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In response to information provided by the competent authorities, any factual error noted in the draft report has been corrected; any clarification appears in the form of a footnote.

Executive Summary

The European Centre for Disease Prevention and Control (ECDC) and the European Commission's Directorate General for Health and Food Safety jointly carried out this country visit to Sweden from 16 to 20 September 2024. The visit was at the invitation of the Swedish government, to assist in the review of their national strategy and plan for tackling antimicrobial resistance (AMR), based on a One Health approach.

Sweden has among the lowest levels of AMR and antimicrobial consumption in Europe and has made a long-standing effort to prevent the emergence and spread of AMR through promoting appropriate use of antibiotics in both humans and animals. There have been longstanding, joint national activities in human and animal health and food, and more recently in the environmental sector, addressing the risk of AMR in a truly One Health fashion. The collaboration between different authorities and stakeholders on a national level is coordinated through the Intersectoral Coordinating Mechanism. Joint reporting and communication activities resulted in broad awareness among all the relevant actors and society about the risk of AMR and importance of maintaining the effectiveness of antibiotics. This, together with the political commitment of considering AMR as an issue of high priority, nationally and internationally, could be considered the key elements of success of Sweden in addressing AMR.

The national One-Health strategy on AMR and the Swedish One-Health cross-sectoral action plan are coming to an end in 2025. As the review process has now started, this is an opportunity for finetuning the strategy and the plan, and this report includes many observations and considerations intended for their review.

In the human health sector, long-standing activities promoting appropriate use of antibiotics through the unique Strama programme, wide use of treatment guidelines and point-of-care tests, and access to high-quality laboratory services, resulted in low antibiotic use and a favourable AMR situation compared to other EU/EEA countries, including low prevalence of multidrug-resistant organisms (MDROs). Infection prevention and control (IPC) is viewed as an essential requirement for safe patient care with designated infection control teams in the regions and IPC doctors and IPC nurses in healthcare settings. Comprehensive risk-based MDRO screening allows for the rapid control and prevention of outbreaks. However, the focus of IPC is mainly personal and environmental hygiene, as well as the use of PPE, with less emphasis on the implementation of prevention bundles such as for the proper use and management of indwelling devices. While there are good quality data on MDROs, there is a lack of systematically collected actionable surveillance data on hospital acquired infections.

In the veterinary sector, the successful Swedish model based on the principle: 'Healthy animals do not need antibiotics' consists of: a) long-standing efforts by the authorities and stakeholders to eradicate and control various notifiable diseases, resulting in an exceptionally good animal health situation; b) comprehensive monitoring of AMR predating the European Union's harmonised surveillance system; and c) collection of data on

antimicrobial consumption by the competent authorities and stakeholders; and d) national requirements for IPC in veterinary settings (a best practice model for other Member States to follow). There were, however, concerns about the availability of veterinarians, and some indication that additional training may be needed to ensure that all are fully familiar with the Swedish model and their obligations when prescribing antimicrobials. While the overall picture of compliance was positive, challenges were faced in implementing the official controls as planned, highlighting the need to redefine the risk criteria to streamline the selection of veterinarians and establishments to be inspected.

In the environmental sector, there is a vast body of research, in particular in the role of wastewater in the occurrence of AMR. The first full-scale wastewater treatment plants utilising advanced treatment methods are now in operation. In 2025, the competent authorities will pilot financial incentives scheme promoting the sustainable production of pharmaceuticals. There is an important need to develop a framework for systematic surveillance of antimicrobials, AMR resistant bacteria and resistance genes in the environment.

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ANNEX 1 – LEGAL REFERENCES

Abbreviation	Explanation			
AMR	Antimicrobial resistance			
AMEG	Antimicrobial Advice ad hoc Expert Group			
AMS	Antimicrobial stewardship			
ASF	African Swine Fever			
AST	Antimicrobial susceptibility testing			
BI	Behavioural insights			
BCW	Behaviour Change Wheel			
CARe	Centre for Antibiotic Resistance Research			
СОМ-В	Capability (C), opportunity (O), and motivation (M) as key factors capable of changing behaviour (B)			
CPD	Continuing professional development			
CRE	Carbapenem-resistant Enterobacterales			
CRP	C-reactive protein			
DDD	Defined daily dose			
ECDC	European Centre for Disease Prevention and Control			
EFSA	European Food Safety Authority			
EMA	European Medicines Agency			
EQA	External quality assessment			
ESC	Extended-spectrum cephalosporin			
ESBL	Extended-spectrum beta-lactamase			
ESBLA	ESBL plasmid-mediated, inhibited by clavulanic acid (A = classical)			
ESBL _M	ESBL inhibited by cloxacillin, also called plasmid-mediated AmpC (M = miscellaneous)			
ESBL _{CARBA}	ESBL with carbapenemase activity, also called ESBL CPE			
ESVAC	European Surveillance of Veterinary Antimicrobial Consumption			
EU	European Union			
EUCAST	European Committee on antimicrobial susceptibility testing			
GAC	Granular activated carbon			
GAP	Global action plan on AMR			
GP	General practitioner			
HAI	Healthcare-associated infection			
ICM	Intersectoral coordinating mechanism			
ICU	Intensive care unit			
IPC	Infection prevention and control			
Läkemedelsregistret	National Prescribed Drug Register			

ABBREVIATIONS AND DEFINITIONS USED IN THIS REPORT

Abbreviation	Explanation		
LIMS	Laboratory information management system		
LTCF	Long-term care facility		
MALDI-TOF MS	Matrix-assisted laser desorption/ionisation-time of flight mass spectrometry		
MDR(O)	Multidrug-resistant (organism)		
MPA	(Swedish) Medical Products Agency		
MRSA	Meticillin-resistant Staphylococcus aureus		
MRSP	Meticillin-resistant S. pseudintermedius		
NAP	National action plan		
NRL	National Reference Laboratory		
OH-NAP	One Health - National Action Plan		
PCU	Population correction unit		
PHAS	Public Health Agency of Sweden		
PNSP	Penicillin-non-susceptible Streptococcus pneumoniae		
PPE	Personal protective equipment		
PPS	Point prevalence survey		
SALAR/SKR	Swedish Association of Local Authorities and Regions		
SBA	Swedish Board of Agriculture		
SLU	Swedish University of Agricultural Sciences		
Strama	Swedish strategic programme against antibiotic resistance		
SVA	Swedish Veterinary Agency		
SVASP	Swedish Veterinary Network for Antibiotic Stewardship		
Svebar	Swedish national monitoring system for antibiotic resistance (Svensk bevakning av antibiotikaresistens)		
THP	Tailoring Health Programmes		
ViLA	Conditional use of medicinal products (Villkorad läkemedelsanvändning).		
VMP	Veterinary medicinal product		
VMP Regulation	Regulation (EU) 2019/6 on veterinary medicinal products		
VRE	Vancomycin-resistant Enterococcus spp.		
WGS	Whole genome sequencing		
WHO	World Health Organization		
WOAH	World Organisation for Animal Health, previously known as OIE		
WWTP	Wastewater treatment plant		

1 INTRODUCTION

The European Centre for Disease Prevention and Control (ECDC) and the European Commission's Directorate-General for Health and Food Safety were invited by the Swedish government through the Ministry of Health and Social Affairs to carry out a joint country visit from 16 to 20 September 2024. The visit followed-up on the Commission's One Health Action Plan against antimicrobial resistance (AMR) published on 29 June 2017 (¹) and reviewed the current status of efforts to tackle AMR in Sweden, in particular, the development and implementation of national strategies and policies against AMR based on a One Health approach.

The ECDC team focussed on the human health aspects of AMR while the Commission team focussed on veterinary aspects and, to a limited extent, environmental aspects. Both teams included national experts from the Member States. This report brings together the main observations and conclusions of the two teams and identifies areas where further developments could be beneficial.

An opening meeting was held on 16 September 2024. At this meeting, the objectives and scope of, and itinerary for, the joint country visit were confirmed.

2 OBJECTIVES AND SCOPE

The overall objective of this joint country visit was to aid the review of the AMR strategies, as requested by Sweden. This objective involved (a) discussing the situation regarding the prevention and control of AMR with the relevant competent authorities, professional organisations and other stakeholders, and (b) exchanging information on examples of good practice implemented by Sweden and other Member States in addressing these issues, which could potentially be helpful in further developing and implementing national AMR strategies.

The scope of this joint country visit was as follows:

- For the human aspects of AMR, the visit focussed on the prevention and control of AMR through the prudent use of antimicrobials, and infection prevention and control (IPC).
- For the veterinary aspects of AMR, the visit focussed on the policies to tackle AMR through the reduced and more prudent use of antimicrobials, and national requirements for IPC practices in veterinary settings.
- The discussions on the national AMR strategies, action plans and inter-sectoral coordination and cooperation took into account relevant guidance and documentation, from various EU and international organisations: the European Medicines Agency (EMA) (²), the European Food Safety Authority (EFSA) (³) and, specifically, the *Manual for developing national action plans* jointly adopted by the World Health Organization (WHO), the Food and

¹ <u>https://ec.europa.eu/health/amr/sites/amr_files/amr_action_plan_2017_en.pdf</u>

² http://www.ema.europa.eu/ema/index.jsp?curl=pages/special_topics/general/general_content_000439.jsp& mid=WC0b01ac0580a7815

³ <u>https://www.efsa.europa.eu/en/topics/topic/antimicrobial-resistance</u>

Agriculture Organization (FAO) of the United Nations, the World Organisation for Animal Health (WOAH – previously known as the OIE) (⁴).

In pursuit of these objectives, the following meetings and visits took place:

Visits / Meetings		No	Comments
Competent authority	Central	3	Opening and closing meetings with Ministry of Health and Social Affairs, Ministry of Rural Affairs and Infrastructure, Public Health Agency of Sweden (PHAS), The National Board of Social Affairs and Health, Swedish Board of Agriculture (SBA), Swedish Veterinary Agency (SVA), Swedish Medical Products Agency (MPA), Swedish Food Agency (SFA), Swedish Research Council, National Board of Health and Welfare, Swedish Work Environment Authority, Swedish Environmental Protection Agency, Dental and Pharmaceutical Benefits; communications meeting with PHAS and SBA Professional associations and other stakeholders, such as the Research
X 7.4		4-1	Institutes of Sweden were also present at the meetings.
Veterinary a	ind environmen	ital aspects	
Competent authority		2	Day 2: SBA, County Administrative Board (CAB), SVA, SFA, MPA; Day 3 representatives of SBA and local CAB present
		1	Day 1 (meeting on environmental aspects of AMR): Swedish Environmental Protection Agency SBA, SVA, MPA, SFA, Swedish Research Council, PHAS
Visits		1	Small animal hospital in Stockholm
Professional associations and other stakeholders		2	Day 1: Swedish University of Agriculture (SLU), University of Gothenburg, Lund University, University of Kristianstad; Day 2: Meeting with stakeholders: SLU, SVA, Swedish Veterinary Association, The District veterinarians, Farm and Animal Health, Federation of Swedish Farmers, Växa Sverige, _Lunden Animal Health, Swedish Poultry Meat Association, Swedish Egg Association, The Swedish Horse Industry Foundation, _Swedish Meat Industry Association, Axfoundation, veterinarians, farmers/animal keepers (dairy, beef, pig, poultry, and horse)
Human heal	th aspects		
Competent authority		3	Day 1: PHAS, MPA, National Board of Health and Welfare, Swedish Work Environment Authority Day 2-3: PHAS
Professional associations and other stakeholders		1	National Working Group Strama, National Working Group for IPC, Swedish Association for Infection Control, Swedish Association of General Practice, Swedish Association for Clinical microbiology, Association of County Medical Officers for Communicable Disease Control, Swedish Association of Health Professionals, The Swedish Society of Infectious Disease specialists, local Strama and local IPC groups, National Dental Care-Strama
Hospitals		3	Västmanland Hospital in Västerås (including visits to medical ward, intensive care unit (ICU) and microbiology laboratory), Enköping hospital in Enköping (including visits to medical ward, surgical ward and intermediate care ward), Karolinska University Hospital in Stockholm (including visits to surgical ward, ICU and microbiology laboratory).

⁴

http://apps.who.int/iris/handle/10665/204470 In 2018, the 3 organisations (WHO, WOAH, FAO) formed the Tripartite. In 2022, they were joined by the United Nations Environment Programme and became formally as the Quadripartite. The Quadripartite has recently launched the AMR Multi-Stakeholder Partnership Platform: https://www.fao.org/antimicrobial-resistance/quadripartite/the-platform/en/

Laboratory	1	PHAS reference laboratory	
Long-term care facility (LTCF)	1	LTCF in Stockholm	
General practitioners (GPs)	1	GP in Stockholm	
Community pharmacy	1	Pharmacy in Västerås	

A list of the legal instruments referred to in this report is provided in Annex I and refers, where applicable, to the last amended version at the time of the visit.

3 BACKGROUND

Joint country visits are one of the many initiatives set out in the EU One Health Action Plan against AMR (⁵) and contribute to its aim of making the EU a best practice region in the fight against AMR. The term 'One Health' recognises that human and animal health are interconnected, that diseases are transmitted from one to the other, and that the threat of AMR should therefore be tackled in both. The One Health approach also encompasses the environment as another link between humans and animals and likewise a potential source of new antimicrobial-resistant organisms. The importance of adopting a One Health approach to tackling AMR has been recognised globally.

In 2015, the 68th World Health Assembly, endorsed by the FAO and OIE, adopted the WHO global action plan on AMR (GAP) (⁶). In 2016, the 71st session of the UN General Assembly adopted a political resolution $(^{7})$ reaffirming that the blueprint for tackling AMR is the GAP and its five overarching strategic objectives. In the EU, the 2016 Council Conclusions (⁸) called on Member States to have in place, by mid-2017, national action plans (NAPs) based on a One Health approach and in line with the GAP objectives. The 2019 Council Conclusions (⁹) further elaborated on the necessary features of the NAPs, to ensure that all relevant initiatives contributing to the fight against AMR are pursued within a coherent framework, that maximises the impact of each action. In addition, in 2023, the Council adopted a new Recommendation (¹⁰) aimed at stepping up EU action to combat AMR in a 'One Health' approach, calling for voluntary actions in human health, animal health and the environment. The proposed measures include: (a) targets to reduce antimicrobial use by 2030, including a 20% reduction in total human consumption of antibiotics and a 50% reduction in overall EU sales of antimicrobials used for farm animals and aquaculture, (b) strengthening of the NAPs to help implement these targets and monitor the use of antibiotics to assess progress, (c) better surveillance of AMR and antimicrobial consumption at all levels, (d) efforts to improve the

⁵ https://health.ec.europa.eu/system/files/2020-01/amr_2017_action-plan_0.pdf

⁶ <u>http://www.who.int/antimicrobial-resistance/national-action-plans/en/</u>

⁷ Political Declaration of the High-Level Meeting of the General Assembly on Antimicrobial Resistance: (un.org)

⁸ Council conclusions on the next steps under a One Health approach to combat antimicrobial resistance (2016/C 269/05). OJ C 296, 23.7.2016, p. 26.

⁹ Council conclusions on the next steps towards making the EU a best practice region in combatting antimicrobial resistance (2019/C 214/01). OJ C 214, 25.6.2019, p. 1.

¹⁰ Council Recommendation on stepping up EU actions to combat antimicrobial resistance in a One Health approach 2023/C 220/01. OJ C 220, 22.6.2023, p. 1.

health and welfare of food-producing animals to decrease the spread of infectious diseases in farming, and (e) awareness raising among the public and all relevant professionals.

Joint country visits aim to support Member States in the design and implementation of their NAPs, and to build upon previous work carried out by the ECDC and the Commission.

In the human health sector, ECDC has developed a process for country visits to discuss and assess the situation regarding the prevention and control of AMR through the prudent use of antibiotics and IPC. These are based on Council Recommendation of 15 November 2001 on the prudent use of antimicrobial agents in human medicine (¹¹), which invites Member States to consider a range of actions to be taken to prevent and control the development of AMR. The Council conclusions on AMR of 10 June 2008 (¹²) reiterated the call for action to tackle AMR. On 9 June 2009, the Council adopted a Recommendation on patient safety including the prevention and control of healthcare-associated infections (¹³), which further stressed the importance of combating AMR as a patient safety issue. In response to a call contained in the Council Conclusions on the next steps under a One Health approach to tackle AMR of July 2016 (¹⁴), EU guidelines on the prudent use of antimicrobials in human health were published in June 2017 (¹⁵).

In the veterinary sector and as part of the Commission's work to tackle AMR, the Directorate for Health and Food Audits and Analysis of the Directorate-General for Health and Food Safety carried out a project on the Member States' measures to tackle AMR relating to the use of veterinary medicines. The project also identified examples of good practice, which could potentially be helpful to other Member States in addressing this issue, and took into account the guidelines for prudent use of antimicrobials in veterinary medicine, which were published in 2015 (¹⁶). As part of this project, between 2016 and 2018, the Directorate carried out 14 fact-finding missions, with a final overview report published in 2019 (¹⁷). The report of the visit to Sweden within this project (ref. DG(SANTE)2017-6201 – hereafter, the prudent use report) (¹⁸) should be read in conjunction with the present report.

¹¹ <u>https://eur-lex.europa.eu/legal-content/EN/TXT/?qid=1571828703539&uri=CELEX:32002H0077</u>

¹² http://www.consilium.europa.eu/ueDocs/cms_Data/docs/pressData/en/lsa/101035.pdf

 $[\]frac{13}{\text{https://eur-lex.europa.eu/legal-content/EN/TXT/?qid=1571829439267\&uri=CELEX:32009H0703(01)}$

¹⁴ <u>https://publications.europa.eu/en/publication-detail/-/publication/963104ce-5096-11e6-89bd-01aa75ed71a1/language-e</u>

¹⁵ <u>https://eur-lex.europa.eu/legal-content/EN/ALL/?uri=OJ%3AC%3A2017%3A212%3ATOC</u>

¹⁶ <u>http://ec.europa.eu/health/antimicrobial_resistance/docs/2015_prudent_use_guidelines_en.pdf</u>. While they are still valid, some of the aspects covered by the guidelines are now governed by EU legislation, in particular the preventive use of antimicrobials:

⁻ Regulation (EU) 2019/6 of the European Parliament and of the Council on veterinary medicinal products and repealing Directive 2001/82/EC, OJ L 4, 7.1.2019, p. 43 (hereafter, the VMP Regulation), and

⁻ Regulation (EU) 2019/4 of the European Parliament and of the Council 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, OJ L 4, 7.1.2019, p. 1.

¹⁷ <u>https://publications.europa.eu/en/publication-detail/-/publication/be1710ba-b1aa-11e9-9d01-</u>

⁰¹aa75ed71a1/language-en/format-PDF/source-search

¹⁸ <u>https://ec.europa.eu/food/audits-analysis/audit-report/details/3957</u>

More recently, the Directorate has conducted a review of EU Member States' One Health NAPs (including the NAPs submitted by Sweden). An overview report summarising the findings was published in 2022 (¹⁹).

ECDC's mission, as set out in Regulation (EC) 2022/2370 of the European Parliament and the Council amending its Founding Regulation (Regulation (EC) No 851/2004 of the European Parliament and of the Council) (²⁰), is to identify, assess and communicate current and emerging threats to human health from communicable diseases, to report thereon and, where appropriate, to ensure that information thereon is presented in an easily accessible way. As part of this mission, ECDC may organise on-site visits in Member States, on a case-by-case basis, in close collaboration with the Member States concerned, to provide additional support to prevention, preparedness and response planning activities.

ECDC and EFSA have published a summary report on AMR in bacteria from humans, animals and food, including data from Sweden (European Union summary report on AMR in zoonotic and indicator bacteria from humans, animals and food in 2021-2022) (²¹). ECDC, EFSA and the EMA have also issued a fourth joint report on the integrated analysis of the consumption of antimicrobial agents and occurrence of AMR in bacteria from humans and food-producing animals (Joint Interagency Antimicrobial Consumption and Resistance Analysis report – JIACRA IV), including data from Sweden (²²). These reports largely draw conclusions for the EU based on the complete range of data available.

4 OBSERVATIONS AND CONCLUSIONS

4.1 AMR STRATEGIES, ACTION PLANS AND COORDINATION, BASED ON A ONE HEALTH APPROACH

4.1.1 National strategies and action plans on AMR

1. Sweden has made long-standing efforts to promote appropriate use of antibiotics, both in the human and animal health sectors and based on evidence-based guidelines, as well as the prevention of infections. Thanks to the political commitment as well as broad AMR awareness and involvement of the relevant actors and society, Sweden has one of the lowest levels of AMR and antimicrobial consumption in Europe. Sweden has also played a significant international role in advocating for action, applying innovative approaches and supporting other countries in their effort to control AMR. Many of these efforts predate the first Swedish AMR strategy, which was published in 2005. Moreover, Sweden has a national 10-year research programme for antibiotic resistance, with a strategic research agenda outlining priority areas for knowledge generation to support AMR mitigation efforts.

¹⁹ <u>https://health.ec.europa.eu/publications/overview-report-member-states-one-health-national-action-plans-against-antimicrobial-resistance_en</u>

²⁰ <u>https://eur-lex.europa.eu/eli/reg/2022/2370/oj</u>

²¹ https://www.efsa.europa.eu/en/efsajournal/pub/8583

Fourth joint report on the integrated analysis of the consumption of antimicrobial agents and occurrence of antimicrobial resistance in bacteria from humans and food-producing animals (JIACRA IV 2019-2021) (europa.eu)

- 2. The current national strategy on AMR for 2020-2023 has been extended to 2025. The strategy includes seven major strategic objectives, addressing availability of surveillance data, prevention of infections, the responsible use of antibiotics, research, public awareness, supporting structures and functions, and international cooperation.
- 3. The national strategy is partly implemented through a One-Health, cross-sectoral action plan on AMR for 2021-2024, which has also been extended to 2025. Together, the strategy and the action plan, constitute the One-Health National Action Plan (hereafter OH-NAP). The action plan includes activities addressing each of the seven objectives of the national strategy. It defines the leading and contributing national agencies and other contributing actors, as well as a timeframe for the implementation of each action. The cross-sectoral action plan only includes activities that require the involvement of more than one agency or actor within or across sectors. Therefore, relevant activities are not addressed in the action plan. The national agencies' activities on AMR are reported separately on a yearly basis to the government.
- 4. The Public Health Agency of Sweden (PHAS) and the Swedish Board of Agriculture (SBA) are responsible for leading the intersectoral coordinating mechanism (ICM) that is responsible for the development and implementation of the cross-sectoral action plan (see 4.1.2 below). There is no specified budget for the activities in the cross-sectoral action plan. The activities must therefore be funded by the regular budget of the involved agencies.
- 5. The actions and the budget for actions in healthcare depend on prioritization made by the regions. This results in regional heterogeneity of activities, with a possible impact on planning, implementation, monitoring and evaluation and a risk for duplication and missed opportunities. The regions have no action plan for the implementation of required actions on AMR in healthcare. Currently, coordinating the regional work on AMR at a national level is challenging. One of the reasons is that the Swedish Association of Local Authorities and Regions (SALAR/SKR) is not actively participating in the ICM.
- 6. An annual report describes the activities that have been completed or modified and sets out the plan for the coming year. However, the OH-NAP does not include a specified monitoring and evaluation plan with indicators and targets, nor an evaluation of the effectiveness and impact of the actions.
- 7. Finally, the OH-NAP is not explicitly linked to other relevant action plans, such as those related to patient safety.

4.1.2 Multi-sectoral collaboration and coordination, including a One Health approach

8. At governmental level, there is an interdepartmental working group that guides the AMR strategy and ensures the collaboration of the relevant ministries. In addition, Sweden has a well-established ICM with broad involvement of the relevant sectors and stakeholders, and with expertise in the areas related to AMR, including healthcare, public health, animal

health and veterinary medicine, food production and safety, the environment, international development collaboration, research and innovation and trade.

- 9. The ICM is established by a governmental mandate and has clear terms of reference. The ICM has regular meetings and minutes of these meetings are available.
- 10. There is no specific budget allocated to the ICM and its functioning depends on existing resources from the involved agencies, in particular, PHAS and SBA. This, together with existing resource constraints, could pose challenges in maintaining the ICM.
- 11. In a One Health perspective, Sweden reports annually on the sales of antibiotics for humans and AMR in human medicine (Swedres) together with the sales of antibiotics for animals and veterinary AMR monitoring (Svarm) (²³).
- 12. It has been challenging to constructively engage all participating actors, such as the environmental sector, in the ICM. In addition, there is no formal participation of relevant actors from educational bodies and the civil society.

4.1.3 Conclusions on AMR strategies, action plans and coordination based on a One Health approach

In Sweden, there have been long-standing, joint, national activities addressing AMR in the human and animal health and food sectors as well as, more recently, in the environmental sector. These activities are incorporated in the national AMR strategy, which is coming to an end in 2025, and have been implemented through a One-Health cross-sectoral action plan for 2021-2025. The ICM overseeing execution of the action plan has representatives from all the above-mentioned sectors and includes the leading and contributing national agencies, and other contributing actors. The plan, however, only includes joint actions implemented by more than one agency or actor within or across sectors and therefore does not include all the relevant activities on AMR. This, together with the lack of indicators and targets, limits the possibilities for tracking progress and evaluating the effectiveness and impact of the strategy and the One-Health cross-sectoral action plan. In addition, there is no specific budget for implementing the actions in the plan, which solely depends on available budget from the contributing actors. Nevertheless, the multi-sectoral collaboration and political commitment to consider the fight against AMR as a high priority, nationally and internationally, is one of the key elements in Sweden's success in this area.

4.2 HUMAN HEALTH ASPECTS OF AMR (ECDC)

4.2.1 Organised multi-disciplinary collaboration

13. In Sweden, there is a strong tradition of multi-disciplinary collaboration at the local level. A typical example is the establishment and evolution of the Swedish strategic programme

²³ <u>https://kxs-sva.euwest01.umbraco.io/media/rrrbjnyl/svakom230-2023-v1-swedres-svarm-2023.pdf</u>

against antibiotic resistance (Strama) that has national, regional and local components bringing together medical doctors, pharmacists and other disciplines to promote appropriate use of antimicrobials. At regional level, Strama groups are often working closely with IPC teams and are building collaboration platforms to develop a common approach, both at regional and national levels. This is supported by the regional Strama budgets, which are decided at regional level, and facilitated by the national Strama coordinating group, which is funded by the Ministry of Health. In addition, local Strama and IPC teams have a broad scope supporting relevant activities in both primary and longterm care.

4.2.2 Clinical diagnostic and reference laboratory services

- 14. Point-of-care tests including C-reactive protein (CRP) and rapid antigen detection tests for group A Streptococcus were available in the primary healthcare centre visited. This centre also reported having good access to microbiology services and received results without perceived delay. In the hospitals visited, clinical microbiology laboratories performed species identification with matrix assisted laser desorption/ionisation time of flight mass spectrometry (MALDI-TOF MS) and antimicrobial susceptibility testing (AST) with disk diffusion using the European Committee on AST (EUCAST) breakpoints. Microbiology services in the regional hospital visited were available six days per week during regular working hours and 24/7 in the university hospital. The results were reported electronically via interfaces to the clinical management system. Urgent results such as positive blood cultures were transmitted by telephone. The university hospital laboratory performed bacterial identification with MALDI-TOF MS within 4 hours from positive blood cultures and rapid AST according to EUCAST methodology. The microbiologists had direct access to the electronic medical charts for information on antimicrobial treatment and the potential focus of infection.
- 15. Laboratories only perform AST for a limited number of antibiotics with disk diffusion based on recommendations of the "Reference group on antimicrobial therapy" (*Referensgruppen för antibiotikafrågor*). Further guidance on AST is also available from the NordicAST collaboration with Denmark, Finland, Iceland and Norway. All clinical microbiology laboratories in Sweden are accredited and participate in required external quality assessment (EQA) exercises. Screening of patients at high risk for carriage of multidrug-resistant (MDR) bacteria was performed at hospital level and in primary care. Screening cultures were processed in the laboratories visited with selective agar plates and/or PCR depending on the pathogen.
- 16. Sweden has 37 nominated national reference laboratories in the reference laboratory network (*Svenskt laboratorienätwerk inom mikrobiologi*). Reference services for phenotypic AST are located: i) at the clinical microbiology laboratories in Karlskrona and Växjö, and complementary National Reference Laboratories (NRLs) for phenotypic AST of anaerobic bacteria at Karolinska University Hospital, and ii) for confirmatory and genomic testing at the Public Health Agency of Sweden (PHAS).

17. In total, 26 microbiological characterisation programmes are in place complementing surveillance and reporting, of which eight are related to AMR and include carbapenem-resistant *Acinetobacter baumannii*, carbapenem-resistant Enterobacterales (CRE), carbapenem-resistant *Pseudomonas aeruginosa*, *Clostridioides difficile*, penicillin-non-susceptible *Streptococcus pneumoniae* (PNSP), meticillin-resistant *Staphylococcus aureus* (MRSA), vancomycin-resistant *Enterococcus* spp. (VRE), and targeted resistance surveillance. For these pathogens, the NRL at PHAS performs confirmatory species identification, AST and whole-genome-sequencing (WGS). PHAS is currently upgrading its WGS capacity from short-read sequencing with Ion Torrent® to long-read sequencing with Oxford Nanopore® technology. The WGS infrastructure is also decentralised and implemented in the regions.

4.2.3 Monitoring of AMR in human health

- 18. The national monitoring system for AMR (*Svensk bevakning av antibiotikaresistens* Svebar) is collecting comprehensive data from clinical laboratories for all processed cultures (including negative cultures) and all sample types and tested antimicrobials. Participation is voluntary and 22 of 26 clinical laboratories in Sweden submit data to Svebar. Although the missing four laboratories correspond to four missing regions, the population coverage of Svebar is about 89%. The remaining four laboratories will be connected during 2025. Currently, Svebar is accessible for PHAS and participating laboratories. An alert function for emerging pathogens or unusual resistance is also covered by Svebar, where for example an alert for detection of Candida auris has been implemented. A downside of the current Svebar is that it does not allow to easily generate AMR statistics and related overviews. Due to the high amount of data, the Svebar software can only handle analysis of about two months of data at the same time. A new version of Svebar (Svebar 2.0) will be launched in early 2025 with major technical updates and a new interface. There are also plans to integrate a data visualisation tool in Svebar to enable easy access to AMR reports and trends.
- 19. Additional data regarding AMR come from the mandatory electronic reporting system of notifiable pathogens (SmiNet) and includes CRE, extended-spectrum beta-lactamase (ESBL)-producing Enterobacterales, MRSA, PNSP and VRE. The respective case numbers are updated monthly and are publicly available by year and region. A comparative analysis of data from the mandatory reporting in SmiNet and the voluntary surveillance in Svebar is reported publicly. Each year, Sweden reports on AMR in human medicine as part of the publicly available One Health Swedres-Svarm report (²⁴).
- 20. In contrast to the national level, comprehensive hospital-specific AMR statistics were not presented in the hospitals visited. In the regional hospital laboratory, such statistics could not be extracted easily out of the laboratory information management system (LIMS) requiring time-consuming manual work and possibly posing challenges in the analyses and interpretation of the findings. A potential explanation of these challenges was that hospitals acquired software for all laboratory services with less specific features for

²⁴ <u>https://www.sva.se/en/what-we-do/antibiotics/svarm-resistance-monitoring/swedres-svarm-reports/</u>

microbiology. In the university hospital, the team was informed that resistance statistics could be extracted, but that required additional manual work for specific questions. Local resistance statistics were available for the Stockholm region for key pathogens based on the data from facilities served by the Karolinska University Hospital laboratory. However, local or national data for specific settings such as long-term care facilities (LTCFs) were not available. In addition, based on the presentations to the visiting team, the antimicrobial stewardship (AMS) and IPC teams did not seem to routinely use detailed local AMR surveillance data for planning and monitoring of their activities.

21. At international level, Sweden participates in several ECDC surveillance networks including the European Antimicrobial Resistance Surveillance Network (EARS-Net), the European Antimicrobial Resistance Genes Surveillance Network (EURGen-Net), the Food-and Waterborne Diseases and Zoonoses Network (FWD-Net) for *Salmonella* species, the European Gonococcal Antimicrobial Surveillance Programme (Euro-GASP), the European Reference Laboratory Network for Tuberculosis (ERLTB-Net) and in the WHO Global Antimicrobial Resistance and Use Surveillance System (GLASS).

4.2.4 Monitoring of antibiotic consumption in human health

- 22. The publicly available Swedres-Svarm report, which is published annually, includes data on antibiotic consumption and on AMR in a One Health perspective (see section 4.1.2).
- 23. Comprehensive national/regional, outpatient antibiotic consumption sales data, with different levels of granularity are easily available on the PHAS website. They seem to meet the needs of the AMS personnel met by the visiting team. There was no specific discussion with the visiting team, or evidence provided, as to the use of such data as part of daily practice in the facilities visited (primary care centre and hospitals) nor with regards to any facility-level antibiotic consumption data. Antibiotic consumption data expressed as defined daily doses (DDDs) per 1,000 inhabitants per day (outpatient and inpatient settings) and number of prescriptions (outpatient setting) per 1,000 inhabitants per year are available, but not DDDs/100 patient-days in hospitals (due to legal reasons) or days-of-therapy (DOTs) in all sectors. Moreover, the potential benefits of using the National Prescribed Drug Register (*Läkemedelsregistret*) (²⁵) maintained by the National Board of Health and Welfare data have not been investigated.
- 24. Quality indicators based on prescription data are available in almost all primary healthcare centres and the visiting team was shown their use in daily practice during the visit to the primary care centre. These quality indicators on the diagnoses reported by the practitioners. In hospitals, the number of available quality indicators (also based on prescription data) is small, and not available in all hospitals. The quality indicators also rely on data reported in the Infection Tool (*Infektionsverktyg*), which may be incorrect or unreliable. Moreover, there is currently no national reporting of these quality indicators data, even though this is a work in progress.

²⁵ <u>https://www.socialstyrelsen.se/statistik-och-data/register/lakemedelsregistret/</u>

25. Antibiotic consumption/use data for long-term care facilities (LTCFs) are available only from point-prevalence surveys performed annually.

4.2.5 Antimicrobial stewardship (AMS) and treatment guidance in human health

- 26. The quite unique, innovative and successful Strama model, which is in place in all regions, has more than 30 years of history. Sharing of knowledge and experience between regions seems efficient and is facilitated by the national Strama coordination. Strama uses a multidisciplinary and multi-sectoral approach, with a collaborative mindset. Strama teams rely mostly on outreach and educational interventions, that are well-known and well-accepted by users. General practitioners (GPs) and hospital practitioners met by the visiting team seemed aware that prudent use of antibiotics is important and tried to contribute to AMS efforts. It is obvious that Strama teams' engagement and continued efforts over the past three decades have been key to achieving the current low antibiotic use and preferred use of narrow-spectrum antibiotics in primary care in Sweden.
- 27. Strama national treatment guidelines are available in several formats and are widely used. Point-of-care tests (CRP, white blood cells (WBC) count and group A streptococcus rapid antigen detection test) seem widely available and used in primary care centres. Having the option of contacting an infectious diseases physician on call during weekdays for advice on the management of challenging cases seems widespread and appreciated by GPs and hospital doctors.
- 28. The "Antibiotic Smart Sweden" project is an innovative initiative aimed at promoting the engagement of stakeholders. "Antibiotic Smart Sweden" acknowledges the work of actors such as organisation, measurement, routines and education related to antimicrobial use and awards the title "Antibiotic Smart" to actors that fulfil specified criteria. Its impact and added value to other existing Strama actions on antimicrobial use in healthcare facilities has not been evaluated.
- 29. The visiting team noted large variations between regions regarding the resources and level of implementation of key AMS activities, that could be a challenge to achieving key outcomes in improving antibiotic use and reducing AMR in Sweden. Most Strama teams seem understaffed; as an example, Strama staffing recommendations (²⁶) were met in only two out of 21 regions. It also seems that systematic monitoring and reporting of structure and process indicators (at facility, regional and national levels) to guide AMS programmes is not performed. Moreover, feedback of antibiotic consumption/use data at department level in hospitals and at prescriber level in primary care is variable. Such feedback does not exist in LTCFs and seems uncommon in dental practices at facility- or prescriber-level. Finally, AMS interventions in hospitals are mainly educational and patient-based (e.g. antibiotic rounds) and include fewer restrictive components compared to other European countries, in part due to cultural and organisational differences.
- 30. Sweden has a long history of stimulating development and of successful efforts with an international leading role to ensure access to existing antibiotics (especially narrow-

²⁶ <u>https://strama.se/wp-content/uploads/2023/10/Foreslagna-minimiresurser-till-regionala-Stramagrupper.pdf</u>

spectrum antibiotics) and to pilot-test innovative models to incentivise access to novel antibiotics.

31. There is currently no per-unit dispensing of antibiotics in Swedish community pharmacies (antibiotics are dispensed by packages). However, the possibility to dispense only the required amount of medicines without the need to discard the remaining ones is currently being explored.

4.2.6 Infection prevention and control (IPC) in human health

- 32. Sweden has a long tradition of IPC within the healthcare system. For many years, IPC and hygiene have been high on the agenda of decision makers who view these initiatives as being essential requirements for safe patient care. This situation was evident in all the visited facilities.
- 33. Swedish law (*Hälso- och sjukvårdslagen* [2017:30]) requires healthcare facilities to have adequate IPC standards as defined by Directives of the National Board of Health and Welfare (e.g., *Basal hygiene i vård och omsorg*) (²⁷).
- 34. There is a national guidance for IPC (*Vägledning för vårdhygieniskt arbete*, 2022) that addresses its eight core components at various organisational levels, based on WHO guidelines on core components of IPC programmes. Furthermore, there is comprehensive national guidance for IPC measures with the focus on standard precautions, cleaning and disinfection, and prevention of infections by specific microorganisms, including multidrug-resistant organisms (MDROs) (*Vårdhandboken*).
- 35. Regional action plans on patient safety often include IPC. There are regional IPC teams consisting of physicians and nurses specialised in IPC. These teams support primary care centres and hospitals, and collaborate with municipalities for providing IPC support to LTCFs.
- 36. In every healthcare setting visited by the team, there were designated IPC doctors and nurses. This was the case both in tertiary care as well as secondary care hospitals.
- 37. There are various factors that the visiting team could identify that undoubtedly support the implementation of high-quality IPC in the country. For a start, the national culture places strong emphasis on collaboration, consultation and dialogue. This clearly supports a collegial environment that is so vital for effective IPC.
- 38. This was seen in several examples throughout our visits, one of which stood out was the acceptance by the staff throughout the healthcare system, irrespective of their grade, to accept peer reminders as being useful tools to help oneself improve and comply effectively with IPC policies. There is an extensive repository of national and local guidelines that are often very detailed and therefore provide good support to healthcare professionals without having the need to regularly resort to IPC experts to ensure the appropriate implementation of IPC practices.

²⁷ In their response to the draft report, the competent authorities noted that, apart from "Basal hygien i vård och omsorg" there are additional relevant legal requirements.

- 39. Sweden has one of the lowest prevalence of MDROs in Europe and this situation has been reasonably maintained despite the significant increase of MDROs in other European countries, leading to the possibility of importation of MDROs, especially through patient transfer and travel. In addition, it has been possible to prevent and quickly control MDRO outbreaks, as illustrated by the low number of such outbreaks reported in Sminet.
- 40. The cornerstone of this success is a comprehensive risk-based MDRO screening programme, which was in place in all facilities visited, even extending to primary care centres. This programme is based on the identification of high-risk individuals/patients, especially those returning from countries with high prevalence of MDROs, and the immediate implementation of screening combined, within hospital settings, with pre-emptive isolation until the screening rules out carriage of MDRO. Information that a patient is MDRO-positive is accessible in the electronic medical records in the form of an alert.
- 41. In addition, the team could identify a very high level of awareness amongst frontline personnel for the need to adhere to strict hygienic precautions both in relation to hand hygiene as well as to the implementation of standard and transmission-based precautions. The hospital infrastructure with a high proportion of single rooms in hospitals is conducive to this effect as is the excellent system of training in hygiene for all newly employed personnel.
- 42. In all the hospitals visited, alcohol-based solutions for hand hygiene as well as personal protective equipment (PPE) were widely available at the point of care. However, it is encouraging to note that despite wide availability, gloves were judiciously used by the staff present at the time of our visit.
- 43. Nevertheless, some gaps were noted in relation to IPC. There are neither formally mandated IPC programmes with action plans, committees or teams at hospital level, nor a national coordinating mechanism. Furthermore, it can be challenging to coordinate IPC in LTCFs, as they are in the remit of the municipalities while the rest of healthcare is managed by the regions.
- 44. The focus on IPC seems to be primarily personal and environmental hygiene, as well as the use of PPE. This was evident in all the visits in hospitals and long-term care facilities.
- 45. However, less emphasis was noted in areas of IPC where evidence shows that impact on healthcare-associated infection prevalence is high. This includes implementation of prevention bundles, especially in relation to the proper use and management of indwelling devices, where little was shown to the visiting team in terms of initiatives and interventions. Whereas in most, if not all, of the healthcare facilities visited, hand hygiene compliance was reported to be high, there was a lack of validation of these results to confirm high hand hygiene compliance. In particular, none of the hospitals visited showed data on alcohol-based hand rub consumption, which could be used as a proxy to confirm high hand hygiene compliance.
- 46. Swedish hospitals have high bed occupancy rates with the occasional provision of care in supplementary beds placed in corridors. This is linked to a reported lack of acute care

beds. High bed occupancy rates are challenging both in terms of staff workload and the appropriate implementation of IPC measures.

- 47. Emphasis on surveillance of HAIs was noted to be variable. Data on surgical site infections were collected by the surgical teams as part of surveillance of post-operative complications. There were limited data on the prevalence or incidence of specific HAIs, even in intensive care units (ICUs). Data on HAIs are available through the Infection Tool that makes possible the reporting of HAIs when antibiotics are prescribed. However, reporting of HAIs in the Infection Tool is based on an assessment by the treating physician that only partially relies on specific criteria fulfilled at the time of the antibiotic prescription. Furthermore, the Infection Tool is not used in all hospitals.
- 48. One of the reasons for the relative lack of HAI surveillance is lack of resources. Ongoing innovative efforts for developing automated or semi-automated surveillance of HAIs based on electronic health record data can make HAI surveillance less resource demanding and improve standardisation.
- 49. Point-prevalence surveys (PPSs) of HAIs were performed annually in acute care hospitals coordinated by the SALAR/SKR. This activity was discontinued in 2023. Sweden performed a nation-wide PPS of HAIs and antimicrobial use in acute care hospitals as part of the European PPS 2022-2023. Sweden has also been participating in the PPS of HAIs and antimicrobial use in European long-term care facilities (Healthcare-associated infections in long-term care facilities (HALT) project).
- 50. However, Sweden does not participate in any of the incidence surveillance modules under ECDC's HAI-Net, i.e. surveillance of surgical site infections, of *C. difficile* infections and of HAIs acquired in intensive care units). Furthermore, there are no objective measurement of the outcome of key HAIs, such as pneumonia, catheter-associated urinary tract infections, and surgical site infections. Lack of data was not only identified in relation to standard surveillance of HAIs, but also in the fact that audits were almost exclusively limited to hygiene-related processes such as hand hygiene and the environment. Very few other audits, particularly those of clinical practices, seemed to be in place, or at least were reported to the visiting team.
- 51. This picture suggests that IPC is focused on standard precautions, as opposed to raising awareness of appropriate medical device management and clinical practices. In addition, the visiting team had the impression that even where audits are undertaken, follow-up seemed to be left in the hands of the end users and the healthcare providers themselves, with little direct involvement of IPC personnel to follow up and ensure that any gaps in practices are addressed. These findings are relevant when noting the high prevalence of HAIs reported by the recent nation-wide PPS.
- 52. This would suggest that whilst HAIs caused by MDROs are infrequent, this may not be the case for HAIs overall. It should be noted that a significant proportion of the high prevalence of HAIs in Sweden in the ECDC PPS 2022-2023 originated from LTCFs, where IPC appeared to be less structured, with low-level involvement of designated IPC professionals, and once again with emphasis almost exclusively on standard precautions.

4.2.7 Educational programmes on AMR and IPC

- 53. A robust system of under- and postgraduate education was observed, which was clearly developed over many years. Training in AMR, AMS, and IPC is included in the undergraduate education of all medical specialities, and effective educational programmes on prudent antibiotic use have been actively developed by Strama at national, regional, and local levels.
- 54. Indeed, Sweden is one of the few countries in Europe where IPC is recognised as a medical speciality. However, on the downside, the same cannot be said for nurses since there is no IPC specialist training for nurses.
- 55. Furthermore, specific education in AMR, AMS and IPC at undergraduate level is universally included in undergraduate curricula. However, the curricula are defined by the individual universities, with no mandatory national curriculum, resulting in the potential for heterogeneity. Strama and a network of infectious disease experts at the university hospitals recently initiated collaborations aiming to define a national core curriculum on AMR and AMS.

4.2.8 Public information related to AMR

4.2.8.1 *Public information*

- 56. Multi-sectoral collaboration through a well-established ICM allows to address AMR comprehensively, including through a common communication strategy and joint communication platform, "Safeguarding antibiotics" (²⁸).
- 57. Sweden's approach to educating the public about antibiotic use and AMR from early ages and throughout life (communication and education materials have been developed and disseminated, including for pre-school children), led to a society with overall good awareness levels about the importance of responsible antibiotic use and the dangers of AMR. Additionally, Sweden provides treatment guidelines and educational resources for both the general public and healthcare professionals, that are easily accessible, and which help healthcare workers in making informed decisions about antibiotic prescribing.
- 58. Nevertheless, while according to 2022 EU Eurobarometer survey on AMR (²⁹), Sweden is performing much better than the EU average regarding knowledge and awareness on AMR related issues, there are still areas to be improved. For example, over 20% of population falsely believes that antibiotics kill viruses.
- 59. Despite the good intersectoral approach, the lack of earmarked budgets from the government for AMR communication initiatives hampers the consistency, predictability and possibility of long-term planning of these communication initiatives. For example, while the PHAS has allocated funds annually for maintaining the "Safeguarding Antibiotics" platform, there are no such earmarked funds for developing new communication/education materials, or for new initiatives. Additionally, the human

²⁸ <u>https://skyddaantibiotikan.se/</u>

²⁹ https://europa.eu/eurobarometer/surveys/detail/2632

resources for AMR communication efforts, are communication officers from the various agencies of ICM, that are allocating time for AMR activities amongst competing priorities. It is also concerning that significant funding and additional resources that have been available to the PHAS and its partners for AMR communication since 2019, in the context of "Antibiotic Smart Sweden", were due to end in November 2024.

- 60. Additionally, there currently are limited mechanisms in place for evaluating the effectiveness of communication activities on AMR.
- 61. According to the 2022 Eurobarometer, internet and social media represent the main source of information on prudent use of antibiotics (higher than doctors and only surpassed by TV). Therefore, there could also be an opportunity to expand communication interventions on a larger variety of social media platforms and types of interaction. Facebook has been used as a main social media communication channel towards the general public.
- 62. Numerous initiatives towards AMR are budgeted, designed and implemented by regional authorities, in line with the country's decentralised governance system. Nevertheless, this can create duplication of efforts. While there are considerations to have the "Safeguarding Antibiotics" platform as a place where all the AMR communication initiatives could be published, this might not meet the agreement of all parties involved.
- 63. While at national level, the ICM has an AMR communication strategy, which recently has been updated with a more focused attention on policy and decision makers, the regions do not have such a strategy, while most of AMR communication efforts towards communities are at their level.
- 64. "Antibiotic Smart Sweden" includes strategies with a good potential for sustained public engagement; however, its future might be uncertain due to funding challenges.

4.2.8.2 Behavioural change interventions

- 65. PHAS has a 'Behavioural Insights' (BI) team embedded within the Agency, which works across different disease groups. In the area of infectious diseases, the focus has particularly been on vaccine-preventable diseases and on AMR, as well as a substantial amount of work conducted on COVID-19 during the pandemic.
- 66. Training and support in methods related to social and behavioural sciences is provided to PHAS staff internally, as well as to external stakeholders, largely following the WHO/Europe 'Tailoring Health Programmes' (THP) approach (³⁰), based on the theoretical COM-B model (³¹) and Behaviour Change Wheel (BCW) framework (COM-B/BCW). In addition to the THP process, much of the Agency's research methodology, expertise and supportive structures are utilised in the social and behavioural related work

³⁰ World Health Organization. A guide to tailoring health programmes: using behavioural and cultural insights to tailor health policies, services and communications to the needs and circumstances of people and communities. Copenhagen: WHO Regional Office for Europe; 2023. Licence: CC BY-NCSA 3.0 IGO https://www.who.int/europe/publications/i/item/9789289058919

³¹ The COM-B model for behaviour change with capability (C), opportunity (O), and motivation (M) as three key factors capable of changing behaviour (B).

at PHAS. The THP approach is a valuable and comprehensive method, but it can also be perceived as quite time consuming and therefore resource intensive. However, the THP approach was used in a more pragmatic way as exemplified by a research project that led to a hotline intervention in different languages for immigrant populations to address questions during the COVID-19 pandemic, including specifically on vaccination.

- 67. The practice of incorporating social and behavioural sciences into the development and evaluation of ongoing projects, rather than initiating whole new streams of work, was also mentioned as a potentially efficient means of maximising its impact. Some examples of a more agile approach to applying methods from social and behavioural sciences were presented in the context of "Antibiotic Smart Sweden", for example through the development and evaluation of target group adapted materials for knowledge and support, and co-design of the "Antibiotic Smart Sweden" criteria.
- 68. The term 'Behavioural Insights' (BI) has been deliberately chosen to describe the team's work, as opposed to 'Behavioural and Cultural Insights' (BCI) the latter term is used quite widely across Europe or 'social and behavioural science'. The word 'cultural' was omitted from the name due a different meaning in the Swedish context, but it may be important to consider re-including the concept in the team's name in one way or another. An explicit recognition of the importance of culture and societal context in shaping preventive behaviours in all population groups should ideally be an inherent part of the BI team 'brand'.

4.2.9 Marketing related issues

- 69. The Swedish Medical Products Agency (MPA) provides independent treatment recommendations for all common primary care infections, including drug of choice, dosage and treatment duration. According to the legal framework, the experts involved in updating or developing treatment recommendations should declare their conflicts of interest. Webinars and independent courses on new treatment recommendations and appropriate antibiotic use are regularly provided to healthcare professionals. MPA collaborates with PHAS and Strama to develop various communication materials.
- 70. The ethical rules for the pharmaceutical industry in Sweden state that all cooperation between healthcare personnel and representatives from the industry should be documented, available for examination, should be reasonable and benefit all cooperators. Financial incentives to prescribers are prohibited, but the industry may offer sponsorship to specific activities or meetings that have a connection to its business area and may only fund the actual costs for a clearly defined activity or meeting. Pharmaceutical representatives do not have access to doctors in training. Advertisement of prescription medicines to the public is prohibited and adherence is being monitored. The dispensation of generic medicines is both allowed and recommended.

4.2.10 Conclusions on human health aspects of AMR

There is broad (a) access to high-quality clinical microbiology laboratory services and point-of-care testing, (b) application of selective AST and reporting and (c) availability of molecular methods to support epidemiology and outbreak investigation. AMR surveillance data for all types of samples are available, accessible and used for informing treatment guidance.

There have been long-standing activities to promote appropriate use of antibiotics in the human healthcare sector through the unique Strama model, as well as national treatment guidance for infections that is widely available and accessible. In addition, quality indicators and targets for antibiotic prescriptions are applied in primary care.

IPC and hygiene have been high on the agenda of decision makers who view these initiatives as being essential requirements for safe patient care and there are designated IPC doctors and IPC nurses in healthcare settings supported by regional IPC teams. There is a comprehensive risk-based MDRO screening programme. As a result, it has been possible to prevent and quickly control outbreaks by MDROs.

However, the focus on IPC is primarily on personal and environmental hygiene, as well as the use of PPE, with less emphasis in other IPC areas such as prevention bundles in relation to the proper use and management of indwelling devices. Furthermore, there is a lack of systematically collected, actionable surveillance data on HAIs.

Sweden applies a broad spectrum of communication activities on AMR with innovative behavioural science approaches.

4.3 VETERINARY AND ENVIRONMENTAL ASPECTS OF AMR (EUROPEAN COMMISSION)

4.3.1 Monitoring of AMR in animals and food, including relevant laboratory capacity

- 71. Sweden has been monitoring for AMR in isolates from animals for over 20 years. These efforts pre-date the EU-harmonised rules on AMR monitoring in certain zoonotic and commensal bacteria, which started in 2014 under Commission Implementing Decision 2013/652/EU and has continued under Commission Implementing Decision (EU) 2020/1729. The prudent use report describes what type of monitoring had been carried out (notably, on isolates from healthy animals and meat, as well as from clinical cases).
- 72. In Sweden, findings of *Salmonella* spp., CRE (Extended Spectrum Beta-Lactamase with carbapenemase activity ESBL_{CARBA} or ESBL CPE), meticillin-resistant *S. aureus* (MRSA) and *S. pseudintermedius* (MRSP) in animals are notifiable. This resulted in additional data on prevalence of MRSA, MRSP and ESBL_{CARBA} available from the passive surveillance (clinical isolates) as well as the current and past screening studies (MRSA and MRSP). In case of ESBL_{CARBA}, screening for extended spectrum cephalosporin (ESC) resistance in suspect clinical samples is funded by the Swedish

Board of Agriculture (SBA), which allows for free confirmatory testing to be done by the Swedish Veterinary Agency (SVA, the NRL for AMR in animals) (³²).

- 73. Enterobacterales producing classical ESBLs (in Sweden referred to as ESBL_A) or plasmid-mediated AmpC (ESBL AmpC or, in Sweden, ESBL_M), as well as VRE, are notifiable in humans only. However, attention is also paid to findings of these in animals with the results analysed and published (³³). Neither carbapenemase-producing nor classical ESBLs (ESBL_A and ESBL_M) are notifiable in food. However, active screening for *Escherichia coli* ESC resistance in meat samples collected at retail and at border control posts is being carried out and the results are available (²⁴).
- 74. As mentioned in the previous sections (and in the prudent use report), Sweden reports annually on the AMR situation in animals in the Swedres-Svarm report (together with the data for humans and sales of antibiotics in both sectors). The report includes data from the mandatory reporting (Svarm) from meat and healthy animals. In addition to that, the report includes voluntarily reported data on resistance in isolates obtained from diseased animals, either under Svarm (*Salmonella*, MRSA/MRSP, ESBL/AmpC/CPE and other animal pathogens from horses, dogs and cats) or SvarmPat (animal pathogens obtained from cattle, pigs, sheep and farmed fish). The SvarmPat project, the collaboration between the Farm and Animal Health and SVA, is financed by the SBA and supplements Svarm since 2005 (for more information, see the prudent use report).
- 75. The AMR situation in Sweden is exceptionally favourable. The prevalence of resistance in indicator bacteria (*E. coli* from the intestinal flora of healthy animals) is very low: in 2023, 69% of broiler isolates and 73% of pig isolates were susceptible to all tested antibiotics. The resistance to commonly used antibiotics occurs in clinical isolates of *E. coli* from farm and companion animals; however, most isolates were still susceptible to all tested substances. This is apart from isolates from pigs, with 50% isolates susceptible and 14% multi-resistant (2023 data), and young cattle calves, with 7% and 26% respectively (2021-2022 data). Similarly, respiratory pathogens from farm animals and horses are mostly susceptible to benzylpenicillin (first line of treatment), with the exception of *Pasteurella multocida* in calves.
- 76. Additional data on prevalence of MRSA, MRSP and ESBL_{CARBA} is available due to their notifiable status. In 2023, there were 6 cases of MRSA in cats, 9 in dogs and 12 horses (numbers of cases in horses are fluctuating). The most recent screenings of healthy animals were carried out in dogs, in 2017-2018, and in horses, in 2010, with no positive samples. The last survey in pigs was done over 10 years ago (also, with no positive samples). The Swedres-Svarm report provides information on the last surveys in other farm animals, such as screening of dairy-goats in 2019 following few earlier outbreaks. It is accepted that the MRSA situation in farm animals is largely unknown. The number of

³² In their response to the draft report, the competent authorities noted that, the SBA also funds confirmatory testing in suspect clinical samples of MRSA and MRSP, which is performed at SVA.

³³ <u>https://www.sva.se/en/what-we-do/antibiotics/svarm-resistance-monitoring/swedres-svarm-reports/supplementary-material/</u>

MRSP cases in dogs (44 in 2023) has been stable for over a decade and 50% lower than in 2009 (the peak of cases in Sweden).

- 77. There were no findings of ESBL_{CARBA} detected in domestic animals and meat samples. As mentioned previously ESBL_A and ESBL_M. are not notifiable, but thanks to the ESC screening, the SVA has data on around 50 cases per year in cats, dogs and horses. There is very low prevalence of ESC resistance in samples taken at slaughter from healthy farm animals in 2023 (fattening pigs and broilers). Currently, only the isolates from the susceptibility testing done at SVA are included in the surveillance, which limits the number of isolates available. One activity of SvarmPat is to encourage practitioners and pathologists to submit samples for microbiological culture and susceptibility testing. This applies specifically to *Pasteurella* spp. and *Mannheimi*a spp. from cattle as currently only a few isolates per year are being tested, but also *S. suis* and *Actinobacillus pleuropneumoniae* from pigs.
- 78. There is an ongoing discussion about including AST data from pathogens analysed in laboratories other than SVA and not included in the surveillance. As AST is required to justify prescription of antibiotics from EMA's Antimicrobial Advice ad hoc Expert Group (AMEG) Category B *Restrict* (³⁴) (see Part 5.3.4), it could be expected that there are some AST data already available. Therefore, participation of the additional laboratories could provide a better picture on the AMR situation. The 3-year project aimed at building laboratory capacity, which started in 2016, has been described in the prudent use report. The project resulted in the establishment of the network of veterinary laboratories (SKRUV *Samarbete, Kvalitet, Resistens, Utbyte, Veterinärmedicinska laboratorier* Cooperation, Quality, Resistance, Substitution, Veterinary Laboratories). After the project ended in 2018, the SVA has continued to coordinate the network by, among other activities, providing technical expertise and organising the yearly proficiency testing for the AST and network meetings.

4.3.2 Monitoring the use of antimicrobials in animals

79. As described in the prudent use mission report, monitoring of the sales of veterinary antibiotics in Sweden begun in 1980. Sweden was one of the first Member States reporting the sales data to the European Surveillance of Veterinary Antimicrobial Consumption (ESVAC) (³⁵) established in 2009. According to the latest ESVAC report, in 2022, Sweden reported total sales of 10.6 mg/PCU (³⁶), which were the lowest sales of antimicrobials in the EU. In 2022, 88.3% of the antimicrobial veterinary medicinal products (VMPs) sold belonged to AMEG category D (*Prudence*), 11.5% to C (*Caution*) and only 0.3% to B (*Restrict*). In addition to that, approximately 90% of the antibiotics are being administered to individual animals, rather than being used for treating groups of animals. The most recent Swedres-Svarm report includes data for 2023 with total sales

³⁴ <u>https://www.ema.europa.eu/en/documents/report/infographic-categorisation-antibiotics-use-animals-prudent-and-responsible-use_en.pdf</u>

³⁵ https://www.ema.europa.eu/en/veterinary-regulatory-overview/antimicrobial-resistance-veterinarymedicine/european-surveillance-veterinary-antimicrobial-consumption-esvac-2009-2023

³⁶ Population correction unit

of antibiotics for animals at 11.6 mg per kg estimated biomass (used as a proxy for PCU). This figure includes tablets, which are excluded from the ESVAC reports. This is a small increase since 2022, as the Swedres-Svarm 2022 report, indicates total sales at 11.3 mg per kg estimated biomass.

- 80. With the exception of the fish sector, most data come from the pharmacies, which are obliged to report all sales to the eHealth Agency. The agency maintains a database of sales to animal owners (from veterinary prescriptions, including information of the species) and to veterinarians (requisition for use in practice without the indication of species for which the VMPs are to be used). Approx. 95% of veterinary prescriptions are electronic, which eases the task of reporting of data (the remaining prescriptions are also transcribed by the pharmacies before being reported to the eHealth Agency).
- 81. As described in the prudent use report, the data on use of antimicrobials in the poultry sector has been collected by the industry for many years. Also, the dairy industry has analysed data collected by the SBA for many years. Detailed information on the sources of data on sales and use of antibiotics in different species can also be found in the Swedres-Svarm reports.
- 82. SBA started collection of the data on use of antimicrobial medicinal products for (certain) animal species at the beginning of 2023. The obligation for the veterinarian to provide these data was regulated by the SBA's Regulation SJVFS 2023:7 of 9 March 2023, which came into force on 1 April 2023. There are different timelines for reporting of antimicrobials prescribed, used and left depending on the types of farms (see the prudent use report and Part 5.3.4 for details on conditional use of medicinal products on ViLA farms). When veterinarians prescribe antimicrobials for the ViLA farms (for the VMPs to be administered by the operators), they collect and report data on the antimicrobials used in-between their visits. This causes some delays, but the data are deemed to be more precise. Similarly, in case of the veterinarians administering the antimicrobials themselves, the data reported refers to the amount used. In cases when the antimicrobials are prescribed on non-ViLA farms, the data reported are what was prescribed.
- 83. Reporting to SBA can be done either via the veterinarians' own IT systems for record keeping, or the system developed by the SBA called RAAL. Once the data is in the database, it is then reviewed by SBA and SVA for possible inconsistencies. Any errors could be due to the transfer of data (from own IT systems) or due to the veterinarians reporting incorrectly. It was accepted that the IT system still need some finetuning. When errors are identified, the prescribing veterinarians are contacted, and the data is corrected before its submission to EMA.
- 84. The competent authority stated that not all veterinarians report their use of antimicrobial medicinal products. While the SBA continues to provide the information to the veterinarians on their obligations to report, the County Administrative Boards (CABs) have started to enforce the new requirements. The enforcement usually starts with a written warning followed by an injunction. If no effect, an injunction with fines is issued. In case of further non-compliance, a report will be sent to SBA. In the county visited, there were injunctions issued, but no fines served as yet.

4.3.3 Activities to promote the reduced and/or prudent use of antimicrobials in animals

4.3.3.1 Reducing the need for veterinary antimicrobials

- 85. As described in the prudent use report, Sweden prides itself on the Swedish model (in principle: *'Healthy animals do not need antibiotics'*) (³⁷). It consists of:
 - Effective surveillance and eradication of various notifiable diseases, which results in a favourable animal health situation.
 - Efforts to collect and analyse sales of antimicrobials and resistance patterns, predating the EU- harmonised surveillance systems.
 - National requirements for IPC procedures in veterinary practices.
 - Long-standing cooperation between the authorities and stakeholders, including One Health collaboration.
 - Awareness of AMR among all actors.
- 86. The points above are translated into several actions and included in the *cross sectoral action plans* (when there are many competent authorities involved) or managed by individual authorities. However, the long-standing tradition of *"Prevention is better than cure"*, predates the AMR strategies and plans. The first successful eradication campaigns were of rinderpest (eradicated in 18th century) and rabies (in 19th century). The first tuberculosis and brucellosis eradication schemes (1940-1960), Salmonella control programme (1960s), as well as industry run udder health programmes (1950s) coincided with the growing concerns about AMR among the Swedish veterinarians. While these actions were caused by the zoonotic potential of the pathogens concerned, and, in case, of Salmonella by the outbreak in 1953 affecting thousands of people, these diseases affected flock or herd health, and could have led to an increased use of antibiotics.
- 87. Sweden is now also free from many devastating infectious diseases, such as Aujeszky's disease, Porcine Reproductive and Respiratory Syndrome (PRRS), enzootic bovine leukosis, bovine viral diarrhoea, infectious bovine rhinotracheitis and paratuberculosis. These diseases are all notifiable and subject to strict surveillance programmes. Apart from the national control plan for Salmonella in poultry, pigs and cattle, there are other ongoing control programmes (e.g., Campylobacter in poultry, Maedi Visna in sheep and caprine arthritis encephalitis virus in goats). The aim of these programmes is to prevent and combat or eradicate the disease or an infectious agent.

³⁷ Apart from the prudent use report, there are two publications, which explain the Swedish model and should be consulted for more details:

[&]quot;The Swedish experience" – a summary on the Swedish efforts towards a low and prudent use of antibiotics in animal production', by the Swedish University of Agricultural Science (SLU) Framtidens djur, natur och hälsa, 2020, Uppsala and 'Successful Prevention of Antimicrobial Resistance in Animals — A Retrospective Country Case Study of Sweden,' Reference: Wierup, M.; Wahlström, H.; Bengtsson, B. Antibiotics 2021, 10, 129.

- 88. The success of these programmes requires close cooperation between industry and the competent authorities. The competent authorities provide the financial resources for surveillance and control, and grants to improve infrastructure. Financial resources are also allocated for the projects run by farmers' organisations promoting animal health. However, the resources are not unlimited, and the SBA stated that its budget has remained the same since 2006. The representative of the farming sectors met by the team highlighted the issues of profitability. While the grants might be available, the need for investments on some smaller and older holdings outstretches the funds available. There is a tendency for these farms to close down, with larger establishments taking over. As described in the prudent use report, there is also technical support from various services available to the farmers.
- 89. While admitting that the Swedish model proves costly, the representatives of the farmers and the food-producing industry met, were overwhelmingly in favour of it and had driven many of the actions themselves. When Sweden joined the EU in 1995, the farming industry established voluntary import requirements, additional to the official requirements, which had to be aligned with EU rules. This was to ensure that the favourable animal health situation, achieved by decades of efforts to control and eradicate various diseases and adhere to industry-run health schemes, was preserved and maintained. While voluntary, the additional requirements had to be complied with, in order to slaughter the imported animals or to sell their milk. Similarly, the ban on the antibiotic growth promotors in 1986, was also an initiative from the farming sector. More recently, at the emergence of the African Swine Fever (ASF) in Europe, the pig sector with the financial support from the SBA started working on an additional biosecurity module, so called 'wild boar package'. When the first case of ASF was discovered in September 2023, this work was close to completion (at the time of the visit, Sweden was waiting to be declared free from ASF).
- 90. As described in the prudent use report, the detection of meticillin-resistant staphylococci (MRSA and MRSP) in dogs in 2006 and in horses in 2008, highlighted the increased demand on IPC procedures in veterinary settings. As a result, in 2013 the SBA published national legislation (SJVFS 2013: 14), which was then updated in 2021 by Regulation K112 (SJVFS 2021: 5). The requirements for veterinary practices to have formalised procedures for infection control for animal health care activities, so called 'hygiene plans,' entered into force in 2014.
- 91. In 2022, the SBA financed a follow up project on the application of Regulation K112's hygiene plans. The project was led by two IPC and HAI experts supported by the Swedish University of Agricultural Sciences (SLU). The teams, including at least one county veterinarian from the local CAB, visited 37 small animal, equine and district veterinary clinics in five counties. The results showed that all clinics had a hygiene plan, however the implementation of the different elements of the hygiene plan varied between the clinics. This included availability of basic equipment, such availability of suitable protective clothing, washbasins, or hand disinfectants, as well as deficiencies in cleaning and laundry procedures. The lack of technical knowledge and support was also mentioned,

so were some deficiencies in monitoring, in particular measurements of the practices' own compliance (self-monitoring) and the prevalence of the HAIs.

- 92. The follow up projects highlighted some deficiencies in the unified implementation of the hygiene plans. This concern was shared by the veterinarians met in the small animal hospital visited by the team. The practice was part of a group, priding itself on the highest IPC standards (as well as the advanced AMS). As mentioned in the prudent use report, setting up an effective IPC programme is essential, but can be costly. The practice visited benefitted from well-designed facilities and the availability of all hygiene essentials plus the knowledge of the local IPC staff and IPC hub at central level (IPC director and national IPC managers). The local team consisted of one veterinarian, a veterinary nurse or other staff in each department. They were specifically trained and responsible for identifying problems during their every-day work. They also benefitted from the induction of new staff to the company's IPC policies, to organisation of periodic hand hygiene events, via measuring the air-quality in operating theatres.
- 93. As mentioned in the prudent use report, checking compliance with the hygiene plans was challenging for the CAB officials. The practice's representative mentioned that official controls were not always adequate and geographically diverse and suggested a need for a national IPC certification. The recent follow up project was not aimed at training the official veterinarians, however its results were distributed among the CABs and discussed among the staff. The visit team noted that Sweden pioneered the work on IPC in veterinary settings, which is still considered the best practice for other Member States to follow (other than the IPC policies in human healthcare). There are no known examples ready to copy and implement.

4.3.3.2 Availability of veterinary antimicrobials and veterinary care, and treatment guidelines

- 94. As described, in the prudent use report, in Sweden veterinarians cannot sell antimicrobial VMPs. They can only provide small amounts of medicines, to bridge between the start of the treatment and its continuation (once the product is collected from the pharmacy). This is to ensure that there is no conflict of interest as it is not in the interest of the veterinarian to prescribe antimicrobials. This approach also reinforces the strong focus on prevention where the veterinarian is in charge of optimising the animal health situation on the farm.
- 95. As mentioned, in the prudent use report, the farmers of certain species (cattle, pigs, sheep or goats) can enter into a specific contract with their veterinarians for the 'conditional use of medicinal products' according to specific regulation (SJVFS 2023:7) with a range of different requirements. Such farms are referred to as ViLA farms (*Villkorad läkemedelsanvändning*). Before such an agreement can be signed, the veterinarian must assess the farm in terms of animal health and welfare conditions. The veterinarian must develop an animal health plan for the farm, provide written, farm -specific and detailed treatment instructions for the farmer, who is also required to complete a specific ViLA-training. Once these conditions are fulfilled and the contract signed, the veterinarian can prescribe medicinal products, including antimicrobials, so that the farmer can treat certain

predetermined symptoms according to the treatment instructions without contacting the veterinarian before each treatment. Some additional restrictions apply, such as a ban on using antimicrobials for prophylaxis, restrictions on metaphylaxis and strict requirements for record keeping. The amounts of VMPs prescribed should not exceed the estimated consumption of a maximum of eight weeks at a time. The veterinarians must visit the farm at fixed intervals, which vary between animal species and type of production for follow-up checks on the animal health and welfare conditions, to review the treatment carried out since the last visit and prescribe further treatment if necessary. Following the visit, the veterinarian is obliged to report the amount of antimicrobial medicinal products used on the farm to the SBA as a part of the reporting according to Article 57 of the VMP Regulation (at present, this applies only to pigs and cattle).

- 96. Some stakeholders and the authorities had concerns about the availability of veterinarians. The industry, especially the horse and dairy, proposed additions to the current veterinarian-farmer contracts, in particular, to extend the scheme to stud farms and to allow for the treatment of hypocalcaemia in milking cows (at present, the farmers are not allowed to administer intravenous treatments). The representatives of the SBA stated that the extension of the ViLA scheme to other species would need to be carefully considered, with the pros and cons assessed, and that setting one up is complicated and very resource consuming. Regarding allowing the addition of intravenous treatments to be administered by the farmers, there was some opposition from the veterinarians for such a change.
- 97. As mentioned in Section 5.2, the Swedish MPA is taking actions to improve the access to antibiotics (in a One Health perspective). The reported shortages of antibiotics (9% of all shortages are anti-infectious agents), include some antibiotics used only in animals, but the majority are antibiotics used in humans and animals. It is acknowledged that the Swedish market, in both human health and veterinary sectors, is not particularly attractive for the pharmaceutical industry for several factors. Apart from being relatively small, the market is dominated by the narrow-spectrum, generic and therefore cheap antibiotics. In the veterinary sectors, the total sales of antibiotics are also much lower than in the human sector (in 2023^(23,24), 8.9 tonnes vs 64 tonnes), making the market even less attractive. In addition to that, there is a need for a wide variety of formulations and strengths due to many different animal species. The veterinarians from the small animal practice visited mentioned specifically the lack of narrow-spectrum penicillins (namely phenoxymethylpenicillin) available on the market for treating small animals. While the human medicines can be used under cascade, the dosage and formulations are not convenient, and most often, the veterinarians chose to use amoxicillin instead. The problems are not limited to antimicrobials, but also to some vaccines. The stakeholders met mentioned that obtaining VMPs authorised in other EU Member States is particularly difficult $(^{38})$.

³⁸ In their response to the draft report, the competent authorities noted that the time for a special licence to be issued by the MPA is normally up to seven working days, counting from the day the MPA has received the application. The time it takes for a pharmacy or wholesaler to procure the product from another country can vary depending on demand and product.

- 98. Antimicrobial treatment in different species is covered in various guidelines produced by the MPA (pigs, dogs, horses, cattle and sheep) and by the Swedish Veterinary Association (*Sveriges Veterinärförbund*) (cattle, pigs, sheep and goats, dogs and cats, horses). The guidelines are produced by the experts and reviewed when necessary. Most recently, in 2022, the MPA revised its guidance for pigs.
- 99. As described in the prudent use report and still the case, in some instances, the treatment guidelines allow for increased dosing of penicillins (above the regime listed in their marketing authorisation). This is not in line with the provision laid down by Article 106(1) of the VMP Regulation. The authorities are of the view that the adjustment of the dosing recommendations given in the product information, in certain cases, to obtain efficacious and safe treatment for the individual animal and thus reduce the risk for resistance, is in line with the VMP Regulation expressing the overall aim to promote prudent use of antimicrobials and thus reduce the risk for resistance. The SVA presented an example of respiratory infections in pigs caused by A. *pleuropneumoniae*, for which benzylpenicillin is the recommended as a first-choice treatment but is not always effective. The lack of clinical efficacy is not related to resistance since isolates of A. pleuropneumoniae from Swedish pigs are susceptible to penicillins in vitro. The objective of the study was to investigate the benzylpenicillin exposure in both healthy and experimentally infected pigs after administration of two benzylpenicillin products available on the Swedish market. In case of one product, the approved intramuscular dosage resulted in insufficient plasma benzylpenicillin exposure to guarantee a successful therapy. It was concluded that to improve its efficacy more frequent dosing or an increased dosage would improve exposure $(^{39})$.
- 100. As mentioned above, the overarching principle of the guidelines, when treatment with antibiotics is considered necessary, is to use penicillins when they are expected to be effective. If not, a substance with a low risk of resistance as possible, according to EMA's AMEG classification, should be chosen. The veterinarians' rights to prescribe antibiotics from AMEG Category B *Restrict* is governed by national legislation (Regulation SJVFS 2023:21) and could only be justified in specific circumstances. In case of 3rd and 4th generation cephalosporins and fluoroquinolones, since 2013, they can only be prescribed after an AST, with some exemptions (when sampling is not possible due to the location of infection or the nature of disease and, when it is scientifically and experientially proven that treatment with another medication is ineffective). Since 2023, a veterinarian may only decide on treatments with polymyxins for systemic use, if the results of microbiological investigation including AST show that treatment with another medicinal product would not be effective. Also, in addition to the antimicrobials reserved for treatment of certain infections in humans (according to Commission Implementing Regulation (EU) 2022/1255) (⁴⁰) mupirocin and rifabutin are also prohibited for use in animals. Additional

³⁹ https://www.sva.se/en/what-we-do/research-at-sva/research-projects-at-sva/foka/prevention-of-antibioticresistance-and-preservation-of-available-antibiotics-through-optimized-penicillin-dosing-in-pigs/ and <u>https://pmc.ncbi.nlm.nih.gov/articles/PMC7499853/</u>

⁴⁰ Commission Implementing Regulation (EU) 2022/1255 of 19 July 2022 designating antimicrobials or groups of antimicrobials reserved for treatment of certain infections in humans, in accordance with Regulation (EU) 2019/6 of the European Parliament and of the Council; OJ L 191, 20.7.2022, p. 58–60

restrictions are in place for rifampicin, which can only be used in horses with *Rhodococcus* equi infection.

- 101. While there is no requirement to submit AST results to the competent authority, the veterinarians must keep a record of them, together with additional clarifications in the patient record: a) why the animal had to be treated with antibiotics; b) justification of their choice of antibiotics. These records should be made available to the competent authority in charge of enforcement (i.e., by county veterinarians working for CABs as described in the prudent use report).
- 102. As mentioned in the previous section, the industry organisation from the poultry and cattle sectors, have long collected the data on the use of antimicrobials in these species. In addition to that, the District Veterinarians, the cattle veterinarians working for *Växa Sverige* (see prudent use report) met by the team and veterinarians from the small animals practice visited, were looking at their own prescription data and applied benchmarking among their peers. In the latter, the company's AMS ambassadors analysed and reported the use of antibiotics at country (the group operates also outside Sweden), practice and individual level. The company's representatives mentioned the lack of clear national targets and procedures for measuring antibiotic use as a challenge.
- 103. In veterinary medicine, AMS is still a relatively new field. In Sweden, interested clinicians can join the Swedish Veterinary Network for Antibiotic Stewardship (SVASP) founded in 2018 and, since 2024, forms part of the Swedish Veterinary Infection Control Association. SVASP has approximately 80 members and meets yearly for lectures, seminars, and workshops. Apart from the practical and organisational aspects of implementing AMS tasks in veterinary settings, SVASP members discuss and keep up to date with the antibiotic guidelines and resistance situation. The network is also keen to work on the prudent use of antibiotics in dentistry, better prophylactic use of antibiotics in surgery and prevention of surgical site infections.
- 104. According to the representatives of two CABs met, the other risk factors considered when selecting the veterinarians for controls, were mainly a) history of non-compliance; b) ViLA contracts, c) size of the practice (smaller considered more problematic). In one CAB, the veterinarians engaged by ViLA schemes were targeted for yearly checks (although some of the controls could be administrative and, if no previous non-compliance, there was also a possibility of less frequent checks). Also, while the CAB in more rural counties were under pressure to maintain frequent enough controls on the veterinarians working with farm animals and with ViLA contracts, the counties with big agglomerations would have a higher number of small animal veterinary practices, each with a hygiene plan, to be controlled at sufficient intervals. It was accepted by the representatives of the CABs that, due to the shortage of resources, the desired frequency of controls could not always be fully adhered to.
- 105. Since June 2024, the CABs have been given access to data on pharmacy sales collected by the eHealth Agency and some were using them as a tool to select veterinarians for official controls. There was however no unified nation-wide approach among the different CABs, on how these data could potentially be used to guide and target risk-based controls.

4.3.3.3 Educational programmes and public information related to AMR

- 106. Only the SLU runs the undergraduate veterinary and veterinary nursing courses. There are no single AMR or IPC modules, but the relevant content is taught through various subjects, from microbiology, via the clinical application to the global perspective. The Veterinary Public Health course also explains the farm-to-fork approach and the One Health implications of the use of antimicrobials in veterinary medicine. According to the veterinarians and farmers met, the Swedish veterinary graduates are well aware of the principles of prudent use of antimicrobials and IPC, Swedish model and the national legislation.
- 107. Given the shortage of veterinarians, practitioners who graduated outside of Sweden are filling in the gaps. The stakeholders met, especially from the horse industry where the shortage is particularly problematic, highlighted the problems of foreign veterinarians not being aware of the Swedish model. Graduates from other Member States can apply and receive their licence to practice automatically, while graduates from third countries most often need to complete a two-year course at SLU or an adaptation period before obtaining a licence). The lack of requirements for mandatory continuing professional development (CPD) to maintain their right to practice means some of the newly licensed veterinarians might not be aware of their obligations to prescribe antibiotics in a certain manner and other national provisions. The issue of foreign graduates not being fully aware of the Swedish model, was already known to the authorities (also included as one of the actions in the cross-sectoral action plan on AMR). The authorities and academia prepared a guidance document (emphasising the Swedish model) which will be distributed to the veterinarians in the near future, at the same time as they receive the licence. The draft document was presented to the team.
- 108. Despite the lack of CPD requirements, the stakeholders from the veterinary and farming sectors as well as the management of the small animals practice, pointed to various fora where the veterinarians and veterinary nursing staff can further their education. This varied from the yearly conferences dedicated to specific sectors, e.g. poultry or pigs, to specialist training on IPC or the meetings of the SVASP network. However, the representative of the small animal practices also pointed out the lack of communication routes to pass new and advanced ideas to the veterinarians. She stated that Swedish veterinarians are generally very receptive, but communication must reach them in the first place. The veterinarians met were very knowledgeable on the national and EU requirements relevant to AMR and committed to the Swedish model.
- 109. In Sweden, the general public is well aware of the effort of the farming sector to produce meat with minimal use of antimicrobials and good welfare standards. According to a survey from 2023, nearly 9 out of 10 people buy meat from Sweden. Swedish meat was also considered not too expensive (data from the Swedish Meat Industry Association). This is despite the results of another study from 2024, 3 out of 5 people would consider paying more to support the Swedish farmers. Another statistic from 2024 showed that, when multiple answers were allowed, supporting national farming was the first reason to buy Swedish food (86% of responders), followed by support for the national food industry

(75%) and the perception that Swedish farmers use less antibiotics (72%). The concerns for animal welfare and climate and environment came fifth and sixth in the ranking (69% and 65% respectively).

110. Despite Swedish consumers being highly aware of the risk of AMR, the efforts undertaken by the Swedish farming industry and the national favourable AMR situation, some misconceptions remain. According to another study from 2024, half of the respondents believed that there are antibiotic residues in meat and 34% were unsure. The authorities and stakeholders identified the need for further information campaigns and continued awareness raising education and it was included in the cross-sectoral action plan on AMR.

4.3.4 Environmental aspects of AMR

- 111. There are many past and ongoing research activities aimed at addressing the knowledge gaps on the role of the environment as a driver of AMR and providing practical solutions to address the already known problems. There are two major multidisciplinary research hubs in Sweden; the Centre for Antibiotic Resistance Research (CARe) (⁴¹) in Gothenburg and Uppsala Antibiotic Centre (UAC) (⁴²) in Uppsala. In CARe, over 150 scientists from 18 departments at the University of Gothenburg and Chalmers University of Technology, are working together to address the antibiotic crisis and inform policy change at a global level. In addition to that, UAC, a partnership between Uppsala University and SLU, brings together and supports AMR research, also covering a wide array of disciplines and with a One Health perspective.
- 112. The research focusses on the prevention and control of the spread of AMR in the environment aiming to:
 - examine the impact of the release and presence of antibiotics and resistant bacteria in the environment and various environmental factors on the risk of emergence and spread of AMR between humans, animals, food and the environment.
 - examine how economic instruments, procurement requirements, regulatory and/or behavioural measures can reduce the risk of the emergence and spread of antibiotic resistance in the environment, and
 - develop and evaluate technical, innovative solutions to reduce the risk of the emergence and spread of antibiotic resistance in the environment.
- 113. Over the past year, researchers from CARe have looked into possible environmental contamination with resistant bacteria and ARGs from municipal wastewater treatment

⁴¹ <u>https://www.gu.se/sites/default/files/2024-06/CARe%20activity%20report%202022-23%20final_0.pdf</u>

⁴² https://www.uu.se/en/centre/uppsala-antibiotic-center

plants (WWTPs) (43), hospital effluent (44), and the strongest selection pressure caused by pollution from pharmaceutical manufacturing around the world (45).

- 114. Advanced treatment methods of wastewater have been a priority area for research for many years. As stated in the cross-sectoral action plan, from 2018 until 2023, the Swedish Environmental Protection Agency (EPA) was tasked with distributing grants for measures aimed at increasing the pace of work to reduce discharge of pharmaceutical residues into seas, lakes and waterways. The grants lead to concrete measures in the form of full-scale installations, and invested funds were also contributed to an increased build-up of knowledge around advanced purification. From 2018 to-date, the Agency has spent a total of 16.5 M€. This has led to a number of full-scale WWTPs in operation benefitting from the installation of advanced treatment methods, with more under development.
- 115. Examples of larger Swedish research projects on environmental dimensions of AMR that are currently ongoing are as follows:
 - Sewage monitoring, a new resource-efficient method for population-based surveillance of antibiotic resistance (2022-2025) (⁴⁶), to investigate the potential of microbiological analyses of sewage, containing excreted bacteria from thousands of people, as a resource-efficient complement for population-level AMR surveillance of a particular value in low- and middle-income countries.
 - EDAR (⁴⁷) *The Environment as a Driver of Antibiotic Resistance* (2019-2024), to improve scientific understanding of the role the environment plays in the emergence and dissemination of antibiotic resistance and aid development of measures to effectively manage resistance threats arising from the environment.
 - SEARCHER (⁴⁸) Surveillance for Emerging Antimicrobial Resistance through Characterization of the uncharted Environmental Resistome (2024-2027), to characterise emergent ARGs in the environment, allowing for their inclusion into AMR surveillance and detection before they become clinical problems.

 ⁴³ A comprehensive screening of *E. coli* isolates from Scandinavia's largest sewage treatment plant indicates no selection for antibiotic resistance Flach CF, Genheden M, Fick J, Larsson DGJ. (2018). Environ Sci Technol, 52 (19), pp. 11419–11428.
<u>https://www.researchgate.net/publication/327661716_A_Comprehensive_Screening_of_Escherichia_coli_</u>

Isolates from Scandinavia's Largest Sewage Treatment Plant Indicates No Selection for Antibiotic Resistance

⁴⁴ Kraupner N, Hutinel M, Schumacher K, Gray DA, Genheden M, Fick J, Flach C-F, Larsson DGJ. (2021). Evidence for selection of multi-resistant *E. coli* by hospital effluent. Environment international. Vol. 150:106436. <u>https://doi.org/10.1016/j.envint.2021.106436</u>

⁴⁵ Larsson DGJ, de Pedro C, Paxeus N. 2007. Effluent from drug manufactures contains extremely high levels of pharmaceuticals. J Haz Mat. 148 (3), 751-755. <u>https://www.researchgate.net/publication/6134174 Effluent From Drug Manufactures Contains Extrem</u> ely High Levels of Pharmaceuticals

⁴⁶ https://www.gu.se/en/about/find-staff/carl-fredrikflach

⁴⁷ <u>https://www.gu.se/en/research/the-environment-as-a-driver-of-antibiotic-resistance-edar-0</u>

⁴⁸ https://www.jpiamr.eu/projects/searcher/

- Aquatic Pollutants BIOCIDE (⁴⁹) Antibacterial biocides in the water cycle an integrated approach to assess and manage risks for antibiotic resistance development (2021-2024), to determine how and to what extent antibacterial biocides contribute to the development and spread of antibiotic-resistant bacteria in different freshwater/marine ecosystems.
- Aquatic Pollutants PARRTAE *Probing Antibiotic Residues and Resistance transfer in Aquatic Environments (International co-operation led by Karolinska Institute)*, to determine common ARG plasmids circulating in European waters and their inherent properties as a fundament to understand and prevent their dissemination.
- APRIORA (⁵⁰) Improved risk assessment for strategic water management to reduce micro-pollutant emissions in the Baltic Sea Region (2023-2026), to develop and implement measures allowing the environmental authorities to assess, prioritise risks and propose cost-effective mitigation measures for future investments in cooperation with WWTP operators.
- LIMIT (⁵¹) Innovative concepts for sustainable water treatment targeting PFAS and other critical micro-pollutants from point sources in the South Baltic Sea area (2023-2026), to develop sustainable techniques to reduce several substances harmful to health and the environment, such as per- and polyfluoroalkyl substances (PFAS), pesticides and antibiotics from hotspots and other point sources and therefore protect groundwater and surface water in the South Baltic Sea region.
- Impact of antimicrobial chemicals on the emergence of antimicrobial resistance in aquatic environments (⁵²), as most antimicrobial chemicals break down to potentially more persistent transformation products in the environment, this project aims to close the knowledge gap regarding the contribution of these products to the antimicrobial resistance in the recipient aquatic environment.
- 116. In 2025, the Swedish MPA will start a new 4-year pilot offering financial incentives (a premium) to pharmaceutical manufacturers to adhere to strict limits for environmental contamination. The premium will be linked to the product-of-the-month scheme operating in the Swedish pharmacies (generic pharmaceuticals, including four antibiotics, with the lowest prices that pharmacies must offer customers when substituting pharmaceuticals). The applying companies, which must be able to prove that they produce pharmaceuticals with low emissions of active pharmaceutical ingredients (API) to the environment, will receive the environmental premium and will be able to lower the price of the drugs produced. This will increase their chances to win the bid for product-of-the-month and therefore generate more sales and income. In the result, environmentally sustainable

⁵¹ <u>https://portal.research.lu.se/en/projects/innovative-concepts-for-sustainable-water-treatment-targeting-pfa</u>

 ^{49 &}lt;u>http://www.waterjpi.eu/joint-calls/joint-call-2020-aquaticpollutants/aquaticpollutants-rdi-funded-projects-booklet</u>
50 <u>bttps://integrog</u>

⁵⁰ <u>https://interreg-baltic.eu/project/apriora/#:~:text=In%20the%20project%20APRIORA%2C%20environmental,water%20management%20and%20reduce%20emissions.</u>

⁵² <u>https://www.slu.se/en/ew-cv/paul-loffler/</u>

manufacturers will gain a larger market share for products with less risks. Despite stringent criteria that need to be fulfilled in order to apply and be successful, the representative of the Swedish MPA stated that there is a good level of interest from the potential applicants. In the longer term, the Agency hopes that the criteria can be used for other causes (e.g., priority procurement of medicines produced by environmentally sustainable manufacturers). In the future, the criteria could also be harmonised with other initiatives (e.g., WHO and a prolonged or permanent environmental premium, including more antibiotics, established).

- 117. Despite the relevant actions included in the intersectoral-action plan, the needs and framework for the systematic monitoring of antimicrobials, AMR resistant bacteria and resistance genes in the environment have not yet been set. The authorities and researchers explained that they are waiting for the review of EU Urban Wastewater Directive (⁵³).
- 118. Regarding monitoring of surface waters for substances from the EU Watch List (⁵⁴), Sweden reported the results of sampling in 2021 and the first set of results from 2022, at the end of 2022 (⁵⁵).
- 119. On top of the lack of systematic monitoring of AMR in the environment, the vast environmental research generates AMR relevant data, which are not reported in the Swedres-Svarm report in a truly One Health fashion.

4.3.5 Conclusions on veterinary and environmental aspects of AMR

Sweden consistently reports the lowest sales of veterinary antimicrobials among EU Member States and favourable resistance picture in isolates from animals and food of animal origin. The country prides itself on the Swedish model (in principle: '*Healthy animals do not need antibiotics*'), which consists of:

• Effective surveillance and eradication of various notifiable diseases, which resulted in an exceptionally good animal health situation.

• Efforts to collect and analyse sales of antimicrobials and resistance patterns, predating the EU- harmonised surveillance systems.

• National requirements for infection prevention of control procedures in veterinary settings (a best practice model for other Member States to follow).

Long-standing cooperation between the authorities and stakeholders.

⁵³ <u>https://environment.ec.europa.eu/topics/water/urban-wastewater_en#revision</u>

⁵⁴ Commission Implementing Decision (EU) 2022/1307 establishing a watch list of substances for Union-wide monitoring in the field of water policy pursuant to Directive 2008/105/EC of the European Parliament and of the Council; OJ L 197, 26.7.2022, p. 117. The Watch List of the EU Water Framework Directive was created to provide monitoring data for chemicals of potential concern in the aquatic environment (the current list includes the following antimicrobials: sulfamethoxazole and trimethoprim, clindamycin, and ofloxacin).

⁵⁵ In their response to the draft report, the competent authorities noted that data will be reported in January 2025, except for ofloxacin. The authorities noted that there are no pharmaceuticals (human or veterinary) containing ofloxacin approved for use or sale in Sweden and ofloxacin had been monitored since 2010 in effluents from 9 WWTPs in Sweden and not been detected (Limit of Quantification (LOQ) 3-20 ng/l).

• Awareness of AMR among all actors.

There were however concerns about the availability of veterinarians and the possible lack of AMR awareness among veterinarians from outside Sweden, who were filling in the gaps. There were limited resources to implement the official controls at the planned frequency, highlighting the need to redefine the risk-criteria to streamline the selection of veterinarians and establishments to be inspected.

The treatment guidelines allow for increasing the dosage of penicillins (above the regime listed in their marketing authorisation). This is not in line with the provision laid down by the VMP Regulation. The authorities are however of the view that such adjustments are in line with the above Regulation expressing the overall aim to promote prudent use of antimicrobials and thus reduce the risk for resistance.

In the environmental sector, advanced treatment methods of wastewater have been a priority area for research for many years. With financial support from the authorities, full-scale treatment plants are already in operation. From 2025, the Swedish Medicinal Products Agency will pilot offering financial incentives to pharmaceutical manufacturers to adhere to strict limits for environmental contamination. Despite relevant actions included in the NAP, the needs and framework for the systematic monitoring of antimicrobials, AMR resistant bacteria and resistance genes in the environment, have not yet been set.

5 OVERALL CONCLUSIONS

Sweden has among the lowest levels of AMR and antimicrobial consumption in Europe and has made a long-standing effort to prevent the emergence and spread of AMR through promoting appropriate use of antibiotics in both humans and animals. There have been long-standing, joint national activities in human and animal health and food, and more recently in the environmental sector, addressing the risk of AMR in a truly One Health fashion. The collaboration between different authorities and stakeholders on a national level is coordinated through the ICM. Joint reporting and communication activities resulted in broad awareness among all the relevant actors and society about the risk of AMR and importance of maintaining the effectiveness of antibiotics. This, together with the political commitment of considering AMR as an issue of high priority, nationally and internationally, could be considered the key elements of success of Sweden in addressing AMR.

The national One-Health strategy on AMR and the Swedish One-Health cross-sectoral action plan are coming to an end in 2025. As the review process has now started, this is an opportunity for finetuning the strategy and the plan, and this report includes many observations and considerations intended for their review.

In the human health sector, long-standing activities promoting appropriate use of antibiotics through the unique Strama programme, wide use of treatment guidelines and point-of-care tests, and access to high-quality laboratory services, resulted in low

antibiotic use and a favourable AMR situation compared to other EU/EEA countries, including low prevalence of multidrug-resistant organisms (MDROs). Infection prevention and control (IPC) is viewed as an essential requirement for safe patient care with designated infection control teams in the regions and IPC doctors and IPC nurses in healthcare settings. Comprehensive risk-based MDRO screening allows for the rapid control and prevention of outbreaks. However, the focus of IPC is mainly personal and environmental hygiene, as well as the use of PPE, with less emphasis on the implementation of prevention bundles such as for the proper use and management of indwelling devices. While there are good quality data on MDROs, there is a lack of systematically collected actionable surveillance data on hospital acquired infections.

In the veterinary sector, the successful Swedish model based on the principle: 'Healthy animals do not need antibiotics' consists of: a) long-standing efforts by the authorities and stakeholders to eradicate and control various notifiable diseases, resulting in an exceptionally good animal health situation; b) comprehensive monitoring of AMR predating the European Union's harmonised surveillance system; and c) collection of data on antimicrobial consumption by the competent authorities and stakeholders; and d) national requirements for IPC in veterinary settings (a best practice model for other Member States to follow). There were, however, concerns about the availability of veterinarians, and some indication that additional training may be needed to ensure that all are fully familiar with the Swedish model and their obligations when prescribing antimicrobials. While the overall picture of compliance was positive, challenges were faced in implementing the official controls as planned, highlighting the need to redefine the risk criteria to streamline the selection of veterinarians and establishments to be inspected.

In the environmental sector, there is a vast body of research, in particular in the role of wastewater in the occurrence of AMR. The first full-scale wastewater treatment plants utilising advanced treatment methods are now in operation. In 2025, the competent authorities will pilot financial incentives scheme promoting the sustainable production of pharmaceuticals. There is an important need to develop a framework for systematic surveillance of antimicrobials, AMR resistant bacteria and resistance genes in the environment.

6 CONSIDERATIONS FOR POSSIBLE FUTURE ACTIONS

6.1 ONE HEALTH ASPECTS OF AMR

• While reviewing the current OH-NAP, consider the development of an integrated operational One Health NAP, including all relevant actions with clear roles and responsibilities, with dedicated budget and timeline for each action, a monitoring and evaluation plan with indicators and targets, assessment of the effectiveness and impact of the actions, and regular public reporting and communication to all relevant political levels.

- Ensure that overarching strategic directions outlined in the national strategy on AMR define the vision, long-term aims, and overall direction to guide the planning and prioritisation of the actions. The strategy can have a longer scope than the action plan with flexibility for updates if dictated by significant developments.
- Consider how to safeguard the functions of the ICM and further facilitate these by making clear that contribution to the ICM is a priority for all participating actors and by making sure that there are sufficient resources and supporting structures.
- Consider including civil society such as patient advocacy groups in the ICM.
- Explore how to align the integrated operational One Health NAP for AMR with other relevant action plans and strategies, such as the one on patient safety and the national strategic research agenda for AMR.

6.2 HUMAN HEALTH ASPECTS OF AMR

6.2.1 General

- Enhance the use of data for action through advancing health data linkage and improving data access, while ensuring personal data protection.
- Support collaboration of Strama and IPC teams at the local, regional and national levels.
- Align efforts on AMR, IPC and AMS to avoid duplication of work and the formation of silos.
- Support the implementation of actions at regional level with close collaboration of all stakeholders involved and explore strategies to promote alignment of regional activities with the national action plan, e.g., by introducing regional action plans for the activities under the remit of the regions.
- Continue to promote work at international level.
- Continue support to research, development and innovation.

6.2.2 Infection prevention and control (IPC)

- Consider a greater emphasis on IPC practices beyond the standard hygienic measures that seem to have been the main focus of IPC activities so far. This is especially relevant given that urinary and respiratory tract infections represented more than 40% of HAIs in Sweden, as reported in the most recent PPS. A large proportion of healthcare-associated urinary and respiratory tract infections is related to medical devices.
- HAI surveillance could be strengthened with the addition of structure, process and especially outcome indicators. This would be particularly recommended for HAIs acquired in ICUs, for which participation in ECDC's HAI-Net surveillance would be strongly encouraged.

- Consider extending hand hygiene and environmental cleaning audits to clinical procedures that are relevant to IPC and ensuring a greater involvement of IPC professionals, especially in the follow-up and implementation of change.
- Similarly, more direct involvement of and support by IPC professionals in LTCFs could be warranted, especially considering the high proportion of HAIs identified in the PPS that originate from LTCFs.
- Ensure that the WHO core IPC components are present in all healthcare facilities and consider the introduction of harmonised structure, process and outcome indicators with targets across all entities and regions.
- Support for research and development of innovative approaches to surveillance, including automated and semi-automated surveillance based on electronic health records should be continued aiming to ensure the feasibility and sustainability of HAI surveillance.

6.2.3 Surveillance of antimicrobial consumption and antimicrobial stewardship

6.2.3.1 Surveillance of antimicrobial (antibiotic) consumption/use

- Explore the possibility of collecting DOT data in all sectors (hospitals, primary care, LTCFs), at facility, regional and national levels in order to have a range of different metrics of antibiotic consumption/use, as all metrics have limitations.
- Explore the potential added value of using data from the National Prescribed Drug Register (*Läkemedelsregistret*), as patient-level antibiotic use data might have an added value as compared to antibiotic consumption sales data.
- In hospitals, pursue the development and use of quality indicators as well as proxy measures for appropriateness of antibiotic prescriptions. Collection of such data and feedback to all departments should be encouraged. Also, explore the possibility to assess the appropriateness of prescriptions based on a short questionnaire ("quick audit") during some of the antibiotic rounds. Encourage the ongoing work aimed at national reporting of data on the hospital and primary care quality indicators.
- Thoroughly explore the possibility of collecting antimicrobial use data specifically for LTCFs (at LTCF, regional and national levels), as AMR and antibiotic use in LTCFs are different from primary care and specific data are needed to inform AMS efforts in this population.
- Consider the added value of proxy indicators, in addition to existing quality indicators and quantity metrics, since all metrics/indicators have limitations (⁵⁶).

⁵⁶ <u>https://doi.org/10.1093/cid/ciaa1221</u> <u>https://pubmed.ncbi.nlm.nih.gov/32672150/</u> <u>https://pubmed.ncbi.nlm.nih.gov/33685893/</u>)

6.2.3.2 Antimicrobial stewardship (AMS)

All settings

- Sustain and enhance the activities of Strama at national and regional levels, particularly taking into account the Strama staffing recommendations (⁵⁷). Given Strama's long-standing existence, wide recognition and undoubtable success, consider maintaining its leading role in AMS.
- Based on existing guidance (⁵⁸) and national consensus procedures: i) define key/core structure and process elements of AMS programmes at regional, hospital, LTCF and primary care levels, and ii) adjust the Strama staffing recommendations accordingly, if needed.
- Regularly monitor AMS structure, process and outcome indicators with targets (aligned with the national strategy) at all administrative levels (national, regional, local) and healthcare settings (hospital, primary care, LTCF). Encourage public reporting with benchmarking between regions (e.g. results presented visually on a map of Sweden, showing the different regions) of key indicators.
- Use quality improvement, implementation science and behaviour change strategies (with training for Strama teams if needed), as well as a whole-of-society approach (including civil society involvement) in all Strama teams.
- Assess the added value of the Antibiotic Smart Sweden project.
- Continue and enhance activities on ensuring access to older antibiotics (especially narrow-spectrum antibiotics), as well as on models for incentivising the development of and access to novel antibiotics.

Community & LTCFs

- Promote the use of Strama ambassadors in all facilities, with a defined role (and include this as a key element).
- Systematically feedback and discuss quality indicator data in primary care with GPs and antibiotic consumption/use data at dental practice level with dentists.
- GPs (and if possible, dentists in the future) should be regularly sent their individual quality indicator data by their manager and encouraged to discuss it with colleagues and the Strama team.
- Consider pilot-testing novel AMS interventions (e.g., no reporting of AST for urine cultures of LTCF residents'– unless requested by the GP) (⁵⁹) and assessment of the diagnostic process.

https://strama.se/wp-content/uploads/2023/10/Foreslagna-minimiresurser-till-regionala-Stramagrupper.pdf
WHO: https://www.who.int/publications/i/item/9789241515481;

ECDC/CDC: <u>https://www.cdc.gov/tatfar/media/pdfs/Rec1-Report-2015-508.pdf</u>, US CDC: <u>https://www.cdc.gov/antibiotic-use/hcp/core-elements/index.html</u>)

⁵⁹ <u>https://pubmed.ncbi.nlm.nih.gov/31928257/</u>.

• Encourage, as currently explored, the possibility of per-unit dispensing of medicines, including antibiotics, without the need to discard the remaining pills as currently practiced.

Hospitals

- Apply a more systematic approach based on the defined key AMS elements, such as antibiotic rounds, champions in each department, data on antibiotic consumption/use and on quality indicators in all hospitals that must be fed back to each department.
- Consider expanding the range of AMS interventions (based on international evidencebased guidance and the above-mentioned key elements; exchange of practices with AMS centres of excellence in other countries might be inspiring for all) and pilot-testing new AMS interventions, such as:
 - IT tools (e.g. alerts, computerised decision support systems);
 - Quick audits during antibiotic rounds, including auditing the diagnostic process;
 - Not reporting of AST for catheter urine samples (unless requested by the treating physician).

6.2.4 Laboratory capacity and surveillance of AMR

- Improve the user-friendliness of Svebar to facilitate extraction and visualisation of data, with different levels of granularity.
- Use the opportunity of the new Svebar system to generate data specifically for LTCFs, at national, regional and facility levels.
- Improve the availability of phenotypic AMR statistics in hospitals and their use for informing and evaluating interventions.
- Improve collection of data on antifungal resistance in fungal pathogens.
- Consider making *C. auris* a notifiable disease.

6.2.5 Communication

- Further enhance the regular mechanisms to conduct assessments of AMR communication needs and capture attitudes, beliefs, misinformation or information gaps, e.g. to better understand knowledge gaps within population groups. Establishing such mechanisms could support better segmentation of audiences, more targeted and effective communication strategies, ensuring that efforts to raise awareness and promote prudent use of antibiotics are as impactful as possible.
- Employ systematic communication needs assessments and add evaluation components to communication interventions to enable the continuous improvement of AMR communication efforts, ensuring that they are responsive to evolving needs and challenges.

- Explore additional social media platforms, especially for reaching younger target audiences. As it might be difficult to manage institutional accounts on such platforms, consider working with social media influencers and implementing communication activities with/through them, which might be a solution to be present on these platforms.
- Consider creating a closed-circuit repository for all campaign materials and initiatives from various institutions for use by all partners and organisations with interest and activities in AMR. This could improve "institutional memory" on the available AMR communication resources, created both at central and regional level, and would allow regions/ agencies to have a full overview of already created materials that can be reused or adapted.
- Whilst respecting the independence of the regional authorities, encourage regional communication plans, for example by sharing templates and toolkits created at central level. This could have the potential to encourage earlier planning in the regions, improve partner coordination to communicate on a One Health approach, identify communication moments throughout the year (not only on European Antibiotic Awareness Day EAAD), and eventually allocate extra resources.
- Consider how to improve the AMR communication initiatives by receiving systematic input from professional associations, non-governmental organisations (NGOs) and civil society representatives, as was presented in the context of "Antibiotic Smart Sweden". The involvement of these actors in communication activities, from the designing phase to implementation, could facilitate the participation of target audiences, increase acceptance and maximise impact. Encouraging community participation not only fosters a sense of collaboration but also promotes a sense of ownership of the intervention among community members.
- Consider how to secure consistent financial support for "Antibiotic Smart Sweden" and implement good practices from this project into the regular work on AMR communication.
- Consider strengthening educational efforts targeting children at school and explore innovative ways to engage civil society (e.g., through TV series, museums, musicals).

6.2.6 Behavioural change interventions

- Consider conducting an internal inventory of in-house skills and competencies to better target training and thereby create a larger internal cadre of colleagues with some level of social and behavioural science expertise.
- It may be important to consider supplementing the WHO/Europe THP approach with more agile methodologies from the social and behavioural sciences, on the basis that 'good enough' rapid research can also provide important insights for action. An example of this more agile approach to applying methods from social and behavioural science was presented in the context of "Antibiotic Smart Sweden", through the development and evaluation of materials adapted for different target groups. This and

other good practices within the context of "Antibiotic Smart Sweden" can be lifted as examples for further development and inspiration.

- The practice of incorporating social and behavioural science research into the development and evaluation of ongoing projects, rather than initiating whole new streams of work, was also mentioned as a potentially efficient means of maximising its impact.
- Evaluation of social and behavioural interventions should be prioritised as a means of demonstrating impact on specific public health challenges, and through this showing the added value of PHAS's work in this area. This is especially important since social and behavioural sciences are not always seen by the wider public health community as core to the prevention and control of infectious diseases; and evidence to illustrate its full potential is needed. Focusing on the evaluation of interventions that target a specific health-related behaviour in a specific population (as opposed to measuring, for example, more upstream or distal determinants of behaviour) may be an effective way to do this. An example was the suggestion to initiate a pilot intervention in hospitals, targeting a reduction in HAIs by working to reduce antibiotic use in surgical patients prior to the operation (as opposed to the recommended perioperative antibiotic prophylaxis). Similarly, there was discussion about the increasing focus on changing specific behaviours within the "Safeguarding Antibiotics" initiative.
- Another potential social and behavioural research area concerned the identified need to investigate how different population groups understand and relate to AMR, as a means of building interventions that are relevant, sustainable and acceptable to given target populations. As part of such a research initiative, it would be beneficial to formally document the changing narratives around the way people publicly discuss AMR, specifically in relation to how these may reflect the language used by PHAS as was noted during our discussion regarding the term 'safeguarding antibiotics'. This could be a powerful means of highlighting the value that can be added with the addition of a social and behavioural science approach to the work.
- Since many generic lessons (i.e., not specific to AMR) relating to the application of social and behavioural sciences were learned at both regional and national levels in Sweden during the COVID-19 pandemic, it would be important to properly document and publish these lessons learned both as a means of recognising the work done in Sweden, but also to provide inspiration for other European countries to learn from.

6.2.7 Training

- Introduce specialist training in AMR, AMS, and IPC for nurses, with certification requirements equivalent to those required for doctors. Recognise the status of IPC nurses as a profession.
- Establish minimum training curricula and core competencies in AMR, AMS and IPC, for all relevant professions and at both undergraduate and postgraduate levels.

- Consider involving student associations in the process related to the above and gauging their feedback through regular surveys of perceived preparedness regarding the core competencies of final year students.
- Finally, consider defining requirements and establishing, where necessary, training in AMS, with defined core competencies for all Strama teams.

6.3 VETERINARY ASPECTS OF AMR

6.3.1 Monitoring of AMR in animals and food

- Continue working towards widening the laboratory network to provide more comprehensive monitoring data to have a better picture of the AMR situation readily available for the prescribers.
 - Consider mandatory submission of AST results (required to justify prescription of higher-risk antibiotics) to obtain more data, in particular for the pathogens with limited numbers of isolates available.
 - With improved availability of isolates and data, create a mechanism for disseminating of the findings, including regional epidemiological data trait.

6.3.2 Monitoring the use of antimicrobials in animals

- Consider setting up the protocols and guidelines for benchmarking of veterinarians using the data on pharmacy sales already available from the eHealth Agency. This is to enable:
 - the veterinarians to analyse their prescriptions patterns and to compare with their peers in a more formalised way, and
 - $\circ~$ a unified approach to handling data that could inform the risk-based regulatory controls.
- Consider the use of specific data available (e.g., on colistin prescribing), to target veterinarians for regulatory controls to check compliance and further raise AMR awareness among the individual prescribers.

6.3.3 Activities to promote the reduced and/or prudent use of antimicrobials in animals.

- Consider developing unified, nationwide risk-based criteria for selection of veterinarians and establishments for inspection.
- Taking into account the specifics of different counties, review the inspection frequency targets to ensure that the competent authorities can achieve them.
- Consider setting up CPD requirements for practising veterinarians to ensure that they are aware of and up to date with their obligations to prescribe in a prudent manner and

to improve the communication about any new developments (e.g., AMS in veterinary settings)

6.4 Environmental aspects of AMR

- Develop the needs and framework for the systematic environmental monitoring of antimicrobials, resistant bacteria and antimicrobial resistance genes as intended in the current cross-sectoral action plan.
- Consider how to include the findings on environmental contamination from the vast AMR-related research, as well as the results from environmental monitoring (above paragraph) once established, in the new editions of the Swedres-Svarm report. This is to build on the One Health approach.

7 CLOSING MEETING

The ECDC and Commission teams presented the main findings and preliminary conclusions of the visit to the competent authorities in a closing meeting held on 20 September 2024.

ANNEX 1 - LEGAL REFERENCES

Legal Reference	Official Journal	Title
Reg. 851/2004	OJ L 142, 30.4.2004, p. 1-11	Regulation (EC) No 851/2004 of the European Parliament and of the Council of 21 April 2004 establishing a European Centre for disease prevention and control
Reg. 2016/429	OJ L 84, 31.3.2016, p. 1–208	Regulation (EU) 2016/429 of the European Parliament and of the Council of 9 March 2016 on transmissible animal diseases and amending and repealing certain acts in the area of animal health ('Animal Health Law')
Reg. 2019/6	OJ L 4, 7.1.2019, p. 43–167	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
Reg. 2019/4	OJ L 4, 7.1.2019, p. 1–23	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/EEC
Reg. 2022/1255	OJ L 191, 20.7.2022, p. 58–60	Commission Implementing Regulation (EU) 2022/1255 of 19 July 2022 designating antimicrobials or groups of antimicrobials reserved for treatment of certain infections in humans, in accordance with Regulation (EU) 2019/6 of the European Parliament and of the Council
Dir. 2008/105/EC	OJ L 348, 24.12.2008, p. 84-97	Directive 2008/105/EC of the European Parliament and of the Council of 16 December 2008 on environmental quality standards in the field of water policy, amending and subsequently repealing Council Directives 82/176/EEC, 83/513/EEC, 84/156/EEC, 84/491/EEC, 86/280/EEC and amending Directive 2000/60/EC of the European Parliament and of the Council

Legal Reference	e Official Journal Title	
Dir. 2000/60/EC	OJ L 327, 22.12.2000, p. 1-73	Directive 2000/60/EC of the European Parliament and of the Council of 23 October 2000 establishing a framework for Community action in the field of water policy
Dec. 1082/2013/EU	OJ L 293, 5.11.2013, p. 1-15	Decision 1082/2013/EU of the European Parliament and of the Council of 22 October 2013 on serious cross-border threats to health and repealing Decision No 2119/98/EC
Dec. (EU) 2022/1307	OJ L 197, 26.7.2022, p.117-121	Commission Implementing Decision (EU) 2022/1307 of 22 July 2022 establishing a watch list of substances for Union-wide monitoring in the field of water policy pursuant to Directive 2008/105/EC of the European Parliament and of the Council
Dec. 2020/1729/EU	OJ L 387, 19.11.2020, p. 8–21	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