



**INTERAGENCY ASSESSMENT**

**ECDC/EC/EFSA country visit to  
Serbia to advance One Health  
responses against antimicrobial  
resistance**

**24-28 February 2025**

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## Abbreviations

ALIMS	Agency for Medicines and Medical Devices, Serbia
AMC	Antimicrobial consumption
AMEG	European Medicines Agency's Antimicrobial Advice Ad Hoc Expert Group
AMR	Antimicrobial resistance
AMS	Antimicrobial stewardship
AST	Antimicrobial susceptibility testing
ATC	Anatomical therapeutic class
CAESAR	Central Asian and European Surveillance of Antimicrobial Resistance network
CIA	Critically important antimicrobials for human medicine
COVID-19	Coronavirus disease 2019
CPD	Continuous professional development
CPE	Carbapenemase-producing Enterobacterales
CSF	Cerebrospinal fluid
DDD	Defined daily dose
DG NEAR	Directorate-General for Neighbourhood and Enlargement Negotiations (European Commission)
DG SANTE	Directorate-General for Health and Food Safety (European Commission)
EAAD	European Antibiotic Awareness Day
EARS-Net	European Antimicrobial Resistance Surveillance Network
ECDC	European Centre for Disease Prevention and Control
ECOFF	Epidemiological cut-off values (from EUCAST)
EEA	European Economic Area
EFSA	European Food Safety Authority
EMA	European Medicines Agency
EQA	External quality assessment
ESBL	Extended-spectrum beta-lactamase
ESUAvet	European Sales and Use of Antimicrobials in veterinary medicine
ESVAC	European Surveillance of Veterinary Antimicrobial Consumption
EU	European Union
EUCAST	European Committee on Antimicrobial Susceptibility Testing
EURGen-Net	European Antimicrobial Resistance Genes Surveillance Network
FAO	Food and Agriculture Organization
GAP-AMR	Global action plan on AMR (WHO)
GLASS	Global Antimicrobial Resistance and Use Surveillance System
GP	General practitioner
HAI	Healthcare-associated infection
ICU	Intensive care unit
IPA	Instrument of Pre-accession Assistance
IPC	Infection prevention and control
ISO/IEC	International Organization for Standardization/International Electrotechnical Commission
LIMS	Laboratory information and management system
MALDI-TOF MS	Matrix-assisted laser desorption/ionisation – time of flight mass spectrometry
MDR	Multidrug-resistant
MDRO	Multidrug-resistant organism
MIC	Minimum inhibitory concentration
NAP	National action plan
NRL	National reference laboratory
OTC	Over-the-counter
PCU	Population correction unit
PCR	Polymerase chain reaction
PPS	Point prevalence survey
SARI	Severe acute respiratory infection
SARS-CoV-2	Severe acute respiratory syndrome coronavirus 2
SVL	Specialist veterinary laboratory
ToR	Terms of reference
VIS	Veterinary information system
WAAW	World AMR Awareness Week
WASP	Western Balkan Strategic Partnership
WGS	Whole genome sequencing
WHO	World Health Organization
WOAH	World Organisation for Animal Health.

## Summary

The European Centre for Disease Prevention and Control (ECDC), the European Commission's Directorate-General for Health and Food Safety (DG SANTE) and the European Food Safety Authority (EFSA) conducted a country visit to Serbia from 24 to 28 February 2025. The visit was supported by a consortium composed of Epiconcept and Integrated Quality Laboratory Services (IQLS) and based on the 'Methodology for conducting One Health country visits on antimicrobial resistance in the Western Balkans' [1]. The visit was part of [ECDC Accession Support to the Western Balkans and Türkiye](#) activities for the advancement of a One Health approach against antimicrobial resistance (AMR) in the Western Balkans, funded by the Directorate-General for Neighborhood and Enlargement Negotiations (DG NEAR) of the European Commission.

The findings of the report indicate that the situation related to AMR in Serbia is of major concern and requires immediate attention to ensure patient safety and preserve hospitals' capacity to deliver high-quality care. At the time of the visit, only a few national initiatives had been launched to tackle AMR challenges in the sectors of human health, animal health and food safety. The national intersectoral coordinating mechanism, the multidisciplinary working group for AMR management, was re-established in January 2025 to prepare a new National Action Plan (NAP). The previous NAP on AMR for the period 2019–2021 was postponed due to the COVID-19 pandemic and it was not possible to implement all the outlined activities. The development of the new NAP presents an opportunity to create a detailed operational plan, based on situational analysis, that encompasses all essential activities, clearly defines targets, indicators, roles, and responsibilities, and is backed by a specific budget and timeline. There should also be consistent and transparent public reporting to promote accountability and encourage participation from all relevant political entities.

For the human health sector in Serbia, the high levels of resistance to key pathogen-antibiotic combinations, including very high levels of carbapenem resistance in Gram-negative bacteria such as *Klebsiella pneumoniae* and *Acinetobacter baumannii*, are of major concern. In the hospitals visited there was evidence of ongoing transmission of multidrug- and pan-drug-resistant clones with very few remaining treatment options. For this reason, physicians often resort to recently approved antimicrobials, against which resistance is also emerging. In addition, the first cases of *Candida auris* in the country had recently been reported.

Nevertheless, many useful elements are in place in Serbia that could be leveraged to improve control of AMR, including a committed and well-trained workforce and the existence of legally mandated and multi-disciplinary infection prevention and control (IPC) committees in all hospitals. Microbiology services were of a good standard and were responsive, providing results in a timely manner. The National Reference Laboratory (NRL) for AMR surveillance provides a reliable baseline of surveillance data for AMR which is reported to the appropriate authorities and disseminated through scientific media, including publications and congresses. However, there appears to be little or no use of the data to inform public health actions at local, regional or national level.

National clinical practice guidelines for the rational use of antibiotics were published in 2018 and are used extensively by clinicians when prescribing antibiotics. There do not appear to have been any audits to check that antibiotic prescribing adheres to these guidelines and there has been no major review or revision since its first publication in 2018. The primary focus of antimicrobial stewardship (AMS) committees in the hospitals visited was to provide supervision and approval for the prescription of reserve antibiotics. These committees also provided varying amounts of guidance, feedback, and continuing professional education to prescribers. However, since the end of the 'Second Serbia Health Project' (which conducted well-planned AMR campaigns targeting various audiences), only limited awareness-raising activities had been undertaken to reduce the high antimicrobial consumption. There is a strong need to develop and implement awareness and behaviour change communication to strengthen AMR control activities within hospital services and raise awareness in primary care services and among the general public.

In the animal health and food safety sectors, Serbia's network of veterinary laboratories, including the Scientific Veterinary Institute of Novi Sad (SVI-NS), which serves as the NRL for AMR, provides diagnostic and monitoring services. The SVI-NS collaborates with EU reference laboratories, adhering to international standards, but faces challenges, such as limited on-site sequencing capacity and inconsistent confirmatory testing of samples from other laboratories. The NRL has adopted EU methodologies and participates in proficiency testing, however the absence of a harmonised national monitoring system and limited antimicrobial susceptibility testing data hinder comprehensive AMR surveillance. Although there is limited data on AMR in isolates from animals and foods, a worrying trend in multi- drug resistance organisms is emerging from research studies and clinical samples, including samples from wildlife. Plans are in place to commence EU-harmonised AMR monitoring in animals and food in 2025, but have not been fully validated.

The Agency for Medicines and Medical Devices of Serbia (ALIMS) oversees veterinary medicinal products' registration and quality control, collecting and publishing aggregated sales data on antimicrobials authorised for animals. However, the lack of detailed analysis and adjustment for animal population size limits the usefulness of these data. In addition, data on the levels of antimicrobial use in different species are unavailable, and the IT system for this purpose is still under development. There has been an increase in sales of colistin in recent years, highlighting the need for increased resources to conduct a detailed analysis. Serbia has begun taking steps to encourage the

responsible use of antimicrobials, aligning its current Medicines and Medical Devices law with Directive 2001/82/EC. A new law, which is being drafted to harmonise with Regulation (EU) 2019/6, will also address the regulation of antimicrobials. While positive practices were noted, such as vaccination and biosecurity, challenges persist with the over-use of broad-spectrum antibiotics, including third and fourth-generation cephalosporins, fluoroquinolones, and colistin, often chosen for economic reasons or perceived effectiveness. Worrying reports indicate that farmers sometimes obtain antimicrobials illegally without veterinary supervision. Educational efforts at the Veterinary Medicine Faculty in Belgrade and through continuing professional development programmes underscore Serbia's commitment to raising AMR awareness. However, a fragmented approach to AMR education and limited integration of the One Health concept suggest that there are areas for improvement.

In the environmental sector, challenges include the lack of systematic monitoring of antimicrobials, resistant microorganisms and antimicrobial resistance genes in the environment and inadequate disposal routes for unused and expired medicines. The latter problem was identified in the previous NAP but remains largely unresolved. Limited information was available on the monitoring of antimicrobials in surface waters, but details are pending. There is currently no data or plans for surveillance of AMR levels in the environment, a situation mirrored in many EU Member States.

## Introduction

Antimicrobial resistance (AMR) represents a serious threat to people's health as well as to economies around the world. Recent estimates of the burden of AMR in the World Health Organization (WHO) European Region revealed that in 2019 alone, nearly 700 000 deaths were associated with or attributed to bacterial AMR [2]. A study estimated that between 2016 and 2020, 70% of antibiotic-resistant bacterial infections in the European Union and European Economic Area (EU/EEA) were healthcare-associated infections, and the number of deaths ranged from 30 730 in 2016 to 38 710 in 2019 [3]. AMR also has significant costs, especially for healthcare systems, which could cost the world economy up to USD 100 trillion by 2050, based on the currently increasing AMR trends [4].

In line with the Global Action Plan on AMR (GAP-AMR) [5], adopted in May 2015 by WHO's World Health Assembly and subsequently by the World Organisation for Animal Health (WOAH) and the Food and Agriculture Organization (FAO), the European Commission published its own EU One Health Action Plan against AMR in 2017 [6]. The key objectives of this plan are built on three main pillars: (i) making the EU a best practice region; (ii) boosting research, development and innovation, and (iii) shaping the global agenda. As part of this agenda, the European Commission commits to supporting candidate countries for accession to the EU in aligning and implementing EU legislation on AMR.

One of the five strategic objectives of the ECDC Strategy 2021–2027 [7] is to increase health security in the EU through international collaboration and alignment of infectious disease policies and practice by strengthening cooperation and coordination between ECDC and partners in non-EU countries, especially EU enlargement countries. On 10 December 2019, the EU Contribution Agreement No 2019/409-781 was signed between ECDC and DG NEAR of the European Commission, and amended on 23 December 2020 to implement ECDC's 'Preparatory measures for the participation of the Western Balkans and Türkiye in ECDC activities' with special focus on OneHealth responses to AMR and severe acute respiratory infection surveillance, 2020–2024 (ECDC-IPA6 project) and external financial assistance under the Instrument of Pre-accession Assistance (IPA).

During the joint ECDC and EFSA regional workshop 'One Health approach against AMR for EU pre-accession countries', held in 2019 in Belgrade, Serbia, relevant national representatives recognised that there was an urgent need to strengthen the response to AMR and implement the relevant legislation in the region to an appropriate, EU-equivalent level [8]. National governments needed to establish regulatory requirements, necessary laboratory infrastructure and capacity, efficient comprehensive and inter-operable electronic surveillance systems, training, additional workforce in the human and animal health sector, and awareness raising and commitment to ensure the sustainability of efforts.

Work Stream 2 of the ECDC-IPA6 project focuses on the advancement of a One Health approach to AMR in the Western Balkans, including discussion of AMR issues, identification of gaps and support for the development of roadmaps on AMR in different sectors: human health, animal health, food safety and the environment. In addition, to align with previous One Health country visits on AMR in the EU/EEA countries, the visits to countries receiving pre-accession assistance are joint visits with experts from ECDC, DG SANTE and EFSA to cover areas relevant for AMR surveillance, infection prevention and control (IPC) and antimicrobial use from a One Health perspective.

## Objectives and scope

The overall objective of this joint country visit to Serbia was to discuss and review the advancement of a One Health approach against AMR through (i) the identification of strengths and weaknesses in the current national AMR strategies, action plans and the intersectoral coordination mechanism; (ii) a review of the functioning of NRLs for AMR and their capacity to detect and report AMR; (iii) the documentation of the current state and efforts being made by Serbia on AMR surveillance, antimicrobial consumption (AMC) and healthcare-associated infections (HAIs); (iv) a review of actions related to the prudent use of antibiotics in human and animal health, (v) actions related to AMR from the perspective of food safety, as well as in the environmental sector; and (vi) a review of activities and approaches to raising awareness of AMR. A detailed agenda of the One Health country visit is provided in Annex 1.

The visit focused on: (i) the laboratory capacity to process, collect and share AMR data in humans and animals at national and local level; (ii) monitoring activities on AMR in the human, animal and food sector; (iii) monitoring of AMC in the human sector and surveillance of sales and use of antimicrobials in the veterinary sector; (iv) antimicrobial stewardship (AMS), treatment guidelines and prudent use of antimicrobials in humans and policies to tackle AMR through the reduced and more prudent use of antimicrobials in animals; (v) IPC; and (vi) communication, behavioural change interventions and awareness activities. The evaluation and discussions on the human aspect of AMR were guided by the assessment tool developed by ECDC [9]. To a limited extent, the visit also covered environmental aspects of AMR, such as the disposal of expired and unused drugs in the food production sector.

## Background

Serbia is a member of the WHO Regional Office for Europe (WHO Europe) and of the Central Asian and Eastern European Surveillance of Antimicrobial Resistance network (CAESAR), and has reported data on the antimicrobial susceptibility of invasive (i.e. from blood and cerebrospinal fluid) bacterial isolates for key bacterial species since 2013 [10]. A recent analysis of the global burden of AMR from 1990–2021, estimated that in 2021 the mortality rate attributable to AMR for all ages in Serbia was in the range 18–21/100 000 [11]. AMR surveillance is well established in Serbia, with an estimated national population coverage of 80% and a high geographical and hospital representativeness for the period 2017–2021. However, because of the low blood culture rate (23 blood culture sets per 1 000 patients reported each year) and the collection of samples mainly from intensive care units (ICU), the representativeness of isolates collected for AMR surveillance was reported as medium. Within the CAESAR network, Serbia reported a high percentage of resistance to carbapenems in *Escherichia coli* (3.2%), *Pseudomonas aeruginosa* (63%) and *Klebsiella pneumoniae* (63%); resistance to penicillins in *Streptococcus pneumoniae* (48%), and resistance to vancomycin in *Enterococcus faecium* (55.3%). The levels of resistance are among the highest in the region reported to the CAESAR network, although there are important sources of heterogeneity (e.g. population, healthcare systems) and only limited data are available in many other Western Balkan countries. The percentage of resistance reported in Serbia was above the EU/EEA weighted averages for all pathogen-antimicrobial agent combinations, except for fluoroquinolone-resistance in *Escherichia coli* [12].

According to data from the national HAI surveillance system in 2023, the most common bacterial species associated with HAIs were *Klebsiella pneumoniae* (21%), *Clostridium spp* (12%), *Acinetobacter spp* (10%), *Enterococcus spp* (8%) and *Pseudomonas aeruginosa* (5%). Of the 2 484 isolates of *Klebsiella spp*, 69% were resistant to carbapenems and 69% resistant to third-generation cephalosporins. Of the 1 209 isolates of *Acinetobacter spp*, 92% were resistant to carbapenems. Of the 624 isolates of *Pseudomonas spp*, 61% were resistant to carbapenems and 69% were resistant to ceftazidime.

In accordance with its responsibilities outlined in the Medicines and Medical Devices Act ('Official Gazette of the RS' No. 30/2010 and 107/12, 105/17-A state law and 113/17-state law), the Agency for Medicines and Medical Devices of Serbia (ALIMS) collects and processes data on the sales of medicines in Serbia to provide an insight into the extent and types of medicines used. ALIMS publishes annual reports containing aggregated data on AMC, based on wholesale data obtained from the medicine licence holders, or from manufacturers or their authorised representatives/agents. Consumption is reported for Anatomical Therapeutic Chemical (ATC) classification group J.01 (antibacterials for systemic use) in defined daily dose (DDD) per 1 000 inhabitants.

WHO's Regional Office for Europe established the AMC network to monitor the consumption of antibiotics for non-EU countries. In the latest AMC network report, consumption in Serbia was 21.1 DDD/1 000 in 2017 but has since risen steadily so that in 2023 it had the second highest reported AMC among the 14 AMC network countries (31.4 DDD per 1 000 inhabitants) [13]. WHO has set a country-level target of at least 60% of total AMC being Access group antibiotics. In 2023, 50% of total AMC in Serbia were from the Access group [13].

Legislation has mandated the establishment of a national programme for IPC and the establishment of IPC committees at all healthcare facilities. All HAIs are notifiable to the national surveillance system. In 2024, among 10 609 HAIs reported by hospitals in Serbia, the most common sites of infection were urinary tract (22%), gastrointestinal tract (21%), surgical site (12%) and bloodstream (11%). The most common pathogens isolated were *Klebsiella spp* (21%), *Acinetobacter spp* (10%) and SARS-CoV-2 (7%). Five national point prevalence surveys have been conducted (1998, 2005, 2010, 2017 and 2022), the last two of which were undertaken as part of the European point prevalence survey (PPS) of HAIs and antimicrobial use, and these surveys recorded an HAI prevalence of 7.4%, 3.5%, 5.3%, 4.6% and 4.8%, respectively.

In 2022, the Food and Animal Organisation (FAO) conducted a survey on antimicrobial use in Serbia's livestock industry. The report reveals notable gaps in knowledge and practices among farmers, veterinarians, and pharmacy staff, along with deficiencies in hygiene and biosecurity practices on farms. While the report indicates that most farmers tend to avoid antibiotics, many do not fully grasp their correct usage and the risks of AMR. In addition, the report states that, although pharmacies keep sales records, they often sell directly to farmers without prescription. In the veterinary sector, the tasks related to the controls and monitoring of sales and use of antimicrobials have been entrusted to the Veterinary Directorate within the Ministry of Agriculture, Forestry, and Water Management (MoAFWM), as well as the ALIMS.

The Veterinary Directorate oversees official inspections of distributors (importers) of veterinary medicinal products, veterinary clinics, pharmacies, and agricultural producers. Furthermore, the Veterinary Directorate conducts inspections focusing on safety, hygiene, traceability, and the labelling of food and feed products. In terms of monitoring of AMR, the Veterinary Directorate is collaborating with the Scientific Veterinary Institute of Novi Sad (SVI-NS) on the introduction of the EU's harmonised monitoring of AMR in zoonotic and commensal bacteria in specific foods and food-producing animals.

# Observations

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

### Multi-sectoral collaboration and coordination

There is good cooperation among the relevant sectors in discussing AMR issues from a One Health perspective, following on from work previously done by a formalised inter-sectoral coordinating group before the COVID-19 pandemic. However, this group was deprioritised during the COVID-19 pandemic. On 30 January 2025, the Minister of Health re-appointed the National Multisectoral Coordination Group for Control of Antibiotic Resistance (Coordination Group). This group is chaired by the Minister of Health and has two vice-chairs including one chair from the Medical Faculty in Belgrade for the human health sector and the other from the Ministry of Agriculture, Forestry and Water Management for the animal health sector. The Coordination group has 21 representatives from the following institutions:

- Institute of Public Health 'Dr Milan Jovanovic Batut'
- Ministry of Health represented by sectors responsible for international coordination, medicines, public health, campaigns on prudent use of antibiotics, international relations and EU projects, inspection services and the implementation of the World Bank project on COVID-19
- Medical Faculty of Novi Sad, University Clinical Centre of Vojvodina, Novi Sad
- Medical Faculty of Belgrade, University Clinical Centre of Serbia
- NRL for AMR at the Institute of Public Health of Vojvodina
- ALIMs
- Pharmaceutical Chamber of Serbia
- Ministry of Agriculture, Forestry and Water Management represented by the Veterinary Department and the Plant Protection Directorate
- Ministry of Environmental Protection.

Members of the Coordination Group are expected to contribute to the tasks defined in the ministerial decision and attend this group as part of their responsibilities as national officials from their respective institutions. At the time of the country visit in February 2025, the Coordination Group had not yet met to initiate activities. As outlined in the terms of reference for the Coordination Group, it will supervise and coordinate actions for the control of AMR by promoting good clinical practice for the rational use of antibiotics, implementing awareness campaigns and providing national information and advice.

### National action plan on antimicrobial resistance

A One Health National Action Plan (NAP) on AMR based on the WHO guidelines with involvement of human health, the veterinary and environmental sectors was in place during the period 2019–2021<sup>1</sup>. The NAP included a description of activities, outcomes, indicators, responsible entities and budget allocations for the human health and animal health sectors. However, due to the COVID-19 pandemic, there were no progress reports or assessments of the effectiveness and impact of measures. At the time of the country visit, there were no ongoing activities and plans related to drafting a new NAP based on available data and situational analysis, nor had a timeline for the preparation been established and tasks distributed among the Coordination Group members.

## Human health aspects of antimicrobial resistance

### Organised multidisciplinary collaboration at local level

There appeared to be strong multidisciplinary collaboration within the hospitals visited through the IPC committees established by law in each healthcare facility. The IPC committees fostered strong networking between laboratories, pharmacies, IPC specialists and clinicians (see Section 4.2.5 and 4.2.6 for further details). The IPC committees worked not only to identify, prevent and control HAIs but also to incorporate some AMS activities and related roles. However, there appeared to be only limited multidisciplinary collaboration related to AMR between public health services, primary care, hospitals and long-term care facilities at the local level. Although local institutes of public health are required to assist hospitals in HAI outbreak investigations, there appeared to be little formal or regular engagement between them and local hospitals or other healthcare facilities. Consequently, there appeared to be an absence of strategic planning and coordination of interventions between major healthcare services and stakeholders (e.g. public health services, primary care providers, hospitals and pharmacies) at local or national level.

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<sup>1</sup> The NAP was shared with country visit team prior to the visit.

## Clinical diagnostic and reference laboratory services

In Serbia, there are 59 microbiological laboratories in the public sector, including 12 laboratories in tertiary hospitals, 25 in secondary hospitals and 22 in institutes of public health. The number of laboratories capable of microbiological testing in the private sector is unknown. While good microbiology laboratory capacity was available in the country, it was fragmented between many laboratories and not always allocated according to needs. For example, some of the laboratories visited had good capacity for species identification with Matrix-Assisted Laser Desorption/Ionisation–Time of Flight Mass Spectrometry (MALDI-TOF MS), including the Milan Jovanovic Batut Institute of Public Health and the University of Belgrade. However, the nearby University Clinical Centre of Serbia, with more than 3 000 beds and status as a reference hospital for the Western Balkan region, lacked this capacity.

The clinical microbiology laboratories in the public hospitals visited provided services during working hours and, depending on the facility visited, offered varying levels of service outside of working hours and at weekends. The University Clinical Centre of Serbia did not have any out-of-hours microbiological services. Laboratory Information Management Systems (LIMS) with connection to electronic patient management systems were in place and facilitated the rapid reporting of results. The blood culture rate (sets/1 000 patient days) reported to CAESAR in 2021 was higher (23.6) than the rates for other Western Balkan countries, but still within the lowest quartile of rates reported in the EU [10]. A National AST Committee was established in 2017 and all laboratories visited, including the NRL for AMR, were using EUCAST breakpoints to report AST results. There was no national accreditation body. National guidance on screening for multidrug-resistant organisms (MDRO) was not available. MDRO screening was not systematically performed at the healthcare facilities visited and related laboratory capacity was not established.

Serbia has 25 NRLs located in 12 different institutions. The NRL for AMR was established in 2008 and is located at the microbiology department of the Vojvodina Institute of Public Health. Although the NRL for AMR is officially nominated by the government, specific funding for reference services is not provided. The NRL also provides species identification and/or confirmation for some of the smaller laboratories in its network, as well as clinical laboratory services for the ICU of the local pediatric hospital. The NRL is equipped with MALDI-TOF MS for microbiological identification and a VITEK® system for AST. Although Illumina sequencing machines have been purchased for three laboratories in Serbia, these had not been deployed for genomic AMR surveillance and outbreak control in hospitals. Many difficulties were reported related to the purchasing of reagents and the limited availability of technical in-country support for laboratories. For this reason, all three laboratories were using external contractors for whole genome sequencing (WGS) as this was less expensive and faster. Due to lack of access to reagents in the country, the NRL for AMR had also not been able to establish WGS, despite receiving a MinION® device funded by the EURGen-RefLabCap project and related training.

## Monitoring of antimicrobial resistance

The NRL collects data from a network of 24 clinical microbiology laboratories on specific bacterial species - antimicrobial agent combinations for invasive isolates (i.e. from blood and cerebrospinal fluid (CSF)) in line with the CAESAR protocol [10]. In addition, some laboratories submit isolates for confirmatory testing which are stored by the NRL for AMR. Population coverage of the national AMR surveillance has increased over time, reaching 80% in 2023. National surveillance has good representativeness for the different geographical areas and hospital types but medium isolate representativeness due to the low blood culture rate and the high proportion of isolates originating from ICUs.

Collected AMR data are regularly analysed, and reported in aggregated format on an annual basis to the Ministry of Health, the laboratories participating in the network (although individual laboratory results are only provided on request), and at the international level to the CAESAR Network (since 2013). Although data from the NRL are reported to the appropriate authorities and disseminated through public and scientific media, including publications and congresses, there appears to be little use of the data to inform treatment guidance and public health actions at local, regional or national level within Serbia.

In the CAESAR report for 2021, Serbia reported a high percentage of resistance for various bacterial species – antimicrobial agent combinations compared to neighbouring countries in the Western Balkans. It should be noted that Serbia was the only Western Balkan country that reported sufficient isolates to be presented in the latest CAESAR report. The reported proportions of resistance for invasive isolates were higher than the EU average for all bacterial species – antimicrobial agent combinations reported and frequently showed an increasing temporal trend, especially for Gram-negative bacteria [12]. In 2023, the NRL reported that the percentages of resistance to third-generation cephalosporins (ceftriaxone) for invasive isolates were 30.7% and 92.6% for *E. coli* and *K. pneumoniae*, respectively. Resistance to carbapenems (meropenem) in Gram-negative bacteria was also high: 67.4% for *K. pneumoniae*, 96.3% for *Acinetobacter* spp, 48.8% for *Pseudomonas aeruginosa* and 0.6% for *E. coli*. The percentages of resistance for Gram-positive bacteria for the key bacterial species – antimicrobial agent combinations were 47.9% for vancomycin resistance in *Enterococcus faecium*, 23.8% for methicillin resistance in *Staphylococcus aureus*, and 22.4% penicillin non-wild type in *Streptococcus pneumoniae* [personal communication].

In the hospitals visited, healthcare professionals were concerned about the frequent occurrence of MDROs and the very limited options remaining for treatment of severe infections, especially for *K. pneumoniae* and *Providencia stuartii*. Example antibiograms were presented of pan-drug-resistant bacteria which were resistant to all or almost all antimicrobials in both of the university hospitals visited, including antimicrobials only recently approved and available on the market.

Although strong systems have been implemented for the surveillance of notifiable diseases and AMR in Serbia, several shortcomings remain. Firstly, there is no comprehensive national AMR surveillance including sample types, other than for blood and CSF. Secondly, national data are reported with limited frequency (annually) to a limited number of national partners (i.e. the Ministry of Health and participating laboratories). There is no dissemination of local AMR data (e.g. by laboratory, hospital) to data providers or clinicians. In addition, available data are not used to inform antimicrobial treatment guidance at community level or to develop national strategies for the control of AMR. Finally, an integrated analysis of data from the different AMR and AMC surveillance systems is not performed.

## Monitoring of antimicrobial consumption

Two data sources – data from total sales and data from electronic prescription by general practitioners (GPs) – can be routinely accessed to monitor AMC. It is the responsibility of ALIMIS to collect, analyse and report total sales of antimicrobials in Serbia, as mandated under the Medicines and Medical Devices Act ('Official Gazette of the RS' No. 30/2010 and 107/12, 105/17-A state law and 113/17-state law). Wholesale data are collected from the 127 marketing authorisation holders who hold 442 drug licences for 136 international non-proprietary antimicrobials. There are legal requirements for data submission to ALIMIS by marketing authorisation holders and reporting to the relevant ministries by ALIMIS. Consumption is reported for the ATC classification group J.01 (antibacterials for systemic use) as DDD per 1 000 inhabitants.

National aggregate summary statistics based on sales, which cover total consumption (community and hospital combined), are available on the Ministry of Health website and provided to WHO. In 2023, the total antibiotic consumption was 31.4 DDD per 1 000 inhabitants per day. The percentage of antibiotics, in the Access group of the WHO AWaRe classification [13] was below the respective WHO target. According to the latest AMC network report, AMC in Serbia was 21.1 DDD/1 000 inhabitants/day in 2017 but has since risen steadily. In 2023, Serbia had the second highest reported AMC (31.4 DDD/1 000 inhabitants/day) among the 14 non-EU/EEA countries in the WHO European Region that provided data [13].

The pharmacy information systems of the hospitals visited, which record prescriptions for individual patients, allow for data extraction and presentation of statistics by department. With additional steps it is also possible to obtain prescriptions by diagnosis and convert antimicrobial use into DDD. Hospital-specific data on antimicrobial use were also obtained through the PPS on HAI and antimicrobial use in acute care. The last two PPS, conducted in 2017 and 2022 following the ECDC protocol, showed an increase in the prevalence of antimicrobial use (from 41.3% to 44.8%). In the 2022 PPS, a high percentage of the total antimicrobial use was prescribed for medical (19.2%) and surgical (20.5%) prophylaxis. Surgical prophylaxis was continued for more than one day in three out of four patients [15,16]. Serbia also participated in ECDC's PPS on HAI and antimicrobial use in long-term care facilities (LTCF) in 2016–2017. The prevalence of AMC in the six participating LTCF in Serbia was 4.9%, the same as the EU/EEA average [17].

The data sources mentioned have several limitations. The total sales data do not allow for monitoring of antimicrobial consumption by setting (i.e. community, hospital). The e-prescription system covers only prescriptions from GPs that are reimbursed by the health insurance system. Although it has become more difficult to receive antibiotics without a prescription due to legal restrictions and inspections in pharmacies, there is a proportion of prescriptions that are not recorded via the e-prescription registration. These include antibiotics prescribed by specialists or private doctors which are paid for by patients. Moreover, the e-prescription system does not cover medicines available on the market, but not reimbursed by the health insurance system (e.g. oral penicillin). Despite these limitations, the data available would make it possible to provide feedback to decision makers and prescribers, even though this is not always done. GPs are not provided with any feedback on their prescribing compared to other GPs or the average for prescribers in their area. In addition, only one of the three hospitals visited provided feedback on consumption measured in DDD to the clinical departments on a quarterly basis.

## Antimicrobial stewardship and treatment guidelines

National clinical practice guidelines for the rational use of antibiotics for infections in hospitals and in the community were published in 2018. Clinicians in most of the healthcare facilities visited were aware of these guidelines but did not always prescribe antibiotics in line with the guidance. It is interesting to note that the use of antibiotics for surgical prophylaxis appeared to vary widely among the hospitals visited and included the use of third-generation cephalosporins in at least one hospital and the administration of antibiotics for more than five days in other hospitals. Systematic audits of the adherence of prescribers to the national guidelines have not been conducted. Furthermore, although there have been specific updates, there has been no major review of the guidelines since they were published in 2018.

All hospitals in Serbia are expected to have established a committee for antimicrobial stewardship (AMS), although there was some uncertainty regarding the legal framework for these committees and whether they had been established in all hospitals. All the hospitals visited had such a committee consisting of, as a minimum, clinicians (internal medicine and infectious disease specialists), hospital epidemiologists, microbiologists and pharmacists. However, the AMS committees operated without a designated budget and allocated working time. In the hospitals visited, the committees provided oversight and approval for the prescribing of reserve antibiotics. Use of reserve antibiotics (e.g. meropenem) required the signatures of the prescribing physician, the head of the respective department and the hospital director. For antibiotics not reimbursed by the insurance system (e.g. ceftazidime-avibactam) or not marketed in Serbia (e.g. cefiderocol), approval required the completion of additional forms, with attached AST results to justify the prescription. The AMS committees also provided varying levels of guidance (e.g. surgical prophylaxis), feedback (by individual, ward and department) and continuing professional education to prescribers.

Despite the efforts of the AMS committees, the use of reserve antibiotics has steadily increased in recent years at the hospitals visited. In addition, there was inappropriate use of antibiotics, including frequent administration of broad-spectrum antibiotics, and antimicrobial treatment of longer duration than indicated. None of the hospitals visited had local protocols for the management of severe infections including guidance on antibiotic treatment and diagnostic procedures. There was agreement among the professionals that blood cultures were frequently not performed before initiating empirical antimicrobial treatment which often consisted of carbapenems/colistin and linezolid.

Legal regulation is in place to restrict antibiotic dispensing to prescriptions. However, even though antibiotics are mainly only dispensed with a doctor's prescription in community settings, there is still significant overuse of antimicrobials such as amoxicillin-clavulanic acid and third-generation cephalosporins, as mentioned by professionals met by the visiting team. During discussions with stakeholders, it became evident that there is still a widespread public belief that it is necessary to treat respiratory tract infections with antibiotics. This results in significant pressure on doctors to prescribe antibiotics to meet patient expectations. Broad-spectrum antibiotics, such as fluoroquinolones, are frequently prescribed. The use of broad-spectrum antibiotics is further exacerbated by the frequent unavailability of key narrow-spectrum antibiotics, including amoxicillin and flucloxacillin, in pharmacies. A more proactive and robust approach to providing feedback to prescribers and stronger and more consistent recommendations for antibiotic prophylaxis could contribute to more adequate prescriptions.

## Infection prevention and control

As mandated by law in Serbia, all healthcare workers have a responsibility for IPC and all healthcare facilities are required to employ IPC staff, although no minimum staffing ratio was reported. The IPC law was adopted in 2013, with updates in 2015 and 2020, but a national IPC programme does not exist. All healthcare facilities are required to establish IPC committees consisting of, as a minimum, an epidemiologist (in healthcare facilities with more than 400 beds), a microbiologist and a specialist in hygiene and environmental medicine, and these committees should meet at least quarterly. The committees are obliged to prepare a programme with activities (both annual and multi-year), record and report HAIs, offer vaccination to healthcare workers, provide local IPC guidance, undertake outbreak investigation and response and ensure the continuing education of healthcare workers in relation to IPC.

There is a national IPC committee comprising experts from national and regional public health institutes and tertiary university clinics, but there was little evidence of its interaction with local committees, central coordinating role or the provision of guidance. The IPC committees prepare reports on HAIs surveillance that are discussed internally during meetings, but these reports are neither sent to hospitals or healthcare workers, nor used to develop and implement interventions. Limited coordination was observed among the regional and local IPC committees during the visit. Despite the absence of a national IPC programme, most healthcare facilities visited mentioned their own guidelines, documents and training activities. In addition, the Institute of Public Health of Serbia has developed recommendations for prevention of infections and hygiene in healthcare facilities and hospital infections caused by *Clostridioides difficile*.

In the hospitals visited, the team observed varying levels of adherence to IPC practices. In particular, multidisciplinary IPC committees were in place at most of the facilities visited, with dedicated and enthusiastic personnel who had adequate IPC expertise. There was the impression that IPC staff were accepted and appreciated by other departments. The IPC nurse to bed ratio varied between 1:200 – 1:250. There was no formal IPC training or certification for nurses or doctors and most training was conducted on a peer-to-peer basis.

All hospitals visited reported that they monitored hand hygiene and promoted good practice, usually in connection with 'Hand Hygiene Day' in May. Nevertheless, the team observed examples of inappropriate use of gloves and poor hand hygiene practices, especially before and after contact with patients, despite the presence of alcohol-based handrub dispensers in most of the wards visited. In most areas, the placement of dispensers was not optimal and did not follow the principle of having alcohol-based handrub available at the point of care. Moreover, some facilities only had posters showing handwashing with soap and water and staff acknowledged that the most common hand hygiene practice was hand washing with water and soap rather than the use of alcohol-based handrub. Some hospital pharmacies keep registries of alcohol-based hand rub consumption, and this information was used for IPC monitoring. In all the healthcare facilities visited, healthcare workers were observed wearing

watches and jewellery and with long or artificial nails. The team therefore felt that more rigorous action and follow-up could be undertaken in hospitals to monitor and promote hand hygiene, especially to ensure more active feedback of monitoring results to departments and individual healthcare workers.

In the ICUs visited, there were patients infected with or carrying multiple MDROs. The limited distance between ICU beds and insufficient time for thorough environmental cleaning between patient admissions was of particular concern. Evidence-based strategies had been implemented to prevent device-associated infections. For example, to reduce the risk of ventilator-associated pneumonia, the heads of ICU beds accommodating ventilated patients were elevated to an appropriate angle. Similarly, urinary drainage bags were not overfilled and were properly positioned, hanging below the level of the patient's bed. Transparent dressings with chlorhexidine were used at central line insertion sites to prevent central catheter-associated bloodstream infections. These dressings were appropriately labelled with the application date and daily care activities were documented using a standardised checklist.

Although the hospitals visited were screening transplant and oncology patients for MDRO, there was no admission screening for patients transferred from other hospitals. Screening practices varied widely between hospitals due to limited laboratory capacity and budget. Neither national guidelines, nor hospital-specific guidelines were in place to screen patients for MDROs at the hospitals visited. This lack of systematic screening for MDROs presents a substantial risk of cross-transmission that is further exacerbated by the absence of alerts or notifications of MDRO carriage in patient records. Warning signs and the practice of isolation or cohorting of patients infected or colonised with MDROs were observed in some of the units visited. There was awareness of the need for contact precautions in relation to MDROs, and appropriate personal protective equipment was available. However, there were also instances where patients colonised with MDROs were treated in the same room as non-colonised patients, compromising IPC measures. The first case of *Candidozyma auris* had been detected in a hospital patient in Serbia and may pose further challenges for IPC in the future.

A digital platform for the reporting of HAIs by healthcare facilities is maintained by the Institute of Public Health of Serbia. In 2023, all nine tertiary care hospitals reported HAI. Of the 40 secondary hospitals, 26 reported HAIs, eight hospitals reported only cases of *Clostridioides difficile* and six hospitals did not report. In 2024, 73 outbreaks were reported in healthcare facilities, half of the 146 outbreaks reported in 2023. However, the number of non-COVID outbreaks was higher in 2024 (33 outbreaks) than in 2023 (24 outbreaks). A total of 10 609 HAI were reported by hospitals in 2024. The most common HAIs were urinary tract infections (22%), gastrointestinal infections (21%), surgical site infections (12%) and bloodstream infections (11%). The most frequently associated pathogens were *Klebsiella* spp (21%), *Acinetobacter* spp (10%) and SARS-CoV-2 (7%). Data from surveillance of HAIs at national and local level are not used to provide feedback and drive actions within hospital units although they could provide valuable information on quality of care and enable the monitoring of trends and the identification of outbreaks.

## Educational programmes on antimicrobial resistance and infection prevention and control

The principles of AMR and the rationale for the prescribing of antibiotics are included in the curriculum of medical undergraduate students at various stages of their training. Although the topics of AMR and antimicrobial use are covered in mandatory microbiology and pharmacology courses, undergraduates are not obliged to take specific modules for these subjects. According to a survey conducted in 2023 among programme directors at medical schools in Serbia, One Health was included in 34 obligatory and nine elective modules, spread throughout the six years of studies required for a medical degree. Over half (53%) of programme directors responded that they were familiar with the term One Health and actively engaged or incorporated it into their lectures. However, programme directors considered that limited awareness, curriculum challenges (e.g. overloading students, resistance to changing traditional curricula) and institutional factors (financial constraints, focus on clinical disciplines) resulted in limited integration of the One Health approach into faculty curricula.

Healthcare professionals are obliged to undertake continuing professional education (CPD) and there are many CPD courses offered that cover the topics of One Health, IPC, AMR and rational antibiotic use. However, there is no obligation for health professionals to attend courses on these topics as part of their CPD. In hospitals and larger healthcare facilities, topics such as IPC, AMR and rational antibiotic use were promoted through events linked to Hand Hygiene Day in May and European Antibiotic Awareness Day (EAAD)/World Antibiotic Awareness Week (WAAW) in November each year.

## Public information and behavioural change interventions on antimicrobial resistance

Between 2015 and 2022, as part of the 'Second Serbia Health Project', funded by the World Bank, the Ministry of Health conducted numerous activities with respect to public education campaigns for AMR, related training for healthcare professionals, and development of policies to improve the efficiency and quality of Serbia's public health system. Campaigns targeted healthcare professionals through seminars on the rational use of antibiotics and hand hygiene and were estimated to have reached more than 25 000 doctors, pharmacists, nurses and medical and pharmacy undergraduates throughout the duration of the programme. From 2017 onwards, awareness-raising campaigns focusing on the general public and healthcare professionals were conducted using

adapted ECDC and WHO materials which were distributed through a variety of media including billboards, small posters and flyers, and traditional and social media channels.

Since the end of the 'Second Serbia Health Project', limited awareness-raising activities have been undertaken by the national Institute of Public Health during the period 2023–2024. These campaigns targeted specialist and hospital healthcare professionals through seminars and congresses, usually held to coincide with European and global events (e.g. EAAD, WAAW). However, since then there have been no further campaigns or activities targeting primary healthcare professionals or the general public. A planned approach to develop antibiotic awareness campaigns, allocate necessary resources and evaluate the effectiveness or impact of implemented communication and behaviour change campaigns was lacking at the time of the visit. Furthermore, the visit team noticed the lack of visibility of any messages on antimicrobial use in the healthcare facilities visited.

## Marketing-related issues

Since 2010, ALIMS has been responsible for approving promotional materials from pharmaceutical companies aimed at either professional or public audiences for medicines and medical devices ('Official Gazette of RS': 79/2010 and 102/2018). ALIMS ensures that all promotional materials for antibiotics are aligned with the updated Summaries of Product Characteristics/Package Information Leaflets and adhere to national guidelines for antibiotic prescribing. Nevertheless, the country visit team were concerned by examples of marketing materials that appeared to promote the use of third-generation cephalosporins to health professionals.

Regulations governing the commercial marketing practices of pharmaceutical companies and their influence on prescribers, such as the provision of gifts and other benefits at conferences, are in place. Codes of conduct have been adopted by professional associations of marketing authorisation holders regarding the types of gifts that can be provided. Doctors are required to register received gifts, sponsored conference participation or related networking activities, although there appears to be no mechanisms to monitor these declarations.

## Animal health, food safety and environmental aspects of antimicrobial resistance

### Diagnostic laboratory services and reference laboratory services

The network for diagnosing and managing various animal diseases of veterinary laboratories in Serbia comprises two scientific institutes of veterinary medicine and ten specialist veterinary institutes. The laboratory network for diagnosing and testing food and feed includes five laboratories within 12 institutes and 18 private laboratories, providing services nationwide. One of the 12 accredited state laboratories, the Scientific Veterinary Institute of Novi Sad (SVI-NS) was founded in 1950 and is registered as a scientific and research institution with the Ministry of Science, Technological Development and Innovation, and in the Ministry of Agriculture Food and Water Management (MAFW)'s registry of veterinary institutions.

The SVI-NS is responsible for the supervision, diagnosis, control, prevention, and management of animal diseases, as well as the distribution of immunoprophylactic agents in the Južnobački and Sremski districts. The SVI-NS is organised into sectors for epizootiology, clinical diagnostics, and food safety. In 2020, the Department of Clinical Bacteriology, Mycology, and Parasitology of the SVI-NS was designated as the NRL for AMR. The NRL actively collaborates with the EU Reference Laboratory for AMR (EURL-AR), including participation in the EURL-AR proficiency testing schemes.

The NRL, which is ISO 17025 accredited, employs various testing methods, including disc diffusion, microdilution for determination of minimum inhibitory concentration (MIC) and polymerase chain reaction (PCR). It adheres to EUCAST and CLSI guidelines for interpreting results, ensuring consistency with international standards. The SVI-NS has a LIMS to manage and track data. Although there is a sequencing machine in the virology laboratory, the department of Clinical Bacteriology, Mycology, and Parasitology does not use it for bacterial AMR due to the high cost of the reagents, limiting on-site WGS capacity. This constraint, combined with the relatively small size of the laboratory, could pose challenges in handling increased workloads and future demands.

The SVI-NS does not have MALDI-TOF MS for species identification but collaborates with the local institute of public health to use their MALDI-TOF. The NRL's oversight of the laboratory network is limited, with confirmatory or second-line testing performed only sporadically and no guidance on national standard methods for AST, such as disc diffusion and micro broth dilution, issued for other laboratories. This could lead to inconsistencies in testing protocols and related results across the network.

## Monitoring of antimicrobial resistance in animals and food

Serbia is preparing to engage in EU-harmonised monitoring of AMR in animals and food. The Veterinary Directorate plans to commence sampling and testing in 2025. Specific details of the related plan have not been presented to the visiting team. However, the need for ministerial approval of the monitoring programme and the uncertain political situation could hinder the timely initiation and planning of AMR surveillance activities for 2025. In anticipation of the launch of the monitoring programme, in 2019 the NRL hosted EU experts to train its staff in standardised EU methodologies, such as microdilution MIC testing. Since then, the NRL has regularly participated in training sessions organised by the EURL AR and actively seeks advice when necessary. It was reported that the NRL has consistently passed external proficiency testing conducted by the EURL AR.

As there is no comprehensive data collection in place, only limited data on AMR are currently available from *ad hoc* studies, which might not be representative of the entire country. Nevertheless, these studies, with small sample sizes, have indicated high resistance levels to commonly-used antimicrobials (e.g. tetracyclines and also critically important antimicrobials for human health, such as third- and fourth-generation cephalosporins and fluoroquinolones in *E. coli*, *Salmonella*, and *Enterococci* bacteria), although no carbapenemase producers were found in pig and cattle samples in older studies. In addition, resistance to third-generation cephalosporins was found in *E. coli* from wild animals, including seagulls, highlighting the potential spread of AMR in wildlife populations. Based on the scarce data available, the situation regarding resistance levels appears alarming, underscoring the urgency for establishing a robust national monitoring system to determine the baseline, analyse the trends and take informed action to address AMR.

## Monitoring the sales and use of antimicrobials in animals

The ALIMS oversees the registration and quality control of veterinary medicinal products. Reporting the aggregated sales data on antimicrobials to ALIMS is a legal requirement<sup>2</sup>. Marketing authorisation holders are required to provide their sales data from each year by 15 February of the following year (Article 137 of the law). The ALIMS prepares the reports which are then sent to the relevant ministries by 31 March (Article 58 of the Law) and published on the ALIMS website. The processing of sales data on veterinary medicinal products for food-producing and companion animals is reported on the ANIMUSE platform of the World Organization for Animal Health (WOAH), however, data are not stratified by animal category. In addition, the team noted that marketing authorisation holders reported data from 'human medicinal products' which include some of the antimicrobials used in pet companion animals. While this may not be a considerable amount, it highlights the need to collect antimicrobial sales and usage data by species. However, plans to collect data on antimicrobial use per animal species have been initiated, with the development of an IT system underway to support this effort. The personnel at ALIMS are highly skilled and recognise the importance of the data they handle.

Furthermore, only aggregated data on total sales per antimicrobial group are reported, without including the route of administration, which limits the depth of possible analysis. Similarly, the sales data are not adjusted to account for the animal population mass, making it difficult to contextualise the data regarding actual usage rates. There is currently no further data analysis due to a lack of resources, which hinders the ability to derive actionable insights. In addition, it is unclear how the results are communicated to veterinarians and farmers, potentially limiting the usefulness of the data for informing practice and policy.

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

The requirements for veterinary prescriptions in order to obtain antimicrobials and other veterinary medicinal products are aligned with previous EU legislation, and both the Veterinary Directorate and ALIMS are fully aware of the need to transpose current EU legislation on veterinary medicinal products and medicated feed into national law. National legislation prohibiting the use of antimicrobial growth and yield promoters is already in place<sup>3</sup>, and legislation banning the use of antimicrobials reserved for human treatment, as listed in Commission Implementing Regulation (EU) 2022/1255, has been drafted. However, there is still a need to transpose Regulation (EU) 2019/6 in order to prohibit the use of antimicrobials for the purpose of promoting growth and enhancing yield.

Positive practices reported by individual veterinarians and farmers include extensive vaccination, increased biosecurity, the use of alternatives to antibiotics on pig farms and the culling of cows with mastitis caused by *S. aureus*. The poultry sector has taken additional steps towards reducing antibiotic use and AMR awareness-raising activities for farmers, and veterinarians are credited with decreased antibiotic use in broiler flocks. Certification schemes for meat produced from flocks without or with reduced antibiotic treatment have also been implemented.

However, despite these efforts, veterinarians often choose broad-spectrum antibiotics, including third- and fourth-generation cephalosporins, fluoroquinolones, and colistin, based on economic factors or convenience. Veterinarians report pressure from clients to choose antibiotics with shorter withdrawal periods to avoid economic losses or to opt for treatment with broad-spectrum antibiotics instead of conducting AST. The NRL reported that

<sup>2</sup> Law on Medicines and Medical Devices ('Official Gazette RS', No. 30/10, 107/12, 105/17 – other law and 113/17 – other law).

<sup>3</sup> According to the national legislation on feed quality, complete feed should not contain antibiotics and sulfonamides.

AST results often leave little room for narrow-spectrum options, and other factors, such as economic considerations, may prevail. Veterinarians admitted that antibiotics are sometimes used to compensate for poor hygiene conditions on farms, with the example of dry cow therapy used on dairy farms. Old farm infrastructure also affects good husbandry and effective biosecurity. There have been also reports of farmers obtaining antimicrobials illegally without veterinary supervision, either from veterinary pharmacies without a prescription or from abroad.

Implementing activities to encourage the prudent use of antimicrobials and minimise their unnecessary application in animals would encounter challenges in reaching all farms in Serbia, where the farming sector predominantly consists of numerous small-scale backyard operations. However, the existing framework which mandates formal agreements between farmers and veterinarians for animal health oversight, an adequate number of practising veterinarians and the requirement to maintain treatment records, provides a solid foundation. These elements could be used to enhance initiatives promoting responsible antimicrobial use across the animal farming sector.

## Communication activities on antimicrobial resistance and the prudent use of antimicrobials in animals

The Veterinary Medicine Faculty in Belgrade has integrated the study of antimicrobial modes of action and AMR mechanisms into its curriculum as part of various courses, including microbiology and pharmacology. In addition, a new course focused on the One Health approach has recently been added to the curriculum. The faculty also emphasises the development of 'soft skills' to empower future veterinarians in effectively interacting with clients, including resisting pressure to prescribe antimicrobials unnecessarily. In the realm of postgraduate education, CPD requirements are already in place, and the Veterinary Chamber actively promotes further education on AMR. Faculty members and staff from the NRL have delivered various seminars on AMR and antimicrobials. Furthermore, the European Medicines Agency (EMA) leaflet<sup>4</sup> on the European Medicines Agency's Antimicrobial Advice Ad Hoc Expert Group (AMEG) categorisation of antimicrobials has been translated into Serbian to support educational efforts.

However, there are areas for improvement. The approach to AMR education at the Veterinary Medicine Faculty in Belgrade appears to be fragmented. A more integrated approach, taking into account that AMR is not confined to a single discipline but intersects public health, microbiology, pharmacology and environmental science, could give students a holistic understanding of AMR across these fields. There is a need for greater focus on clinical aspects to enhance preparedness, as studies have shown that students often perceive clinical rotations as more effective for learning about antimicrobial use than pre-clinical modules.

The new One Health model, a practical approach to the One Health concept, which emphasises the interdependence of human, animal, and environmental health, is not fully integrated into the curriculum. This integration could foster a more comprehensive understanding of how AMR affects different sectors. Moreover, there is a limited understanding of how AMR is regulated at the EU level. Specific examples of national policies and legislation from the EU Member States, which were particularly successful in addressing the problem of AMR, and in particular, prescribers' reliance on broad-spectrum antibiotics, could serve as models for Serbia.

During the development of the first NAP, the Veterinary Medicine Faculty and other universities offering veterinary education in Serbia were not consulted, despite the NAP including specific actions for improved education on prudent prescribing principles for both veterinary and human medicine students. While many veterinarians reported participating in postgraduate education seminars and training courses, prescription habits remain suboptimal, particularly in the pig and dairy sectors. This suggests that current communication regarding AMR levels and the implications of antimicrobial use in both animal and human health sectors is not entirely effective. Apart from AMR awareness campaigns carried out by the poultry sector, it is unclear if there are other initiatives focusing on farmers or animal owners, and this highlights the need for broader educational efforts.

## Environmental monitoring of antimicrobials and antimicrobial resistance

The team was informed that the Environmental Protection Agency is actively monitoring certain pharmaceutical substances in surface waters as part of its annual programme. This included monitoring of antimicrobial substances on the Watch List, although specific details were not provided. Serbia is participating in the Whole Danube River project<sup>5</sup>, focusing on the faecal pathways of antibiotic resistance along the Danube River. Serbia is starting its alignment with European standards by adhering to the Urban Waste Water Directive and other relevant legislation. However, a significant gap exists in ecological surveillance, as environmental contamination with resistant bacteria and AMR genes is not currently monitored in Serbia. Serbia participates in the Danube River Basin Protection Convention.

<sup>4</sup> [https://www.ema.europa.eu/en/documents/report/infographic-categorisation-antibiotics-use-animals-prudent-and-responsible-use\\_en.pdf](https://www.ema.europa.eu/en/documents/report/infographic-categorisation-antibiotics-use-animals-prudent-and-responsible-use_en.pdf)

<sup>5</sup> <https://www.kl.ac.at/en/research/whole-danube-river-amr>

Serbia has taken a positive step in preventing antimicrobial contamination by not registering plant protection products containing antibiotics<sup>6</sup>. The country complies with EU regulations for active substances in plant protection products, prohibiting antibiotics as active substances. However, there is no data collection system for the volumes of plant protection products and biocides, limiting the assessment and management of potential environmental impact. To address this, Serbia is developing special software to collect data on plant protection products, with plans to commence data collection by 2027.

Regarding waste management and disposal practices, several challenges persist. There is an insufficient number of disposal routes for expired and unused medicines available to the general public, an issue identified in previous NAPs but which has not been addressed due to COVID-19 and other factors. Citizens are encouraged to return expired medicines to pharmacies, but not all pharmacies accept them due to financial constraints related to disposal costs. A United Nations Food and Agriculture Organization (FAO) survey conducted in 2022 revealed that around 25% of farmers dispose of drugs improperly, either in household waste or down the sewage. A small percentage did not specify the methods used. The unsafe disposal of unused and expired medicines remains a significant concern for both veterinary and human healthcare sectors, necessitating joint efforts for effective resolution.

The team was informed that to address these challenges, Serbia has adopted a waste prevention plan which has been approved by the government. This plan focuses on significant changes and reductions in waste management over the next six years, emphasising waste prevention as a critical component. The plan aims to reduce waste generation through various strategies and amendments to existing regulations. Past projects to improve healthcare waste management have included activities related to the collection of pharmaceutical waste from citizens.

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<sup>6</sup> European Parliament. 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. OJ L 327, 22.12.2000, p. 1–73. Available at: <http://data.europa.eu/eli/dir/2000/60/oj>

# Conclusions

## AMR strategies, action plan and coordination, based on a One Health approach

The establishment, in January 2025, of a Coordination Group with representation from all ministries and disciplines relevant for AMR and antimicrobial use was an important first step towards improving national coordination from a One Health perspective. The role of the Coordination Group is to supervise and coordinate actions for the control of AMR by promoting good practice for the rational use of antibiotics, implementing awareness campaigns and providing national information and advice. However, the Coordination Group is yet to meet, and it will need to decide upon priority actions very quickly. The most urgent action is to prepare a new One Health NAP for AMR which is based on a thorough situational analysis, and outlines the objectives, activities, budgets, responsibilities and timelines to address AMR in Serbia in the short to medium term.

## Human health aspects of antimicrobial resistance

The AMR situation in Serbia is of **major concern and demands urgent attention**. The reported percentages of resistance for key bacterial species-antimicrobial agent combinations for Serbia are among the highest in the region, although there are important sources of heterogeneity and only limited data for other Western Balkan countries. There are very high levels of carbapenem resistance in Gram-negative bacteria, including *K. pneumoniae* and *A. baumannii*, and evidence of ongoing transmission of multidrug- and pandrug-resistant lineages in hospitals. This forces clinicians to prescribe antimicrobials which have only recently been approved, with evidence of resistance emerging already. In addition, the first case of *Candida auris* has recently been reported in Serbia. These findings confirm an urgent need for Serbia to take action to ensure continuing patient safety and preserve hospitals' capacity to deliver high-quality care.

Nevertheless, there are many strengths within the healthcare system of Serbia that can form the basis of a reinvigorated response to prevent and control AMR, not least the well-trained, highly knowledgeable and committed workforce encountered by the country visit team. In addition, there is a strong legal framework and appropriate structures for the prevention and control of AMR. All hospitals in Serbia are required by law to establish multi-disciplinary IPC committees with minimum staffing levels. In the hospitals visited, the IPC committees were active in seeking to prevent and control HAIs through the promotion of good clinical practice. Hospitals are required to report all HAIs to the institutes of public health using their portal and when outbreaks are identified, the local institute of public health is required to support the investigation.

Microbiology services were of a good standard and responsive, providing results in a timely manner. The NRL, located in the microbiology department of the Institute of Public Health Vojvodina, collects data on relevant bacterial species-antimicrobial agent combinations of invasive isolates from a network of 24 hospitals. Population coverage of the national AMR surveillance had increased over time (reaching 80% in 2023) and has good representation of different geographical areas and hospital types. The data collected are regularly analysed and reported on an annual basis to the Ministry of Health, the laboratories participating in the network and the CAESAR Network. There is a strong and reliable baseline of surveillance data for AMR which are reported to the appropriate authorities, and disseminated through scientific media, such as publications and congresses. However, there appears to be little or no use of the data to inform public health action at local, regional or national level within Serbia.

There was good awareness of the national clinical practice guidelines for the rational use of antibiotics which are available either in printed form or on-line. However, no audits of the adherence of antibiotic prescribing to these guidelines appear to have been conducted. Furthermore, there has been no major review or revision since the first publication of these guidelines in 2018. All hospitals are expected to have established an AMS committee, although there was some uncertainty regarding the legal framework for these committees and whether they had been established in all hospitals. The hospitals visited had AMS committees in place, whose primary focus was to provide oversight and approval for the prescription of reserve antibiotics. These committees also provided varying amounts of guidance (e.g. on surgical prophylaxis), feedback (by prescriber, ward and department) and continuing professional education to prescribers. Despite the efforts of the AMS committees, the use of reserve antibiotics had steadily increased in recent years in the hospitals visited.

There is a need to develop and implement awareness and behavioural change communication campaigns to reduce antimicrobial use by raising awareness in primary care services (e.g. GPs and community pharmacies) and among the general public. The public information and behavioural change interventions for AMR should be based on a situational analysis to identify AMR communication needs and cultural drivers of antimicrobial consumption, defined goals, targets and objectives, specific target groups, tools and channels, frequency and duration of the campaign, monitoring of misinformation, allocation of resources, and evaluation of impact.

## Veterinary and environmental aspects of antimicrobial resistance

The management of AMR in Serbia's animal health and food safety sectors is multifaceted, with efforts underway to align with EU standards and tackle emerging challenges. The extensive network of veterinary laboratories, including public and private institutions, provides comprehensive diagnostic and monitoring capabilities. However, the gaps in systematic monitoring and data collection for AMR in animals and the environment highlight the need for enhanced surveillance and coordinated efforts. The presence of multidrug-resistant bacteria in both livestock and wildlife underscores the urgency for robust monitoring systems and targeted interventions to mitigate AMR risks.

The Scientific Veterinary Institute of Novi Sad (SVI-NS) serves as the NRL for AMR and collaborates closely with the EURL-AR. Despite the laboratory's advanced capabilities, challenges remain, such as the lack of the NRL's oversight across the laboratory network and limited on-site WGS capacity. Serbia plans to commence EU-harmonised AMR monitoring in 2025, demonstrating a commitment to obtaining a better understanding of the current AMR situation and analysing relevant trends. In recent years, in preparation for the work ahead, the NRL has adopted EU methodologies and participated in proficiency testing. However, the start of the harmonised national monitoring programme has been severely delayed. Limited and fragmented data on AMR and concerns over unregulated antimicrobial use highlight the need for a more comprehensive and coordinated approach to AMR surveillance.

Legal frameworks and the ALIMIS support the monitoring of antimicrobial sales and use in Serbia, overseeing the registration and quality control of veterinary medicinal products. Although aggregated sales data are collected and published, the lack of detailed analysis and adjustment for animal populations limits their usefulness. Enhancing data collection systems, particularly for species-specific antimicrobial use, and improving communication of findings to stakeholders will be vital for informing policy and practice. Serbia has implemented measures to promote the prudent use of antimicrobials, including aligning prescription requirements with EU legislation and drafting laws prohibiting specific antimicrobial uses. Positive practices, such as vaccination and biosecurity measures, were noted, however challenges persist with the overuse of broad-spectrum and the illegal procurement of antibiotics. Educational initiatives and stricter adherence to biosecurity protocols are necessary to reduce reliance on antimicrobials and enhance animal health management practices.

Educational initiatives at the Veterinary Medicine Faculty in Belgrade and through continuing professional development programmes reflect Serbia's commitment to raising awareness concerning AMR. However, the fragmented approach to AMR education and the limited integration of the One Health concept indicate that there is room for improvement. Enhancing the curriculum to provide a more holistic understanding of AMR and improving communication strategies will be essential to fostering a well-informed and proactive veterinary community.

In the environmental sector, the lack of systematic monitoring for AMR in the environment and inadequate disposal routes for expired medicines present significant challenges. Implementing comprehensive waste management strategies, improving data collection for plant protection products, and enhancing public awareness will be crucial for mitigating the environmental impact of antimicrobials.

## Considerations for future action

The options for future action outlined below have been identified by the visiting team of experts from ECDC, EFSA, DG SANTE, Epiconcept and Integrated Quality Laboratory Services to support Serbia's competent authorities and stakeholders in the development and implementation of a One Health AMR Action Plan and immediate and long-term sectoral actions.

### Priority recommendations

- Ensure an active national intersectoral coordinating mechanism for AMR.
- Develop a National Action Plan on AMR with a One Health perspective.
- Establish a dedicated AMR team at the Institute of Public Health to coordinate and oversee the interventions and support activities.
- Develop targeted interventions based on integrated analysis of available data on AMR, AMC and HAIs.
- Improve IPC measures to reduce transmission of MDROs in hospitals.
- Reduce the high antimicrobial usage with structured antimicrobial stewardship activities and behavioural change and communication campaigns.

### Intersectoral collaboration and national action plan on antimicrobial resistance

- Ensure effective functioning of the recently established Coordination Group on AMR.
- Urgently develop a national action plan on AMR in a One Health perspective that is aligned with the WHO Global Action Plan on AMR, contains the five overarching strategic objectives and includes the following elements:
  - situational analysis based on latest available data;
  - agreed objectives;
  - activities to achieve each objective;
  - targets, milestones and deliverables;
  - indicators to monitor progress;
  - allocation of responsibilities;
  - timelines;
  - budgets;
  - monitoring and evaluation framework, including public reporting on progress.

### Human health aspects of antimicrobial resistance

#### Diagnostic laboratory services

- Establish comprehensive screening for carbapenem-resistant gram-negative bacteria as a minimum:
  - develop national guidance with criteria and methods for screening;
  - establish related enhanced laboratory capacity;
  - assure adequate funding to support laboratory services.
- Consolidate existing laboratory capacity for public health purposes:
  - establish capacity for whole genome sequencing and bioinformatics competences for outbreak investigation and control;
  - provide adequate funding for national reference laboratories.

#### Monitoring of AMR

Strengthen national AMR surveillance system including:

- Ensure appropriate use of blood and other cultures before initiation of antimicrobial treatment through diagnostic stewardship activities.
- Establish national AMR surveillance for:
  - samples other than blood and CSF (e.g. urine);
  - community settings.
- Regularly provide stratified results to stakeholders and data providers.
- Use of AMR data to update national treatment guidelines.

#### Monitoring of AMC

- Expand electronic prescription system to all medicines, including non-reimbursed.
- Analyse and present consumption data based on the electronic prescription system (in the community and hospital settings) by indication, healthcare centre, departments and provider.
- Disseminate the analysis reports to increase awareness on antimicrobial consumption among healthcare providers and hospital prescribers.

## AMS and treatment guidelines

- Introduce legislation for AMS committees with allocation of dedicated resources.
- Update the national antibiotic treatment guidelines from 2018 based on the latest available evidence and national AMR data.
- Promote adherence to treatment guidelines by all prescribers.
- Provide feedback reports on antimicrobial use to prescribers with trends and benchmarking.
- Develop protocols for surgical prophylaxis and hospital antibiotic treatment tailored to the local epidemiology.

## Infection prevention and control (IPC)

- Use existing HAI data for action and plan interventions accordingly.
- Promote and monitor hand hygiene, especially the use of alcohol-based hand rub.
- Reduce use of gloves when not indicated.
- Establish screening for carbapenem-resistant gram-negative bacteria, at least in high-risk departments.
- Ensure that targeted contact precautions for identified carriers of carbapenem-resistant gram-negative bacteria and appropriate control measures are promptly implemented to limit further spread.

## AMR and IPC education

- Develop Continuing Professional Development (CPD) courses focusing on the latest antimicrobial treatment guidelines.
- Establish an accreditation programme for nurses to attain a formal IPC certification, recognised by professional associations. The programme should be designed to validate their expertise in IPC practices and ensure consistent standards of IPC within healthcare facilities.

## Public information and behavioural change interventions for AMR

- Develop and implement an awareness and behavioural change communication plan to reduce the high antimicrobial use.
- Develop and implement awareness and behavioural change interventions for AMR that should:
  - be based on situation analysis to identify AMR communication needs and identification of cultural drivers of antimicrobial consumption;
  - have clear goals, targets, objectives and target groups;
  - have allocated sustainable budget and human resources at the national level;
  - be developed and conducted in a One Health perspective and include mandated leads in the human health sector;
  - be implemented at various levels (national, regional, local, facility levels);
  - enable evaluation and measurement of the impact of interventions;
  - target different groups of healthcare professionals (e.g. primary care, hospital professionals), and the general public.
- Distribute available materials (e.g. translated ECDC awareness-raising materials in Serbian) with key messages in primary care centres and pharmacies for the general public (list of materials are available in Annex 2).

## Animal health and food safety aspects of antimicrobial resistance

### Diagnostic and reference laboratory services

- Expand the mandate of the NRL to oversee other veterinary laboratories to ensure standardised practices:
  - centralise confirmatory testing for complex or rare cases of AMR;
  - develop national external quality assessment schemes, to ensure the accuracy and reliability of AMR testing across the country;
  - serve as a reference point for the identification and characterisation of new or emerging resistance mechanisms.
- Perform detailed planning on the number of samples and isolates expected per month/year and ensure that there is adequate qualified human resource capacity to achieve the objectives of the national monitoring programme.

### Monitoring of AMR in animal health and the food sector

- Implement the scheduled national monitoring programme for AMR in 2025, ensuring it encompasses pigs and cattle (unless using the derogation due to low production) and meat derived from them.
- Advocate for increased central government funding and support to address financial constraints and political uncertainty.
- Establish an IT system to collect and manage AMR data at the national level, complementing the planned IT system for antimicrobial use.
- In view of future data communication to EFSA, the database should comply with EU data standards and formats.

## Monitoring of sales and use of antimicrobials in animals

- As a first step, report the existing data in a more granular form according to the administration route, followed by reporting of historical data in a more granular form to facilitate the analysis of existing trends.
- Adjust sales data based on the animal population mass, and report changes in the animal population per category. This adjustment should also apply to the historical data.
- Investigate the opportunities for collaboration with the animal industry, veterinary institutions, and veterinary organisations to analyse changes in sales data before the usage data becomes available.
- Examine how the data can be utilised for the communication and training of veterinarians and farmers regarding consumption patterns of antimicrobials in farm animals.
- In the long term, proceed to joint reporting of the results from both the monitoring of antimicrobial consumption and AMR surveillance (when established).

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

- Develop measures to promote a reduction in the use of antimicrobials, facilitating the phasing out of systemic antimicrobials crucial for human health (EMA's AMEG category Restrict).
- Investigate methods to encourage the systematic use of diagnostic tests and antibiograms.
- Examine how to strengthen the role of veterinarians, for instance, through legislation governing the use of antimicrobials, ensuring that their choices are not influenced by factors such as short withdrawal periods.
- In the longer term, consider identifying and initiating surveillance of AMR in veterinary priority pathogens across all major food-producing species to enhance integrated surveillance.
- Explore how to use the findings from AMR research and, in the long run, monitoring, to raise awareness and inform treatment guidelines).

## Education and communication

- Adopt a multidisciplinary, integrated approach to teaching AMR in veterinary education that can significantly enhance students' understanding and preparedness to control AMR.
- Integrate knowledge from various disciplines and incorporate practical experiences, to ensure that veterinary programmes can adequately equip graduates to effectively address AMR in a One Health context.
- Foster collaborative educational activities with students from other biomedical and environmental sciences faculties.
- Ensure that the principles of prudent antimicrobial use are included in the undergraduate clinical training.
- Consider how to improve current AMR training for veterinarians; in the longer term, consider making relevant training a mandatory component of CPD requirements.
- Reflect on how to communicate on AMR to other stakeholders, especially farmers and animal keepers, to enhance understanding of the situation in Serbia, its One Health implications, and their role in addressing it.

## Environmental aspects of antimicrobial resistance

- Urgently, establish safe disposal routes for expired and unused medicines.
- Once established, ensure that the relevant stakeholders and the general public are aware of the importance of safe disposal of antimicrobials.
- Consider further potential monitoring of antimicrobials and resistant bacteria/ARG in the environment (including food production) to address the knowledge gaps in environmental contamination.
- Consider how to collect data for the volumes of plant protection products and biocides.
- Continue harmonising the national environmental legislation with the EU environmental legislation (and, in the longer term, take gradual steps to implement it – e.g. monitoring of AMR/ARG, advanced treatment methods for wastewater treatment plants).

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## Annex 1. Agenda of the country visit

DAY 1: Monday 24 February 2025		
08:30–09:15 (45 min) + group photo at the end of the session	<p><b>Opening meeting with national authorities and stakeholders</b> All teams</p> <ul style="list-style-type: none"> <li>- Ministry of Health</li> <li>- Ministry of Agriculture, Forestry and Water Management</li> <li>- Director of the Veterinary Directorate</li> <li>- Ministry of Environment</li> <li>- Director of the Institute of Public Health of Serbia</li> <li>- Agency for Medicines and Medical Devices of Serbia (ALIMS)</li> <li>- World Health Organization Regional Office for Europe.</li> </ul> <p>With participation of all members of the Intersectoral Working Group on Antimicrobial Resistance (IWGAMR)</p> <p>Presentation on objectives of the visit, expected outputs and outcome, One Health concept (ECDC and DG-SANTE)</p>	<p><u>Location:</u> <b>Institute of Public Health 'Dr Milan Jovanovic Batut', Dr Subotica str. 5, Belgrade</b> <b>Plenary meeting hall</b></p>
09:15–12:45 (3.5 h)	<p><b>Meeting with the Intersectoral Working Group on Antimicrobial Resistance (IWGAMR) (ECDC, EFSA and DG SANTE Team)</b></p> <p><b>Governance, surveillance and One Health aspect of AMR</b></p> <p><b>Objective:</b> gather information on the current situation of AMR governance and AMR surveillance strategies in Serbia</p> <p><b>Presentations: (10 minutes each)</b></p> <ol style="list-style-type: none"> <li>1. National AMR strategy and its implementation in Serbia: current policy and legislation in Serbia</li> <li>2. Monitoring of antimicrobial use and consumption in human population in Serbia</li> <li>3. Monitoring of sales of antimicrobials in human and animal health in Serbia</li> <li>4. Monitoring AMR in human health in Serbia</li> <li>5. Monitoring AMR in animals and foods - planned activities and laboratory capacity in Serbia</li> <li>6. Laboratory capacity in human health</li> <li>7. Antibiotic awareness activities.</li> </ol> <p><b>Q&amp;A session/Discussions on: (Approx. 1h)</b></p> <ul style="list-style-type: none"> <li>- Inter-sectoral coordination mechanism (indicators in Section 1.1 of the ECDC Assessment Tool)</li> <li>- National Action Plan (indicators in Section 1.2)</li> <li>- Organised multidisciplinary collaboration at local level (indicators in Section 2)</li> <li>- Monitoring of AMR (indicators in Section 4) and antimicrobial consumption (indicators in Section 5)</li> <li>- Clinical diagnostic and reference laboratory services (indicators in Section 3)</li> <li>- Public information and behavioural change interventions related to AMR (indicators in Section 9).</li> </ul> <p><b>Moderator: ECDC</b></p>	<p><u>Location:</u> same as above</p>
11:00–11:15 Coffee break		
12:45–13:45	Lunch break	
13:45–14:45 (1 h)	<p><b>Meeting with representatives of the Ministry of Health, Ministry of Environment, Ministry of Agriculture Forestry and Water Management, Veterinary Directorate on Environmental aspects of AMR</b></p> <p><b>Presentation (10 min):</b> The environmental aspect of AMR and surveillance of AMR in the environment (main gaps identified and plans)</p> <p><b>Discussion on:</b></p> <ul style="list-style-type: none"> <li>- Environmental surveillance of AMR and residues of antimicrobials</li> </ul>	<p><u>Location:</u> same as above</p>

	<ul style="list-style-type: none"> <li>- EU harmonised monitoring of Watch list substances under the Water Framework Directive<sup>7</sup></li> <li>- Role of environment in the spread of AMR throughout the food chain and possible risk mitigations measures</li> <li>- Policies for disposal of unused and expired medicines</li> </ul> <p><b>Moderator: EFSA and DG-SANTE</b></p>	
<b>Separate parallel meetings</b>		
14:45–16:15 (1.5 h)	<b>ECDC team</b>	<b>DG SANTE and EFSA team</b>
Same location, different rooms	<p><b>AMR in the human health sector – Antimicrobial stewardship and IPC Presentations (10 min each):</b></p> <ul style="list-style-type: none"> <li>- Antimicrobial stewardship and infection prevention and control (IPC) in Serbia</li> <li>- How do we prepare for One Health: Competency development through curricula of future physicians and veterinarians</li> <li>- Campaign for the rational use of antibiotics – activities implemented and results achieved</li> </ul> <p><b>Discussions on:</b></p> <ul style="list-style-type: none"> <li>- Antimicrobial stewardship and treatment guidelines (indicator in Section 6),</li> <li>- IPC (indicator in Section 7)</li> <li>- AMR and IPC education (indicators in Section 8)</li> <li>- Public information and behavioural change interventions related to AMR (indicators in Section 9)</li> </ul> <p><b>Moderator: ECDC</b></p>	<p><b>AMR in the Animal and food production</b> Representatives from VD</p> <p><b>Presentations (10min each):</b></p> <ul style="list-style-type: none"> <li>- Overview of the farming sector structure</li> <li>- Veterinary model for veterinary care for food-producing animals and companion animals, including sales mechanism –</li> <li>- ‘Combating AMR in food and agriculture with a One Health approach’ –FAO.</li> </ul> <p><b>Discussions on:</b></p> <ul style="list-style-type: none"> <li>- initiatives to promote prudent use</li> <li>- organisation of official controls on the use of veterinary medicinal products</li> <li>- the sales mechanism for antimicrobials in the farming sector</li> <li>- model for veterinary care for food-producing animals and companion animals.</li> </ul> <p><b>Moderator: DG-SANTE</b></p>
16:15 – 16:30	Coffee break	
16:30–18:00 (1.5hrs)	<p><b>Meeting with professional association representatives and heads of chambers: (ECDC team only)</b></p> <p><b>Presentation (Participant introduction and brief 3 min oral presentation of their activity related to AMR):</b></p> <p>Serbian Medical Chamber Serbian Pharmaceutical Chamber Chamber of Nurses and Health Technicians of Serbia Serbian Society for Clinical Microbiology Serbian Medical Society section for general practice Pharmaceutical Association of Serbia Serbian Medical Society section for epidemiology Serbian Medical Society social medicine section</p> <p><b>Discussion</b> on educational programmes and awareness campaigns, treatment guidelines, strategies and initiatives to reduce antimicrobial consumption, antibiotic stewardship.</p> <p><b>Moderator: ECDC</b></p>	<p><b>AMR in the animal and food production</b></p> <p>Continuation of discussions.</p>

<sup>7</sup> 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, 22.12.2000, p.1.

DAY 2: Tuesday 25 February 2025					
Human Health Team (ECDC)			Animal Health and Food Safety team (EFSA & DG SANTE)		
08:30–09:30 (1 h)	<p><b>Institute of Microbiology and Parasitology, Faculty of Medicine, University of Belgrade</b></p> <ul style="list-style-type: none"> <li>- Introductory meeting <b>(15 min)</b></li> <li>- Visit to the microbiology laboratory <b>(45 min)</b></li> </ul> <p><b>Discussion</b> with laboratory manager on AMR reporting, activities performed, type of antibiotics tested, quality assurance.</p> <p><b>Moderator: ECDC</b></p>	<p><u>Location:</u> <b>IMP Belgrade,</b> Currently in the Pulmonology Clinic building.</p>	08:30–10:30 (2 h)	<p><b>Meeting with the representatives of Veterinary Chamber and Chamber of Commerce of Serbia:</b></p> <p><b>Discussion</b> with veterinary representatives of Chamber of Commerce of Serbia, professional organisation(s),</p> <p><b>Chamber of Commerce: Representative of sectorial branch</b> Short PPT (10min) activities of Chamber of commerce</p> <p><b>Short oral presentation (3 min)</b> by the associations on the farming sectors they cover, the memberships levels and activities on AMR undertaken by the associations representative of sectorial branch</p> <p><b>Moderator: DG SANTE</b></p>	<p><u>Location:</u> <b>Chamber of Commerce of Serbia</b></p>
09:30–11:30 (2 h)	<p><b>University Clinical Centre of Serbia</b></p> <p><b>Introductory meeting</b> with hospital managers and healthcare professionals from different wards/departments (surgery, adult ICU, paediatrics/neonatology, infectious diseases, IPC, and pharmacy).</p> <p><b>Visit to the respective departments</b> of the hospital:</p> <ol style="list-style-type: none"> <li>1. Surgical ward</li> <li>2. ICU</li> <li>3. Hospital pharmacy</li> <li>4. Microbiology laboratory.</li> </ol> <p><b>Discussion during visit</b> on prudent use/stewardship of antibiotics, AMR prevention and control measures, healthcare-associated infection/IPC guidelines, related needs with hospital managers and healthcare professionals from different wards/departments (surgery, ICU, paediatrics/neonatology, infectious diseases, IPC, microbiology laboratory and pharmacy)</p> <p><b>Moderator: ECDC</b></p>	<p><u>Location:</u> <b>University Clinical Centre of Serbia, Belgrade</b></p>	10:30–12:00 (1.5 h)	<p><b>Meeting with Veterinary Chamber</b></p> <p><b>Veterinary Chamber of Serbia</b> Representatives of Veterinary Chamber</p> <p><b>Presentation (10 min)</b> Overview of the Finnish experience in combating AMR – the veterinary angle.</p> <p>AMR awareness and promoting reduced and prudent use of antimicrobials activities carried out by the Veterinary Chamber</p> <p>Short presentation of AMR awareness and activities promoting reduced and prudent use of antimicrobials carried out by the relevant sectors of the Chamber of Commerce</p> <p><b>Discussion:</b> on above topics with the representative of Veterinary Chamber and Chamber of Commerce members, veterinarians working in the veterinary pharmacy/wholesalers and practicing veterinarians</p> <p><b>Moderator: DG SANTE</b></p>	<p><u>Location:</u> <b>Chamber of Commerce of Serbia,</b> Resavska 15, Belgrade, Room 3 AB.</p>

12:00–13:00 Lunch break at Institute of Public Health					
13:30–15:30 (2 h)	<p><b>Agency for Medicines and Medical Devices of Serbia (ALIMS)</b></p> <p><b>Discussions</b> on policy and regulation on the prudent use of antibiotics, AMC monitoring in the human health sector<sup>8</sup> and marketing-related issues (indicators in Section 10), and current alignment plans with EU acquis and next steps.</p> <p><b>Moderator: ECDC</b></p>	<p><u>Location:</u> <b>ALIMS</b></p>	13:30–15:30 (2 h)	<p><b>Agency for Medicines and Medical Devices of Serbia (ALIMS)</b></p> <p><b>Presentation: (10 min)</b> Reporting of antimicrobial sales and use in the EU and the Finnish experience in combatting the AMR and collecting antimicrobial sales and usage data.</p> <p><b>Discussions</b> on policy and regulation on the prudent use of antibiotics and antimicrobial sales and usage monitoring in the animal sector (sales at present, use to follow)<sup>9</sup>, ensuring that antimicrobials reserved for treatment of humans (Regulation (EU) 2022/12550 are not used in animals, marketing-related issues (indicators in section 10), current alignment plans with EU acquis and next steps; disposal of expired and unused medicines.</p> <p><b>Moderator: DG SANTE</b></p>	<p><u>Location:</u> <b>ALIMS_</b> Vojvode Stepe 458, Belgrade</p>
16:00 – 18:00 (2 h)	<p><b>Institute of Public Health in Serbia</b></p> <ul style="list-style-type: none"> <li>- Short meeting (<b>15 min</b>) with the Institute of Public Health Serbia (presentation of the OH country visit)</li> <li>- Visit to the microbiology lab (<b>30 min</b>)</li> </ul> <p><b>Discussion (45min)</b> 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.</p> <p><b>Moderator: ECDC</b></p>	<p><u>Location:</u> <b>Institute of Public Health Serbia</b></p>			

<sup>8</sup> This agency does not cover antibiotics for use in the veterinary sector, or medicated feed.

<sup>9</sup> This agency does not cover antibiotics for use in the veterinary sector, or medicated feed.

## DAY 3: Wednesday 26 February 2025

Human Health Team (ECDC)			Animal Health and Food Safety team (EFSA & DG SANTE)		
09:00–10:00 (1 h)	<b>Travel from Belgrade to Novi Sad</b>	<b>Meeting point: Institute of Public Health Serbia, Dr Subotica 5, Belgrade</b>	09:00–10:00 (1 h)	<b>Travel from Belgrade to Novi Sad</b>	<b>Meeting point: Institute of Public Health Serbia, Dr Subotica 5, Belgrade</b>
10:00–12:00 (2 h)	<p><b>Visit to the regional hospital UCC Vojvodina</b></p> <p><b>Introductory meeting</b> with hospital managers and healthcare professionals from different wards/departments (surgery, adult ICU, paediatrics/neonatology, infectious diseases, IPC, and pharmacy).</p> <p><b>Visit to the respective departments</b> of the hospital.</p> <p><b>Discussion during visit</b> on prudent use/stewardships of antibiotics, 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, IPC, microbiology laboratory and pharmacy). <b>Moderator: ECDC</b></p>	<u>Location:</u> Novi Sad	10:00–13:00 (3 h) with one coffee break	<p><b>Visit to the NRL for AMR in animals and Scientific Veterinary Institute Novi Sad</b></p> <ul style="list-style-type: none"> <li>- Introductory meeting <b>(15 min)</b> at the director's office of the Scientific Veterinary Institute (presentation of the OH country visit)</li> <li>- Visit to the microbiology laboratory <b>(45 min)</b> (vet laboratory and food safety).</li> </ul> <p><b>Presentation on:</b></p> <ul style="list-style-type: none"> <li>- Monitoring of AMR in food and food-producing animals, planned activities</li> <li>- AMR in clinical isolates from animals.</li> </ul> <p><b>Presentation (10 min) (EFSA):</b> EU harmonised AMR monitoring in zoonotic and commensal bacteria in certain food producing-animals and food</p> <p><b>Discussions (50 min)</b> on AMR surveillance, prevention and control and research initiatives (veterinary and environmental sectors) and undergraduate education on AMR within veterinary medicine. <b>Moderator: IQLS and EFSA</b></p>	<u>Location:</u> NIV Novi Sad, Rumenački put 20, Novi Sad

12:00–13:00	Lunch break near <b>Institute of Public Health Vojvodina</b>		13:00–14:00	Lunch break somewhere near	
13:00–15:00 (2 h)	<b>Visit of the public health laboratory, IPH of Vojvodina</b> <b>Presentation:</b> Surveillance data collected by IPH <b>Discussion</b> on AMR reporting, activities performed, type of antibiotic tested, quality assurance. <b>Moderator: ECDC</b>	<u>Location:</u> <b>Institute of Public Health Vojvodina, Novi Sad</b>	14:00–17:00 (3 h)	<b>Meeting at the regional centre of Veterinary inspectors</b> Representatives from veterinary inspection.  <b>Discussion</b> in the office of the regional veterinary services with local farmers, practising veterinarians and veterinary inspectors on actions taken locally and/or by the stakeholders to reduce the use of antimicrobials / use antimicrobials more prudently in food-production and companion animals, organisation of official control, organization of veterinary station, treatment of animals, record keeping. <b>Moderator: DG SANTE</b>	<u>Location: NIV Novi Sad,</u> Rumenački put 20, Novi Sad_
15:30–16:30 (1 h)	<b>Visit to a community pharmacy</b>  <b>Discussion on</b> prudent use/stewardship of antibiotics, AM sales mechanism, pharmaceutical waste collection schemes <b>Moderator: ECDC</b>	<u>Location:</u> <b>Pharmacy 'Janković', Kej žrtava racije 8, Novi Sad</b>	17:00– 18:00 (1h)	<b>Travel from Novi Sad to Belgrade</b>	
16:30–17:30 (1 h)	<b>Travel from Novi Sad to Belgrade</b>				

DAY 4: Thursday 27 February 2025					
Human Health Team (ECDC)			Animal Health and Food Safety team (EFSA & DG SANTE)		
09:00–10:00	<b>Debriefing meeting at the Ministry of Health</b> <b>Ministry of Health, "Palace of Serbia", Blvd Mihajla Pupina 2, Belgrade, 4<sup>th</sup> floor, Room 407</b>				
09:00–11:00	<b>Visit to the General hospital VIZIM (private hospital) Belgrade</b>  <b>Introductory meeting</b> with hospital managers and healthcare professionals from different wards/departments (surgery, adult ICU, infectious diseases, IPC, microbiology laboratory and pharmacy).  <b>Visit to the respective departments</b> of the hospital  <b>Discussion during visit</b> about prudent use/antimicrobial 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, IPC, microbiology laboratory and pharmacy). <b>Moderator: ECDC</b>	<b>Location:</b> <b>General Hospital 'Vizim', Zdravka Čelara 14a Belgrade</b>	11:00–13:00 (2 h)	<b>Faculty of Veterinary medicine Belgrade</b>  Presentation ( <b>10 min</b> ) Education on AMR in curriculum of health professional and antibiotic awareness activities.  <b>Discussion:</b> undergraduate education on AMR from a One Health perspective, postgraduate education on AMR for practising veterinarians.  <b>Moderator: DG SANTE</b>	<b>Location: Faculty of Veterinary Medicine, Bulevar oslobođenja 18, Belgrade, I floor</b>
			11:00–13:00	<b>Clarification meeting with Veterinary Directorate, if necessary.</b>	<b>Location:</b> Veterinary Directorate
11:30–12:30 (1 h)	<b>Clinical Centre Zvezdara, Department for geriatrics and palliative care</b> <b>Introductory meeting</b> with hospital managers and healthcare professionals <b>Discussion during visit</b> about prudent use/antimicrobial stewardship, AMR prevention and control measures, healthcare associated infection / IPC guidelines, and related needs with hospital managers and healthcare professionals <b>Moderator: ECDC</b>	<b>Location:</b> <b>CC Zvezdara, Preševska 31, Belgrade</b>			
13:00–13:30	Lunch Break (near PHC "Savski venac")		13:00–14:00	Lunch Break	
13:30–14:30 (1 h)	<b>Meeting with GPs at a primary healthcare centre, (Belgrade) – Primary Health Centre 'Savski Venac'</b>  <b>Discussion with</b> General practitioners and Paediatricians about prudent use/antimicrobial stewardship, AMR prevention and control measures and related needs. <b>Moderator: ECDC</b>	<b>Location:</b> PHC Savski venac, Pasterova 2, Belgrade	14:00–16:00	Report preparation	
14:30 onwards	Report preparation			Report preparation	

<b>DAY 5: Friday 28 February 2024</b>		
08:30–12:00	<p><b>Closing meeting with the national authorities:</b></p> <ul style="list-style-type: none"> <li>- Ministry of Health/Ministry of Agriculture, Natural Resources and Environment and relevant agencies and stakeholders</li> <li>- Technical experts from national institutions, including the members of <b>IWGAMR</b></li> </ul>	<p>Location:</p> <p><b>Ministry of Health, "Palace of Serbia" Govt building, Blvd Mihajla Pupina 2, Belgrade</b></p> <ul style="list-style-type: none"> <li>• One coffee break</li> <li>• Fourth floor, meeting room 407.</li> </ul>
12:00	<b>Departure of the experts</b>	

## Annex 2. List of ECDC antibiotic awareness materials for potential use in Serbia

The following ECDC EAAD materials could be translated into Serbian language for the use during national campaigns on prudent antimicrobial use in Serbia (<https://antibiotic.ecdc.europa.eu/en/plan-campaign>)

- [Communication toolkit to promote prudent antibiotic use aimed at primary care prescribers;](#)
- [Communication toolkit for professionals in hospitals and other healthcare settings;](#)
- [Communication toolkit to promote prudent antibiotic use with focus on self-medication with antibiotics;](#)
- [Communication toolkit to promote prudent antibiotic use aimed at general public;](#)
- [Toolkit for engaging in social media activities promoting prudent antibiotic use.](#)

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