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TECHNICAL REPORT

Methodology for conducting One Health country visits on antimicrobial resistance in the Western Balkans

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This document was commissioned by the European Centre for Disease Prevention and Control (ECDC) and produced by the consortium, Epiconcept and Integrated Quality Laboratory Services, with the financial support of the European Union under CN/2019/409-781, as part of the Specific Contract No 1 ECD.14631 ID 25341, implementing Framework contract No ECDC/2022/006 'Country support to advance One Health responses against antimicrobial resistance in Western Balkans' OJ/2022/DIR/23891.

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The human health part of this document is based on ECDC's 'Assessment tool for joint One Health country visits in relation to antimicrobial resistance'.

Suggested citation: European Centre for Disease Prevention and Control. Methodology for conducting One Health country visits on antimicrobial resistance in the Western Balkans. Stockholm: ECDC; 2024.

Stockholm, August 2024

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Abbreviations

AMC	Antimicrobial consumption
AMR	Antimicrobial resistance
AMS	Antimicrobial stewardship
ASP	Antimicrobial stewardship programme
AST	Antimicrobial susceptibility testing
ASU	Antimicrobial sales and use
CAESAR	Central Asian and European Surveillance of Antimicrobial Resistance network
EAAD	European Antibiotic Awareness Day
EARS-Net	European Antimicrobial Resistance Surveillance Network
ECDC	European Centre for Prevention and Disease Control
EEA	European Economic Area
EFSA	European Food Safety Authority
EMA	European Medicines Agency
EQA	External quality assessment
EU	European Union
EUCAST	European Committee on Antimicrobial Susceptibility Testing
EURGen-Net	European Antimicrobial Resistance Genes Surveillance Network
FAO	Food and Agriculture Organization of the United Nations
FVA	Food and Veterinary Agency
FWD-Net	Food and Waterborne Diseases and Zoonoses Network
GAP	Global action plan on AMR (World Health Organization)
GLASS	Global Antimicrobial Resistance and Use Surveillance System
HAI	Healthcare-associated infection
ICM	Intersectoral Coordination Mechanism
ICU	Intensive care unit
IPA	Instrument of Pre-accession Assistance
IPC	Infection prevention and control
MOH	Ministry of Health
NAP	National action plan
NRL	National reference laboratory
VMP	Veterinary medicinal products
WHO	World Health Organization
WOAH	World Organisation for Animal Health

Introduction

Antimicrobial resistance (AMR) is an increasing public health problem that poses a serious threat to human and animal health, as well as to the environment, which is why it is currently a key priority for the European Centre for Disease Prevention and Control (ECDC)[1]. AMR also has substantial economic implications: it is estimated that in 2019 alone, over 38 710 deaths were attributable to bacterial infections with AMR in the European Union/European Economic Area (EU/EEA), with associated costs of nearly EUR 11.7 billion due to increased health expenditure and reduced work productivity[2].

In 2015, the Global Action Plan (GAP) on AMR was adopted by all World Health Organization (WHO) Member States through decisions at the World Health Assembly, the Food and Agriculture Organization of the United Nations (FAO) and the World Organisation for Animal Health (WOAH, founded as OIE). Countries agreed to have a National Action Plan (NAP) on AMR, aligned with the GAP, that coordinates action among human health, food production and animal health systems, and to implement relevant policies and plans to prevent, control and monitor AMR.

In 2016, the GAP was endorsed by all the WHO Member States who committed to the development and implementation of a collaborative and multisectoral NAP addressing individual national priorities for AMR, including disease burden, human-animal interactions and environmental practices, in line with the GAP. The GAP sets out five strategic objectives to address AMR:

- improved awareness of AMR and behaviour change in key sectors and the general population;
- strengthened knowledge and evidence base to inform decisions on policy and practice;
- reduced incidence of infections in humans and animals, as well as reduced environmental contamination;
- optimised use of antimicrobials in human and animal health, with growth promotion phased out; and
- increased research and development on new medicines, vaccines, diagnostics and other interventions.

In 2022, FAO, the United Nations Environmental Programme, WHO and WOAH published a One Health Joint Plan of Action (2022–2026) to respond to international requests to prevent future pandemics and to promote health sustainably through the One Health approach. Addressing the silent pandemic of AMR was one of the five key objectives which required action to strengthen national capacity, bolster global and regional initiatives and reinforce global AMR governance structures.

At ECDC, AMR is identified as one of three priority conditions[1], with the aim of supporting the European One Health Action Plan, intensifying cooperation with other international organisations, and continuing to coordinate the European Antibiotic Awareness Day[3].

To increase health security in the EU, ECDC supports Western Balkan countries in strengthening their infectious disease prevention and control systems and public health workforce. Since 2011, ECDC has undertaken several national technical assessments and convened regional meetings to prepare for the participation of Western Balkan countries in ECDC activities, most recently focusing on a One Health approach to AMR.

In 2019, the joint ECDC and European Food Safety Authority (EFSA) regional workshop on a One Health approach against AMR for EU pre-accession countries highlighted the urgent need to boost national responses to AMR to achieve the level of implementation required for relevant EU legislation in the region[4]. National governments need to put in place regulatory requirements, laboratory infrastructure and techniques, comprehensive and interoperable electronic surveillance systems, training and additional human resources in human and animal health, while raising awareness and commitment to ensure sustainability of efforts. During this regional workshop, the Western Balkan IPA beneficiaries agreed upon and committed to a regional One Health approach to AMR, starting with One Health country visits to discuss AMR issues in each beneficiary country[5]. This priority was reiterated at the meetings of the national ECDC correspondents in the Western Balkans and Türkiye in November 2022[6] and December 2023[7].

[1] European Centre for Disease Prevention and Control. Single Programming Document, 2023–2025. https://www.ecdc.europa.eu/en/publications-data/single-programming-document-2023-2025 [accessed 15 June 2023]
[2] European Union. Conclusions on the next steps towards making the EU a best practice region in combating antimicrobial resistance. https://data.consilium.europa.eu/doc/document/ST-9765-2019-INIT/en/pdf [accessed 28 May 2023]
[3] European Union. A European One Health Action Plan against Antimicrobial Resistance (AMR). https://health.ec.europa.eu/system/files/2020-01/amr_2017_action-plan_0.pdf [accessed 14 June 2023]
[4] European Centre for Disease Prevention and Control. Meeting report 2019 ECDC EFSA Regional workshop on One Health against AMR in Western Balkan countries (europa.eu)
[5] European Centre for Disease Prevention and Control Meeting Report: Regional workshop on a 'One Health' approach to antimicrobial resistance in EU pre-accession countries. https://www.ecdc.europa.eu/sites/default/files/documents/antimicrobial-resistance-one-health-approach-EU-preaccession-countries.pdf [accessed 12 April 2023]
[6] European Centre for Disease Prevention and Control Meeting Report: Annual meeting of national ECDC correspondents in the Western Balkans and Türkiye, November 2022 Annual Meeting of national ECDC correspondents in the Western Balkans and Türkiye 2023 (europa.eu) and https://www.ecdc.europa.eu/sites/default/files/documents/western-balkans-turkiye-meeting-report-national-ECDC-correspondents-november-2022.pdf [accessed 29 April 2024]
[7] European Centre for Disease Prevention and Control Meeting Report: Annual meeting of national ECDC correspondents in the Western Balkans and Türkiye, December 2023 Annual meeting of national ECDC correspondents in the Western Balkans and Turkiye 5-6 Dec 2023 (europa.eu)

Scope and purpose

Each country visit is designed to contribute to the advancement of a One Health approach to AMR through the development of One Health AMR country roadmap, the securing of political commitment for national interventions and the exchange of best practices between participating countries.

The specific objectives of each One Health country visit are to:

- discuss AMR issues at national level;
- map existing resources and encourage collaboration between stakeholders to prevent AMR;
- document the situation and efforts being made by the country in human and animal health, as well as in the environmental sector;
- identify examples of best and good practice, as well as gaps in current activities;
- assess the need for awareness-raising campaigns on the prudent use of antibiotics and prevention and control of AMR;
- ascertain progress and capacity for establishing electronic surveillance of AMR in the country; and
- inform the development of a One Health country roadmap on AMR, covering the human and animal health and environmental aspects of AMR.

Preparation of the country visit

It is important to establish contacts and communication with a national core group to facilitate preparatory work before the country visit. The national core group should include, as a minimum, one designated contact point for human health and one for animal health/food safety who should be able to liaise with the Intersectoral Coordination Mechanism (ICM) on AMR and the national authorities (Ministry of Health, Ministry of Agriculture, national authority in charge of water and sanitation; national authority in charge of the environment, etc).

With the guidance and agreement of the national core group, the dates for the visit should be selected and a draft outline agenda developed for the country visit (template agenda included in the Annex 1), including possible stakeholders to be consulted and sites to be visited (listed in Annex 2).

Prior to the country visit, a country overview should be prepared in collaboration with the national core group, describing the national One Health AMR response under 12 separate headings (see Annex 3). The country overview should summarise available documentation, including the NAP and its implementation, tripartite country self-assessment surveys, and data from AMR and antimicrobial consumption (AMC) surveillance systems. This country overview should include a comparison/benchmark of the country against the EU average and should also highlight gaps in the national response and examples of best practice. It should also help to inform the draft agenda and the checklist for the country visit.

The national core group is responsible for the in-country logistics during the visit, which includes informing and involving national stakeholders and authorities in the country visit, liaising with stakeholders to identify suitable times for meetings, reserving rooms of adequate capacity, and mobilising transportation for site visits, if needed.

The country visit team usually consists of five to eight experts. Composition of the team should be communicated to the national core group as soon as such information becomes available and preferably at least two weeks ahead of the start of the country visit. It is anticipated that the country visit team will include the following expertise as a minimum:

- Two or three ECDC experts and one EU/EEA country expert in the field of AMR and healthcare-associated infections.
- One EFSA expert, one DG SANTE expert, and one EU/EEA country expert in the field of animal health and veterinary medicine.
- One or two external contractors to coordinate the visit, cover agreed areas of human and animal health, and draft the report.

The official lead of the country visit team is ECDC. The external contractor is responsible for the country visit report. Under the leadership of the country visit team lead, all experts in the country visit team should participate in all designated activities during the country visit and contribute to the development of the findings, to be presented as preliminary at the end of the country visit and finalised in the subsequent report. The country visit team and the national core group should review and agree on the country visit report before any further dissemination.

Programme of the country visit

In collaboration with the Intersectoral Coordination Committee (ICM) and other national stakeholders, the aim of each country visit is to discuss and review the advancement of a One Health approach to AMR through: (i) the identification of strengths and weaknesses in the current national AMR strategies, action plans and intersectoral coordination mechanisms; (ii) a review of the functioning of national reference laboratories (NRLs) for AMR and their capacity to detect resistance trends; (iii) the documentation of the situation and efforts being made by the country on AMR surveillance, antimicrobial consumption (AMC) and healthcare-associated infections (HAIs); (iv) a review of action related to the prudent use of antibiotics in human and animal health and food safety, as well as in the environmental sector; and (v) a review of activities and approaches to awareness-raising on AMR. The strengths and gaps analysis will inform further development of the national One Health roadmap for AMR. The purpose of each visit should therefore be to:

- review the current level of NAP development, implementation and progress made in all sectors, including human and animal health, food production and the environment;
- assess the areas of collaboration between and within the various national and regional stakeholders and identify opportunities for improvement;
- identify best practices and gaps in the national response to AMR; and
- ascertain the importance of gaps identified in the national response to AMR and explore the options for addressing them in a national AMR roadmap.

During the visit, the country visit team and the designated contact points should employ a variety of methods to complement and supplement the country visit review (Annex 3), including presentations from national stakeholders and in-depth discussion, break-out groups and site visits with national stakeholders.

Country visits are normally planned for five days (Monday–Friday). A short description is provided below. An example of a detailed country visit agenda is provided in Annex 1.

Short description of a country visit

Day	Description of activities
Day 1	Plenary meeting with relevant ministries (health, agriculture, veterinary, environment), the inter-sectoral coordinating mechanism (ICM) and all national stakeholders participating in the country visit. The meeting is an opportunity for the country visit team to engage with national stakeholders, present the purpose of the visit and understand country expectations and specific needs. The plenary meeting should include: - A presentation from the country visit team on the objectives, outcomes, outputs and the preliminary agenda for the visit. - A presentation from national stakeholders on the NAP, overview of the current situation with AMR and antimicrobial consumption (AMC) data available at country level gaps, country needs to advance with its national strategy and plans related to AMR. All sectors (i.e. human and animal health, food safety and the environment) should be covered. Following this, discussions with the ICM should take place to address areas for evaluation shared by all sectors, including[8] the ICM itself; the NAP; organised multidisciplinary collaboration at local level; clinical diagnostic and reference laboratory capacity services; monitoring of AMR and AMC in humans and of veterinary antimicrobials sales and use; public information and behavioural change interventions for AMR, and marketing-related issues. From the afternoon of Day 1 onwards, the country visit team should be divided in two groups, with parallel programmes for the respective meetings. - For human health (ECDC), discussions should cover national level activities on antimicrobial stewardship and treatment guidelines (indicators in Section 6), IPC (indicators in Section 7), and AMR and infection prevention and control (IPC) education (indicators in Section 8). - For animal health/food safety (DG SANTE and EFSA), the discussions should cover policies to tackle AMR through the reduced and more prudent use of antimicrobials. These should include communication and awareness activities; undergraduate and postgraduate education of veterinary professionals; availability of veterinary antimicrobials and veterinary care and reduction of the need for veterinary antimicrobials; monitoring of AMR in animals and food (EFSA lead), and surveillance of sales and use of antimicrobials in the veterinary sector (DG SANTE with the help of the national expert from the European Medicines Agency (EMA) ESVAC/ESUAvet working group). Discussions in this group (DG SANTE and EFSA) should also cover the environmental aspects of AMR. It is important that the country representatives deliver a short presentation for each of the topics listed above (and mentioned in the ECDC assessment tool), including a situational analysis and a description of activities, achievements and perceived gaps. Each presentation should be followed by discussion.

[8] For further details on the indicators, please see One Health assessment tool for country visits relating to AMR (europa.eu).

Day	Description of activities
Day 2 to Day 4 (morning)	Meetings and site visits with national stakeholders as identified in the country visit agenda. During these days, the country visit team will split into two groups (e.g. human health and animal health/food safety) to meet with national stakeholders and visit sites of specific interest. ECDC experts are foreseen for visits to hospitals, pharmacies, laboratories, long-term care facilities and general practitioners' offices, including paediatricians. Healthcare facilities should be visited in at least one, or preferably two regions, outside of the capital. At hospital level, the team would like to visit and meet medical staff, mainly from the following departments/wards: infection control, infectious diseases, intensive care unit, surgery, microbiology laboratory and pharmacy. The intention of the hospital visits is to discuss prudent use of antibiotics/antibiotic stewardship, AMR prevention and control measures with the different stakeholders and their perception of the current status and requirements for tackling AMR. DG SANTE and EFSA team should not carry out farm visits, but should meet with multiple stakeholders (veterinary, farming and veterinary medicinal product (VMP) sectors) to discuss various aspects of AMR, including the measures that can be taken to encourage the reduced and prudent use of antimicrobials.
Day 4 (afternoon)	The country visit team will meet to debrief all country visit team members on the information collected during the country visit and prepare a draft report with preliminary findings and initial conclusions.
Day 5 (morning)	Meeting with the relevant ministries with national authorities and stakeholders during which the visiting team will present its preliminary findings from the country visit and recommendations. This session will enable the country visit team to share its initial conclusions and facilitate a discussion with national stakeholders regarding examples of best practice, gaps identified and possible solutions. Country visit ends by 12:00 noon.

The country visit report should update country desk research with the information gained during the visit to provide a situational analysis of the current One Health activities to prevent and control AMR, highlight best practices, identify gaps in the national response, and propose issues to be raised and discussed in the national One Health AMR roadmap. The country visit report should include the following sections:

1. Introduction.
2. Objectives and scope.
3. Background.
4. Observations and conclusions on:
   - AMR strategies, action plans and coordination, based on a One Health approach;
   - AMR and AMC in the human health sector including antimicrobial stewardship, HAI and IPC;
   - AMR and AMC monitoring in the animal health sector;
   - Prudent use of antimicrobials in the food production sector;
   - Environmental aspects of AMR.
5. Overall conclusions.
6. Considerations for possible future action, including a proposal for key priorities, targets and timelines for a national roadmap.
7. Annexes relating to the country visit programme and a list of all participants.

The observation and conclusions section for human, veterinary and environmental aspects should employ the country visit review structure (Annex 3) as a framework and report on topic areas such as:

- country context;
- inter-sectoral coordinating mechanism and AMR governance;
- clinical diagnostic and reference laboratory services;
- monitoring of AMR;
- monitoring of AMC at national level;
- antimicrobial stewardship and treatment guidelines;
- IPC;
- AMR and IPC training;
- public information related to AMR;
- marketing-related issues;
- electronic surveillance;
- international and other research perspectives.

If the report is prepared by external contractors, the country visit team (ECDC, DG SANTE, EFSA, external experts) should review the draft. Once the draft report has been reviewed and agreed upon by the country visit team, it should be made available to the national stakeholders, via the national core group, in order for them to check facts and provide comments and suggestions to improve the report. ECDC will finalise the report and formally share it with the national authorities. The finalised report may be published on ECDC's website, subject to the prior agreement of the national public health and animal health/food safety authorities.

Annex 1. Example of country visit agenda

One Health country visit on antimicrobial resistance (AMR) to [COUNTRY]

XX month – XX month 202X

Country visit team and areas of coverage	
ECDC	✓ **Name, surname,** Role and expertise ✓ **Name, surname,** Role and expertise
European Commission	✓ **Name, surname,** Role and expertise ✓ **Name, surname,** Role and expertise
EFSA	✓ **Name, surname,** Role and expertise
External contractors	✓ **Name, surname,** Role and expertise ✓ **Name, surname,** Role and expertise

Country-designated contact points and other national contacts	
	✓ **Name, surname,** Role and expertise ✓ **Name, surname,** Role and expertise ✓ **Name, surname,** Role and expertise ✓ **Name, surname,** Role and expertise

Sunday XX month 202X		
Arrival of visit team	Given that they will be arriving at different times, the team members are kindly asked to arrange their own transfer to the hotel.	**Hotel:**

DAY 1: Monday XX month 202X		
09:00–09:45 (45 min)	**Opening meeting with national authorities and stakeholders** All country visit team - Ministry of Health – Representative A - Ministry of Agriculture Forestry and Water Economy - Representative B - Ministry of Environment and Physical Planning **– Representative C** - Director of the Food and Veterinary Agency - Representative D - Director of the Institute of Public Health - Representative E - Director of Pharmacy department/Advisor to the Director of the Health Insurance Found – Representative F - Director of the Agency for Drug and Medical Devices - Representative G - All members of the national committee for AMR control. **Short presentation of participants** Presentation on objectives of the visit, expected outputs and outcome, One Health concept – **ECDC country team lead**	**Location**: • Room booked by the XXX, two rooms for Day 1 in the afternoon. • Maximum capacity of the room – XX-XX • The reservation is made for XX people. • Two coffee breaks and lunch are planned. Address: Contact person(s): Telephone: +
09:45–13:15 (3.5 hours)	**Meeting with the Intersectoral Coordinating Mechanism (ICM) on AMR Human health team (ECDC); Animal health and food safety team (DG SANTE and EFSA)** **Governance, surveillance and One Health aspect of AMR** **Objective:** gather information on the current situation regarding AMR governance and AMR surveillance strategies in the country. **Presentations: (10 min/presentation)** 1. National AMR strategy and its implementation in the country: current policy and legislation– Person A 2. Monitoring of antimicrobial use/consumption in human health – Person B 3. Monitoring of AMR in human health – Person C 4. Monitoring of antimicrobial sales/use in animal health sector – Person D 5. Monitoring AMR in animals and foods, Person E 6. Electronic surveillance of AMR – Person F 7. Laboratory capacity in human and animal health - Person G 8. Antibiotic awareness activities – Person H.	**Location**: same as above
11:30–11:45 Coffee break + group photo	**Q&A session/Discussion on** (based on One Health assessment tool for country visits relating to AMR (europa.eu)): (approx. 1 hour) - Inter-sectoral coordination mechanism (indicators in section 1.1)	

	- National Action Plan (indicators in Section 1.2) - Organised multidisciplinary collaboration at local level (indicators in Section 2) - Monitoring of AMR (indicator 4) and antimicrobial consumption (indicators in Section 5) - Clinical diagnostic and reference laboratory services (indicators in Section 3) - Public information and behavioural change interventions related to AMR (indicators in Section 9). **Moderator: Country contacts**	
13:45– 14:45	Lunch break	
14:45 – 15:45 (1 hour)	**Meeting with representatives of the Ministry of Environment, Ministry of Agriculture, Food and Veterinary Agency on environmental aspects of AMR** **Presentation (10 min):** The environmental aspect of AMR and surveillance of AMR in the environment (main gaps identified and plans) – Person A **Discussion on:** - Environmental surveillance of AMR and residues of antimicrobials - EU harmonised monitoring of Watch List substances under the Water Framework Directive[9] - Role of environment on the spread of AMR throughout the food chain and possible risk mitigation measures - Policies for disposal of unused and expired medicines. **Moderator**: **EFSA/DG SANTE**	**Location**: same as above The Human health team (ECDC) can arrange alternative meetings during this time if needed.

	Separate parallel meetings	
15:45 – 17:15 (1.5 hours) *Same location but different rooms*	**Human health team (ECDC) AMR in the human health sector – Antimicrobial stewardship and IPC** **Presentations (10 min each):** - Antimicrobial stewardship and IPC – Person A - Education on AMR/IPC in curriculum of healthcare professionals – Person B. **Discussions on:** - Antimicrobial stewardship and treatment guidelines (indicators in Area 6) - IPC (indicators in Area7) - AMR and IPC education in undergraduate and postgraduate students (indicators in Section 8) - Public information and behavioural change interventions related to AMR (indicators in Section 9). **Moderator**: **ECDC**	**Animal health and food safety team (DG SANTE & EFSA) AMR in the animal and food production** **Presentations (10 min each):** - Overview of the farming sector structure – Person A. - Veterinary model for veterinary care of food-producing animals and companion animals, including sales mechanism – Person B. **Discussions on:** - initiatives to promote prudent use - organisation of official controls on the use of VMPs - the sales mechanism for AB on farming - model for veterinary care of food-producing animals and companion animals. **Moderator: EFSA/DG SANTE**
16:15 – 16:30	Coffee break	
16:30–17:30 (1 hour) *Same location but different rooms*	**Meeting with representatives of professional associations and heads of chambers: (ECDC team only)** **Presentation (participant introduction and brief 5 min presentation of their activity related to AMR):** List representatives **Discussion** on educational programmes and awareness campaigns, treatment guidelines, disease management protocols, strategies and initiatives to reduce antimicrobial consumption/antibiotic stewardship. **Moderator**: **ECDC**	**Meeting with representatives of professional associations and heads of chambers:** **Discussion** with veterinary professional organisation(s), pharmacists, wholesalers of VMPs, veterinary associations/chambers.. **List of representatives** **Short presentation (5 min)** by the associations for the farming sectors they cover, memberships levels and activities undertaken by the associations related to AMR. **List of speakers** **Moderator: EFSA/DG SANTE**

[9] Directive 2000/60/EC of the European Parliament and of the Council establishing a framework for community action in the field of water policy, OJ L 327, 22 Dec. 2000 (p.1).

DAY 2: Tuesday XX month 202X					
Human health team (ECDC)			**Animal health and food safety team (DG SANTE & EFSA)**		
08:30 –10:30 (2 hours)	**Human AMR Reference Laboratory** - Introductory meeting **(15 min)** at the director's office - Visit the microbiology lab **(45 min)**. **Discussion** with laboratory manager on AMR reporting, activities performed, type of antibiotics tested, quality assurance. **Moderator: ECDC**	Location: Contact person(s): Telephone: E-mail: **Transportation arrangement**	08:30 – 10:30 (2h)	**Veterinary Service** - Introductory meeting **(15 min)** at the director's office: presentation of the One Health country visit. - Visit the microbiology lab (**45 min)** (vet lab and food safety). **Presentation (10 min) (EFSA)**: EU harmonised AMR monitoring in zoonotic and commensal bacteria in certain food producing-animals and food. **Discussions (50 min)** on AMR surveillance, prevention and control and research initiatives (veterinary and environmental sectors) and AMR education for veterinary medicine undergraduates. Moderator: **EFSA/DG SANTE**	Location: Contact person(s): Telephone: E-mail: **Transportation arrangement**
10:30–12:30 (2 hours)	**University Hospital** **Introductory meeting** with hospital managers and healthcare professionals from different wards/departments (surgery, adult ICU, paediatrics/neonatology, infectious diseases, infection control and pharmacy). **Visit to the respective departments** of the hospital: 1. Department A 2. Department B 3. Department C **Discussion during visit** about prudent use/antibiotic stewardship, AMR prevention and control measures, healthcare-associated infection/IPC guidelines, and related needs with hospital managers and healthcare professionals from different wards/departments (surgery, ICU, paediatrics/neonatology, infectious diseases, infection control, microbiology laboratory and pharmacy). **Moderator: ECDC**	Location: Contact person(s): Telephone: E-mail: **Transportation arrangement**	11:15–13:00 (1 hr 45)	**Food Institute** **Presentation:** - Monitoring of AMR in food and food-producing animals - Monitoring of AMR in wastewater from slaughterhouses - AMR in clinical isolates from animals. **Q&A/Discussion:** **Moderator: EFSA/DG SANTE**	Location: Contact person(s): Name: Telephone: E-mail: logistics attendees

12:30–13:00 (30 min)	**Visit to a community pharmacy** **Discussion on** prudent use/antibiotic stewardship, antimicrobial sales mechanism. **Moderator: ECDC**	Location: person(s): Name: Telephone: E-mail:			
13:00–14:00	Lunch Break		12:30–13:30	Lunch Break	Near FVA
13:30–14:30 (1 hour)	**National agency for drugs and medical devices** **Discussions** on policy and regulation on the prudent use of AMR antibiotic and AMC monitoring in the human health sector, on waste and disposal in the human health sector and marketing-related issues (indicators in Section 10), current alignment plans with EU acquis and next steps. **Moderator: ECDC**	Location: Contact person(s): Name: Telephone: E-mail:	14:00–16:00 (2 hours)	**Food and Veterinary Agency** **Presentation:** - **ESVAC/ASU project in general** - **collection of data on sales/use** **Discussion** on available data for antimicrobial sales and use and possibilities for obtaining data (use by species). **Moderator: EFSA/DG SANTE**	Location: Contact person(s): Name: Telephone: E-mail:
14:30–16:30 (2 hours)	**National Institute of Public Health** - Short meeting **(15 min)** with the director of the Institute of Public Health (presentation of the One Health country visit) - Visit of the microbiology lab. **Discussion (45 min)** on opportunities and challenges of AMR surveillance, electronic surveillance, prevention and control in human health, and challenges in implementing the One Health approach on AMR. **Moderator: ECDC**	Location: Contact person(s): Name: Telephone: E-mail:	16:00–18:00 (2 hours)	**The Food and Veterinary Agency** **Presentations** - Measures taken to encourage prudent use of antimicrobials in the veterinary sector. - Biosecurity and health plan (vaccination plan, endemic disease action plan, interventions). **Discussions** on any measures taken to raise awareness of AMR among prescribers and animal keepers to encourage more prudent use of antimicrobials in production and companion animals. Discussion on the current EU VMP legislation and its AMR aspects (in terms of EU acquis). Moderator: **EFSA/DG SANTE**	Location: Contact person(s): Name: Telephone: E-mail:

DAY 3: Wednesday XX month 202X					
Human health team (ECDC)			**Animal health and food safety team (DG SANTE & EFSA)**		
8:30–09:30 (1 hour)	**Travel to regional centre**		8:30–9:30 (1 hour)	**Travel to regional centre**	
9:30–13:00 (3 hours)	**Visit to regional clinical hospital** **Introductory meeting** with hospital managers and healthcare professionals from different wards/departments (surgery, adult ICU, paediatrics/neonatology, infectious diseases, infection control, and pharmacy). **Visit to the respective departments** of the hospital. **Discussion during visit** on prudent use/antibiotic stewardship, AMR prevention and control measures, healthcare-associated infections/IPC guidelines, and related needs with hospital managers and healthcare professionals from different wards/departments (surgery, ICU, paediatrics/neonatology, infectious diseases, infection control, microbiology laboratory and pharmacy). **Moderator: ECDC**	Location: Contact person(s): Telephone: E-mail:	09:30–10:30 (1 hour)	**Meeting at the regional centre of the Food and Veterinary Agency/regional centre for veterinary practices** **Discussion** at the office of the regional veterinary services with veterinary inspectors on the official control on use of antimicrobial VMPs in animals and any measures taken locally to raise awareness of AMR and encourage the reduced and/or more prudent use of antimicrobials in production and companion animals. **Moderator: DG SANTE**	Location: Contact person(s): Name: Telephone: E-mail:
		Location: **Regional hospital** Contact person(s): Telephone: E-mail:	11:00–13:00 (2 hours)	**Meeting at the regional centre of the Food and Veterinary Agency/regional centre for veterinary practices** **Discussion** in the office of the regional veterinary services with local farmers, practising veterinarians and veterinary inspectors on actions taken locally and/or by stakeholders to reduce the use of antimicrobials/use antimicrobials more prudently in food-production and companion animals. **Moderator: EFSA/DG SANTE**	Location: Contact person(s): Name: Telephone: E-mail:
13:00–14:00	Lunch Break		13:00–14:00	Lunch Break	
14:00–15:00 (1 hour)	**Visit to regional public health laboratory** **Discussion** with laboratory manager on AMR reporting, activities performed, type of antibiotics tested, quality assurance. **Moderator: ECDC**	Location: Contact person(s): Telephone: E-mail:	14:00–15:00 (1 hour)	**Discussion (continued)**	Location: Contact person(s): Name: Telephone: E-mail:
14:00–16:00 (1 hour)	**Meeting with general practitioners at a primary healthcare centre or general practitioner's office.** Discussion with general practitioners and paediatricians on prudent use/antibiotic stewardship, AMR prevention and control measures and related needs. **Moderator: ECDC**	Location: **XXXX** Contact person(s): Name: Telephone: E-mail:			
16:30–17:30 (1 hour)	**Return travel**				

DAY 4: Thursday XX month 202X					
	Human health team (ECDC)		Animal health and food safety team (DG SANTE & EFSA)		
08:30–11:00 (2.5 hours)	**Visit to long-term care facility and/or private hospital** **Introductory meeting** with hospital managers and healthcare professionals from different wards/departments (surgery, adult ICU, infectious diseases, infection control, microbiology laboratory and pharmacy). **Visit to the respective departments** of the hospital. **Discussion during visit** on prudent use/antibiotic stewardship, AMR prevention and control measures, healthcare associated infection/IPC guidelines, and related needs with hospital managers and healthcare professionals from different wards/departments (surgery, ICU, infectious diseases, paediatrics/neonatology, infection control, microbiology laboratory and pharmacy). **Moderator: ECDC**	Location: Contact person(s): Telephone: E-mail: **Transportation arrangement** **Additional information**	08:30–11:00 (2.5 hours)	**Faculty of Veterinary medicine** Presentation **(10 min)** Education on AMR in curriculum of health professional and antibiotic awareness activities. **Discussion:** undergraduate education on AMR under One Health perspective **Moderator: DG SANTE**	Location: Contact person(s): Telephone: e-mail: **Transportation arrangement** **Additional information**
13:00–14:00	Lunch Break		13:00–14:00	Lunch Break	
14:00–16:00 (2 hours)	Report preparation	Location: Contact person(s): Name: Telephone: E-mail:	14:00–16:00 (2 hours)	Report preparation	Location: Contact person(s): Name: Telephone: E-mail:

DAY 5: Friday XX month 202X		
09:00–12:00 (3 hours)	**Closing meeting with the national authorities:** - Ministry of Health/Ministry of Agriculture, Natural Resources and Environment and relevant agencies and stakeholders. - Technical experts from national institutions, including the members of national AMR coordination committee.	Location: - Maximum capacity of the room – 25 people. - One coffee break
12:00	**Departure of the experts** Each expert should arrange their own transportation to the airport, in accordance with their departure time.	

Annex 2. List of potential participants and site visits

The country visit team would like to meet or visit:

- inviting national authorities, including representatives for public health, healthcare, food, agriculture and the veterinary sector;
- Intersectoral Coordination Committee (ICM) - i.e. the national coordination group;
- regional/local coordination groups;
- organisations involved in surveillance of AMR, AMC and HAIs, and in IPC and antimicrobial stewardship;
- National Public Health Institute;
- Department of Veterinary Services/Animal Health;
- Department of Food Safety;
- Ministry of Environment: Water and Sanitation, Waste management
- National reference laboratory for AMR (both human and veterinary if separate);
- National Medicines Agency (both human and veterinary if separate);
- healthcare facilities (if possible, different patient populations and areas):
  - hospitals (between two and five) with visits to/meetings with the IPC committee/team, microbiology laboratory, pharmacy, ICU and relevant wards (medical or surgical and infectious disease wards);
  - long-term care facilities/nursing homes;
  - primary care/general practice/outpatient clinic;
  - community pharmacy.
- Animal health/food safety site visits (e.g. veterinarian service and pharmacy, abattoir/slaughterhouse);
- educational institutions: medicine, veterinary medicine, food production, agriculture;
- professional societies including representatives of human health (infectious disease specialists, microbiologists, IPC specialists, general practitioners, paediatricians, nurses, pharmacists, public health specialists, epidemiologists) and animal health (e.g. veterinarian, para-veterinarian, agricultural);
- patient organisations, other NGOs, including animal welfare and consumer protection groups;
- representatives of health insurance companies (if applicable).

This list is not exhaustive and can be adapted to the needs of the country.

Annex 3. Country visit tool

The country visit is based on ECDC's One Health assessment tool for country visits relating to AMR (europa.eu)[10]. In addition, country visit reports developed by DG SANTE have been used to inform the checklists for animal health/food safety and the environment.

There are 12 sections in the tool, divided into human health, animal health/food safety and the environment, where appropriate. The sections below that are based on the ECDC assessment tool are highlighted with an *. Where appropriate, checklists have been presented separately for human health, animal health/food safety, agriculture and the environment (Checklists 3, 4, 5, 6, 7 and 10).

The 12 sections in the tool are:

1. Country context
2. Inter-sectoral coordinating mechanism and AMR governance
3. Clinical diagnostic and reference laboratory services
4. Monitoring of AMR
5. Monitoring of AMC
6. Antimicrobial stewardship and treatment guidelines
7. Infection prevention and control (IPC)
8. AMR and IPC education
9. Public information
10. Marketing-related issues
11. Electronic surveillance
12. International perspectives.

This tool is also used to draft the country review which is prepared prior to the visit and to collect further details to update the country review during the country visit.

1. Country context

1.1. Country context

Area	Indicators
Political organisation	Outline of country. Geographical situation. Political organisation, nationally. Political organisation, sub-nationally with the number and responsibilities of regions/districts. Organigrammes of ministries (Ministry of Health, Agriculture, Food safety, Environment, etc.) with departments and officials responsible for AMR issues and governmental/non-governmental institutions.
Overview of health system for humans	Funding of health services and patient payments Human health service structure (tertiary, secondary and primary services)
Overview of health system for animals	Number of key food-producing animals: • heads of cattle (number diary), • pigs, • sheep (number milked), goats (number milked) • equidae (number horses), • poultry (number broiler hens), • beehives • aquaculture (tonnes overall and by species). National veterinary service – structure, responsibilities. National programmes for disease control in animals.

[10] ECDC assessment tool for joint One Health country visits in relation to antimicrobial resistance: https://www.ecdc.europa.eu/sites/default/files/documents/One-Health-AMR-assessment-tool-for-country-visits.pdf

2. Inter-sectoral coordinating mechanism and AMR governance

2.2 Inter-sectoral coordinating mechanism (ICM)*

Area	Indicators
Composition of ICM	• Intersectoral composition (human health, animal health and environmental sectors). • High-level chairpersons from the above sectors. • Inclusion of relevant stakeholders (government, industry, professional societies, patient representatives, relevant organisations). • Inclusion of relevant expertise (infectious diseases, epidemiology, IPC, microbiology, pharmacology, surveillance, communications).
Terms of Reference (ToR)	• Description of governmental mandate/authority. • Clearly-defined roles, responsibility, and accountability. • Responsibility for national action plan.
Regular meetings of ICM	• Frequency of meetings. • Regular attendance of participants. • Minutes with defined action items.
Budget of ICM	• Established national funding. • Adequate size and sustainability of funding.
Provision of support to regional/local working groups	• Examples of supported activities. • Type of assistance provided (technical, coordination, financial).

2.2 National action plan (NAP)*

Area	Indicators
Development of national action plan	• Existence of a national action plan and latest update. • Based on thorough situational analysis. • Plan written from a One Health perspective. • Alignment with the overarching objectives of the Global Action Plan on AMR (WHO). • Working groups with involvement of all relevant sectors and stakeholders for the development and implementation of the national action plan. • High-level endorsement. • Comprehensive country coverage with participation of all regions (also autonomous regions) or separate regional plans.
Strategic plan	• Clearly outlined goals, objectives, priorities and interventions.
Operational plan	• Clearly outlined activities and interventions, implementation arrangements, timetable, responsible entities, detailed budget and costing.
Monitoring and evaluation plan	• Clearly outlined performance indicators, targets and timelines, data collection and reporting methods.
Periodic reviews of progress and impact	• Regular and publicly available progress reports. • Assessment of effectiveness and impact of measures.
Budget	• Availability of appropriate budget for outlined activities.
Integration into other action plans/regulatory efforts	• Links to other national action plans on related topics (e.g. communicable disease surveillance, healthcare-associated infections/IPC, EU-harmonised AMR monitoring in certain animals and foodstuffs) or specific disease areas (e.g. tuberculosis, HIV).
Preparedness/response planning for AMR	• Preparedness and response planning for outbreaks of highly antimicrobial-resistant pathogens in humans and animals, and detection of novel AMR mechanisms in isolates of human, animal and environmental origin. • Strategy for use and to ensure availability of new and old antimicrobial agents.

2.3 Organised multidisciplinary collaboration at local level

Area	Indicators
General structure*	• Organised local activities. • Funding or incentives for these activities (for example recognition as a form of continuing education). • Inclusion of hospital as well as primary care level. • Extent of regional/national coverage. • Support from hospital/local leadership and at national level. • Established link between activities in primary and hospital care and surrounding long-term care facilities.
Local activities in human health*	Structure: • Multidisciplinary team (pharmacist, microbiologist, ID physician, IPC specialist, nurses), participation of private providers where necessary. • Evidence of direct involvement of senior management. • Access to local AMR surveillance and antimicrobial consumption data. • Administrative level to which the group reports. • Public (non-commercial) funding. • Regular meetings. • Availability of data/IT tools (for benchmarking or self-evaluation). Coverage of work areas: • IPC, antimicrobial stewardship, educational activities. • Analysis of local antimicrobial consumption and AMR data. • Feedback of data to prescribers – at the hospital level and in primary care. • Development of local guidelines based on/supported by local data. • Coordination of interventions, including local hospitals/primary care providers. • Implementation of local guidelines. • Feedback to and meetings with local prescribers.
Local activities in animal health/food safety	Structure: • Multidisciplinary team (e.g. veterinarian, para-veterinarian, farmers, veterinary pharmacist, microbiologist), participation of private providers where necessary. • Organisation of activities and reporting by both food production sector (e.g. livestock farming, aquaculture and companion animals) and by administrative level. • Funding source (public, private). Coverage and areas of work: • Activities covered (biosecurity, antimicrobial stewardship, educational). • Access to and analysis of local AMR surveillance and antimicrobial consumption data (for benchmarking or self-evaluation). • Development and implementation of local guidelines based on/supported by local data. • Coordination of interventions, including local veterinary services and famers. • Feedback to and meetings with local prescribers and farmers.

3. Clinical diagnostic and reference laboratory services

3.1 Human health*

Area	Indicators
Access to clinical diagnostic services	• Access for acute care hospitals, specialist care hospitals and community healthcare - residential care, ambulatory care and primary care. • Independence of access irrespective of the type of healthcare provider (private or public). • Adequate funding of microbiological testing in patient care (hospital and primary care), e.g. by defining reimbursement rules or including microbiological diagnostics in treatment pathways for the health insurance system. • Use of services by healthcare providers, e.g. blood culture rate.
Quality of sampling and clinical diagnostic testing	• Provision of guidelines for sampling and transport to providers. • Operation under a nationally approved quality management system. • Participation in external quality assurance (EQA) schemes. • Accreditation of laboratories.
Timeliness of reporting and communication of results	• Time to reporting for critical results (positive cultures from blood, cerebrospinal fluid or other samples from invasive infections). • Regular reporting of preliminary results (species identification). • Time to reporting of culture and antimicrobial susceptibility testing (AST) results for primary and hospital care. • Use of selective reporting of AST results. • Reliable communication of results (oral, paper, electronic). • Availability of microbiological consultation for clinicians. • Availability of out-of-hours microbiology services for the processing and reporting of results (weekday nights, weekends).
Point-of-care testing (POCT)	• Access to POCT. • Governance of POCT. • Interface with laboratory information system. • Reporting format.
National standardisation and guidelines	• Established national AST Committee. • Use of the European Committee on AST (EUCAST) breakpoints and methods in clinical laboratories. • Availability of national guidelines for diagnostic testing and screening.
Availability, access to and funding of reference laboratory services	• Access to national/international reference laboratory services for relevant pathogens with AMR. • Official nomination of national reference laboratories by national authorities. • Capacity of reference laboratory services for pathogen identification and AST. • Capacity of reference laboratory services for identification of (newly emerging) AMR mechanisms. • Capacity of reference laboratory services for typing/whole genome sequencing of pathogens with AMR. • Capacity of reference laboratory services to support local, regional and national outbreak investigations. • Provision of individual support/quality assessment/reference materials to laboratories. • Timeliness and user-friendly format of feedback to local laboratories. • Regular analysis of trends and publication of reports on submitted isolates. • Integration into national AMR surveillance systems. • Adequate and sustainable public funding of reference laboratory services.

3.2 Animal health/food safety and environment

Area	Indicators
Assessment of veterinary services	Laboratory capacity: • testing samples (animal, food, feeds) • sites for testing of animal, food and feeds • national reference laboratories • testing sites (centralised/decentralised) • Funding for microbiological testing (i.e. national programmes, reimbursement, private). National standards and guidelines: • Accreditation of laboratories including participation in external quality assessment (EQA) schemes. • Sampling and testing of different food-producing animals (farm, market or slaughter), products for human consumption and feed (ingredients or feed)[11]. • Organised sentinel programme of food-producing animals and possible vectors. • Established national AST committee • Use of European AST breakpoints and methods (EUCAST/VetCAST) National reference laboratory: • Official nomination of national reference laboratories for different types testing (animal, food, feed). • Access to national/international reference laboratory services for relevant AMR pathogens. • Capacity of reference laboratory services for: - pathogen identification and AST. - (newly emerging) AMR mechanisms. - typing/whole genome sequencing of pathogens with AMR. - support local, regional and national outbreak • Regular analysis of trends and publication of reports on submitted isolates. • Integration into national AMR surveillance systems. • Adequate and sustainable public funding of reference laboratory services.
Use of POCT tests in animal health	• Deployment of POCT for different food-producing (cattle, pigs, poultry) and companion animal species/groups • Governance for use of POCT • Existence of an interface with laboratory systems and reporting format
Assessment of environmental services	Laboratory capacity: • National reference laboratories. • Testing sites (centralised/decentralised). • Use of public and private networks for AST. • Source samples tested (sewage urban or hospital, watercourses, surface water, farm run-off). • Types of testing undertaken (antibiotic residues, pathogens with AMR, AMR genes). National guidelines for AST: • Accreditation of laboratories and participation in EQA. • Source of samples (e.g. sewage, water course) submitted for AST. • Use standardised AST methodology and EUCAST breakpoints.
Integration with public health sector	• Integration of animal and environmental sector data with public health. • Combined reporting of data from more than one sector (human health, animal health, food production and environment).

[11] World Organisation for Animal Health. OIE Standards, Guidelines and Resolutions on Antimicrobial Resistance and the use of antimicrobial agents. https://www.woah.org/app/uploads/2021/03/book-amr-ang-fnl-lr.pdf

4. Monitoring of AMR

4.1 Human health*

Area	Indicators
National surveillance systems for key bacteria with AMR	National surveillance system for key bacteria with AMR including: • Meticillin-resistant *Staphylococcus aureus* (MRSA), • *Streptococcus pneumoniae* resistant to penicillin or macrolides, • *Escherichia coli* resistant to third-generation cephalosporins, • *Klebsiella pneumoniae* resistant to aminoglycosides, fluoroquinolones and third-generation cephalosporins, • *K. pneumoniae* resistant to carbapenems in accordance with the list in the joint opinion by ECDC, the European Food Safety Authority (EFSA) and the European Medicines Agency (EMA). Additional national surveillance for: • *Acinetobacter baumannii* resistant to carbapenems • Multidrug-resistant *Pseudomonas aeruginosa* • *Enterococcus faecium* resistant to vancomycin. Sub-national analysis of data for rates, trends and distribution of AMR.
National surveillance of resistance patterns linked to healthcare-associated infections	AMR patterns collected from surveillance systems of healthcare-associated infections (HAIs), including HAIs in intensive care units (ICUs), surgical site infections and *Clostridoides difficile* infections.
National/local surveillance of AMR patterns in the community	Sentinel AMR surveillance of urine isolates from general practices to avoid bias by only analysing specimens from cases of treatment failure. AMR surveillance for *S. pneumoniae* isolates from blood cultures as an indicator for community levels of AMR.
National surveillance data on other pathogens with AMR	Surveillance of AMR in *Neisseria gonorrhoeae* and *Mycobacterium tuberculosis*.
National surveillance of emerging healthcare-associated pathogens/AMR genes	Provision of data on specific emerging healthcare-associated pathogens/AMR genes – e.g. carbapenemase genes, *Candida auris*. Sub-national analysis and trending of data.
Participation in European-level surveillance of pathogens with AMR	• Coverage, quality and representativeness of data submitted to the CAESAR and compatibility with European Antimicrobial Resistance Surveillance Network (EARS-Net). • Participation in the European Antimicrobial Resistance Genes Surveillance Network (EURGen-Net). • Participation in the European Gonococcal Antimicrobial Surveillance Programme (EuroGASP). • Participation in the European Reference Laboratory Network for Tuberculosis (ERLTBNet).
Public and comprehensive reporting of AMR data	• Integrated analysis of data from different AMR surveillance systems and antimicrobial consumption surveillance data. • Timely provision of data to the ICM for the planning of future interventions. • Publication of AMR surveillance data in regular 'One Health' reports.
Integration of local routine clinical laboratory data into surveillance	• Integration of data from routine AST of diagnostic laboratories into local, regional, national AMR surveillance systems. • Participation of private laboratories in AMR surveillance. • Procedure for notification of notifiable pathogens with AMR. • Provision of timely feedback and reports to participating laboratories. • Rapid feedback in outbreak situations. • Provision of an interface/platform where data providers can compare their data to the national AMR surveillance data. • Provision of AMR statistics to local clinicians and care providers.

4.2 Animal health/food safety and environment

Area	Indicators
National surveillance systems for key bacteria with AMR in animals	National surveillance system for key bacteria with AMR for different food-producing animals (cattle, pigs, poultry)[12]: • *Salmonella* spp., • *Campylobacter jejuni*, • *Campylobacter coli*. • indicator commensal *E. coli*, and • ESBL-, AmpC- or carbapenemase-producing *Salmonella* spp. and *E. coli* Additional national surveillance for indicator commensal *Enterococcus faecalis* and *Enterococcus faecium*. Sub-national analysis of data for rates, trends and distribution of AMR.
Regulation for antimicrobial waste	Regulatory framework for the discharge of antimicrobials and waste potentially contaminated with antimicrobials into the environment. National scheme for collection of expired antimicrobials and monitoring of their disposal.
National surveillance systems for key bacteria with AMR in environment	National environmental surveillance for AMR. Testing for *E. coli* and ESBL-producing *E. coli* and reporting of ratio[13]. Number and types of sites selected within country and at city level Sampling frequency. Typing/whole genome sequencing of ESBL-producing *E. coli*.
Participation in European-level surveillance of pathogens with AMR	Participation in AMR surveillance of *Salmonella* spp. and *Campylobacter* spp. isolates related to the Food- and Waterborne Diseases and Zoonoses Network (FWD-Net). Global Sewage Surveillance Consortium (https://www.nature.com/articles/s41467-022-34312-7#ref-CR4)

[12] EU Decision 2020/1729 https://eur-lex.europa.eu/legal-content/en/TXT/?uri=CELEX%3A32020D1729
[13] WHO integrated global surveillance on ESBL-producing E. coli using a One Health approach: Implementation and opportunities https://apps.who.int/iris/bitstream/handle/10665/340079/9789240021402-eng.pdf?sequence=1

5. Monitoring of AMC

5.1 Human health*

Area	Indicators
Availability of valid national data on AMC in humans	• Data source (e.g. reimbursement, sales, prescriptions). • Legal framework for data collection. • Responsibility for collection, analysis, interpretation and dissemination the data. • Level (granularity) of the data. • Calculation of the denominator. • Frequency of data collection. • Public availability of data.
National electronic prescription system (mainly ambulatory care)	• Existence of national electronic prescription system. • Use of data for feedback on prescription patterns. • Applicability for private and public sector.
Benchmarking of AMC	• Data available by sector (primary care, hospitals, long-term care). • Date available by level of administration (local, regional, national). • Data available by type of provider (private/public). • Data available by prescriber. • Prescription data linked to indication (and pathogen, if available).
Financial support for data collection	• Public funding for data collection. • Adequate size and sustainability of the budget.
Public dissemination of data on AMC	• Publicly available report. • Publicly available raw data. • Level of disaggregation for the analysis. • Regular update. • Link of AMC data to AMR data.
Primary indicator (ECDC/EMA) of AMC	• Total consumption of antibacterials for systemic use (mg/kg biomass). • Total consumption of antibacterials for systemic use (ATC group J01), in Daily Defined Doses (DDD) per 1 000 inhabitants per day) • Benchmarking of data with other Western Balkan and EU countries.

5.2 Animal health/food safety

Area	Indicators
Availability of valid national data on AMC in animals	• Data source (e.g. marketing authorisation holders, wholesalers, retailers, feed mills, pharmacies). • Legal framework for data collection (mandatory, voluntary). • Responsibility for collection, analysis, interpretation and dissemination the data. • Funding for data collection and whether this is adequate. • Level (granularity) of the data. • Frequency of data collection. • Public availability of data.
Benchmarking of AMC for farmed animals and aquaculture[14]	• Data by sales (mg/kg biomass) • Method to obtain population correction units for key food-producing species and categories. Data presented by: • Trends in use (year of start) • Total antibiotic use in animals • ATC vet codes • Route of administration • Food-producing species and categories within, e.g. beef and dairy cattle. Use of methodology to calculate Defined Daily Doses for animals (DDDvet) and Defined Course Doses for animals (DCDvet).
Governance of antibiotic use in animals	• Regulatory framework for antibiotic use in veterinary medical products (including medicated feed) covering all stages of the cycle (manufacture, supply, sale, use, disposal). • Regulations prohibiting the use of antibiotics for growth promotion. • Extent of non-prescribed antibiotic use in veterinary medicine.

[14] European Medicines Agency Draft Guideline on the reporting of antimicrobial sales and use in animals at the EU level – denominators and indicators https://www.ema.europa.eu/en/documents/scientific-guideline/guideline-reporting-antimicrobial-sales-use-animals-eu-level-denominators-indicators_en.pdf

Area	Indicators
	• Restrictions of antibiotic used in animals (e.g. AMEG categorisation[15]) and level of formality (regulations, guidance). • Promotion of regulations/guidance among veterinarians and other related professions (e.g. veterinary pharmacies, farmers). • Regulations/guidance for prescribing antibiotics in animals. • Regulations/guidance for administration of prescribed antibiotics in food-producing animals (individual *vs.* metaphylaxis *vs.* prophylaxis). • Existence of targets for the reduction of antibiotic use in animals. • Measures to ensure compliance with regulations/guidance for antibiotic use in animals including appropriate record keeping.

6. Antimicrobial stewardship and treatment guidelines

6.1 Human health*

Area	Indicators
Structure of antimicrobial stewardship programmes (ASPs) at different levels (local, regional, national)	• ASPs implemented at all levels (local, regional national). • Overarching national plan/strategy/guidelines for ASPs with reference to international standards/professional societies. • Monitoring and reporting of ASP indicators. • Legal framework. • Appropriate human resources with a multidisciplinary approach (antibiotic stewardship committees/teams – ID, microbiology and pharmacy specialists, nurses). • Allocation of budget. • Inclusion of restrictive and persuasive policies into the national strategy. • Indicators for monitoring ASPs in acute and long-term care facilities. • Integration with IPC and other quality improvement activities. • Institutional support (tools, incentives).
National and locally adapted treatment guidelines	• Diseases/topics covered (surgical prophylaxis, urinary tract and respiratory tract infections in ambulatory care, healthcare-associated infections). • Standardised criteria for diagnosis. • Consultation process/involvement of relevant stakeholders in guideline development. • Dissemination strategy. • Monitoring of uptake and compliance. • Frequency of updates. • Up-to-date recommendations for duration of treatment.
Availability of antimicrobials	• Adoption of WHO AWaRe classification of antibiotics in the National Essential Medicines List[16]. • National strategy to ensure the availability of narrow-spectrum antibiotics (penicillin V, flucloxacillin, amoxicillin). • Restriction of over-the-counter dispensation of antimicrobials. • Inspections related to/sanctioning of over-the-counter dispensation of antimicrobials. • Possibility of per-unit dispensing (ambulatory care). • Frequency of shortages/disruption of supply of key antimicrobials.
Use of rapid diagnostic tests (RDTs)	• Use of RDTs in ambulatory care to inform prescription decisions. • Public funding for reimbursement of RDTs.
Decision-making tools	• Availability of IT tools to improve data collection and decision-making
Assessment of the appropriateness of antimicrobial prescriptions	• Use of indicators for compliance with guidelines, de-escalation, switch from intravenous to oral treatment, duration of treatment. • Frequency of collection and analysis. • Regular feedback of prescription patterns to prescribers.
Targets for antimicrobial prescribing	• Use of qualitative and quantitative targets. • Level of target setting. • Incentives/sanctions.

[15] European Medicines Agency. Antimicrobial Advice Ad Hoc Expert Group (AMEG) Categorisation of antibiotics for use in animals. https://www.ema.europa.eu/en/documents/report/infographic-categorisation-antibiotics-use-animals-prudent-responsible-use_en.pdf

[16] World Health Organization. 2021 AWaRe classification. https://www.who.int/publications/i/item/2021-aware-classification

6.2 Animal health/food safety and agriculture

Area	Indicators
Antimicrobial stewardship programmes (ASPs) in animal health	• Governance of antibiotic use for animals (see also box 5.2) • Overarching national plan/strategy/guidelines for ASPs for animal health. • ASPs implemented in key animal health sectors (different food-producing animal groups and companion animals). • Inclusion key stakeholders (e.g. veterinary, farmers). • Allocation of appropriate human resources and allocation of budget. • Monitoring and reporting of ASP indicators. • Integration with IPC and other quality improvement activities.
National and locally adapted treatment guidelines	• Diseases and species covered. • Development of guidelines and frequency of updates. • Up-to-date recommendations for duration of treatment. • Standardised criteria for diagnosis including use of POCT tests (see Box 3.2). • Regulations/guidance for administration of prescribed antibiotics in food-producing animals (individual versus metaphylaxis versus prophylaxis). • Guidance for de-escalation of treatment. • Dissemination and promotion of guidelines. • Existence and use of feedback on prescribing practice. • Monitoring of uptake and compliance, especially for prescribing antibiotics reserved for humans.
Use of antimicrobials in agriculture	• Regulatory framework for non-medicinal antimicrobials for whole cycle (production, supply, sale, use, disposal). • Collection and reporting on quantity of pesticides used to control bacterial or fungal diseases in plant production.

7. Infection prevention and control (IPC)

7.1 Human health*

Area	Indicators
IPC programmes – national level	• National IPC programme with clearly defined objectives, functions and activities for the prevention of HAIs. • National up-to-date IPC guidelines. • National curriculum for IPC training and evaluation of its performance. • Technical group for national HAI surveillance and IPC monitoring. • Use of multimodal strategies. • National monitoring and auditing of IPC programmes. • National standards for staffing levels – healthcare and IPC staff. • National standards for construction/equipment of healthcare facilities.
IPC programmes – hospital level	• Presence of an IPC coordinating entity/committee with involvement of all relevant departments (IPC, clinical, microbiology) and direct, routine involvement of senior management. • Existence of an IPC plan approved by the hospital's Chief Executive Officer. • Sufficient human resources (i.e. one full-time IPC nurse for ≤250 beds), dedicated physician trained in IPC, epidemiology and microbiology and data management support. • Specific tasks outlined. • IPC programme linked to quality-of-care and patient safety activities.
IPC guidelines at hospital level	• Guidelines and checklists on prevention of HAIs. • Guidelines on standard and enhanced precautions. • Guidelines on prevention of transmission of multidrug-resistant organisms • Training of staff on guidelines
Education and training for IPC professionals	• Titles, diplomas, certifications (nurses, physicians) • Career paths for IPC (nurses, physicians, academia) • Participation of IPC staff in continuous medical education/professional development. • Use of core competencies (ECDC, WHO).
Surveillance of HAI	• Prospective surveillance of HAIs in place (infections acquired in ICUs, bloodstream infections, surgical site infections, *Clostridioides difficile* infections). • National network for HAI surveillance and its national coverage. • Voluntary or mandatory participation in HAI surveillance networks. • Regular feedback of HAI rates to healthcare personnel. • Public availability of reference data on HAIs (aggregated or hospital-specific). • Inclusion of HAI data in quality-of-care hospital key performance indicators. • Regular discussion of HAIs on hospital management board.
Prevention programmes /multimodal strategies	• Combined interventions including guidelines, bundles, checklists, training, audit, surveillance and feedback for the prevention of HAIs. • Awareness of the institution's organisational culture in relation to IPC prevention.
Monitoring and audits of IPC practices	• Hand hygiene compliance observations. • Surveillance of alcohol-based hand rub consumption. • Audits of device management (e.g. for intravenous cannulas, urinary catheters). • Monitoring of adherence to guidelines.
Workload and staffing	• Bed occupancy. • Full-time equivalents of registered nurses, hospital-wide and in ICUs. • Challenges, brain-drain.
Infrastructure, environment, equipment	• Number of patients per room. • Number of single rooms. • Number of airborne isolation rooms. • Alcohol-based hand rub dispensers at point-of-care.
Long-term care facilities (LTCFs) and community care	• National IPC programmes and indicators established for LTCFs. • IPC audits of LTCFs. • IPC staff and/or consultations available for LTCFs. • Established link between LTCFs and surrounding acute care facilities. • Availability of alcohol-based hand rub and personal protective equipment. • Appropriate management of patients with multidrug-resistant organisms. • Monitoring of IPC in outpatient facilities and homecare.

7.2. Animal health/food safety

Area	Indicators
IPC programmes – national level	National IPC programme by key animal food production (cattle, pork, goats, sheep, poultry, aquatic): • disease control • objectives and if clearly defined • intervention - e.g. vaccination, isolation, etc. • responsible partners and functions • activities. National up-to-date IPC guidelines. National monitoring and auditing of IPC programmes. National curriculum for IPC training in key professional groups (veterinarians, para-veterinarians, veterinarian pharmacy and farmers) and evaluation of its performance.
Management and hygiene practices to reduce the use of antimicrobials (terrestrial and aquatic)	Guidelines for enhanced infection prevention control by husbandry means (indoor versus outdoor; batch versus continuous production) for main categories of livestock (beef, pork, sheep and goats, poultry, fish): • separation of groups • documentation of origin enabling tracking and tracing of animals • housing • nutrition (including water supply) • vaccination.
National monitoring system for use of antimicrobials and pesticides in plant production	Establishment of national system to monitor antimicrobial use in plant production
Biosafety and mitigation measures	Recommendations for farm level biosecurity measures[17]: • primary prevention: external biosecurity/bio exclusion (e.g. minimise introduction of new animals, cleaning and disinfection, pest control, clothing and footwear); • secondary prevention: internal biosecurity/ biocontainment (all-in-all-out production, IPC protocols, housing including bedding, management sick animals); • tertiary prevention: individual animal resilience (vaccination, management, nutrition, housing).

8. AMR and IPC education*

8.1 AMR and IPC education*

Area	Indicators
Pre-graduate education	Inclusion of basic IPC training and education on AMR in the curriculum for professions in: • human healthcare, • veterinary and • agricultural sectors. AMR teaching to include the One Health approach. Curricula and allocated time.
Post-graduate education	Inclusion of IPC and antimicrobial stewardship training in the post-graduate education of • human health professions (physicians, clinical microbiologists, pharmacists, and nurses) and • animal health professions (veterinarian, para-veterinarians, pharmacists). Incentives, career paths, credits, diplomas and certifications for this type of training course. Availability of online training.
Recognised positions for AMR/ASP	Qualifications and training needed. Job description. Performance incentives given to dedicated persons, key personnel, ambassadors.
In-Service training	Inclusion of AMR issues in continuing professional development (CPD) for • human health professions (physicians, clinical microbiologists, pharmacists, and nurses) and • animal health professions (veterinarian, para-veterinarians, pharmacists) • farmers (by different food-producing sectors). Training at start of employment, regular refresher courses. Mandatory versus voluntary.

[17] Lloyd DH, Page SW. Antimicrobial stewardship in veterinary medicine. Microbiology Spectrum 2018 https://doi.org/10.1128/microbiolspec.arba-0023-2017

9. Public information*

9.1 Public Information*

Area	Indicators
Planned approach to campaign development	Needs assessment/situation analysis to identify AMR communication needs in general population and key sectors. Awareness of possible cultural drivers of antimicrobial consumption. Goals, targets and objectives of communication plan outlined. Specific target groups and related activities identified, including tools and channels. Frequency and duration of the campaign. Campaign branding and materials. Incorporation of social marketing and behaviour change strategies. Monitoring of misinformation.
Resources	Appropriate and sustainable funding for communication /behaviour change campaigns.
Examples of collaborative communication activities	Activities related to European Antibiotic Awareness Day (Annex 4). Activities conducted together with WHO (e.g. World AMR Awareness Week) or other international/national-level communication initiatives. Activities conducted at various levels (national, regional, local, facility level). Activities conducted in collaboration with different institutions/organisations (including professional associations). Activities conducted with a One Health approach.
Type of campaign media	Use of traditional and social media.
Evaluation	Evaluation of campaigns, including campaigns related to behaviour change. Influence of campaigns on national results in the Eurobarometer on AMR.

10. Marketing-related issues

10.1 Human health*

Area	Indicators
Drug information	Availability of independent (not industry-supported) drug information for prescribers, professional organisations and professionals involved in ASPs. Access to independent (not sponsored by the pharmaceutical industry) educational seminars for physicians, especially for doctors in training, and nurses.
Relations between doctors and industry	Policy/legal framework for mandatory disclosure of doctors' conflicts of interest, including grants, sponsorship, speaker fees. Website with publicly accessible information on the disclosure of doctors' conflicts of interest. Financial incentives to prescribers. Regulations regarding gifts from pharmaceutical industry to physicians. Regulations regarding sponsorship of educational activities. Access of pharmaceutical representatives to doctors in training. Monitoring of adherence to regulations.
Generic prescriptions	Permission for pharmacists to dispense generic medication.

10.2 Animal health/food safety

Area	Indicators
Drug information	Availability of independent (not industry-supported) drug information for prescribers, professional organisations and professionals involved in ASPs. Access to independent (not sponsored by the pharmaceutical industry) educational seminars for veterinarians, especially for those in training.
Relations between veterinarians and industry	Code of conduct for veterinarians includes a policy on declarations of gifts. Policy on pharmaceutical industry support of student veterinarians. Regulations regarding sponsorship of continuing professional educational activities. Monitoring of adherence to regulations.
Generic prescriptions	Permission for veterinary pharmacists to dispense generic medication.

11. Electronic surveillance

11. 1 Electronic surveillance

Area	Indicators
General overview	Systems to collect and combine data from human health and other sectors such as animal health, food safety and environment
For each possible electronic surveillance source	Responsible institution. Geographical coverage. System design: sentinel versus comprehensive. Population under surveillance. Reporting legal status (mandatory/voluntary). Centralised vs decentralised system. Automated/semi-automated versus manually-entered data. Unique patient identifier and ability to link with other data sources which should be nominated (human health). Data sharing (GDPR). Data system and storage. Data format: aggregated data/case-based data. Frequency of reporting. Reported data: • Type of data: pathogen/AST/clinical data • Data storage. Lab data: Availability of Laboratory Information Management Systems (LIMS) in clinical microbiology laboratories. Challenges and priorities to improve digitalisation and automation.

12. International perspectives

12.1 International perspectives

Area	Indicators
Participation in other international projects	List of participation in international projects
Other research activities	List of research activities

Annex 4. European Antibiotic Awareness Day (EAAD)

Toolkits and materials are available from ECDC to support European Antibiotic Awareness Day (EAAD) at https://antibiotic.ecdc.europa.eu/en. These are grouped into the following seven categories:

1. Toolkits
2. Key messages
3. Factsheets
4. Infographics
5. Posters
6. Videos
7. Patient stories.

1. Toolkits

ECDC provides toolkits for national health authorities and the National Focal Points for AMR to prepare campaigns and materials targeting specific professional groups and the general public. The aim is to ensure a comprehensive and consistent messaging across Europe in relation to the rational use of antibiotics. The toolkits provide a checklist of activities for the organisation of campaigns and template materials which can be adapted nationally to support them.

Toolkits are available at https://antibiotic.ecdc.europa.eu/en/plan-campaign and aimed for the following five target groups:

a. Primary care prescribers: This toolkit advises on working with primary care prescribers and provides template materials, key messages and tactics to engage both primary care providers and their patients (https://antibiotic.ecdc.europa.eu/en/toolkit-primary-care-prescribers)
b. Professionals in hospitals and other healthcare settings**:** This toolkit is targeted at a wide list of professional groups in various healthcare settings, such as long-term care facilities (https://antibiotic.ecdc.europa.eu/en/communication-toolkit-professionals-hospitals-and-other-healthcare-settings)
c. Self-medication: This toolkit includes awareness raising ideas and tactics for promoting key messages https://antibiotic.ecdc.europa.eu/en/toolkit-general-public-self-medication)
d. General public: This toolkit offers template materials and approaches to engage with the general public with a focus on the key message of avoiding self-medication (https://antibiotic.ecdc.europa.eu/en/publications-data/communication-toolkit-promote-prudent-antibiotic-use-aimed-general-public)
e. Social media: This toolkit provides lists social media activities to target key groups of general public and hospital and primary care prescribers (https://antibiotic.ecdc.europa.eu/en/plan-campaign/toolkit-social-media).

2. Key messages

Key messages support the toolkits for all of the above listed target groups and can be viewed at https://antibiotic.ecdc.europa.eu/en/get-informed/key-messages. The key messages available are listed below with the exception of those related to the health burden of antibiotic resistance for which the data presented are EU/EEA-specific:

a. Antimicrobial use in healthcare settings: Key-messages-Antimicrobial-use-in-healthcare-settings-EN.pdf (europa.eu)
b. Self-medication with antibiotics for the general public: Key-messages-for-the-general-public-EN.pdf (europa.eu)
c. General public: Key-messages-general-public-EN.pdf (europa.eu)
d. Primary care prescribers: Key-messages-for-primary-care-prescribers-EN.pdf (europa.eu)
e. Hospital prescribers: Key-messages-for-hospital-prescribers_EN.pdf (europa.eu)
f. Professional in hospitals and other healthcare settings: separate key messages are available for 13 different professional groups which includes:
   - All prescribers
   - Healthcare professionals in hospitals and other healthcare settings
   - Hospital infectious disease specialists
   - Hospital managers/administrators
   - Infection prevention and control professionals and hospital epidemiologists
   - Emergency departments - physicians and managers
   - Clinical microbiologists
   - Intensive care unit - physicians and managers
   - Long-term care facilities - physician and managers
   - Nurses
   - Hospital pharmacists
   - Hospital prescribers
   - Junior doctors and students.

3. Factsheets

Factsheets are available at https://antibiotic.ecdc.europa.eu/en/get-informed/factsheets for four key specific groups:

- Factsheet for experts
- Factsheet for general public
- Factsheet for hospital prescribers
- Factsheet for primary care prescribers.

4. Infographics

Infographics are available at https://antibiotic.ecdc.europa.eu/en/get-informed/infographics. These are available for each country in the EU/EEA. Infographics with a general message that may be transferrable to Western Balkan countries include:

- Antibiotic resistance: a growing threat to human health https://antibiotic.ecdc.europa.eu/en/publications-data/antibiotic-resistance-growing-threat-human-health and https://antibiotic.ecdc.europa.eu/en/publications-data/antibiotic-resistance-increasing-threat-human-health
- Antimicrobial use in European hospitals https://antibiotic.ecdc.europa.eu/en/publications-data/antimicrobial-use-european-hospitals-and-long-term-care-facilities
- Antimicrobial use in: Long-term care facilities https://antibiotic.ecdc.europa.eu/en/publications-data/antimicrobial-use-long-term-care-facilities
- Healthcare-associated infections – a threat to patient safety in Europe https://antibiotic.ecdc.europa.eu/en/publications-data/healthcare-associated-infections-threat-patient-safety-europe
- Antibiotics: be responsible https://antibiotic.ecdc.europa.eu/en/antibiotics-be-responsible
- How does antibiotic resistance spread? https://antibiotic.ecdc.europa.eu/en/how-does-antibiotic-resistance-spread.

5. Posters

Posters are available at https://antibiotic.ecdc.europa.eu/en/get-informed/posters. These include posters for the general public addressing the risks linked to self-medication with antibiotics, as well as checklists for clinical staff.

6. Videos

Eight videos are available at https://antibiotic.ecdc.europa.eu/en/get-informed/videos.

7. Patient stories

Twelve stories are available detailing how individuals were dramatically affected by antibiotic resistance. These stories are available as videos or text at https://antibiotic.ecdc.europa.eu/en/patient-stories, although they are country specific.

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This activity has been prepared with the financial support of the European Union, Contribution Agreement ECDC-IPA6/ 2019/409-781 *'Preparatory measures for the participation of the Western Balkans and Türkiye in the European Centre for Disease Prevention and Control with special focus on OneHealth against AMR and enhanced SARI surveillance'*

Funded by the European Union

Publications Office of the European Union