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ECDC Meeting Report

International Relations Section/Director's Office

Regional workshop on a 'One-Health' approach to antimicrobial resistance in EU pre-accession countries

26–27 February 2019, Belgrade, Serbia

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Executive summary

In February 2019, a total of 44 participants with expertise in human and animal health from six Western Balkan countries, Turkey, four European Union (EU) and European Economic Area (EEA) countries, the European Commission, WHO's Regional Office for Europe, the European Centre for Disease Prevention and Control (ECDC) and the European Food Safety Authority (EFSA), gathered together for the first time. Their objectives were to:

- reflect on the work done by countries in prevention and control of antimicrobial resistance (AMR) since 2012;
- get an update on the new EU 'One-Health' action plan for AMR and related EU *acquis*
- share best practices from EU Member States and exchange experience on a 'One-Health' response to AMR in the areas of human and animal health and the environment;
- identify key priority areas that need to be addressed at regional level to advance with a 'One-Health' response to AMR[1].

The discussions among the 26 experts from the Western Balkan countries also aimed to promote a 'One-Health' response to antimicrobial resistance in the region and define key building blocks for multi-country 'One-Health' action against AMR with tangible, time-bound interventions to be financed by the EU.

The countries concerned have made progress and are currently at different levels of advancement in their national responses to AMR. It is now necessary to continue successful initiatives and embark on a next phase of accelerated activities using all available resources and partnerships at national and international levels.

A 'One-Health' conference among Western Balkan countries at governmental level, involving ministers of health, agriculture and the environment would send a strong message on the importance of joining forces to address AMR in a comprehensive manner. The conference conclusions would serve as a commitment by the ministers to common goals and would include a mechanism for following up on countries' progress towards their commitments after the conference.

Countries need to review and/or fully align their national legal framework to enable effective implementation of EU legislation relating to AMR and EU standards. Setting specific and measurable targets should be the basis for national strategies and action plans. Moreover, having regular information updates on AMR and antimicrobial consumption available would enable proper monitoring against targets.

Writing an annual joint 'One-Health' report on antimicrobial consumption and AMR in bacteria from food animals, foods, and humans represents an opportunity for each Western Balkan country to increase collaboration between the different sectors, analyse the information from available data and see how the data can be improved. It is also an opportunity to provide clear information to stakeholders and the media.

The capacity of microbiology laboratories to detect cases needs to be further developed, including improvement of laboratory testing methods and equipment, such as rapid diagnostic tests, antibiotics susceptibility testing (AST) or new technologies and bioinformatics.

Developing an electronic AMR surveillance system represents an opportunity for electronic and automatic reporting of standardised AMR data from clinical and veterinary laboratories. Electronic reporting of data would facilitate the notification of AMR cases to health authorities and the exchange of data between institutions in each country. EU support for digitalisation of laboratory data sharing system would be needed to ensure that IT infrastructure allows interconnectedness with epidemiological data and veterinary data for better information flows between sectors and public health fields, as well as between the countries in the region (and the EU).

There is a need at all levels for training on monitoring and surveillance of AMR, infection prevention and control, sample collection, microbiology laboratory data analysis, bioinformatics tools, providing feedback, and antibiotic stewardship programmes.

'One-Health' country visits to discuss AMR issues in each of the Western Balkan countries would help to identify gaps in the individual countries and support the development of roadmaps on AMR in different sectors: human health, animal health and patient safety.

[1] This activity was prepared with financial support from the European Union under ECDC grant - IPA5/2017/386-267

1. Background

EU candidate and potential candidate countries (Albania, Bosnia and Herzegovina, Kosovo[2], Montenegro, Serbia, North Macedonia, and Turkey) have been the focus of ECDC technical assistance to non-EU/EEA countries since 2008. During the ten years of ECDC cooperation and with financial support from the European Commission's Instrument of Pre-accession Assistance (IPA), experts from Western Balkan countries and Turkey have participated regularly, together with EU/EEA country experts, in ECDC technical discussions on various topics related to communicable disease prevention and control, including antimicrobial resistance (AMR), healthcare-associated infections (HAIs) and public health microbiology systems.

In 2011, at the request of the Commission, ECDC assessed country capacity in the area of communicable disease prevention and control in Montenegro (2013), Serbia (2013), Turkey (2015), North Macedonia (2016), and Albania (2017). The countries' compliance and implementation of EU legislation, and availability of human resources for this were assessed to draw up recommendations on the reforms needed to meet essential public health system requirements as part of the accession process. Antimicrobial resistance and hospital-associated infections (HAIs) were among the areas assessed as part of the review of vertical national disease programmes.

Similar to ECDC, EFSA has also been developing and implementing technical cooperation with the national food safety authorities of these countries on the food and feed safety issues coming under its remit as part of its pre-accession programme. EFSA is providing support for food safety scientific expertise capacity building; transfer of risk assessment and communication methodologies and harmonisation of national food safety data collections; the improvement of IPA countries' capacity to generate scientific advice and perform data analysis and preparedness for food safety crises and issues of mutual concern.

After the adoption of the European Strategic Action Plan on Antibiotic Resistance (2011–2020) by all 53 Member States of the WHO European Region, the WHO Regional Office for Europe coordinated the establishment of the Central Asian and Eastern European Surveillance of Antimicrobial Resistance (CAESAR) network in 2012. This network was set up to assist countries outside of the EU/EEA in establishing or strengthening national AMR surveillance. All Western Balkan countries and Turkey are part of the CAESAR network and report (with exception of Albania) their national AMR data from blood and cerebrospinal fluid samples for nine bacterial pathogens of public health and clinical importance. In addition to reporting AMR data to CAESAR, many countries are taking necessary steps to set up or strengthen their national comprehensive AMR surveillance systems, enabling them to obtain a better insight into the AMR situation in their country. Most of the countries are still facing many challenges, and strong political support is needed to continue making progress.

ECDC activities aimed at strengthening Western Balkan country capacity to implement the *EU acquis* on AMR acknowledge that these countries still need to (i) develop and reinforce high-level national strategies for AMR and HAIs, (ii) define and further strengthen functional systems for surveillance of AMR, antimicrobial consumption and HAIs based on EU standards and the functioning of national reference laboratories for AMR, including capacity of microbiology laboratories to detect cases and (iii) establish national inter-sectorial coordination mechanism to address AMR as part of a 'One-Health' approach.

EU strategic context

The new EU strategy for **A credible enlargement perspective for and enhanced EU engagement with the Western Balkans** confirms the European future of the region as a geostrategic investment in a stable, strong and united Europe based on common values. Applying EU rules and standards, not only in law but also in practice, remains a key priority in the enlargement process. Supporting socio-economic development, including investment in health to support social inclusion, is one of the six flagship initiatives set out in the strategy for EU's unprecedented support to the transformation process in the Western Balkans. The strategy spells out the need to develop the digital society in the Western Balkans, including the support to e-health services. A credible enlargement perspective, as part of a larger strategy to strengthen the Union by 2025, requires sustained efforts and irreversible reforms by the Western Balkans. For all the Western Balkan countries, progress along their respective EU paths will be at their own speed and will depend on the concrete results achieved.

In order to deliver long-lasting results and create the necessary impetus, it is important that the EU legislation concerning AMR (e.g. rules on AMR monitoring in food-producing animals and food, use of veterinary medicinal products and medicated feed) and related EU operational standards (e.g. harmonised outcome indicators to assist EU Member States in assessing their progress to reduce use of antimicrobials and antimicrobial resistance in both humans and food-producing animals) are properly implemented in the Member States. This includes implementation of the **new EU Action Plan against Antimicrobial Resistance**. The fourth pillar of this EU Action Plan (Shaping the global agenda) foresees support from the Commission – supported by EU agencies – to EU candidate and potential candidate countries benefitting from a pre-accession strategy in the alignment and implementation of EU legislation related to AMR.

[2] This designation is without prejudice to positions on status, and is in line with UNSCR 1244/1999 and the ICJ Opinion on the Kosovo declaration of independence

Objectives

The overall aim of the regional workshop was to encourage a 'One-Health' response to antimicrobial resistance in the Western Balkan countries and Turkey. More specifically, the objectives of the Regional workshop on a 'One-Health' approach to AMR were:

- to reflect on the work done by countries to prevent and control AMR since 2012, including programming the post-assessment national action plans;
- to get an update on the new EU 'One-Health' Action Plan against AMR and related EU *acquis*;
- to share Member State best practices and exchange experience on 'One-Health' responses to AMR in the areas of human health, animal health, and the environment;
- to identify key priority areas to be addressed at regional level to advance the 'One-Health' response to AMR.

It was anticipated that discussions at the regional workshop would define key building blocks and high-level commitment from the countries for a multi-country 'One-Health' project to counteract AMR in the Western Balkans with tangible, budgeted and time-bound interventions to be financed by the EU. The agenda of the regional workshop is available in Annex 1.

Participants

A total of 44 participants from six Western Balkan countries, Turkey, four EU and EEA countries, the European Commission, WHO's Regional Office for Europe, ECDC, and EFSA attended the regional workshop to discuss priorities for 'One-Health' responses to AMR in Europe and the Western Balkan countries.

In all, there were 26 experts in human and animal health from the Western Balkan countries with the following profiles:

- National ECDC correspondent or equivalent representing national policy and governance responsible for implementation of AMR strategy (ensuring a 'One-Health' approach) in the country
- Observer ECDC National Microbiology Focal Points or equivalent, involving leadership of national microbiology laboratory system supporting AMR monitoring (national reference laboratory for AMR);
- Observer ECDC National Surveillance Focal Points or equivalent, involving leadership of national communicable disease surveillance system, including surveillance of AMR and HAIs
- Observer to EFSA Advisory Forum or equivalent, involving management of national strategy against AMR in animal health and food production.

A list of participants is available in Annex 2.

2. Discussion

2.1 The new EU 'One-Health' Action Plan and priorities at Member State, EU, and global partner level

The presentations briefly summarised below are available via four web-stream recordings on EFSA's YouTube channel:

Part 1 Part 2 Part 3 Part 4

Status of implementation for the new EU 'One-Health' Action Plan against Antimicrobial Resistance

The EU has achieved several important milestones to reduce AMR in the EU Member States:

- In the area of animal health:
  - EU ban on antibiotics for growth promotion in livestock
  - Surveillance of AMR and antimicrobial consumption
  - Adopted EU law on veterinary medicinal products
  - Adopted animal health law
  - Harmonised monitoring of AMR in food and food-producing animals
  - Guidelines on prudent use of antimicrobials in veterinary medicine

- In the area of human health:
  - Strengthened surveillance of AMR and consumption of antimicrobials
  - Promoting appropriate and prudent use of antimicrobials by establishing guidelines on prudent use of antimicrobials in humans
  - Strengthening infection prevention and control
  - Antibiotic Awareness Day

- In the area of research and development:
  - Coordinating research collaboration
  - Seven projects to develop antibiotics, vaccines or alternative treatments ; EU and pharmaceutical industry
  - Establishment of pan-EU clinical trial network
  - Addressing new business models in antibiotic research.

A new European 'One-Health' Action Plan against Antimicrobial Resistance (June 2017) is underpinned by a 'One-Health' approach that addresses resistance in both humans and animals, and includes guidelines to promote prudent use of antimicrobials in both humans and animals. The plan foresees key actions to make the EU a best-practice region and this requires better evidence, coordination and surveillance, along with improved control measures. It is therefore imperative that countries establish, implement and monitor their national 'One-Health' action plans on AMR in line with the commitment they made at the 2015 World Health Assembly.

The new plan contains specific actions with EU added-value that the Commission will develop and strengthen as appropriate in the coming years for a more integrated, comprehensive and effective approach to combatting AMR at EU level. However, the actions on AMR have to be delivered at Member-State level, in hospitals, farms, clinics and laboratories by national professionals (e.g. doctors, veterinarians, farmers, pharmacists, nurses, managers, lawyers, pharmaceutical companies and investors.) The EU ensures strategic policy formulation, a legal basis, and coordination (e.g. Health Security Committee, AMR One-Health Network), funding (e.g. in the areas of research and agriculture, and through an external financial instrument IPA), technical support (ECDC, EFSA, European Medicines Agency (EMA) and European Environment Agency (EEA)), other non-legislative activities, such as partnerships with international organisations and other stakeholders.

The EU laws and *acquis* relevant to AMR include:

- Decision 1082/2013 on serious **cross-border threats to health**;
- Commission Implementing Decision (EU) 2017/253 of 13 February 2017 laying down procedures for the notification of alerts as part of the early warning and response system established in relation to serious cross-border threats to health and for the information exchange, consultation and coordination of responses to such threats pursuant to Decision No 1082/2013/EU of the European Parliament and of the Council;
- Commission Implementing Decision (EU) 2018/945 of 22 June 2018 on the communicable diseases and related special health issues to be covered by epidemiological surveillance as well as relevant case definitions;
- **(New) Regulation (EU) 2019/16 on veterinary medicinal products** (Dec 2018) which includes the power to reserve some antibiotics for human use only.
- **Water Framework Directive** – requirement to monitor five antibiotics in water.

The EU cooperates closely with WHO's Regional Office for Europe on AMR, with a three-year co-funding grant agreement (2018–2021).

Better Training for Safer Food (BTSF) is a Commission training initiative covering food and feed law, animal health and welfare and plant health rules. The initiative promotes a 'One-Health' approach focussing on surveillance, human and animal public health and consisting of three-day courses. EU pre-accession countries are also eligible.

The National Food Institute of Denmark has been appointed by the European Commission as an **EU Reference Laboratory for Antimicrobial Resistance** (EURL-AR) with the overall task of providing scientific advice to the Commission on matters relating to antimicrobial resistance.

A recent report by the Organisation for Economic Co-operation and Development (OECD) **'Stemming the Superbug Tide'** estimates that high AMR rates are projected to grow further and, if no effective action is taken, they will produce a significant health and economic burden in OECD and EU countries. This report reviews policies and identifies a set of 'best buys' to tackle AMR which, if scaled up to the national level, would provide an affordable and cost-effective instrument in the fight against AMR.

An **ECDC and OECD briefing note for EU/EEA countries** suggests that investing EUR 1.5 per capita per year in a comprehensive package of mixed public health interventions would avoid around 27 000 deaths per year in EU/EEA countries. In addition to saving lives, such a public health package could pay for itself within just one year and end up saving around EUR 1.4 billion per year in EU/EEA countries.

The Horizon 2020 work programme for 2018–2019 commits nearly EUR 200 million for research and innovation in the field of communicable diseases, allocating EUR 30 million to early detection of infectious diseases threats and resistant pathogens, EUR 10 million to HIV and TB and EUR 95 million to prevention, treatment and cure of infectious diseases. Through the Innovative Medicines Initiative (the world's biggest public–private partnership in the field of AMR with a budget of EUR 650 million), a number of major projects are devoted to the development of new antibiotics and new diagnostic methods, and this includes tackling obstacles to their adoption.

The Romanian EU Presidency set AMR and HAIs as a priority and held a ministerial 'One-Health' conference during the period 28 February to 1 March 2019. Council conclusions on AMR are expected in June 2019. There will be a global AMR conference in the Netherlands on 19–20 June 2019 and a workshop on AMR for European Neighbourhood Policy partner countries is planned for December 2019.

Overall in the EU/EEA, there has been a significant decrease in the use of antibiotics in animals (20% decline in sales of antibiotics during the period 2011–2016 in mg/PCU for 25 countries). However, the decrease in antibiotic use for humans has been much less significant (2013–2017) while at the same time there has been a rise in the number of deaths and disabilities resulting from AMR. Although there has been an increase in action at all levels, this needs to continue in the coming years if AMR issues are to be brought under control.

AMR and antimicrobial consumption in humans, animals and food at EU level

European Antimicrobial Resistance Surveillance Network (EARS-Net) is a network of representatives from clinical microbiological laboratories in EU/EEA countries collecting routine AMR data from invasive isolates (blood/cerebrospinal fluid). The network data collected includes eight bacteria of high public health importance for the EU/EEA, as well as more than 30 bacteria/antimicrobial group combinations under regular surveillance. ECDC supports countries to ensure high quality and network sustainability by means of:

- annual laboratory external quality assessments (EQA), also designed to estimate the comparability of the AST data and provide robust, transparent data on the overall data quality;
- detailed protocols and analysis plan;
- WHONET software support for national and laboratory level data extraction;
- fast feedback and dedicated support during data call.

EARS-Net outputs include enhanced annual surveillance report (including trends, country summaries, EAAD summary) and ECDC Surveillance Atlas.

EARS-Net outputs are also used for the ECDC/EFSA/EMA joint report on the integrated analysis of antimicrobial agent consumption and antimicrobial resistance in bacteria from humans and food-producing animals (known as JIACRA), as well as for WHO Global Antimicrobial Resistance Surveillance System (GLASS).

The overall objective of **European Surveillance of Antimicrobial Consumption Network (ESAC-Net)** is public access to EU/EEA reference data (analysis of trends) for monitoring progress on the prudent use of antimicrobials. ESAC-Net covers 30 EU/EEA countries and collects data on antimicrobial consumption of Anatomical Therapeutic Chemical (ATC) groups for systemic use from community and hospital sectors based on sales, reimbursement or/and both. The main indicator used by ESAC-Net is defined daily doses (DDDs) per 1 000 inhabitants per day. ESAC-Net outputs on antimicrobial consumption data with public access include:

- an annual epidemiological report
- a summary of annual data
- an annual surveillance report
- an antimicrobial consumption surveillance protocol.

ESAC-Net interactive database includes antimicrobial consumption data of 30 EU/EEA countries, seven selectable reports including country sheets, and indicator results (DDD per 1 000 inhabitants per day).

Monitoring and epidemiology of AMR in food-producing animals and food in the EU

EFSA is mandated to monitor and analyse the situation on antimicrobial resistance in food and animals across Europe. The EU legal framework includes:

- Directive 2003/99/EC on the monitoring of zoonoses and zoonotic agents (Art. 7(3) and 9(1) and Annexes II (B) IV);
- Commission Implementing Decision 2013/652/EU on the monitoring and reporting of antimicrobial resistance in zoonotic and commensal bacteria;
- EFSA technical documents:
  - Technical specifications on harmonised monitoring and reporting of AMR in *Salmonella, Campylobacter,* indicator commensal *E. coli* and *Enterococcus spp.* transmitted through food;
  - Technical specifications on harmonised monitoring and reporting of MRSA in food-producing animals and food;
  - Technical specifications on randomised sampling for harmonised monitoring of AMR in zoonotic and commensal bacteria.

The objectives of EFSA's EQA system is to detect any potential differences between laboratories relating to methods and interpretative criteria of resistance and to harmonise monitoring and enhance comparability of reported data. EFSA data collection activities are supported by:

- training courses to ensure knowledge transfer in the country, harmonise the reporting and encourage sharing of experiences;
- recommendations and follow-up steps to improve reporting systems, identify data sources and data providers and establish cooperation and communication.

Indicators for measuring progress in implementing action plans against AMR:

- AMR in bacteria from animals
  - Primary indicator: proportion of *E. coli* completely susceptible to antimicrobials tested in the EU monitoring* system (* all indicators are weighted for all food-producing animals (broilers, turkeys, pigs, calves);
  - Secondary indicators:
    - Proportion of samples containing ESBL-/AmpC-producing *E. coli**;
    - Proportion of *E. coli* resistant to three or more antimicrobial classes*;
    - Proportion of *E. coli* resistant to fluoroquinolones;
- Antimicrobial consumption in animals
  - Primary indicator: Overall sales of veterinary antimicrobials (in mg/PCU);
  - Secondary indicators:
    - Sales of third and fourth generation cephalosporins (in mg/PCU);
    - Sales of quinolones (in mg/PCU), specifying the proportion of fluoroquinolones;
    - Sales of polymyxins (in mg/PCU).

For the time being provision of data to the **European Surveillance of Veterinary Antimicrobial Consumption (ESVAC)** is voluntary, however the EU Regulation 2019/6 on veterinary medicinal products of 11 December 2018 (new) makes it mandatory. Article 57 makes it mandatory for the EU/EEA countries to provide data on sales and use by animal species to EMA (ESVAC). A delegating act will be developed on data requirements in order to ensure that standardised and harmonised data are provided by all countries.

A protocol developed by EMA with the involvement of stakeholders in EU/EEA Member States describes which antimicrobials are included in the current data collection[3] and which variables. Templates guide the web-based data collection of EMA for sales data and animal population data.

Sales data are provided in a number of packages sold for each product and calculated in a harmonised manner to be express as the weight of the active substance (tonnes; numerator is weight of active substance). As a denominator ESVAC uses a population correction unit (PCU) for the size of the food-producing animal population (including horses), as per PCU methodology defined by ESVAC/EMA.

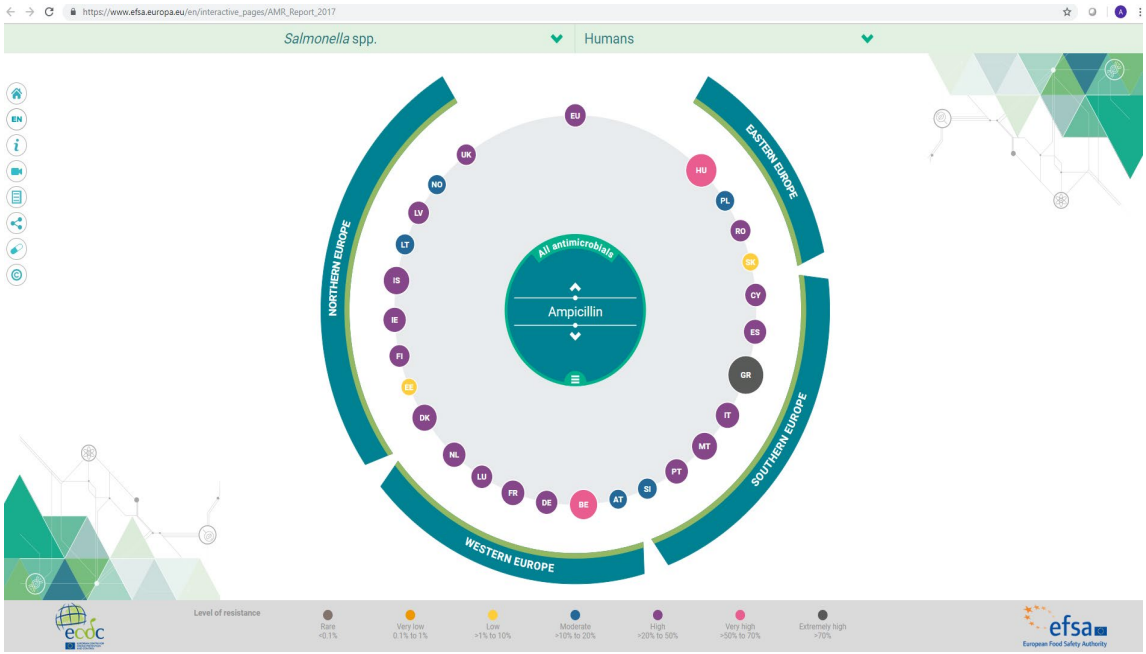
The European database for sales of veterinary antimicrobial agents provides public access to data collected by the European Surveillance of Veterinary Antimicrobial consumption (ESVAC) project on the sales of veterinary antimicrobials in EU/EEA countries.

Joint ECDC/EFSA/EMA activities on antimicrobial resistance (AMR)

The European Union summary report on AMR in zoonotic and indicator bacteria from humans, animals and food covers 'One-Health' monitoring of AMR in food-borne bacteria. Resistance in bacterial isolates of zoonotic *Salmonella* and *Campylobacter* from humans, animals and food, and resistance in indicator *Escherichia coli* as well as in methicillin-resistant *Staphylococcus aureus* from animals and food were addressed and analysed jointly by ECDC and EFSA. The ECDC/EFSA joint report is accompanied by a data visualisation tool, which displays data on antimicrobial resistance levels of some bacteria found in foods, animals and humans by country.

[3] growth promoters are not permitted in the EU

Figure 1. ECDC/EFSA data visualisation tool

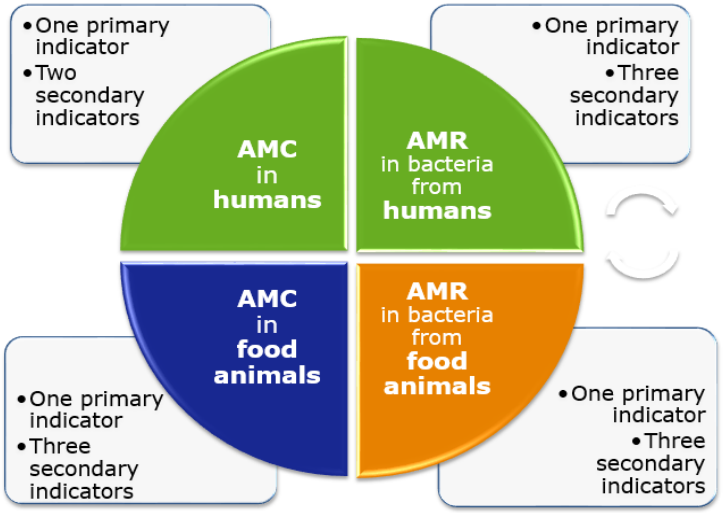


The Joint Interagency Antimicrobial Consumption and Resistance Analysis (JIACRA) reports provide an integrated analysis of relationships between antimicrobial consumption in human and veterinary medicine and the occurrence of AMR in bacteria from humans and food-producing animals. The first JIACRA report was released in January 2015, the second JIACRA report was published in July 2017 and the next JIACRA report is planned for December 2020. The purpose of the JIACRA reports is to:

- perform analysis on data from five EU-wide surveillance networks managed by the three agencies (ECDC, EFSA, EMA);
- assess the relationship between antimicrobial consumption and AMR in food-producing animals and humans;
- provide conclusions and recommendations from a 'One-Health' perspective based on the results of an integrated analysis of data (logistic regression and multivariate analysis).

In October 2017 ECDC, EFSA and EMA published a **joint scientific opinion on outcome indicators as regards surveillance of AMR and antimicrobial consumption in humans and food-producing animals** on established outcome indicators for the different sectors. This opinion provided an assessment of the situation regarding antimicrobial consumption and AMR at national level, and support for Member States in assessing their progress and the effectiveness of measures implemented to reduce antimicrobial consumption and AMR in both humans and food-producing animals. A total of 15 indicators are divided into primary indicators (4) for monitoring essential points and secondary indicators (11) for monitoring highly recommended points to assess progress in Member States' plans. The sets of indicators are suitable for estimating progress made in reducing AMR to key antimicrobials in accordance with definitions from the World Health Organization (WHO), the European Medicines Agency's Antimicrobial Advice Ad Hoc Expert Group (EMA AMEG) and the Organisation for Animal Health (OIE). The robust indicators were established taking into account a 'One-Health' approach to track and compare improvements in human and veterinary sectors. The selected indicators broadly reflected the situation concerning antimicrobial consumption and AMR, were based on data that had already been collected and were designed to remain relevant for at least five years. The 15 indicators relate to each of the four topics/sectors in Figure 2.

Figure 2. ECDC, EFSA and EMA outcome indicators relating to surveillance of antimicrobial resistance and antimicrobial consumption in humans and food-producing animals



The proposed indicators will summarise the overall AMR and antimicrobial consumption situation in humans and food-producing animals and serve as a tool for EU/EEA countries to assess their progress and possibly for risk managers to set targets as a complementary tool.

Comparisons on progress and any summarising of values must be undertaken with caution as information might not be complete. The indicators are often unsuitable for monitoring the effects of targeted interventions in a specific sector (e.g. in one animal species). In addition, with the exception of single indicators (e.g. Methicillin-resistant *Staphylococcus aureus* (MRSA) for AMR in humans), management decisions should never be based on these indicators alone, but should take into account the underlying data and results of the data analysis.

ECDC, EFSA, EMA are planning further integration of the AMR and antimicrobial consumption indicators into analyses and reports (ESAC-Net and ESVAC, EARS-Net and EU summary report on AMR) to ensure ongoing monitoring of AMR and antimicrobial consumption (trend analyses) in connection with the planned third JIACRA report in 2020. The agencies will continue to work together and contribute to scientific advice/scientific opinions/risk assessments.

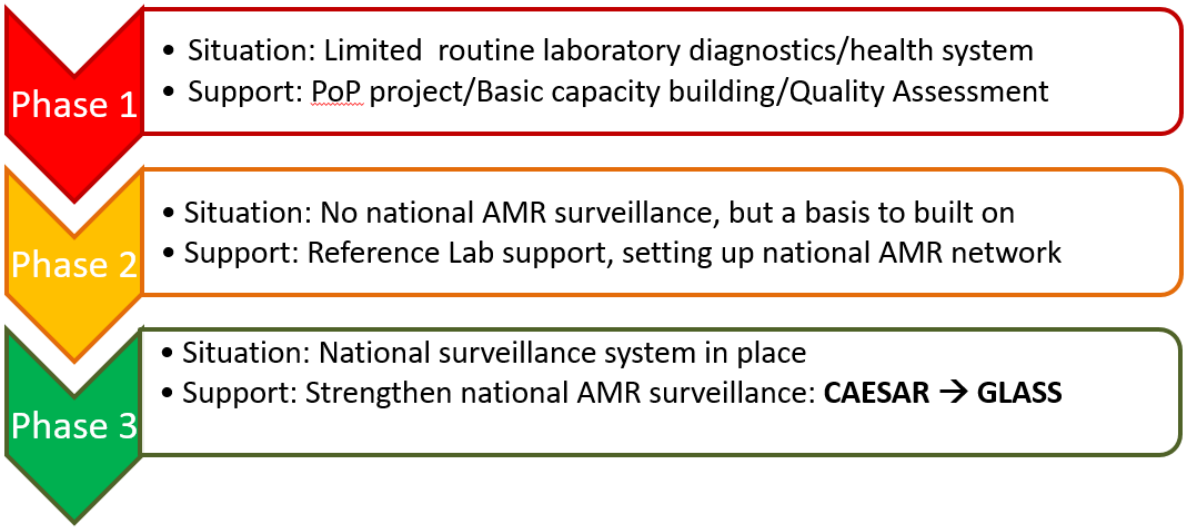
WHO supporting activities and the AMR epidemiological situation in the Western Balkans and Turkey

European strategic action plan on antibiotic resistance (2011–2020), adopted by all 53 Member States of the WHO European Region, recognises that AMR is neglected in many countries and that there is no systematic AMR surveillance in large parts of the European Region. Consequently, there is a need for inter-sectoral coordination, international standards and data sharing.

Implementation activities by WHO's Regional Office for Europe include:

- Country situation analysis (including debriefing at the Ministry of Health with observations from the country visits, recommendations, follow-up activities, and WHO commitment)
- Policy support
  - National stakeholder meetings
  - Intersect oral Coordination Mechanism
  - National AMR action plans
  - Evidence-informed policy briefs
  - Food and Agriculture Organization (FAO)/OIE/WHO 'One-Health' policy meetings.
- Resources, such as protocols, templates, tools, videos and consultants/experts
- Training/capacity building on antimicrobial stewardship, infection prevention and control, and Point Prevalence Studies
- Awareness and behaviour change campaigns
- Research/demonstration projects
- Surveillance network activities – Antimicrobial Medicines Consumption network (AMC, methodology compatible with ESAC-Net) and Central Asian and Eastern European Surveillance of Antimicrobial Resistance network (CAESAR, methodology compatible with EARS-Net).

Figure 3. National AMR surveillance development phases



CAESAR network activities include:

- strengthening national AMR reference laboratories
  - wet-lab/dry-lab training
  - quality control and management
  - introducing EUCAST methodology
  - introducing WHONet
  - supporting national laboratory network
  - feedback on submitted data
- data management and analysis training
- providing External Quality Assessments
- annual regional and national network meetings.

Launched in October 2015, the **Global Antimicrobial Resistance Surveillance System (GLASS)** aims to foster national AMR surveillance systems through harmonised global standards to monitor AMR trends, detect emerging resistance, and inform estimates of AMR burden. GLASS initially focused on surveillance data for the human priority bacterial pathogens considered to be the greatest threat globally. It then progressively incorporated information from other surveillance systems related to AMR in humans, such as foodborne AMR, monitoring of antimicrobial use and surveillance of infections associated with healthcare. As of 13 February 2019, 74 countries were enrolled in GLASS.

GLASS collects data on:

- status of national AMR surveillance system (indicators collected: overall coordination, surveillance system structure, and quality control);
- AMR data
  - specimens from patients suspected to have infections
  - priority specimens: blood, urine, stool, and cervical and urethral specimens
  - population data.

WHO notes that progress is being continuously made at regional and global levels for all strategic objectives of AMR, with broad collaboration and targeted support to countries via tools, materials, and technical expertise. WHO's Regional Office for Europe and ECDC work closely to support countries that are enrolled in GLASS and are submitting data to EARS-Net/CAESAR or ESAC-Net/AMC by submitting data to GLASS on their behalf to avoid double-reporting.

EU/EEA countries' experiences in implementing a 'One-Health' approach to respond to AMR: achievements, challenges, and lessons learned

Austria

An inter-sectoral coordination mechanism was set up in Austria in 2001, EU Zoonoses Directive 2003/99/EC entered into force and Austrian Zoonoses Law was adopted in 2005. A formal inter-ministerial AMR platform was established in 2008 following an ECDC assessment in 2007. After implementation of the 2014 National Action Plan for AMR, new plans on AMR and MRE were adopted in 2019. The 'all in one' structure is possible as all sectors (human, veterinary and food) are covered under one ministry and there is a long tradition of cooperation since the national authorities formalised the zoonoses platform. The EU Zoonoses Directive created a strong legal basis for structuring cooperation at national and federal state levels though a Zoonoses Commission whose primary task was to combat zoonoses. Austria has a very strong intersect oral group on AMR functioning under the auspices of the Federal Ministry of Labour, Social Affairs, Health and Consumer Protection.

There have been some important achievements on AMR in Austria:

- the National Action Plan on AMR established a strong basis for all actions in human, animal, and food sectors;
- there is a national digital reporting system of anonymised data on HAIs and AMR
- national standards for hospital hygiene are approved and are underway for antimicrobial stewardship programmes;
- annual reports on AMR, HAI, and antibiotic consumption; these reports present achievements expressed in numbers and agreed indicators – for example:
  - MRSA – 9.6 in 2013 to 5.9 in 2017; AT is within the lower third in comparison with the EU Member States
  - there are issues with gram-negative pathogens compared with EU averages
  - HAI situation is under or at EU level for all HAI-Net indicators
  - antibiotic consumption is steadily decreasing and Austria is in the lower third compared with the EU.

There are remaining challenges to be addressed, such as:

- decision-making at political, national and Federal State levels;
- legal basis for
  - HAI reporting of pseudonymised data;
  - AMR reporting of pseudonymised data;
  - antimicrobial consumption in hospitals;
  - linkage of prescription and therapy.
- inter-ministerial cooperation is functional but needs to be intensified and strengthened, as many activities are based on voluntary contributions by engaged experts and institutions;
- there are issues with EU data protection regulations.

Lessons learned:

- speak with the 'front-line workers' and academics;
- build communities by meeting and cooperating (face-to-face);
- actively involve all stakeholders;
- build regional cooperation;
- cooperate with WHO and ECDC and make use of their offers;
- adapt best practice models and do not 're-invent the wheel';
- start with a voluntary approach and then establish a legal basis;
- never give up.

Norway

The first reports on surveillance data covering both the animal- and human sectors were published as early as 2000. These reports, which applied a 'One-Health' concept, put together information from surveillance systems on:

- Use of antimicrobial agents
  - Use in animals
  - Use in humans
- Occurrence of AMR
  - Indicator bacteria from animals
  - Indicator bacteria from food
  - Zoonotic and non-zoonotic enteropathogenic bacteria
  - Human clinical isolates.

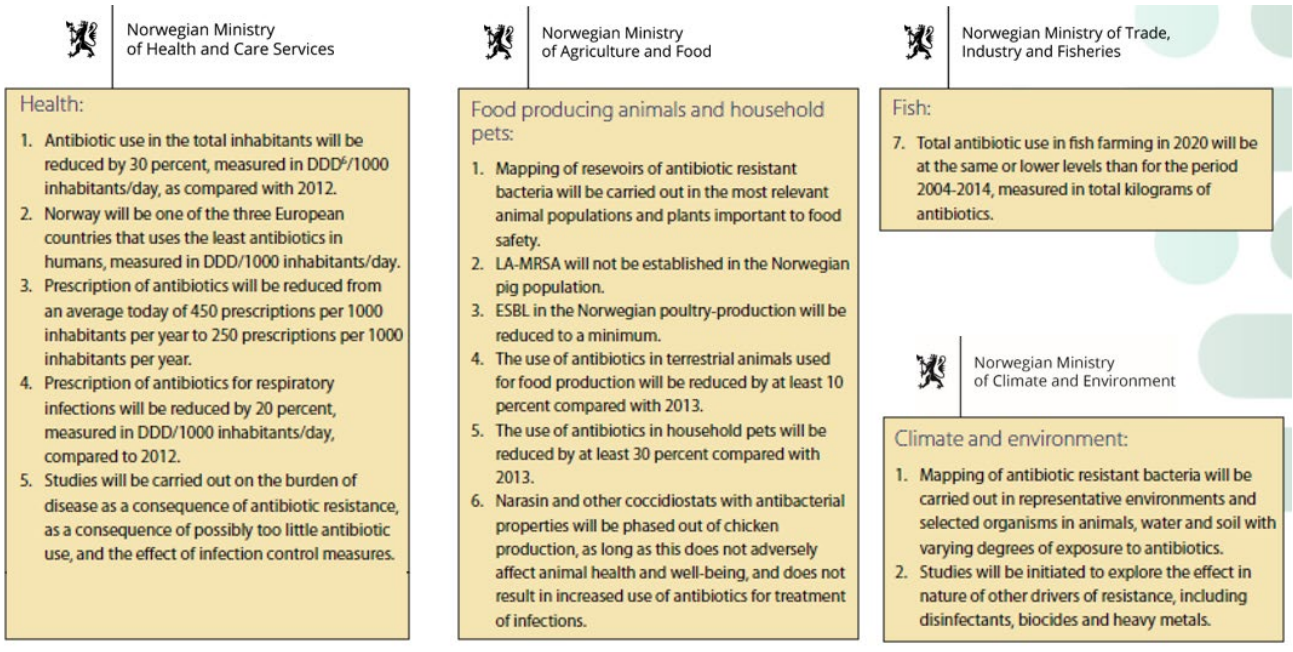
In Norway, the livestock industry phased out antimicrobial growth promoters in mid-1995 and this was followed by an action plan on AMR in the animal sector, which was published in 1996. This action plan provided therapeutic guidelines and set targets for reducing the use of antibiotics.

The first national strategy covering both the human and animal sector was adopted in 2000. The current national strategy against antibiotic resistance 2015–2020 has been approved at governmental level and aims to:

- Reduce the total use of antibiotics
- Encourage more appropriate use of antibiotics
- Improve knowledge of what drives the development and spread of antibiotic resistance
- Be a driver in international and normative work to improve access, responsible use and development of new antibiotics and vaccines and better diagnostic tools.

The current national AMR strategy, a joint strategy at ministry level, sets specific targets for different sectors. Its implementation is supported by action plans (e.g. for human health) which specify how the sector ministries will deliver their targets. For the animal sector an action plan has been established by the livestock industry. The mechanism of setting targets for aspects such as antimicrobial consumption in the animal and human sectors (followed by the implementation of measures in order to achieve the goals) has proven to be effective in Norway.

Figure 4. National AMR strategy Norway



One example of integrated 'One-Health' action on AMR is the prevention of the spread of livestock-associated MRSA. These actions were established after an outbreak of MRSA which was followed by a commitment from the authorities to eradicate the pathogen in the country. Veterinarians, food scientists and experts from public health institutes have worked closely together to establish and enforce the strategies for eradicating livestock-associated MRSA (LA-MRSA).

There is little data available on the occurrence of AMR in the environment in Norway, however some studies have been conducted in wild animals.

Risk assessments by the Norwegian Scientific Committee for Food and Environment are an important part of the collaborative efforts by different sectors to combat AMR and serve as an essential tool for decision makers.

Involvement of all relevant stakeholders has been very important in Norway. In the animal sector it has resulted in a reduction in the usage of antibiotics; the phasing out of antimicrobial growth promoters (1995); the phasing out of coccidiostat feed additives in broiler production (2016); eradication of MRSA in swine and a reduction in the prevalence of ESBL/AmpC in chickens.

Lessons learned

- Start small, think big!
- Set specific and measurable targets
- Combine top-down and bottom-up approaches
- Strong collaboration on specific activities across professions, competent authorities and other stakeholders
- Joint reporting of surveillance data can often be a 'low-hanging fruit'
- Build trust among stakeholders in government and industry
- Coordinate messaging and communication strategies to avoid conflict and misunderstanding.

Croatia

Within the remit of the Ministry of Agriculture, measures and programmes for animal and human health protection include:

- Measures for animal health protection from parasitic and infectious diseases and their financing (annually, based on the epidemiological situation, with the involvement of veterinary experts, covering significant animal diseases and zoonoses, financed by the state budget)
- Residue monitoring plan (food) in line with Commission Regulation No 37/2010
- Feed monitoring plan that includes antimicrobials – florfenicol, oxytetracycline, tylosin
- Food monitoring plan that includes AMR.

In Croatia, the Ministry of Agriculture participates in EFSA and EMA (ESVAC) activities and the Ministry of Health participates in the work of ECDC. The laboratory for general bacteriology and mycology, under the auspices of the Ministry of Agriculture, participates in the EURL-AR network and EFSA activities, including reporting AMR data, and using EFSA's technical specification and manuals for decision-making and improving laboratory capacities. The National Reference Laboratory for AMR Surveillance was appointed by the Ministry of Health to collect AMR data from clinical isolates, monitor resistance, standardise and interpret AST.

Data on antimicrobial consumption in veterinary medicine has been collected since 2014 and in 2018 Croatia reported sales data to ESVAC (EMA). Antimicrobial consumption in human medicine is monitored through the collection of wholesale and retail data and reported to ESAC-Net at ECDC. The inter-sectoral coordination body – ISKRA – was established by the Ministry of Health with the overall aim of tackling antibiotic resistance in Croatia and developing related national guidelines. The objectives of the current national programme for AMR monitoring 2015–2020 (Ministry of Health, Ministry of Agriculture) are:

- to improve and protect the health of the population by ensuring quality healthcare and preserving the efficacy of antimicrobials
- to monitor the use of antimicrobial drugs and antibiotic resistance in the field of human and veterinary medicine
- to increase awareness of the repercussions of excessive antimicrobial use
- to prevent and control the spread of infection
- to optimise the use of antimicrobial drugs in human and veterinary medicine
- to maintain strong international co-operation with institutions dealing with antibiotic resistance (ECDC, EFSA, WHO, OIE).

Within the Croatian Agency for Food and Agriculture a working group on zoonoses was established in 2014 engaging experts from the Ministry of Agriculture and Ministry of Health. The Institut Ruđer Bošković (the Laboratory for Environmental Microbiology and Biotechnology) analyses antimicrobial resistance in the environment. There are currently three research projects on antibiotic resistance - in wastewater from the pharmaceutical industry, linkage of environmental contamination to antibiotic resistance in humans and biodegradation of macrolide antibiotic azithromycin.

2.2 Gaps, challenges and priorities in Western Balkan countries

State-of-play on implementation of *EU AMR acquis* and related standards in Western Balkan countries after the regional meeting in Dubrovnik in 2012 and the subsequent EU assessments

On 27–29 June 2012 in Dubrovnik, Croatia, ECDC organised a meeting entitled **Strengthening regional antimicrobial resistance and healthcare-associated infection surveillance and networking in the EU enlargement countries.** The objectives of the meeting were:

- to increase understanding of the activities of ECDC's Antimicrobial Resistance and Healthcare-Associated Infections (ARHAI) disease programme, including related EU acquis, EU practices and the standards of EU surveillance networks (EARS-Net, ESAC-Net, HAI-Net, the ECDC point prevalence survey on HAIs and antimicrobial use), as well as knowledge of European Antibiotics Awareness Day (EAAD) and e-Bug
- to share experiences and best practices on AMR and HAI surveillance, prevention and control
- to help build stronger networks of experts
- to initiate mapping of surveillance capacity for AMR, antimicrobial consumption and HAI.

The meeting highlighted different levels of capacity to implement the *EU acquis* on AMR and ECDC requirements for participating in ECDC surveillance activities on AMR, antimicrobial consumption, and HAI. The short-term perspectives were identified only for Croatia and Turkey. Other Western Balkan countries were facing urgent challenges and barriers to developing their capacity and resources in order to take effective national measures to ensure progress in implementing key AMR control policies. The majority of the EU candidate and potential candidate countries (notably Western Balkan countries) had yet to develop and implement their national legislative frameworks, action plans, and surveillance networks.

Table 1. Country perspectives for participation in ECDC activities in the area of AMR and HAIs in 2012

	EARS-Net			ESAC-Net			HAI-Net		
	Participation perspective	Challenges	Common challenges	Participation perspective	Challenges	Common challenges	Participation perspective	Challenges	Common challenges
North Macedonia	Long-term	Establish AMR surveillance network; compatibility of the data with EARS-Net	• Identification of the central laboratory / institution responsible for standardization of AST, data collection, data analysis, retesting, EQAS • Lack of manpower and financial support • Development of IT support • Attracting laboratories to participate in the network† • More government involvement	Long-term	• Lack of legal framework and financial support • Lack of formal mechanism for data collection • Insufficient human resources	• Access to and validation of data • Lack of financial resources • Lack of human resources • Need for strengthened political support and better coordination and interaction between national surveillance teams and political authorities	Long-term	• Professional training in prevention and control of HAI • Implement ECDC methodologies of surveillance of HAI	• Limited financial resources • Stakeholders commitment • Shortage of trained staff • Implementation of legislation • Infrastructure • Decreasing enthusiasm in data collection • Coordination and collaboration
Montenegro	Long-term	Establish AMR surveillance network		Long-term	Improvement of information system		No information	No information	
Serbia	Long-term	Establish ICM - national strategy; standardisation of laboratory testing and attracting more laboratories		Long-term	• Private practices not yet in the health care system • No national team for data collection		Short-term	• Professional training in prevention and control of HAI • Improvement of legislative basis	
Turkey	Immediate	Human resources and re-organisation of the public health authority		Short-term	Lack of human resources and re-organisation of national public health authority		Immediate	Translation into national language	
Albania	Long-term	Establish AMR surveillance network		No information	No information		No information	No information	
Kosovo	Long-term	Establish AMR surveillance network		Long-term	• Lack of IT systems • No national team for data collection		Short-term	Implement ECDC methodology of HAI surveillance	
Bosnia and Herzegovina	Long-term	Establish AMR surveillance network		Long-term	• No register of pharmacies and hospitals at national level • No national team for data collection		No information	No information	

Certain developments and progress have been made by countries and key international partners since 2012:

- WHO's Regional Office for Europe has established the CAESAR network
  - to support countries in setting up and strengthening national AMR surveillance
  - CAESAR methodology is compatible with ECDC-administered surveillance of AMR (i.e. EARS-Net)
  - AMR data was reported to CAESAR in 2018 by Bosnia and Herzegovina, Kosovo, North Macedonia, Serbia, Turkey and Montenegro (Albania did not report).
- WHO's Regional Office for Europe has initiated the WHO Antimicrobial Medicines Consumption network (WHO AMC)
  - to support countries in collecting antimicrobial use data
  - using AMC methodology compatible with ECDC-administered surveillance of AMR - i.e. ESAC-Net
  - using AMC data reported to WHO AMC in 2018 by Albania, Bosnia and Herzegovina, Kosovo, Montenegro, Serbia, and Turkey).

- ECDC pre-accession technical cooperation and support included:
  - participation of experts from Western Balkan countries in technical ECDC meetings on AMR and HAIs (81 participants during the period 2013–2018);
  - an offer to participate in EU-level point prevalence surveys on HAIs and antimicrobial use (only Serbia and North Macedonia attempted this);
  - an EULabCap survey (six countries participated) indicated the low level of public health microbiology system capability/capacity in all Western Balkan countries except Serbia and North Macedonia;
  - Antimicrobial Susceptibility Testing EQA schemes for certain pathogens.
- ECDC/European Commission assessments of communicable disease surveillance and control systems were carried out in Montenegro and Serbia in 2013, Turkey in 2015, North Macedonia in 2016, and Albania in 2017, and Kosovo in 2018. The technical assessment covers six areas: health governance; human resource capacity development; surveillance and control; preparedness and response; public health microbiology and national disease programmes, including AMR and HAIs.

The assessments, in particular those of the Western Balkan countries, suggest the following common needs in the region:

- to develop and reinforce high-level national strategies for AMR and HAIs;
- to define and further strengthen functional systems for surveillance of AMR, antimicrobial consumption and HAIs based on EU standards and the operational functioning of national reference laboratories for AMR, including the capacity of microbiology laboratories to detect cases
- to establish and operationalise a national inter-sectorial coordination mechanism to address AMR in the framework of a 'One-Health' approach.

EULabCap survey results with 2017 data suggest low but gradually increasing levels of public health microbiology capabilities and capacities.

Figure 5. EULabCap survey results – 2017 data

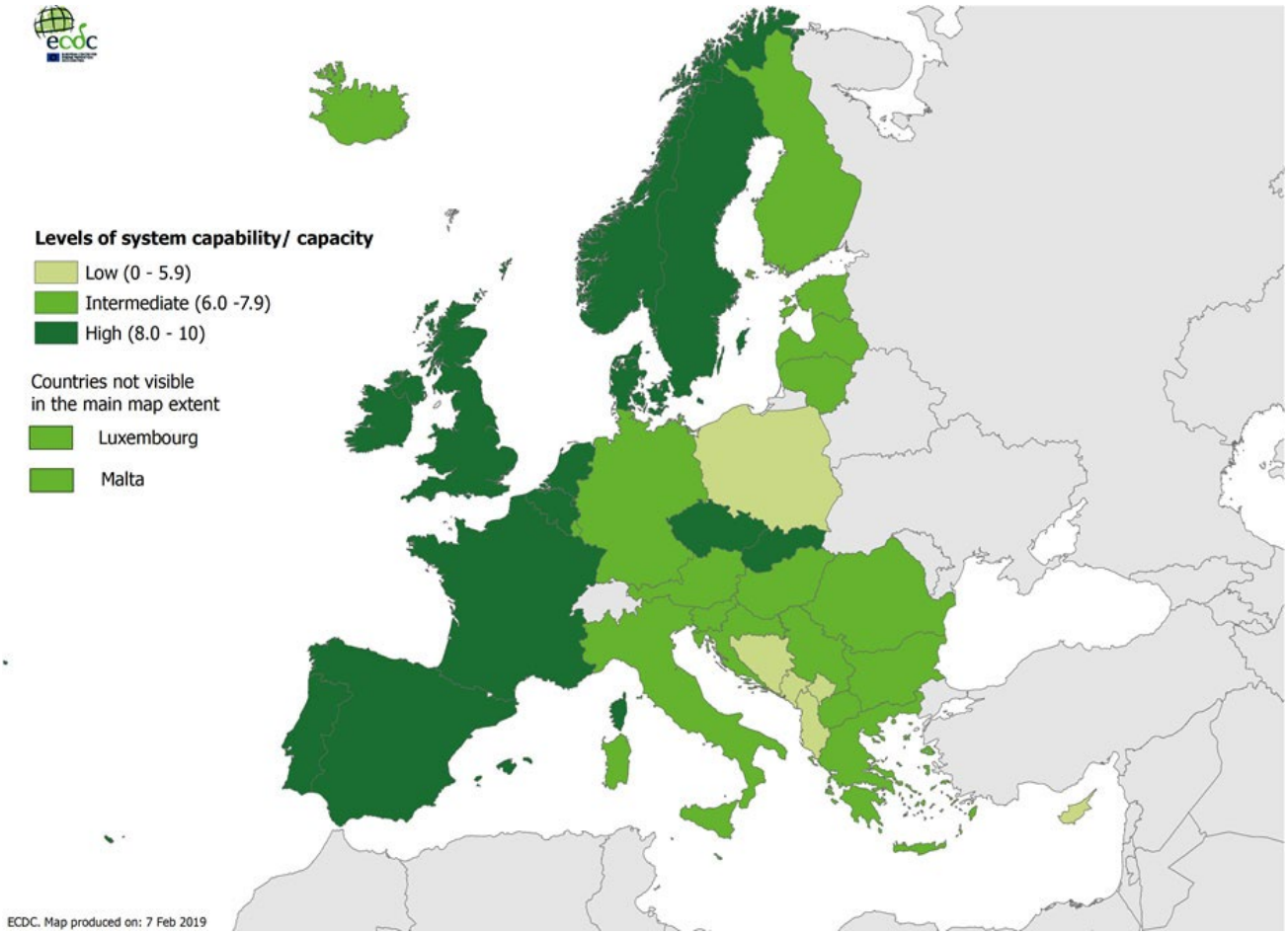
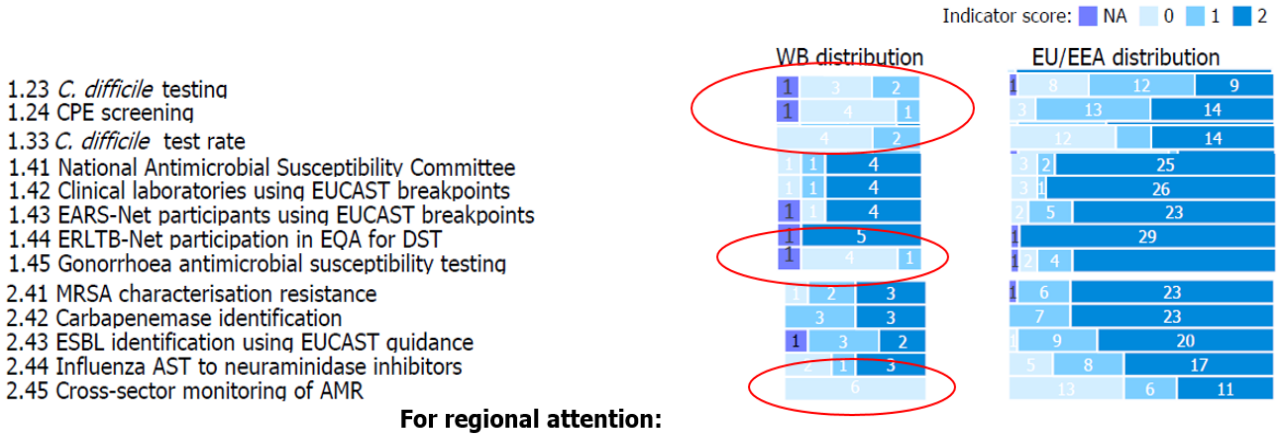


Figure 6. Distribution of selected indicators for West Balkan countries in 2017 and EU/EEA countries in 2016 (EULabCap)



For regional attention:

- Clinical practice and improved utilisation of diagnostic testing C.difficile testing
- Carbapenemase-producing *Enterobacteriaceae* screening
- AST for gonorrhoea
- Cross-sector monitoring of AMR in human and annual bacterial isolates

Low, 0 'No or limited capability/capacity'; Intermediate, 1 'Partial capability/capacity'; High, 2 'Complete capability/capacity' – i.e. EU target reached.

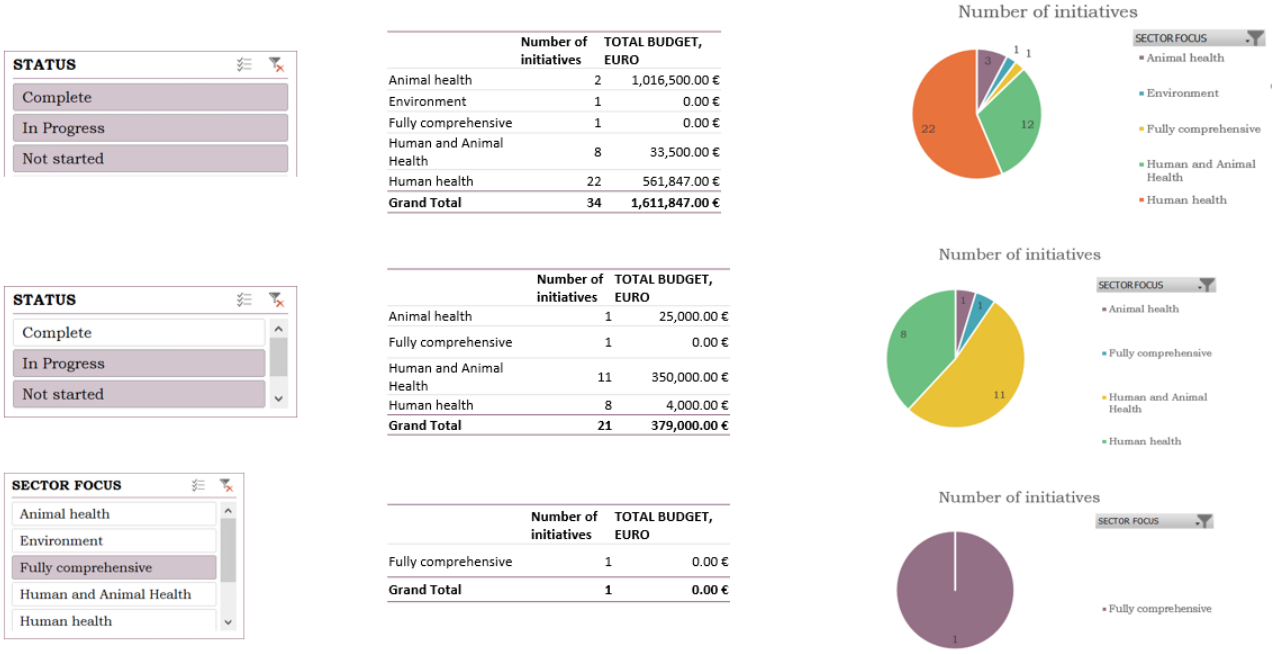
Together with Observer National Microbiology Focal Points (NMFPs) in the Western Balkan countries, ECDC has discussed the importance of investments made as IPA preparatory measures to support countries' public health microbiology systems in an article entitled **Investing in Public Health Microbiology Laboratories in Western Balkan Countries Enhances Health Security From Communicable Disease Threats in Europe**. The in-depth analysis of information on countries' capacities in communicable disease prevention and control suggests that:

- there is an urgent need for Western Balkan countries to improve their public health microbiology systems before they join the EU to guarantee optimal outbreak detection, control measures, and patient management;
- under a 'One-Health' approach, whereby human, animal, and environmental health are considered together, combining advanced technologies in laboratory diagnostics and epidemiology could have the potential to improve public health (e.g. in settings lacking robust laboratory capacity);
- there is a clear case to be made for integrating improvement of laboratory capacities and capabilities for more effective pathogen detection, characterisation and control in regional investment to boost a 'One-Health' approach to tackling AMR in Western Balkan countries;
- bilateral and multilateral cooperation in the region of all EU pre-accession countries, coordinated activities with WHO's Regional Office for Europe, technical cooperation between the competent institutions of EU Member States and Western Balkan countries, and the use of available expertise in the adjoining countries is imperative for the enhancement of health security to counteract communicable disease threats in Europe.

Before the ECDC/EFSA regional workshop ECDC asked countries to map their complete, ongoing, and planned 'One-Health' initiatives in the area of AMR. The information collected demonstrates that:

- there are a number of completed, ongoing and planned initiatives in the countries and most of them relate to human health;
- the majority of the ongoing and planned initiatives receive less financial support, but more often cover combined human and animal health;
- there are no initiatives planned or budgeted covering a complete 'One-Health' approach (only the Kosovo National Action Plan was reported as fully comprehensive.

Figure 7. Complete, ongoing and planned 'One-Health' initiatives to combat AMR



No initiatives reported by Albania or Montenegro.

Given that some countries have made greater progress than others and all are currently at different levels of advancement, there are still missing elements for the provision of effective AMR responses across sectors at strategic, systems, and operational levels. Sustainability, including the maintenance of sufficient trained personnel, is an issue and a fully comprehensive approach is not yet ensured in the Western Balkan region.

Key developments, challenges and national priorities on 'One-Health' responses to AMR in Western Balkan countries

Prior to the workshop countries were offered an opportunity to send their country overview to ECDC in a structured format as a country poster. The interactive session with country posters provided an overview for each country, covering public health, animal health, and food safety. The posters detailed key recent developments, remaining challenges, and national priorities in 'One-Health' responses to AMR in a comparable manner. Country posters are available in Annex 3 of this report.

2.3 Group discussion on regional joint action for a 'One-Health' approach to AMR in Western Balkan countries

Methodology

The overall objective of the group discussions was to initiate the development of joint regional action for a 'One-Health' approach to AMR in the Western Balkan countries. It is expected that such large-scale regional action would strengthen 'One-Health' surveillance and reporting of AMR and antimicrobial use, increase awareness and understanding, improve coordination among countries' in their 'One-Health' responses to AMR, advance implementation of EU rules, and enhance prevention and control of AMR. The group discussion aimed to define key building blocks to establish a possible budgeted regional joint action for a 'One-Health' approach to AMR in Western Balkan countries.

To achieve this objective, participants were divided into five groups and invited to discuss the five questions one by one. The participants discussed one of the five questions for 20 minutes at their assigned table and then passed the envelope with the question and their answers to the next group. After all five groups had discussed the answers to all five questions, the list of possible regional actions was presented in the plenary. The inputs resulting from the group discussions provided a good basis for the technical description of the regional joint action for the Western Balkan countries. Each pair of facilitators were assigned one question, which they kept for all five groups.

Table 2. Details of questions, groups and facilitators

Question	Facilitators	Starting group
Q1	Dominique L. Monnet (ECDC) and Pierre-Alexandre Beloeil (EFSA)	Group A
Q2	Gunnar Skov Simonsen (NO) and Gordan Kompes (HR)	Group M
Q3	Charles Price (DG SANTE) and Kari Grave (ESVAC)	Group R
Q4	Tommi Kärki (ECDC) and Gerhard Steffes (DG SANTE)	Group W
Q5	Maarit Kokki (ECDC) and Danilo Lo Fo Wong (WHO Regional Office for Europe)	Group B

The envelopes and the paper for questions were labelled with different colours to distinguish areas covered by *EU acquis* and EU law:

- Blue – EU acquis on AMR (e.g. Decision of the European Parliament and of the Council)
- Yellow – EU law on implementation of AMR acquis (e.g. Council Recommendation, Commission Notice).

Q1. Please identify how the EU could support your countries to reach EU acquis on:

- surveillance of AMR in bacteria from humans,
- surveillance of AMR in bacteria from animals and food.

1) Establish national reference functions for AMR

There is an opportunity for strengthening and reorganising national reference laboratories/functions on AMR, both for human health and animal health (food animals and foods). The term 'AMR reference function' may be more correct than 'AMR national reference laboratory' since, in small countries, some laboratories may perform other functions while still serving as a national reference.

One single AMR reference laboratory covering all sectors may not be possible, thus two separate AMR reference laboratories, one for human health and one for animal health may be a more feasible option. In this case there should be a mechanism to ensure close collaboration between these two laboratories to avoid duplication of efforts and analyses.

Another model that was discussed was a regional AMR reference laboratory for the Western Balkans. However, in this case sending samples across borders might be difficult and costly.

2) Capacity building for local clinical microbiology

For human health, surveillance of AMR is not possible without quality data from local clinical microbiology laboratories. It is essential to ensure that such data are available to enable capacity building for clinical microbiology, and in particular microbiology diagnostics, species identification, and antimicrobial susceptibility testing.

The current momentum on AMR activities represents an opportunity for developing clinical microbiology services in general.

3) Training

Training on the monitoring and surveillance of AMR was identified as an important element, possibly covering areas such as:

- how to set up a national AMR reference laboratory/function;
- how to take samples (i.e. apply the EU protocol for AMR monitoring in food animals);
- how to improve the frequency of clinical samples in hospitalised patients;
- how to build a surveillance/monitoring system (representativeness, etc.);
- how to make sense of AMR surveillance data (epidemiology, trend analyses, etc.)

The first training would most probably involve national professionals with a certain level of experience or even expertise who could themselves become trainers. Subsequent trainings would gradually involve less experienced professionals. These courses should be implemented at all levels (national, regional, local), and if possible from a one-health perspective to foster the collaboration between sectors.

The impact of implementing these activities should subsequently be evaluated in each country.

4) One-health AMR surveillance reports, at country level

Writing an annual joint one-health report on antimicrobial consumption and AMR in bacteria from food animals, foods and humans represents an opportunity for each Western Balkan country to increase collaboration between different sectors, learn from available data and how they can be improved, and provide clear information to stakeholders and the media.

The EU could help by providing an outline, and even a standard template for this type of one-health report.

5) Develop electronic surveillance of AMR, in each country

Developing an electronic AMR surveillance system represents an opportunity for electronic and automatic reporting of standardised AMR data from clinical and veterinary laboratories (as opposed to extracting data to a file and sending this file to the national surveillance system).

Electronic reporting of data would facilitate notification of AMR cases to health authorities as well as the exchange of data between institutions in each country. The EU could help by providing a standard (generic) AMR surveillance tool to facilitate data extraction, standardisation, analysis and reporting. This could then be adapted by each Western Balkan country (e.g. for data extraction, reporting and layout.)

6) Monitoring of AMR in bacteria from food animals

There is a need to monitor AMR in *Salmonella* spp./*Campylobacter* spp./indicator *E. coli* and monitor AMR in animal pathogens. These two monitoring systems should be built simultaneously (rather than consecutively) to make sure that they are fully compatible.

7) Surveillance of AMR in the environment

This should be implemented, most probably not immediately but as the start of a time-limited project.

8) Ministerial 'One-Health' conference on AMR in the Western Balkans

Organising a 'One-Health' conference, involving the ministers of health, agriculture and the environment of each country would send a strong message from the European Commission. The conference should involve both Ministers (or high-level ministerial representatives) and experts/technical participants. Ideally, the conference should end with a set of conclusions and a commitment by the Ministers to common goals.

Finally, there should be a mechanism for following-up the countries' progress towards their commitments.

9) 'On-Health' country visits to discuss AMR issues in each country

There should be 'One-Health' country visits on AMR to each of the Western Balkan countries.

There may be an issue if animal health matters are discussed with colleagues from the Directorate General for Health and Food Safety (DG SANTE)/F and these colleagues are perceived to be 'EU auditors' since, for animal health, the conclusions of the visit may have (or be perceived as having) consequences on the export of food to/from the country to the EU. If difficulties arise, one solution may be to keep the country visit reports confidential, although this would not be ideal. Another solution would be that the European Commission is represented by a Unit other than DG SANTE/F.

There should be a mechanism for following up the implementation of recommendations with each individual country, after the country visit.

10) Annual 'One-Health' meeting on AMR in the Western Balkans

There is a value in organising a meeting of this type with representatives and experts from Western Balkan countries. Such a meeting/workshop should be organised every year, and possibly back-to-back with training sessions on various relevant topics (two consecutive days).

After Belgrade, the meeting should rotate between the countries' capitals, starting with Skopje and Tirana, which may be more accessible to all participants. Another possibility, some participants thought, could be to have sub-regional (rather than regional) meetings so more participants from a smaller number of Western Balkan countries could participate in each meeting/workshop/training session.

Finally, ECDC should strive to have an equal number of representatives (governmental and non-governmental) from human and animal health representing each country and, if possible, also participants representing agriculture/phytosanitary controls and the environment.

Q2. Please identify the three most important elements the EU could contribute to support the improvement of microbiology laboratory capacities in your countries for collecting/taking and analysing clinical microbiology samples, including antimicrobial susceptibility testing (the overall aim of improving laboratory capacity is that laboratory results will be used more effectively).

1) Strengthening laboratories

Microbiology laboratory testing methods and equipment should be improved in the majority of countries, including utilisation of rapid diagnostic tests. There is a need to increase the number of laboratory staff and maintain additional human resources to address the current lack of microbiologists. Improvement of regional laboratories for reference functions should also be considered.

2) Quality system

Written procedures, including national standards and guidelines on sampling and transportation of samples, are missing in many countries and this hampers the delivery of effective microbiology laboratory services. There is a lack of harmonised guidelines that would be applicable for all laboratories. Implementation of a quality assurance system is required, along with a system for accreditation and external quality control which includes regional laboratories..

3) Training at all levels

Countries need capacity strengthening for doctors in relation to sample collection and training of laboratory staff on data analysis and how to provide feedback. It is important to build and provide training courses on whole genome sequencing (WGS), WGS technology and applications, and bio-informatic tools. It is essential that professionals are able to analyse the data and apply it to surveillance of bacteria, including species identification, typing and characterisation of antimicrobial resistance.

Other regional needs identified were: training of epidemiologists in the analysis of laboratory information; training of laboratory staff on new tools and methods; sampling training for laboratory staff and improving sensitisation of hospital staff. Moreover, AMR programmes are not available in veterinary medicine.

4) Stakeholders' involvement

Involvement of clinicians is essential, as if clinicians are not taking samples from patients, there will be no samples, no isolates for microbiology diagnostics and identification and no antimicrobial susceptibility testing. Conducting a cost-benefit analysis might provide country policy makers with evidence confirming that it is more expensive not to take samples than do so.

5) IT system

There is a need to address the issue of data sharing/flow between clinicians and microbiology laboratories in all countries. Electronic information systems that are interconnected with epidemiological data and veterinary data need to be built for

the laboratories. Information systems should allow relevant information to be shared between other systems and enable operational laboratory networking. EU could support Western Balkan countries through provision of IT infrastructure for better information flows between sectors and public health fields.

6) Government commitment

EU could facilitate the commitment of countries' at government level to delivering results and prioritising budget to the areas that need to be addressed immediately. AMR frameworks need to be put high on the political agenda of Western Balkan countries, including better policies, budgeted action plans and delivery to meet targets.

Q3. Please list what would be needed to make the data on antimicrobial consumption in humans and in animals useful for improving prescription practices. What would be needed to effectively implement the EU Guidelines for the prudent use of antimicrobials in human health and the Guidelines for the prudent use of antimicrobials in veterinary medicine in the country?

1) Collection and reporting data on surveillance of antimicrobial consumption in humans in the community, in hospitalised patients and in animals

Some countries need to draft legislation on prescriptions in veterinary medicine. Probably all Western Balkan countries need to conduct analysis and assessment on the distribution of antimicrobials/drug supply chains to better understand the state-of-play.

Study visits to exchange experience and best practices would be needed (within Western Balkan countries and in the EU). This could be supported by conducting workshops for Western Balkan countries on legislation and application of EU law into national legal frameworks. Implementation of the new EU law on veterinary medicines is a challenge in all countries – there is a need for a national legal framework before it can be implemented.

The region should modernise collection of the antimicrobial consumption data and there is a need for standardised methodology (protocols, training programmes) for the implementation of antimicrobial consumption surveillance, particularly in the veterinary sector. In connection with this, infrastructure and human resources remain as issues.

Information technology should be used to implement electronic prescriptions (in some countries) and electronic systems for collection and analysis of data; electronic prescribing for veterinary medicine and humans.

Reporting of data to ECDC/EFSA/EMA should become a routine.

2) Using data to make a change, using antimicrobial consumption data to improve the national practices

- Analysing data and providing feedback to prescribers
- Improving access to data
- Organising stakeholder meetings
- Carrying out a study on cross-border trade of antimicrobials in veterinary and human medicine
- Organising training workshops, including a series of training courses on surveillance at the technical level
- Awareness-raising, including awareness-raising campaigns throughout the region.

3) Implementation of guidelines

Development and implementation of national guidelines for antimicrobial prescription should include:

- meetings/workshops to review and adapt national guidelines through analysis of national antimicrobial consumption data
- applying guidelines nationally
- developing schemes (e.g. incentives) or tools for the implementation of guidelines to ensure they are followed and effective.

Audits in hospitals to assess how guidelines are being implemented and surveys on audit implementation at community level were seen as a useful means for ensuring implementation of guidelines.

Expert support would be needed for guideline development or definition of rules on prudent use of antimicrobials. In addition, training on prudent use of antimicrobials in human health and in veterinary medicine could be provided in the form of expert workshops and meetings to exchange experience and practices. Stewardship in hospitals is limited in all countries.

Q4. What is needed to effectively implement infection prevention and control (hospital hygiene) practices in all hospitals and other healthcare settings?

1) National action plan and strategy

A national action plan is needed to effectively implement infection prevention and control (IPC). The plan should define clear roles and responsibilities for implementation, monitoring and reporting, both for the inter-sectoral coordination committee and in hospitals. Drafting and implementing action plans at hospital level might also be beneficial, with a clear framework for monitoring, auditing and reporting. A specialised IPC budget should also be allocated.

2) Legal framework for IPC

It is important to formally nominate infection prevention and control staff and formalise Infection Control Committees (ICC). The legal framework should also include directives from the ministries that hospital should have IPC staff and infection control practices in place. The official appointment of the ICCs (if possible, also with the involvement of a director/management holding executive powers) and IC nurses under a legal framework would empower responsible

professionals to enforce effective practices. The mandate of the ICC could include implementation of the guidelines for infection control and related recommendations.

The option to set up 'ministerial' level Infection Control Committee would ensure political commitment and enforce implementation of national standard operational procedures in hospitals.

The legal framework should also provide a basis for internal and external audits of practices, agreement on audit methods in healthcare settings (including different specialisations) and surveys to audit implementation of the action plans.

3) Training, education, and communication to change current culture and reach behavioural change

Pre- and postgraduate training should include infection prevention and control and be made available for medical staff and in-service IPC staff. A curriculum or specialisation for infection control nurses would be useful. Feedback on HAIs and AMR to doctors, including GPs, is very important and often missing. For example, trained hospital staff should be given the resources to improve awareness on infection prevention and control right down to the level of primary care/long-term care facilities.

Hand hygiene is extremely important for IPC staff, other hospital staff, visitors and the general public. Training and awareness campaigns are needed to achieve culture and behavioural change.

4) Written guidelines and standard operating procedures

National harmonised guidelines and standard operating procedures (SOPs) on infection prevention and control are missing in many countries, however it is important to ensure that, once introduced, the guidelines are actually followed by the staff. Internal and external audits in healthcare settings (including different specialisations) should be in place to monitor the implementation of guidelines and practices.

It goes without saying that infection prevention and control is strongly linked to laboratory capacity and availability of standardised methods for the isolation and identification of bacterial agents from clinical specimens, including antimicrobial susceptibility testing techniques and criteria for interpretation.

5) Strengthening surveillance and encouraging reporting

Surveillance systems are at different stages of development in the countries, however there is a need in all countries to address underreporting. Specialists agreed that an approach is urgently needed to incentivise reporting rather than applying 'punishment' or 'blame' (a carrot rather than a stick')

It would also be useful to better understand the current situation in many countries and a 'snapshot' of IPC and HAIs and AMR could provide a baseline for the issue. PPS, as per ECDC methodology, would be useful to feed into further national planning of activities and monitoring against targets.

Q5. How could the established Inter-sectoral Coordinating Mechanism (ICM) deliver more effective implementation of a national 'One-Health' action plan on AMR?

1) Nomination of formal ICMs

The legal basis for establishing the ICM is the starting point. Countries should have the legal framework in place at government level to nominate the ICM based on adopted terms of reference that should be in line with WHO recommendations.

The ICM should include all sectors and appoint empowered professionals (having strong expertise on AMR, not just representatives) from human health, the veterinary and environmental sector. Institutions should agree on the official mandate of the ICM and facilitate this structure. The mandate should include monitoring and evaluation of the action plan and a strategy for implementing corrective measures based on the results. ICMs should have secretarial support to ensure smooth functioning and continuity. The ICM should be independent of political situations and should be sustainable, including financial sustainability.

Communication between institutions and experts is important. Awareness-raising and data transparency should be key principles of ICM work practices.

2) There is a need to determine and agree on what 'One-Health' means in practice

It is extremely useful to learn from the experience of EU/EEA Member States that have already gone through a similar process of initiation with regard to 'One-Health' action to combat AMR.

3) Regional cooperation

In terms of regional cooperation among Western Balkan countries, there could be a mechanism for monitoring and evaluating the implementation of 'One-Health' action plans in the region, reporting to the regional high-level ministerial conference.

3. Meeting conclusions and follow-up

1. **Keep up the momentum in the Western Balkan region to tackle AMR and regularly exchange experiences**

Countries have certainly made progress but they are currently at different levels of advancement in terms of their national responses to AMR. There is a need to continue with successful initiatives and embark on the next phase of accelerated activities using all available resources and partnerships at national level (covering human health, food safety, animal health and the environment) and international level (such as EU institutions, ECDC, EFSA, EMA, EU/EEA countries, WHO Regional Office for Europe, OIE).

Annual meetings from 2020 onwards on the subject of a one-health approach to AMR, with representatives and experts from Western Balkan countries would serve as a platform to share achievements and planned initiatives, and address the remaining challenges. Such meetings could possibly be organised back-to-back with training sessions on various relevant topics. An equal number of representatives from the human and animal health sectors would be desirable, and if possible also participants representing agriculture/phytosanitary controls and the environment.

2. **Mobilise political commitment and support for 'One-Health' responses to AMR in Western Balkan countries**

A 'One-Health' conference among Western Balkan countries at governmental level, involving ministers of health, agriculture, and the environment would send a strong message on the importance of addressing AMR appropriately and joining forces to do so. The conference should involve ministers (or high-level ministerial representatives) and experts/technical participants to ensure the uptake of a 'one-health' approach to AMR. The conference conclusions should serve as a commitment by the ministers to common goals and should include a mechanism for follow-up on progress towards commitments after the conference.

3. **Improve coordination and implementation of *EU acquis* to tackle AMR**

Countries need to review and/or fully align their national legal framework to enable effective implementation of EU legislation related to AMR and EU standards. The legal framework should enable coordination of 'One-Health' responses to AMR and provide a basis for ICM, with clear tasks and responsibilities. Setting specific and measurable targets should be the basis for national strategies and action plans. Provision of regular information on AMR and antimicrobial consumption would enable proper monitoring against targets.

Strong collaboration on specific activities among professionals in different sectors and between national agencies has yet to be built up in many Western Balkan countries.

There are many examples of good practices from EU/EEA Member States concerning strategies and action plans to combat AMR that Western Balkan countries could apply.

4. **Start with preparing 'One-Health' AMR surveillance reports at country level**

Writing an annual joint 'One-health' report on antimicrobial consumption and AMR in bacteria from food animals, foods, and humans represents an opportunity for each Western Balkan country to increase collaboration among the different sectors, learn from available data and how they can be improved, and provide clear information to stakeholders and the media. Joint reporting on surveillance is a 'low hanging fruit' for all countries in the region.

5. **Strengthen microbiology laboratory system capabilities**

There is an opportunity for strengthening and reorganising national reference laboratories/AMR functions, both for human health and animal health (food animals and foods). Microbiology laboratories' capacity to detect cases needs to be further developed, including improvement of laboratory testing methods and equipment, such as rapid diagnostic tests and AST, or using new technologies and bioinformatics. EU support would assist countries in building appropriate laboratory capacity for AMR surveillance and control.

6. **Benefit from digitalisation of surveillance systems on AMR and interoperability of data flows**

Development of an electronic AMR surveillance system represents an opportunity for electronic and automatic reporting of standardised AMR data from clinical and veterinary laboratories. Electronic reporting of data would facilitate notification of AMR cases to health authorities and well as exchange of data between institutions in each country. The EU could help by providing a standard (generic) AMR surveillance tool to facilitate data extraction, standardisation, analysis and reporting, which could be adapted by each Western Balkan country - e.g. for data extraction, reporting and layout.

EU support for digitalisation of laboratory data sharing systems would be needed to ensure that IT infrastructure allows interconnectedness between epidemiological data and veterinary data for better information flows between sectors and public health fields, as well as between the countries in the region (and the EU).

7. **Invest in capacity building, education and training of specialists on AMR and antibiotic stewardship at all levels of human health and animal health**

There is a need at all levels for training on the monitoring and surveillance of AMR, infection prevention and control, sample collection, microbiology laboratory data analysis, bioinformatics tools, providing feedback, and antibiotic stewardship programmes. Training courses should be implemented at all levels (national, regional, local) and, if possible, from a 'One-health' perspective to foster collaboration between sectors. The impact of implementing such activities in each country should also be evaluated.

8. **Consider regional action taking a 'One-health' approach to AMR in the Western Balkan countries, starting with 'One-health' country visits to discuss AMR issues in each country**

'One-health' country visits to discuss AMR issues in each of the Western Balkan countries would serve as a tool for identifying individual country gaps and supporting the development of roadmaps on AMR in different sectors: human health, animal health and patient safety. The recommendations of the country visits would also show the way forward for the Western Balkan region, both at regional or country level, and could be supported by EU financial assistance. There should be a mechanism for follow-up in each individual country after the visit.

Annex 1. Agenda

Regional workshop on 'One-Health' approach to antimicrobial resistance in EU pre-accession countries

26–27 February 2019

Belgrade, Serbia

	Monday, 25 February 2019 Arrival of participants **Venue: Hotel Hyatt Regency Belgrade**
19:30	*Welcome reception invited by ECDC*
DAY 1	**Tuesday, 26 February 2019** **Plenary session I: The New EU 'One-Health' Action Plan and priorities at Member State, EU and global partners level** *Chair: Charles PRICE, Directorate-General for Health and Food Safety (DG SANTE)* *Co-chair: Dominique L. MONNET, Head of ARHAI Disease Programme, ECDC*
08:30–09:00	***Registration***
09:00–09:20	**Opening and welcome** *Hosting country* *ECDC, EFSA, European Commission*
09:20–09:50	**State of play of the implementation of the new EU 'One-Health' Action Plan against Antimicrobial Resistance** *Charles PRICE, DG SANTE*
09:50–11:00	**AMR and antimicrobial consumption in humans, animals and food at EU level** *Presentation on AMR situation, technical priorities, harmonised outcome indicators for antimicrobial consumption and AMR monitoring, EU-level standards, and activities to support efforts against AMR in EU candidate and potential candidate countries* ***Surveillance of AMR and antimicrobial consumption in humans in the EU/EEA.*** *Tommi KÄRKI, ARHAI Disease Programme, ECDC (15')* ***Monitoring and epidemiology of AMR in food-producing animals and food in the EU/EEA.*** *Pierre-Alexandre BELOEIL, BIOCONTAM Unit, EFSA (15')* ***European Surveillance of Veterinary Antimicrobial Consumption (ESVAC).*** *Dr Kari GRAVE, Chair of the ESVAC sales expert advisory group (10')* ***Joint ECDC/EFSA/EMA activities on AMR.*** *Dominique L. MONNET, Head of ARHAI Disease Programme, ECDC (15')*

	Discussion
11:00–11:30	*Coffee break*
11:30–11:55	**WHO supporting activities and AMR epidemiological situation in Western Balkans and Turkey** *Presentation by Danilo LO FO WONG, WHO Regional Office for Europe, on participation of Western Balkans and Turkey in CAESAR and the standardised AMR surveillance under Global Antimicrobial Resistance Surveillance System*
11:55–12:15	**Austria's experience to implement 'One-Health' approach to respond to AMR: achievements, challenges, and lessons learned** *PD Dr. Reinhild STRAUSS, Director AMR/HAI, Federal Ministry of Labour, Social Affairs, Health and Consumer Protection*
12:15–13:30	**Group photo and lunch**
13:30–13:50	**Norway's experience to implement 'One-Health' approach to respond to AMR: achievements, challenges, and lessons learned** *Dr. Gunnar Skov SIMONSEN, Head of Department, Norwegian Organisation for Surveillance of Antimicrobial Resistance, University Hospital of North Norway*
13:50–14:15	**Croatia's experience to implement 'One-Health' approach to respond to AMR: achievements, challenges, and lessons learned** *Dr. Gordan KOMPES, Manager, Laboratory for General Bacteriology and Mycology, Croatian Veterinary Institute*
14:15–14:45 coffee break	
	Plenary session II: Gaps, Challenges and Priorities in Western Balkan countries *Chair: Pierre-Alexandre BELOEIL, BIOCONATM Unit, EFSA* *Co-chair: Maarit KOKKI, Head of International Relations Section, ECDC*
14:45–15:15	**State-of-play on implementation of EU AMR *acquis* and related standards in Western Balkan countries after Regional meeting in Dubrovnik in 2012 and the following EU assessments** *Maarit KOKKI, Head of International Relations Section, ECDC*
15:15–17:15	**Interactive poster presentations by countries on key recent developments, remaining challenges and national priorities on 'One-Health' responses to AMR** *Western Balkan countries, one poster per country covering public health and food safety as per template provided (6 x 20')*
17:15–17:30	**Wrap up day 1**
19:00	*Dinner as the guest of ECDC*

DAY 2	**Wednesday, 27 February 2019** **Working group discussions: Developing the Regional Joint Action on 'One-Health' against AMR in Western Balkan countries**
09:00–12:30 *Coffee served at 10:30–11:00*	**<u>Group discussions</u> to develop regional project that could strengthen 'One-Health' surveillance and reporting of AMR and antimicrobial use, increase awareness and understanding, improve coordination among countries' 'One-Health' responses to AMR, advance implementation of EU rules, and enhance prevention and control of AMR.** *Facilitators:* ➢ *Q1 – Dominique L. MONNET (ECDC) and Pierre-Alexandre BELOEIL (EFSA)* ➢ *Q2 – Gunnar Skov SIMONSEN (NO) and Gordan KOMPES (HR)* ➢ *Q3 – Charles PRICE (DG SANTE) and Kari GRAVE (ESVAC)* ➢ *Q4 – Tommi KÄRKI (ECDC) and Gerhard STEFFES (DG SANTE)* ➢ *Q5 – Maarit KOKKI (ECDC) and Danilo LO FO WONG (WHO Regional Office for Europe)*
12:30–13:30	***Lunch***
	Plenary session III: Regional approach to 'One-Health' response to AMR in Western Balkans as part of their EU accession process *Chair: Maarit KOKKI, Head of International Relations, ECDC* *Co-chair: Charles PRICE, DG SANTE*
13:30–15:00	**Presentations from the group discussion resulting in key building blocks for technical proposal on Regional 'One-Health' Project against AMR in Western Balkans to be financed by the EU** *Group A – Q1* *Group M – Q2* *Group R – Q3* *Group W – Q4* *Group B – Q5* *Discussion*
15:00–15:30	***Coffee break***
15:30–16:30	**Conclusions, next steps and closure** *DG SANTE, DG NEAR, ECDC, EFSA, WHO Regional Office for Europe*

	Thursday, 28 February 2019 Departure

Annex 2. List of participants

Regional workshop on 'One-Health' approach to antimicrobial resistance in EU pre-accession countries

Hotel HYATT Regency, Belgrade, 26–27 February 2019

List of participants

Country	First Name	Last Name	Role and affiliation
EU candidate and potential candidate countries			
ALBANIA	**Andi**	**KORAQI**	*ECDC Observer NMFP* MD, PhD, Microbiologist Tirana University Hospital Centre
	Eugena	**TOMINI**	*ECDC Observer NSFP* MD, PhD, Head of Surveillance Office Institute of Public Health
	Renis	**MACI**	*EFSA Observer SN Zoonoses Data Collection (AMR topic)* Institute of Food Safety and Veterinary Deputy director
BOSNIA AND HERZEGOVINA	**Pava**	**DIMITRIJEVIĆ**	*Alternate ECDC Observer NMFP* MD, Microbiologist, Head of the Department of Microbiology, Public Health Institute of the Republic of Srpska
	Nijaz	**TIHIĆ**	*Alternate ECDC Observer NSFP* Prof., Head of Department of Microbiology University Clinical Center Tuzla
	Džemil	**HAJRIĆ**	*EFSA Advisory Forum Observer* Director, Food Safety Agency of Bosnia and Herzegovina
KOSOVO*	**Lul**	**RAKA**	*National ECDC Correspondent* Dr. Professor assistant of Microbiology National Institute of Public Health of Kosovo*
	Gjyle	**MULLIQI-OSMANI**	*ECDC Observer NMFP* Microbiologist, Professor of Microbiology National Institute of Public Health of Kosovo*
	Ariana	**KALAVESHI**	*ECDC Observer NSFP* Epidemiologist, Head of Department of Surveillance of communicable diseases National Institute of Public Health of Kosovo*

	Bekim	**ZHUBI**	*EFSA Observer SN Zoonoses Data Collection (AMR topic)* *Food and Veterinary Agency of Kosovo** Head of Sector for Veterinary Medicinal Products
MONTENEGRO	**Boban**	**MUGOŠA**	*National ECDC Correspondent* Ass. Professor Dr., Director, Epidemiologist Institute of Public Health of Montenegro
	Zoran	**VRATNICA**	*ECDC Observer NMFP* Director of the Centre for Medical Microbiology Institute of Public Health of Montenegro
	Božidarka	**RAKOČEVIĆ**	*ECDC Observer NSFP* Director of Department for Control and Prevention of Communicable Diseases, specialist in Epidemiology Institute of Public Health of Montenegro
	Vesna	**DAKOVIĆ**	*EFSA Advisory Forum Observer* Director of Administration for Food Safety, Veterinary and Phytosanitary Affairs
SERBIA	**Goran**	**STEVANOVIĆ**	*National ECDC Correspondent* Director Clinic for infectious and tropical diseases
	Ivana	**ĆIRKOVIĆ**	*ECDC Observer NMFP* MD, PhD, Assistant Professor of Microbiology, Head of Reference Laboratory for Staphylococcus and Enterococcus Institute of Microbiology and Immunology
	Verica	**JOVANOVIĆ**	*Alternate ECDC Observer NSFP* Acting Director Institute of Public Health of Serbia "Dr Milan Jovanovic Batut"
	Ljiljana	**PAVLOVIĆ**	*Alternate ECDC Observer NMFP* Head of the Center for Microbiology Institute of Public Health of Serbia "Dr Milan Jovanovic Batut"
	Tatjana	**LABUS**	*EFSA Observer SN Zoonoses Data Collection (AMR topic)* Senior Adviser Ministry of Agriculture, Forestry and Water Management, Veterinary Directorate, Department for Animal Health
	Radmila	**VELIČKOVIĆ-RADOVANOVIĆ**	Prof. dr, MD, PhD, Vice Dean University of Nis, Faculty of Medicine Clinic of Nephrology, Clinical Centre Niš
	Lazar	**MILOJEVIĆ**	Institute of Meat Hygiene and Technology, Serbia
NORTH MACEDONIA	**Nikola**	**PANOVSKI**	Professor, MD, microbiology, president of multisectorial committee for AMR SS. Cyril and Methodius University in Skopje, Medical Faculty, Institute of Microbiology and parasitology
	Golubinka	**BOSEVKSA**	*Alternate ECDC Observer NMFP* Assoc. Prof. MD, specialist in Microbiology, national AMR focal point, member in the national multisectorial committee for AMR, Institute of Public Heath
	Gordana	**KUZMANOVSKA**	*ECDC Observer NSFP* Member in the national multisectorial committee for AMR; Epidemiologist, Head of Department for Prevention and Control of Communicable Diseases, National Public Health Institute
	Sashko	**ARSOV**	Head of Department for Veterinary Public Health, Food and Veterinary Agency Food and Veterinary Agency

	Romel	**VELEV**	Professor of Pharmacology Faculty of Veterinary Medicine, Skopje
TURKEY	**Güzin**	**ŞAHİN**	*EFSA Advisor Forum Observer* Coordinator in Public Health Department, Ministry of Food Agriculture and Livestock, General Directorate of Food and Control
EU/EEA country experts			
AUSTRIA	**Reinhild**	**STRAUSS**	PD Dr, Director AMR/HAI Federal Ministry of Labour, Social Affairs Health and Consumer Protection
CROATIA	**Gordan**	**KOMPES**	Dr, Manager, Laboratory for General Bacteriology and Mycology Croatian Veterinary Institute
NORWAY	**Gunnar Skov**	**SIMONSEN**	Dr, Head of Department, Norwegian Organisation for Surveillance for Antimicrobial Resistance University Hospital of North Norway
	Kari	**GRAVE**	Dr, Chair of the ESVAC sales advisory group
ROMANIA	**Valeriu**	**GHEORGHITA**	ID Senior Physician, Assistant Professor Central Military University Emergency Hospital "Dr Carol Davila"
European Commission and EEAS			
Directorate General for Health and Food Safety DG SANTE	**Charles**	**PRICE**	Dr, Policy Officer Unit C3 – Country Knowledge and Crisis Management
	Gerhard	**STEFFES**	Dr, Policy Officer Unit C4 – Health Determinants and International Relations
EU Delegation to Serbia	**Maja**	**VUCKOVIC-KRCMAR**	Programme Officer – EU policies / Horizontal coordination and Health / DMO Delegation of the European Union to the Republic of Serbia
	Andrej	**PAPIC**	Food safety and animal health Delegation of the European Union to the Republic of Serbia
ECDC and EFSA			
ECDC	**Maarit**	**KOKKI**	Senior Adviser to the Director, Head of International Relations
	Dominique	**MONNET**	Head of Disease Programme Antimicrobial Resistance and Healthcare-Associated Infections (ARHAI), OCS
	Agne	**BAJORINIENE**	International Relations Officer, DIR
	Tommi	**KÄRKI**	Expert ARHAI, Surveillance, SRS
EFSA	**Drago**	**MAROJEVIĆ**	Engagement and Scientific Cooperation Officer, EU Cooperation Team
	Pierre-Alexandre	**BELOEIL**	Senior Scientific Officer, BIOCONTAM Unit
WHO Regional Office for Europe			
WHO Regional Office for Europe	**Danilo**	**LO-FO WONG**	Programme Manager Control of AMR Health Emergencies and Communicable Diseases

* This designation is without prejudice to positions on status, and is in line with UNSCR 1244 and the ICJ Opinion on the Kosovo Declaration of Independence

Annex 3. Country posters

efsa European Food Safety Authority

ecdc EUROPEAN CENTRE FOR DISEASE PREVENTION AND CONTROL

Regional workshop on One Health approach against antimicrobial resistance in EU pre-accession countries

26-27 February 2019, Belgrade, Serbia

One Health Against AMR in Western Balkans — Albania

Legal framework, implementation of *EU acquis*, and status of national One Health Action Plan on AMR

What is the legal basis to implement One Health approach against AMR?

- Law on the Prevention and Fight Against Infectious Diseases (15/2016), in particular Articles 10, 31 and 32
- The Order to establish a Joint AMR Committee serves as a legal document under the Law 15/2016. Further actions to ensure the legal basis implementation of One Health are under way.
- National One Health Action Plan has been prepared and budgeted, pending its endorsement (some activities of the Plan have started before the endorsement)

Is there a national One Health strategy endorsed?

○ Yes ◉ No

Is there a national One Health action plan and what is the status of its implementation?

◉ Actional plan drafted, but not endorsed or no Action plan on AMR in One Health approach

○ Action plan endorsed, budgeted, implementation pending or just started

○ Action plan successfully being implemented, monitored, and reviewed

Intersectorial Coordination Mechanism

Is there inter-sectorial coordination body formalised and its work budgeted?
What is the coordinating institution and who is responsible/accountable for implementation of the actions?
How One Health approach is operationalised and coordinated in the country?

A joint One Health AMR Coordination Committee has been established and the National Institute of Public Health (also IHR Focal Point) has been appointed recently as the coordinating institution responsible for implementation of actions

One Health expert group has been established under IHR, as well as for zoonosis control, influenza and for preparing joint risk assessment guidelines. The group is working together on joint risk assessments for different issues

Successful case story or good practice example of achievement

- A joint One Health Committee on AMR has been established and a joint National Strategy on AMR with budgeted Action Plan has been prepared. In this framework, a joint plan of joint training has been prepared and different joint trainings were organised with the support of different partners, such as WHO, etc.
- A joint study on the prevalence of Salmonella and Campylobacter spp and the corresponding AMR patterns in patients with diarrhoea and health broiler chickens has been accomplished
- The number of laboratories participating in CAESAR external quality assurance and the number of isolates has been increased over the years.
- An AMR reporting form has been approved together with the list of priority pathogens and responsible laboratories in the framework of establishing sentinel AMR surveillance in Albania
- Recently Albania has started the preparation of organising in May 2019 a Point Prevalence Survey study in Tirana and two other regional hospitals
- Joint AMR actions have been identified as a priority one during the recent One Health bridging workshop organised in collaboration with WHO in December 2018 in Tirana.

Microbiology laboratory capacities

To which extent the country has sufficient microbiology laboratory capacities to support AMR surveillance?
Are there reference laboratories for AMR supporting human, animal, food side?
How communication between animal and human laboratory side is organised to arrive at common understanding about the lab data that is being collected?

No information

Education, training, awareness raising

What has been done to develop and apply training curricula and education of specialists on One Health approach against AMR in the country?
Are antimicrobial stewardship programmes for healthcare specialists and veterinarians available and sustainable?
Please give examples of public campaigns on the prudent use of antibiotics in human and veterinary areas at national and local levels

No information

Surveillance systems in antimicrobial resistance, antimicrobial consumption, and healthcare associated infections in human health, animal health, and food

Brief description of surveillance systems and information databases; are those comprehensive?
Are EU-level standards used/applied for surveillance of AMR and antimicrobial consumption monitoring?
How data on consumption of veterinary antimicrobial agents and human health data are used for public health purposes?
Is country applying combined analysis and reporting from surveillance of antimicrobial use and resistance in humans, animals, food?
Are data from environmental monitoring integrated into overall combined analysis?

A joint event based surveillance guideline has been recently drafted to improve the joint event based surveillance in the country

Recently a new sentinel surveillance system document on AMR has been prepared with selected priority pathogens and new reporting form that has been approved. The system will be part of the National surveillance system recently digitalised, Albania needs more support to develop such system with its database with the new digitalised one. Reporting of AMR, has been ad hoc so far; AMR outbreak investigation data and some data from some laboratories and the entire information was stored in an Excel dataset.

A new antimicrobial consumption system has been developed but its database needs improvement.

Not all EU standards are applied for AMR surveillance and antimicrobial monitoring.

The data on the consumption of veterinary antimicrobial agents are still scarce and no data have been used for human health purposes so far.

A general One Health joint surveillance document is under way of preparation and will guide also combined analysis of data from surveillance of antimicrobial use and resistance in humans, animals and food.

Challenges and future outlook

What are the key challenges in your country to advance implementation of One Health approach against AMR:
- at national policy formulation level
- at multi-sectorial coordination level
- at operational level (e.g. institutions, bodies, sustainability of actions)
- at functional level (laboratory capacities, procedures, guidelines, etc.)

No information

ISP INSTITUTE OF PUBLIC HEALTH

TIRANA UNIVERSITY LUNG DISEASE MEDICAL CENTRE Shefqet Ndroqi

ISUV

AKU NATIONAL FOOD AUTHORITY

Regional workshop on One Health approach against antimicrobial resistance in EU pre-accession countries

26-27 February 2019, Belgrade, Serbia

One Health Against AMR in Western Balkans

Bosnia and Herzegovina

Legal framework, implementation of *EU acquis*, and status of national One Health Action Plan on AMR

Veterinary Office of Bosnia and Herzegovina, Veterinary - Food Safety sector:

- Rulebook about residue limits of pharmacologically active substances in foodstuffs of animal origin
- Rulebook about monitoring zoonosis and zoonotic agents
- Rulebook on goals for reduction of the presence of bacteria of the species *Salmonella enteritidis* and *Salmonella typhimurium* at the laying hens
- Decision on agreed monitoring antimicrobial resistance species Salmonella in poultry and pigs

Republic of Srpska:

- The Law on Protection of Population from Communicable Diseases
- Rulebook on manner of reporting, content of records and notification form for communicable diseases
- Rulebook on mutual notification of the health service and veterinary organization

For Republic of Srpska AMR is reported to the PHI of RS. It is envisaged exchange of information between PHI of RS and Veterinary Institute of Republic of Srpska "Dr. Vaso Butozan" about AMR to zoonotic agents.

Federation of Bosnia and Herzegovina:

- The Law on Protection of Population from Communicable Diseases
- The Rulebook of reportingg communicable diseases
- The Law on records in the field of health
- The Law on drugs used in veterinary sector
- The rulebook on prescribing drugs in veterinary sector
- The law on pharmacy

According to the legislation, all laboratories in Federation of Bosnia and Herzegovina are obliged to report AMR to PHI of FBH.

Is there a national One Health strategy endorsed?

○ Yes ◉ No*

Is there a national One Health action plan and what is the status of its implementation?

◉ Actional plan drafted, but not endorsed or no Action plan on AMR in One Health approach**
○ Action plan endorsed, budgeted, implementation pending or just started
○ Action plan successfully being implemented, monitored, and reviewed

Intersectorial Coordination Mechanism

Ministry of Civil Affairs is responsible for carrying out tasks which are within the BIH competence in regard to establishing basic principles of coordination of activities, alignment of Entity bodies plans and defining an international strategy in health and social protection.

In accordance with competences in Bosnia and Herzegovina inter-sectorial coordination body and One Health Action plan on AMR are not established.

Republic of Srpska:

Commission for Control of AMR of Republic of Srpska.

Part of activities of Commission for zoonosis control of Republic of Srpska are related to data on AMR.

Members of these bodies are experts in human and veterinary medicine. The activities of these bodies and the work of it's members are carried out as part of regular activities.

Federation of Bosnia and Herzegovina:

There is no formalized inter-sectorial coordination body.

Committee for AMR of Academy for Science of Bosnia and Herzegovina brings together experts from different fields, including microbiology, veterinary, food, biology, pharmacy and agriculture.

Surveillance systems in antimicrobial resistance, antimicrobial consumption, and healthcare associated infections in human health, animal health, and food

AMR surveillance activities in Bosnia and Herzegovina are conducted by two networks; one in the Federation of Bosnia and Herzegovina and one in Republic of Srpska.

Federation of Bosnia and Herzegovina

AMR surveillance network includes six laboratories. They provide diagnostic support for three secondary care hospitals, one tertiary care hospital and two hospitals providing both secondary and tertiary care. AMR surveillance covers about 75% of the population of the Federation. Antimicrobial susceptibility in the tertiary level of care is tested using automated systems. Gradient tests and disk diffusion are used as supplementary methods. If highly resistant microorganisms or exceptional phenotypes are found, strains are usually sent to a clinical microbiology laboratory at a university hospital in the capital for confirmation. Methodology of examination antimicrobial susceptibility is standardized in participating laboratories. Laboratories use EUCAST standards.

EU standards are applied and surveillance system is compatible with EARS-Net. Data are presented in annual report of CAEASR network published by WHO. AMR BA CAEASAR network organised annual meeting in country. Since 2017 AMR data from Federation are included in the GLASS network, too.

Antimicrobial consumption monitoring is conducted by Agency for Drugs of Bosnia and Herzegovina for human sector, which collects data about antimicrobial consumption as part of AMC network led by WHO. Data are on country level. Data are analysed according to ATC classification and expressed as DDD/1000 inhabitants.

There is no established combined analysis and report from antimicrobial use and resistance in humans, animals and food. Also, data from environmental monitoring are not included in report.

Republic of Srpska

The Commission for Control of AMR coordinates and monitors implementation of the Program for Control of AMR 2016–2020. The AMR focal point and data manager of Republic of Srpska, who are members of the Commission, are responsible for collecting data from the University Clinical Centre of Republic of Srpska. All results from the routine antibiotic susceptibility testing of clinical bacteriology cultures are collected electronically from the clinical information system. The University Clinical Centre of Republic of Srpska covers at least 85% of the population of Republic of Srpska.

For the veterinary sector, registration of veterinary medicines is mandatory; according to legal basis on pharmaceutical activity, the Rulebook on the content and manner of keeping reports on the circulation and consumption of medicines, among other things, authorises the PHI of RS to compile reports on drug consumption in Republic of Srpska.

Microbiological laboratories for human diagnostics in the Republic of Srpska report data to CAESAR and the GLASS network.

Microbiology laboratory capacities

Federation of Bosnia and Herzegovina

There is sufficient laboratory capacity for AMR surveillance; all microbiology laboratories are able to perform susceptibility testing. The Microbiology laboratory for human sector is part of University Clinical Hospitals, Cantonal Hospitals, PHI of FBH and Primary Care Centers.

The laboratory for animals is organized in Cantonal Veterinary Institute and Faculty of Veterinary Medicine, University of Sarajevo. Microbiology laboratory for food are organized in human and veterinary sectors: Public Health Institute at cantonal and federation level and Veterinary Institute at Cantonal level, as wells as in Faculty of Veterinary Medicine, University of Sarajevo.

There is no officially nominated Reference laboratory for AMR surveillance, however Microbiology Laboratory of University Hospital Sarajevo operates as Reference laboratory for human sector supporting other laboratories in AMR surveillance. It organizes training and gives support in confirmation special mechanism of resistance and recommendation for AMR surveillance. Faculty of Veterinary Medicine, University of Sarajevo is supporting laboratory for AMR surveillance for animals and food.

Republic of Srpska

Law on Protection of Population from Communicable Diseases foresees designation of a reference laboratory for the registration and monitoring of resistant strains on antimicrobial drugs.

Existing laboratories have basic antimicrobial resistance surveillance capacities. It is necessary to harmonize database collection point .

There are no reference laboratories for antimicrobial resistance surveillance in the Republic of Srpska, that support human, animal and food side.

There are experts in the field of human and veterinary medicine in the Commission for Control of AMR performing food safety control in their laboratories as well.

There are accredited laboratories in the Republic of Srpska that can perform AMR surveillance in veterinary sector.

Education, training, awareness raising

Federation of Bosnia and Herzegovina

Since 2015, AMR meeting and trainings about AMR are organized annually with CAESAR network support, for laboratories, representatives of Public Health and Ministry of Health.

Campaigns on rationale use of antibiotics have been conducted throughout Federation and included different stakeholders and targeting health care professionals, general public, media and government.

In 2018, Microbiology Society of Bosnia and Herzegovina with different partners (including Association of Medical Students, Agency for Drugs of Bosnia and Herzegovina) conducted World Antibiotic Awareness Week campaign, which included seminars for doctors, experts, students of medicine and pharmacy and general public.

Republic of Srpska

Campaigns (through CAESAR project) were conducted on 2015, 2016, 2017, 2018. Key achievements:

- EAAD materials for the campaign translated and adapted
- 92 professionals reached during two trainings
- At least 1000 professionals reached using posters and leaflets with key messages for prescribers
- 1500 patients reached using leaflets with key messages for patients
- Information for professionals and patiens shared via official web-sites
- wide media coverage during campaign and EAAD, including articles, TV and radio shows

Challenges and future outlook

Republic of Srpska

At policy formulation level and multi-sectorial coordination level – to further strengthen cooperation between health and veterinary sector, and a common approach for collecting comparable data.

Federation of Bosnia and Herzegovina

- Development of Strategy and Action Plan
- Implementation of One Health concept
- Coordination activities between different sectors
- Securing budget for the activities
- Data communication between health and animal sectors

* Republic of Srpska: Policy for Improvement of Health of the Population in the Republic of Srpska by the Year 2020
** Republic of Srpska: Program for control of AMR 2016-2020, monitoring of implementation by the Commission for Control of AMR of Republic of Srpska. There is no One Health action plan at Federation level.

Regional workshop on One Health approach against antimicrobial resistance in EU pre-accession countries

26-27 February 2019, Belgrade, Serbia

One Health Against AMR in Western Balkans — Kosovo*

Legal framework, implementation of *EU acquis*, and status of national One Health Action Plan on AMR

What is the legal basis to implement One Health approach against AMR?

- The Law for Prevention and combating Infectious Diseases (02/L-109, adopted in 2008). It doesn't include any reference to AMR.
- "Administrative instruction 01/2010 on Prescriptions in the Health System in Republic of Kosovo" . Based on this instruction it's prohibited to sell antimicrobials

Is there a national One Health strategy endorsed?

◉ Yes ○ No

Is there a national One Health action plan and what is the status of its implementation?

- ○ Actional plan drafted, but not endorsed or no Action plan on AMR in One Health approach
- ◉ Action plan endorsed, budgeted, implementation pending or just started
- ○ Action plan successfully being implemented, monitored, and reviewed

Intersectorial Coordination Mechanism

Is there inter-sectorial coordination body formalised and its work budgeted?
What is the coordinating institution and who is responsible/accountable for implementation of the actions?
How One Health approach is operationalised and coordinated in the country?

- Intersectorial Group for Containment of Antimicrobial Resistance in Kosovo (GNKRA), is implementing body for the implementation of National Action Plan. Its work is budgeted
- All relevant stakeholders are enrolled in GNKRA
- One health approach is coordinated and operationalized through GNKRA

Successful case story or good practice example of achievement

- Surveillance of antibiotic consumption (wholesale data, all hospitals and primary care level)
- Grants awarded through open call competition
- Significant decrease in antibiotic consumption (25%)
- International collaboration and research
- Awareness of population and health care workers
- E-bug

Surveillance systems in antimicrobial resistance, antimicrobial consumption, and healthcare associated infections in human health, animal health, and food

Brief description of surveillance systems and information databases; are those comprehensive?
Are EU-level standards used/applied for surveillance of AMR and antimicrobial consumption monitoring?
How data on consumption of veterinary antimicrobial agents and human health data are used for public health purposes?
Is country applying combined analysis and reporting from surveillance of antimicrobial use and resistance in humans, animals, food?
Are data from environmental monitoring integrated into overall combined analysis?

- Kosovo has submitted AMR data to CAESAR network during the last four years
- Surveillance of Antibiotic consumption is part of WHO-AMC network since 2012
- Surveillance data are used for quality improvement
- No structured data for antibiotic consumption in the veterinary sector and no combined analysis and reporting
- AMR genes from sewage: msr(E), blaOXA and aaDa

Microbiology laboratory capacities

To which extent the country has sufficient microbiology laboratory capacities to support AMR surveillance?
Are there reference laboratories for AMR supporting human, animal, food side?
How communication between animal and human laboratory side is organised to arrive at common understanding about the lab data that is being collected?

- National level laboratory has sufficient capacities to support AMR surveillance
- Reference laboratory for AMR is anticipated to be established within NAP
- Communication between human and animal laboratory side is insufficient

Education, training, awareness raising

What has been done to develop and apply training curricula and education of specialists on One Health approach against AMR in the country?
Are antimicrobial stewardship programmes for healthcare specialists and veterinarians available and sustainable?
Please give examples of public campaigns on the prudent use of antibiotics in human and veterinary areas at national and local levels

- AMR in Continuous Professional Education for healthcare workers
- Antimicrobial stewardship program is in its initial phase of preparation
- Lectures on AMR in all municipalities and all 8 hospitals
- Video promotion on AMR in social media and broadcasting at national TV, Awareness campaigns since 2009; E-bug already translated into Albanian language

Challenges and future outlook

What are the key challenges in your country to advance implementation of One Health approach against AMR:
- at national policy formulation level
- at multi-sectorial coordination level
- at operational level (e.g. institutions, bodies, sustainability of actions)
- at functional level (laboratory capacities, procedures, guidelines, etc.)

- Limited budget to implement planed activities
- Over the counter sale of antibiotics
- Pressure from pharmaceutical industry and corruption
- Insufficient laboratory capacities at regional level (understaffed and underutilised)
- Lack of clinical guidelines and protocols officially approved by MoH

Republika e Kosovës
Republika Kosova-Republic of Kosovo
Qeveria -Vlada-Government
Ministria e Shëndetësisë - Ministarstva Zdravstva - Ministry of Health

Agjencia e Ushqimit dhe Veterinarisë

* This designation is without prejudice to positions on status, and is in line with UNSCR 1244/1999 and the ICJ Opinion on the Kosovo declaration of independence.

Regional workshop on One Health approach against antimicrobial resistance in EU pre-accession countries

26-27 February 2019, Belgrade, Serbia

One Health Against AMR in Western Balkans — Montenegro

Legal framework, implementation of *EU acquis*, and status of national One Health Action Plan on AMR

The legal framework for the implementation of the National plan for antimicrobial resistance in veterinary and food are:

- Law on Veterinary (Official Gazette of Montenegro 30/12)
- Law on Food Safety (Official Gazette of Montenegro 57/15).

There is a National Strategy for the Control of Bacterial Resistance to Antibiotics for the period 2017-2021. The Strategy determines the objectives, plan of activities and procedures to be implemented in Montenegro in order to stop escalation of bacterial resistance to antimicrobial agents used in human and veterinary medicine. Implementation of the planned activities should lead to the rationalization of the consumption of antibiotics, and therefore the control of the increase of bacterial resistance to antibiotics.

Is there a national One Health strategy endorsed?

(●) Yes ( ) No

Is there a national One Health action plan and what is the status of its implementation?

( ) Actional plan drafted, but not endorsed or no Action plan on AMR in One Health approach
(●) Action plan endorsed, budgeted, implementation pending or just started
( ) Action plan successfully being implemented, monitored, and reviewed

Intersectorial Coordination Mechanism

The coordinating body is the **National Interdisciplinary Commission for Antibiotic Resistance (NIKRA)** with the allocated budget.

Ministry of Health, Ministry of Agriculture and Rural Development, Directorate for Food safety, Veterinary and Phytosanitary Affairs in accordance with the competencies prescribed by the law.

NIKRA monitors and coordinates activities aimed at controlling resistance to antibiotics.

Surveillance systems in antimicrobial resistance, antimicrobial consumption, and healthcare associated infections in human health, animal health, and food

- The database on the consumption of antibiotics is owned by the Agency for Medicines and Medical Devices of Montenegro. The control over antibiotic resistance in veterinary medicine is planned to be implemented from January 2019 and it will be regulated by law.
- In accordance with the Rulebook on the method of monitoring zoonosis and zoonotic agents, the monitoring of the resistance of zoonosis and their agents to antimicrobials is done in order to collect data on their occurrence of resistance to antimicrobials in the causative agent of zoonosis and other agents to the extent that poses a threat to human health.

  Antimicrobial resistance monitoring includes the information on:
  1. animal species included in monitoring;
  2. bacterial species and / or strains included in monitoring;
  3. how the samples are taken for monitoring purposes;
  4. antimicrobials included in monitoring;
  5. laboratory procedures used to detect resistance;
  6. laboratory procedures used to identify microbial isolates;
  7. the methods used to collect data.

Successful case story or good practice example of achievement

European MediLabSecure Project (MLS) has brought together the Institute for Public Health of Montenegro and Diagnostic Veterinary Laboratory.

The project's main aim was to reinforce prevention and control of arbovirus infections with a One Health approach. MLS involved 19 countries of the Mediterranean Basin and Black Sea Region and it would like to extend to five Sahel countries. MLS has recently started to reinforce the Veterinarian Public Health component with the inclusion of country Veterinarian Public Health Officials and enhancing joint work with the Human Public Health Officials. Recently, the effective cooperation between secors has resulted in a joint presentation at One Health Scientific conference in Rome on 26th of November, 2018.

- By monitoring the resistance to antimicrobial agents, appropriate data regarding the representative number of isolates *Salmonella spp*, *Campylobacter jejuni* and *Campylobacter coli*, indicative commensal *Echerichia coli (E. coli)*, and indicative commensal bacteria *Enterococcus faecalis* and *Enterococcus faecium (E. faecalis* and *E. faecium* should be provided from samples of certain animal populations from which certain foods are produced).
- Antimicrobial resistance monitoring is subject to *Salmonella spp.* and *E. coli* that produce the following enzymes:
  1. Extended spectrum β-Lactamases, ESBL);
  2. Class C (beta-lactamase) (AmpC β-Lactamases, AmpC);
  3. Carbapenemase.

  The collection of isolates for the monitoring of resistance to antimicrobial agents is carried out by taking samples in accordance with the Rulebook.
- The control of HAIs is regulated by the Ministry of Health. For hospitals, framework legislation is defined at the country level by The Law on the Protection of the Population against Infectious Diseases (2018).

  Article 56 defines the obligation of healthcare institutions to provide hygienic-technical conditions and to carry out professional, organizational and other mandatory measures to prevent the occurrence of hospital infections and to secure their early detection and control. Hospitals and other types of stationary healthcare institutions are obliged to establish a team for the prevention and control of hospital infections for every 200 beds, consisting of a medical doctor, a specialist in epidemiology, specialized in supervision, prevention and control of hospital infections, and one sanitary/medical technician with a higher or high level of education, specifically trained in the prevention and control of hospital infections. Health facilities that have less than 200 beds are obliged to establish a qualified team for the control and prevention of hospital infections.

  The infection control team in the hospital is responsible for monitoring and analysing the current situation, for reporting, suggesting quality improvements and implementing infection control measures with regard to HAIs. The Rulebook on the Reporting of Contagious Diseases, Nosocomial Infections, Conditions and Deaths from Contagious Diseases (2015) defines the obligation of reporting as well as how and to whom to report on HAIs. A new Rulebook on Prevention and Control of Nosocomial Infections is in the adoption phase.
- The regulations on surveillance of AMR and antimicrobial consumption monitoring are aligned with the *EU acquis* in accordance with the Pre-Accession Plan.
- Data on the consumption of antibiotics in the veterinary sector are used in the assessment and rationalization of consumption and in the preparation of the plan which implementation is planned for 2019.

Uprava za bezbjednost hrane, veterinu i fitosanitarne poslove

- The Ministry of Health in cooperation with the Ministry of Agriculture and Rural Development - Directorate for Food safety, Veterinary and Phytosanitary Affairs, will exchange data on the resistance of bacteria to antibiotics among the causative agents of zoonosis, especially alimentary infections and bacteria that make up the physiological microflora of animals and represent a reservoir of potential causes of diseases in humans.

  Indirectly, this exchange of information will stimulate research on the relationship between the resistance of bacteria to antibiotics among human causes and the consumption of antibiotics in the veterinary field, which will lead to more rational consumption of antibiotics in veterinary medicine and control of the spread of resistance of bacteria to antibiotics in the physiological flora of animals. In order to ensure the adequate and effective implementation of the measures for the systematic monitoring of zoonosis, zoonotic agents and their resistance to antimicrobial agents, as well as the epidemiological examination of foodborne illnesses and the exchange of information regarding zoonosis and zoonotic agents, the Ministry of Agriculture and Rural Development, in cooperation with the Ministry of Health, will adopt programs for monitoring zoonosis, zoonotic agents and monitoring their resistance to antimicrobials.
- No environmental data available.

Microbiology laboratory capacities

- Laboratory testing for AMR in veterinary medicine will be performed by the Specialized Veterinary Laboratory. In case of a positive finding, the sample is sent to the national AMR reference laboratory in the Institute for Public Health that has been accredited according to the WHO and National requirements and standards.
- There is a national reference laboratory for AMR supporting human, animal, food side and it is a integral part of the Centre for Medical Microbiology of the Institute for Public Health of Montenegro.
- Communication between animal and human laboratory side needs to be improved in order to achieve a common understanding about the lab data that is being collected. Currently done on basis of official reports exchange on request from any of the stakeholders.

Education, training, awareness raising

- Education on:
  1. BTSF (Better Trainig for Safer Food) Antimicrobial resistance in June 2018, Sofia, Bulgaria
  2. EFSA Scientific Network on Antimicrobial Resistance Data Reporting , 7-8 November 2018, EFSA – Parma
  3. Antimicrobial Resistance Awareness day 18th November 2018, Podgorica, Montenegro – presentation by MoH and MoARD representatives
  4. Meeting of the National Network on antimicrobial resistance (CAESAR), November 2018
- Antimicrobial stewardship programmes for healthcare specialists and veterinarians are available and sustainable
- Antimicrobial Resistance Awareness day 18th November 2018, Podgorica, Montenegro – presentation by MoH and MoARD representatives.

Challenges and future outlook

- At national policy formulation level, successful implementation is foreseen
- At multi-sectorial coordination level, continuous multisector cooperation
- At operational level, lack of administrative capacities and possibilities for continuation of education
- At functional level, preparation of the Guidelines and procedures as well as education of the veterinaries in field

Regional workshop on One Health approach against antimicrobial resistance in EU pre-accession countries

26-27 February 2019, Belgrade, Serbia

One Health Against AMR in Western Balkans

North Macedonia

Legal framework, implementation of *EU acquis*, and status of national One Health Action Plan on AMR

- Law on protection of the population against communicable diseases
- Rulebook for reporting and report forms
- National Strategy with action plan
- Law for medicines and medical devices
- Rulebook for prescription and distribution of medicines
- List of essential medicines (according to WHO list)
- Law for health insurance
- Rulebook on detailed criteria for prevention and suppression of intra-hospital infections
- Law on Food Safety
- Law of Veterinary Medical Products
- Program for antimicrobial resistance for the period 2017-2021, harmonised with the provisions of the Decision (EC) no. 652/2013 for monitoring and reporting of antimicrobial resistance to zoonotic and commensal bacteria
- Annual Plan for the monitoring of antimicrobial resistance was published in the Annual Order for carrying out veterinary measures and controls for protection of public health from contaminants or residues that are transferred from animals or products of animal origin in 2018 and 2019
- Guideline to the traceability system for veterinary medicinal products throughout the chain of their placing on the market and use
- Guideline of unexpected effects from the use of VMP (pharmacovigilance)
- Document for responsible use of antimicrobials in veterinary medicine

Is there a national One Health strategy endorsed?

(●) Yes ( ) No

Is there a national One Health action plan and what is the status of its implementation?

(●) Actional plan drafted, but not endorsed or no Action plan on AMR in One Health approach
( ) Action plan endorsed, budgeted, implementation pending or just started
( ) Action plan successfully being implemented, monitored, and reviewed

Intersectorial Coordination Mechanism

Multisectorial Commission for Control of Antimicrobial Resistance (MCCAMR), current MCCAMR is active as of 06.11.2018

There is no dedicated budget for MCCAMR.

MCCAMR members include: microbiologists; epidemiologist; clinicians – infectious diseases, pediatrician, family doctors representative, intensivist, pulmologist, national coordinator for TB; pharmacist- national coordinator for AMC; representative of the Ministry; nongovernmental organization; WHO representative, representative of the FVA and representative of the Veterinary Faculty.

Surveillance systems in antimicrobial resistance, antimicrobial consumption, and healthcare associated infections in human health, animal health, and food

Surveillance of AMR in human sector:

Since 2013 participation in CAESAR. Key outputs include:

- translated CAESAR manual
- 2013-2018 - CAESAR workshops
- National CAESAR team
- CAESAR data manager
- 2014 – 2018 - Participation in EQA UK - NEQAS organized by WHO – CAESAR

Since 2017 - participation in Global Antimicrobial Resistance Surveillance System (GLASS)

Successful case story or good practice example of achievement

- Nomination of national AMR focal point and first awareness campaign in 2008 (in collaboration with ECDC)
- **Multisectorial Commission for Control of Antimicrobial Resistance (MCCAMR)** since 2009
- First National strategy with action plan for control of antimicrobial resistance 2012-2016
- **New Strategy with One Health approach** with action plan was drafted in 2017 (adoption still awaited by the Ministry and Government)
- **Coordinating institution is Ministry of Health**
- WHO partnership – 6 years successful participation in CAESAR
- In the area of veterinary and food safety, **the competent authority is the Food and Veterinary Agency (FVA)**, an independent state administration body with a legal personality. The competences include food safety, feed safety, animal health, welfare and identification and registration of animals, animal by-products, veterinary medicinal products
- In the area of food safety there is a **close collaboration with Ministry of Health, Institute of Public Health, 10 regional Centres of Public Health, FVA and Faculty of Veterinary Medicine** - Skopje

Surveillance system for antimicrobial consumption (AMC)

- Responsible institution for collecting and analyzing consumption data is Health Insurance fund (HIF)
- National focal point for AMC
- The ATC classification of medicines has been incorporated
- HIF determines ID codes for all reimbursing drugs with Reference price
- Technical manuals have been prepared and distributed to all health care institutions (primary, secondary and tertiary healthcare level) on how they should report medicines consumption electronically to HIF
- HIF contracted pharmacies are obliged to report every month the prescription medicines dispensed in primary health care on HIF's burden

Surveillance of AMR in veterinary sector

- Detection of AMR started in July 2018. After the final data processing, the data will be available to the public. For the purpose of monitoring of the AMR, isolates of each of the following types and categories of animals and food are collected:
  - *Salmonella spp.* in accordance with the National Control Plan for Salmonellosis Reduction in layng hens (Gallus gallus)
  - *Salmonella spp.* from carcasses of broilers, carcases of pigs and carcasses of cattle under one year old when slaughtered in slaughterhouses
  - *C. Jejuni* from broilers at slaughtering in slaughterhouses
  - Indicator commensal *E. Coli* from broilers, pigs and cattle under one year old when slaughtering in slaughterhouses
  - *E.coli* that produces ESBL, AmpC or carbapenemasis from broilers, pigs and bovine animals under one year old when slaughtered in slaughterhouses and samples from fresh poultry, pork and beef, collected from retail
  - *C. Coli*
  - Commensal indicator *E. faecalis* and *E. Faecium*
- For detected AMR official veterinarians are informed in the respective areas, which inform the veterinary practitioners.

AMC data in human sectors are reported regularly during national meetings (they are used in National strategy and action plan 2019-2025, as well as reported to WHO)

In the veterinary sector, the amount of used antimicrobials is calculated on the basis of imported and put into circulation VMP. Since 2019, AHV has started implementing a system for monitoring the use of VMP, which would provide accurate data on the used antimicrobials.

Report on the use of antimicrobials, on an annual basis, is submitted to OIE. For now, data on the use of antimicrobials are not used for other purposes

Microbiology laboratory capacities

2013 – EUCAST clinical breakpoints, expert rules are translated and distributed to all labs

2016 – EUCAST team, NAC in human sector

There are 30 public and private microbiology laboratories in human sector. **Two reference laboratories** according the national strategy are at the IPH and Institute of Microbiology-Medical Faculty, Skopje

Microbiology laboratories for food investigation are 12 (IPH, 10 regional CPH and Veterinary Faculty). They are all accredited according ISO 17025

FVA designated the Faculty of Veterinary Medicine Skopje for AMR investigation

Education, training, awareness raising

European Antibiotic Awareness Day (EAAD) – 18 November

Year	Target
2008	General population
2009	Primary health care– GPs and stomatologist. General population
2010	Hospital doctors. General population
2011	Pharmacists. General population
2012	Veterinarians. General population
2013	Microbiologist, General population
2014	Healthcare workers. General population

2015 - 2018 World Antibiotic Awareness Week (WAAW)

2015 CAESAR meeting – microbiologist and hospital doctors. Presentation in 5 primary school. Visit in 5 University clinics – local AMR

2016 CAESAR meeting - AMR and infection prevention and control. Conference - "*Days of Preventive Medicine*". Symposium on Antibiotics in Primary Care. 6 companies from diverse branches of industry in 5 cities. Antibiotic Guardian initiative

2017

- Development of antibiotic stewardship programme in two selected hospitals
- 3rd Symposium AFMS-RG: ANTIBIOTICS IN PRIMARY CARE
- Satellite workshop: Antimicrobial Stewardship in Hospitals - Interventions to promote reducing antibiotic use at hospital level

2018

- Educational meeting with the students of the Faculty of Veterinary Medicine, Skopje, organized by the student union at the faculty - IVSA, and with the support of MCCAMR in the Ministry of Health, OIE, FAO, WHO office in Skopje, the Faculty of Veterinary Medicine, Skopje and the Institute for Public Health (IPH).
- ONE HEALTH meeting between the two sectors – health (primary care), veterinary medicine, Red Cross and WHO office in Skopje with media coverage
- National CAESAR meeting – microbiology labs with hospital doctors; WHO supported
- Hand hygiene campaign: 5 May - World Day for Hand Hygiene "Save Life - Clean Your Hands"– 2014, 2015, 2016 , 2017

Workshops

- 2014: Combatting Bacterial Resistance in Europe (COMBACTE) - International workshop for microbiological labs in Skopje, Macedonia and 6 Balkan countries
- 2016: AMR included in the National Strategy *Health 2020* – 3 regional multisectorial workshops
- 2017: Face to face COMBACTE GCP (Good clinical practice) training in Podgorica, Montenegro - 15 medical doctors (microbiologist and clinicians) were present
- 2015: On-line course *Antimicrobial Stewardship: Optimization of Antibiotic Practices* organized by the Stanford University of Medicine, supported by MCCAMR, Medical Faculty – Skopje and the WHO with 26 modules on MOOC platform
- 2017 Course "*How to improve antibiotic use in my hospital: a practical introduction to antibiotic stewardship*" organized by ESCMID Study Group for Antibiotic Policies and WHO, Institute of Public Health, Centre for Regional Policy Research and Cooperation Studiorum

Challenges and future outlook

- To adopt **of the second National strategy and action plan 2019 – 2025**
- To organize **joint working groups for surveillance of AMR and AMC** in the frame of MCCAMR for combined analysis and reporting surveillance in humans, animals and food.
- To start **environmental monitoring** – which is covered with the new action plan
- To implement **antimicrobial stewardship program in hospitals**
- **To update of the treatment guidelines** according national AMR
- **To ensure continuous education**
- **To secure budget** for all activities

The process of changing people's behavior and habits is difficult, long and slow. It takes time, dedication, patience, constant activities, and a gradual increase of the critical mass of experts

Министерство за здравство на Република Македонија

УНИВЕРЗИТЕТ „ГОЦЕ ДЕЛЧЕВ" ШТИП

FOOD AND VETERINARY AGENCY

Regional workshop on One Health approach against antimicrobial resistance in EU pre-accession countries

26-27 February 2019, Belgrade, Serbia

One Health Against AMR in Western Balkans — Serbia

Legal framework, implementation of *EU acquis*, and status of national One Health Action Plan on AMR

Law on Protection of Population from Communicable Diseases (in line with EU legislation)

Rulebook on notification of communicable diseases and special health issues

Rulebook on forms and manner of implementation of epidemiological surveillance over communicable diseases and associated specific health issues

Rules on prevention, early detection and prevention of hospital infections

Rulebook on the method of monitoring zoonoses and zoonotic agents

Decree on the Programme of Protection against Communicable Diseases

National Action plan for communicable diseases which are in line with Decision No 1082/2013/EU and all other relevant EU Decisions and Recommendations, and it is part of Serbian negotiations position for Chapter 28.

Law of Veterinary Matters

Rulebook on the determination of the Program of Animal health protection measures (program is adopted on annual basis)

One Health approach legislation – Decree on the National Programme to control bacterial resistance to antibiotics 2019-2021

Is there a national One Health strategy endorsed?

(●) Yes ( ) No

Is there a national One Health action plan and what is the status of its implementation?

- ( ) Actional plan drafted, but not endorsed or no Action plan on AMR in One Health approach
- (●) Action plan endorsed, budgeted, implementation pending or just started
- ( ) Action plan successfully being implemented, monitored, and reviewed

Intersectorial Coordination Mechanism

There is a formalised inter-sectorial coordinating body and the Ministry of Health is accountable for the implementation of its actions.

The National Programme and Action Plan to control bacterial resistance to antibiotics 2019-2021 is in accordance with WHO Global Strategy for Containment of Antimicrobial Resistance, WHO European strategic action plan on antibiotic resistance, and in line with EU acquis in the field of antimicrobial resistance (including Council Recommendation on prudent use of antimicrobial agents in human medicine (2002/77/EC), Council Recommendation on patient safety, including the prevention and control of healthcare associated infections (2009/C 151/01/ EC), Decision No 1082/2013/EU on serious cross-border threats to health, Regulation (EC) No 1831/2003 on additives for use in animal nutrition and European Parliament resolution of 27 October 2011 on the public health threat of antimicrobial resistance).

Authorities are developing new National good clinical practice guideline for the rational use of antibiotics, strengthening the capacity of national reference laboratories for the etiologic diagnosis of hospital-acquired infections, provide additional professional training for health professionals, as well as launching a national campaign on the rational use of antibiotics.

Surveillance systems in antimicrobial resistance, antimicrobial consumption, and healthcare associated infections in human health, animal health, and food

Serbia is a member of Antimicrobial medicine consumption (AMC) Network and CAESAR Network, established by WHO, since 2011 and 2013 respectively. National surveillance of AMR and antimicrobial consumption are performed by NRL for AMR (Institute of Public Health Vojvodina) and Medicine and medical Devices Agency of Serbia. Annual reports on AMR and antimicrobial use are published by WHO. Surveillance of healthcare-associate infections is performed comprehensively and Serbia participated in ECDC PPS 2016-2017.

In order to ensure the adequate and effective implementation of measures for the systematic monitoring of zoonosis, zoonotic agents and their resistance to antimicrobial agents, as well as the epidemiological examination of foodborne disease and the exchange of information regarding zoonoses and zoonotic agents, the Ministry of Agriculture, Forestry and Water management, Veterinary Directorate, in cooperation with the EU, began Twinning Project SR13IBAG01 *"Enhancing the Capacities of the Serbian Authorities in Zoonoses and Food Borne Disease Control"* in December 2016. Ministry of Health of Serbia was co-partner for project implementation.

Improved professional capacity of the competent authorities to implement and enforce standards and regulations on zoonotic, food borne diseases and AMR Control.

Successful case story or good practice example of achievement

Ministry of Agriculture, Forestry and Water Management (Veterinary Directorate) in cooperation with the Ministry of Health initiated Twinning Project "Enhancing the Capacities of the Serbian Authorities in Zoonoses and Food Borne Disease Control" which is implemented in period December 2016 – February 2019.

The project was managed by the Ministry of Finance of Serbia and was implemented by animal health and public health authorities of Hungary and France.

Project Purpose

To enhance food safety and disease control systems in the Republic of Serbia, by improving management of zoonotic animal diseases, food borne diseases and **antimicrobial resistance /AMR**/ and further alignment with EU requirements, through harmonization of legal framework and strengthening of institutional and professional capacities.

Component 1: The strategic, institutional and legal framework for detection, surveillance, prevention, control and reporting on zoonoses, food borne diseases and AMR defined and developed in compliance with EU requirements

Component 2: Improved professional capacity of the competent authorities to implement and enforce standards and regulations on zoonotic, food borne diseases and AMR Control

Component 3: Awareness amongst the stakeholders and general public on the problem of zoonotic, food borne diseases and AMR increased

Capacity building (component 2)

Four (4) educative seminars/trainings for representatives of Ministry of Agriculture / Veterinary Directorate, Public health service / Ministry of Health and other relevant stakeholders, have been implemented in period January – March 2018. The total number of participants in all four locations (Belgrade, Novi Sad, Jagodina and Niš) was 138, respectively 80 participants of the Ministry of Agriculture/VD, 27 participants from the Public health authorities and 31 stakeholders from university (Veterinary and Human Medicine), pharmaceutical industry, field veterinarians, human physicians, laboratories (epizootiologists, microbiologists), etc.

Several topics have been presented, such as AMR in general and its transmission, monitoring of AMR in veterinary medicine in line with the EU regulation and requirements, Draft National Program for the Control of AMR, importance of AMR for certain pathogenic microorganisms (Salmonella, Clostridium), misuse of antibiotics, AMR surveillance in public health medicine, recipe in veterinary medicine, medicated feed - legal basis, case studies of human medicine/practice, etc.

In line with the National Program for the Control of AMR, the Monitoring of AMR in veterinary medicine is developed in December 2018 and training for inspectors and laboratory staff is planned in February 2019, with the attention of sampling procedure in this regards.

Data on consumption of veterinary antimicrobial collected during past few years were used for drafting National program and action plan as well as drafting guidelines for prudent use of antimicrobials in animals and will used for further developing the relevant documentation.

In this moment environmental monitoring is not established yet.

Microbiology laboratory capacities

Capacity and capability of Serbian microbiology laboratories have been evaluated by ECDC ENLabCap survey. With an overall ENLabCap index of 6.1/10 in 2016, data provided by our country indicate an intermediate capability/capacity level for Serbian public health microbiology system. High performance was scored for implementation of EU standards on antimicrobial susceptibility testing and AMR characterisation and monitoring by the national reference laboratories.

Serbian NRLs were established in 2008 by MoH, and six different NRLs besides NRL for AMR are directly involved in data collection, monitoring, phenotypic and genetic investigations in AMR, but only in human sector.

Communication between human and animal laboratories on AMR surveillance has not been established yet.

Education, training, awareness raising

In cooperation with professional associations and partner organizations, special attention is paid to the continuous education of health professionals, doctors of various specialties and levels of health care (infectious disease specialists, microbiology specialists, paediatricians, general practitioners, and surgeons), pharmacists and other medical professionals, as well as education for veterinarians, and medicine, pharmacy and veterinary students. From November 2015 till now over 35 educational seminars were held, attended by 6900 health professionals. Special attention was paid to the education of paediatricians (36% paediatricians trained) and pharmacists (32% pharmacists in primary health care trained).

National campaign on the rational use of antibiotics, aimed at citizens, primary health care doctors who prescribe medications, secondary and tertiary health care doctors, pharmacists and representatives of the media, has been implemented successfully (28/08-20/09 2017). Visual identity and campaign materials have been prepared on the basis of ECDC materials. Outdoor campaign included: 30 lit billboards positioned in the advertising network on the teritory of Serbia and city of Belgrade, in prominent locations; over 80 bilaterally illuminated displays on public lighting posts in prominent city locations, buses and in train stations; 3000 posters distributed in 158 primary helath centres in Serbia, in state and private pharmacies.

From November 2015 till now over 450 media publications in the national and local, printed and electronic media and web portals.

Challenges and future outlook

- At national policy formulation level adoption of all necessary documents has been completed so we do not expected any key challenges in the human health sector. In the veterinarian and environmental sector it is still necessary to make some legislative changes where key challenge is time necessary to perform it.
- At multi-sectorial coordination level, cooperation and effective exchange of information between sectors especially with environmental protection part can be key challenge.
- At operational level (e.g. institutions, bodies, sustainability of actions) the implementation by itself will be key challenge
- At functional level (laboratory capacities, procedures, guidelines, etc.) laboratory capacities probably will not be a problem (some improvement is necessary), on the other side unifications of the procedures, protocols and reports is of crucial importance, and implementation of all of this will be a major challenge. Some guidelines are in place (Use of antibiotics for example), but some other should be developed or their development is in process in this moment (Microbiology laboratory procedure guidelines).