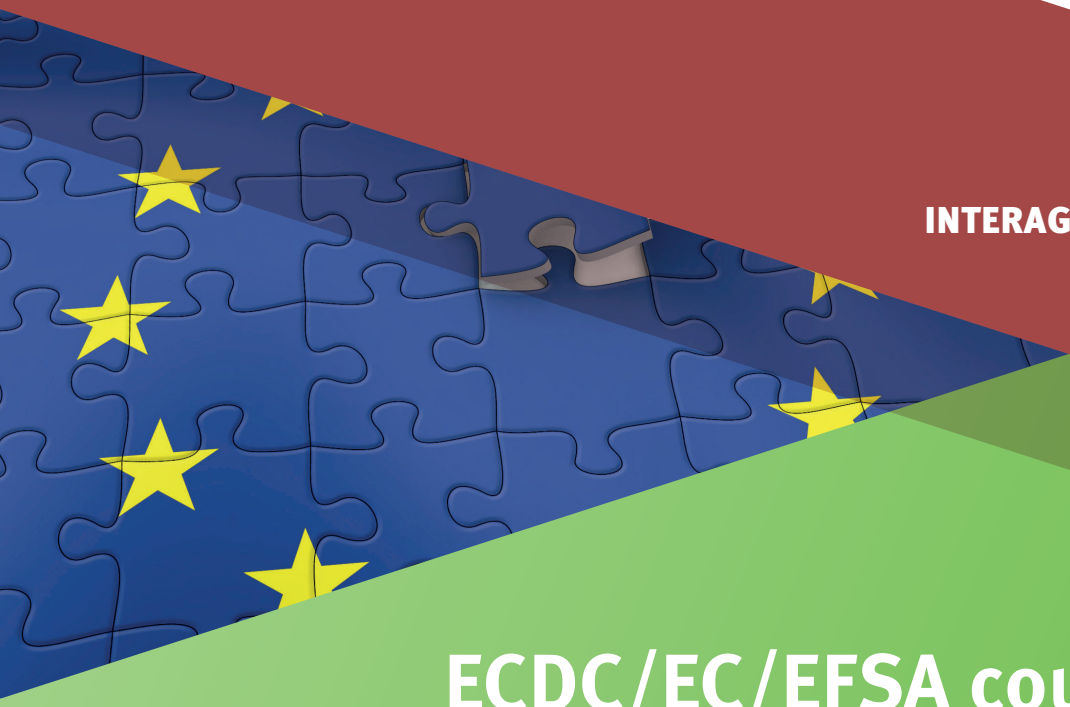

INTERAGENCY ASSESSMENT

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

10–14 June 2024

INTERAGENCY ASSESSMENT

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

10–14 June 2024

The preparation of the country visits to the Western Balkans is commissioned by ECDC from the consortium of Epiconcept and Integrated Quality Laboratory Services, with financial support from the European Union under CN/39/409-781 as part of contract ECDC/2022/006 'Country support to advance One Health responses against antimicrobial resistance in Western Balkans'.

This report was commissioned by ECDC, coordinated by Agnė Bajorinienė (ECDC) and produced by the consortium representatives Cyril Buhler (Integrated Quality Laboratory Services) and Alexis Sentís (Epiconcept). The European Commission's Directorate-General for Health and Food Safety (DG SANTE), European Food Safety Authority (EFSA), and national experts from Spain also contributed to its content.

Contributing authors
In alphabetical order: Agnė Bajorinienė (ECDC), Cyril Buhler (IQLS), José Miguel Cisneros Herreros (Hospital Universitario Virgen del Rocío/IBiS, Sevilla), Anke Kohlenberg (ECDC), Anna Machowska (ECDC), Dominique Monnet (ECDC), Aikaterini Mougkou (ECDC), Anthony Nardone (Epiconcept), Alexis Sentís (Epiconcept), representatives from the Health and Food Safety Directorate-General for Health and Food Safety (DG SANTE) of the European Commission, the European Food Safety Authority (EFSA), and the Spanish Agency for Medicines and Medical Devices.

This report was sent for consultation to the Institute of Public Health and the Administration of Food Safety, Veterinary and Phytosanitary Affairs (AFSVPA) of Montenegro.

Acknowledgements
ECDC, DG SANTE, EFSA and the consortium team would like to thank Milena Lopičić (Institute of Public Health of Montenegro), Jelena Vračar Filipović (AFSVPA), and Mirjana Lekić (EFSA focal point from Montenegro) for arranging the visit.

Suggested citation: European Centre for Disease Prevention and Control. ECDC/EC/EFSA country visit to Montenegro to advance One Health responses against antimicrobial resistance. 10–14 June 2024. Stockholm: ECDC; 2025.

Stockholm, April 2025

ISBN 978-92-9498-792-1
doi: 10.2900/7420309
Catalogue number TQ-01-25-022-EN-N

Contents

Abbreviations

AFSVPA	Administration for Food Safety, Veterinary and Phytosanitary Affairs Montenegro
AMC	Antimicrobial consumption
AMEG	European Medicines Agency's Antimicrobial Advice Ad Hoc Expert Group
AMR	Antimicrobial resistance
AMU	Antimicrobial use
ASP	Antimicrobial stewardship programme
AST	Antimicrobial susceptibility testing
ASU	Antimicrobial sales and use
ATC	Anatomical therapeutic class
ATC/DDD	Anatomical therapeutic class/defined daily dose
AWaRe	Access, Watch, Reserve classification (WHO)
CAESAR	Central Asian and European Surveillance of Antimicrobial Resistance network
CInMED	Institute for Medicines and Medical Devices of Montenegro
CPE	Carbapenemase-producing Enterobacterales
CSF	Cerebrospinal fluid
DDD	Defined daily dose
DG NEAR	Directorate-General for Neighbourhood and Enlargement Negotiations (of the European Commission)
DG SANTE	Directorate-General for Heath and Food Safety (of the European Commission)
EAAD	European Antibiotic Awareness Day
ECDC	European Centre for Disease Prevention and Control
EEA	European Economic Area
EFSA	European Food Safety Authority
EMA	European Medicines Agency
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	Global action plan on AMR (WHO)
GLASS	Global Antimicrobial Resistance and Use Surveillance System
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
MDRO	Multidrug-resistant organism
NAP	National action plan
NIKRA	National Interdisciplinary Commission for the Control of Antibiotic Resistance
NRL	National reference laboratory
PCU	Population correction unit
PCR	Polymerase chain reaction
PPS	Point prevalence survey
SARS-CoV-2	Severe acute respiratory syndrome coronavirus 2
SVL	Specialist veterinary laboratory
VIS	Veterinary information system
WAAW	World AMR Awareness Week
WGS	Whole genome sequencing
WHO	World Health Organization
WOAH	World Organisation for Animal Health

Summary

From 10 to 14 June 2024, 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 Montenegro which was supported by a consortium composed of Epiconcept and Integrated Quality Laboratory Services (IQLS) and was 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, to advance a One Health approach to antimicrobial resistance (AMR) in the Western Balkans, funded by the Directorate-General for Neighbourhood and Enlargement Negotiations (DG NEAR) of the European Commission.

The report concludes that continued efforts are required at national level, starting with the planning and implementation of education and communication campaigns on the prudent use of antibiotics to reduce excessive use; introduction of targeted interventions based on surveillance data; provision of access to good-quality, timely microbiology services, and the development of guidelines and protocols for microbiological diagnostics, antimicrobial treatment and infection prevention and control (IPC). In addition, it would be useful to strengthen the role of the National Interdisciplinary Commission for the Control of Antibiotic Resistance (NIKRA) as the national body in charge of supervising AMR activities in a One Health perspective. NIKRA's current mandate and terms of reference require revision to include specific roles, responsibilities, dedicated time and budget. Furthermore, it would be useful to strengthen intersectoral and interdisciplinary collaboration and the visibility of NIKRA. Evaluation of the current National Action Plan (NAP) 2022–2024 could guide the development of the next NAP, the implementation of which will also require continuous monitoring.

Montenegro has a well-equipped national reference laboratory (NRL) for the human health sector but faces significant challenges with clinical microbiology laboratories, including shortage of staff, equipment and supplies. Clinical microbiology laboratory services are under-utilised and timely reporting of results remains challenging. AMR data are only collected for invasive isolates from blood and cerebrospinal fluid (CSF). Montenegro participates in the Central Asian and European Surveillance of Antimicrobial Resistance network (CAESAR). However, there is a need for comprehensive national AMR surveillance beyond invasive isolates and at the local level. This would help to better inform the selection of antimicrobial treatments within healthcare facilities and across community settings, enabling data-driven decision-making and targeted interventions. Antimicrobial consumption (AMC) is monitored through antibiotic sales data. Incorporation of analysis using the Access, Watch, Reserve (AWaRe) classification could strengthen the understanding of antibiotic usage patterns in the country. Analysing reimbursement data by indication and disseminating findings to healthcare providers could improve awareness of antimicrobial consumption trends.

Montenegro has well-trained human resources for antimicrobial stewardship (AMS) in hospitals supported by legal mandates for AMS teams. However, further implementation work is required, such as the development of comprehensive AMS programmes with clear objectives, indicators, interventions, and evaluation mechanisms. There is also a need for robust guidelines on microbiological diagnostics, antimicrobial treatment and IPC, as well as regular monitoring of compliance with best practices. While IPC committees exist in hospitals, IPC practices are suboptimal, and there is a lack of regular monitoring of hand hygiene compliance. Enhanced training of healthcare workers in IPC practices, including hand hygiene, glove use, and urinary catheter maintenance, is essential. Although the reporting of healthcare-associated infections (HAIs) is mandatory, data analysis and feedback to clinicians is insufficient, limiting effective interventions.

In the animal health and food safety sectors, Montenegro has the laboratory capacity to support AMR monitoring with accredited procedures in bacteriology and competent staff at the Specialist Veterinary Laboratory (SVL). The Laboratory Information and Management System (LIMS) is adequately linked with the Veterinary Information System of the Administration for Food Safety, Veterinary and Phytosanitary Affairs (AFSVPA), facilitating data sharing. The country has just started its engagement in EU-harmonised monitoring of AMR in zoonotic and commensal bacteria in certain animals and foods. However, the SVL has not been designated as the national reference laboratory for AMR, and the high cost of proficiency testing has hindered participation in essential EU proficiency programmes. The absence of early planning for AMR monitoring activities at the national level had also hindered effective planning for the provision of reagents and consumables in the laboratory.

The transposition of EU legislation on sales and use of antimicrobials in animals into national legislation has already begun. However, full incorporation of the requirements of Regulation (EU) 2019/6 into the national legal framework still have to be completed. There is also a need to further develop legal mandates, data collection frameworks, and database interoperability between the AFSVPA and the Institute for Medicines and Medical Devices of Montenegro (CInMED) for optimal analysis and use of the data collected. Positive practices have been noted among veterinarians and farmers, however there are still challenges, such as inadequate human resources, incomplete incorporation of EU legislation, and prevalent use in veterinary settings of broad-spectrum antimicrobials that are critically important for human health.

The environmental sector faces significant challenges, particularly with the disposal of expired and unused medicines, a gap recognised in the NAP. Although Montenegro is participating in the Global Sewage Project, the lack of representation of the environmental sector in NIKRA and the absence of a National Waste Management Plan are hindering comprehensive oversight.

1 Introduction

Antimicrobial resistance (AMR) not only represents a serious threat to people's health, but also to the global economy. Recent estimates of the AMR burden in the World Health Organization (WHO) European Region revealed that, in the year 2019 alone, nearly 700 000 deaths were associated with or attributed to bacterial AMR [2]. An ECDC study estimated that between 2016 and 2020, 70% of the bacterial infections with antibiotic resistance in the European Union and European Economic Area (EU/EEA) were healthcare-associated infections (HAIs), 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, and could cost the world economy up to USD 100 trillion by 2050 based on the current increasing trends in AMR [4].

In line with the Global Action Plan (GAP) on 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 EU accession with the alignment and implementation of EU legislation on AMR.

One of the five strategic objectives of ECDC's Strategy 2021–2027 [7] is to increase health security in the EU through international collaboration and alignment of infectious disease policies and practice, and 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 the European Commission's DG NEAR. It was then amended on 23 December 2020 to include ECDC's action 'Preparatory measures for the participation of the Western Balkans and Türkiye in ECDC activities with special focus on OneHealth responses against AMR and severe acute respiratory infection surveillance, 2020–2024' (ECDC-IPA6 project) with external financial assistance under the Instrument of Pre-accession Assistance (IPA).

During the joint ECDC and European Food Safety Authority (EFSA) regional workshop on a One Health approach to AMR for EU pre-accession countries, held in Belgrade, Serbia in 2019, national representatives recognised that there was an urgent need to boost the advancement of AMR responses and attain a certain level of implementation of related EU legislation in the region [8]. National governments need to put in place regulatory requirements and ensure necessary laboratory infrastructure and capacity, efficient comprehensive and interoperable electronic surveillance systems and training. They also need to increase the workforce in the human and animal health sector, and carry out awareness raising and commitment activities 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 to discuss AMR issues, identify gaps and support the development of roadmaps on AMR in different sectors: human health, animal health, food safety and the environment. In order to align with previous One Health country visits on AMR in the EU/EEA countries, the visits to countries under the pre-accession assistance programme will be joint visits, with experts from ECDC, DG SANTE and EFSA to cover areas relevant for AMR surveillance, IPC and AMU from a One Health perspective.

2 Objectives and scope

The overall objective of this joint country visit to Montenegro was to discuss and review the advancement of a One Health approach to AMR through: (i) identification of strengths and weaknesses in the current national AMR strategies, action plans and intersectoral coordination mechanisms; (ii) a review of the functioning of national reference laboratories (NRLs) for AMR and their capacity to detect and report AMR; (iii) documentation of the current status and efforts being made by Montenegro on the surveillance of AMR, antimicrobial consumption (AMC) and HAIs; (iv) a review of actions related to the prudent use of antibiotics in human health, animal health, food safety, as well as in the environmental sector; and (v) a review of activities and approaches to raising AMR awareness. A detailed agenda of this 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 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 respective 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.

3 Background

Montenegro comes under the WHO Regional Office for Europe (WHO/Europe) and is a member of the Central Asian and Eastern European Surveillance of Antimicrobial Resistance network (CAESAR). It has been reporting data on the antimicrobial susceptibility of invasive bacterial isolates (i.e. from blood and cerebrospinal fluid samples) for key bacterial species since 2016 [10]. AMR surveillance is well established in Montenegro, with an estimated national population coverage of 100% and a high geographical and hospital representativeness for the period 2017–2021 [11]. However, because of the low blood culture rate (with only three to six blood culture sets per 1 000 patients reported each year), AMR surveillance provides a poor representation of the microorganisms causing invasive infections. The most common bacterial species among the isolates reported for 2021 were *Acinetobacter* spp. (n=57, 30%), *Staphylococcus aureus* (n=33, 17%), *Klebsiella pneumoniae* (n=32, 16.7%), *Enterococcus faecalis* (n= 29, 15%) and *Pseudomonas aeruginosa* (n=16, 8.3%), with 56% of all *K. pneumoniae* and 35% of *Acinetobacter* spp. isolates originating from intensive care units (ICUs). As for other Western Balkan countries, higher proportions of AMR were found in Montenegro for most of the pathogen-antimicrobial combinations monitored in invasive isolates than in other countries in the WHO European Region.

Since 2014, Montenegro has been part of the Antimicrobial Medicines Consumption network established by WHO's Regional Office for Europe. In 2018, as indicated in the joint report by WHO's Regional Office for Europe and the European Observatory on Health Systems and Policies, Montenegro had the fourth highest rate of antibiotic consumption per 1 000 inhabitants per day in the participating countries [12]. For 2021, the report from the WHO Regional Office for Europe Antimicrobial Medicines Consumption Network, published in 2023 (presenting data from 2021), showed that Montenegro was the country with the second highest total consumption of antibacterials for systemic use (Anatomical Therapeutic Class (ATC) group J01), with 31.7 defined daily doses (DDD) per 1 000 inhabitants per day among the ten countries which provided data to the network [13]. Data from the Institutes for Medicines and Medical Devices of Montenegro (CInMED) showed that between 2020 and 2021, consumption of ceftriaxone had increased by 28% and consumption of meropenem by 43% [14].

The Ministry of Health regulates the prevention and control of HAIs. For hospitals, the legislation applicable at country level is the law on the protection of the population against infectious disease from 2018 [15]. This law specifies that for every 200 beds in a hospital or other healthcare institution, a three-person team must be established, consisting of a medical doctor, an epidemiologist, and a specialised technician for the prevention and control of HAIs. This team is responsible for HAI surveillance and the follow-up of control measures. The rulebook on the reporting of contagious diseases, nosocomial infections, conditions and deaths from contagious diseases (2015) defines the requirement to report HAIs [16]. In the most recent ECDC point prevalence survey (PPS) of HAIs and antimicrobial use in European acute care hospitals 2022–2023, HAI prevalence for Montenegro was 3.3%, which was lower than the reported mean of 7.1% for the EU/EEA. The prevalence of patients being prescribed antimicrobials was 48.7% – higher than the reported mean of 35.5% for the EU/EEA. HAIs were most frequently reported in patients in ICUs and in psychiatry wards (13.9% and 11.4%, respectively). The most frequent types of HAI were surgical site infections and pneumonia (23.7% and 21%, respectively), and the most frequently associated pathogens were *Escherichia coli* and *Clostridioides difficile* (22.7% and 13.6%, respectively) [17].

In the veterinary and food production sectors, the responsibility for addressing AMR, including the monitoring of AMR in bacteria from foods and animals and the collection of data on antimicrobial sales and use (ASU) rests with the Administration for Food Safety, Veterinary and Phytosanitary Affairs (AFSVPA). The Specialist Veterinary Laboratory performs microbiological analysis for AMR surveillance. At present, there is very limited monitoring for AMR that conforms with the Commission Implementing Decision (EU) 2020/1729 laying down harmonised rules for the monitoring and reporting of antimicrobial resistance in zoonotic and commensal bacteria. To date, only 15 *Salmonella enteritidis* isolates, collected in 2022 from poultry, have been tested for antimicrobial susceptibility and the resulting data submitted to EFSA [18]. Data on a slightly larger number of commensal *E. coli* and *Salmonella* isolates, collected in 2023 from pigs and fresh meat from pigs and cattle, were also reported to EFSA (data not yet published).

4 Observations

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

4.1.1 Multi-sectoral collaboration and coordination

The National Interdisciplinary Commission for the Control of Antibiotic Resistance (NIKRA) was established by the Ministry of Health in October 2011. The intersectoral composition of NIKRA was revised on 13 March 2024 and now includes the following representatives:

- Professor of Faculty of Medicine, microbiologist, President of NIKRA
- State Secretary, Ministry of Health
- Microbiology expert, Institute of Public Health
- Epidemiologist, Clinical Centre of Montenegro
- General practitioner, Primary Healthcare Centre of Podgorica
- Infectious disease specialist, Clinical Centre of Montenegro
- Paediatrician, Institute of Children's Diseases
- Pharmacologist, human health (CInMED),
- Veterinary and phytosanitary authority representatives
- Veterinary specialist, animal health (CInMED)
- Lawyer, Ministry of Health (secretary of NIKRA).

NIKRA is an advisory body which prepares guidelines, issues recommendations, implements activities and raises concerns. Decision-making remains the prerogative of the Ministry of Health. The decree of the Ministry of Health of 13 March 2024 gives NIKRA responsibility for:

- monitoring AMR and AMC in humans and the veterinary sector;
- proposing ways in which to raise awareness and continue professional training on the prudent use of antibiotics;
- monitoring the spread of resistant strains in hospitals;
- submitting an annual report to the Ministry of Health.

Despite the absence of a representative of the environmental sector, NIKRA has a multi-disciplinary composition and includes high-level representatives from the Ministry of Health. Since June 2021, NIKRA has held 24 meetings, indicating regular activity and frequent discussions. However, NIKRA operates without a dedicated budget. The tasks performed by NIKRA's members are part of the responsibilities of their post as national officials at their respective institutions. Some activities and events, such as drafting guidelines and campaigns to raise awareness of AMR among the general population and professionals during World AMR Awareness Week (WAAW) are organised and supported through collaboration with WHO or partnerships with other institutions, such as the Robert Koch Institute, Germany. Limited national funding has been allocated from the budget of the institutions represented in NIKRA. However, funding for NIKRA is insufficient to support all its assigned tasks. Despite this insufficient funding, NIKRA has supported some activities at regional level through workshops and training for hospital staff.

4.1.2 National strategies and action plans on antimicrobial resistance

The national programme for bacterial resistance to antibiotics for 2022–2024 is the latest national strategic document on AMR endorsed by the Ministry of Health[1]. This is the national action plan (NAP) on AMR. It covers human health as well as the veterinary and environment sectors with a total budget of EUR 219 000 for the period 2022–2024. The NAP was prepared based on a partial situational analysis only covering the human health sector. The NAP has the following objectives:

- Improved monitoring of antimicrobial consumption and resistance of bacteria to antibiotics;
- Optimised application of antimicrobials in human medicine;
- Optimised application of antimicrobials in veterinary medicine;
- Reduced pollution of the environment with antibiotics.

Each objective includes a budgeted list of activities with indicators and targets. NIKRA has been assigned to collect data on programme progression and spending of the funds allocated by the Ministry of Health, although the funding mechanism for this evaluation is unclear. There is no centralised management and supervision for tracking progress and achievement of goals; this is the responsibility of each assigned agency. However, NIKRA reviews the implemented activities and is expected to prepare a report by the end of 2024. An interim report was not available to the visiting team at the time of the visit in June 2024.

[1] The document with the national programme was shared with the country visit team prior to the visit.

Financing of this national programme is expected to come from the Ministry of Health and donors. However, estimated budgets were not available for all the planned activities, and it was not possible to report on activities with expenditure. The budget allocated to the veterinary sector is very modest. The budget for AMR surveillance and antimicrobial consumption monitoring is earmarked separately. Some activities are funded by the World Bank and international partners (e.g. Robert Koch Institute). There is no preparedness and response plan for outbreaks of highly drug-resistant pathogens in humans and animals, or for the detection of novel AMR mechanisms in isolates of human, animal and environmental origin.

4.2 Human health aspects of antimicrobial resistance

4.2.1 Organised multidisciplinary collaboration at local level

During the country visit, healthcare workers did not describe any multidisciplinary collaboration related to AMR between primary care, hospitals and long-term care facilities at the local level. Several issues were observed with interdisciplinary collaboration at the local level including (i) lack of collaboration between microbiologists and clinicians within or between different levels of care; (ii) absence of multidisciplinary teams in both public and private healthcare facilities to promote collaboration for the control of AMR; (iii) limited access to AMR surveillance, HAI surveillance and antimicrobial consumption monitoring data at all levels; (iv) absence of local guidelines based on or supported by local data, and (v) absence of coordination of interventions between local hospitals and primary care providers. Despite these gaps, there was one example of interdisciplinary collaboration involving primary care professionals regularly providing training on various health topics to pharmacy personnel. These training sessions were identified by pharmacy staff as an opportunity to enhance their knowledge and awareness of AMR.

4.2.2 Clinical diagnostic and reference laboratory services

There are 13 microbiological laboratories in the public sector covering inpatients and outpatients in Montenegro. The number of laboratories capable of microbiological testing in the private sector is unknown. The microbiology laboratory in the private hospital visited was not yet functional. The clinical laboratories in the public hospitals visited provided very limited services and suffered from a serious lack of staff, equipment and material. In the regional hospital visited, blood cultures were processed manually using an Oxoid signal system. Apart from this system, only media prepared in-house were available. There was no laboratory information management system (LIMS) in this hospital and the AST results were handwritten on paper forms. This regional hospital laboratory was staffed by only one microbiologist who had been working without any back-up or leave for four years. Blood cultures were processed only during the mornings on regular working days.

During the visit, it was reported that the taking of microbiology samples from patients with signs of infection was infrequent and that clinical microbiology services were under-utilised. For example, in the regional 200-bed hospital, only about 70 blood cultures were processed each year, around three to five of which were positive. In the tertiary care hospital visited, only 350 blood cultures were processed in the month preceding the visit (May 2024) for this 820-bed facility, although an automated blood culture system was in place in the laboratory. In the ICU of this hospital, blood cultures had only been performed for two out of ten patients admitted at the time of the visit. From these blood cultures, carbapenem-resistant *Acinetobacter baumannii* had been detected in both patients and carbapenem-resistant *P. aeruginosa* in one of the patients. Screening cultures were not performed in this ICU, so it is very likely that carriage of multidrug-resistant organisms (MDROs) is much higher than detected. *Candida* species were rarely isolated from blood cultures but, if detected, they were always identified to species level with VITEK® or matrix-assisted laser desorption/ionisation – time of flight mass spectrometry (MALDI-TOF MS). However, at the time of the visit, the MALDI-TOF MS instrument had been out of order for a month.

Other issues encountered were delayed reporting of results to clinicians as well as lack of communication between microbiologists and clinicians. Clinicians complained that they rarely received any positive results and that getting results took too much time, resulting in low confidence in laboratory results and potentially explaining the low demand for laboratory testing. At the tertiary care hospital, clinicians reported having to wait four days for a preliminary result for isolates from positive blood cultures and seven days until the final result was available. Furthermore, there was absence of communication between clinicians and microbiologists in the form of regular meetings or written reports describing the local AMR situation in the hospitals visits. Nevertheless, after a high number of blood cultures were found to be contaminated with coagulase-negative staphylococci, training on blood culture sampling procedures had been performed in the tertiary hospital, with a consequent decrease in the number of contaminations.

The national reference laboratory (NRL) is located at the Institute of Public Health and its bacteriology department also serves as the clinical laboratory for the Clinical Centre of Montenegro. The NRL is equipped with an automated blood culture system, MALDI-TOF MS for microbiological identification, and a VITEK® system for antimicrobial susceptibility testing (AST). The NRL and all other laboratories use EUCAST breakpoints to analyse AST results. A LIMS that supports the microbiology services from the Clinical Centre of Montenegro is in place at the Center for Medical Microbiology. The Center for Medical Microbiology is staffed with eight medical microbiologists (one of

them employed by the NRL), while other clinical laboratories typically have only one or two microbiologists. The Center for Medical Microbiology also has a well-equipped molecular diagnostic section with two ion semi-conductor sequencers. However, whole genome sequencing (WGS) was used almost exclusively for viral pathogens, including for SARS-CoV-2 sequencing during the COVID-19 pandemic, and has not been implemented for bacterial genomics. In 2024, a specific study on carbapenemase-producing Enterobacterales (CPE) was initiated at the NRL with the main carbapenemases being identified using immunochromatographic tests. PCR-testing for bacterial AMR genes is not available.

4.2.3 Monitoring of antimicrobial resistance

Although microbiology testing is limited in Montenegro, the NRL collects AMR surveillance data on invasive isolates from all public clinical laboratories. AMR data from invasive isolates are regularly analysed and reported using the methodology of the CAESAR network. The LIMS at the Center for Medical Microbiology's Department of Bacteriology is only connected with the electronic platform from the Clinical Centre of Montenegro (still under implementation at the centre) and with the primary care centres in Podgorica. Therefore electronic reporting is limited. AMR data from invasive isolates prepared by the NRL are submitted at the national level to NIKRA and the Ministry of Health, and at the international level to the CAESAR Network (since 2016). However, Montenegro is not yet reporting data to the Global Antimicrobial Resistance and Use Surveillance System (GLASS-AMR). National AMR data have been presented at national and international conferences.

At the community level, epidemiology services located at the Institute of Public Health (central or regional services) or in the primary care health centres are responsible for monitoring notifiable diseases and can detect and respond to outbreaks. When necessary, the Institute of Public Health and primary care epidemiologists can also assist in outbreak responses at the hospital level, collaborating with hospital epidemiology services where they are available. Nevertheless, despite having this structure in place, it is not operational for outbreaks due to pathogens with AMR. Most of the outbreaks to which epidemiologists respond are food-borne disease outbreaks in the community.

Several shortcomings hinder both a comprehensive understanding of the burden of AMR in Montenegro and the use of collected data. Firstly, data collected for CAESAR are not particularly representative of isolates due to the low frequency of microbiological samples taken. Secondly, there is no comprehensive national AMR surveillance for samples other than from blood and CSF. Thirdly, laboratory data are only reported annually to NIKRA and the Ministry of Health, and internationally to the CAESAR Network, but are not included in the monthly or annual reports of the community and hospital epidemiological services. In addition, local AMR data are not used to provide stratified surveillance results (for example by laboratory, ward or primary care centre) to data providers or clinicians to inform antimicrobial treatment at hospital, ward and community level. However, a specific surveillance project for CPE monitoring is now being implemented and is expected to be operational soon. This project will allow the collection and analysis of AMR-related data through the electronic system for notifiable diseases reported by epidemiologists on a weekly basis.

An integrated analysis of data from the different AMR and AMC surveillance systems is not performed. Within the framework of the collaboration between Montenegro and the Robert Koch Institute, there are plans to analyse AMR surveillance data from different sectors with a 'One-Health' approach.

4.2.4 Monitoring of antimicrobial consumption

Total antibiotic sales data from public and private wholesalers are collected and analysed by CInMED using the WHO ATC/DDD methodology and are published annually. Montenegro also reports data on antimicrobial consumption (AMC) to WHO's Global Antimicrobial Resistance and Use Surveillance System (WHO-AMC GLASS). The most frequently consumed antibiotics (from total consumption – i.e. community and hospital level combined) were ceftriaxone, metronidazole, ciprofloxacin, azithromycin and meropenem. An increase in carbapenem use in the hospital sector was reported to the team during the visit. However, data are not analysed according to the WHO AWaRe classification, and secondary consumption indicators, such as the reporting of broad versus narrow-spectrum antibiotics, are missing in the CInMED report. The CInMED report is not widely disseminated and specific feedback is not provided to healthcare providers. The insufficient dissemination and the lack of targeted knowledge transfer leaves healthcare workers largely unaware of AMC issues.

Another source of data is reimbursement data from the public sector that are collected and analysed by the National Health Insurance Fund, although this analysis does not follow the ATC/DDD methodology. Furthermore, the data from the National Health Insurance Fund do not capture AMC in the private sector and are not analysed at the level of prescriptions. Hospital pharmacy services do not keep records of AMC as a number of defined daily doses (DDD), or by different services, and do not regularly provide reports or conduct meetings to discuss AMC trends with clinicians. Since 2011, ceftriaxone has been increasingly replacing narrow-spectrum penicillins.

During the visit, a shortage of narrow-spectrum penicillins was described. The management of shortages comes under the jurisdiction of the Ministry of Health. It is reportedly still possible to obtain antibiotics over the counter at pharmacies, without a medical prescription, although this is illegal. Pharmacies are not consistently inspected.

4.2.5 Antimicrobial stewardship and treatment guidelines

The visiting team identified several strengths that could support the development and enhancement of a national AMS programme, including well-trained human resources for AMS in hospitals, a legal mandate requiring AMS teams in hospitals, and access to AMC data. However, significant challenges were also observed. AMS programmes were not established in the hospitals visited and multidisciplinary teams of clinicians, microbiologists and pharmacists were not in place to implement such programmes. AMS in the community did not exist. Key indicators, such as AMC in hospitals, were not available, and available AMC data were not analysed for AMS purposes. Basic metrics, such as pharmacy records on AMC in DDD and AMR data to estimate the magnitude of AMR across different health care centres were lacking. In general, there was little awareness among hospital professionals and management teams about the importance of implementing AMS programmes to address AMR.

The visiting team noted the high frequency of antimicrobial use in hospitalised patients, especially in ICUs, without phenotypic AMR data available to inform treatment decisions. Healthcare workers reported that healthy young people without comorbidities were admitted to hospital with 'simple' infections that could have been treated at home with oral antibiotics. It is apparently common, due to patient demand, for primary care doctors to initiate antimicrobial treatment before referral to a hospital. This results in hospital physicians feeling compelled to escalate with more antibiotics and with a broader spectrum of activity. This practice reflects a 'defensive medicine' culture, where doctors excessively prescribe antibiotics to 'feel' secure that the patient is adequately treated. Many healthcare workers seemed unaware or disinterested in the issue of AMR. The visiting team also observed a low frequency of microbiological sampling, especially blood cultures, leading to prolonged antibiotic treatment without the possibility to stop or de-escalate treatment based on microbiological results.

National and local guidelines for treating infections in hospitalised patients were not available, and the guidelines for surgical prophylaxis and treatment of infections in the community were insufficient or outdated. The few antimicrobial treatments that the team was able to observe in the hospitals visited did not comply with international guidelines, with antibiotic treatment duration exceeding the recommend length. There were no protocols at hospital level for the management of patients with infections and many doctors relied on personal experience rather than specific guidelines. For example, pneumonia was being treated with meropenem and vancomycin for more than 10 days and surgical prophylaxis extended beyond one day, sometimes lasting a week or more, with patients continuing oral antibiotics at home, irrespective of the surgical intervention.

4.2.6 Infection prevention and control

In the hospitals visited, IPC committees had been established, as mandated under Montenegrin law, however these committees had limited activity. Although healthcare workers consulted these committees on IPC-related questions, the committees did not engage in any systematic active surveillance, data analysis or trend monitoring of HAIs to guide interventions as needed. A comprehensive national programme for the prevention and control of HAIs, particularly those caused by MDROs is lacking. In addition, active surveillance of MDROs was not in place and routine screening cultures were not performed at the ICUs visited.

In Montenegro, it is mandatory to report HAIs and this is done by means of a paper form, completed by the doctor/epidemiologist of the health institution where the HAI occurred [8]. When available, AMR data are included on the HAI report form. The completed forms are sent to the Institute of Public Health's central epidemiological service, where local and national data are compiled and presented to a national commission for hospital infections. However, only bloodstream infections and central nervous system infections are recorded. Surgical site infections and device-associated infections, such as ventilator-associated pneumonia and urinary catheter-associated urinary tract infections, are not reported. Despite some data on HAIs being collected at the Institute of Public Health, there was no analysis or translation of these data into interventions for clinicians and other stakeholders. Furthermore, hospitals and wards did not receive appropriate feedback on HAI data, resulting in limited awareness among healthcare workers of the situation regarding HAIs, AMR, antimicrobial use, and hand hygiene practices. Montenegro recently participated in ECDC's point prevalence survey (PPS) of HAIs and antimicrobial use in European acute care hospitals [17], however the survey found few HAIs, probably due to under-detection of cases, given the low frequency of microbiological sampling.

The visiting team observed suboptimal IPC practices in the hospitals visited, especially in relation to hand hygiene, glove use and the management of urine drainage bags. Examples included healthcare workers touching patients and using gloves without having disinfected their hands (i.e. before donning and after doffing) and ICU patients' urinary bags lying on the floor, a practice justified by nurses because of the poor quality of the urinary bags. Challenges with hospital infrastructure were also observed, such as a limited number of single-bed rooms and insufficient distance between beds in ICUs. Most of the rooms in ICUs have three beds, positioned close to one another, often without en-suite bathrooms, leading to patients sharing bathrooms. Moreover, there was no regular monitoring of hand hygiene compliance. Although hand hygiene observation studies had been conducted occasionally, they were not performed systematically or regularly enough to provide meaningful feedback on hand hygiene practices to healthcare workers and hospital management, making it difficult to monitor trends and implement interventions.

4.2.7 Educational programmes on antimicrobial resistance and infection prevention and control

AMR is included in the curriculum of medical undergraduate studies as part of microbiology courses in the second and third year of studies. Hand hygiene is being taught to both medical and nursing students. However, dedicated courses on appropriate antimicrobial use during medical undergraduate studies are not available. A continuous professional education programme exists and credits (10 points per year) are required for renewal of medical licences every seven years. Only a limited number of postgraduate courses on AMR and appropriate use of antimicrobials were available. Attendance of doctors at conferences was described as limited, unless sponsored by pharmaceutical companies.

4.2.8 Public information and behavioural change interventions on antimicrobial resistance

In the human health sector, numerous activities were carried out as part of the European Antibiotic Awareness Day (EAAD) and the World AMR Awareness Week (WAAW) between 2017 and 2023. These included professional conferences, public appearances of physicians, veterinarians and pharmacists on TV and radio, and articles published in newspapers and scientific journals. Educational messages targeting the general population were made available on the websites of the Ministry of Health and the Institute of Public Health. In addition, there were successful education campaigns conducted with university students, although there was insufficient support for these activities. One of the most recent initiatives was a first survey in Montenegro on knowledge, attitudes, and behaviour related to AMR, in line with the methodology of WHO's Regional Office for Europe [19].

Despite the activities mentioned above, there remains low awareness among the general public of AMR and the need for prudent use of antibiotics. Moreover, there are currently no plans for awareness campaigns on prudent use of antibiotics and AMR designed for the general public or healthcare professionals. Similarly, there was no educational material available at any the healthcare facilities visited. All stakeholders consulted during the country visit acknowledged that the prevailing preconceptions, attitudes and opinions of the general population regarding antibiotics pose difficulties for prescribers wishing to avoid prescription of antibiotics when not indicated, and this issue needs to be addressed.

4.2.9 Marketing-related issues

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, were not in place. Doctors were not required to register gifts received, sponsored conference participation or related networking activities as there was no mechanism for declaration of interests.

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

4.3.1 Diagnostic laboratory services and reference laboratory services

The Specialist Veterinary Laboratory (SVL) has good laboratory facilities with competent and enthusiastic staff. The laboratory has been accredited for International Organization for Standardization/International Electrotechnical Commission (ISO/IEC) 17025 since 2011 by the accreditation body of Montenegro (Akreditaciono tijelo Crne Gore - ATCG), recognised at EU level. The most recent re-accreditation (2023) is valid until 2027. AST for the purpose of AMR monitoring was performed using the broth microdilution method in accordance with the reference method ISO/IEC 20776-1:2019 (as required in the EU by Commission Implementing Decision (EU) 2020/1729). In addition, the laboratory possesses adequate capacity to conduct AST on clinical samples using the disc diffusion method. The SVL's electronic information system, including the LIMS, was linked to the AFSVPA's veterinary information system (VIS) for sample management down to animal or flock level. The SVL also has the capacity and expertise to perform real-time-PCR. With one short read sequencer at the facility, SVL has the possibility to develop WGS services, however this would require additional capacity building.

The SVL has not been designated as the NRL for AMR by the relevant competent authority, as required by Regulation (EU) 2017/625. In addition, Montenegro did not participate in proficiency testing for the broth microdilution AST method, as required by Decision (EU) 2020/1729, due to the prohibitive cost. Apart from this year's mastitis programme, the laboratory's diagnostic capabilities were under-utilised, with services being used only for a limited number of official and clinical samples. Uncertainty about the start date of the EU harmonised AMR monitoring in 2024 had hindered the SVL's ability to plan its workload and procure the necessary reagents and consumables.

4.3.2 Monitoring of antimicrobial resistance in animals and foods

Montenegro's participation in the EU harmonised monitoring of animals and foods for AMR in zoonotic pathogens and indicator bacteria, as mandated by Decision (EU) 2020/1729 for EU Member States, began in 2023, albeit with only 15 isolates collected in 2022. Data on a slightly higher number of isolates of commensal *E. coli* and *Salmonella,* collected in 2023 from pigs and fresh meat from pigs and cattle, were also reported to EFSA (data not yet published). In addition to the low number of samples analysed, several weaknesses were identified making it difficult to assess the AMR situation. The sampling period began late in the year, covering only a few months (from October to December) and the testing performed did not fully comply with EU standards, lacking analyses for European Antimicrobial Resistance Genes (EURGen) extended-spectrum beta-lactamase (ESBL), AmpC, or carbapenemase-producing *E. coli*. Similarly, at the time of the country visit, the 2024 AMR monitoring programme was not fully harmonised with EU legislation; for example, samples were not evenly distributed throughout the year, due to a delayed start. Furthermore, the implementation at national level of the *Salmonella* control programme in poultry farms has still not been confirmed.

4.3.3 Monitoring the sales and use of antimicrobials in animals

Legal requirements for the collection and reporting of data on imports and sales of veterinary medicinal products have been established, with the Rulebook (Official Gazette of Montenegro 2/13) outlining detailed provisions on the form, content, manner and period for reporting sales of medicines. Efforts are also underway to incorporate the requirements of Regulation (EU) 2019/6 into the national legal framework for the collection of data on sales and use of antimicrobials. The Veterinary Information System (VIS) offers the capability to track veterinary medicinal products from import to end user, including detailed information on individual animals, diagnoses and treatments. Once operational, this system should provide extensive opportunities for analysing antimicrobial consumption. In addition, there is good coordination among the institutions responsible for monitoring veterinary antimicrobial consumption (AFSVPA and CInMED).

Montenegro has been providing sales data to WOAH since 2018, and using the ANIMUSE platform since 2023. Well-defined and structured animal census records allow the calculation of Population Correction Unit (PCU), as used in the European Surveillance of Veterinary Antimicrobial Consumption (ESVAC) reports (the WOAH denominator for biomass uses mg/kg, thus limiting the comparison with EU data). The staff handling the data had a good knowledge of veterinary medicinal products and their distribution chains, and attempts have been made to assess trends in this area.

Despite these strengths, several weaknesses remain. The mandate for AFSVPA to collect the data on sales and use of antimicrobials is not clearly established, leading to potential gaps in data collection. While effective communication and coordination between CInMED and AFSVPA does exist, the terms of reference and funding for their shared tasks are not clearly defined. Furthermore, there is no legal basis for the full implementation of the veterinary medicinal product module of the VIS. The VIS is not fully compatible with the CInMED database, lacking live links to import permits issued, or the capability to trace the use of human medicines in animals. Moreover, there is a lack of information on the route of administration. In addition, current data on the use of antimicrobials are not stratified by animal species, pending the full implementation of the VIS.

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

The regulatory framework governing the use of veterinary medicinal products demonstrates several strengths that align with EU legislation. The requirement for prescriptions to obtain antimicrobials is in line with previous EU legislation. Furthermore, both the AFSVPA and CInMED were fully aware of the current EU legislation on veterinary medicinal products and the need to incorporate these laws into national legislation. National legislation prohibiting the use of antimicrobials as growth promoters and for the purpose of yield increase had been adopted in 2024. The same act also contains a provision prohibiting the use of antimicrobials reserved exclusively for use in human medicine, in line with Commission Implementing Regulation (EU) 2022/1255.

However, the system has several weaknesses that need to be addressed. One significant issue is inadequate human resources within the competent authorities for the work ahead. Another is the need for educational activities and the development of treatment guidelines for priority species. Similarly, incorporation of the relevant EU legislation into national law is incomplete, complicating regulatory efforts, and this is exacerbated by uncertainty regarding the responsible authority for each regulatory aspect. Finally, the critical understaffing of control bodies, with a notable shortage of official veterinary inspectors, limits the ability to enforce regulations.

In addition, the recent FAO survey on antimicrobial use practices in the livestock sector in Montenegro [20] listed other areas of concern, which were confirmed or reported to the visiting team. These include (i) limited use of diagnostic tests, limited antimicrobial susceptibility testing and samples only taken when prolonged treatment is ineffective; (ii) widespread use and sale of the antimicrobials ceftiofur and enrofloxacin that belong to the list of critically important antimicrobials for human health (the European Medicines Agency (EMA) Antimicrobial Advice ad

hoc Expert Group (AMEG) Category B Restrict [21]); (iii) treatment of mastitis relying mostly on cefalexin (AMEG Category C Caution) and ceftiofur; (iv) reported limited availability of veterinary medicinal products for farm animals, as well as limited availability of veterinarians in remote areas, allegedly affecting the choice of antimicrobials to ensure their responsible use, resulting in farmers using veterinary medicinal products smuggled across the border; (v) a dispersed farming sector with a large number of small farms with poor biosecurity and hygiene measures in place, and (vi) over half of the farmers surveyed admitting to not keeping treatment records.

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

The personnel met at CInMED, AFSVPA and SVL were dedicated and had good knowledge of AMR and the principles of responsible use of antimicrobials. Guidelines, incorporating the EMA classification of antimicrobials and advice on their responsible use, were made accessible through the CInMED website and distributed via the Veterinary Chamber. In addition, a WHO poster on AMR and the use of antimicrobials in animals had been translated into Montenegrin.

Since 2015, the EAAD campaigns have included targeted messages from veterinarians, addressing both veterinarians and the general public. Spots on TV and social media (YouTube) have been used to promote awareness of responsible antimicrobial use in animals. Postgraduate education initiatives have also been effective, even in the absence of a veterinary faculty in Montenegro. The veterinarians were aware of the guidelines and new legislation restricting the use of antimicrobials reserved for human treatment. Continuous professional development requirements were in place to ensure that practising veterinarians remain informed. However, only a small number of veterinarians had attended the Veterinary Days, organised by the Veterinary Chamber, featuring lectures on AMR and responsible antimicrobial use with guest speakers from CInMED and AFSVPA.

Significant weaknesses were identified during the visit, including reliance on broad-spectrum antimicrobials that are critically important for human health. In addition, the FAO 2022 survey revealed that only a small number of farmers had received education or training in animal health or related subjects, and their knowledge of antimicrobials and AMR was very limited. More than half of the farmers expressed a lack of interest in acquiring more information on these topics.

4.3.6 Environmental monitoring of antimicrobials and antimicrobial resistance

The lack of safe disposal routes for expired and unused medicines for the general public and farmers is the most pressing problem related to the environment. This has been acknowledged and included in the current NAP along with the decision to create a national Waste Management Plan. As described in the NAP, Montenegro participated in the Global Sewage Project by carrying out bi-annual monitoring of wastewater. However, at the time of the visit, the environmental sector was not represented in NIKRA and the national waste management plan was not yet in place. The provisions for waste disposal, including pharmaceutical waste, were limited to hospitals and other healthcare facilities. According to the FAO survey, most farmers reported either consulting with a veterinarian or disposing of expired/unused veterinary medicinal products in household waste. Only 9% reported returning antibiotics to the place of purchase. The visiting team did not receive any specific information on the monitoring of antimicrobials in surface waters (as per EU Watchlist [22])[2].

[2] In their response to the draft report, regarding the transposition of the EU Water Framework Directive, the competent authorities noted that the Law on Waters ('Official Gazette of the Republic of Montenegro', No. 84/18) and the RULES ON THE METHOD AND DEADLINES FOR DETERMINING THE STATUS OF SURFACE WATERS ('Official Gazette of the Republic of Montenegro', No. 025/19) were adopted. This includes Annex 12, Table 1, with an ADDITIONAL LIST OF POLLUTANTS containing antibiotics. In addition to that, the competent authorities noted that although a system for monitoring antibiotic residues in surface waters has not yet been established, the visit team was made aware that monitoring of surface and groundwater is carried out in accordance with the Law on Waters.

5. Conclusions

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

The NIKRA has a multisectoral composition, is active and meets frequently. A high-level Ministry of Health representative (State secretary) has recently been appointed as a NIKRA Member. However, the environmental sector is still not represented. The NIKRA has a narrow governmental mandate and primarily serves as a national expert group, with limited authority to enforce changes and address AMR issues from a One Health perspective. A NAP is in place for the period 2022–2024 with indicators and targets for the human health, veterinary and environmental sectors. However, the NAP is based on a partial situational analysis only covering the human health sector. In addition, the level of implementation of the NAP is unclear as no progress report has been made available. There is insufficient budget for the activities outlined in the NAP. There is no preparedness and response plan for outbreaks of highly drug-resistant pathogens in humans and animals, or for the detection of novel AMR mechanisms in isolates of human, animal and environmental origin.

5.2 Human health aspects of antimicrobial resistance

Appropriate diagnostic capacity for AMR is available at the NRL located at the Institute of Public Health, with a well-equipped laboratory for bacteriology, a functional LIMS, availability of MALDI-TOF MS for bacterial identification and use of EUCAST breakpoints for AST. The NRL capacity is also used for routine clinical microbiology testing by the Clinical Centre of Montenegro, located nearby. However, a serious lack of staff and equipment was observed at the regional hospital-based clinical laboratory, including the absence of LIMS to collect data electronically. Overall, there was a low frequency of microbiology sampling from patients with signs of infection and under-utilisation of clinical microbiology services, even at the Clinical Centre of Montenegro which has access to NRL-level diagnostic capacity. Clinicians' poor confidence in laboratory results, lack of timely reporting and lack of communication between clinicians and microbiologists are among the reasons explaining this low utilisation of microbiology diagnostic services. A specific study collecting isolates of carbapenem-resistant Enterobacterales had recently been initiated at the NRL. However, molecular testing, such as PCR or WGS, for the determination of AMR genes and to support outbreak investigations was not available in the country.

A national electronic surveillance system for notifiable diseases is operational and is being used by epidemiologists at the national and regional level to detect and report outbreaks, but it is not used for AMR reporting. Epidemiologists are available throughout the country. For AMR surveillance, data are regularly collected from regional hospitals by the Institute of Public Health, although there is no national electronic data collection system for AMR. AMR data are only collected and reported to the national level and WHO's Regional Office for Europe (i.e. CAESAR) for invasive isolates. The low frequency of microbiology sampling has resulted in a low isolate representativeness, despite a high geographical and hospital representativeness in CAESAR reports since 2017. Comprehensive national AMR surveillance for samples other than blood and CSF does not exist. In addition, local AMR data, which could be used to inform antimicrobial treatment at hospital, ward and community level, is not available.

Antimicrobial consumption (AMC) data are collected from wholesalers and analysed by CInMED using the WHO ATC/DDD methodology. AMC reports are published annually, and data are also reported to the WHO-GLASS AMC module. Despite a comprehensive overview of antibiotic sales data, these are not analysed using the WHO AWaRe classification and secondary consumption indicators are absent. The CInMED report is poorly disseminated, leaving healthcare providers largely unaware of AMC issues. Reimbursement data from the public sector are collected and analysed by the National Health Insurance Fund. However, these data do not capture AMC in the private sector and are not analysed at prescription level.

Montenegro has favourable conditions for developing AMS programmes in hospitals, including well-trained staff, a legal mandate for AMS teams in hospitals, and access to antibiotic expenditure data. However, AMS programmes in hospitals are not yet operational: multidisciplinary teams are not established, AMR indicators are lacking and proper analyses of AMC data are not performed at the local level. There is also limited awareness among healthcare professionals and hospital management of the importance of AMS programmes. A high frequency of antimicrobial use was observed in hospitalised patients, especially in ICUs. Under-reporting of HAIs caused by MDROs was described, which represents a risk for the undetected and uncontrolled spread of MDROs in healthcare. Furthermore, there were no national and local guidelines for the treatment of infections in hospitalised patients, and insufficient or outdated guidelines for surgical prophylaxis and the treatment of community infections. Most of the antimicrobial treatments witnessed by the visiting team in the hospitals visited did not comply with international guidelines.

IPC committees have been established in hospitals, as required by law, but they have limited activity. These committees are consulted on IPC issues but do not perform systematic HAI surveillance, data analysis or trend monitoring. There is no comprehensive programme for preventing HAIs, particularly those caused by MDROs. Active surveillance for MDROs is not performed, even in ICUs. While reporting of some HAIs is mandatory, surgical site infections and ventilator-associated pneumonia are not included as part of mandatory reporting. In addition, the data collected are not analysed or used to identify and implement interventions. Feedback of HAI surveillance data to hospitals and wards is minimal, leading to low awareness of HAIs, AMR, and antimicrobial use among healthcare staff The visiting team observed poor IPC practices, including inadequate hand hygiene, improper use of gloves, and issues related to management of urinary catheters. Challenges with hospital infrastructure, such as overcrowded ICUs and lack of hand hygiene monitoring, further hinder effective IPC in hospitals.

AMR and IPC education is included in the curriculum of medical undergraduate studies as part of microbiology courses, and hand hygiene is being taught to both medical and nursing students. However, there are no dedicated courses on appropriate antimicrobial use during medical undergraduate studies. With regard to public information and behavioural change interventions on AMR, Montenegro conducted various activities for EAAD and World AMR Awareness Week between 2017 and 2023. These included organising conferences, media appearances by doctors, veterinarians and pharmacists, and public information distributed through the Ministry of Health and Institute of Public Health websites. Despite these efforts, the general public's awareness of AMR remains low, and there are currently no plans or materials for public or professional awareness campaigns on the prudent use of antibiotics and AMR. Stakeholders recognise the need to address prevailing misconceptions and attitudes to improve prescribing practices.

5.3 Veterinary and environmental aspects of antimicrobial resistance

Montenegro has the laboratory capacity to support AMR monitoring with accredited procedures in bacteriology and competent staff. In addition, the LIMS is effectively integrated into the AFSVPA's VIS, facilitating data sharing. The SVL also has real-time PCR capacity and the possibility to develop WGS capacity. However, the SVL has not been designated as the national reference laboratory for AMR, and the high cost of proficiency testing has hindered participation in essential EU proficiency programmes. Apart from this year's mastitis programme, the laboratory testing capacities for AMR monitoring and clinical samples requiring AST are largely under-utilised. Although the country has engaged in EU harmonised monitoring of AMR in animals and foods, issues such as delayed sampling, limited data collection and non-compliance with testing standards persist. The 2024 monitoring programme also faces challenges, such as uneven sample distribution and incomplete implementation of the *Salmonella* control programme that is the source of the *Salmonella* isolates from poultry to be tested under the EU harmonised AMR monitoring.

Efforts to monitor the sales and use of antimicrobials are supported by legal requirements and a capable VIS. The VIS offers the possibility to track veterinary medicinal products from import to end user and, once operational, will provide many possibilities for the analysis of antimicrobial consumption. There is good, well-organised collaboration among the institutions responsible for monitoring the consumption of veterinary antimicrobials (AFSVPA and CInMED). However, gaps in legal mandates, data collection frameworks, and compatibility issues with the CInMED database remain. The requirement for veterinary prescriptions to obtain antimicrobials and other requirements for veterinary medicinal products is in line with the previous EU legislation. National legislation prohibiting use of growth and yield promotors and antimicrobials reserved for the treatment of humans, as listed in Commission Implementing Regulation (EU) 2022/1255, is already in place.

Positive practices among veterinarians and farmers have been noted but challenges remain, such as the common use in veterinary settings, of broad-spectrum antimicrobials that are critically important for human health. Added to this challenge is the fact that there are a large number of small farms with poor biosecurity and hygiene measures. It was reported that the availability of veterinary medicinal products for farm animals is limited and that farmers cannot always access veterinary services, meaning that they resort to purchasing medicines from unofficial retailers.

Communication efforts on AMR and responsible use of antimicrobials are in place, with dedicated staff, accessible guidelines, and awareness campaigns. However, the high reliance on antimicrobials that are critically important for human health and the fact that farmers have limited knowledge of AMR are areas which require improvement.

The environmental sector faces significant challenges, particularly in the disposal of expired and unused medicines, a gap recognised in the NAP. Although the country is participating in the Global Sewage Project, the lack of representation of the environmental sector in NIKRA and the absence of a National Waste Management Plan hinder comprehensive oversight. The fact that most farmers rely on household waste disposal for expired veterinary medicinal products underscores the need for better pharmaceutical waste management practices.

6. Considerations for future action

6.1 Priority and key actions

- Planning and implementing education and communication campaigns on prudent use of antibiotics to reduce excessive antibiotic use;
- Introducing data-driven decision-making and targeted interventions based on surveillance data;
- Improving access to timely and good-quality microbiology services;
- Developing guidelines and protocols for microbiological diagnostics, antimicrobial treatment and IPC, and monitoring compliance with these guidelines and protocols;
- Strengthening the role and visibility of NIKRA and intersectoral and interdisciplinary collaboration.

6.2 Governance and One Health aspects of antimicrobial resistance

Intersectoral collaboration and NAP

- Strengthening NIKRA by:
  - defining terms of reference with specific roles, responsibilities, dedicated time and budget;
  - including behaviour change and communication competence;
  - improving collaboration from a One Health perspective and including representation of the environmental sector.
- Preparing the next NAP by:
  - conducting a thorough situational analysis;
  - ensuring a One Health perspective for objectives and activities;
  - providing sustainable national funding of activities;
  - performing regular monitoring and evaluating implementation of the NAP.
- Enhancing interdisciplinary collaboration through:
  - stronger linkages, at national and local levels, between epidemiologists, microbiologists, statisticians, clinicians, pharmacists and nurses.

6.3 Human health aspects of antimicrobial resistance

Diagnostic laboratory services

- Improving access to timely and good-quality clinical microbiology services by:
  - providing appropriate equipment and staffing for clinical laboratories;
  - ensuring regular, good-quality supplies;
  - establishing LIMS in clinical laboratories;
  - establishing immediate reporting of critical results.
- Increasing microbiological testing by:
  - providing protocols with guidance on indications for sampling and appropriate sampling procedures;
  - training healthcare staff accordingly.
- Improving feedback and reporting to providers by:
  - improving communication and collaboration between clinicians and microbiologists.

Monitoring of AMR

- Development of a comprehensive national AMR surveillance system with:
  - defined objectives, data collection protocols, specified data processing and analysis;
  - advancement of laboratory data digitalisation and integration of the different existent eHealth platforms;
  - regular provision of stratified results to stakeholders and data providers;
  - regular public reporting;
  - use of this data for the preparation of national treatment guidelines.

Monitoring of AMC

- Analysing and presenting consumption data based on the AWaRe classification to determine the percentage of antibiotic use from antibiotics in the 'Warning' and 'Reserve' categories;
- Disseminating the CInMED report to stakeholders to increase awareness of AMC among healthcare providers;
- Analysing reimbursement data per indication, healthcare centre and healthcare provider;
- Strengthening AMC monitoring in the private sector with implementation of an electronic prescription system.

AMS and treatment guidelines

- Ensuring support from the Ministry of Health for the development of AMS teams and including the objective of combating AMR as a priority objective;
- Developing national guidelines for diagnosis and antimicrobial treatment, with broad authorship representing the AMS teams and relevant professions.

In each hospital:

- Ensuring institutional support from the hospital management for the AMS programme and teams, including the programme's objectives among the hospital's annual goals;
- Activating AMS teams with the development of the AMS programme, including objectives, indicators, interventions, evaluation and necessary resources;
- Presenting the AMS programme to all hospital departments;
- Generating local data on AMR and consumption and analysing this data to target AMS activities.

Infection prevention and control (IPC)

In each hospital:

- Intensifying training of healthcare workers on IPC practices (e.g. hand hygiene, glove use, urinary and central catheter maintenance);
- Monitoring IPC practices with regular audits and feedback to healthcare workers;
- Involving hospital management in the monitoring of IPC-related practices and regular reporting of compliance data and trends analysis in different hospital wards;
- Considering systematic screening for carbapenem-resistant *A. baumannii* and carbapenem-resistant Enterobacterales in ICUs.

AMR and IPC education

- Investing in a professional development plan to train future healthcare professionals by including dedicated modules on AMR and AMS in the undergraduate curricula of medical and nursing schools and for pharmacology students;
- Offering in-person and online courses on AMR, IPC and appropriate antimicrobial use for healthcare professionals in the primary care and hospital sectors, and providing incentives to encourage broad participation;
- Incorporating AMS- and IPC-related training into the continuous professional education priorities of professional societies.

Public information and behavioural change interventions for AMR

- Starting awareness raising campaigns on the prudent use of antibiotics and AMR with a One Health approach, for healthcare professionals in the human and animal health sectors;
- Planning and implementing long-term behaviour change communication efforts to raise awareness in the general public of the prudent use of antibiotics and AMR, including how to dispose of unused/expired drugs, basic hygiene and infectious diseases:
  - performing a needs assessment and situation analysis to identify communication needs;
  - formulating the goals, targets and objectives of a communication plan;
  - specifying target groups and appropriate activities, including tools and channels;
  - defining the frequency and duration of the campaign;
  - agreeing on campaign branding and materials;
  - incorporating social marketing and behaviour change strategies;
  - monitoring misinformation.

6.4 Animal health and food safety aspects of antimicrobial resistance

Laboratory services

- Proceeding with the designation of the SVL as the NRL for AMR;
- Securing the budget required for proficiency testing;
- Increasing the use of laboratory testing capacity, including urgent implementation of the 2024 AMR monitoring programme and early start of implementation for the coming years.

Monitoring of AMR

- Estimating and agreeing on the budget allocated for the implementation of the AMR monitoring programme over several years to ensure more effective resource management and enable an earlier start to the programme;
- Continuing to harmonise the AMR monitoring programme with EU requirements:
  - prioritising the implementation of the *Salmonella* National Control Programme;
  - considering the inclusion of all priority species (e.g. laying hens);
- Continuing to submit all data to EFSA and ensuring further harmonisation to make the data comparable with EU results.

Monitoring of sales and use of antimicrobials

- Organising and structuring the data collection system, defining responsibilities and, if possible, increasing human resources;
- Adapting the national legal framework to Regulation (EU) 2019/6 on the collection of antimicrobial consumption data;
- Considering the establishment of a legal basis to enable the full implementation of the VIS;
- Promoting the VIS to its final users (veterinarians):
  - providing potential incentives;
  - providing periodic consumption reports to veterinarians to increase their involvement in the fight against AMR;
  - developing infographics and audiovisual material to continue with 'user friendly' training on how to use the system;
- Aligning the VIS with the CInMED database to make it a 'live' platform;
- In the longer term, developing a roadmap for the monitoring of antimicrobial consumption:
  - starting with the adoption of the EU PCU and aiming to achieve use data collection stratified by animal species;
  - developing the data quality system (a tool to evaluate the degree of integrity and precision of the data);
  - once more data are available, performing trend analysis and computing of AMR and antimicrobial consumption for better interpretation of AMR trends;
- Investigating the possibility of creating a communication channel with the EU Working Group (European Sales and Use of Antimicrobials in veterinary medicine ESUAvet) for the full development of the collection system in line with EU guidelines.

Activities to promote the reduced and prudent use of antimicrobials

- Urgently investigating and scaling up human resources for the work ahead, in particular:
  - drafting national legislation to align with the EU acquis;
  - allowing for systematic official controls to ensure that the legislative provisions are complied with;
- Developing measures to promote reduced use of antimicrobials, allowing the phasing out of the widespread use of antimicrobials that are critically important for human health, by investigating:
  - how to encourage a more systematic use of diagnostic tests and antimicrobial susceptibility testing;
  - how to improve the availability of antimicrobials;
  - how to use the results of AMR monitoring, the mastitis programme and other AST results (by species/diseases/regions) to spread awareness and inform prescribers (in the longer term, the results could feed into the development of treatment guidelines);
- In the longer term, consider identification and surveillance of other priority pathogens (similarly to the ongoing mastitis programme) in major food-producing species, and the sampling and testing strategies to enhance surveillance.

Education and communication

- Planning targeted AMR awareness campaigns for certain groups, namely veterinarians and animal keepers (starting with the food-producing sectors and moving on to pet owners);
- Using the findings of the FAO report, the data from the monitoring of antimicrobial consumption and of AMR in indicator bacteria, the results of the mastitis health programme and other information available to highlight the current AMR situation, incorrect prescribing patterns and the risk for the general public.

6.5 Environmental aspects of antimicrobial resistance

- Ensuring that the environmental sector is represented in NIKRA and fully included in the review of the current NAP;
- Urgently establishing safe disposal routes for the expired and unused medicines;
- Once established, ensuring that the relevant stakeholders and general public are aware of the importance of disposing of antimicrobials in a safe manner;
- Considering further potential monitoring of antimicrobials, resistant bacteria/antimicrobial resistance genes in the environment (including food-production) to address the knowledge gaps on environmental contamination.
- Monitoring antimicrobials from the EU Watchlist under the EU Water Framework Directive and other relevant legislation.

References

1. European Centre for Disease Prevention and Control (ECDC). Methodology for conducting One Health country visits on antimicrobial resistance in the Western Balkans. Stockholm: ECDC; 2024. Available at: https://www.ecdc.europa.eu/sites/default/files/documents/methodology-one-health-country-visits-antimicrobial-resistance-western-balkans.pdf
2. Mestrovic T, Robles Aguilar G, et al. The burden of bacterial antimicrobial resistance in the WHO European region in 2019: a cross-country systematic analysis. The Lancet Public Health, Volume 7, Issue 11 e897 - e913 2022. DOI: 10.1016/S2468-2667(22)00225-0
3. European Centre for Disease Prevention and Control (ECDC). Assessing the health burden of infections with antibiotic-resistant bacteria in the EU/EEA, 2016–2020. 17 November 2022. Stockholm: ECDC; 2022. Available at: https://www.ecdc.europa.eu/sites/default/files/documents/Health-burden-infections-antibiotic-resistant-bacteria.pdf
4. Jonas O, Irwin A, Berthe F, Le Gall FG, Marquez PV, at al. Drug-resistant infections: a threat to our economic future (Vol. 2): final report. HNP/Agriculture Global Antimicrobial Resistance Initiative. Washington, D.C.: World Bank Group. Available at: http://documents1.worldbank.org/curated/en/323311493396993758/pdf/final-report.pdf
5. World Health Organization (WHO). Global action plan on antimicrobial resistance. Geneva: WHO; 2015. Available at: https://www.who.int/publications/i/item/9789241509763
6. European Commission (EC). A European One Health Action Plan against Antimicrobial Resistance (AMR). EC; 29 June 2017. Available at: https://health.ec.europa.eu/document/download/353f40d1-f114-4c41-9755-c7e3f1da5378_en?filename=amr_2017_action-plan.pdf (Accessed 18 December 2024)
7. European Centre for Disease Prevention and Control (ECDC). Amended ECDC Strategy 2021–2027. Stockholm: ECDC; 2023. Available at: https://www.ecdc.europa.eu/sites/default/files/documents/amended-ECDC-Strategy-2021-2027_0.pdf (Accessed 18 December 2024)
8. European Centre for Disease Prevention and Control (ECDC). ECDC/EFSA Regional workshop on One Health approach against antimicrobial resistance in EU pre-accession countries. Stockholm: ECDC; 2019. Available at: https://www.ecdc.europa.eu/sites/default/files/documents/antimicrobial-resistance-one-health-approach-EU-preaccession-countries.pdf
9. European Centre for Disease Prevention and Control (ECDC). Assessment tool for joint 'One Health' country visits in relation to antimicrobial resistance. Stockholm: ECDC; 2021. Available at: https://www.ecdc.europa.eu/sites/default/files/documents/One-Health-AMR-assessment-tool-for-country-visits.pdf
10. World Health Organization (WHO) Regional Office for Europe. Central Asian and Eastern European Surveillance of Antimicrobial Resistance: annual report 2016. Copenhagen: WHO; 2016. Available at: https://iris.who.int/handle/10665/344085
11. European Centre for Disease Prevention and Control (ECDC) and World Health Organization (WHO). Antimicrobial resistance surveillance in Europe 2023–2021 data; Stockholm: ECDC; 2023. Available at: https://www.ecdc.europa.eu/sites/default/files/documents/Antimicrobial%20resistance%20surveillance%20in%20Europe%202023%20-%202021%20data.pdf
12. World Health Organization (WHO) Regional Office for Europe. Health system in Action. Insight for Montenegro. 2022 edition. Copenhagen: WHO; 2022. Available at https://iris.who.int/bitstream/handle/10665/362325/9789289059183-eng.pdf?sequence=1
13. World Health Organization (WHO). WHO Regional Office for Europe Antimicrobial Medicines Consumption (AMC) Network. AMC data 2020–2021. Copenhagen: WHO; 2023. Available at: https://iris.who.int/bitstream/handle/10665/373913/9789289060042-eng.pdf?sequence=1
14. Institute for Medicines and Medical Devices of Montenegro. Analysis of medicines consumption in Montenegro in the period 2017–2021; Montenegro: 2022. Available at: https://cinmed.me/wp-content/uploads/2023/01/2022.12.01.-Analiza-potrosnje-ljekova-u-Crnoj-Gori-za-period-2017-2021.pdf
15. Law on the Protection of the Population from Infectious Diseases. Montenegro. Published 12/2018, 64/2020 and 59/2021. Available at: https://faolex.fao.org/docs/pdf/mne194462.pdf
16. European Centre for Disease Prevention and Control (ECDC). Meeting report of the ECDC/EFSA Regional workshop on the One Health approach against antimicrobial resistance in EU pre-accession countries in 2019. Stockholm: ECDC; 2024. Available at: https://www.ecdc.europa.eu/sites/default/files/documents/antimicrobial-resistance-one-health-approach-EU-preaccession-countries.pdf
17. European Centre for Disease Prevention and Control (ECDC). Point prevalence survey of healthcare associated infections and antimicrobial use in European acute care hospitals. Stockholm: ECDC; 2024. Available at: https://www.ecdc.europa.eu/sites/default/files/documents/healthcare-associated-point-prevalence-survey-acute-care-hospitals-2022-2023.pdf

18. European Food Safety Authority (EFSA). Montenegro trends and sources of zoonoses and zoonotic agents in foodstuffs, animals and feeding stuffs in 2022. Parma: EFSA; 2022. Available at: https://www.efsa.europa.eu/sites/default/files/2024-02/zoocountryreport22me.pdf
19. World Health Organization (WHO) Regional Office for Europe. People's knowledge, attitudes and behaviours pertaining to antimicrobial resistance: cross-sectional survey of 14 Member States in the WHO European Region. Copenhagen: WHO Europe; 2024. Available at: https://www.who.int/kazakhstan/publications/i/item/WHO-EURO-2024-10244-50016-75268
20. Food and Agriculture Organization (FAO). Antimicrobial use practices in the livestock sector in Montenegro – Survey report. Understanding Antimicrobial Use in Food and Agriculture. Budapest 2024. Available at: https://openknowledge.fao.org/server/api/core/bitstreams/24d9ee6d-705f-488b-a299-87c13c855686/content
21. European Medicines Agency (EMA). Categorisation of antibiotics in the European Union Answer to the request from the European Commission for updating the scientific advice on the impact on public health and animal health of the use of antibiotics in animals. December 2019, EMA/CVMP/CHMP/682198/2017. Available at: AMEG 2018 - Categorisation of antibiotics
22. European Commission (EC). Commission Implementing Decision (EU) 2022/1307 of 22 July 2022 establishing a watch list of substances for Union-wide monitoring in the field of water policy pursuant to Directive 2008/105/EC of the European Parliament and of the Council (notified under document C(2022) 5098). Available at: http://data.europa.eu/eli/dec_impl/2022/1307/oj
23. European Commission (EC). Consolidated text: 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. Available at: http://data.europa.eu/eli/dir/2000/60/2014-11-20

Annex 1. Agenda of the country visit

DAY 1: Monday 10 June 2024		
08:30 – 09:15	**Opening meeting with national authorities and stakeholders** - Ministry of Health - Ministry of Agriculture, Forestry and Water Management - Ministry of Tourism, Ecology, Sustainable Development and Northern Region Development - Agency for Natural and Environmental Protection - National Committee for Antimicrobial Resistance Control (NIKRA) - Institute for Public Health of Montenegro - Clinical Centre of Montenegro - Administration for Food Safety, Veterinary and Phytosanitary affaires (AFSVPA) - Institute for Medicine and Medical Devices of Montenegro - Specialist Veterinary Laboratory - Representatives from regional hospital and primary healthcare centre. **Welcoming address from Institute of Public Health Montenegro** **Round table:** short presentation of participants **Presentation from ECDC, EFSA and DG SANTE** on the objectives of the visit, expected outputs and outcomes, and the One Health concept	**Location**: Institute of Public Health
09:15 – 12:45 11:00 – 11:15 Coffee break	**Meeting with the National Interdisciplinary Committee for Antimicrobial Resistance Control (NIKRA) on governance, surveillance and One Health aspects of AMR** **Objective:** gather information on the current situation of AMR governance and AMR surveillance strategies in Montenegro. **Presentations:** - National AMR strategy and its implementation in Montenegro and current policy and legislation - Monitoring AMR in human health - Monitoring AMR in animal health - Monitoring of antimicrobial use/consumption in human health - Monitoring of antimicrobial sales and use in animal health and foods - Laboratory capacity in human health, animal health and food safety - Antibiotic awareness activities. **Q&A session/discussion on:** - Intersectoral coordination mechanism (indicators in Section 1.1 of ECDC assessment tool) - National Action Plan (indicators in section 1.2) - Organised multidisciplinary collaboration at local level (indicators in Section 2) - Monitoring of AMR (indicators in section 4) and antimicrobial consumption (indicators in Section 5) - Clinical diagnostic and reference laboratory services (indicators in Section 3) - Public information and behavioural change interventions related to AMR (indicators in Section 9).	**Location**: same as above
12:45– 13:45	Lunch break	
13:45 – 14:15	**Meeting with the National Interdisciplinary Committee for Antimicrobial Resistance Control (NIKRA) on the environmental aspects of AMR in all sectors** **Presentations:** - Presentation from EFSA on environmental aspects of AMR - Presentation by the representative of the Agency for Natural and Environmental Protection - Environmental aspects of AMR surveillance/disposal of expired antimicrobials and veterinary medicinal products. **Discussion on:** - Environmental surveillance of AMR and residues of antimicrobials - EU harmonised monitoring of Watch list substances under the Water Framework Directive[3] - Policies for disposal of unused and expired medicines.	**Location**: same as above

[3] 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.

	Separate parallel meetings	
14:15 – 16:15 Same location but different rooms.	**ECDC team** **AMR in the human health sector - Antimicrobial stewardship and IPC** **Presentations:** - Clinical diagnostic and reference laboratory services in human health - Antimicrobial stewardship - Infection Prevention and Control (IPC) and HAI monitoring - Education about AMR in the curriculum of the Faculty of Medicine - Electronic surveillance of AMR in human health. **Discussions on:** - Antimicrobial stewardship and treatment guidelines (indicators in Section 6), - IPC (indicators in Section 7), - AMR and IPC education (indicators in Section 8) - Public information and behavioural change interventions related to AMR (indicators in Section 9).	**DG SANTE and EFSA team** **AMR in animals and food production** **Presentations:** - Overview of the farming sector structure - Veterinary model for veterinary care for food-producing animals and companion animals, including sales mechanism. **Q&A/discussion:** - Initiatives and guidelines to promote prudent/reduced use of antimicrobials - Organisation of official controls on the use of veterinary medicinal products - Authorized veterinary medicinal products and sales of antibiotics in farms in Montenegro; - Model for veterinary care for food-producing animals and companion animals.
15:45 – 16:30	Coffee break	
16:30 – 17:00	**Meeting with professional associations representatives and heads of chambers (ECDC team only)** **Presentation** (Participant introduction and brief presentation of their activity related to AMR) - Representatives from the Medical Chamber - Representative from the Association of General Practitioners - Representative from the Association of Paediatricians. **Discussion** on educational programmes and awareness campaigns, treatment guidelines, strategies and initiatives to reduce antimicrobial consumption/antibiotic stewardship.	**AMR in animals and food production** (Continued discussion)
17:00 – 17:30	**Discussion on consumption and reimbursement plan** - Representatives from the Pharmaceutical Chamber - Representatives from the National Healthcare Fund - Representative from the Chamber of commerce (Coordinating Board of Pharmaceutical and Medical Industry) - Representative from a wholesaler.	

DAY 2: Tuesday 11 June 2024		
Morning	**ECDC team** **Institute for Medicines and Medical Devices** **Discussions** on policy and regulation on antibiotic stewardship and AMC monitoring in the human health sector, marketing-related issues (indicators in section 10), current alignment plans with EU acquis and next steps	**DG SANTE and EFSA team** **Visit to the Administration for Food Safety, Veterinary and Phytosanitary affaires (AFSVPA)** **Presentations** EU harmonised AMR monitoring in zoonotic and commensal bacteria in certain food producing-animals and food (EFSA) AMR in clinical isolates from animals in Montenegro. Monitoring of AMR in food and food-producing animals in Montenegro. **Discussion on:** AMR surveillance and the potential for Montenegro to establish surveillance based on the EU model. Priority pathogens, active surveillance and passive surveillance.
	Institute of Public Health of Montenegro Visit to Centre for Prevention and Control of Disease Visit to a microbiology laboratory. Visit to the Centre for Hygiene and Environmental Health. **Discussions 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; Organised multidisciplinary collaboration at local level (indicators in Section 2).	
LUNCH	Lunch Break	
Afternoon	**ECDC team** **Hospital 1** **Introductory meetings** with the hospital director, managers and healthcare professionals from different wards/departments (surgery, adult, pediatric and neonatal ICU, oncology department, infectious diseases, IPC, microbiology laboratory and pharmacy). **Discussions on:** - antibiotic stewardship, - AMR prevention and control measures and related needs - HAI/IPC guidelines - How AMR is covered in curriculum of future healthcare workers - Sample transportation, time to microbiological results.	**DG SANTE and EFSA team** **Institute for Medicine and Medical Devices – CInMED** **Presentations:** - Regulation (EU) 2019/6 on veterinary medicinal products and implementing/delegated acts, key topics related to AMR (DG SANTE) - Marketing authorisations of veterinary medicines and import permits (CInMED) - Collection of data on sales (CInMED) - Activities on prudent use of antimicrobials (CInMED) - Collection of sales data for veterinary antimicrobials and of use data on antimicrobials in animals in the EU - experience from Spain (EU expert). **Discussions on:** - Enforcement of veterinary medicinal product control at borders - Marketing authorisation of veterinary medicines - Treatment guidelines - Whole sales data on veterinary medicinal products - Authorisation of premixture - Import permits issued by the institute.

<table>
<tr><th colspan="3">DAY 3: Wednesday 12 June 2024</th></tr>
<tr><td>Morning</td><td>ECDC team
Visit to Hospital 2

Discussion on antimicrobial stewardship, AMR prevention and control measures and related needs with hospital managers and healthcare professionals from different wards/departments (surgery, infectious diseases, IPC, microbiology laboratory and pharmacy).</td><td>DG SANTE and EFSA team
Visit to AFSVPA
Topic: Monitoring sales and use of antimicrobials in animals

Presentations
- Electronic surveillance system to collect usage data from veterinarians; (IT teams)
- Data on antimicrobial use in Montenegro
- FAO study on antibiotic use in livestock in Montenegro.

Discussion on:
- Regulation and guidelines for antimicrobial use in the veterinary/ animal health sector; food producing and companion animals;
- Authorised veterinary medicinal products in Montenegro;
- Treatment guidelines;
- Available data and analysis of antimicrobial sales and use by species;
- Access to antimicrobial drugs for animal keepers;
- Restrictions on using antimicrobials for prophylactics/metaphylactics.</td></tr>
<tr><td colspan="3">LUNCH</td></tr>
<tr><td rowspan="2">Afternoon</td><td rowspan="2">ECDC team

Visit to Hospital 3

Discussion about antimicrobial stewardship, AMR prevention and control measures and related needs with hospital managers and healthcare professionals from different wards/departments (surgery, infectiousdiseases, IPC, microbiology laboratory and pharmacy).</td><td>DG SANTE and EFSA team
Visit to AFSVPA
Topic: Measures to encourage prudent use of antimicrobials

Presentations
- EU Member State’s experience promoting prudent use of antimicrobials in animals
- Measures taken to encourage prudent use of antimicrobials in the veterinary sector in Montenegro, AFSVPA.

Discussions on
- Any measures taken to raise awareness of AMR among prescribers and animal keepers to encourage more prudent use of antimicrobials in production and companion animals;
- Discussion on the current EU veterinary medicinal product legislation and its AMR aspects (in terms of EU acquis).</td></tr>
<tr><td>Meeting with veterinary professional organisation(s), veterinary medicinal product stakeholders and farming associations of Montenegro

- Representatives of the Veterinary Chamber (livestock veterinarians and pet practitioners)
- Representatives of the Montenegro Association of Small Animal Practitioners
- Representative from a veterinary wholesaler
- Advisory services for animal production from the Ministry of Agriculture
- Associations of farmers (cluster of agricultural producers).</td></tr>
</table>

DAY 4: Thursday 13 June 2024		
Morning	**ECDC team** **Meeting with GPs at a primary healthcare centre in Podgorica** Discussion on prudent use/antimicrobial stewardship, AMR prevention and control measures and related needs. **Visit to a care home for the elderly in Podgorica** Discussion of prudent use/stewardship of antibiotics, AMR prevention and control measures and related needs.	**DG SANTE and EFSA team** **Visit to the Specialist Veterinary Laboratory (SVL)** **Objective:** Overview of bacteriology capacity for AMR testing; laboratory workforce; EUCAST standards for AST; quality management system and accreditation; data management; throughput of samples. **Discussion on:** - Diagnostic laboratory services and reference laboratory services - Official control plan with inspector responsible for sample collection.
LUNCH		
Afternoon	Visit team will prepare for the closing meeting/preliminary report preparation	

DAY 5: Friday 14 June 2024	
Morning	**Closing meeting with the national authorities at the Institute of Public Health, Montenegro:** - Ministry of Health/ Ministry of Agriculture, Natural Resources and Environment and relevant agencies and stakeholders - Technical experts from national institutions, including the members of NIKRA.

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

The following ECDC EAAD materials could be translated into Montenegrin language for use during national campaigns on prudent antimicrobial use in Montenegro:
(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.

European Centre for Disease Prevention and Control (ECDC)

Gustav III:s Boulevard 40
16973 Solna, Sweden

Tel. +46 858601000
ECDC.info@ecdc.europa.eu

www.ecdc.europa.eu

Follow ECDC on social media
Twitter: @ECDC_EU
Facebook: www.facebook.com/ECDC.EU
Linkedin: www.linkedin.com/company/ecdc/

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

Funded by the European Union

Publications Office of the European Union