strategy⁷⁴, a tool to help shape the EU's path towards sustainable food systems with an objective to cut the total value of EU sales of antimicrobials for farmed animals and aquaculture by 50% by 2030. The achievement of this objective is supported by two new Regulations (Regulation (EU) 2019/6 on Veterinary Medicinal Products⁷⁵ and Regulation (EU) 2019/4 on Medicated Feed⁷⁶). In November 2020, the new Commission Implementing Decision (EU) 2020/1729 was adopted

⁶⁷ Communication from the Commission to the European Parliament, the Council and the European Economic and Social Committee - European Union Strategic Approach to Pharmaceuticals in the Environment, COM (2019) 128 final, 11 March 2019. Available from: <u>https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A52019DC0128&gid=1605854880622</u>

⁶⁸ European Commission. Employment, Social Policy, Health, and Consumer Affairs Council Session on 15 June 2021. Joint Action on AMR and Healthcare-Associated Infections (JAMRAI) and State of Play on Antimicrobial Resistance. Accessed from https://data.consilium.europa.eu/doc/document/ST-9629-2021-INIT/en/pdf Last accessed on 21 March 2022

⁶⁹Regulation (EU) 2022/2371 of the European Parliament and of the Council of 23 November 2022 on serious cross-border threats to health and repealing Decision No 1082/2013/EU, <u>https://eur-lex.europa.eu/eli/reg/2022/2371/oj</u>

⁷⁰ See: <u>https://ec.europa.eu/commission/presscorner/detail/en/IP_22_4474</u>

⁷¹ See: <u>https://www.consilium.europa.eu/en/policies/protecting-against-cross-border-health-threats/</u>

⁷² European Commission. Overview report Member States' One Health National Action Plans against Antimicrobial Resistance. 2022. Available from: <u>https://health.ec.europa.eu/system/files/2022-11/amr_onehealth_naps_rep_en.pdf</u>

⁷³ Regulation (EU) 2016/429 on Animal Health Law. Available from: <u>https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A02016R0429-20210421</u>

⁷⁴ Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions A Farm to Fork Strategy for a fair, healthy and environmentally-friendly food system, COM (2020) 381 final. Available from: <u>https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A52020DC0381</u>

⁷⁵ Regulation (EU) 2019/6 of the European Parliament and of the Council of 11 December 2018 on veterinary medicinal products and repealing Directive 2001/82/EC. Available from: <u>https://eur-lex.europa.eu/eli/reg/2019/6/oj</u>

⁷⁶ Regulation (EU) 2019/4 of the European Parliament and of the Council of 11 December 2018 on the manufacture, placing on the market and use of medicated feed, amending Regulation (EC) No 183/2005 of the European Parliament and of the Council and repealing Council Directive 90/167/EE. Available from: <u>https://eur-lex.europa.eu/legal-</u> <u>content/EN/TXT/?uri=celex%3A32019R0004</u>

laying down rules for the period 2021-2027 for the monitoring and reporting of AMR in zoonotic and commensal bacteria to be carried out by the Member States.⁷⁷

The COVID-19 pandemic also highlighted the need for further funding, cooperation, and coordination. In response, the EU adopted the EU4Health⁷⁸ (2021-2027) programme, investing EUR 5.1 billion and making it the largest ever health-spending programme. The programme included a focus on reducing the number of antimicrobial-resistant infections by promoting the optimal and prudent delivery and use of medicinal products and antimicrobials.

In April 2023, the Commission presented its proposal for Council Recommendations on AMR,⁷⁹ (and adopted in June⁸⁰) and proposed AMR provisions, as part of the revision of the EU pharmaceutical legislation.⁸¹

The policy context and international initiatives presented above provide the frame for action at national level, which is the subject of the research conducted as part of the present study and detailed in the rest of the report. The next section, Section 3, introduces the study objectives and scope, and provides an overview of the methodology. The study findings are described in Section 4.

3. Methodology

3.1. Study objectives and scope

The study objective is to support the preparation of future policy initiatives on AMR, responding to the call for action in the 2019 Council Conclusions on AMR and supporting the implementation of the EU One Health Action Plan against AMR. The results of the study should bring evidence for future policy initiatives or actions at EU level to support Member States in the effective development and implementation of AMR policies and measures. Further details on the scope of the study are provided in Table 5.

Table 5: Study scope

Sco	ope	Description
Mat	erial scope	The study provides a detailed analysis of the existing barriers to the development and effective implementation of:
		 national One Health action plans to address AMR (Study Area 1);

⁷⁷ Commission Implementing Decision (EU) 2020/1729 of 17 November 2020 on the monitoring and reporting of antimicrobial resistance in zoonotic and commensal bacteria and repealing Implementing Decision 2013/652/EU. Available from: <u>https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A32020D1729</u>

⁷⁸ Regulation (EU) 2021/522 of the European Parliament and of The Council of 24 March 2021 establishing a Programme for the Union's action in the field of health ('EU4Health Programme') for the period 2021-2027, and repealing Regulation (EU) No 282/2014. Available from: <u>https://eur-lex.europa.eu/legal-</u> content/EN/TXT/?uri=uriserv%3AOJ.L_.2021.107.01.0001.01.ENG

⁷⁹ Commission proposal for a Council Recommendation on stepping up EU actions to combat antimicrobial resistance in a One Health approach, COM (2023) 191 final. Available from: <u>https://health.ec.europa.eu/system/files/2023-04/com_2023_191_1_act_en.pdf</u>

⁸⁰ Council Recommendation on stepping up EU actions to combat antimicrobial resistance in a One Health approach. Available from : <u>https://data.consilium.europa.eu/doc/document/ST-9581-2023-INIT/en/pdf</u>

⁸¹ Proposal for a Directive on the Union code relating to medicinal products for human use, COM(2023) 192 final. Available from: <u>https://health.ec.europa.eu/system/files/2023-04/com 2023 192 1 act en.pdf</u>. Proposal for a Regulation laying down Union procedures for the authorisation and supervision of medicinal products for human use and establishing rules governing the European Medicines Agency, COM(2023) 193 final. Available from: <u>https://health.ec.europa.eu/system/files/2023-04/com 2023 193 1 act en.pdf</u>

Scope	Description
	 effective infection prevention and control measures in human health (Study Area 2); and effective antimicrobial stewardship measures in human health (Study areas 3 and 4).
	Study Area 1: Identification and analysis of barriers to the development and implementation of One Health national action plans (NAPs) on antimicrobial resistance, including barriers related to the coordination across the One Health spectrum, as well as barriers specific to each sector (i.e., human, animal, plant, the environment, etc.) and the identification of potential measures (legislative, non-legislative, financial) to overcome such barriers.
	Study Area 2: Identification and analysis of barriers to the development and implementation of effective IPC measures in human health, notably in acute healthcare settings (hospitals) and in long-term-care facilities (LTCFs) (e.g., care homes, nursing) and the identification of actions (legislative, non-legislative, financial) to overcome those barriers. This requires an in-depth analysis and assessment of the state-of-play at national level.
	Study Area 3: Identification and analysis of barriers to the development and implementation of effective AMS measures, and measures aiming at prudent use of antimicrobials in human health, in acute healthcare settings (hospitals) and in LTCFs, including the identification of actions (legislative, non-legislative, financial) to overcome those barriers. This area entails indepth analysis and assessment of the state-of-play at national level.
	Study Area 4: Identification and analysis of barriers to the development and implementation of effective AMS measures and measures aiming at prudent use of antimicrobials in primary care and in pharmacies, and the identification of actions (legislative, non-legislative, and financial, etc.) to overcome these barriers. This area entails in-depth analysis and assessment of the state-of-play at national level.
	The study includes an analysis covering the barriers existing at institutional/policy level in each study country, including financial barriers; the barriers existing at clinical level (e.g., clinical guidelines/practices available in the country) and at behavioural level (e.g., behaviour and practices of healthcare professionals or other relevant stakeholders, despite existing guidance). The study also identifies the suggested ways to overcome the barriers through alternative approaches or good practices.
Geographical scope	The geographic scope of the study is all EU-27 Member States, plus Norway and Iceland.
Temporal scope	The data collection and analysis covers the period since the adoption of the 2017 EU Action Plan until April 2023.

3.2. Data collection

The study included the following data-collection activities:

- literature review;
- in-depth interviews with stakeholders at EU and national level;

- targeted surveys of relevant groups of stakeholders;⁸² and a
- virtual workshop with stakeholders, held on 18 and 19 October 2022.

The study engaged a total of 473 stakeholders through the consultation activities. The following overview of consulted stakeholders demonstrates the collection of a range of different perspectives, using consultation tools selected for their appropriateness to each stakeholder group. The consultation topics were also tailored to the profile, knowledge, experience, and interest of each group.

Consultation activity	Stakeholder group	Nr of stakeholders targeted	Nr of stakeholders responding	Level of engagement
Exploratory interviews	Commission DGs and health- related agencies (DG SANTE, HERA, EMA, ECDC, EFSA) Other bodies: OECD, WHO, and Expert Panel on Effective Ways of Investing in Health (EXPH)	9	9	High
In-depth interviews	Country-level stakeholders responsible for setting up and implementing NAPs, IPC, and AMS measures across the 29 study countries, including: national/regional authorities in human health; representatives of hospitals and LTCFs; and representatives of primary care and pharmacists.	Up to 5 per study country	125 ⁸³	High
Targeted surveys	National/ regional authorities	29	62 (from 29 countries)	High
	Hospital and LTCF stakeholders (i.e. health professionals and representatives of hospitals and LTCFs)	N/A	86 (from 18 countries)	Medium ⁸⁴
	Primary care and pharmacy stakeholders (e.g. physicians, nurses, dentists, pharmacists, etc.)	N/A	108 (from 22 countries)	High

Table 6 : Stakeholders engaged per consultation activity

⁸² The surveys included questions on the extent to which countries have IPC and AMS programmes/ measures that fulfil the WHO "Minimum requirements infection prevention control for and programmes" (https://ww w.who.int/publications/i/item/97 241516945) and the "EU Guidelines for the prudent use of antimicrobials in health" human https://eur-lex.europa.eu/legalcontent/EN/TXT/?uri=uriserv:OJ.C_.2017.212.01.0001.01.ENG&toc=OJ:C:2017:212:TOC.

⁸³ Researchers have complemented this with additional phone calls, meetings and emails aimed at filling in data gaps and validating findings.

⁸⁴ While the number of responses was high, respondents were from only 18 countries.

Consultation activity	Stakeholder group	Nr of stakeholders targeted	Nr of stakeholders responding	Level of engagement
	Other stakeholders (i.e. stakeholders from the animal, plant environmental and health (not captured above) sectors)	N/A	42 (from 17 countries)	Medium
Virtual workshop (4 sessions)	Session 1: EU-level stakeholders with an interest in NAPs and AMR policies	48 (registered)	28	High
	Session 2: EU-level stakeholders with an interest in IPC measures in hospitals and LTCFs	38 (registered)	17	Medium
	Session 3: EU-level stakeholders with an interest in AMS measures in hospitals and LTCFs, and the fight against AMR in hospitals and LTCFs	39 (registered)	21	Medium
	Session 4: EU-level stakeholders with an interest in AMS measures in primary care and pharmacies	38 (registered)	17	Medium

The study team conducted a quantitative and qualitative analysis of data gathered through the different consultation activities. The quantitative analysis included a descriptive statistical analysis of the results of the targeted surveys. The views and information provided in the interviews and the open questions of the targeted surveys were analysed using qualitative data analysis techniques. Where answers were provided in languages other than English, these were translated to English and integrated into the evidence base for coding and analysis.

The analysis was conducted in several phases. First-stage analysis focused on the results generated by individual data collection tools. Initial findings were then triangulated and contrasted with data from the literature review, to produce the study's overarching key findings and conclusions.

3.3. Study limitations

There are some limitations to the findings of this study, as follows:

- Amount and quality of evidence varied across countries, including in some casestudy areas. Where possible, researchers used interviews and surveys to fill in data gaps identified during the desk research. However, the depth of the analysis of results from different countries related directly to the amount and quality of the evidence that could be gathered.
- Inventory of barriers to effective AMR policies is non-exhaustive. The study team developed a typology of barriers, using inductive (based on themes which came up from the interviews and workshops) and deductive approaches (based on the desk and field research in Member States). The inventory provides examples of significant barriers affecting effective AMR policies and measures across 29 countries. Countries

may be facing other barriers, which have not yet been identified as such in the consultations or identified in the literature reviewed.

- Assessment of the magnitude of barriers in the different countries has some limitations. Certain barriers, such as the lack of funding or qualified staff, or the challenges imposed by poor or old hospital infrastructure, naturally have a different magnitude in each country. Also, impact of problems related to the COVID-19 pandemic was much more significant in some countries than others. This report focuses on identifying common challenges faced by European countries in combating AMR. Therefore, we provide a typology of barriers under each study area, including a description of the barriers, their effects and countries affected by them. However, it was not always possible to establish whether the barriers are more serious in some countries than others.
- Focus on EU actions to help address the barriers. Related to the above, there was variability in the type and cost of the measures needed in each country to address the identified barriers. Moreover, as per the Treaty on the Functioning of the European Union (TFEU), primary responsibility for any measures impacting on national healthcare systems continues to stay with Member States. Thus, the measures presented in this report provide suggestions for ways in which the EU can support the Member States in addressing the identified barriers.

4. Study findings

This section presents the findings of the study based on the data collected across the study countries through desk reasearch, interviews and surveys. The findings are presented by study area, first providing a short overview of the state of play, followed by an account of the institutional/policy, clinical, and/or behavioural barriers identified. While it needs to be stressed that health is a national competence and that national/regional governments are the ones who need to design and implement policies and measures against AMR, the study presents possible ways in which the EU can help countries in addressing some of the barriers that have been identified. Finally, for each of the areas studied, examples of good practices identified in some countries are also presented.

4.1. National One Health Action Plans

4.1.1. State of play

The assessment of the National One Health Action Plans (NAPs) carried out for the present study generally reflects the results of the review conducted by the European Commission (DG SANTE) and published in November 2022.³⁶ It is also aligned with the ECDC and WHO Regional Office for Europe's recent joint report on AMR surveillance in Europe.³⁶ NAPs are in place (or are in the process of being reviewed/updated) in 28 of the 29 study countries (see section 6.3.1), with most following a One Health approach, but still with some limitations. Based on national level research, the implementation of NAPs across Europe is very diverse (see Annex 3). Many NAPs focus on the human and animal health sectors and

⁸⁵ European Commission. Overview report Member States' One Health National Action Plans against Antimicrobial Resistance. 2022. Available at: <u>https://health.ec.europa.eu/system/files/2022-11/amr_onehealth_naps_rep_en.pdf</u>

⁸⁶ WHO Regional Office for Europe and ECDC. Antimicrobial resistance surveillance in Europe 2022. Available at <u>https://www.ecdc.europa.eu/en/publications-data/antimicrobial-resistance-surveillance-europe-2022-2020-</u> data#:~:text=Antimicrobial%20resistance%20(AMR)%20remains%20a,people%20die%20as%20a%20direct.

tend to leave out or not cover the environmental dimension sufficiently. This was confirmed in the interviews conducted across all 29 study countries.

Although most countries have structures or mechanisms in place to support cross-sectoral cooperation and, at least, oversee the development and/or implementation of their NAP, in practice intersectoral cooperation remains a challenge under the One Health approach. In the survey of national/regional authorities, 74% (n=39) of respondents reported that there was a mechanism for cross-sectoral coordination in place at national/regional level to support the development and/or implementation of the NAP; however, less than half (48%, n=14) confirmed that it was an effective mechanism. This finding is aligned with the views of stakeholders who participated in the country-level interviews, who emphasised that these mechanisms were either limited or not fully operational. In this respect, and in line with the Commission's review, the present study found that governance aspects, including oversight, are better addressed in the more recent One Health NAPs, for example in Ireland's second NAP.

In line with the Commission's findings, the research across 29 study countries found that NAPs focus mostly on Member States' strategy and vision to tackle AMR, while other core components, such as the operational, monitoring and evaluation aspects, are generally not well developed.⁸⁷ The assessment of NAPs also found that budgetary information is absent in the majority of the NAPs. National-level interviewees, which included national authorities, stakeholders representing hospitals, LTCFs, primary care and other stakeholders, were unsure or unaware of how much money had been (or would be) allocated to the implementation of the NAP. Moreover, the survey of national authorities confirmed that 48% of countries (n=14) were implementing their NAP and, from these, less than half (43%, n=6) had dedicated resources for implementation.

The research also found examples of international collaboration for the development of NAPs and the implementation of AMR-related activities, such as the programme "European Public Health Challenges" in Romania, which was funded under the EEA Financial Mechanism 2014-2021 with the Norwegian Institute of Public Health as a project partner. Funding from this mechanism allowed Romania to develop its National Strategy and NAP as well as the elaboration of standards and protocols, among other activities.⁸⁸

As detailed in the next sub-sections, the research conducted at national level highlighted the barriers to the development and implementation of NAPs to address AMR, which provide additional context for the assessment of the NAPs. Progress targets and indicators for monitoring the implementation of the NAPs sometimes exist in the field of human health (for example the NAPs of Belgium, France, and Spain), but they are less common in the other One Health sectors. This issue was also raised in the Opinion on Managing AMR Across the Health System issued by the Expert Panel on Effective Ways of Investing in Health (EXPH), which recommended that the European Commission should prioritise the development of a comprehensive set of indicators and structured data to measure progress on tackling AMR⁸⁹. The Opinion of the Expert Panel highlighted the work already done under Joint Action on AMR EU-JAMRAI in the development of harmonised data collection and surveillance of AMR in different sectors.

The country reports suggested additional measures to overcome the identified barriers. The need for education and awareness of the problem of AMR addressed to all stakeholders, including health professionals, could also enable public authorities to pay greater attention

⁸⁸See: <u>https://eeagrants.org/sites/default/files/resources/Romania%20Health%202014-</u> 2021%20%E2%80%93%20Programme%20agreement.pdf.pdf

⁸⁷ European Commission. Overview report Member States' One Health National Action Plans against Antimicrobial Resistance. 2022. Available at: <u>https://health.ec.europa.eu/system/files/2022-11/amr_onehealth_naps_rep_en.pdf</u>

⁸⁹ Expert Panel on Effective Ways of Investing in Health (EXPH), Managing antimicrobial resistance across the health system, 2022. Available from: <u>https://health.ec.europa.eu/publications/managing-antimicrobial-resistance-across-health-system_en</u>

to this challenge, as well as to further promote the One Health approach. However, increased intersectoral communication and collaboration are needed to achieve this, which could be supported by setting up permanent cross-sectoral intergovernmental oversight structures.

In addition, governments should allocate or dedicate funds to the training of human resources involved in the implementation of the NAPs at several levels (national, regional and facility-level) and from the various One Health sectors.

4.1.2. Barriers to the development and implementation of NAPs

This section presents cross-cutting findings on the barriers to the development and implementation of the NAPs, including COVID-19 related barriers, and possible EU measures to overcome them, as well as selected examples of good practices. Barriers were identified based on the analysis of 29 country reports. First we present barriers for the development of NAPs, followed by barriers for their implementation.

4.1.2.1. Barriers to the development of NAPs

Institutional / policy barriers

There is limited political focus on developing, updating or approving the NAP. In many EU/EEA countries, the topic of AMR is not high on the political agenda or has slipped down in recent years, especially due to COVID-19 (for example in Cyprus, Hungary, Lithuania, Poland, Slovakia, Slovenia, Spain, and Sweden). In the interviews and workshop, stakeholders explained that there are competing health priorities, which is one reason why AMR does not receive enough attention. Limited political awareness of the challenges brought by the problem of AMR was also raised as a barrier (Denmark, Latvia, Norway). Lack of political will or an enabling political context was the most often selected barrier among hospitals and LTCFs stakeholders (55%, n=36). It was also selected as a significant barrier by over half of primary care and pharmacy stakeholders (58%, n=37) and a third of national/regional authorities (36%, n=21).

In a sub-set of countries, a contributing factor for the limited support is political instability: the frequent changes in governments slow down or altogether stall progress on the issue at the political level, especially as it requires cross-sectoral coordination (Bulgaria, Poland). In Italy, the decentralised organisation of healthcare adds an additional layer of complexity that needs to be considered in planning AMR actions. Regions have a strong independence in establishing their own systems for the implementation of the NAP. In this context, there is an incomplete framework of interregional cooperation with the involvement of different stakeholders based on the One Health approach: a national multi-sectoral coordination table and regional multi-sectoral groups have been established but their authority is limited.

There are some positive exceptions. For example, in Portugal AMR and infection control have been declared public health priorities and a corresponding programme to address these issues has been legislated (see also Good Practices section). Since 2014, Ireland has identified AMR as a national risk and included it in its National Risk Assessment (NRA), which lists strategic risks that may have an adverse impact on Ireland's wellbeing and aims to ensure that appropriate prevention and mitigation frameworks are in place. Sweden is another country where political engagement on AMR has been high, regardless of the political makeup of the government, which has ensured continuity in the efforts to combat AMR. In Luxembourg, there are limited resources to execute the planned activities, but there is political will and a good governance team (the National Antibiotics Committee, CNA).

The One Health approach is not fully reflected in the design of the NAP-AMR. The review of the NAPs shows that the One Health approach is occasionally not reflected in their design, due to the limited involvement of some relevant sectors (see the next barrier).

The Commission's review, published in 2022, found that the NAPs in place in most Member States are to some extent based on a One Health approach.³⁰ Similar to the review of NAPs undertaken for the present study, the Commission's review shows that the plans cover human health, animal health and, to some extent, food production and food safety, although food is often not referred to as a standalone sector and tends to be included under the animal health/veterinary sector. The environment is often missing from the NAPs, with plant health, agriculture and aquaculture often not included at all. In some cases, all or most sectors have their own strategic documents pertaining to AMR, but they have not been integrated within a single strategy to address AMR. There are significant gaps in the scope of NAPs, even within single sectors. For example, in the human-health sector, in some cases LTCFs or other sectors such as primary care or pharmacies are overlooked in the planned actions. There are a variety of reasons for the lack of multi-sectoral involvement. In some countries, not all sectors have the resources and capacity to contribute or to participate in the development of NAPs. In other cases, it appears that awareness of the One Health approach and the benefits that it brings to addressing AMR have not been well communicated or well understood at national level, and there is no interest or willingness of all sectors to get involved.

There are deficiencies in the design of the NAP. Another problem with NAPs is that they are often not fully developed or made sufficiently specific via, for example, an (effective) operational plan (in Croatia, Germany, Iceland, Portugal, Slovakia, Slovenia, and Spain). NAPs often focus more on strategy rather than implementation.⁹¹ This was, for example, the case of the previous two German NAPs: The two NAPs that existed in Germany so far were characterised as being "strategies" rather than focusing on actions to be implemented. The upcoming NAP, which was expected to be published by the end of 2022 but has not been released (as of April 2023), is expected to also focus on implementation.⁹²

NAPs often lack or have insufficiently developed monitoring systems to track outputs and outcomes. In Czechia, interviewees noted the scarcity of information on the achievements of the NAP and on how it will continue to be implemented beyond 2022. Objectives are not linked to indicators measuring implementation progress or impact of the NAP. Clear or realistic timelines or the assignment implementation responsibilities are also sometimes missing. Some countries have less knowledge and experience of how to develop these types of plans. Some do not allocate sufficient human resources to the development of the NAP, with the implication that experts are expected to develop the NAP alongside their regular duties. For example, smaller countries experience shortage of AMR experts (who often have to participate in multiple committees) and of qualified human resources. In Croatia, Estonia, Latvia, and Luxembourg a single person is in charge of coordinating the implementation of the NAP.

In France, the NAP includes too many actions, too many indicators, with no clear allocation of responsibilities. In Portugal, there is an imbalance in the type of indicators to support NAP implementation and monitoring. There are specific indicators to monitor targeted interventions, as well as timelines, especially in hospitals and human medicine (infection rates, AMR indicators, IPC compliance, etc.), whereas targets or indicators for other healthcare sectors (primary care, LTCFs) as well as for non-human (veterinary, food production) and environmental sectors are qualitative or non-existent. The availability of data relates to several different factors, such as the non-compulsory nature of the established protocols for data collection, individual awareness regarding AMR, institutional

⁹⁰ European Commission. Overview report Member States' One Health National Action Plans against Antimicrobial Resistance. 2022. Available from: <u>https://health.ec.europa.eu/system/files/2022-11/amr_onehealth_naps_rep_en.pdf</u>

⁹¹ Challenges in the implementation of NAPs have been highlighted by the EXPH in their 2022 opinion "Managing antimicrobial resistance across the health system". Available from: <u>https://health.ec.europa.eu/publications/managing-antimicrobial-resistance-across-health-system en</u>

⁹² Interview with Federal Ministry of Health (BMG), Germany

policies and priorities, and/or human resources available to be dedicated to this task. This is a limitation for the authorities to measure progress in the achievement of the strategic objectives of the NAP, as well as to determine the impact of the actions undertaken on AMR. In Slovenia, the NAP was described simultaneously as too broad and too narrow. It is seen as being too broad because it lists measures (45) and activities (123) within these measures but there is no hierarchy. It is too narrow, because of its focus on the specifics of what needs to be done (by whom, with which partners, within which budget, to achieve a certain type of qualitative result), but it does not set out quantitative targets for NAP achievements.

The availability of funding for drafting of the NAP. As explained above, funding is a recurrent issue affecting the effective implementation of policies and measures against AMR, including in some instances the drafting process of NAPs. As seen above, in many countries the process of developing the NAP has been underfunded with no dedicated financial- and human-resource allocation. In many cases, the amount of time and cost involved in cross-sectoral coordination has been significantly underestimated. In other cases, the insufficiency of funds for combatting AMR has already been factored in at the development stage, resulting in less ambitious NAPs.

There are examples of NAPs, which have not been approved or have expired. Even when countries have drafted a NAP, challenges exist to bring it into force. In Hungary and Czechia, the draft NAP has been stalled in the formal approval process. In other cases, the draft NAP expired before being formally adopted (Bulgaria), the NAP expired without being replaced by an updated document (Lithuania) or the expired NAP has been extended due to lack of progress during the COVID-19 pandemic (Luxembourg). Cyprus developed a National Strategy for Combating Antimicrobial Resistance in 2012, but it was never implemented. The NAP has now expired, and the country is in the process of developing a new one.

4.1.2.2. Barriers to the implementation of NAPs

Institutional / policy barriers

Lack of or insufficient inter-ministerial government structures to support the NAP implementation and cross-sectoral coordination of measures. While in the 2020/21 TrACSS survey, all Member States reported having set up some type of multi-sector and One Health collaboration/ coordination (see key indicators presented in Annex 3), issues in relation to cross-sectoral collaboration have been raised in numerous study countries. Lack of cross-sector engagement and action, and challenges working across sectors have also been highlighted as significant barriers in the findings of the "Study on a future-proofing analysis of the 2017 EU AMR Action Plan", undertaken for the Commission.³³ The European Commission's review of NAPs indicated that the duration, form and structure of the intersectoral mechanisms overseeing national plans is generally unclear.⁹⁴ The Commission found that some Member States refer to an intersectoral structure, which is exclusively responsible for developing the NAP, while others refer to the structure coordinating implementation. Often, the mandate of these structures is not defined. Some NAPs include the creation of an overseeing structure as an action to be implemented, be it in the form of an inter-sectoral coordination mechanism or working groups.

Several countries have no, limited, or informal intersectoral structures or somewhat inadequate mechanisms to ensure cross-sectoral cooperation and oversee the development and/or implementation of the NAP (no structure: Austria, Bulgaria, Denmark, Hungary, Portugal, Romania, Slovakia, Spain; limited / informal structure: Belgium, Cyprus,

⁹³ Beaujet, H. et al. Study on a future-proofing analysis of the 2017 EU AMR Action Plan. 2023

⁹⁴ European Commission. Overview report Member States' One Health National Action Plans against Antimicrobial Resistance. 2022. Available from: <u>https://health.ec.europa.eu/system/files/2022-11/amr_onehealth_naps_rep_en.pdf</u>

Czechia, Greece, Italy, Slovenia,). But even for countries that have established permanent structures, cross-sectoral cooperation still remains a challenge.

In Cyprus, consulted stakeholders noted that there are no formal mechanisms for ensuring intersectoral cooperation; coordination of certain actions under the previous NAP were implemented only on a voluntary basis. In Bulgaria, the human, animal, food and environmental sectors had been working separately and had developed their own national plans to combat AMR. There is currently no intersectoral coordination mechanism to enable communication and cooperation between the sectors. In Iceland, one of the main barriers to the development and implementation of the NAP highlighted by interviewees is the lack of a formal multi-sectoral coordination mechanism. Hungary has experienced difficulties in aligning strategies and taking forward intersectoral cooperation to support the development of the NAP. It proved challenging to develop a cross-sectoral NAP given the limited capacity, willingness for intersectoral cooperation and/or lack of an internal strategy of some sectors. In Italy, a clear chain of command ensuring proper intersectoral coordination (i.e., human and animal health, environment protection, waste management, agriculture and water use and reuse) is currently missing. In Denmark, the temporary committee tasked with drafting the NAP was dissolved once the document was completed, which left no one in charge with "ownership" of the NAP to ensure follow-up.

In some cases, there is a lack of tradition of collaboration between authorities across sectors (Poland). In others, the lack of resources or capacity in relevant sectors hinders engagement in the One Health approach to combatting AMR. In Slovakia, despite what is established in the NAP in terms of joint activities, there is still limited cooperation between the Ministry of Agriculture and Rural Development and the Ministry of Health to ensure rational anti-infective treatment and antibiotic policy. In Slovenia, while specific roles and responsibilities are clearly defined in the NAP, there is as yet no coordinating authority or body at national level. It was expected to establish the latter in 2019/2020, but this is not yet in place.

In Sweden, while collaboration exists, it requires more time to be fully implemented. In Portugal, the different sectors involved (human health, food and veterinary, and the environment) report to different governmental ministries (Directorate of Health, Directorate of Food and Veterinary and the Portuguese Environmental Agency, respectively), complicating the adoption and integration of measures that need to be applied in a One Health perspective. In Slovenia, "ownership" of the NAP is spread over ten different bodies, which makes monitoring and accountability difficult. In Latvia, Lithuania and Norway, structures are in place but need strengthening to cover all sectors equally.

Limited cross-sectoral coordination/cooperation of stakeholders was the top barrier for primary care and pharmacy stakeholders (66%, n=42), and highlighted as a barrier by 45% of hospital and LTCF stakeholders. In the interviews, the lack of financial or human resources or capacity faced by all One Health sectors emerged as a factor hindering cross-sectoral cooperation.

In sum, even if the process of developing the NAP was inclusive, maintaining cross-sectoral cooperation in the implementation phase is difficult without well-resourced permanent structures or processes to ensure inter-ministerial coordination. There is a need to establish mechanisms to ensure strong and long-lasting ministerial collaboration in NAP implementation.

Lack of dedicated funding for the implementation of NAPs. Lack of dedicated funding limits NAP development and implementation and is therefore a significant barrier to bridging the gap between having a document on paper and producing change on the ground. According to data in the TrACCS survey (2020-2021), most countries do not earmark a

dedicated budget for the development and implementation of their NAP.⁹⁵ Only three countries (Austria, Croatia, and Sweden) reported that the NAP has a costed and budgeted operational plan and has monitoring mechanisms in place. Four countries (Belgium,⁹⁶ France,⁹⁷ Norway⁹⁸ and Spain⁹⁹) reported that they have a financial provision for the NAP implementation within their national budget. The Commission's review of NAPs indicates that budgeting is included in only two NAPs, and that there is limited information on its inclusion in 12 plans.¹⁰⁰ In the survey with national competent authorities across all One Health sectors, 41% of participants reported that the main weakness of their NAP relates to funding (followed by 24% of participants indicating that the main weakness relates to implementation). When asked how much funding was/will be allocated for the implementation of the NAP, more than half of participants (56%, n=30) responded that they did not know. A quarter (24%, n=13) reported that there were no dedicated funds available. The rest (21%, n=11) gave answers ranging from EUR 0 to 100 million (with 11% of the total saying the funding was under 25 million).

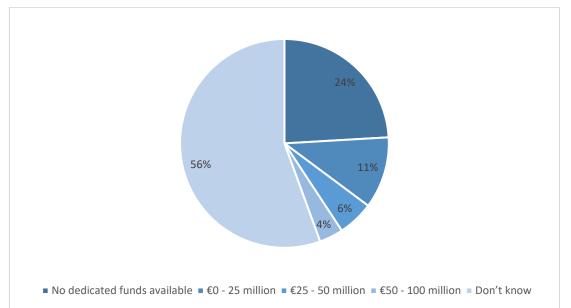


Figure 1: Survey question to national authorities: How much funding was/will be allocated for the implementation of the NAP? (N=54)

According to the national-level research, many NAPs do not contain financial estimates for the planned actions (Austria, France, Latvia, Italy, Iceland, and Norway) or do not indicate or allocate specific sources of funding for them (Czechia, Finland, Hungary, Latvia, Malta,

⁹⁵ See: <u>https://amrcountryprogress.org/#/visualization-view</u>

⁹⁶ In Belgium, the NAP includes both existing actions (with already-committed budgets) and new actions for which a new budget of 20.8 million EUR has been allocated to finance the implementation of the NAP between 2022 and 2025. This budget includes all actions that will be taken at a federal level.

⁹⁷ In France, budgetary implications of measures to combat AMR are outlined with more or less detail (depending on the measure) in the interministerial AMR roadmap of 2016: https://sante.gouv.fr/IMG/pdf/interministerial_amr_roadmap_en.docx.pdf

⁹⁸ In Norway, the NAP only contains the following reference to budgetary/ financial implications of the expected actions: "The description of measures is limited to measures that can be implemented within applicable budget frameworks" (page 20, <u>https://www.regjeringen.no/contentassets/5eaf66ac392143b3b2054aed90b85210/antibiotic-resistance-engelsk-lavopploslig-versjon-for-nett-10-09-15.pdf</u>).

⁹⁹ While the data collected for the latest TrACSS survey corresponds to Spain's previous NAP, the new plan contains references to where resources will come from and how they will be allocated, but no specific funding allocations are provided: (<u>https://www.resistenciaantibioticos.es/sites/default/files/2022-</u>09/Plan%20Nacional%20Resistencia%20Antibi%C3%B3ticos%20%28PRAN%29%202022-2024.pdf)

¹⁰⁰ European Commission. Overview report Member States' One Health National Action Plans against Antimicrobial Resistance. 2022. Available from: <u>https://health.ec.europa.eu/system/files/2022-11/amr_onehealth_naps_rep_en.pdf</u>

and Portugal). Instead, they draw on the AMR budget lines of the authorities tasked with implementing actions in the NAPs. In some cases where funding is allocated, it is considered insufficient (Croatia, Finland). Similarly, insufficient human resources are dedicated to NAP implementation (Estonia, Finland, Latvia, Portugal, and Sweden) or there is no clear allocation of responsibilities for the various actions and tasks under the NAP (Czechia and Denmark). In Italy, there is a lack of dedicated funding for the full implementation of the NAP at both national and regional levels. In Malta, the lack of budget and resources significantly hinder the effective planning of the national antimicrobial susceptibility committee's (NAC) activities. As described in the ECDC country-visit report¹⁰¹, since NAC members have full-time commitment and contribute to the NAC voluntarily, the lack of designated administrative support limits the delivery and execution of its activities.

Missing legal framework. Another challenge with implementation is that in some cases the legal framework required to implement some NAP actions is not in place. For example, lack of legislation in animal health, especially in food animal husbandry, poses a major barrier to implementation in Malta. In Hungary, the National Public Health Centre, a national-level institution in charge on infectious control, does not have the legal power to audit infection control at healthcare institutions. In Norway, interviewees noted a lack of legal provisions providing a framework for the measures indicated in the NAP, leaving the health facilities without direction on what to prioritise.

In addition, a lack of adequate governance or institutional arrangements to deliver actions was seen as a significant barrier by 39% (n=14) of hospitals and LTCF stakeholders responding to the survey. The interviews also revealed that in some cases the legal framework required to implement some NAP actions is not in place.

Clinical barriers

These barriers relate mainly to the availability of AMR data, which limits the implementation of evidenced-based actions, as foreseen in the NAPs.

Limited coverage of data, heterogeneity, and fragmentation. The research revealed several problems with surveillance and consumption data needed to fight AMR. First, data do not systematically cover all types of healthcare facilities and regions within countries, resulting in data gaps. Second, there are issues with the harmonisation of indicators on the collected data within and across One Health sectors and countries. Third, there are different IT systems and databases within countries that are not always interoperable, especially in federal countries. Thus, data aggregation is challenging and sometimes not possible. Finally, the data (however incomplete, divergent, and not properly aggregated in some cases) has limited use for policymaking or research because stakeholders (government officials, researchers, and experts, etc.) might be unaware of the type and amount of data available. Further details on these issues are provided below.

• Limited coverage of data: gaps in surveillance data in the human-health sector were often reported. Although countries report AMR data to the ECDC, this does not necessarily mean that they have robust national surveillance systems. For instance, countries report to the ECDC on a subset of pathogens and only invasive isolates (i.e. from blood and cerebrospinal fluid samples), which does not reflect the complete AMR situation in each country. Also, current EU surveillance (EARS-Net) is meant for benchmarking rather than detection of emerging events such as outbreaks. A new network coordinated by ECDC, i.e. the European Antimicrobial Resistance Genes Surveillance Network (EURGen-Net), aims at making use of whole-genome sequencing for the identification of clusters and outbreaks of multidrug-resistant

¹⁰¹ ECDC country visit to Malta to discuss antimicrobial resistance issues, 3-7 July 2017. Available from: <u>https://www.ecdc.europa.eu/sites/default/files/documents/AMR-ECDC-mission-report-malta-2017.pdf</u>

organisms. However, initial detection relies on alerts posted by countries in the Early Warning and Response System (EWRS) and/or ECDC's EpiPulse platform.

In several countries, surveillance data do not cover all types of healthcare facilities or infections. For example, infections occurring outside hospital settings (outpatient, private or semi-private settings), or common but less invasive infections (urinary tract infections (UTIs), wound infections) are not tracked at national level (Ireland, Denmark and Finland). In the Netherlands, hospitals automatically attach diagnostic results to electronic health records of patients, but this is not possible for GPs and in LTCFs. Furthermore, the completeness of data is affected by additional factors such as the generally non-compulsory nature of the established protocols, professionals' awareness of AMR, facilities' policies and priorities on data collection and reporting, as well as human resources available for these tasks. In Italy, there is **limited** standardisation of methods and tools for the collection of data and management of information flows. In addition, the complete, uniform and timely implementation of methods and procedures throughout the country is hindered by consistent subnational variations due to the regional health systems configuration.

- Data heterogeneity: another major concern is data heterogeneity. In some cases, the type of data collected (e.g., types of microorganisms or types of samples) are not harmonised, not only across sectors (e.g., human vs non-human) (Latvia, Luxembourg and Portugal), but sometimes even within the area of human health, between regions (Finland and Sweden) or hospitals (Spain). This can occur due to differences in data collection methodologies or protocols. Data heterogeneity can also result from different ways of aggregating the data. For example, Cyprus does not report separate data on antibiotic consumption by hospitals and community use.
- Data fragmentation: fragmentation of data due to the use of a variety of IT/data systems is another challenge. Hospitals and laboratories use bespoke IT/data systems which are not always interoperable, which makes data aggregation challenging. This was mentioned as a problem, for example, in Slovakia, where the increasing diversity of information systems used by laboratories is making data reported to the National Antibiotic Resistance Database delayed or partially incomplete. Furthermore, the samples are sent to various laboratories throughout the country rather than a local catchment laboratory, which creates data aggregation problems. In Finland, for example, it is reported that departments within the same hospitals use different IT systems, which impedes communication and reporting. In Portugal, patient data from different types of healthcare facilities (hospitals, primary care, and LTCF) is not shared.
- Other data issues: the management of information flows between different institutions and stakeholders is also a critical issue, especially where health competences are at the sub-national level, as mentioned above for Italy. Similarly, in Belgium, relevant data(bases) are not always accessible by or shared between national organisations. According to a recent audit by the Court of Auditors of Belgium, data requests by the Court were not always honoured and national institutes did not have access to the same data. As an example, the National Institute for Health and Disability Insurance has access to all dispensed antimicrobials (both reimbursed and non-reimbursed), but only shares information on reimbursed antimicrobials with Sciensano, the Belgian Institute for Health. Also, the Belgian authorities rely on third-party databases (both commercial and non-commercial) to determine antimicrobial consumption in the country¹⁰². In addition, the collection of surveillance and other relevant data from different platforms implemented by different institutions within the human-health sector (e.g., hospitals, primary care, and LTCFs) makes it challenging to aggregate and interpret surveillance data (Cyprus and Portugal). Similar issues exist

¹⁰² Rekenhof. Beleid inzake het voorschrijven en afleveren van antibiotica. Brussels; 2022.

across sectors. For example, in Slovakia there are problems linking the veterinary data with that on identical infectious disease pathogens in human medicine. Even when data is available, it does not always reach the policy-making level to feed into, e.g., evidencebased design of the next iteration of NAPs or other policy outcomes, such as guidelines (Croatia). Also in Croatia, AMR-related data are available at all levels of care, and reports are published regularly. For example, there are good data on the prescription of antibiotics in primary care gathered by the Health Insurance Fund as Croatia has almost 99% e-prescriptions since 2009. However, these data are not publicly available and, therefore, are generally not used to monitor or evaluate the actions implemented to combat AMR.

Sector-specific barriers

- **Animal health:** there are some AMR-related issues in animal health. For example, there is a lack of routine surveillance of AMR in bacteria from food-producing animals, no national reference laboratory to perform it (Malta) or insufficient laboratory capacity (Latvia). There is lack of legal framework to mandate all actors to report AMR data in animal health (Belgium) or legal requirements need to be updated (Iceland). In the Belgian animal-health sector, data on resistance among animal pathogens from farm animals is currently provided by the national veterinary authorities (DGZ and ARSIA), but private laborates are not yet mandated to report or publish their data on antimicrobial resistance in animal pathogens¹⁰³. Legal requirements in the animal sector in Iceland need to be updated to include obligations on registering antimicrobial use in animals other than cattle and horses. In Ireland, surveillance is largely confined to pigs and poultry. In Luxembourg, there is no national monitoring of AMR in bacteria from companion animals. In Estonia, the veterinary sector shows low testing rates. At the same time, there is an increasing trend of antibiotic use in animals, which may indicate that some veterinarians are prescribing antibiotic treatment without bacteriological diagnosis or susceptibility testing. In the Irish veterinary sector, there are limited levels of farmer engagement with some of the stakeholder-driven initiatives to reduce the use of antimicrobials. The iNAP initiatives linked directly to prudent use of antimicrobials are generally voluntary. Also, the iNAP has a limited scope as it only focuses on farmed animals. There is a gap in the coverage of companion animals, such as horses. In Italy, while there is a mandatory electronic system of antibiotic prescription in the veterinary sector, it is still not fully enforced. In some countries, the barriers go beyond surveillance and monitoring issues. For example, in Malta, the lack of legislation in animal health, especially in food for animal husbandry, poses a major barrier to the implementation of the NAP from a One Health perspective.
- Plant health, food and agriculture: compared to the human and animal health sectors, there is a limited capacity for training and professional education on AMR in the food and agriculture sectors, as it pertains to plant health. Furthermore, there is a disconnect between the policy and the practitioner level with regard to AMR, but this differs between countries. In some countries, there is an awareness of the One Health approach at the policy level but that has not trickled down to the practitioner level (Sweden). In other countries, the expertise on AMR is with experts at the practitioner level but it does not reach the policy-making level.
- Environment: while, according to the 2020-2021 TrACCS survey, environment is generally included in the list of sectors actively involved in multi-sectoral coordination in a large majority of study countries (see Annex 3), it is the sector that is most often

¹⁰³ AMCRA, ARSIA, Brussels Environment, CHU Liège, DGZ, EARS-BE, et al. BELMAP: One health report on antibiotic use and resistance 2011–2021. 2022.

neglected within the One Health approach.¹⁰⁴ The inclusion of environmental authorities is deemed problematic in at least 13 Member States.¹⁰⁵ For example, in Latvia, cooperation with the Ministry of Environment and Regional Development, which oversees the environment sector, is perceived as difficult. In Germany, the Environmental Agency has been included in the drafting of the new NAP, but its role is unclear. There is no environmental national action plan connected with the One Health strategy (for example, Denmark) and there is generally a low level of awareness of AMR in that sector (for example, Ireland). Another common problem is the lack of or limited systematic surveillance in this sector, which results in limited availability of data, thus reinforcing the low level of awareness (Czechia and Estonia). In some countries, the issue is not high on the agenda due to specific local circumstances. For example, in Denmark, most of the water comes from underground sources and, therefore, the risk of contamination is considered less prominent. However, this might change in accordance with changes in rainfall patterns, so increased attention is also warranted in this case.

4.1.3. Possible measures to overcome the identified barriers

This section presents possible measures that, with EU support, may help the study countries to overcome several barriers to the development and implementation of the NAPs identified. The section focuses on measures that the EU can support within the scope of its competences in the area of health, which limits the range of options.

To help Members States overcome issues related to deficiencies in the design of NAPs, reinforce the One Health approach and support implementation:

- provide guidance and a support structure for the development (or renewal) of NAPs and their implementation. Suggested actions include:
 - developing a live practical guide for the development of NAPs with signposting to existing guidance (for example by WHO),¹⁰⁶ up-to-date examples of recently developed NAPs, and a proposed a minimum set of indicators that could be used by Member States in monitoring the NAP implementation;
 - providing recommendations for priority actions for future NAPs, a customisable roadmap for the implementation of NAPs, and an indication on the allocation of funding that the more important measures need for their effective implementation;
 - co-funding a one-year project to re-launch the NAP development, adoption, and implementation in countries where NAPs have expired or need further refinement; and
 - setting up an AMR expert group to support countries in need of guidance in the development and implementation of NAPs.

To help Members States overcome issues related to limited cross-sectoral collaboration:

¹⁰⁴ European Commission. Overview report Member States' One Health National Action Plans against Antimicrobial Resistance. 2022. Available from: <u>https://health.ec.europa.eu/system/files/2022-11/amr_onehealth_naps_rep_en.pdf</u>

¹⁰⁵ Croatia, Germany, Greece, Hungary, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Portugal, Slovakia, Slovenia.

¹⁰⁶ WHO implementation handbook for national action plans on antimicrobial resistance: guidance for the human health sector. Available from: <u>https://www.who.int/publications/i/item/9789240041981</u>

promote the establishment of a One Health structure or cooperation mechanisms on AMR. Encourage Member States to set up a permanent inter-ministerial government structure (providing guidance for a better governance of the NAP which, for example, expands and redefines the responsibilities of current authorities and entities responsible for the NAP) or other mechanisms for cross-sectoral coordination that involve all relevant sector ministries. This would ensure that the One Health approach is reflected not only in the design of the NAP but also in its implementation (for example, by suggesting the development of an Operational NAP-AMR Plan, defining responsibilities, targets and roles amongst all sectors and stakeholders). Developing a NAP is a continuous process rather than a one-time activity. It should be viewed as an ongoing cycle in which the design phase is followed by monitoring of implementation that in turn informs the next iteration of the NAP. A permanent or long-term mechanism or structure institutionalising cross-sectoral cooperation can provide input from all sectors during each phase of the cycle, while ensuring accumulation and continuity of knowledge and expertise to produce more effective and impactful NAPs. This structure or mechanism should be seen as an investment and resourced appropriately.

To help Members States overcome issues related to insufficient dedicated funding:

provide specific funding and signpost existing financial instruments to be used in fighting AMR. In addition to co-funding for the re-launch of NAPs, the EU could provide targeted funding for specific actions under the NAPs, as long as this is in line with existing limitations of EU competence, notably in public health. Funding from other EU/EEA instruments can be brought in to support efforts in controlling AMR and Member States should be encouraged to explore these opportunities. For example, instruments such as the Recovery and Resilience Facility (RRF), REACT-EU, European Structural Funds¹⁰⁷ can fund digital transition elements or interoperable ICT systems, rehabilitate existing hospital and clinic infrastructure and technical equipment, modernise laboratories, train human resources or other initiatives. Some positive examples already exist. For instance, Cyprus received a grant from the European Commission's RRF to design an electronic platform for the surveillance of HAIs and of nosocomial antibiotic consumption in hospitals. The European Commission also provided Structural Reform Support to Latvia in the implementation of their One Health national action plan, in collaboration with the Swedish Board of Agriculture (SBA) and the Swedish Public Health Agency of Sweden (PHAS).¹⁰⁸ The EEA Financial Mechanism 2014-2021 supported the development of Romania's NAP as well as other AMR related activities in Czechia, Poland, Portugal, and Romania. The availability of such funding opportunities as they broadly pertain to AMR should be further promoted. Co-funding for specific projects to tackle AMR was also raised in the surveys. It was the preferred action among national/ regional authorities (67%, n=41). It was also selected by 55% (n=46) of hospitals and LTCF stakeholders and 55% (n=23) of other stakeholders. Stakeholders explained that the EU could provide targeted funding for specific actions under the NAPs or for the development of the NAPs themselves.

To help Members States overcome issues related to limited monitoring of the implementation of NAPs:

• support Member States in monitoring progress made with the implementation of the NAPs with a harmonised list of indicators. The EU could recommend annual reviews/updates to be made publicly available to improve transparency and

¹⁰⁷ See: <u>https://commission.europa.eu/funding-tenders/find-funding/eu-funding-programmes_en</u>

 ¹⁰⁸ See:
 https://www.folkhalsomyndigheten.se/the-public-health-agency-of-sweden/communicable-diseasecontrol/antibiotics-and-antimicrobial-resistance/international-collaborations/support-to-latvia/

accountability. One option could be to introduce a harmonised list of indicators with an online reporting system to track progress. The EU could also provide a model or examples of technical specifications for the integration of national information systems, as well as signposting to available funding for the development and integration of these systems. However, it is possible that NAPs are too context-specific in which case a flexible approach might be more suitable. The possibility of EU support on monitoring NAP implementation was supported by survey participants: 67% of national/regional authorities (n=41), 58% (n=61) of primary care and pharmacy stakeholders, 55% (n=23) of other stakeholders, and 49% (n=41) of hospitals and LTCF stakeholders advocated for this measure.

To help Members States improve their surveillance systems:

• support extension, frequency and further harmonisation of data collection methodologies and indicators. Member States already report to designated EU agencies (ECDC, EMA, EFSA) data on AMR and human and veterinary antibiotic consumption, as well as monitoring data on zoonoses and food and waterborne diseases. The EU could continue to support further harmonisation of indicators and data-collection methodologies to overcome problems with data heterogeneity. It is possible that efforts in areas where little is done at the national level (e.g. environmental sector) could yield easier results in terms of harmonisation. The EU could also support the further strengthening of AMR surveillance. This includes defining the priority list of pathogens to be monitored from the AMR perspective; providing guidance on the creation of national diagnostic and referral guidelines; and harmonising minimal requirements for antibiotic susceptibility testing. Among possible measures, it was also mentioned that the EU still needs to fully implement the provisions laid down in Regulation (EU) 2022/2371 on serious cross-border threats to health,¹⁰⁹ besides the future development of the new HERA.

Another suggested measure is the development of a network for AMR data collection in the veterinary and environmental sectors, similar to the one used in the human-health sector (EARS-Net). This could also help to provide a standardised approach across the EU to the collection, analysis and sharing of AMR data from these sectors. The development of EARS-Vet (European Antimicrobial Resistance Surveillance network in Veterinary medicine), the design of which was one of the initiatives of the JAMRAI Joint Action, is one of the One Health Network's top suggestions for AMR action.¹¹⁰

To further support Members States in the implementation of NAPs:

• promote peer support, expert exchanges and twinnings, while encouraging follow-up on findings from country visits and EU-funded projects. The EU could further encourage the implementation of recommendations resulting from findings from EU-funded projects related to AMR or from country visits and audits by EU agencies. A self-assessment form to monitor progress on the recommendations suggested by the ECDC in country visits could support their implementation. This may encourage Member States to consider findings in the development and implementation of NAPs more systematically. Conducting peer review visits based on the WHO/World Bank Joint Assessment of a National Health Strategy (JANS) manual, as well as peer joint-external evaluations, based on the procedures agreed by WHO within the IHR implementation, was also proposed as a measure to overcome NAP development and implementation issues.

¹⁰⁹ See: <u>https://eur-lex.europa.eu/eli/reg/2022/2371/oj</u>

¹¹⁰ See: <u>https://health.ec.europa.eu/system/files/2022-09/amr_ohn_top-priorities_en.pdf</u>

The EU could also promote expert exchanges and twinning projects with other Member States, such as on-site visits and exchange programmes for policymakers and sectoral coordinators.¹¹¹ This could serve to promote knowledge-exchange and capacity-building, to exchange good practices and learn from what has worked better in other countries. For example, the Swedish-Latvian project (Latohop) and activities within the JAMRAI Joint Action (work package 5) allowed both countries to exchange experiences and best practices. Additionally, the EU could develop good-practice briefs in the area of AMR, IPC, and AMS and making them accessible to national health authorities. Contact details of people responsible/implementing the good practices could be provided so that interested parties can get in touch and obtain further information. The promotion of collaboration and sharing of good practices between Member States could be further extended to other human and animal health sectors to support systematic review of environmental issues. Finally, the identification of European centres of IPC and AMR excellence was suggested, and the provision of funding for the exchange of professionals (e.g., hospital managers, healthcare workers, clinicians, IPC staff, laboratory staff and pharmacy staff).

support the provision of training activities. Half or over half of survey respondents from all groups (hospitals and LTCFs, primary care and pharmacies, and national/ regional authorities) would like the EU to support/provide training activities for national/regional coordinators (59%, n=49; 52%, n=55 and 49%, n=30 respectively). In the consultations at Member State level, stakeholders proposed that the EU support the development (funding and coordination) of an online training platform for national/regional coordinators, health managers, health professionals and other stakeholders. This can include fora and/or peer-exchange chat rooms. The online platform could be used for sharing experiences, knowledge, and good practice. To encourage health professionals to follow continuous training on AMR, it was suggested to create several incentives (for example, attribution of accreditation points, professional valorisation, career progression), and the development of easy-to-use training modules such as suitable e-learning tools or introducing compulsory training (e.g. for farmers and animal producers).

Other measures proposed by national-level stakeholders, which are not directly linked to the barriers analysed in Section 4.1.2, include to:

- increase awareness and knowledge of AMR and One Health at national level. The EU should maintain awareness-raising activities to continuously keep AMR high on the political and policy agenda. It should emphasise the seriousness of the problem and turn the issue from a "silent pandemic" to a "loud pandemic". It should also take measures to continue to educate on and promote the One Health approach among relevant stakeholders at national level. In addition, the link between the One Health approach and AMR could be made clearer and stronger, including reinforcing the arguments for the benefits of a cross-sectoral cooperation. Educational and awareness-raising campaigns targeted at multiple levels (the general public, healthcare professionals, practitioners from non-human sectors, e.g., breeders and farmers, and policy-makers) would be an important way to keep the AMR issue on the agenda.
- better communicate new research findings and emerging trends. The EU should facilitate the sharing of new knowledge and research on AMR, especially that emerging from EU-funded projects and research, as well as analysis of trends from EU-wide data collected by EU agencies. Dissemination of that knowledge to the national level and feeding it into the policy-making processes, including the NAP, is a crucial step in controlling AMR. The EU could also further promote specific research topics in all EU

¹¹¹ During the pandemic, periodical webinars, for example the Regional joint ECDC/WHO Europe COVID-19 network calls, provided a good opportunity for knowledge sharing and experience exchange.

research and development budgets. New antibiotics discovery and development can also be promoted by increased participation in the GARDP or in CEPI (Coalition for Epidemic Preparedness Innovations), for instance, or similar international programmes, exploring new ways to incentivise R&D.

• **support global work on AMR.** The EU should continue to advocate at the global level on behalf of its Member States to keep the AMR-issue high on the international political agenda. It is well recognised that AMR is a global problem. The EU is better-placed than each individual Member State to exert influence on a global scale, which is a form of indirect support to the Member States.

4.1.4. Good practices

- Cross-sectoral exchange of progress and good practices:
 - In Ireland, a 2021 conference brought together stakeholders from all sectors participating in the NAP (human and animal health and the environment). The conference goal was to share progress and exchange knowledge and good practices between sectors. Participants found the event very valuable, in particular as it helped advance understanding of the importance of interdisciplinary approaches to tackling AMR, and it created a sense of shared purpose and community. Also, reports of progress from other sectors provided encouragement that combatting AMR is a surmountable problem.
 - In Denmark, the National Antibiotic Council organised the collection of good, concrete experiences with initiatives where healthcare workers, educators, doctors, nurses, and others contributed positively to the common fight against antibiotic resistance. The efforts are presented in a catalogue "20 ways to use fewer antibiotics".¹¹² The focus is on prevention through better hygiene and ways to reduce the use of antibiotics. This type of initiative helps to inspire and promote good practice.
 - Funded under the Priority Research Program on Antibiotic Resistance, the PROMISE project in France is a One Health professional meta-network on antibiotic resistance, which brings together 21 national networks and over 40 academic partners. One of the main objectives is the creation of initial training modules involving veterinarians, medical students, and pharmacists. These training modules have a One Health approach and aim to build bridges between different scientific communities and reinforce prevention practices by all health professionals.¹¹³

• Evidence of political support for combating AMR:

- In Portugal, AMR and infection control were designated as a Priority Public Health problem and a vertical structure for general governance and implementation at national, regional and institutional levels was created as a result.
- A dedicated unit was created in Ireland: the Health Service Executive's Antimicrobial Resistance and Infection Control Division (AMRIC). It gives policy direction and strong guidance and leadership to the AMR agenda.

¹¹² See: <u>https://sundhedsstyrelsen.dk/da/Udgivelser/2019/Inspirationskatalog_-20-veje-til-at-bruge-mindre-antibiotika</u>

¹¹³ See: <u>https://weekly.chinacdc.cn/fileCCDCW/journal/article/ccdcw/2022/49/PDF/220211.pdf</u>

- In France, a high-level AMR leader position within the Ministry of health has been created to coordinate actions across the One Health sectors.
- Dedicated AMR teams at sub-national/local level: in Lithuania, AMR management teams were established in ten regions in 2015. These teams are still in operation. Among their activities, the AMR teams conduct awareness-raising campaigns on antibiotic use and antibiotic resistance for public healthcare professionals, the general public, educational institutions, veterinarians and animal farmers. They also provide methodological support to municipal public health offices and other institutions implementing activities related to antibiotic use and antimicrobial resistance, and perform the assessment of antimicrobial resistance management activities according to established evaluation criteria.
- Support to the implementation of NAP: the objective of the SPINCAR project in Italy was to support the implementation of the Italian NAP to combat AMR by identifying and agreeing on national standards to drive prevention, management, and control of AMR at community and hospital level. It provides a framework for action based on seven pillars (governance, surveillance and monitoring, appropriate use of antimicrobials, control and prevention of healthcare-associated infections, education and training, alliance among stakeholders, and implementation) and two levels (minimum and advanced requisites). The total number of standards for the regional framework was 34 with 264 criteria. There were 279 standards in the local version and 36 criteria. This framework, which was developed based on international evidence and recommendations that were tailored to the Italian context, supports monitoring of improvements achieved over time, and the planning of next steps in Italy.

• EU-funded components of NAP and bilateral support:

- An expert mission of the Swedish Board of Agriculture and the Public Health Agency of Sweden worked with their Latvian counterparts from the Ministry of Health and the Ministry of Agriculture to share knowledge and provide training to trainers and training toolkits. The cooperation took place in the framework of the EU Structural Reform Support Programme to "Support to the implementation of the One Health action plan for containing antimicrobial resistance in Latvia", which ran from 2019 to 2022. Key project outcomes included the development of a sustainability plan for continued work on implementing the One Health NAP and a Roadmap for the improvement of One Health intersectoral coordinating mechanisms.
- The Norwegian Institute of Public Health cooperated as a project partner with Czechia and Romania. In Czechia, a EUR 2.6 million grant from the EEA Funds (2014-2021) funded the Antibiotic Resistance Prevention Project to stop the rise in antibiotic consumption in the community. In Romania, the funds supported the development of the NAP, three guides and a methodology for reporting infections associated with medical assistance.
- Examining cases of overprescribing antimicrobial medicines: in Slovenia, the ZZZS (National health insurance fund) is examining which physicians in primary healthcare, hospitals or LTCFs are prescribing too many antimicrobials. The fund's interviews identify overprescribing physicians and examine their cases to see why they are using too many antimicrobial medicines and discover whether such actions were necessary to contribute to lower levels of drug use.
- Systems for improved surveillance and monitoring across the One Health sectors, for example:

- The Danish DANMAP¹¹⁴ programme is a successful model for One Health integrated surveillance that can be adopted or inspire other countries. The objectives of the programme are: to monitor the consumption of antimicrobial agents for food animals and humans; to monitor the occurrence of antimicrobial resistance in bacteria isolated from food animals, food of animal origin and humans; to study associations between antimicrobial consumption and antimicrobial resistance; and to identify routes of transmission and areas for further research studies. The monitoring of antimicrobial resistance is based on three categories of bacteria: Human and animal pathogens, zoonotic bacteria, and indicator bacteria. The collaboration between institutions from the human, animal, and food chain, demonstrates a success story, which provides a detailed record of antibiotic consumption and antimicrobial resistance in animals, humans, and food.
- The quality index (PPCIRA-IQ) was created in Portugal as a programme monitoring 0 tool. The index uses several monitoring indicators to support benchmarking, which also create an incentive-mechanism for compliance by healthcare institutions. The index is created by obtaining data and indicators, per hospital institution, on hospital consumption of antibiotics, AMR, and HAIs. The PPCIRA-IQ is composed of the following variables: antimicrobial consumption; antimicrobial resistance; IPC practices; and epidemiological surveillance. The data are evaluated twice per year by an inter-institutional working group composed of several authorities covering all hospitals from the National Health Service and are used to guide interventions and continuous improvement strategies. Since 2017, the index is associated with a "Pay for Performance"-based programme of incentives in the contracts established between each hospital and the Regional Health Administrations. Though the PPCIRA-IQ was not developed specifically to monitor the NAP-AMR, it contributes to the monitoring of actions already implemented and in progress. The PPCIRA aims to extend the PPCIRA-IQ to primary health care.
- In Czechia, the introduction of innovative software for electronic (automated) data processing and transmission is one of the objectives of the NAP. In this context, scientists from the Veterinary Research Institute¹¹⁵ are working closely with institutions such as the Institute for State Control of Veterinary Biopreparations and Medicines¹¹⁶ to develop an application to digitalise veterinary records. The digitalisation of livestock health records is a prerequisite to enable the processing, sharing and analysis of data for use by farmers, veterinarians, businesses, authorities, and other stakeholders involved in animal-health management. So far, the most important application of the project's outputs concerns dairy cattle, where the web application is being used by 160 farmers, and the number is still increasing.
- As part of the NAP in Czechia, an annual evaluation of the results of the National AMR Monitoring Programme for Veterinary Pathogens was carried out between 2016 and 2021. This was initiated in 2015 with a pilot study¹¹⁷. Regular testing started in 2016 in three state veterinary institutes (SVÚ Jihlava, SVÚ Prague, SVÚ Olomouc). The study focuses on the detection of resistance of broad-spectrum beta-lactamases. In total, over 8 000 isolates from cattle, pigs and domestic poultry were investigated for their susceptibility to selected antibiotics. The study provided valuable results for many livestock farmers and veterinarians. It also provided

¹¹⁴ See: <u>https://www.danmap.org/</u>

¹¹⁵ See: <u>https://www.vri.cz/en/900-2/</u>

¹¹⁶ See: <u>https://www.uskvbl.cz/en</u>

¹¹⁷ See: <u>https://www.svujihlava.cz/data/fotogalerie/files/zprava-rl-za-rok-2021-pdf.pdf</u>

important information in the field of AMR for the entire veterinary professional community, including supervisory authorities.

o Furthermore, the Czech NAP has an objective to establish a framework for monitoring AMR-resistant bacterial strains in soil, and possibly other parts of the environment, as well as residues of pharmaceutical substances used in livestock farming, which incur environmental risks. The NAP also proposes the incorporation of AMR monitoring issues into the soil-monitoring programme in Czechia. A series of reports¹¹⁸ have been prepared addressing this objective, which include the optimisation of the methodology and determination of enrofloxacin residues in the required matrices (medicated water, treated broiler litter, soil with treated animal litter and soil with enrofloxacin enriched litter).

4.2. Infection prevention and control measures in hospitals and long-term care facilities

4.2.1. State of play

Stakeholders engaged in interviews and surveys¹¹⁹ confirmed that IPC guidelines and legislation were generally developed at the national or regional level, and that healthcare facilities develop their IPC programmes and measures based on these guidelines. In the survey, 82% (n=36) of human health national/regional authorities affirmed that IPC guidelines and legislation are in place at the national or regional level. Almost half (48%, n=21) claimed that these are also in place at organisational/facility level. This was also confirmed by hospitals and LTCF stakeholders.

In terms of IPC measures that were currently in place at national/regional level, the most selected measure by national/regional authorites was the existence of an established multidisciplinary technical group for surveillance of HAIs and IPC monitoring (71%, n=25). For hospitals and LTCFs stakeholders, the most selected measure was a national/ regional strategic plan for HAI surveillance and for monitoring of IPC indicators (72%, n=33 and 50%, n=13 respectively). The latter was selected also by 60% (n=21) of national/ regional authorities. 67% of hospitals stakeholders (n=31) and 50% of LTCFs stakeholders (n=13) also pointed to the existence of a national/ regional strategic plan which proposes recommendations for minimum indicators (e.g., hand hygiene), develops an integrated system for the collection and analysis of data (e.g., protocols, tools) and provides training at the facility level to collect and analyse the data. Other frequent measures selected by national/ regional authorities and hospital stakeholders were evidence-based, ministry approved guidelines adapted to the local context and reviewed at least every five years (57%, n=20 and 63%, n=29, respectively). It is worth noting that in an open question, 48% (n=12) of 25 hospitals and LTCFs stakeholders stated that more training and guidence was needed for these types of guidelines to be effective in supporting their hospitals/LTCFs in developing and implementing their own IPC actions.

In terms of IPC measures that were being implemented in the majority (over 50%) of hospitals and LTCFs, according to national/ regional authorities the top four measures were: (1) a functional facility-based IPC programme (77%, n=34); (2) facility adapted IPC standard

¹¹⁸ See: <u>https://eagri.cz/public/web/file/691658/Zprava_AMR_2021_FINAL_s_tit.pdf</u>

¹¹⁹ The surveys included questions on the extent to which countries have IPC programmes/measures that fulfil the WHO "Minimum requirements for infection prevention and control programmes" (https://www.who.int/publications/i/item/9789241516945).

operating procedures and their monitoring (70%, n=31); (3) a system for HAI surveillance following national or sub-national plans (68%, n=30); and (4) a clean and hygienic built environment that facilitates practices related to the prevention and control of HAI and AMR, including all elements around WASH (water, sanitation and hygiene) infrastructure and services and the availability of appropriate IPC materials and equipment (64%, n=28).

Stakeholders from hospitals and LTCFs confirmed these results by agreeing that these measures were being implemented in their facilities. In the case of both hospitals and LTCFs, stakeholders also mentioned the existence of a system for facility-based monitoring of hand hygiene (69%, n=46). However, for all the measures, percentages were significantly lower regarding LTCFs. Most likely, this reveals a lower level of implementation of IPC measures in LTCFs overall. Indeed, in the interviews, stakeholders from several countries have reported that there are no dedicated programmes or plans for IPC in LTCFs.

For both hospitals and LTCFs, the least selected IPC measure, acording to national/ regional authorities, was the existence of a system to standardise bed occupancy to reduce HAIs. This was also the least selected measure by hospital stakeholders when asked about the IPC measures that were being implemented in their facilities. As for LTCFs, the least selected measure by stakeholders was a system for patient flow, a triage system (including referral system) and a system for the management of consultations to reduce overcrowding.

In many countries, the barriers detected in developing and implementing IPC measures in hospitals and LTCFs go beyond the specific problem of AMR. Countries' health sectors (and in many cases also the social services sector) face organisational, legal, funding, and staffing challenges that affect them deeply. In many cases, these were aggravated during the COVID-19 pandemic. IPC is considered by health professionals in the majority of countries as an essential aspect of healthcare, but they struggle to deliver specific actions when there are other (in many cases more pressing) issues to address. This results in a very heterogenous implementation of IPC measures across the EU.

In relation to hospitals, one finding from the research at national level is that, while there is legislation making IPC mandatory in most countries, this is not fully implemented. Moreover, only a few countries have defined the composition of IPC teams (e.g. Bulgaria, Estonia, France, Hungary, Ireland, Italy, Portugal, Spain¹²⁰). Generally, IPC teams should be multidisciplinary with at least a microbiologist, infectious disease specialist, pharmacist, epidemiologist, infection control nurses and a clear appointed leader.

Across countries, IPC programmes are linked to AMR control. However, the monitoring of compliance of IPC programmes is very diverse across hospitals, as well as annual reporting of indicators. There are countries where hospitals report about HAIs annually, but in most countries, cases of multidrug-resistant organisms are not being reported, although most of the countries are aware of the importance of AMR surveillance. In some countries, all identified cases of certain MDROs are considered notifiable at national level, and the list of notifiable MDROs varies between countries. In other countries, pathogens and corresponding MDROs are only reported once a year in the EARS-Net report (invasive isolates only, i.e. blood and cerebrospinal fluid sample), and sometimes in a national surveillance report (may include more than just invasive isolates). Finally, it was noted that across study countries, IPC measures in hospitals are often perceived as an issue of hygiene and not necessaily related to a more comprehensive approach towards patient safety.

The situation is even more heterogeneous across the study countries when looking at longterm care facilities. The responsibility for LTCFs generally sits across different authorities (welfare, labour, pension, family and social policy). There is also variability and certain

¹²⁰ In some countries, legislation goes into the detail of defining the minimum number of doctors and nurses required in IPC teams (e.g., in Spain, there should be one doctor (a specialist in preventive medicine) for every 500 beds and one IPC nurse for every 250 beds).

confusion regarding the definition of LTCFs, including care homes for elderly people who are healthy, and those for elderly people who are sick, and sometimes these are hybrid facilities that include both sick and healthy people. Normally, the definition of LTCF is different and reflects the organisation of health and welfare in each country. In this setting, IPC is usually limited to some basic hygiene requirements, seasonal vaccination and disinfection of medical devices. In addition, there are no measures addressing AMR specifically, although LTCFs have been identified as important reservoirs of MDROs and only a few countries have inspections of LTCFs. These findings are also aligned with the results of a recent OECD survey that shows that very few countries have policies that specifically address AMR in LTCFs, with a majority of EU/EEA countries reporting they plan to include references to LTCFs in their next national action plan.¹²¹

Overall, it seems that social, cultural and organisational factors are playing an important role in the implementation of IPC in LTCFs. Several guidelines to implement measures to prevent the transmission of MDROs have been reported, however they focus mainly on the hospital setting, not on LTCFs.

Across hospitals and LTCFs, during the COVID-19 pandemic, the majority of countries mentioned that activities of their IPC programmes were put on hold, including control of AMR.

4.2.2. Barriers to the development and implementation of IPC measures

In this section we present key cross-cutting findings in relation to barriers affecting the development and implementation of IPC measures in the EU Member States, Iceland and Norway. These are based on the review of 29 country reports, which were developed based on desk research and interviews with stakeholders from the national governments, hospitals and LTCFs. They also feed from the results of the surveys of national and regional authorities, and of hospital and LTCF stakeholders, with regards to barriers identified and possible measures to overcome these barriers. First we present barriers for hospitals, followed by those identified for LTCFs.

4.2.2.1. Barriers faced by hospitals

Institutional / policy barriers

Weak monitoring/ auditing of healthcare facilities by national authorities to ensure compliance of existing national IPC guidelines/ legislation. Our research found that, although in a majority of countries hospitals are mandated to have an IPC programme in place, there is weak control/ audit of the extent to which this is done and how (Belgium, Croatia, Czechia, Estonia, Greece, Iceland, Italy, Latvia, Slovenia). This results in a very heterogeneous situation in relation to the implementation of IPC measures across European countries.¹²² For instance, in some countries stakeholders reported that different IPC protocols exist in the different regions/ counties and/or in hospitals across the country (Bulgaria, Croatia, Estonia, Italy, Latvia, Luxembourg, Poland, Spain, Romania). In other countries, stakeholders have reported a lack of tailored IPC protocols at a more decentralised level (for instance, at regional or local-level) to address specific local risks or patient populations (Croatia, Greece, Latvia, Portugal, Slovenia). There are however exceptions; for instance, in Ireland, there is a designated authority, the Health Information and Quality Authority (HIQA), which monitors the implementation of IPC programmes in

¹²¹ Briefing note on Antimicrobial Resistance in the EU/EEA: A One Health Response. Available here: <u>https://www.oecd.org/health/Antimicrobial-Resistance-in-the-EU-EEA-A-One-Health-Response-March-2022.pdf</u>

¹²² Tripartite AMR country self-assessment survey – TrACSS (5.0) 2020–2021. Geneva: World Health Organization; 2021 (<u>https://www.who.int/publications/m/item/tripartite-amr-country-self-assessment-survey-(tracss)-2020-2021</u>). Accessed November 2022.

hospitals (and LTCFs) across the country by conducting unannounced inspections. In Denmark, there are infection control teams at the regional and hospital levels, which develop local guidelines based on the national ones, perform audits, and educate healthcare professionals.

Finally, it is worth noting that the weak control is especially prevalent in relation to private healthcare providers. Consequently, the extent to which private hospitals and clinics comply with the national IPC guidelines/ legislation is unclear in some countries (Bulgaria, Czechia, Germany, Slovakia). Even in countries with well-established control mechanisms (Ireland, Portugal, Spain), private healthcare facilities are not monitored or adhere voluntarily.

Lack of harmonised indicators for monitoring and evaluating IPC measures. This has been identified as a problem in most countries and at several levels (national, regional and facility-level). It was seen as a barrier affecting both hospitals and LTCFs by national/ regional authorities, as well as hospital and LTCF stakeholders (between 51% and 29% of respondents selected this barrier, with a higher predominance of this barrier among LTCF stakeholders). There are some exceptions though were IPC plans and guidance are updated and improved in response to monitoring (Austria, Belgium, Croatia, Finland, France, Germany, Greece, Ireland, Malta, Netherlands, Portugal, and Spain). However, even in these countries some limitations exist. For instance, Finland has reported a lack of data on compliance and implementation of IPC standards and measures, and a lack of evidence on the causes of non-compliance. Austria has reported a lack of consensus on how the performance of hygiene teams can be objectively measured (there is an on-going discussion about indicators in this respect). Belgium and France also reported inadequate monitoring and/or evaluation mechanisms to track progress and results of IPC measures. Particularly in Belgium, IPC indicators are in place, but there is no external validation of hospitals' indicators.

Technological/ methodological barriers

Limitations in the methodologies or information systems in place at national or facility level to collect, process and use surveillance data. This limits the extent to which tailored IPC measures can be designed to address emerging risks in relation to HAIs and AMR, both at national and facility level.

- **National level:** in most countries, hospitals are legally mandated to report data on HAIs to the national authorities. However, in several countries there is no feedback from national authorities to hospitals on these data. In many countries, it is unclear to hospitals where the data are stored and how it is used (Czechia, Estonia, Hungary, Romania and Slovenia). This is demotivating for hospital staff, and leads to an underreporting of infections, despite the legal obligations. In other countries, stakeholders have reported problems with the available surveillance data, such as insufficient breakdown of data (e.g., by region or facility), difficulties in accessing the data due to, for example, the lack of integrated digital information systems at national level (Ireland, Italy, Portugal and Sweden).
- **Facility level**: in many hospitals across Europe, information systems do not support good quality analytics and/or there are no analysts or IT personnel who can analyse or use surveillance data (Croatia, Estonia, Italy, Romania and Portugal).

Clinical barriers

Variability of IPC practices across hospitals relating to hospital management approaches towards productivity and patient safety. Stakeholders in several countries have reported conflicting priorities in hospitals in relation to patient safety, profitability, and cost-saving issues (Austria, Croatia, Hungary, Italy, Finland, Latvia, Lithuania and Portugal).

Limited testing capacity to detect and control cases of infection. IPC specialists and antibiotic committees, where they exist, do not have a full understanding of all infection cases, due to limited or absent testing, including via rapid diagnostic methods. This affects

evidence-based decision-making in relation to IPC measures and the control of outbreaks in hospital settings (Bulgaria, France, Hungary, Malta and Portugal). In Bulgaria, for example, it was reported that there are high levels of expertise within diagnostic microbiology and a well-established system for AMR surveillance, for which improvements such as electronic reporting are ongoing. However, too few clinical microbiology samples are taken in hospitals, as most clinical microbiology laboratories are not open 24/7. This is detrimental for the management of patients since there is no rapid detection of the etiological agents of the infection. In Portugal, the national reference laboratory does not have enough capacity, which results in test results taking too long to support outbreak- and infection-control management practices in real-time. IPC measures are designed empirically, based on susceptibility data. In Denmark, in response to the need for mass testing during the pandemic, several new collaborations were established, including with private companies. This opened new paths for quick sample processing. Hospitals also received new equipment to manage the pandemic, which will impact positively on future work on infection.

Suboptimal interaction and/or information exchange between IPC practitioners and laboratories. Whether they are present or not in the same facility, there are no standardised communication or coordination mechanisms in place. This represents a barrier to evaluate, implement and/or adjust IPC measures in real-time (Croatia, France, Italy and Portugal).

Behavioural barriers

Low adherence of medical and non-medical staff to IPC practices due to several structural factors:

 Shortages of staff, especially of motivated and qualified staff: shortages of specialists such as sanitary inspectors, epidemiologists, IPC/hygiene nurses were highlighted in several countries (Bulgaria, Croatia, Cyprus, Estonia, France, Germany, Greece, Hungary, Iceland, Italy, Latvia, Luxembourg, Malta, Romania, Slovenia and Sweden). In Germany, stakeholders reported shortages of cleaning staff, which leads to practices such as "visual cleaning" (i.e., cleaning of noticeable stains and dust only), which happens in 38% of hospitals on Sundays.

Staff shortages were aggravated during the pandemic when staff were reallocated to address the emergency. An ageing healthcare workforce was also mentioned as an issue in several countries (Belgium, Bulgaria, Czechia and France). This was seen to reinforce the risk of shortages due to planned retirements, as well as the continued use of outdated medical practices and resistance to change. Even in countries with relatively higher numbers of healthcare professionals with IPC qualifications, their number was still reported to be insufficient to meet actual needs, especially in small hospitals (Austria, Finland, Ireland and Sweden).

In terms of motivation, the limited career-advancement possibilities, low wages, and difficult working conditions were also mentioned as exacerbating staff shortages in many countries (Bulgaria, France, Hungary, Ireland, Portugal, Slovakia, Spain and Romania). Other identified factors, which negatively impact motivation included the general absence of IPC-related Key Performance Indicators (KPIs) linked to funding or staff performance, as well as the limited data on the potential positive financial impact of proper hospital IPC strategies.

• Limited awareness or understanding of IPC is essential to patient safety: as reported in some countries, hygiene measures are not always perceived as being part of routine patient management or the responsibility of every professional (doctors, nurses and others) who may be in contact with the patient (Croatia, Greece, Italy, Latvia, Malta and Spain). Finland also reported a lack of support from hospital management to IPC measures and a narrow understanding that these mostly related to hospital hygiene instead of, more broadly, to patient safety.

• Limited resources: these were mostly financial, but also included poor or old infrastructure (e.g., insufficient number of single rooms to isolate patients with MDROs), insufficient hygiene products (e.g., hand disinfectants), and insufficient testing capacity (e.g., to detect MDROs) (Bulgaria, Cyprus, Italy, Latvia, Malta, Poland and Spain).

Limited coverage of AMR and IPC in the undergraduate education of healthcare professionals. These topics are more commonly found in postgraduate education. There is also an insufficient focus on IPC measures in the training and education of nurses (Croatia, Germany, Greece, Malta, Slovenia and Spain). In Italy, stakeholders reported a lack of shared criteria for defining what to include in IPC training and what IPC-fluency means.

4.2.2.2. Barriers faced by long-term care facilities

Institutional / policy barriers

Different governance structures impacting on the implementation of IPC measures in LTCFs. Depending on countries' organisation of their health and social care systems, long-term care may be a national, regional or local competence, may fall under the scope of health, social services or both, and may be provided by public or private organisations or at home. This challenges the coordinated development and effective implementation of IPC measures in LTCFs (Croatia, Denmark, Finland, Latvia, Lithuania, Luxembourg, Norway, and Sweden). For example, in Denmark and Sweden, LTCFs are the responsibility of the municipalities. These have varying budgets, priorities, technical and scientific competences, resulting in varying levels of IPC implementation. In Luxembourg, LTCFs were not considered as healthcare providers until 2022; meaning that no IPC measures were envisaged for these facilities until recently. As mentioned in the introduction of this section, the challenges of the sector are significant and go beyond the specific problem of AMR.

Lack of or limited implementation of dedicated IPC programmes or operational plans for LTCFs. For the reasons explained above, several countries have reported that there are no dedicated programmes or plans for infection prevention in LTCFs (Austria, Bulgaria, Czechia, Denmark, Estonia, Latvia, Portugal, Romania, Slovakia, Slovenia, and Spain). Exceptions are Belgium, Italy, Malta, and the Netherlands, where IPC guidelines are available for LTCFs. However, in Belgium and Malta, for instance, there is no process for auditing the quality of care provided in LTCFs that includes indicators associated to IPC. In effect, a recent OECD survey revealed that only six countries have a process for auditing the quality of care provided in LTCFs which includes indicators related to AMR, AMS and IPC.¹²³ In the Netherlands, national guidelines for contact precautions for carriers of MDRO (other than MRSA) in LTCFs were published in 2014 and revised in 2019.¹²⁴ However, it has been challenging to ensure consistent adherence to the guidelines due to differences between facilities in staff training, resources, and awareness of the guidelines.

No systematic surveillance of HAIs in LTCFs. Occasional attempts to collect data on HAIs in LTCFs have been made in some countries (Austria, Ireland, Latvia, and the Netherlands). However, the results of the OECD survey showed that only six EU/EEA countries have guidelines, protocols or requirements for the adoption of surveillance of AMR in LTCFs.¹²⁵ This has led to a generalised lack of data about HAIs and prevalence of MDROs in LTCFs, limiting the design and implementation of targeted IPC measures. It is important

¹²³ 94. OECD. Briefing note on Antimicrobial Resistance in the EU/EEA: A One Health Response. . 2022. Available from: <u>https://www.oecd.org/health/Antimicrobial-Resistance-in-the-EU-EEA-A-One-Health-Response-March-2022.pdf</u>.

¹²⁴ Werkgroep Infectie Preventie (WIP). Bijzonder resistente micro-organismen (BRMO) - Verpleeghuizen, woonzorgcentra en voorzieningen voor kleinschalig wonen voor ouderen. 2019.

¹²⁵ OECD. Briefing note on Antimicrobial Resistance in the EU/EEA: A One Health Response. . 2022. Available from: <u>https://www.oecd.org/health/Antimicrobial-Resistance-in-the-EU-EEA-A-One-Health-Response-March-2022.pdf</u>.

to note that, at EU level, the ECDC regularly coordinates point prevalence surveys of HAIs and antimicrobial use in European LTCFs. There is a standardised protocol for these surveys. The last survey (HALT-3) took place in 2016-2017, and a fourth survey (HALT-4) is taking place in 2023.¹²⁶

Clinical barriers

Old and poor infrastructure of LTCFs. Stakeholders from several countries have reported that LTCFs are in old buildings which are not equipped for modern care and make it difficult to implement IPC measures effectively. For instance, several countries have reported a shortage of single rooms, insufficient ventilation, and access to sanitary facilities (e.g. not all rooms have a washbasin and a separate toilet). These types of problems were reported in Croatia, Cyprus, Denmark, Greece, Iceland, Ireland, Latvia, Slovenia, and Slovakia.

Lack or shortages of staff with qualifications on IPC, in particular nurses. Several countries face the challenge of insufficient human resources in LTCFs and particularly in retaining nurses (Belgium, Estonia, France, Germany, Greece, Iceland, Latvia, the Netherlands, Portugal, Spain, and Sweden). Several factors explain this, including the inexistence of a nursing specialisation for this type of facility and the low wages. This results in nurses' preference for hospitals. In countries with higher numbers of staff with qualifications in IPC, there are still limited career advancement possibilities in LTCFs, leading to the loss of experienced and motivated staff to other sectors where grade advancement is easier (Austria, Finland, Germany, Ireland, and Sweden). It is also worth noting the limited awareness of IPC measures of non-medical staff in LTCFs (e.g., voluntary staff, caretakers), with often a very low level of knowledge and adherence to cleaning and hygiene measures.

Lack of or limited dedicated financial resources for the implementation of IPC measures in LTCFs (Belgium, Estonia, France, Germany, Ireland, Latvia, Lithuania, Sweden). In the surveys of national/ regional authorities and of stakeholders representing LTCFs, insufficient funding was the second most selected barrier (after insufficient human resources) affecting LTCFs (between 58% and 48% of respondents, respectively, selected this barrier).

Behavioural barriers

Adherence to IPC programmes and guidelines is significantly lower than in hospitals. This is also the case in countries that are more advanced in IPC in human health, according to TrACSS data (Germany, Portugal, Sweden). The factors that explain this are similar to those applicable to hospitals, although their severity is higher. This includes shortages of staff, lower levels of education and specialisation in IPC, and limited resources (money and equipment).

4.2.3. Possible measures to overcome the identified barriers

In this section, we present possible measures to overcome the identified barriers that emerged from the analysis of country reports and stakeholder surveys.

To support Member States in strengthening IPC in LTCFs:

• ensure that the development and implementation of IPC measures in LTCFs features as a priority in Member States' new/updated NAPs. This can be a way of encouraging Member States to systematically incorporate IPC into their long-term care policies. Member States should set concrete targets, activities, roles and

¹²⁶ ECDC - Healthcare-associated infections and antimicrobial use in long-term care facilities: HAI-Net HALT database, <u>https://www.ecdc.europa.eu/en/all-topics-z/healthcare-associated-infections-long-term-care-facilities/surveillance-and-disease</u>

responsibilities, deadlines, monitoring tools, and dedicated funds for strengthening IPC in LTCFs in the next years.

To support Member States in developing and updating their national IPC policies:

- promote the timely revision and update of national IPC guidelines. Through surveillance and research, the EU can recommend Member States to revise or update their IPC guidelines when a significant change in AMR is detected, if there is new evidence and/or guidelines on the management of specific infections, new medicines/ technologies, and/or at regular intervals.
- continue developing and promoting the ECDC's directory of online resources for prevention and control of AMR and HAIs.¹²⁷ This should be a user-friendly one-stop-shop or single repository of the latest guidelines and frameworks on IPC applying to specific types (and sizes) of healthcare facilities and infections. The ECDC repository currently includes standards/guidelines for hospitals, primary care and dentistry, as well as for infections caused by different types of microorganisms. Other resources that could be added in the repository are the EU-JAMRAI Universal Infection Control Framework (UICF)¹²⁸. A regularly updated and easy to navigate repository could enhance access and help Member States to base their national IPC policies on the latest international recommendations. If gaps in the coverage of the available guidelines/standards are identified, for instance there are yet no specific guidelines/standards applying to LTCFs, laboratories, and pharmacies, the EU, in cooperation with Member States, could aim to develop EU guidelines through consultation with international experts. It is also important to work on optimising the organisation of information in the directory, as well as on increasing awareness of its existence, not only among national/ regional authorities, but also hospital and LTCF managers and healthcare professionals more generally. This could be done, for example, through EU and national-level professional associations.
- define, with the support of experts, a set of common outcome indicators and guidelines for the monitoring and evaluation of IPC measures in hospitals and LTCFs. Having a set of key outcome indicators for the EU could help Member States see their progress and benchmark themselves against others. The guidelines should provide recommendations on data collection and analysis methods and how to aggregate and break down data coming from hospitals and LTCFs. The guidelines should also provide advice on how to feed back results to healthcare facilities and professionals. Moreover, the publishing of a yearly report or online dashboard to show progress in EU countries on the implementation of IPC measures (based on the set of common indicators) could be considered.

In the surveys, 71% (n=29) of national/ regional authorities said that they would like the EU to provide a harmonised list of indicators to track progress on the effectiveness of IPC measures¹²⁹. This was also selected by 67% (n=56) of hospital and LTCF stakeholders. In the country-level interviews, national/ regional authorities also suggested establishing a set of indicators for the monitoring of IPC across Europe.

¹²⁷ ECDC - Directory of online resources for prevention and control of antimicrobial resistance (AMR) and healthcareassociated infections (HAI), <u>https://www.ecdc.europa.eu/en/publications-data/directory-online-resources-prevention-andcontrol-antimicrobial-resistance-amr</u>

¹²⁸ EU-JAMRAI, D 6.2, A Universal Infection Control Framework with specific roles, priorities, resources & interventions for ICP implementation in healthcare settings, <u>https://eu-jamrai.eu/wp-content/uploads/2021/04/EUjamrai_D6.2_Universal-Infection-Control-Framework_WP6.1_EODY_280221.pdf</u>

¹²⁹ In full, the statement said: "EU to provide guidelines on IPC norms/ standards for hospitals and LTCFs, including a harmonized list of indicators to track progress on the effectiveness of IPC measures."

• promote the integration of IPC-related KPIs to healthcare facilities' decisions on funding and staff performance assessments, for example through the identification and dissemination of good practices in this area. The identification of IPC-related KPIs for hospitals and LTCFs, together with regular monitoring and evaluation, through a positive pay-for-performance incentive mechanism, can strengthen adherence to IPC measures. This also implies a more effective use of surveillance data to monitor and evaluate quality of healthcare provided to patients. In section 4.1.4, we provided an example of a quality index (PPCIRA-IQ) developed in Portugal which includes IPC indicators and is associated to a pay-for-performance programme of incentives. France has also developed healthcare quality and safety indicators (QSI) that are used for improving quality of care and patient safety, as well as for hospitals' certification procedures, and for the pay-for-performance system (IFAQ). Adding to this example, the Ministry of Health in Slovenia yearly reports on 31 Key Indicators of Quality, of which two are IPC indicators: MRSA infections and results of hand hygiene monitoring.

To help Member States to address structural barriers (e.g., lack of funding and skilled human resources):

- advise Member States on existing EU sources of (co)-funding. As recommended under Study Area 1 (see section 4.1.3), several EU sources of funding exist already, managed by different DGs and EU institutions, which could help Member States address structural barriers such as education and training of healthcare workers; construction / renovation of healthcare facilities; setting up or updating IT infrastructures at national level or in hospitals and LTCFs; etc. For example, in Estonia, funding from the Recovery Assistance for Cohesion and the Territories of Europe programme (REACT-EU) has been used to contract infection commissioners to monitor and advise on IPC in LTCFs (see section 4.2.4). Funds available, as well as requirements for accessing these funds and using them for improvements in IPC, are not always known to human health national authorities. The EU could proactively reach health national authorities to alert them of available sources of funding, provide guidance on requirements and application procedures, and concrete examples of how Member States have used (or are using) these funds to introduce changes that can positively impact on IPC and AMR.
- use existing and future EU funds to support IPC/patient safety efforts in Member States. For instance, this includes activities that (i) adopt a patient safety approach (and not only link IPC to hygiene) and are implemented in accordance with the NAP-AMR (see good pactice examples in Ireland, Malta and Belgium in section 4.2.4) and (ii) focus on healthcare facilities that lag behind in the implementation of IPC measures, for instance, LTCFs, small hospitals and outpatient clinics. In relation to EU funds available for improving healthcare facilities' infrastructure, it is important that construction or renovation activities are required to integrate IPC considerations and are based on the latest recommendations in terms of IPC (see good practice example in Ireland in section 4.2.4).
- promote IPC mainstreaming in Member States' undergraduate, postgraduate, and vocational education and training programmes. This also includes the creation of IPC career specialisations (for doctors, nurses, pharmacists, microbiologists, etc.). The EU could also play a role in defining minimum requirements for IPC education and training of medical and non-medical staff working in specific healthcare facilities (hospitals, LTCFs, primary care, pharmacies). All this could potentially enhance valorisation of dedicated-IPC jobs (e.g., IPC nurses), career development, motivation, and staff retention.
- continue funding, delivering and promoting training opportunities on IPC (and AMR more generally) targeting national policy-makers and healthcare professionals. Initiatives such as the training programme on AMR provided by the

EU under the Better Training for Safer Food (BTSF)¹³⁰ should be promoted further in the Member States. This initiative could potentially offer training activities for hospital/LTCF managers and health professionals to be appointed by the Member States. The WHO also offers free online courses for healthcare workers aimed at building competencies to help combat AMR in their daily clinical practice.¹³¹ There are also some interesting training initiatives in the Member States targeting healthcare workers, for instance in Sweden (VRI-Smart®), which could be promoted as good practice. The surveys and interviews conducted in this study revealed a strong apetite for training activities by hospitals and LTCFs stakeholders¹³², which could also indicate that the existing opportunities are still not well known in the Member States.

To enhance awareness of the importance of IPC measures to combat AMR in Europe:

• continue delivering public awareness campaigns aimed at establishing a culture of patient safety. The EU should continue to work closely with WHO/Europe on campaigns to raise public awareness and understanding of infection control and its importance. This includes awareness of the high presence of MDROs in hospitals and measures that healthcare staff and patients can take to prevent transmission. Hand-hygiene campaigns continue to be in demand and are considered essential by many Member States. An example of a hand-hygiene campaign targeting health workers in nursing homes in Denmark is presented in section 4.2.4. This could be replicated in other countries with EU funding.

To help Member States to exchange good practice and learn from each other:

- create or support existing fora for the sharing of good practices in IPC. For example, good practices in relation to incentives to increase reporting of HAIs and AMR prevalence by hospitals and LTCFs; public awareness campaigns to enhance adherence to IPC measures by patients and healthcare staff; education and training of IPC nurses; etc. Measures can involve organising meetings, workshops and conferences, or providing funding for joint initiatives. Italy, for example, has a national system for identification, collection and dissemination of patient-safety good practices (see section 4.2.4), which could be considered for development at EU-level.
- promote/ fund the establishment of IPC networks at national level, which can work
 as platforms for collaborating, exchanging information and providing advice on IPC
 between healthcare professionals, facilities, and laboratories (see the good practice
 example in Belgium in section 4.2.4). Exchanges of knowledge and expertise and
 collaboration would be particularly beneficial between LTCFs and hospitals.

To support Member States in strengthening surveillance and research:

- develop a framework for strengthening epidemiological surveillance across the EU, especially surveillance of MDROs. This should be aimed not only at quantifying the burden of infectious diseases, but also at identifying determinants and risks of infection, assessing the impact of prevention interventions.
- (co-)fund IPC research activities. IPC research priorities identified by EU-JAMRAI are particularly relevant in this respect.¹³³ In particular, the EU should produce or co-fund

¹³⁰ See: <u>https://better-training-for-safer-food.ec.europa.eu/training/course/index.php?categoryid=56</u>

¹³¹ See: <u>https://openwho.org/channels/amr?locale=en</u>

¹³² In the survey, over half of national/ regional authorities (54%, n=22) would like the EU to organise or promote training activities on IPC measures. This was selected also by 58% (n=48) of hospital and LTCF stakeholders. In the country-level interviews, stakeholders also saw a role for the EU in addressing education and training gaps in relation to IPC.

¹³³ EU-JAMRAI Policy Brief "The urgent need to foster research on infection prevention and control to improve health security". <u>https://eu-jamrai.eu/wp-content/uploads/2021/02/201207_EUJAMRAI_policy-brief_WP9_research-on-IPC.pdf</u>.

research projects and studies showing the impact of effective IPC strategies and measures on patient safety but also on hospitals and LTCFs' budgets. This is important to change beliefs and behaviours and increase adherence and promotion of measures by facilities management and staff.

4.2.4. Good practices

- Mainstreaming patient safety approaches:
 - In Ireland, the prevention of HAIs is part of the patient-safety programme of the Health Service Executive. The NAP-AMR established a back-to-basics approach that focuses on hand hygiene, standard precautions and the prevention of infections associated with medical devices. There is also a dedicated team (AMRIC Team) that provides leadership for AMR and IPC in the health sector by developing and publishing clinical guidance for patient and client care (in collaboration with stakeholders); providing education, training, and resources to implement this guidance; and providing specialist advice and support to services. The team also prepares information leaflets for patients¹³⁴ and engages with several media channels to communicate with policymakers and the wider public. Further developments in education and training by AMRIC include initiatives such as the IPC Link Practitioner Programme and development of a set of eLearning modules for health and social care staff.
 - In Italy, there is a national system for identification, collection and dissemination of patient-safety practices (formerly Observatory on Good Practice for Patient Safety). It was established in 2008 and is managed by the national agency for regional health services (AGENAS). The collection of good practices is based on regular observation and validation of protocols implemented at the point of care with strict evidence criteria. Nominations are collected via voluntary submission, as well as with yearly calls in priority areas.¹³⁵
- Functioning of multidisciplinary IPC teams: Hospital Mater Dei in Malta (the main hospital in the country) launched a hospital-wide AMR Strategy in 2010. The hospital has a multidisciplinary Infection Control Department (ICD) with dedicated resources, support from the local authorities, and effective surveillance infrastructure. The Department coordinates all activities related to the prevention and control of HAIs in the hospital. It also provides technical assistance to other public hospitals, each of which has an appointed Practice Nurse in IPC. The ICD has developed a comprehensive set of policies and Standard Operating Procedures that are also used by the other public hospitals, is active in IPC education and organises an annual national conference. The unit adopts a Plan-Do-Study-Act approach utilising Root Cause Analysis tools to identify and address causative factors for serious infections, such as MRSA. In addition, a strong emphasis is placed on process audits including hand hygiene facilities and performance, management of central lines, peripheral venous cannula care, compliance with contact precautions, and environmental cleaning amongst others. By 2018, the hospital had achieved a 70% reduction of MRSA.136
- Networks of hospitals/professionals for strengthening IPC: in Belgium, the Hospital Outbreak Support Team (HOST) pilot projects were established in 2021 in

¹³⁴ See: <u>https://www2.hse.ie/conditions/c-diff/</u>

¹³⁵ See: <u>https://buonepratiche.agenas.it/default.aspx</u>

¹³⁶ Ministry of Health. A Strategy and Action Plan for the Prevention and Containment of Antimicrobial Resistance in Malta, 2018 – 2025. <u>https://meae.gov.mt/en/Public Consultations/MEH-HEALTH/Documents/AMR%20Strategy_FINAL_EN_%20Public%20Consultation_NOV2018.pdf</u>

the framework of the implementation of the NAP-AMR and in the context of the COVID-19 pandemic. The latter demonstrated how consolidating existing links between hospitals in a network, with residential facilities and front-line actors, can support expertise-sharing.¹³⁷ The HOST pilot projects are aimed at strengthening IPC and AMS in hospitals, LTCFs and primary care through the establishment of networks of hospitals at regional level. The projects are developed through two complementary axes: on the one hand, a local-regional approach based on cooperation between hospitals, and on the other hand, a cross-cutting approach where hospitals' expertise is made available to both residential facilities and other healthcare providers.

Hospital local-regional networks establish a HOST team composed of experts in infectious diseases, medical microbiology and hospital hygiene. The team's task is to improve IPC by harmonising surveillance, collection and coding processes and developing a common data-sharing strategy. So far, 24 HOST pilot projects were launched between 2021 and 2022, of which 4 were in the Brussels region, 12 in Flanders and 8 in Wallonia. In France, the CPias were created in 2017 to implement the national policy for the prevention and control of HAIs. These regional structures also lead and coordinate networks of IPC professionals and hygiene teams at regional level.¹³⁸ The CPias are a public entity embeded in university hospitals.¹³⁹

- Integration of IPC into construction and renovation of acute hospital structures: in Ireland, the Health Service Executive (HSE) has produced guidance that addresses the role of IPC in renovations and the construction of acute hospitals. The guidance, that also applies to building standards for new primary care centres, has been updated in May 2022.¹⁴⁰ It covers IPC related concerns, including material choice, space, and design of sinks among other requirements.
- Strengthening IPC in LTCFs with the support of EU funding: since 2020, the supervision of residential LTCFs in Estonia is organised by the Social Insurance Fund in cooperation with the Health Board and the State Agency of Medicines. The Social Insurance Fund uses contracted infection commissioners to monitor and advise, with the aid of funds from the European Commission's Recovery Assistance for Cohesion and the Territories of Europe (REACT-EU) programme.
- Hand-hygiene campaigning: in Denmark, the Copenhagen Municipality's home care has developed a 'Monday kit' with tools for nail care, which is handed out to employees to focus their attention on preventing the spread of infection. The 'Monday kit' contains nail cleaners, acetone, cotton pads, nail clippers and a safety pin for jewellery and watches. This is to facilitate the transition from private zone (weekend) to professional zone, and to create a better understanding of the importance of sufficient hand hygiene to avoid the spread of infections.

¹³⁷ See: <u>https://organesdeconcertation.sante.belgique.be/fr/projet-pilote-hospital-outbreak-support-teams-host</u>

¹³⁸ See: <u>https://sante.gouv.fr/prevention-en-sante/les-antibiotiques-des-medicaments-essentiels-a-preserver/des-politiques-publiques-pour-preserver-l-efficacite-des-antibiotiques/article/prevention-des-infections-et-de-l-antibioresistance-a-l-echelleregionale and <u>https://www.santepubliquefrance.fr/maladies-et-traumatismes/infections-associees-aux-soins-et-resistance-aux-antibiotiques/articles/des-reseaux-de-surveillance-nationaux</u></u>

¹³⁹ See: <u>https://www.cpias.fr/quisommesnous.html</u>

¹⁴⁰ See: https://www.hpsc.ie/a-

z/respiratory/coronavirus/novelcoronavirus/guidance/infectionpreventionandcontrolguidance/buildingsandfacilitiesguidance/lnfection%20Control%20Guiding%20Principles%20for%20Building.pdf

4.3. Antimicrobial stewardship measures in hospitals and long-term care facilities

4.3.1. State of play

AMS measures in hospitals

Antimicrobial stewardship is covered in most of the countries' NAPs on AMR. However, as reported across countries, to date there has been limited monitoring of the extent of the implementation of AMS measures as part of the NAPs.

AMS governance in the different countries is generally dependent on the level of centralisation of health policy. On the one hand, there are countries with more centralised and vertical governance structures where the Ministry of Health or a national committee establishes the AMS policy to follow at the regional/ local level. For example, Austria, Denmark, and Finland have developed national AMS guidelines. On the other hand, countries with more descentralised governance structures may have a NAP-AMR that provides a general framework for AMS measures, but these are to be adapted/designed by the regions according to the local context. For example, in Italy, there are regional plans in place for the correct use of antibiotics which are submitted to the regional Commission for Care-Related Infections, which is available in each region. In Czechia, expert advice on antibiotic treatment is provided by local antibiotic centers in large university or regional hospitals (77 in total).

In terms of AMR and antibiotic consumption surveillance, EU countries have surveillance mechanisms in place, in line with the reporting requirements of the ECDC. Countries report data to the European Antimicrobial Resistance Surveillance Network for AMR and the European Surveillance of Antimicrobial Consumption Network for antibiotic consumption. Nevertheless, this reporting has some limitations. For instance, in some countries, only a non-representative sample of laboratories participate and provide data to the EARS-Net, and hospital antibiotic consumption data reported to ESAC-Net are aggregated for the whole hospital sector rather than reported for each individual hospital. However, national surveillance systems have been further developed in some countries to improve the representativeness of hospitals at the national level, and extend the spectrum of pathogens with AMR or of antimicrobials surveyed (e.g., AURES and AGES in Austria, BulSTAR in Bulgaria, the System for the Surveillance of Antimicrobial Resistance in Greece).

Regarding the availability of specilaised AMS human resources, there are examples of local AMS committees set up in hospitals (e.g. infection control and antibiotic committees (ICACs) in Hungary¹⁴¹ or AMS committees in Ireland¹⁴²). However, the availability of AMS teams or staff with AMS specialists is generally limited, even when their set-up is specified in national or regional action plans. The lack of specialised human resources has led some countries to redefine roles for non-infectious disease specialists in the field. For example, in Ireland, the potential role of nurses (particularly IPC nurses who are part of AMS teams) in positively influencing antimicrobial prescribing and AMS is strongly emphasised in the 2022 AMS guidance.¹⁴³ Clinical pharmacology is a new field since 2010 in Czechia.

¹⁴¹ These are multidisciplinary advisory forums reporting to the hospital management.

¹⁴² Health Service Executive. Antimicrobial Stewardship: Guidance for all healthcare settings (2022). Available from : <u>https://www.hse.ie/eng/services/list/2/gp/antibiotic-prescribing/antibicrobial-stewardship-audit-tools/hse-amric-antimicrobial-stewardship-guidance-for-all-healthcare-settings-v1-published-august-2022.pdf</u>

¹⁴³ Ibid.

In this study's survey,¹⁴⁴ when asked about AMS measures that were currently being implemented in the majority (over 50%) of hospitals, according to national/ regional authorities and hospitals stakeholders, the top measures were: (1) guidelines for the diagnosis and management of infections and for perioperative antimicrobial prophylaxis (64%, n=27 and 62%, n=41); (2) a system for the documentation in the patient records of indication, drug choice, dose, route and duration of treatment (50%, n=21 and 33%, n=22); (3) an antimicrobial committee or similar formal organisational structure with senior management support (45%, n=19 and 58%, n=38); and (4) an AMS team including a clinician with training, expertise and professional involvement in the diagnosis, prevention and treatment of infections, a hospital pharmacist and a microbiologist (43%, n=18 and 47%, n=31). For hospital stakeholders, other AMS measures which were frequently implemented included microbiology laboratory services provided on a 24/7 basis for critical specimens, as well as validated rapid and/or point-of-care diagnostics for defined patient groups to complement clinical assessment and optimise antimicrobial treatment (47%, n=31 each).

AMS measures in long-term care facilities

AMS measures in LTCFs are in a very early stage of development in most EU countries or do not exist at all in some (this is the case in particular in countries without established AMS programmes in hospital settings, such as Latvia or Luxembourg). The development and implementation of AMS measures in these types of facilities is challenged by the large number of LTCFs and the heterogeneity of their governance and administration. Stakeholders explained that when AMS actions are implemented in these settings, they tend to be dependent on the individual action of GPs or nurses, without national/central coordination.

In the survey of national/ regional authorities, the most mentioned AMS measures in place at national/ regional level addressing LTCFs were campaigns on antibiotic awareness (55%, n=18); national/ regional mechanisms/legislation for restriction of antimicrobial use e.g. reserve list or last resort antimicrobial (39%, n=13); and national/ regional programme/ legislation for AMS (30%, n=10). The most mentioned AMS measures by LTCF stakeholders were national/ regional guidelines/recommendations on (prudent) antimicrobial use (67%, n=18) and national/regional campaigns on antibiotic awareness (56%, n=15).

Concerning AMS measures that were currently being implemented in the majority (over 50%) of LTCFs, 48% (n=11) of national/ regional authorities answered 'don't know'. The LTCF stakeholders said that the top AMS measures were validated rapid and/or point-of-care diagnostics for defined patient groups to complement clinical assessment and optimise antimicrobial treatment (44%, n=11) and a system for the education/training of prescribers and health personnel involved in antibiotic use (36%, n=9).

Data coming from the European Point Prevalence Survey of HAIs and antimicrobial use in European LTCFs (HALT-3) showed that 28.5% of the surveyed LTCFs did not have any of the ten specified antimicrobial stewardship elements in place. The two most commonly reported elements were, 'therapeutic formulary, comprising a list of antibiotics' (45.6%) and 'written guidelines for appropriate antimicrobial use (good practice) in the facility' (39.4%). A restrictive list of antimicrobials for prescription was only available in 24.0% of the LTCFs. The HALT-3 survey collected data from a total of 3052 LTCFs in 24 EU/EEA countries.¹⁴⁵

¹⁴⁴ The survey included questions on the extent to which countries have AMS programmes/ measures that follow the "EU Guidelines for the prudent use of antimicrobials in human health" (<u>https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv:OJ.C .2017.212.01.0001.01.ENG&toc=OJ:C:2017:212:TOC)</u>.

¹⁴⁵ Please see: Ricchizzi Enrico, Latour Katrien, Kärki Tommi, Buttazzi Rossella, Jans Béatrice, Moro Maria Luisa, Nakitanda Olivia Aya, Plachouras Diamantis, Monnet Dominique L, Suetens Carl, Kinross Pete, the HALT Study Group. Antimicrobial use in European long-term care facilities: results from the third point prevalence survey of Healthcare-associated infections and antimicrobial use, 2016 to 2017. Euro Surveill. 2018;23(46):pii=1800394

Moeover, less than a quarter of facilities (20.7%) had annual regular training on appropriate antimicrobial prescribing and 24.0% had a 'restrictive list' of antimicrobials to be prescribed. As an example, in Denmark, 95 LTCFs were surveyed, with 10.5% of residents on antibiotics, only 2% of the institutions with specific written guidelines, none with regular training, and only 1.1% (n=1) with a specific restrictive list. Ireland found an overall national crude prevalence rate for Irish LTCFs to be twice as high as the European average for antimicrobial use (9.8% vs 4.9%).¹⁴⁶ Adding to this, a common problem was found across countries: the high prophylactic use of antibiotics for, for example, the prevention of UTIs. For instance, in Ireland, the 2020/2021 Point Prevalence Study of Antimicrobial Use in HSE Older Persons Residential Care Facilities conducted by Community Healthcare Organisations (CHO) pharmacists, found that 57% of prophylactic prescriptions had been prescribed for more than 12 months, which is beyond the recommended duration.

4.3.2. Barriers to the development and implementation of AMS measures in hospitals and LTCFs

In this section we present key cross-cutting findings in relation to the development and implementation of AMS across the 29 study countries. First barriers for hospitals, followed by those identified for LTCFs.

4.3.2.1. Barriers faced by hospitals

Institutional / policy barriers

Limited policy focus on AMS measures. Consultations with national stakeholders highlighted that health sectors across European countries need to address several challenges (including organisational, legal, funding and staffing problems), which undermine support for AMS measures, as these are not considered to be a priority in healthcare systems. In Bulgaria, the lack of national or regional-level definitions and/or legal framework on AMS hinders the development and implementation of measures in hospitals. Consequently, there is limited attention to AMS in the healthcare system. In the survey, limited attention to AMS was identified as a barrier affecting hospitals (and LTCFs) by national/regional authorities, as well as by hospitals and LTCF stakeholders (between 45% to 36% of respondents selected this barrier).

Lack of national AMS strategies or operational plans covering prudent antibiotic prescriptions in healthcare facilities (including in hospitals and LTCFs). This has been identified as a barrier in several countries across Eastern and Southern Europe, in particular Bulgaria, Croatia, Cyprus, Estonia, Hungary, Latvia, Portugal, Slovakia and Spain. The absence of comprehensive national AMS strategies or plans has resulted in AMS measures being developed at regional or healthcare facility level, which reinforces the fragmentation of approaches and measures. The lack of a national AMS framework has also created some issues within hospitals, for example the lack of defined working hours for antibiotic officers (Austria) or the coexistence of different AMS programmes across regions and hospitals, as well as difficulties in approving a quality mandatory certification at national level (Spain). In Hungary, while there are national guidelines and recommendations on (prudent) antimicrobial use for hospitals, as well as on surgical prophylaxis, these have not been updated or adopted as part of a national strategy to improve prudent use of antimicrobials. In the survey, a lack of national/regional definitions or legal frameworks for AMS was a significant barrier for hospitals, according to hospital stakeholders (44%, n=28). This was also identified as a barrier by a third of national/regional authorities (33%, n=13%).

^{(&}lt;u>https://www.eurosurveillance.org/docserver/fulltext/eurosurveillance/23/46/eurosurv-23-46-5.pdf</u>) for participation in HALT-3. Bulgaria, Czechia, Estonia, Iceland, Latvia, Romania, Slovenia did not participate.

¹⁴⁶ Ibid.

Lack of dedicated funds for AMS measures in hospitals. The lack of dedicated funds for AMS measures impacts on several dimensions of healthcare professionals' work. In Latvia, AMS measures are not included in the state budget for healthcare services, which results in medical institutions taking different approaches to provision. This results in variable access to services, including examinations and specialists for people in different territories due to the lack of specialists in infection surveillance, volume of patient flows and funding. In Portugal, excessive workload has demotivated healthcare professionals who have limited prospects for career progression and increased remuneration, which has negatively impacted their work capacity. In Latvia as well, most AMS activities are additional to the core work of the professionals responsible. According to these professionals, the current situation prevents the development and implementation of meaningful AMR measures and programmes in hospitals. A lack of staff and resources results in reduced compliance with AMS measures, limits the implementation of interventions (Belgium, Finland, France, Germany, Iceland and Norway), or makes it difficult to set up dedicated AMS teams (Austria).

Difficulties in implementing measures and harmonising practices within and between hospitals. Consulted healthcare professionals confirmed that administrative procedures and protocols sometimes delay the implementation of AMS measures in hospitals. Linked to this, stakeholders also highlighted difficulties in getting different hospital management structures to agree on common actions and encouraging cooperation between institutions.

Technological / methodological barriers

Absence of systematic and integrated data on prescriptions for antimicrobials. Paper-based prescribing in hospitals, or the nature of data reporting, inhibits the easy monitoring of antimicrobial prescriptions (Bulgaria, Ireland, Latvia, Luxembourg, Portugal and Romania). This in turn results in highly heterogeneous practices within and between hospitals. In Latvia, hospitals have different and incomparable systems for recording antibiotic consumption, which make data analysis difficult. Calculations of antibiotic consumption have to be made manually and there is no standardised, uniform system for labelling and recording medications, which makes the process complex and timeconsuming. In Ireland, where hospital prescriptions are paper-based, data on inpatient antimicrobial use are generally obtained from the volume of ward stock issued. In the absence of electronic prescribing systems, these data have limitations in terms of reflecting actual patient use and facilitating prescriber-level feedback. In some countries (such as Croatia), there are data on the prescription of antibiotics, but hospital information systems do not support good analytics at facility level to monitor the consumption of antibiotics in adequate measurement units and to monitor resistance. Consultations with national stakeholders have identified efforts in several countries to optimise the monitoring of antimicrobial prescriptions through the development of electronic systems (Finland and Malta), or through the introduction of restricted antibiotic lists and requirements for preauthorisation or post-prescription review of antibiotics (Bulgaria, Ireland and Sweden).

Logistical delays in receiving laboratory results. Many hospitals across European countries outsource the laboratory services, which results in long waiting times to receive microbiological results (for example, in Latvia and Hungary). It is not always possible to receive intermediate laboratory results due to the lack of electronic systems and the use of paper-based information-sharing. In addition, microbiology laboratories have capacity constraints (one laboratory typically serves several hospitals and clinics), even in the case of national reference laboratories (Portugal). Thus, prescribers in hospitals (and also LTCFs) have limited access to diagnostics before they prescribe antimicrobials. In some cases, both laboratory equipment and communication technology need to be updated/modernised (for example, in Slovakia). In Iceland, not all laboratories working on AMR are accredited or have their methods validated. Moreover, in the human-health sector, non-accredited laboratories are generally small, and their results are not included in the report to the EARS-net. This is also a problem in countries, such as Latvia, that still rely on

paper-based information-sharing, which limits the inclusion of these laboratories in national and European AMR surveillance networks.

Clinical barriers

Evidence-based guidelines for the treatment of common infections are not always available or are not widely distributed in hospitals. The absence of evidence-based guidelines for prescribing antibiotics results in doctors having to rely on their clinical experience, peers, and/or information provided by pharmaceutical companies (Bulgaria, Estonia, Italy, Portugal and Spain). In some countries, detailed hospital guidelines are available for the clinical management of infections (for example, in Ireland and Iceland) but they are not widely distributed among local AMS teams, which limits their application in practice.

Lack of specialised staff in hospitals. Stakeholders consulted in several countries highlighted that there is a shortage of infectious-disease specialists, clinical microbiologists and clinical pharmacists in hospital settings (Austria, Bulgaria, Croatia, Cyprus, Hungary, Italy, Lithuania, Portugal and in small hospitals in Germany). The lack of specialised staff results in a lack of professional leadership to implement AMS measures in hospitals (Spain). In Ireland, an initiative to establish antimicrobial stewardship teams in hospitals was not impactful as teams lack time to implement the activities foreseen. In Belgium, Antibiotic Therapy Policy Groups within each hospital have been in place since in 2007. While the current regulatory framework makes it obligatory for hospitals to establish these groups, allocate financial resources, and mandate the delivery of a yearly activity report, it does not define the minimal human resources, set targets, define consequences for underperformance or make hospital management teams fully accountable for their use of allocated budgets.

Lack of dedicated education and training in AMS practices and protocols. This barrier impacts both academic curricula and subsequent professional training in hospitals. The absence of education strategies results in the lack of awareness among healthcare professionals on the importance and impact of AMS measures (Belgium, Croatia, Estonia, Germany, Latvia, Lithuania, Romania). In some countries, younger doctors are mainly influenced by the behaviour and practices of senior prescribers in their hierarchy (Ireland and Sweden). In Bulgaria, AMS teams have been established, at least in large and university hospitals. However, to date, activities could not be conducted to an optimal level, due to either a lack of trained staff or time. In addition, in Ireland, current guidelines and procedures aim to address knowledge gaps, however there are no measures in place to help hospitals establish a prudent prescribing culture within clinical teams. This is particularly relevant for junior doctors who are influenced by the behaviour of senior prescribers or hierarchy within teams.

Supply shortages and limited availability of narrow-spectrum antimicrobials. Supply shortages of certain types or classes of antibiotics make it difficult to shift the consumption in a direction recommended in respective guidelines (Denmark, Sweden, Finland and Malta). This makes narrow-spectrum antimicrobials expensive and difficult to access, which increases the use of broad-spectrum antibiotics where a narrow-spectrum alternative would be more appropriate, resulting in a negative impact on antimicrobial resistance. To limit the use of broad-spectrum antibiotics, several countries (Bulgaria, Croatia, Czechia, Ireland, Netherlands, Slovenia, Spain and Sweden) have established prescribing lists. Supply shortages of narrow-spectrum antibiotics affect both hospital and community pharmacies. This problem is further described in Section 4.4.2.

Behavioural barriers

Pressure from patients: medical staff in several countries (Bulgaria, Croatia, Denmark, Greece, Latvia, Portugal, Slovakia, Slovenia and Spain) reported that there is pressure from patients to prescribe antibiotics. In Belgium, related behavioural barriers include the idea that over-use of antibiotics presents fewer risks than limiting their use (this has also been

reported as common in Malta). Also, some patients view antibiotics as quick fixes, and have difficulties accepting that self-limiting infections do not always require an antimicrobial treatment. This problem is further detailed and discussed in Section 4.4.2 as it also affects primary-care prescriptions.

4.3.2.2. Barriers faced by long-term care facilities

Institutional / policy barriers

Lack of legislation on LTCFs; LTCFs not included in NAPs or AMR strategies. The limited legislation on LTCFs in most countries has a significant impact on the heterogeneity of structures, protocols, human resources, and knowledge of AMS measures between these organisations. Long-term care is fragmented, with a myriad of private and public providers, and overlapping competencies between public-health and social-service authorities. In the absence of mandatory requirements, LTCFs rely on management and staff willingness to implement AMS actions (Austria, Belgium, Czechia, Finland and France). In Slovakia, there is no specific reference to long-term care in the NAP and LTCFs are not included in the antibacterial resistance strategy. This means there is no legislation, policies, and/or programmes aimed at addressing antibacterial resistance in long-term care facilities.

Lack of or limited implementation of dedicated AMS programmes or operational plans for LTCFs. Across most countries, the situation in long-term care facilities is more uncertain than in hospitals due to the lack of or limited implementation of concrete programmes or plans aimed at addressing antibacterial resistance. The lack of LTCF representation in countries, which are developing and implementing NAPs on AMR, also exacerbates the lack of data and measures in the sector (Austria and France).

Lack of, or inadequate, monitoring mechanisms in LTCFs. Linked to the above challenges, some countries find it hard to track the progress and results of AMR measures in long-term care facilities (Estonia, France, Germany, Greece, Ireland, Italy, and Romania) due to a lack of auditing procedures. In Croatia, the only data available for LTCF clients outside of the health sector are the antibiotics prescriptions provided by family doctors. However, antibiotics which are paid out-of-pocket may only be visible in wholesalers' reports on consumed antibiotics but cannot be linked to the relevant LTCFs. In Ireland, the current surveillance system for antimicrobial use is collected for primary care and LTCFs together. This poses an important challenge to understanding trends in the care facilities, which hinders the development of effective measures.

Clinical barriers

Lack of specialised staff in LTCFs and off-site GPs. In many countries (Germany, Greece, Italy, Latvia, and Luxembourg) LTCF AMS-health professionals (infectious disease physicians, pharmacists, and microbiologists) as well as GPs (for example, Bulgaria, Denmark and Ireland) are usually based off-site. This means prescriptions can be carried out by professionals who are not directly employed by the facility. The lack of specific guidelines for LTCFs (Denmark, Ireland, Italy and Romania) and for physicians who work outside the LTCF may lead to discrepancies in the measures adopted or result in inconsistent approaches to the diagnosis and management of infections within the facilities.

Educational gaps between staff in LTCFs. There is variability in the educational background of staff employed in long-term care facilities, who are not well-trained in AMS measures. There is also high staff turnover and a sub-optimal ratio between staff and patients, which limits the time that health professionals in LTCFs can dedicate to AMS. This creates a challenging environment for implementing AMS measures, which are given less priority.

Shortages of GPs and GP Practice Nurses. In Ireland, there are GP shortages, which affect rural areas and private nursing homes. The situation is exacerbated by nurse shortages, which make it harder for GPs to leave their practice and attend nursing homes

or LTCFs.¹⁴⁷ Moreover, there is some reluctance among GPs to work in nursing homes because of already being overworked, which is linked to the lack of financial incentive for this work and the additional paperwork/form signing that is required.¹⁴⁸ The General Medical Services (GMS) contract does not cover the administrative work GPs are being asked to complete in nursing homes.¹⁴⁹

Behavioural barriers

Lack of effective communication in LTCFs. Linked to the lack of specific guidelines and specialised staff highlighted above, communication and teamwork in LTCFs were also considered challenging in some countries (Latvia, Slovakia, and Denmark). Problems include the maintenance of medical records, coordination of care services, collaboration with the GP and communication between staff, patients, and families during handover. In the survey, insufficient coordination or cooperation between care staff was a significant barrier for LTCFs, according to LTCF stakeholders (46%, n=12). There is also lack of coordination with external support services like clinical laboratories, pharmacies, and even GPs.

4.3.3. Possible measures to overcome the identified barriers

In this section, we present possible measures that the EU may support to overcome the identified barriers that emerged from the analysis of country reports.

To support Member States in developing and updating their national AMS policies:

- encourage Member States to include AMS programmes and goals in their One Health National Action Plans and/or their related national policies and strategies. This could be done by producing or compiling an EU toolkit for the development of AMS strategies and legislation at national level, including detailed descriptions of measures and practical examples. The toolkit could propose a harmonised list of indicators to support the monitoring of measures. Furthermore, the EU could support the creation of an online reporting system for monitoring AMS implementation at EU level, providing functional and technical specifications for integration to national information systems. The Commission could signpost to and provide guidance on available funding for the development and integration of these systems. A harmonised list of indicators to track progress on the effectiveness of AMS measures was proposed by 63% (n=25) of national/ regional authorities and 61% (n=52) of hospital and LTCF stakeholders. Moreover, establishing a mechanism for countries to report on the implementation and/or results of their AMS measures was proposed by 48% (n=19) of national/ regional authorities. In the interviews, stakeholders also suggested that NAPs include AMS programmes and goals for both hospitals and LTCFs, with defined roles and responsibilities.
- support Member States in prioritising AMS measures. AMS needs to be given higher political priority. The EU can support national governments in this effort by offering channels, resources and sharing best practices of good collaboration between governments, health authorities at national, regional and local levels, and healthcare facilities (hospitals and LTCFs). The EU could suggest the inclusion of clearer AMS requirements and targets for hospitals in all new NAPs and provide guidance on how to implement the AMS measures set out in the action plans. In addition, the EU could consider establishing an online platform for sharing ideas and experiences among

¹⁴⁷ Sage Advocacy. *Delivering Quality Medical Care in Irish Nursing Homes Current Practice, Issues and Challenges. A Discussion Document.* Sage Advocacy: Dublin; 2020. Available at: <u>https://www.sageadvocacy.ie/media/1679/6078-report-medical-care-in-nursing-homes-web2.pdf</u>. Last retrieved October 2022

¹⁴⁸ Ibid.

¹⁴⁹ Ibid.

Member States authorities in relation to the establishment of national AMS strategies, as well as exchange programmes for health authorities. The platform could hold purposefully developed Good Practice briefs in AMS to make them accessible to national health authorities and care professionals. Contact details of people responsible/implementing the identified good practices could be provided so that interested parties can get in touch and obtain further information.

facilitate collaboration and sharing of good practices among EU Member States. For example, by (i) encouraging a more active participation of national policymakers and health stakeholders in AMS-related projects and meetings; (ii) fostering the sharing of data and information between Member States, to enhance organised exchanges and learning processes; (iii) supporting the development of benchmarks for, for example, the recommended number of AMS professionals (nurses, doctors) per number of beds in hospitals and LTCFs (recommendations for benchmarks would be tailored to the specific contexts within which they are to be implemented); and (iv) promoting the development and dissemination of good practices in the area of AMS (for example, examples of good collaboration between clinical microbiologists and physicians in the diagnosis and prescription of antibiotics, or examples of measures and protocols to enhance functional cooperation between hospitals and collaborating laboratories).

To help Member States address structural barriers (e.g., lack of funding and skilled human resources):

- advise Member States on the possibility of using several sources of EU funding for addressing structural barriers affecting the implementation of AMS in hospitals and LTCFs. In the survey, co-funding for specific projects related to developing/implementing AMS measures was selected by 65% (n=26) of national/ regional authorities and 55% (n=47) of hospital and LTCF stakeholders. The areas that could benefit from EU funding according to the national level research relate to:
 - promoting e-prescriptions and health digitalisation through the set-up or update of IT infrastructures. In countries like Ireland, electronic prescribing and digital health records have helped hospitals to be more productive and effective in case finding, workflow auditing and optimisation of infection management;
 - supporting the development of common platforms for sharing data between hospitals and LTCFs; supporting the digitalisation and development of data systems to monitor antimicrobial use in hospitals and LTCFs;
 - improving diagnostics resources, with a view to limiting inappropriate prescribing; and
 - supporting activities of Member States aimed at strengthening AMS measures that

 (i) alleviate financial burdens on regional and local governments, and (ii) focus on
 care facilities that lag behind in the implementation of AMS measures, for instance,
 LTCFs and small hospitals.
- promote training and specialisation in AMS among health professionals, including medical and non-medical staff. The EU could support the development of national strategies for mainstreaming AMS in undergraduate and postgraduate education of health professionals (doctors, nurses, microbiologists, healthcare managers etc.). This could include curricular content covering AMS, tailored at different professionals, and the promotion of multi-disciplinary approaches. Supporting the training and specialisation in AMS for policymakers at national, regional and local level was also suggested. This initiative could include the development of toolkit(s) to support policymakers in the design, implementation and monitoring progress of AMS strategies and programmes (including detailed description of measures, examples, harmonised lists of indicators). Organising/promoting training activities on AMS measures was suggested by 55% (n=47) of hospitals and LTCFs stakeholders.

To further support Member States in the implementation of AMS measures:

- continue developing and promoting the ECDC's directory on Antimicrobial Stewardship.¹⁵⁰ (This measure applies to all sectors covered in this study: hospitals, LTCFs, primary care and pharmacies). This should be a user-friendly one-stop-shop or single repository of the latest guidelines and frameworks on AMS for all types of health and care facilities. The directory could also signpost to funding opportunities for AMS initiatives. Existing guidelines and frameworks on AMS and prudent use of antibiotics include: Commission Notice - EU Guidelines for the prudent use of antimicrobials in human health (2017/C 212/01) (European Commission, 2017); WHO's Antimicrobial stewardship programmes in health-care facilities in low- and middle-income countries. A WHO practical toolkit (WHO, 2019) and Antimicrobial stewardship interventions: a practical guide (WHO Regional Office for Europe, 2021) and others linked on ECDC's page. In a re-vamped directory, resources could also include national level guidelines and toolkits produced within the EU/EEA or internationally, for example, the TARGET toolkit (RCGP - UK)¹⁵¹ or NICE guidelines (UK)¹⁵². This could be complemented with the promotion and further development of the "Repository with guidelines, tools and implementation methods for antibiotic stewardship" put together by EU-JAMRAI, especially for primary care,¹⁵³ and the toolkit for raising awareness on AMR.¹⁵⁴
- establish a set of indicators for monitoring AMS in hospitals and LTCFs at EU level. This could help countries to set minimum standards to see their progress and benchmark themselves against others. The monitoring system could include measures in areas of antibiotic prescription where there is a limited penetration of AMS, namely emergency services, day hospitals and private healthcare units.

To enhance awareness of the importance of AMS measures to combat AMR in Europe:

• work closely with Member States to support specific awareness campaigns aimed at enhancing the importance of AMS. This includes (i) communication actions in medical universities, hospitals and LTCFs to promote AMS to health professionals with the aim of encouraging healthcare workers to pursue the training in AMS; (ii) support or further promote existing awareness campaigns such as those coordinated by the ECDC for the general public, health professionals or cross-sectoral stakeholders to raise awareness of the importance of a more prudent use of antibiotics and, in particular for prescribers, specific campaigns aimed at achieving better understanding of the importance and long-term impact of AMS measures; and (iii) communication initiatives targeted at policymakers and managers of health facilities financing health-related projects to increase awareness of the importance of putting the focus on AMS measures.

To support Member States in strengthening surveillance and research:

foster AMS research: produce studies or data showing the effectiveness of AMS interventions in hospitals and LTCFs and their contribution to improved clinical outcomes and on budgets. EU funding for research could also be allocated to supporting the development of (i) simple diagnostic tools; and (ii) new medications to counter the progression of multiple resistant microorganisms.

¹⁵⁰ See: <u>https://www.ecdc.europa.eu/en/publications-data/directory-guidance-prevention-and-control/prudent-use-antibiotics/antimicrobial</u>

¹⁵¹ See: <u>https://elearning.rcgp.org.uk/course/view.php?id=553</u>

¹⁵² See: <u>https://www.nice.org.uk/guidance/health-protection/communicable-diseases/antimicrobial-stewardship</u>

¹⁵³ See: <u>https://eu-jamrai.eu/repository-stewardship-human-health/</u>

¹⁵⁴ See: <u>https://eu-jamrai.eu/raising-awareness-on-amr-strategies-and-reports/</u>

4.3.4. Good practices

• Implementation and monitoring of the impact of AMS practices in hospitals:

- The National and regional antibiotic guidelines in the Netherlands have been published and monitored by the Dutch Working Party on Antibiotic Policy (SWAB). In addition to these national guidelines, regional antibiotic working groups have been developing regional guidelines on antibiotic prescriptions for hospitals in their regions. As an example, the regional workgroup of Drenthe and Groning (WAGD, *Werkgroep Antibioticabeleid Groningen en Drenthe*) has developed a regional antibiotic handbook that is accessible online. The regional guidelines are based on the national guidelines developed by the SWAB but are tailored to the feedback and clinical practice in the respective regional hospitals. Advantages of this approach include that patients are being treated similarly even if they are transferred to other hospitals within the region; the regional approach divides the work and makes it easier to ensure that the guidelines are up-to-date; and it facilitates knowledge sharing between hospitals.¹⁵⁵
- The University Hospital Olomouc in Czechia monitored the work of the hospital's antibiotic centre and presented the outcomes of the activity over a period of 10 years (2010-2019).¹⁵⁶ The data suggest low rates of bacterial resistance at the hospital, as a result of comprehensive antimicrobial stewardship measures implemented. The work of clinical microbiologists was particularly important, as they contributed to maintaining the effectiveness of antibiotics against bacterial pathogens. The team of microbiologists was tasked with approving the administration of antibiotics to patients with bacterial infections and directly participated in their antibiotic therapy.
- The General Hospital Koprivnica in Croatia implemented a cohort study to rationalise the use of last line antibiotics (intervention period of three months 2017). The study was designed to address the growing amount of antibiotics reserve consumption. It aimed to determine whether the implementation of a multidisciplinary approach led by an antimicrobial stewardship team (infectious disease specialist, clinical microbiologist and clinical pharmacist) would rationalise the use of last line antibiotics. The results of the study presented a reduction of duration of hospitalisation of patients in the intervention period by nearly 40% (from 28 to 17 days of hospitalisation on 100 patient-days) with unaffected rehospitalisations. Seminars and meetings were organised with other Croatian hospitals to showcase the results of the research.¹⁵⁷
- Antibiotic ward rounds led by infectious disease specialists who give advice on antibiotic treatment are standard practice in Swedish intensive care units, oncology, haematology, and other highly specialised units that cater for patients who are at high risk for complicated infections. AMS ward rounds have previously been successfully introduced in a Malmö hospital at internal medicine units, and proven efficient in reducing antibiotic use without any negative effect on patient outcomes or augmented healthcare costs. This type of intervention is now being promoted and is highly recommended for implementation nation-wide by the Swedish strategic programme against antibiotic resistance.

¹⁵⁵ de Jonge L. Kracht van regionaal afstemmen: Mensen vinden het vooral heel overzichtelijk. PW. 2022.

¹⁵⁶ Kolar, M.; Htoutou Sedlakova, M.; Urbanek, K.; Mlynarcik, P.; Roderova, M.; Hricova, K.; Mezerova, K.; Kucova, P.; Zapletalova, J.; Fiserova, K.; et al. Implementation of Antibiotic Stewardship in a University Hospital Setting. Antibiotics 2021, 10, 93. <u>https://doi.org/10.3390/antibiotics10010093</u>

¹⁵⁷ Kuruc Poje, D., Mađarić, V., Janeš Poje, V. et al. Antimicrobial stewardship effectiveness on rationalizing the use of last line of antibiotics in a short period with limited human resources: a single centre cohort study. BMC Res Notes 12, 531 (2019). https://doi.org/10.1186/s13104-019-4572-x

- The OptiCAP project in Denmark includes several interventions in selected hospital departments where attempts have been made to reduce unnecessarily long antibiotic treatment of patients with pneumonia. The intervention was supported with a newsletter (what works well and what can be optimised in the course of pneumonia) as well as a pocket card and leaflets about pneumonia for healthcare professionals (nurses and physicians) in the sampled hospitals.
- AMS support to health and care professionals:
 - In France, the Paris area has developed an AMS hotline available every night and on weekends to provide advice to doctors. Infectious disease specialists in Paris participate in this hotline regularly. This is well used and welcomed by the clinicians.
 - The **antibiotic prescription support programme (PAPA)**¹⁵⁸ in Portugal features the implementation of Local Units that act as local and continuous functional structures, ensuring the operationalisation of the PAPA in the healthcare facilities where the programme is implemented.
 - An ad-hoc repository of validated good practices is available in a repository managed by the National Agency for Regional Health Services (AGENAS) in Italy.¹⁵⁹ The best practices are based on constant observation and validation of protocols implemented at the Points of Care Testing (POCs) with strict evidence criteria. Nominations are collected via voluntary submission and through annual calls in priority areas (the call for 2022 was on medication without harm).
 - Local Strama (strategic programme against antibiotic resistance) groups and network meetings have been set-up in Sweden to support health professionals on treatment guideline adherence, prescription feedback, and other relevant AMS topics. In one example, a local Strama group holds three to four meetings with doctors per year. Some examples of topics discussed include diagnostics, treatment, and prevention of UTIs, skin and soft tissue infection (SSTIs) and respiratory tract infections (RTIs). A short documentary was produced in 2018 that explains this activity. The link can be found on Strama's website¹⁶⁰. This measure is also relevant for primary care.
 - The working group advising on antibiotic policy has been set up by the Region of Southern Denmark. This group is made up of infectious disease doctors, doctors from emergency departments and clinical microbiologists from all the region's hospitals. Currently physicians receive the same guidance and must use the same antibiotics.
 - In Ireland, the website <u>www.antibioticprescribing.ie</u> has a dedicated section of relevant resources for residential care facilities and nursing homes. It provides easy access to relevant resources, as all are in one place. Data on the percentage of residents on antibiotics is collected monthly in residential care facilities for older persons by the Health Service Executive since 2021. This helps to inform local and national quality improvement to optimise the use of antimicrobials in residential care facilities and to help reduce harm associated with antimicrobial use.
- Development of AMS guidelines and recommendations:
 - In Slovenia, the Small Red Guidebooks for prescribing of antibiotics in hospitals and primary care settings, published in 2002 and 2007 have been transferred to a

¹⁵⁸ PAPA aims at optimising antimicrobial therapy by avoiding unnecessary prescriptions, inappropriate prolongation, or unnecessarily extended ecological impact; using educational and behavioural methodologies, including feedback on metrics and indicators of antibiotic prescription; taking special care and attention to evaluate and validate all prescriptions of quinolones, carbapenems, ceftolozane/tazobactam, ceftazidime/avibactam, colistin, vancomycin, linezolid, daptomycin, and new antimicrobials in less than 72 hours.

¹⁵⁹ See: <u>https://buonepratiche.agenas.it/</u>

¹⁶⁰ See: https://strama.se/

computer application and also a mobile app, called Quiba. The usage of the app among prescribing physicians is still very low, but such an app could be integrated into the national e-prescribing solution that covers more than 99% of all outpatient medicines.

- The Children's University Hospital in Latvia developed recommendations for the use of antimicrobials in surgical prophylaxis with the aim of reducing the risks of surgical site infection. The practice defines a uniform approach in the hospital to the prevention of surgical site infection, including recommendations for preoperative antimicrobial prophylaxis. The 10 steps to uniform surgical site infection prophylaxis are developed and detailed, including recommendations for preoperative antimicrobial prophylaxis. The best practice example is posted on the website of the Centre for Disease Prevention and Control (CDPC) and is freely available for use in other hospitals.¹⁶¹
- The Pauls Stradiņš Clinical University Hospital in Latvia developed its own internal recommendations for the responsible use of antimicrobials¹⁶². The guidelines describe when antimicrobial therapy should be used, the principles of rational choice of agents, and the conditions that should be assessed before prescribing antibiotics. For the selection of an antimicrobial agent for a specific pathology, information is summarised in antimicrobial prescribing tables, which provide empirical choices of antimicrobial agents and their doses for specific pathologies.
- the Danish Region of Central Jutland developed and implemented prescription packages in hospitals. These compile the standardised operating procedures related to prescription to make it easier to follow the approved guidelines for the use of antibiotics.
- **Surveillance systems:** Svebar (Sweden) is a national surveillance system for cumulative antimicrobial susceptibility data in which 22 out of 26 clinical microbiology laboratories participate. The information collected covers around 90% of the Swedish population and allows for early detection and subsequent appropriate AMS efforts.
- Training on AMS: The antibiotic stewardship (ABS) training programme (Strukturierte curriculare Fortbildung Antibiotic Stewardship) was developed with initial support of the Ministry of Health and was implemented by the German Medical Association in 2017.¹⁶³ The curriculum includes four one-week training modules, with intensified training in pharmacology and microbiology, infectious disease practice guidelines, antibiotic policy, stewardship activities and quality management. Each participant must present the methods and results of a practical ABS project in his/her hospital and defend it in front of peers. After completion of the course, the participant is considered a certified ABS expert. Information on two other trainings on antibiotic stewardship in Germany is provided on the ECDC website: training courses on antibiotic stewardship in hospitals for doctors and pharmacists by the *Deutsche Gesellschaft für Infektiologie* (DGI) and an antibiotic stewardship course by the *Deutsche Gesellschaft für Krankenhaushygiene* (DGKH).¹⁶⁴

¹⁶¹ See: <u>https://www.spkc.gov.lv/lv/media/4147/download</u>

¹⁶² See: https://www.idready.lv/lv/antimikroba-terapija/atbildiga-antimikrobo-lidzeklu-lietosana

See:
 https://www.bundesaerztekammer.de/fileadmin/user_upload/_old-files/downloads/pdf

 Ordner/Fortbildung/Antibiotic_Stewardship.pdf

¹⁶⁴ See: <u>https://www.ecdc.europa.eu/en/publications-data/directory-guidance-prevention-and-control/training-antimicrobial-</u> stewardship

4.4. Antimicrobial stewardship measures in primary care and pharmacies

4.4.1. State of play

Primary care GPs/family physicians and community pharmacies are often the first point of contact with the healthcare system.^{165,166} GPs also function as the 'gate-keeper' of the system in many of the study countries, requiring referral for access to secondary and other care.^{167,168} These healthcare professionals have an important role in managing symptoms of infection, enhancing patients' knowledge of the adequate use of antibiotics, and shaping patients' behaviours.

The volume of antimicrobials prescribed in primary care is high compared to secondary care in most countries, accounting for up to 90% of total antimicrobial prescribing, for example in Denmark.¹⁶⁹ Factors that contribute to these high rates are social norms around health seeking; awareness of the primary healthcare workforce, public at large and patients about AMR and the role of preventative measures; the technological environment supporting providers and users of care (including electronic health records, apps, etc.) and data availability and use (surveillance, audit and feedback). According to the recent joint report from the WHO Regional Office for Europe and ECDC, most (22) of the EU/EEA countries are scored as having 'very good' or 'excellent' strategies for optimising antimicrobial use in human health.¹⁷⁰ Four countries (Italy, Latvia, Lithuania, Poland) are categorised as 'good', Romania is rated as 'fair' and Cyprus and Hungary as 'poor'. However, these assessments are largely based on secondary/hospital settings. Nevertheless, the report highlights the important role of community and primary care, especially in addressing *E. coli* community-acquired bloodstream infections and urinary tract infections, but also the role in improved management of post-surgical wounds.

In the survey conducted in the framework of this study, over half of national/ regional authorities and primary care stakeholders (53%, n=19 and 59%, n=39 respectively) reported that AMS guidelines/ legislation for primary care were developed at a national/ regional level. Several stakeholders believed that they were also developed at an organisational/ facility level (39%, n=14 and 25%, n=19 respectively). However, 39% (n=30) of primary care stakeholders indicated that they did not know at which level AMS guidelines/ legislation for primary care were developed in their countries.

¹⁶⁵ Kringos D, Boerma W, Bourgueil Y, Cartier T, Dedeu T, Hasvold T, Hutchinson A, Lember M, Oleszczyk M, Rotar Pavlic D, Svab I, Tedeschi P, Wilm S, Wilson A, Windak A, Van der Zee J, Groenewegen P. The strength of primary care in Europe: an international comparative study. Br J Gen Pract. 2013 Nov;63(616):e742-50, <u>https://pubmed.ncbi.nlm.nih.gov/24267857/</u>2013 Nov;63(616):e742-50, <u>https://pubmed.ncbi.nlm.nih.gov/24267857/</u>

¹⁶⁶ Pharmaceutical Group of the European Union (PGEU) (2019) PHARMACY 2030: A Vision for Community Pharmacy in Europe <u>https://www.pgeu.eu/wp-content/uploads/2019/04/Pharmacy-2030 -A-Vision-for-Community-Pharmacy-in-Europe.pdf</u>

¹⁶⁷ Reibling, Nadine & Wendt, Claus. (2012). Gatekeeping and provider choice in OECD healthcare systems. Current Sociology - CURR SOCIOL. 60. 489-505. https://www.researchgate.net/publication/241645682 Gatekeeping and provider choice in OECD healthcare systems

 ¹⁶⁸ Kringos et al. (2015) Building primary care in a changing Europe, Copenhagen: World Health Organization. Regional Office for

 for
 Europe,
 page
 120,

 https://www.euro.who.int/
 data/assets/pdf_file/0018/271170/BuildingPrimaryCareChangingEurope.pdf

¹⁶⁹ Summary DANMAP 2021 - Use of antimicrobial agents and occurrence of antimicrobial resistance in bacteria from food animals, food and humans in Denmark. ISBN 978-87-93565-81-4 <u>https://www.danmap.org/reports/2021</u>

¹⁷⁰ WHO Regional Office for Europe/European Centre for Disease Prevention and Control. Antimicrobial resistance surveillance in Europe 2022 – 2020 data. Copenhagen: WHO Regional Office for Europe; 2022. <u>https://www.ecdc.europa.eu/sites/default/files/documents/Joint-WHO-ECDC-AMR-report-2022.pdf</u>

In relation to community pharmacies, the underlying business model and extent to which these are involved in public health delivery varies widely across Europe, with a few countries moving towards formalised roles for such services.¹⁷¹

As per AMS guidelines/ legislation for pharmacies, over half of national/ regional authorities (53%, n=16) said in this study's survey that they did not know at which level these guidelines/ legislation were developed in their countries. A 37% (n=11) reported that these were developed at national/ regional level. Stakeholders representing pharmacies seemed also to be unsure regarding the origin of such guidelines, with 41% (n=25) saying they did not know at which level AMS guidelines/ legislation were developed. A 49% (n=30) reported that they were developed at a national level.

In terms of AMS measures currently in place at national/ regional level for primary care, national/ regional authorities, as well as by primary care stakeholders, agreed that there were national/ regional guidelines/recommendations on prudent antimicrobial use (75%, n=27 and 80%, n=35 respectively) and national/ regional campaigns on antibiotic awareness (69%, n=25 and 64%, n=28). For national/ regional authorities, there were also national/regional surveillance and feedback of antimicrobial prescription (69%, n=25) and for primary care stakeholders there were national/ regional programmes or legislations for AMS (61%, n=27).

As for pharmacies, national/ regional authorities, as well as pharmacies' stakeholders, thought that national/ regional campaigns on antibiotic awareness was the main measure in place (58%, n=21 and 74%, n=25 respectively). For pharmacies' stakeholders, there were also national/ regional guidelines on (prudent) antimicrobial use (68%, n=23) and national/ regional programmes or legislation for AMS (68%, n=23). Furthermore, over half of national/ regional authorities and pharmacies' stakeholders (53%, n=19 and 56%, n=19) found that national/ regional guidelines/legislation to tackle over-the-counter selling of antimicrobials were also in place.

Survey respondents were also asked which AMS measures were being implemented in the majority (over 50%) of primary care facilities and pharmacies. For national/ regional authorities, as well as primary care stakeholders, the main measure in primary care was the education/ training of prescribers, dispensers and/or health personnel involved in antibiotic use (45%, n=18 and 60%, n=40 respectively), followed by systems for developing and updating standardized medical records and medical charts to ensure that information on patient's medicine is all in one place, and systems for monitoring quantity and types of antibiotic use (purchased, prescribed and dispensed) (between 36% to 25% of respondents selected these measures). It is worth noting that over a third of national/ regional authorities (35%, n=14) did not know which AMS measures were being implemented by the majority of primary care practitioners.

As for pharmacies, the main measure identified by pharmacies' stakeholders was a system where pharmacies can only dispense antimicrobials with prescription, unless specific provisions or circumstances allow for regulated dispensation (69%, n=40). This was selected also by 42% (n=15) of national/ regional stakeholders. Pharmacies thought that there was also provision of advice to patients and health professionals regarding contraindications, drug interaction and food-drug interaction (67%, n=39). It is worth noting that 44% (n=16) of national/ regional authorities did not know about the measures currently implemented in pharmacies.

Across the study countries there is variability in quality of surveillance for community antimicrobial consumption and appropriate use of antibiotics, and in terms of opportunities

¹⁷¹ Mossialos, E., Courtin, E., Naci, H., Benrimoj, S., Bouvy, M., Farris, K., Noyce, P., Sketris, I.: From 'retailers' to health care providers: transforming the role of community pharmacists in chronic disease management. Health Policy **119**, 628–639 (2015)

for feedback and learning for primary care doctors. Examples of well-established surveillance systems at primary care level include Ireland, Denmark and the Netherlands. This comprehensive surveillance enables the setting of targets at the national and regional levels, for example, the reduction in the number of antibiotic prescriptions in the primary healthcare sector or to provide GPs with benchmarking information on how their prescribing behavior compares to that of other practitioners at regional and national levels. Audit and feedback methods which allow GPs to review their own practice within a network of GPs features in many of the successful country strategies. Some countries have additionally developed primary care specific prescribing guidelines, such as The Danish College of General Practitioners (DSAM) guidelines for Respiratory tract infections – diagnosis and treatment" (2014).

In community pharmacy, while most countries have legislation to prevent over the counter sales of antibiotics, enforcement of such legislation is noted to range from comprehensive and strong in countries including Denmark and Sweden, to weak implementation in Hungary, for example.

There are emergent models for AMS, but with inconsistent reach across primary care and community pharmacy. There are notable examples of good practice in terms of involvement and collaboration including the Strama model from Sweden,¹⁷² led by County Medical Officers for Communicable Diseases Control in every county and representatives from general practice and hospital (including general medicine, infectious diseases, paediatrics, otolaryngology, clinical microbiology, and infection control) and community pharmacies (please refer to sections 4.3.4 and 4.4.4 for further details on this AMS initiative). In Greece, a multifaceted campaign targeting primary care physicians, paediatricians, parents of children in kindergarten, and primary school, the general public, and dentists was produced in collaboration with the University of Athens.¹⁷³

As with other areas, some of the issues detected in developing and implementing AMS measures in primary care and pharmacies go beyond the specific problem of AMR. Countries' health sectors (and in many cases also the social services sector) suffer from organizational, legal, funding, staffing issues that affect them deeply. AMS is considered a 'nice to have' but it is not a priority.

4.4.2. Barriers to the development and implementation of AMS measures in primary care and pharmacies

In this section we present key cross-cutting findings in relation to the development and implementation of AMS measures in primary care and pharmacies across the 29 study countries. First barriers for primary care are presented, followed by those identified for pharmacies.

4.4.2.1. Barriers faced in primary care

Institutional / policy barriers

Omission of or limited references to primary care in NAPs and, at the same time, limited awareness of NAPs by primary care professionals. It is uncommon to find NAPs

¹⁷² Mölstad S, Löfmark S, Carlin K, Erntell M, Aspevall O, Blad L, Hanberger H, Hedin K, Hellman J, Norman C, Skoog G, Stålsby-Lundborg C, Tegmark Wisell K, Åhrén C, Cars O. Lessons learnt during 20 years of the Swedish strategic programme against antibiotic resistance. Bull World Health Organ. 2017 Nov 1;95(11):764-773. doi: 10.2471/BLT.16.184374. Epub 2017 Oct 3. PMID: 29147057; PMCID: PMC5677604.

¹⁷³ Plachouras D, Antoniadou A, Giannitsioti E, Galani L, Katsarolis I, Kavatha D, et al. Promoting prudent use of antibiotics: the experience from a multifaceted regional campaign in Greece. BMC Public Health. 2014; 14: 866. https://doi.org/10.1186/1471-2458-14-866 PMID: 25149626

that have explicit mentions to the role of primary care practitioners in AMS¹⁷⁴. Moreover, primary care practitioners arenot always aware of the existence of a NAP to combat AMR in their countriess (for example, Czechia). The lack of national or regional-level definitions and/or legal framework on AMS (for example, Bulgaria) hinders the development and implementation of AMS measures in primary care. Consequently, there is limited attention to AMS in the healthcare system.

Insufficient dedicated funding to develop and/or implement AMS measures in primary care (France, Slovenia, Lithuania, Romania, Portugal, Greece, Cyprus). In this study's survey, insufficient funding was identified as one of the main barrier affecting primary care according to national/ regional authorities (40%, n=16). This was highlighted as a barrier also by stakeholders in the country-level interviews.

Insufficient or inadequate monitoring or auditing of prescribing and dispensing practices by national/ regional authorities (Bulgaria, Slovenia, Slovakia, Finland, Portugal, Greece, Romania). The weak monitoring of prescribing and dispensing practices of primary care doctors and pharmacists derives in the lack of data and feedback to doctors and pharmacists on their prescribing/ dispensing behaviour (Austria, Bulgaria, Hungary, Romania, Greece). The limited digitalisation of healthcare, including the lack of electronic medical records and prescriptions, is a factor limiting the monitoring of prescribing and dispensing practices, as reported by some countries (Luxembourg, Malta¹⁷⁵, Portugal, Czechia).

Countries like Sweden and Belgium reported other data limitations. In Sweden, data on antibiotic prescription and sales from all pharmacies are published monthly, but do not contain information on patient diagnoses.¹⁷⁶ In Belgium, the National Institute for Health and Disability Insurance does not have full access to all data on dispensed antibiotics. Belgium has three databases covering the data on drug reimbursement, prescription, and dispensing. Data on reimbursement of drugs is stored in the Pharmanet, the database managed and maintained by healthcare insurance companies. About 89% of all antimicrobials that are sold by pharmaceuticals suppliers to pharmacies were reimbursed in Belgium in 2019. However, not all antimicrobial medicines are reimbursed, and some antimicrobials are sold without a prescription. The National Institute for Health and Disability relies on data from private operators (IQVIA) to estimate the total number of antimicrobials dispensed per year. The not-for-profit organisation Farmaflux collects antimicrobial prescription data (reimbursed and not reimbursed). The Farmaflux database is managed and maintained by pharmacies and is currently not accessible by the National Institute for Health and Disability.¹⁷⁷

Clinical barriers

Lack of primary care specific guidelines for management of infections and limited awareness of GPs of national and international guidelines on antimicrobials use. Where there is an absence of sectoral strategies or guidelines, there is heterogeneity on the application of the recommendations by healthcare professionals and institutions, especially when they are not of a compulsory nature nor are enforced (Bulgaria, Portugal,

¹⁷⁴ European Commission. Overview report Member States' One Health National Action Plans against Antimicrobial Resistance. 2022. Available from: https://health.ec.europa.eu/system/files/2022-11/amr_onehealth_naps_rep_en.pdf.

¹⁷⁵ In Malta, however, in terms of monitoring the use of antibiotics, the Maltese Antibiotic Stewardship Programme in the Community (MASPIC) has been implemented. It is an ongoing community surveillance system to collect data on antibiotic prescription associated with diagnosis among GPs.

¹⁷⁶ Mölstad S, Löfmark S, Carlin K, Erntell M, Aspevall O, Blad L, Hanberger H, Hedin K, Hellman J, Norman C, Skoog G, Stålsby-Lundborg C, Tegmark Wisell K, Åhrén C, Cars O. Lessons learnt during 20 years of the Swedish strategic programme against antibiotic resistance. Bull World Health Organ. 2017 Nov 1;95(11):764-773. doi: 10.2471/BLT.16.184374. Epub 2017 Oct 3. PMID: 29147057; PMCID: PMC5677604.

¹⁷⁷ Rekenhof. Beleid inzake het voorschrijven en afleveren van antibiotica. Brussels; 2022.

Croatia, Hungary, Romania, Slovakia). Problems related to limited awareness of guidelines include:

- Lack of awareness among community-based practitioners when it comes to prudent use of antibiotics and AMR (Austria, Netherlands, Portugal). If professionals are not aware that measures against it exist at national level, then they will also not be able to take the initiative to inform themselves about it.
- In some countries, there are lists of essential antibiotics which are regularly updated but it is unclear whether doctors are aware of these and consult them regularly; it depends on their interest and proactiveness in looking for the information (Czechia, Spain, Croatia).
- Where there are some treatment guidelines (for example, in Slovakia, the "Standards of preventive, diagnostic, and therapeutic procedures", developed by experts and available on the website of the Ministry of Health), these are not widely promoted among primary care doctors.
- In Bulgaria, except for a guideline on surgical prophylaxis that was developed in 2009, no other guidelines exist or are offered to doctors by medical unions or professional medical or microbiology societies. Physicians normally rely on their clinical experience or on information from the pharmaceutical industry.

Heavy reliance on clinical experience for antimicrobial treatment (empirical prescribing) in the case of limited (or complete absence of) evidence-informed diagnostic (testing). Prescribers at primary care level have limited access to diagnostics before prescription of antimicrobials (Bulgaria, Czechia, Denmark, Estonia, Greece, Hungary, Italy, Lithuania, Luxembourg, Malta, and Slovakia):

- In Italy, laboratory and point of care diagnostic technologies are only occasionally available and/or accessible to primary care prescribers (GPs and community paediatricians), despite a specific fund that was allocated for this by the Ministry of Health in 2019.
- In Slovakia, many procedures are influenced by insurance companies that decide on payments from public insurance. For example, until recently, the c-reactive protein (CRP) test was paid only for children and not adults, therefore the use of antibiotics in outpatient practice was prescribed without any laboratory examination. While it is possible to perform the examination, it is not very commonly done. Physicians are financially penalised by insurance companies for incurring higher costs of treatment and diagnosis. Treatment with antibiotics, even if incorrect, is cheaper than a correct diagnosis.
- In Estonia, the current legislation sets a limit to the amount spent in diagnostic testing by family care centres that can be covered by the Estonian Health Insurance Fund. In many cases, this results in physicians treating patients without proper diagnostics, especially in the case of respiratory infections.
- In Denmark, there are logistics and transportation challenges when it comes to ensuring that microbiological test results are available before reassessment of the diagnosis (within 48 hours). Faster diagnostics (such as point-of-care tests) should be encouraged where relevant and possible, although implementation depends on regional and local opportunities.
- In Lithuania, since the possibility of performing diagnostic tests is relatively new, there is no established practice among doctors, especially paediatricians, to use this possibility. They still rely on general experience and visually diagnose the disease, then prescribe general antibiotics. Therefore, more training, dissemination of information, and evidence would be needed to reach primary care specialists.

Human resources issues affecting AMS in primary care are multifaceted and often occur simultaneously. There is a shortage of infectious disease specialists and infection control physicians in primary/community care in various countries (Bulgaria, Slovenia, Portugal, Greece, and Cyprus). At the same time, education and training (for example, for the correct use of guidelines, where these exist) is often missing. Several countries reported limited AMS training in undergraduate and postgraduate medical education, and in continuous education and training (Bulgaria, Hungary, Romania, Portugal, Cyprus, and Sweden). In Belgium, a fragmentation of infectiology teaching over different subdisciplines and lack of mandatory continuous education on antibiotic prescribing and resistance was reported. In Spain and Portugal, there is no specific training for nurses working in primary health care centres about AMS and prudent use of antibiotics.

- Where doctors have insufficient knowledge (and experience) to identify viral and bacterial infections, they end up prescribing antibiotics (Croatia, Slovakia, Netherlands, Spain, and Greece). As an example, in Slovakia, although a bacterial agent as a cause of sore throat is rare, 60% of patients with sore throat are prescribed antibiotics. When tonsillitis is diagnosed, the prescription of antibiotics increases up to 80%¹⁷⁸. It is assumed that up to 50% of prescribed antibiotics are inappropriate or unfounded^{179,180}.
- Lower awareness of medical staff of existing AMS guidelines results in overprescribing of broad-spectrum antimicrobials (Slovenia, Slovakia).
- Physicians' time constraints result in limited attention to the latest clinical guidance on antimicrobials prescription, as well as impeding detailed discussions and the communication of key messages to patients during consultation (Hungary, Greece, and Estonia). Medical staff do not have sufficient time to explain and educate the patients about the recommended use of the antimicrobials (Slovenia, Czechia). In Sweden, a lack of time and resources for AMS teams, doctors, and nurses to work on AMR priorities in primary care was reported.
- Ageing doctors and specialists were mentioned as a constraint in some countries (Ireland, Czechia, and Romania). There is inertia in the treatment procedures of senior physicians. They are used to prescribing antibiotics, and they continue to do so despite new research findings. For example, in Czechia, 40% of GPs are over 60 years old¹⁸¹. In addition to more traditional prescribing practices, this is linked to higher risks of medical staff shortages due to retirement, which adds to general staff shortages (Sweden).

Payment systems for primary care physicians. Payment systems for doctors based on the number of patients seen can be a barrier to implementing antimicrobial stewardship programmes in primary and community care. This is because educating patients on self-limiting diseases and appropriate use of antibiotics may reduce the number of patients seen and therefore the income of doctors (Belgium).

Behavioural barriers

Limited interaction / communication between the different stakeholders involved in the implementation of AMS in primary care, including pharmacies and laboratories, in addition to complex system of competences between multiple authorities (Belgium,

¹⁷⁸ Foltán, V., 'Utilizácia antibiotík v Slovenskej republike', *Projekt ESAC*. 2013 https://www.health.gov.sk/?antibioticka-komisia Last accessed on 07 November 2022.

¹⁷⁹ Nikš, M., 'Klinická mikrobiológia a účelná antibiotická liečba v praxi*', Dni klinickej mikrobiológie. Nový Smokovec,* Vol. XXVII, No. 1-2, Slovenská spoločnosť klinickej mikrobiológie, Bratislava,2017.

¹⁸⁰ Nikš, M., 'Prehľady antibiotickej rezistencie- metodika, možnosti a výpovedná hodnota' Dni klinickej mikrobiológie. Správy klinickej mikrobiológie, Vol. XVII., Bratislava, 2017.

¹⁸¹ See: <u>https://cesky.radio.cz/ctyricet-procent-praktickych-lekaru-ma-pres-60-let-8109520</u>

Bulgaria, France, Hungary, Portugal, and the Netherlands). Communication and collaboration between primary care professionals is sometimes hindered by a perceived sense of interference with other professionals' decisions (Portugal). In the survey, insufficient coordination/ cooperation between health professionals was a barrier selected by all groups of stakeholders (national/ regional authorities, primary care and pharmacy stakeholders) as affecting both primary care and pharmacies (between 57% to 26% of respondents selected this barrier).

Low levels of awareness and health literacy associated with antibiotic use and antimicrobial resistance among the public. The limited public awareness and understanding of adequate antimicrobials use results in counterproductive beliefs and behaviours. The 2022 Eurobarometer showed that across the EU, half (50%) of respondents correctly indicated that the statement that antibiotics kill viruses was false; however, 39% still incorrectly thought that antibiotics killed viruses.¹⁸² Also, while 85% of respondents correctly said that antibiotic treatment should only be stopped when all of the antibiotics have been taken as directed, 13% incorrectly thought that they should stop taking antibiotics when they felt better. Although the proportion of respondents providing the correct answer to these and other questions on knowledge of antibiotics has increased since 2018 (for responses to these questions across Member States, see Annex 3), the Eurobarometer survey results showed there is still room for improvement in terms of raising awareness and understanding of the adequate use of antibiotics. Indeed, this study's research found that in a high number of countries (Austria, Belgium, Croatia Cyprus, Czechia, Hungary, Italy, Lithuania, Netherlands, Portugal, Romania, Slovakia, Slovenia, and Spain) there is high patient pressure and demand for antibiotics due to a lack of knowledge, awareness or health literacy associated with antibiotic use. In this study's survey, patients' high demand for antimicrobials, as well as patients' inadequate use of antimicrobials, were considered important barriers by over half of primary care and pharmacy stakeholders (between 56% to 46% of respondents selected these barriers).

Fear of leaving patients untreated and developing infectious complications. This study found that in several countries physicians may still prescribe antibiotics if the diagnosis is uncertain to avoid leaving the patient untreated. Some doctors (and patients) believe that over-using antibiotics is safer than limiting their use (Belgium, Hungary, and Malta). Moreover, third generation of cephalosporin is commonly prescribed "just in case" for common infections or even to treat COVID-19 (Slovakia). GPs are often primarily concerned with their patients' direct clinical outcomes, meaning that the risk of antibiotic resistance is a factor less likely to influence their treatment decisions (Hungary). Misuse and overuse of antibiotics is also an issue in Latvia and Malta, even though, in the latter, an increasing adherence to guidelines has been reported. Broad-spectrum antibiotics are still prescribed to accommodate patients' demands. In some countries, there is also a tendency by dentists to over-prescribe antibiotics (Belgium, Norway, and France). On the latter, studies point out that general dental practitioners account for up to 10% of all antibiotic prescriptions in European outpatient care, and that up to 80% of antibiotic prescriptions might be inappropriate in acute dental conditions as local operative procedures are predominantly sufficient.183

Patients' low adherence to treatment. Not all patients adhere to their antibiotic treatment as indicated in the physician's prescription. For example, in Romania, about 30% of the population taking antibiotics interrupt treatment when symptoms improve.¹⁸⁴ The Czech

¹⁸² Special Eurobarometer 522 - Antimicrobial Resistance: <u>https://europa.eu/eurobarometer/surveys/detail/2632</u>

¹⁸³ Böhmer F, Hornung A, Burmeister U, Köchling A, Altiner A, Lang H, Löffler C. Factors, Perceptions and Beliefs Associated with Inappropriate Antibiotic Prescribing in German Primary Dental Care: A Qualitative Study. Antibiotics (Basel). 2021 Aug 16;10(8):987. doi: 10.3390/antibiotics10080987. PMID: 34439037; PMCID: PMC8389002.

¹⁸⁴ Pogurschi, E.N.; Petcu, C.D.; Mizeranschi, A.E.; Zugravu, C.A.; Cirnatu, D.; Pet, I.; Ghimpeţeanu, O.-M. Knowledge, Attitudes and Practices Regarding Antibiotic Use and Antibiotic Resistance: A Latent Class Analysis of a Romanian Population. Int. J. Environ. Res. Public Health 2022, 19, 7263. https://doi.org/10.3390/ijerph19127263

Chamber of Pharmacy has found in a survey¹⁸⁵ it has conducted for nine years that more than 11% of adults do not take antibiotics for the prescribed period of time, but only until symptoms disappear, leading to some resistant bacteria and the patient having to be treated again. In addition, almost 10% of adults save unused antibiotics for later use, usually for an inappropriate condition, dosage, and treatment length. According to a poll in Greece,¹⁸⁶ 30% of the country's citizens keep antibiotics at home for emergencies. In Latvia, interviewees noted that some patients like to stock antibiotics at home. At EU level, 2% of respondents to the 2022 Eurobarometer survey indicated that they used antibiotics left over from previous treatments.¹⁸⁷

Promotional actions and persuasive activities targeting prescribers by pharmaceutical companies. In the EU, consumer advertising of prescription drugs, including antibiotics, is forbidden.¹⁸⁸ However, promotional actions targeting prescribers are legal and a very common practice in several countries (Bulgaria, Hungary, Croatia, and Czechia).

4.4.2.2. Barriers faced in pharmacies

Institutional / policy barriers

Limited or absence of explicit mention of community pharmacy in NAPs. As with primary care, in some countries the omission of the pharmaceutical sector in the NAPs was considered a missed opportunity, as well as a vacuum in terms of pharmacies' accountability in relation to AMS (Czechia, Croatia, Estonia, Latvia, and Slovakia). Equally, the lack or limited involvement of pharmacies in the development of the NAP and other AMS national measures has meant that the role and responsibilities in terms of AMS are unclear to community pharmacies (Bulgaria, Lithuania). In this study's survey, limited attention to AMS was considered a barrier by pharmacy stakeholders (29%, n=10). The lack of national/ regional definitions and/or legal frameworks for AMS measures in relation to pharmacies was also pointed out as a barrier by over half of pharmacy stakeholders (52%, n=29).

No pharmacy policy or strategy around medicines use or optimisation. For example, in Ireland, the pharmacy system is poorly managed and organised with no Chief of Pharmacy appointed and a general lack of recognition of the profession and role.¹⁸⁹ This makes it difficult to support pharmacists and pharmacy development.

Market-related barriers

Shortages and outages of narrow-spectrum antibiotics. While penicillin remains an effective treatment for certain bacterial infections, especially in paediatric practice, and reduces the risk of resistance, there has been a shortage and break in supplies across many European countries since the end of 2022.¹⁹⁰ For instance, in Latvia, drug manufacturers and wholesalers lack incentives to distribute penicilin in the Latvian market due to its low price. In Finland, stakeholders mentioned that narrow-spectrum antibiotics are expensive and difficult to obtain. Their shortage may drive use of broad-spectrum antibiotics, which has negative implications for resistance and is more costly in the long run. Similarly, in Estonia, only a small number of narrow-spectrum antibiotics are available, mostly because of the relatively small market. This is likely to explain the increasing trend

¹⁸⁵ See: <u>https://www.lekarnici.cz/Media/Tiskove-zpravy/Antibiotika-patri-temer-100-let-k-nejzasadnejsim-l.aspx</u>

¹⁸⁶ See: <u>https://www.insider.gr/ygeia/200370/koronoios-33-ton-asthenon-pethainoyn-apo-endonosokomeiaki-loimoxi-armageddon-i-antohi</u>

¹⁸⁷ Special Eurobarometer 522 Antimicrobial Resistance: <u>https://europa.eu/eurobarometer/surveys/detail/2632</u>

¹⁸⁸ Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use; <u>https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=celex%3A32001L0083</u>

¹⁸⁹ See: <u>https://www.irishhealthpro.com/content/articles/show/name/appointment-of-chief-pharmacy-officer-urged</u>

¹⁹⁰ See: <u>https://www.ema.europa.eu/en/news/ema-update-shortages-antibiotics-eu</u>

in consumption of broad-spectrum antibiotics registered in the last years. In Belgium, there are difficulties in accessing the right antibiotic due to shortages or changes in formulation.

In Denmark, the shortage of certain drugs has created barriers in the achievement of national targets. This was an issue in 2017 when shortages of piperacillin/tazobactam formulations meant cephalosporins became necessary as a first line treatment in septic patients in hospitals (in turn hindering achievement of the third goal in the human healthcare national plan). Although no problems were recorded in 2018 or 2019, projections showed expected issues for different formulations of beta-lactams in years to come. This is problematic as these are essential to comply with the national targets for the use of narrow-spectrum molecules. For some small countries, like Iceland, there is limited access to quality medicines. Furthermore, pharmacies do not inform outpatient specialists about shortage or outage in the production of some antibiotics. In those cases, the pharmacy issues a replacement antibiotic without consulting the physician, which can disrupt the AMS monitored by the doctor (Czechia).

Pricing of antimicrobials does not limit access to or prevent excessive consumption of antibiotics. Antibiotics, including broad-spectrum antibiotics, are widely available and not very expensive (Bulgaria, Slovakia, and Spain). In Slovakia, with the entry of new generics into the market, prices of antibiotics have decreased significantly. The low purchase price of antibiotics leads to their increased use. Their price is negligible compared to the price of laboratory tests, so they are prescribed without confirming whether they are needed.

Over-packaging of antibiotics in the market. Linked to the above, antibiotics are often dispensed in larger numbers/amounts than required for the whole treatment course, resulting in self- or over-medication, storage of antibiotics at home, and/or incorrect disposal of antibiotics (Malta, Greece, Belgium, Denmark, and Italy). The over-packaging of antibiotics in the Belgian market is considered a significant barrier to effective AMS in pharmacies. When antibiotics are packaged in large boxes, it becomes difficult for pharmacists to dispense the exact number of tablets needed for a single treatment. As a result, patients often have a leftover of antibiotics at home, which increases the risk of self-medication. In Denmark, pharmacists have the obligation to hand over the cheapest antibiotics if requested by the patient. Although this is a positive measure in many aspects, it may work against AMS as it can result in handing over larger packages than might be needed, resulting in an excess of pills. Furthermore, leftover antibiotics can also pollute the environment if not disposed of properly. Solutions proposed in Denmark include opening the packages and handing over the exact number of pills needed. However, the Danish pharmacists' association has resisted adopting this solution.

Clinical barriers

Limited/ lack of clarity on the role of pharmacies in combating AMR, and lack of clinical guidelines. In some countries (Bulgaria, Austria, Lithuania, and Romania), pharmacies do not sufficiently recognise AMR as a public health challenge due to insufficient education and awareness on AMR. Also, in these countries, pharmacists do not perceive that they have easy access to guidelines and/or information materials that give advice on the prudent use of antibiotics. In other countries (for example, Slovenia), pharmacies lack incentives to go beyond their dispensing role and have no authority in the matter except for generic substitution. In addition, the lack of integration of pharmacies to the health system has led to difficult interactions between doctors and pharmacists, for example, to assist where there are prescription errors (Portugal), ask patients about the doctors' diagnosis to check that the indication is correct or to provide information to patients (Czechia). Pharmacies are unaware of ways in which they can contribute to an adequate administration of antibiotics.

Lack of training among community pharmacists on AMR. Linked to the above, the topic of AMR is only covered in seminars dedicated to those who aim to become hospital pharmacists, but not for pharmacists in the community (Austria). In Estonia, The current pharmacist education is purely pharmacological, and training abroad is required to graduate as a clinical pharmacist. Therefore, there are very few clinical pharmacists who could participate in multi-disciplinary AMS.

Behavioural barriers

Dispensation of antibiotics without a prescription is common in some study countries.¹⁹¹ For example, in Cyprus there are no regulations in place requiring a prescription for the sale of antibiotics for human use¹⁹². This is also a common practice in Bulgaria, Italy (rural areas), Romania, and Greece. This is due to either lack of regulations on the matter or insufficient enforcement and control by authorities. According to a recent poll in Greece,¹⁹³ despite the mandatory need for a prescription of antibiotics, only 65% of antibiotics are prescribed by doctors and 15% of citizens get an antibiotic in the pharmacy without a prescription and then go to the doctor demanding a prescription in order to be reimbursed. In Spain, the QR code of the electronic prescription only informs if the prescription is active or not. It does not record whether the prescription has been dispensed or not and, thus, it does not prevent the possibility of drug dispensation in several pharmacies. According to data from the study carried out by the Spanish Agency for Medicines and Health Products (AEMPS) and the Spanish Society of Family and Community Pharmacy (SEFAC), one in three prescriptions for antibiotics from private physicians demanded in pharmacies does not comply with the current regulations. Moreover, of 5,577 antibiotic requests, 65% (3,569) were private sector prescriptions (of which a third were not compliant), 20% (1,172) were self-medication and 15% (833) were from prescriptions that did not comply with what is established in the official prescription.¹⁹⁴ In the 2022 Eurobarometer, while the vast majority of respondents (92%) indicated having obtained their most recent course of antibiotics from a medical practitioner, 8% responded that they obtained the antibiotics from elswhere, and 4% said they obtained antibiotics without a prescription from a pharmacy (see Annex 3).

4.4.3. Possible measures to overcome the identified barriers

In this section we present possible measures to overcome the identified barriers that emerged from the analysis of country reports.

To support Member States in the effective monitoring of antimicrobials prescriptions and consumption in primary care:

 support the adoption or enhancement of auditing and feedback mechanisms on the prescription of antimicrobials by primary care doctors. Systematic and regular control and feedback to doctors on prescribing trends, with commentary and recommendations, should be promoted by Member States. Auditing and feedback processes should not translate into additional administrative burden for doctors. Such initiatives could be supported by EU funding and/or guidelines for the adoption of eprescriptions, especially when antimicrobials are prescribed. For instance:

¹⁹¹ See: <u>https://www.who.int/europe/news/item/21-11-2022-1-in-3-use-antibiotics-without-prescription--who-europe-s-study-</u> <u>shows</u>

¹⁹² See: 2021 Global Health Security Index: <u>https://www.ghsindex.org/</u>

¹⁹³ See: <u>https://www.insider.gr/ygeia/200370/koronoios-33-ton-asthenon-pethainoyn-apo-endonosokomeiaki-loimoxi-armageddon-i-antohi</u>

¹⁹⁴ See: <u>https://www.aemps.gob.es/informa/notasinformativas/laaemps/2018/ni-aemps_8-2018-sefac/</u>

- There could be guidance providing functional and technical specifications for integration of information systems for electronic prescribing to facilitate monitoring of prescription and dispensing practices.
- There could be guidance or recommendation on how systems for electronic prescribing may incorporate accurate documentation by the doctor of the rational decision criteria to prescribe an antimicrobial therapy.
- A reporting or monitoring system for the prescribing and dispensing data could be developed at EU level, including harmonised criteria or a list of indicators to monitor antimicrobial consumption in primary care. The system could include benchmarking tools between Member States, with regular publication of data and sharing of the best practices and examples.

To support Member States in strengthening AMS in primary care and pharmacies:

• recommend, provide guidance, and monitor that One Health NAPs, and/or their related national policies and strategies, include AMS programmes and goals for primary care and pharmacies, with roles and responsibilities defined. This could include providing recommendations and practical advice on the inclusion of primary care professionals and pharmacists in the development and implementation of AMS measures and the NAPs. In addition, taking forward the EU-JAMRAI recommendations for the EU to make further efforts on developing core elements for AMS programmes implementable at national and facility levels, specific aspects for primary care and pharmacies should be included in the core elements.¹⁹⁵ This could be accompanied by a multi-country implementation strategy with well-established objectives and monitoring targets defined by Member States to achieve sustainable changes in AMS practices.

• promote existing AMS guidelines, and support the creation of new ones:

- Further promote the use of existing guidelines and frameworks on prudent use of antibiotics. See Section 4.3.3 for details.
- Produce guidelines on cooperative approaches across primary care, pharmacies, and microbiology laboratories to implement a more integrated approach to AMS at community level.
- Develop more tools and guidelines that can be used by community pharmacists to provide adequate advice on AMR and infection prevention to the population by assessing what their challenges and needs are.
- support Member States in exploring ways to leverage quality prescribing through reimbursement models for healthcare providers (social insurance and private insurance) which could function as incentives. There are similar examples in other high income country contexts such as North America.¹⁹⁶

<u>To help Member States in addressing structural barriers (e.g., lack of funding and skilled human resources):</u>

 advise Member States on the possibility of using several sources of EU funding for addressing structural barriers affecting the implementation of AMS in primary care and pharmacies. This is relevant especially in relation to education and training of healthcare/ pharmacy staff; setting up or updating IT infrastructures in relation to e-prescriptions and monitoring systems for AMR prescribing and dispensing. Specific lines of funding could be made available for

¹⁹⁵ See: <u>https://eu-jamrai.eu/wp-content/uploads/2021/09/EUjamrai_D2.2_LaymanReport_WP2_AEMPS_09.2021.pdf</u>

¹⁹⁶ For example: <u>CMS Final Rule on Antibiotic Stewardship Programs (asm.org)</u>

investments and roll out of point-of-care diagnostics and technologically enhanced virtual review (especially relevant in real-time innovations (RTIs)).

- (co-)develop training modules/ materials and support (through funding, voluntary country visits, twinnings, or promotion) for the improvement of the training of primary care health professionals and pharmacists on AMS. For example, the EU could do the following:
 - Develop or incorporate into an existing online platform or directory (for example, in the ECDC's) information on training activities available at the EU-level (such as the BTSF) or in Member States, and training materials for healthcare workers, including forums and peer-exchange chat rooms which will serve as a knowledge base on AMS and enable communication on the topic.
 - Promote educational exchange programmes for doctors, nurses and pharmacists. Programmes can also be conducted online.
 - Endorse a certification programme at EU level on excellent AMS implementation in primary care. This could provide a positive incentive for improvement of community care doctors' AMS practice.
 - Promote the training of pharmacists and pharmacy staff in the provision of medicines counselling in pharmacies.

To support Member States in raising awareness and understanding of AMS among the public:

- support Member States (through the provision of technical support and/or guidance, or developing a "model campaign" with materials, templates, etc.) to reinforce communication campaigns to improve awareness and health literacy of citizens. Campaigns may involve the following:
 - Using the capacity and knowledge of pharmacists in increasing the population's literacy regarding the prevention of infections, the correct use of antimicrobials and AMR awareness. This would also give a role to pharmacists in the fight against AMR.
 - Providing information to patients in primary care on the use of antimicrobial substances with a special focus on children and their parents. This could help to reduce patients' pressure on doctors to be prescribed with antibiotics.

The following could help Member States and healthcare professionals in exchanging good practices and learning from each other:

- Exchange of good practices in establishing processes for auditing prescriptions, including mechanisms by which the results of the audit are fed back to the audited doctors in an appropriate way and with qualified commentary/recommendations.
- Exchange of good practices in increasing the use of laboratory testing and the use of point-of-care diagnostic tests by primary care providers, especially for respiratory tract infections such as strep throat tests. Rapid diagnostic tools can potentially lower unnecessary antibiotic prescriptions. Member States should be encouraged to provide incentives for better diagnostics in primary care. This may be complemented with mapping microbiology laboratories and microbiologists that can provide testing services and expert advice to primary care professionals at EU level.
- **Promote the development of networks of pharmacists** (such as PAMS-Net in Ireland; see Section 4.4.4) where pharmacists can liaise with colleagues and get involved, as well as raise awareness on AMS.
- Improve cooperation and knowledge exchange between community pharmacists and hospitals/hospital pharmacists.

To support Member States in strengthening monitoring of prescribing and dispensing practices and research on AMS:

- Establish a set of indicators, guidance, and recommendation for monitoring of antimicrobials prescribing and dispensing at EU level with the increased use of eprescriptions. This could help countries to see their progress and benchmark themselves against others.
- Foster AMS research. Produce studies or data showing the impact of effective AMS strategies and measures on prudent use of antibiotics. Evaluate interventions through natural experiments if RCTs are not feasible to capture the impact of effective AMS strategies and measures on prudent use of antibiotics. This is important to change beliefs and behaviours and increase adherence and promotion of measures by professionals and patients, share and scale up effective interventions, and quantify return on investments into interventions.
- Support research and development of new/rapid diagnostic tests and alternative treatments to antibiotics. This would help to reduce diagnostic uncertainty and ensure that patients receive appropriate treatments, while reducing the overuse of antibiotics.

To support Member States overcoming market barriers affecting access to medicinal products, mostly in community pharmacies (but also at hospital level):

- Recommend authorisation for pharmacists to alter the packaging. Pharmacists should be authorised to dispense only the prescribed amount of antimicrobials. This would help reduce the over-packaging of antibiotics, which is a significant barrier to effective AMS in pharmacies, and reduce issues of incorrect disposal or misuse of leftovers.
- Work with the European Medicines Agency to understand the value of biosimilar agents in the long term to mitigate drug outages and shortages, especially on the production of "old", narrow-spectrum antibiotics. In addition, the European Commission and the EMA could work with the biosimilar industry in the production of packaging that contains a smaller amount of antimicrobials or that can be easily and safely altered by the pharmacists to dispense only the amount prescribed by the doctor.
- Develop together with Member States a list of antimicrobials that should be stocked in public pharmacies. Moreover, the pharmaceutical price support system for antimicrobials should be regularly adjusted, with a relative increase in price support for narrow-spectrum antimicrobials.

4.4.4. Good practices

- Monitoring of antibiotics prescription and dispensation:
 - In Denmark, pharmacists are obliged to register all the medications that they sell and are monitored if the sales exceed the expectations. Similarly, all pharmacies in Sweden are obliged to provide the Swedish eHealth Agency with daily statistics on their sales of medicinal products, including of antibiotics.

Also, since 1994, information on all prescription drugs sold in Denmark has been recorded in the **Register of Medicinal Products Statistics (RMPS)**, maintained by the Danish Medicines Agency. RMPS provides individual-level information on dispensed prescriptions for the entire nation. The tracking of individual prescription histories over time is made feasible by a unique personal identification number assigned to all residents. Extracts of individual-level registers are maintained or administered by Statistics Denmark, including the Danish National Patient Registry that contains information on all prescription drugs dispensed at Danish community

pharmacies as well as individual-level information on prescriptions dispensed to residents of long-term care institutions, such as nursing homes.

In addition, a national tool -**Ordiprax**- has been developed to allow Danish physicians to have an electronic overview of their prescribing practices and antibiotic prescriptions, as well as the ability to compare them with those of other physicians. This can help prevent the over prescription of antibiotics, as well as providing a way to monitor and control if any given physician has a higher-than-expected level of prescriptions. This system also organises GPs in clusters, where they can meet, discuss, and try to inspire each other. This tool is in the process of being replaced by an improved IT system that could be used for quality development, to track and display treatment quality, as well as percentage of antibiotic prescriptions (such as penicillin V) and other national initiatives.

- In Ireland, the national surveillance for community antimicrobial consumption has been in place since 2003. Data is based on pharmacy wholesale data, rather than on individual prescriptions, and cover 95% of community antimicrobial consumption in the country. Data is collected and published bi-annually on the Health Protection Surveillance Centre's website. This dataset allows monitoring of local trends over time and draws comparisons of local with national data so acute hospitals can assess the impact of local AMS programmes and identify targets for future interventions. It also allows comparisons with European antimicrobial consumption data.
- The national IT capability ('*Primärvårdskvalitet*') in Sweden supports AMS in primary care. This infrastructure extracts data from patients' electronic medical records for the close monitoring of antibiotic prescribing and dispensing, as well as antibiotic resistance, in primary care nationwide. The IT system also extracts data on diagnoses and laboratory results linked with antibiotic prescription data. Prescription data are also available in primary care and widely accessible. At the moment 1,049 healthcare centres (87%) and 287 rehabilitation units have access to their own data in Sweden.
- o The National Prescribed Drug Register ('Läkemedelsregisret'), established in 2005, provides a foundation for official statistics about prescribed drugs in Sweden. Using personal identification numbers, it contains all prescribed drugs dispensed at pharmacies. Since the medication dispensing system is completely digitalised and highly regulated, over-the-counter antibiotic dispensing does not occur. All medications for outpatient use are electronically prescribed, both from hospitals and primary care, and are linked to the National Prescribed Drug Registry. Prescribers can access prescriptions by other prescribers with the patient's consent. Patients can also access all their prescribed medications online.
- In the Netherlands, the SABEL project (Reflective Information Antibiotics First Line, Spiegelinformatie Antibotica Eerstelijn) was coordinated by the Utrecht University Medical Center (UMC Utrecht) and the Radboud University Medical Center (Radboud UMC) in collaboration with the two respective regional antibiotic networks and the National Institute for Public Health and the Environment.¹⁹⁷ The main aim of the SABEL project was to provide general practitioners with benchmarking information on how their prescribing behaviour compares with the prescribing behaviour of fellow general practitioners at a regional and national level. As of July 2021, about 200 general practitioners were participating with the SABEL project. The evaluation at the end of 2019 showed that the project was very

¹⁹⁷ Rijksinstituut voor Volksgezondheid en het Milieu (RIVM), Julius Centrum Universitair Medisch Centrum Utrecht (UMCU). Draaiboek juist gebruik antibiotica projecten eerstelijn: Werkdocument. 2020.

well received by the participating general practitioners and that the project provided them with tools to apply in their own practice.

- New ways of collaborative working on AMS, peer education and collaboration:
 - As mentioned in Section 4.4.1, the Strama model from Sweden is led by County Medical Officers for Communicable Diseases Control in every county. It started as a voluntary network of government authorities and professional organisations and with the formation of multi-professional groups in local administrative areas. Since 2012, an intersectoral coordinating mechanism, consisting of 25 agencies and organisations within the public health, animal health, food, and the environmental sectors, is in place. The local groups typically include physicians and other primary care providers, and infectious diseases, paediatrics, ear nose and throat, and clinical microbiology specialists, infection control units and pharmacists.¹⁹⁸ Strama provides a platform at both national and local level for gathering stakeholders, knowledge exchange, for identifying needs, and for implementing treatment guidelines and other policies.¹⁹⁹ The Swedish Strama system has been taken up in Iceland as it is seen as a good system to guide prudent use of antimicrobials in primary healthcare services.²⁰⁰
 - In Belgium, organising local quality circles (groupe local d'évaluation médicale -Glem)²⁰¹ to discuss and improve antibiotic prescribing behaviour allows healthcare professionals to learn from one another and identify areas for improvement in their prescribing practices.²⁰² A Glem is a group of peers, doctors or pharmacist biologists, who share and critically evaluate their medical practices (peer review) to promote the quality of care. Glems must be composed of a minimum of eight accredited or accreditable doctors and a maximum of 25 doctors (except for clinical biology Glems where the term doctors is extended to pharmacist-biologists).
 - In 2014, while implementing a new model of contracting, the Croatian Health Insurance Fund decided to finance **peer review meetings** where healthcare professionals educate each other. Some of the professional groups invited to these peer meetings included primary care doctors, clinicians from hospitals, pharmacists and clinical pharmacologists. In the meetings, all of them discussed prescribing of antibiotics, to try and harmonise their practices based on the best experience, new information and knowledge gained.
 - In Ireland, a Pharmacist Antimicrobial Stewardship Network (PAMS-net) was launched in August 2022. It is a network of pharmacists from across all settings²⁰³ that aims to support pharmacists to work towards the common goal of promoting responsible use of antimicrobials in all patients and limiting the emergence of AMR. The network is the result of collaboration between the HSE Antimicrobial

¹⁹⁸ Mölstad S, Löfmark S, Carlin K, Erntell M, Aspevall O, Blad L, Hanberger H, Hedin K, Hellman J, Norman C, Skoog G, Stålsby-Lundborg C, Tegmark Wisell K, Åhrén C, Cars O. Lessons learnt during 20 years of the Swedish strategic programme against antibiotic resistance. Bull World Health Organ. 2017 Nov 1;95(11):764-773. doi: 10.2471/BLT.16.184374. Epub 2017 Oct 3. PMID: 29147057; PMCID: PMC5677604.

¹⁹⁹ See: <u>https://www.reactgroup.org/toolbox/policy/examples-from-the-field/strama-swedish-model-for-work-against-antibiotic-resistance/</u>

²⁰⁰ Mölstad, S., Löfmark, S., Carlin, K., Erntell, M., Aspevall, O., Blad, L., Hanberger, H., Hedin, K., Hellman, J., Norman, C., Skoog, G., Stålsby-Lundborg, C., Tegmark Wisell, K., Åhrén, C., & Cars, O. (2017). Lessons learnt during 20 years of the Swedish strategic programme against antibiotic resistance. Bulletin of the World Health Organization, 95(11), 764–773. https://doi.org/10.2471/BLT.16.184374

²⁰¹ See: <u>https://www.inami.fgov.be/fr/professionnels/sante/medecins/qualite/accreditation/Pages/medecins-accreditation-glem-index.aspx</u>

²⁰² van Driel ML, Coenen S, Dirven K, et al. What is the role of quality circles in strategies to optimise antibiotic prescribing? A pragmatic cluster-randomised controlled trial in primary care. BMJ Quality & Safety 2007;16:197-202.

²⁰³ This includes community, hospital, education, researchers, Outpatient Parenteral Antimicrobial Therapy (OPAT) services, other HSE and national bodies.

Resistance and Infection Control (AMRIC) team and IIOP (Irish Institute of Pharmacy). The functions of the network are:

- to share knowledge, information, learning and experience in AMS, both across and within sectors;
- to provide a discussion forum for members;
- to share AMS work and foster creativity and innovation in AMS; and
- to assist in the provision of Continuing Professional Development (CPD) for pharmacists with an interest in AMS.

The PAMS-net webpage is hosted on the IIOP website. It provides a discussion forum and resources section. Members receive updates through the network and network events are organised regularly.

- Also in Ireland, two part-time GPs are usually included in the AMRIC Teams to provide support with IPC and AMS measures in community care. This is particularly helpful as it ensures that the primary care perspective is considered when drafting new guidelines and to "translate" AMRIC's ideas into "GP language".
- Wait-and-see prescriptions: this is another measure implemented in Belgium, Croatia, Cyprus, Denmark, Germany, Hungary, Ireland, Italy, Luxembourg, Malta, the Netherlands, and Sweden.²⁰⁴ Studies in Denmark have shown that this measure reduces the consumption of antibiotics in general practice. Doctors dispense a normal prescription that is instructed not to be redeemed unless the symptoms remain unchanged for a predetermined time period determined. These prescriptions are already used for patients with conditions such as bronchitis, middle ear infections or sinus infection. These prescriptions avoid antibiotic use in cases where the symptoms improve or disappear before the waiting period is over, reducing the amount of medication used.
- **Point-of-care tests:** these are rapid testing methods that are being developed for use in general practice in Denmark. They would assist physicians in making quick decisions on antibiotic prescription, helping to prevent unnecessary prescription.
- Threrapeutic decision supporting tools:
 - o The Green/Red Antibiotic Quality Improvement Initiative for Community Prescribers was developed in 2019 by the Medicines Management Programme (MMP) and the AMRIC team in Ireland. It is a list provided as a mouse-mat that aims to help community prescribers with antibiotic decision-making at the point of prescribing. The green agents are the preferred ones which are effective, have fewer side effects and are less likely to lead to resistant infections than red ones. In addition, each quarter, GPs receive a personalised report on the antibiotic use for their General Medical Services (GMS) cohort, detailing the percentage of green and red agents. The report also places a GP's rate with the national average and classifies them into "low", "mid-range" or "high".
 - The ANTIBIOCLIC app has been developed in France as a tool to aid therapeutic decision-making of first line physicians. It aims to support rational antibiotic therapy in primary care, according to the recommendations of French scientific societies. For each bacterial pathology frequently encountered in ambulatory medicine, there is a therapeutic proposal, depending on the patient's profile. The use of the ANTIBIOCLIC app shows potential for enhancing access among healthcare

²⁰⁴ European Commission. Overview report Member States' One Health National Action Plans against Antimicrobial Resistance.2022. Available from: <u>https://health.ec.europa.eu/system/files/2022-11/amr_onehealth_naps_rep_en.pdf</u>

professionals.²⁰⁵ The English version of the tool has been promoted by the British Society for Antimicrobial Chemotherapy (BSAC).

- **Online learning resources:** There are a number of e-learning resources aimed at various groups of stakeholders, from the general public to healthcare providers:
 - 'Antibioticsmart Sweden': ongoing mission-oriented initiative financed by the Swedish innovation agency, Vinnova. Its aim is to get all parts of society involved in ensuring that antibiotics continue to be effective in the future. For instance, by identifying quality indicators that set targets for primary healthcare centres to be able to call themselves antibiotic-smart should those targets be reached. Wound wise, an e-learning platform about the diagnosis and treatment of skin and soft tissue infections (SSTIs) and wounds, and Ditt Inre Apotek, an e-learning platform about the microbiota, have also been developed in Sweden.
 - Launched in November 2019 on the website of the French Ministry of Solidarity and Health, the Antibio'Malin platform offers the general public short and simple thematic sheets describing all the antibiotics prescribed by healthcare professionals, as well as the main infections.²⁰⁶ It aims to inform users on the subject, giving them the means to act themselves to prevent antibiotic resistance. Healthcare professionals can also use this resource in their communication with patients. Antibio'Malin is regularly updated.

• Awareness raising campaigns:

- Each year in Sweden, the National Antibiotics Forum is held in conjunction with the European Antibiotic Awareness Day (EAAD) on 18 November. The last one was a hybrid event held in 2022. The theme was, "Sweden on the global stage", where key actors discussed how to make Swedish international work more visible and sought to identify where further cooperation is needed. The purpose was to inspire more international efforts of high quality and gather input on what should be the highest priority in the work going forward. The programme included an overview of ongoing international work against antibiotic resistance at various levels, examples of how to spread the Swedish experience and knowledge to other countries, as well as a future opportunity for development.
- In Romania, a public information campaign for raising awareness on the consumption of antibiotics without a medical prescription was launched in 2018 at the initiative of a network of private pharmacies (the ETHICA group of pharmacies with over 200 members in more than 30 counties in the country). The ETHICA group designed and distributed information flyers to each of their customers about the dangers of using antibiotics without a doctor's prescription specifically the danger of AMR. Pharmacists were motivated to develop this campaign by the high number of customers soliciting antibiotics without prescriptions.

5. Conclusions

This study provides input to support the EU's overall goal to combat AMR by improving the development and implementation of NAPs which, at the same time, shall contain effective measures in infection prevention and control and prudent use of antimicrobials. The research conducted under the four study areas revealed some commonalities across

²⁰⁵ See: https://antibioclic.com/

²⁰⁶ See: <u>https://sante.gouv.fr/prevention-en-sante/les-antibiotiques-des-medicaments-essentiels-a-preserver/des-</u> antibiotiques-a-l-antibioresistance/article/antibio-malin

countries in the problems they face in combatting AMR. The insufficient funding to deliver on the measures foreseen in the NAPs, the shortages of qualified staff at all levels of care and at government level, the lack of measures targeting LTCFs specifically, the limited involvement of pharmacies in AMS, and the disruptions caused by the COVID-19 pandemic in the health sector, were barriers found in *all* countries. As mentioned in the section on study limitations (3.3), these barriers affect each country differently but they are nevertheless challenges common to all countries, indepedently of their size and socioeconomic situation.

In many cases, the insufficient funding for combating AMR has resulted in less ambitious NAPs. Moreover, the majority of the NAPs do not contain financial estimates nor sources of funding for the planned actions. Generally, the actions are meant to be funded under the relevant ministries' budgets, which were reported to be constrained already. The lack of dedicated funds (at the different levels of government and of healthcare) has resulted in difficulties in setting-up dedicated teams and operational plans to deliver on the objectives of the NAP. It has also resulted in stakeholders' demotivation and, consequently, limited commitment to the envisaged actions. Adding to this, in many countries stakeholders emphasised that the limitations to delivering on the NAP objectives were not only in relation to financial resources but also to other resources such as infrastructure, material and equipment, testing capacity, information systems, and staff. On the latter, the COVID-19 pandemic and the ageing healthcare workforce has aggravated the shortages of staff in the last years. The limited career advancement possibilities, low wages, and difficult working conditions have also resulted in staff shortages in many countries. The shortage of IPC nurses has affected LTCFs particularly.

Beyond these more general and structural issues, the study exposed other important situations on which the EU and Member States should act to enhace the fight against AMR:

- Limited political support and awareness of the challenges brought by AMR. The topic of AMR has slipped down in the political agenda in recent years, especially due to the COVID-19 pandemic. In many countries across Europe, AMR is still not sufficiently recognised as a health priority. While international attention to AMR is growing, the EU and Member States should ensure that the topic remains high in the health policy agenda and that there is sufficient political commitment and resources for providing a coordinated response.
- Lack of dedicated structures and operational plans for delivering on the objectives of the NAPs. The majority of countries have established dedicated intersectoral teams for developing the NAPs, which has resulted in the relatively successful engagement of authorities from all One Health sectors (with the exception of the environmental sector, which is often missing in the NAPs). However, often these were *ad hoc* structures that were dissolved or disused once the NAPs were approved, leaving no dedicated body responsible for overseeing the implementation of the NAP across sectors. Thus, the NAPs are often more comprised of strategies or declarations rather than concrete actionable plans with defined roles and responsibilities, targets, timelines and dedicated structures and resources. Consequently, the level of enforcement of the NAPs since 2017 has been quite modest across Europe.
- Lack of harmonised indicators for monitoring the implementation of actions to combat AMR. Generally, there are no indicators and monitoring mechanisms to track progress and results of the IPC and AMS measures envisaged in the NAPs.
- Weak monitoring/ auditing of healthcare facilities and practitioners. Compliance
 of hospitals, LTCFs, primary care practitioners and pharmacies with existing
 regulations, recommendations and guidelines in terms of IPC and AMS is insufficently
 monitored by national/ regional authorities. This results in a very heterogeneous
 situation in relation to the implementation of IPC and AMS measures across European
 countries. Controls are especially weak in relation to IPC measures and prescribing
 practices of private and primary care healthcare providers.

- Insufficient coverage and targeting of measures in relation to long-term care and pharmacies. The study revealed a very low level of implementation of IPC and AMS measures in LTCFs overall. Indeed, in the majority of countries there are no dedicated programmes or plans for IPC or AMS in LTCFs. The challenges faced by this sector are significant and go beyond the specific problem of AMR. Overall, coordination and collaboration between EU and national stakeholders with competence on long-term care is needed. In terms of pharmacies, they are generally not mentioned in the NAPs, which is considered a missed opportunity given their key role in dispensing antibiotics.
- Insufficient focus on AMS. The study highlighted the lack of national strategies and operational plans covering prudent antimicrobials prescription and use. In the absence of cohesive strategies or plans, the development of AMS measures is highly hetergoneous among the different countries and levels of care, as well as highly reliant on healthcare facilities and professionals' interest, commitment and time for engaging in AMS actions.
- Limited access to laboratories and testing capacity. Many countries face an issue with the access to laboratories and rapid exchange of test results between health practitioners and laboratories. This is especially the case in primary care, but also in hospitals. Long waiting times for test results and laboratory capacity constraints have been reported in many countries. Moreover, due to the lack of interoperable information systems and the paper-based reporting of results, it is not always possible to receive intermediate laboratory results. This means there is a heavy reliance on clinical experience for antimicrobial treatment. It also represents a barrier to designing, implementing and/or adjusting IPC measures to address emerging infection risks in a timely manner.
- Limited coverage of AMR, AMS and IPC in the education and training of healthcare workers. These topics are more commonly found in postgraduate education. There is also an insufficient focus on these topics particularly in the training and education of nurses and non-medical staff (e.g. cleaners, social workers, and carers). This results in limited awareness of AMR among healthcare workers, as well as limited abilities and skills for developing and implementing IPC and AMS measures effecively.
- Limited public awareness of AMR, basic infection prevention practices and adequate antibiotic use. Although there have been improvements in many countries in the last years, especially since the COVID-19 pandemic, including enhanced awareness on certain basic infection prevention measures such as hand washing and disinfection, the majority of countries demand further awareness raising actions targeting the general public. Hand washing campaigns are still considered essential, including for healthcare workers. Interventions on adequate antimicrobial use are also considered necessary for changing beliefs and behaviours.
- Gaps and limitations in AMR data. Important steps have been given at EU level in the last years in terms of AMR and antimicrobial consumption surveillance. However, at national level, surveillance data do not systematically cover all types of healthcare facilities and regions within the countries. There are also issues with the harmonisation of indicators across the One Health sectors, as well as across countries. In addition, the existing information systems and databases within countries are not always interoperable, especially in federal countries; thus, data aggregation is challenging and sometimes not possible. Finally, stakeholders (authorities, hospital managers, researchers, experts, etc.) are often unaware of the type and amount of data available in their countries, which means that the data is not generally used in decision making or for evaluating the effectiveness of measures.
- **Supply shortages and limited availability of narrow-spectrum antimicrobials**. Shortages of certain types or classes of antimicrobials have been reported, especially

in small countries. Shortages also make narrow-spectrum antimicrobials more expensive and difficult to access. This increases the use of broad-spectrum antibiotics, making it difficult to comply with the national antibiotic guidelines.

6. Annexes

6.1. Annex 1: Glossary

Term	Definition	Reference
Antimicrobial resistance (AMR)	AMR occurs when bacteria, viruses, fungi and parasites highly exposed to antimicrobial agents adapt to survive in this environment and no longer respond to these type of medicines making infections caused by these pathogens harder to treat and increasing the risk of disease spread, severe illness and death. As a result of drug resistance, antibiotics and other antimicrobial medicines become ineffective and infections become increasingly difficult or impossible to treat.	WHO, 2021 https://www.who.int/news-room/fact- sheets/detail/antimicrobial-resistance
Antimicrobial Stewardship (AMS)	Antibiotic stewardship is the effort to measure and improve how antibiotics are prescribed by clinicians and used by patients. Improving antibiotic prescribing and use is critical to effectively treat infections, protect patients from harms caused by unnecessary antibiotic use, and combat antibiotic resistance.	OCDC, 2022 https://www.cdc.gov/antibiotic- use/core-elements/index.html
Antimicrobials	Antimicrobials, including antibiotics, antivirals, antifungals and antiparasitics, are medicines used to prevent and treat infections in humans, animals and plants.	WHO, 2021 https://www.who.int/news-room/fact- sheets/detail/antimicrobial-resistance
EU AMR One Health Network	The Network is composed of experts in human, animal and plant health from Member States, EU scientific agencies and the Commission. The Network serves as a platform for exchange of information and best practices and discussion of policy options. It meets biannually.	European Commission, 2022 https://ec.europa.eu/transparency/exp ert-groups-register/screen/expert- groups/consult?lang=en&groupID=38 53
Healthcare-associated infections (HAIs)	Healthcare-associated infections are infections acquired by patients during their stay in a hospital or another healthcare setting. Although some of these infections can be treated easily, others may more seriously affect a patient's health, increasing their stay in the hospital and hospital costs, and causing considerable distress to these patients.	ECDC https://www.ecdc.europa.eu/en/health care-associated-infections

Term	Definition	Reference
Infection Prevention and Control (IPC)	IPC is a scientific approach and practical solution designed to prevent harm caused by infection to patients and health workers. It is a subset of epidemiology, but also serves an essential function in infectious diseases, social sciences and global health.	WHO, 2022 https://www.who.int/teams/integrated- health-services/infection-prevention- control
Long-term care facilities (LTCFs)	Facilities that provide rehabilitative, restorative, and/or ongoing skilled nursing care to patients or residents in need of assistance with activities of daily living. Long-term care facilities include nursing homes, rehabilitation facilities, inpatient behavioural health facilities, and long-term chronic care hospitals.	MedicineNet, 2021 https://www.medicinenet.com/long- term_care_facility/definition.htm
Multi-drug resistant organisms or bacteria	When a single bacterium is resistant at least to one agent in three or more antimicrobial categories it is said to be multidrug-resistant.	ECDC, 2012 In: Magiorakos, AP., Srinivasan, A., Carey, R.B., Carmeli, Y., Falagas, M.E., Giske, C.G., Harbarth, S., Hindler, J.F., Kahlmeter, G., Olsson- Liljequist, B., Paterson, D.L., Rice, L.B., Stelling, J., Struelens, M.J., Vatopoulos, A., Weber, J.T. and Monnet, D.L. (2012), Multidrug- resistant, extensively drug-resistant and pandrug-resistant bacteria: an international expert proposal for interim standard definitions for acquired resistance. Clinical Microbiology and Infection, 18: 268- 281. <u>https://doi.org/10.1111/j.1469- 0691.2011.03570.x</u>
National Actions Plans on Antimicrobial resistance (NAP-AMR)	National plans against AMR that are aligned with the objectives of the global action plan created in May 2015, by the Sixty-eighth World Health Assembly.	https://ec.europa.eu/health/antimicrobi al-resistance/eu-action-antimicrobial- resistance/national-action-plans-and- strategies_en
One Health Action Plan against AMR	The EU AMR Action Plan is based on the One Health approach, which recognizes the interconnectedness of human, animal and plant health and the environment and proposes a coherent way to address the issue across all of these domains. The key objectives of the One Health Action Plan are structured along three pillars: (1) making the EU a best practice region; (2) boosting research, development and innovation; (3) shaping the global agenda.	European Commission, 2017 https://health.ec.europa.eu/system/file s/2020-01/amr_2017_action- plan_0.pdf
One Health	One Health is a term used to describe a principle which recognises that	European Commission, 2017

Term	Definition	Reference
	human and animal health are interlinked	https://ec.europa.eu/health/system/file s/2020-01/amr_2017_action- plan_0.pdf
Zoonotic pathogens	Zoonotic pathogens may be bacterial, viral or parasitic, or may involve unconventional agents and can spread from animals to humans through direct contact or through food, water or the environment.	WHO, 2020 https://www.who.int/news-room/fact- sheets/detail/zoonoses#:~:text=A%20 zoonosis%20is%20an%20infectious.f ood%2C%20water%20or%20the%20 environment.

6.2. Annex 2: Study questions

Research question	Sub-question
1. Barriers to NAPs	
1.1 What are the barriers to setting up/developing One Health NAPs on antimicrobial	1.1.1 What are the barriers at institutional/policy, clinical, and/or behavioural level to setting up/developing One Health NAPs on AMR?
resistance?	1.1.2 Which of the barriers identified are linked to the shock caused by the COVID-19 pandemic and which ones are more structural in nature?
	1.1.3 What are the barriers related to the coordination across the One Health spectrum?
	1.1.4 What are the barriers related to each specific sector (i.e., human, animal, plant health, agriculture/ aquaculture, the environment)
1.2 What are the barriers to the implementation of One Health NAPs on antimicrobial	1.2.1 What are the barriers at institutional/policy, clinical, and/or behavioural level to the implementation of One Health NAPs on AMR?
resistance?	1.2.2 Which of the barriers identified are linked to the shock caused by the COVID-19 pandemic and which ones are more structural in nature?
	1.2.3 What are the barriers related to the coordination across the One Health spectrum?
	• 1.2.4 What are the barriers specific to each sector (i.e., human, animal, plant health, the environment, etc.)?
1.3 Where can the EU strengthen its role in	1.3.1 Which measures could be undertaken to address the barriers?
supporting the development and implementation of One Health NAPs on antimicrobial resistance?	1.3.2 Where and how can the EU best support the development and implementation of One Health NAPs? These can be measures and/or good practices of a legislative, non-legislative, financial nature.
What are the estimated costs of possible EU financial interventions?	1.3.3 What are the estimated costs of potential EU financial interventions?
2. Barriers to IPC measures	
2.1 How are IPC measures developed and implemented, notably in acute health care	2.1.1 At which level are IPC measures developed and implemented (at health system or organisational level)? Are they integrated in the NAP?
settings (hospitals) and in long- term-care facilities?	2.1.2 Which stakeholders are involved in the development and implementation of IPC measures?
	2.1.3 What type of measures have been implemented, notably in acute health care settings (hospitals) and LTCFs (e.g., hand hygiene, environmental cleaning, disinfection and sterilization,

Table 7: Study questions and indicators

Research question	Sub-question
	education of staff, etc.)? Are there IPC minimum requirements for these facilities?
	2.1.4 Which mechanisms and tools (including novel approaches) are used to implement IPC measures, notably in acute healthcare settings (hospitals) and LTCFs?
	2.1.5 How are IPC measures monitored and evaluated at system- and organisational-level? Who is responsible for this?
	2.1.6 What is the estimated cost of these measures at system- and organisational-level?
	2.1.7 What does the available evidence say about the effectiveness and efficiency of these measures?
2.2 What are the main barriers or shortcomings in the development and	2.2.1 What are the barriers at institutional/ policy, clinical, and/or behavioural level to the development of IPC measures? How frequently they occur?
implementation of IPC measures that limit their effectiveness and efficiency and at which frequency and	2.2.2 What are the barriers at institutional/policy, clinical, and/or behavioural level to the implementation of IPC measures? How frequently they occur?
levels do they occur?	2.2.3 Which of the barriers identified are linked to the shock caused by the COVID-19 pandemic and which ones are more structural in nature?
	2.2.4 What does the available evidence say about how the identified barriers limit the effectiveness and efficiency of these measures, notably in acute health care settings (hospitals) and long-term care facilities?
2.3 What changes are needed to address those barriers –	2.3.1 Which measures could be undertaken to address the identified barriers?
policy, financial, behavioural or other changes? Where can the EU make the biggest	2.3.2 Where and how can the EU best support the development and implementation of IPC measures in hospitals and LTCFs?
difference? What are estimated costs to alleviate financial barriers?	2.3.3 What are the estimated costs of potential EU financial interventions?
3. Barriers to AMS measures in	hospitals and LTCFs
3.1 How are antimicrobial stewardship measures (AMS) measures and measures	3.1.1 At which level are AMS measures developed and implemented (at health system- or organisational-level)? Are they integrated in the NAP (where there is one in place)?
aiming at prudent use of antimicrobials developed and implemented, in acute health	3.1.2 Which stakeholders are involved in the development and implementation of AMS measures?
care settings (hospitals) and in long-term-care facilities?	3.1.3 What type of AMS measures have been implemented, notably in acute health care settings (hospitals) and LTCFs?
	3.1.4 Which mechanisms and tools are used to implement AMS measures, notably in acute health care settings (hospitals) and LTCFs?

Research question	Sub-question
	3.1.5 How are AMS measures monitored and evaluated at system- and organisational-level? Who is responsible for what?
	3.1.6 What is the estimated cost of these measures at system- and organisational-level?
3.2 What are the main barriers or shortcomings in the development and implementation that limit the	3.2.1 What are the barriers at institutional/policy, clinical, and/or behavioural level to the development of AMS measures, notably in acute health care settings (hospitals) and in LTCFs? How frequently they occur?
effectiveness and efficiency of AMS and at what frequency and levels do they occur?	3.2.2 What are the barriers at institutional/policy, clinical, and/or behavioural level to the implementation of AMS measures, notably in acute health care settings (hospitals) and in LTCFs? How frequently they occur?
	3.2.3 Which of the barriers identified are linked to the shock caused by the COVID-19 pandemic and which ones are more structural in nature?
	3.2.4 What does the available evidence say about how the identified barriers limit the effectiveness and efficiency of these measures, notably in acute health care settings (hospitals) and LTCFs?
3.3 What changes are needed to address those barriers – policy, financial, behavioural or other changes? Where can the EU make the biggest	3.3.1 Which measures could be undertaken to address the identified barriers?3.3.2 Where and how can the EU best support the development and implementation of AMS measures in hospitals and LTCFs?
difference? What are estimated costs to alleviate financial barriers?	3.3.3 What are the estimated costs of potential EU financial interventions?
4.Barriers to AMS measures in p	primary care and community pharmacy
4.1 How are AMS measures and measures aiming at prudent use of antimicrobials in primary care and in pharmacies developed and implemented?	4.1.1 At which level are AMS measures and measures aiming at prudent use of antimicrobials in primary care and in pharmacies developed and implemented (at system-, organisational- and/or individual-level)? Are they integrated in the NAP (where there is one in place)?
	4.1.2 Which stakeholders are involved in the development and implementation of AMS measures and measures aiming at prudent use of antimicrobials in primary care and in pharmacies?
	4.1.3 What type of AMS measures and measures aiming at prudent use of antimicrobials have been implemented, notably in primary care and in pharmacies?
	4.1.4 Which mechanisms and tools (including incentives/sanctions schemes) are used to implement AMS measures and measures aiming at prudent use of antimicrobials, notably in primary care and in pharmacies?
	4.1.5 How are AMS measures and measures aiming at prudent use of antimicrobials monitored and evaluated at system-,

Research question	Sub-question
	organisational- and/or individual-level? Who is responsible for this?
	4.1.6 What is the estimated cost of these measures at system-, organisational- and/or individual-level?
4.2 What are the main barriers or shortcomings in the development and	4.2.1 What are the barriers at institutional/policy, clinical, and/or behavioural level to the development of AMS measures, notably in primary care and in pharmacies? How frequently they occur?
implementation that limit the effectiveness and efficiency of AMS measures and at what frequency and levels do they	4.2.2 What are the barriers at institutional/policy, clinical, and/or behavioural level to the implementation of AMS measures, notably in primary care and in pharmacies? How frequently they occur?
occur?	4.2.3 Which of the barriers identified are linked to the shock caused by the COVID-19 pandemic and which ones are more structural in nature?
	4.2.4 What does the available evidence say about how the identified barriers limit the effectiveness and efficiency of these measures, notably in primary care and in pharmacies?
4.3 What changes are needed to address those barriers -	4.3.1 Which measures could be undertaken to address the identified barriers?
policy, financial, behavioural or other changes? Where can the EU make the biggest difference? What are estimated	4.3.2 Where and how can the EU best support the development and implementation of AMS measures in primary care and pharmacies?
costs to alleviate financial barriers?	4.3.3 What are the estimated costs of potential EU financial interventions?

6.3. Annex 3: Key indicators assessed for the study

6.3.1. Indicators on the National Action Plans

Indicator	Status of NAP ²⁰⁷		Sectors actively involved in the multisector coordination mechanism ²⁰⁸	NAP monitoring and evaluation plan ²⁰⁹	Other plans or strategies ²¹⁰	Impact COVID-19 ²¹¹
Source	DG SANTE ²¹² , ECDC ²¹³ , WHO Regional Office for Europe/ECDC ²¹⁴ , and authors' own research	TrACSS				
Year	2022/23	2020/2021				

²⁰⁸ Question in TrACCS survey: Which sectors are actively involved in the multisector coordination mechanism?

²⁰⁷ Cells coloured in green indicate (a) countries who have a valid NAP; (b) countries who have an overarching strategic document on AMR (e.g. Cyprus and Iceland); (c) countries whose NAPs have expired but are in the process of adopting a new one (e.g. Italy). Cells coloured in yellow indicate (a) countries who have not had a NAP in place yet but might have one under development (e.g. Bulgaria); (b) countries whose NAPs have expired and no information is available whether a new draft is under development (e.g. Slovakia).

²⁰⁹ Question in TrACCS survey: Does the country have a monitoring and evaluation plan for the national AMR action plan?

²¹⁰ Question in TrACCS survey: Is your country's national planning on AMR integrated with other existing action plans or, strategies?

²¹¹ **Question in TrACSS survey: How has COVID-19 pandemic and its national response, either positively or negatively, impacted the AMR National Action Plan implementation?** Positive impacts of COVID-19 could refer to one of the following examples: better infection control measures; better public understanding of bacterial vs viral infections and how they should be treated; better biosecurity measures noted in farms; widespread adoption of animal health plans by farmers; higher adoption of antimicrobial stewardship guidelines by antimicrobial users (veterinarians, veterinary paraprofessionals, animal health technicians, farmers); increased awareness about AMR and misuse of antimicrobials; improved management of supply chains for medicines; Improved access to laboratory supplies and to laboratory facilities.

²¹² DG Health and Food Safety (2022) Member States' One Health National Action Plans against Antimicrobial Resistance. Available at https://health.ec.europa.eu/system/files/2022-11/amr_onehealth_naps_rep_en.pdf Last accessed 4 January 2022.

²¹³ ECDC. "Strategies and action plans on antimicrobial resistance" Available at <u>https://www.ecdc.europa.eu/en/publications-data/directory-guidance-prevention-and-control/antimicrobial-resistance-strategies</u> Last accessed 4 January 2022.

²¹⁴ WHO Regional Office for Europe and ECDC. Antimicrobial resistance surveillance in Europe 2022. Available at <a href="https://www.ecdc.europa.eu/en/publications-data/antimicrobial-resistance-surveillance-europe-2022-2020-data#:-:text=Antimicrobial%20resistance%20(AMR)%20remains%20a,people%20die%20as%20a%20direct. Last accessed 5 January 2022.

Indicator	Status of NAP ²⁰⁷	Multi-sector and One Health collaboration/ coordination	Sectors actively involved in the multisector coordination mechanism ²⁰⁸	NAP monitoring and evaluation plan ²⁰⁹	Other plans or strategies ²¹⁰	Impact COVID-19 ²¹¹
Austria	Valid Last updated in March 2022; most actions foreseen up to 2024	E	Human health, animal health, plant health, food production and safety, environment	Yes	Yes: One Health Strategy or One Health mechanism; National Food Safety strategy and policies	Negative impact: Operational impacts
Belgium	Valid NAP not formally adopted but under implementation	E	Human health, animal health, plant health, food production and safety, environment	No	No	Positive impact Negative impact: Governance and administrative impact
Bulgaria	Draft NAP expired before being formally adopted A new draft is under development	В	Animal health, plant health, food production and safety, environment ²¹⁵	No	No	Negative impact: Operational impacts
Croatia	Expired New NAP draft under development; expected adoption in 2023	В	Human health, animal health, plant health, food production and safety	Yes	No	Negative impact: Governance and administrative impact
Cyprus	Valid In process of being updated/drafting a new NAP	В	Human health, animal health, plant health, food production and safety, environment	No	No	Negative impact: Operational impacts Governance and administrative impact

²¹⁵ No human health included in Bulgaria's response to the TrACCS survey

Indicator	Status of NAP ²⁰⁷	Multi-sector and One Health collaboration/ coordination	Sectors actively involved in the multisector coordination mechanism ²⁰⁸	NAP monitoring and evaluation plan ²⁰⁹	Other plans or strategies ²¹⁰	Impact COVID-19 ²¹¹
Czechia	The overarching National Antibiotic Program is in place, but the second Action Plan has expired	В	Human health, animal health, plant health, food production and safety	Yes	No	Negative impact: Operational impacts Governance and administrative impact
Denmark	Denmark has an overarching One Health Strategy and sectoral NAPs for human and animal health. The NAP for animal health was revised (2021-2023). The NAP for human health is expected to be revised (2023-2027). The NAP for environment is expected to be adopted for the first time in 2023	D	Human health, animal health, plant health, food production and safety, environment	Yes	Yes: One Health Strategy or One Health mechanism; National Food Safety strategy and policies; National animal health strategy and policies, Strategy for environmentally dangerous compounds	Positive impact Negative impact: Operational impacts Governance and administrative impact
Estonia	Draft NAP was under development; the process was put on hold due to COVID-19 and resumed in June 2022; expected to be adopted by the end of 2022	В	Human health, animal health, plant health, food production and safety, environment	No	Yes: Water, Sanitation and Hygiene (WASH); Climate change and environmental planning; National Food Safety strategy and policies; National	Negative impact: Operational impacts Governance and administrative impact

Indicator	Status of NAP ²⁰⁷	Multi-sector and One Health collaboration/ coordination	Sectors actively involved in the multisector coordination mechanism ²⁰⁸	NAP monitoring and evaluation plan ²⁰⁹	Other plans or strategies ²¹⁰	Impact COVID-19 ²¹¹
					Agriculture development plans and policies; Veterinary NAP	
Finland	Expired 2021 New NAP being developed in 2022; expected to be published in 2023	D	Human health, animal health, plant health, food production and safety, environment	Yes	Yes: National action plan on health security; National Food Safety strategy and policies; National Agriculture development plans and policies; National zoonosis strategy	Positive impact Negative impact: Operational impacts Governance and administrative impact
France	Valid	E	Human health, animal health, plant health, food safety, environment	Yes	Yes: National health sector plan; National plan on environmental health (PNSE4)	Positive impact Negative impact: Operational impacts Negative impact: Governance and administrative impact
Germany	Expired Final report on the implementation of DART 2020 published in 2022	E	Human health, animal health, plant health, food production and safety, environment	No	Yes: National Food Safety strategy and policies	Negative impact: Operational impacts Governance and

Indicator	Status of NAP ²⁰⁷	Multi-sector and One Health collaboration/ coordination	Sectors actively involved in the multisector coordination mechanism ²⁰⁸	NAP monitoring and evaluation plan ²⁰⁹	Other plans or strategies ²¹⁰	Impact COVID-19 ²¹¹
						administrative impact
Greece	Valid	E	Human health, animal health (terrestrial), plant health, food production and safety, environment	No	No	Negative impact: Operational impacts Governance and administrative impact
Hungary	Draft under development; to be finalised and approved in 2023. There are nevertheless several government plans and actions to combat AMR based on the WHO 2015 GAP on AMR and EU guidelines.	D	Human health, animal health (terrestrial), plant health, food production and safety	No	Yes: One Health Strategy or One Health mechanism; Water, Sanitation and Hygiene (WASH); National health sector plan; National Food Safety strategy and policies; National Agriculture development plans and policies	Negative impact: Governance and administrative impact
Iceland	No official One Health NAP; report from 2017 considered as NAP	D	Human health, animal health (terrestrial), food production and safety, environment	No	No	Negative impact: Governance and administrative impact
Ireland	Valid	D	Human health, animal health, plant health, food	Yes	Yes: One Health Strategy or One	Negative impact: Governance and

Indicator	Status of NAP ²⁰⁷	Multi-sector and One Health collaboration/ coordination	Sectors actively involved in the multisector coordination mechanism ²⁰⁸	NAP monitoring and evaluation plan ²⁰⁹	Other plans or strategies ²¹⁰	Impact COVID-19 ²¹¹
			production and safety, environment		Health mechanism; National health sector plan; National Agriculture development plans and policies	administrative impact
Italy	Updated NAP subject to adoption in 2023	В	Human health, animal health (terrestrial), food production and safety, environment	Yes	Yes: National health sector plan; Veterinary NAP	Negative impact: Operational impacts Governance and administrative impact
Latvia	Updated NAP subject to adoption in 2023	В	Human health, animal health, food safety	Yes	Yes: One Health Strategy or One Health mechanism; Public Health Strategy	Negative impact: Operational impacts Governance and administrative impact
Lithuania	Expired. Unclear whether it is being revised or updated.	В	Human health, animal health, plant health, food production and safety, environment	Yes	Yes: National health sector plan; National development plans; United Nations Sustainable Development Corporation Framework (UNSDCF);	Negative impact: Operational impacts Governance and administrative impact

Indicator	Status of NAP ²⁰⁷	Multi-sector and One Health collaboration/ coordination	Sectors actively involved in the multisector coordination mechanism ²⁰⁸	NAP monitoring and evaluation plan ²⁰⁹	Other plans or strategies ²¹⁰	Impact COVID-19 ²¹¹
					National Food Safety strategy and policies	
Luxembo urg	Valid Extended until 2024	E	Human health, animal health (terrestrial), environment	Yes	Yes: One Health Strategy or One Health mechanism	Negative impact: Governance and administrative impact
Malta	Valid	E	Human health, animal health, plant health	Yes	Yes: One Health Strategy or One Health mechanism; Water, Sanitation and Hygiene (WASH);	Negative impact: Operational impacts Governance and administrative impact
Netherlan ds	Valid Extended for an undefined period	E	Human health, animal health (terrestrial), plant health, food production and safety, environment	No	Yes: One Health Strategy or One Health mechanism; National Food Safety strategy and policies	Negative impact: Operational impacts Governance and administrative impact
Norway	Valid	E	Human health, animal health, plant health, food production and safety, environment	Yes	Yes: One Health Strategy or One Health mechanism; Water, Sanitation and Hygiene (WASH); National health sector plan;	Positive impact Negative impact: Operational impacts Governance and administrative impact

Indicator	Status of NAP ²⁰⁷	Multi-sector and One Health collaboration/ coordination	Sectors actively involved in the multisector coordination mechanism ²⁰⁸	NAP monitoring and evaluation plan ²⁰⁹	Other plans or strategies ²¹⁰	Impact COVID-19 ²¹¹
					National action plan on health security; National Food Safety strategy and policies; National Agriculture development plans and policies	
Poland	No One Health NAP-AMR Nevertheless, there is a reference to AMR in the National Health Programme (2021- 2025) adopted	В	Human health, food production and safety, environment	No	Yes: National health sector plan	Negative impact: Operational impacts Governance and administrative impact
Portugal	Valid	D	Human health, animal health (terrestrial), plant health, food production and safety, environment	No	Yes: National health sector plan; National action plan on health security; Climate change and environmental planning; United Nations Sustainable Development Corporation Framework (UNSDCF);	Negative impact: Operational impacts Governance and administrative impact

Indicator	Status of NAP ²⁰⁷	Multi-sector and One Health collaboration/ coordination	Sectors actively involved in the multisector coordination mechanism ²⁰⁸	NAP monitoring and evaluation plan ²⁰⁹	Other plans or strategies ²¹⁰	Impact COVID-19 ²¹¹
					Food Safety strategy and policies; National Agriculture development plans and policies	
Romania	NAP developed in 2021 with the support of the EEA Fund. Unclear whether it has been formally adopted and is being implemented.	В	Human health, animal health, plant health, food production and safety	No	No	Negative impact: Governance and administrative impact
Slovakia	Expired. Unclear whether it is being revised or updated.	В	Human health, animal health (terrestrial), food safety	Yes	Yes: One Health Strategy or One Health mechanism	Negative impact: Operational impacts Governance and administrative impact
Slovenia	Valid	С	Human health, animal health, food safety, environment	No	No	Positive impact Negative impact: Operational impacts Governance and administrative impact
Spain	Valid	D	Human health, animal health, food safety, environment	Yes	Yes: One Health Strategy or One Health mechanism; National health sector plan; National action	Negative impact: Operational impacts Governance and administrative impact

Indicator	Status of NAP ²⁰⁷	Multi-sector and One Health collaboration/ coordination	Sectors actively involved in the multisector coordination mechanism ²⁰⁸	NAP monitoring and evaluation plan ²⁰⁹	Other plans or strategies ²¹⁰	Impact COVID-19 ²¹¹	
					plan on health security; National Food Safety strategy and policies		
Sweden	Valid	E	Human health, animal health, plant health, food production and safety, environment	Yes	No	Positive impact Negative impact: Operational impacts Negative impact: Governance and administrative impact	
	 A - No formal multi-sectoral governance or coordination mechanism on AMR exists. B - Multi-sectoral coordination mechanism on AMR established with Government leadership. C - Formalized multisector coordination mechanism with technical working groups established with clear terms of reference, regular meetings, and funding for working group(s) with activities and reporting/accountability arrangements defined. D - Joint working on issues including agreement on common objectives. E - Integrated approaches used to implement the national AMR action plan with relevant data and lessons learned from all sectors used to adapt implementation of the action plan. 						

6.3.2. Indicators on IPC and AMS measures

Indicator	IPC in human healthcare	AMS Guidelines ²¹⁶	Awareness campaigns (human health) ²¹⁷	Knowledge on antibiotics ²¹⁸	Information on the use of antibiotics ²¹⁹	Understanding of the use of antibiotics – when to stop ²²⁰
Source	1	TrACSS		Eurobarometer 2022	Eurobarometer 2023	Eurobarometer 2022
Year		2020/2021		2022	2022	2022
Austria	E	D	E	A. Correct 49%; incorrect 45% B. Correct 53; incorrect 40% C. Correct 84%; incorrect 10% D. Correct 77%; incorrect 13%	21 % Yes; 77% No	12% when you feel better; 85% When you have taken all of the antibiotics as directed by your doctor
Belgium	E	D	С	A. Correct 59%; incorrect 37% B. Correct 78%; incorrect 19% C. Correct 83%; incorrect 14%	32% Yes; 68% No	13% when you feel better; 86% When you have taken all of the antibiotics as

²¹⁶ Question in TrACCS survey: Optimizing antimicrobial use in human health refers to the country situation in relation to the following AMS guidelines: WHO Practical Toolkit: Antimicrobial Stewardship Programmes in Health-Care Facilities in Low- and Middle-Income Countries. See https://apps.who.int/iris/bitstream/handle/10665/329404/9789241515481-eng.pdf

²¹⁷ Question in TrACCS survey: Raising awareness and understanding of AMR risks and response – Human health. For all countries "human health" is "a main focus of campaign", except Finland which indicated "some activities done in this sector".

²¹⁸ Question in Eurobarometer 2022: For each of the following statements, please tell whether you think it is true or false. A. Antibiotics kill viruses (FALSE); B. Antibiotics are effective against colds (FALSE); C. Unnecessary use of antibiotics makes them become ineffective (TRUE); D. Taking antibiotics often has side-effects such as diarrhoea (TRUE)

²¹⁹ Question in Eurobarometer 2022: In the last 12 months, do you remember getting any information about not taking antibiotics unnecessarily, for example for a cold?

²²⁰ Question in Eurobarometer 2022: When do you think you should stop taking antibiotics once you have begun a course of treatment?

Indicator	IPC in human healthcare	AMS Guidelines ²¹⁶	Awareness campaigns (human health) ²¹⁷	Knowledge on antibiotics ²¹⁸	Information on the use of antibiotics ²¹⁹	Understanding of the use of antibiotics – when to stop ²²⁰
				D. Correct 65%; incorrect 27%		directed by your doctor
Bulgaria	в	В	В	A. Correct 41%; incorrect 43% B. Correct 46%; incorrect 40% C. Correct 78%; incorrect 10% D. Correct 73%; incorrect 10%	24% Yes; 76% No	18% when you feel better; 79% When you have taken all of the antibiotics as directed by your doctor
Croatia	E	с	D	A. Correct 60%; incorrect 33% B. Correct 60%; incorrect 35% C. Correct 83%; incorrect 12% D. Correct 74%; incorrect 17%	19% Yes; 81% No	15% when you feel better; 85% When you have taken all of the antibiotics as directed by your doctor
Cyprus	с	A	D	A. Correct 34%; incorrect 51% B. Correct 41%; incorrect 50% C. Correct 91%; incorrect 3% D. Correct 75%; incorrect 5%	33% Yes; 67% No	16% when you feel better; 81% When you have taken all of the antibiotics as directed by your doctor
Czechia	с	в	С	A. Correct 56%; incorrect 39% B. Correct 82%; incorrect 14%	35% Yes; 65% No	7% when you feel better; 93% When you have

Indicator	IPC in human healthcare	AMS Guidelines²¹⁶	Awareness campaigns (human health) ²¹⁷	Knowledge on antibiotics ²¹⁸	Information on the use of antibiotics ²¹⁹	Understanding of the use of antibiotics – when to stop ²²⁰
				C. Correct 91%; incorrect 6% D. Correct 66%; incorrect 24%		taken all of the antibiotics as directed by your doctor
Denmark	D	D	E	A. Correct 64%; incorrect 33% B. Correct 81%; incorrect 14% C. Correct 96%; incorrect 2% D. Correct 74%; incorrect 12%	10% Yes; 89% No	6% when you feel better; 93% When you have taken all of the antibiotics as directed by your doctor
Estonia	С	D	С	A. Correct 48%; incorrect 42% B. Correct 61%; incorrect 29% C. Correct 85%; incorrect 8% D. Correct 79%; incorrect 9%	42% Yes; 56% No	11% when you feel better; 85% When you have taken all of the antibiotics as directed by your doctor
Finland	E	D	C	A. Correct 65%; incorrect 31% B. Correct 89%; incorrect 7% C. Correct 96%; incorrect 2% D. Correct 79%; incorrect 16%	50% Yes; 49% No	5% when you feel better; 94% When you have taken all of the antibiotics as directed by your doctor

Indicator	IPC in human healthcare	AMS Guidelines ²¹⁶	Awareness campaigns (human health) ²¹⁷	Knowledge on antibiotics ²¹⁸	Information on the use of antibiotics ²¹⁹	Understanding of the use of antibiotics – when to stop ²²⁰
France	Е	D	E	A. Correct 63%; incorrect 26% B. Correct 71%; incorrect 21% C. Correct 76%; incorrect 14% D. Correct 60%; incorrect 21%	29% Yes; 70% No	15% when you feel better; 83% When you have taken all of the antibiotics as directed by your doctor
Germany	E	D	D	A. Correct 45%; incorrect 37% B. Correct 58%; incorrect 30% C. Correct 83%; incorrect 7% D. Correct 67%; incorrect 13%	24% Yes; 75% No	12% when you feel better; 85% When you have taken all of the antibiotics as directed by your doctor
Greece	Е	E	D	A. Correct 35%; incorrect 58% B. Correct 44%; incorrect 49% C. Correct 92%; incorrect 4% D. Correct 75%; incorrect 10%	23% Yes; 77% No	13% when you feel better; 87% When you have taken all of the antibiotics as directed by your doctor
Hungary	D	В	D	A. Correct 43%; incorrect 52% B. Correct 48%; incorrect 47% C. Correct 73%; incorrect 18% D. Correct 71%; incorrect 18%	11% Yes; 89% No	19% when you feel better; 79% When you have taken all of the antibiotics as directed by your doctor

Indicator	IPC in human healthcare	AMS Guidelines ²¹⁶	Awareness campaigns (human health) ²¹⁷	Knowledge on antibiotics ²¹⁸	Information on the use of antibiotics ²¹⁹	Understanding of the use of antibiotics – when to stop ²²⁰
Iceland	С	С	D	N/A	N/A	N/A
Ireland	E	D	С	A. Correct 66%; incorrect 29% B. Correct 76%; incorrect 20% C. Correct 85%; incorrect 10% D. Correct 63%; incorrect 18%	15% Yes; 85% No	6% when you feel better; 94% When you have taken all of the antibiotics as directed by your doctor
Italy	A	В	D	A. Correct 46%; incorrect 46% B. Correct 74%; incorrect 21% C. Correct 75%; incorrect 15% D. Correct 66%; incorrect 23%	21% Yes; 79% No	16% when you feel better; 83% When you have taken all of the antibiotics as directed by your doctor
Latvia	В	с	С	A. Correct 42%; incorrect 50% B. Correct 53%; incorrect 39% C. Correct 87%; incorrect 7% D. Correct 70%; incorrect 19%	27% Yes; 73% No	15% when you feel better; 81% When you have taken all of the antibiotics as directed by your doctor
Lithuania	С	В	С	A. Correct 40%; incorrect 45% B. Correct 52%; incorrect 34% C. Correct 84%; incorrect 5%	34% Yes; 65% No	19% when you feel better; 78% When you have taken all of the antibiotics as

Indicator	IPC in human healthcare	AMS Guidelines²¹⁶	Awareness campaigns (human health) ²¹⁷	Knowledge on antibiotics ²¹⁸	Information on the use of antibiotics ²¹⁹	Understanding of the use of antibiotics – when to stop ²²⁰
				D. Correct 72%; incorrect 10%		directed by your doctor
Luxembourg	В	A	D	A. Correct 73%; incorrect 22% B. Correct 85%; incorrect 13% C. Correct 89%; incorrect 8% D. Correct 71%; incorrect 21%	47% Yes; 53% No	18% when you feel better; 82% When you have taken all of the antibiotics as directed by your doctor
Malta	E	E	D	A. Correct 48%; incorrect 46% B. Correct 61%; incorrect 34% C. Correct 96%; incorrect 2% D. Correct 75%; incorrect 13%	22% Yes; 78% No	8% when you feel better; 92% When you have taken all of the antibiotics as directed by your doctor
Netherlands	Е	E	E	A. Correct 68%; incorrect 26% B. Correct 81%; incorrect 13% C. Correct 96%; incorrect 2% D. Correct 63%; incorrect 19%	11% Yes; 89% No	5% when you feel better; 95% When you have taken all of the antibiotics as directed by your doctor
Norway	D	E	E	N/A	N/A	N/A
Poland	A	С	В	A. Correct 47%; incorrect 42% B. Correct 45%; incorrect 46% C. Correct 86%;	15% Yes; 84% No	15% when you feel better; 84% When you have taken all of the

Indicator	IPC in human healthcare	AMS Guidelines ²¹⁶	Awareness campaigns (human health) ²¹⁷	Knowledge on antibiotics ²¹⁸	Information on the use of antibiotics ²¹⁹	Understanding of the use of antibiotics – when to stop ²²⁰
				incorrect 9% D. Correct 81%; incorrect 9%		antibiotics as directed by your doctor
Portugal	Е	E	D	A. Correct 42%; incorrect 43% B. Correct 55%; incorrect 32% C. Correct 86%; incorrect 3% D. Correct 73%; incorrect 5%	14% Yes; 86% No	10% when you feel better; 88% When you have taken all of the antibiotics as directed by your doctor
Romania	в	В	С	A. Correct 35%; incorrect 58% B. Correct 30%; incorrect 63% C. Correct 69%; incorrect 21% D. Correct 57%; incorrect 26%	13% Yes; 87% No	19% when you feel better; 78% When you have taken all of the antibiotics as directed by your doctor
Slovakia	D	D	D	A. Correct 46%; incorrect 47% B. Correct 55%; incorrect 39% C. Correct 87%; incorrect 8% D. Correct 79%; incorrect 12%	30% Yes; 69% No	20% when you feel better; 78% When you have taken all of the antibiotics as directed by your doctor
Slovenia	D	D	С	A. Correct 56%; incorrect 36% B. Correct 72%; incorrect 23% C. Correct 91%;	29% Yes; 70% No	10% when you feel better; 87 % When you have taken all of the

Indicator	IPC in human healthcare	AMS Guidelines ²¹⁶	Awareness campaigns (human health) ²¹⁷	Knowledge on antibiotics ²¹⁸	Information on the use of antibiotics ²¹⁹	Understanding of the use of antibiotics – when to stop ²²⁰
				incorrect 6% D. Correct 69%; incorrect 19%		antibiotics as directed by your doctor
Spain	Е	D	Е	A. Correct 42%; incorrect 46% B. Correct 55%; incorrect 36% C. Correct 85%; incorrect 7% D. Correct 65%; incorrect 15%	20% Yes; 80% No	14% when you feel better; 84% When you have taken all of the antibiotics as directed by your doctor
Sweden	D	E	D	A. Correct 77%; incorrect 21% B. Correct 88%; incorrect 10% C. Correct 99%; incorrect 1% D. Correct 64%; incorrect 27%	32% Yes; 68% No	5% when you feel better; 95 % When you have taken all of the antibiotics as directed by your doctor
	A - No national IPC programme or operational plan is available. B - A national IPC programme or operational plan is available. National IPC and water, sanitation and hygiene	A - No/weak national policies for appropriate antimicrobial use including availability, quality, and disposal of antimicrobials. B - National policies	 A - No significant awareness-raising activities on relevant aspects of risks of antimicrobial resistance. B - Some activities to raise awareness about risks of antimicrobial resistance and actions that address it. C - Some awareness activities at local and/or sub-national level about risks of antimicrobial resistance to address it, targeting some but not all 	A. Antibiotics kill viruses (false) – EU average: correct 50%; incorrect 39% B. Antibiotics are effective against colds (false) – EU average: correct 62%; incorrect 30% C. Unnecessary use of antibiotics makes	EU average: No: 77 Yes: 23	EU average: when you feel better- 13% when you have taken all of the antibiotics as directed by your doctor – 85%

Indicator	IPC in human healthcare	AMS Guidelines ²¹⁶	Awareness campaigns (human health) ²¹⁷	Knowledge on antibiotics ²¹⁸	Information on the use of antibiotics ²¹⁹	Understanding of the use of antibiotics – when to stop ²²⁰
	(WASH) and environmental health standards exist but are not fully implemented. C - A national IPC programme and operational plan are available and national guidelines for health care IPC are available and disseminated. Selected health facilities are implementing the guidelines, with monitoring and feedback in place. D - National IPC programme available according to the WHO IPC core components guidelines* and IPC plans and guidelines implemented	promoting appropriate antimicrobial use/antimicrobial stewardship activities developed for the community and health care settings. C - National guidelines for appropriate use of antimicrobials are available and antimicrobial stewardship programs are being implemented in some healthcare facilities. D - National guidelines for appropriate use of antimicrobials are available and antimicrobial stewardship programs are being implemented in some healthcare facilities.	relevant stakeholders, based on stakeholder analysis. D - Nationwide, government-supported antimicrobial resistance awareness raising campaign targeting all or the majority of priority stakeholder groups, utilizing targeted messaging accordingly within sectors. E - Routine targeted, nationwide government-supported campaign implemented to raise awareness of priority stakeholders across sectors, with regular monitoring.	them become ineffective (true) – EU average: correct 82%; incorrect 10% D. Taking antibiotics often has side-effects such as diarrhoea (true) – EU average: correct 67%; incorrect 17%		

Indicator	IPC in human healthcare	AMS Guidelines ²¹⁶	Awareness campaigns (human health) ²¹⁷	Knowledge on antibiotics ²¹⁸	Information on the use of antibiotics ²¹⁹	Understanding of the use of antibiotics – when to stop ²²⁰
	nationwide. All health care facilities have a functional built environment (including water and sanitation), and necessary materials and equipment to perform IPC, per national standards. E - IPC programmes are in place and functioning at national and health facility levels according to the WHO IPC core components guidelines. Compliance and effectiveness are regularly evaluated and published. Plans and guidance are updated in response to monitoring.	most health care facilities nationwide. Monitoring and surveillance results are used to inform action and to update treatment guidelines and essential medicines lists. E - National guidelines on optimizing antibiotic use are implemented for all major syndromes and data on use is systematically fed back to prescribers.				

6.3.3. AMS related to pharmacies

Indicator	Laws for sale of	f antibiotics (human health) ²²¹	Ways of obtaining antibiotics in Member States ²²²		
Source	TrACSS	Sale of antibiotics legislation score on the Global Health Security Index ²²³	Eurobarometer 2022		
Year	2020/2021	2021	2022		
Austria	Yes	Score: 2 Austria has legislation requiring prescriptions for antibiotic use for humans, and there is no evidence of gaps in enforcement.	84% from medical practitioner, 14% not from a medical practitioner		
Belgium	Yes	Score 2 Belgium has in place laws or regulations controlling use of antibiotics in human health, and there is no evidence of any gaps in enforcement	84% from medical practitioner, 16% not from a medical practitioner		
Bulgaria	Yes	Score 1 Current legislation published by the Ministry of Health and the Bulgarian Drug Agency requires prescriptions for antibiotic use for humans, however, the implementation of existing laws and regulations needs closer monitoring in practice.	87% from medical practitioner, 13% not from a medical practitioner		
Croatia	Yes	Score 2 Croatia has national legislation or regulation in place requiring prescriptions for antibiotic use for humans and there is no evidence of weaknesses in enforcement of legislation.	89% from medical practitioner, 11% not from a medical practitioner		
Cyprus	Yes	Score 0 Cyprus has no regulations in place requiring	94% from medical practitioner, 6% not from a medical practitioner		

²²¹ Question in TrACCS survey: Country has laws or regulations on prescription and sale of antimicrobials, for human use.

²²² Question in Eurobarometer: How did you obtain the last course of antibiotics that you used?

²²³ Question in 2021 Global Health Security Index: Is there national legislation or regulation in place requiring prescriptions for antibiotic use for humans?

Indicator	Laws for sale of antibiotics (human health) ²²¹		Ways of obtaining antibiotics in Member States ²²²
		prescriptions for the sale of antibiotics for human use	
		and there is no evidence of a legal requirement for prescription on the websites of the Ministry of Health.	
Czechia	Yes	Score 2 The Czech Republic legally requires prescriptions for antibiotic use for humans, and there is no evidence of gaps in enforcement.	98% from medical practitioner, 2% not from a medical practitioner
Denmark	Yes	Score 2 There is public evidence that all use of antibiotics for humans require a prescription in Denmark, and there is insufficient evidence of gaps in enforcement.	96% from medical practitioner, 3% not from a medical practitioner
Estonia	Yes	Score 2 In Estonia prescriptions are required for antibiotic use for humans, and there is little to no evidence of gaps in enforcement.	88% from medical practitioner, 11% not from a medical practitioner
Finland	Yes	Score 2 Finland has national legislation and regulation requiring prescriptions for antibiotic use for humans and there is no evidence of gaps in enforcement the existing regulation.	94% from medical practitioner, 6% not from a medical practitioner
France	Yes	Score 2 France has in place legislation establishing that a prescription is required for all antibiotic use in humans and there is no evidence of gaps in enforcement the existing regulation.	94% from medical practitioner, 6% not from a medical practitioner
Germany	Yes	Score 2 Germany has legislation requiring prescriptions for antibiotic use for humans, and there is no evidence of gaps in enforcement.	95% from medical practitioner, 3% not from a medical practitioner
Greece	Yes	Score 1 There is national legislation in place requiring prescriptions for antibiotic use for humans, but there is evidence of gaps in enforcement.	94% from medical practitioner, 6% not from a medical practitioner
Hungary	Yes	Score 2 Prescriptions are required for antibiotics in Hungary, and there is no evidence of gaps in enforcement.	87% from medical practitioner, 13% not from a medical practitioner

Indicator	Laws for sale of ant	tibiotics (human health) ²²¹	Ways of obtaining antibiotics in Member States ²²²
Iceland	Yes	Score 2 There is evidence that Iceland has national legislation or regulation in place requiring prescriptions for antibiotic use for humans and there is nothing suggesting gaps in the enforcements of these regulations.	N/A
Ireland	Yes	Score 1 There is evidence of national legislation or regulation in place requiring prescriptions for antibiotic use for humans in Ireland, but there is evidence of gaps in enforcement.	90% from medical practitioner, 10% not from a medical practitioner
Italy	Yes	Score 1 Italy's laws require prescriptions for antibiotic use by humans and mandate good pharmaceutical practice and classification rules for the disbursal of medicines. However, there is some evidence of gaps in enforcement.	90% from medical practitioner, 10% not from a medical practitioner
Latvia	Yes	Score 1 There are national legislation/regulations in place requiring prescriptions for antibiotic use for humans, but there is evidence of gaps in enforcement.	89% from medical practitioner, 11% not from a medical practitioner
Lithuania	Yes	Score 1 Prescriptions are required for human antibiotics, but there is evidence of gaps in enforcement. Although there is no evidence of a legislation explicitly requiring prescriptions for antibiotics on the websites of the Ministry of Health and the State Medicine Control Agency, antibiotics are listed as prescription drugs.	91% from medical practitioner, 9% not from a medical practitioner
Luxembourg	Yes	Score 2 Luxembourg has legislation requiring prescriptions for antibiotic use for humans, and there is no evidence of gaps in enforcement.	90% from medical practitioner, 9% not from a medical practitioner
Malta	Yes	Score 2 Malta has national legislation and regulations in place	90% from medical practitioner, 10% not from a medical practitioner

Indicator	Laws for sale of antibiotics (human health) ²²¹		Ways of obtaining antibiotics in Member States ²²²
		requiring prescriptions for antibiotic use for humans and there is no evidence of gaps in enforcement.	
Netherlands	Yes	Score 2 The Netherlands has regulations for sale or prescribing antibiotics in humans, and there is no evidence of gaps in enforcement.	94% from medical practitioner, 5% not from a medical practitioner
Norway	Yes	Score 2 There is national legislation or regulation in place requiring prescriptions for antibiotic use for humans, and there is no evidence of gaps in enforcement.	N/A
Poland	Yes	Score 1 In Poland most antibiotics for human use require a prescription, and there is no evidence of gaps in enforcement, but less common antibiotics require no prescription.	97% from medical practitioner, 3% not from a medical practitioner
Portugal	Yes	Score 2 Portugal has national legislation in place requiring prescriptions for antibiotics use for humans and there is no evidence of gaps in enforcement.	90% from medical practitioner, 8% not from a medical practitioner
Romania	Yes	Score 1 National legislation in Romania requires prescriptions for antibiotic use for humans, however there is evidence of gaps in enforcement.	80% from medical practitioner, 19% not from a medical practitioner
Slovakia	Yes	Score 2 Prescriptions are required for antibiotic use for humans in Slovakia, and there is no evidence of gaps in enforcement.	92% from medical practitioner, 8% not from a medical practitioner
Slovenia	Yes	Score 2	89% from medical practitioner, 9% not from a medical practitioner

Indicator	Laws for sale of antibiotics (human health) ²²¹		Ways of obtaining antibiotics in Member States ²²²
		National regulations in Slovenia require prescriptions for animal antibiotics and there is no evidence of gaps in enforcement.	
Spain	Yes	Score 1 Spain has national legislation in place requiring prescriptions for antibiotic use for humans, but there is evidence of gaps in enforcement.	95% from medical practitioner, 5% not from a medical practitioner
Sweden	Yes	Score 2 In Sweden, there are national requirements for prescriptions for antibiotic use in humans and the usage is very low.	89% from medical practitioner, 11% not from a medical practitioner

6.4. Annex 4: Bibliography

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