

A scanning electron micrograph (SEM) of various bacterial cells, showing different shapes and textures, some with flagella, set against a black background. The bacteria are rendered in a light brown or tan color.

# INDICATORS FOR THE SURVEILLANCE OF AMR AND ANTIMICROBIAL CONSUMPTION – *Content & gaps*

*Briefing on Outcome Indicators proposed  
by ECDC, EFSA and EMA  
July 2018*



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## Introduction

*The emergence and continuous spread of antimicrobial resistance (AMR) is a global threat to public health. International actors, the European Union (EU), governments and civil society are stressing the need for international cooperation and action in the fight against AMR. Within the last decades, European data collection systems were established and demonstrated European-added value in the surveillance of AMR. However, more harmonised measures are needed to further align the monitoring efforts of Member States, to enable benchmarking and to highlight best practices. One of the steps towards the alignment of indicators was taken by the European Centre for Disease Prevention and Control (ECDC), the European Food Safety Authority (EFSA) and the European Medicines Agency (EMA) in October 2017: As requested by the European Commission, the three European agencies jointly proposed a list of harmonised surveillance outcome indicators in the form of a Joint Scientific Opinion (ECDC, EFSA, & EMA, 2017). This briefing provides a short summary of the proposed indicators, highlights potential gaps and makes recommendations.*

## Summary of Joint Scientific Opinion

The indicators have been designed to assist Member States and the European Union in assessing the progress made in the fight against AMR. They were selected on the basis of data collected by the Member States and will be reconsidered at least every five years. The indicators are derived from four sectors: antimicrobial consumption (AMC) in humans, AMC in food-producing animals, AMR in humans and AMR in food-producing animals. In each of the four sectors, one primary indicator reflects a general impression of the situation, e.g. the total consumption of antimicrobials in humans. Additionally, eleven secondary indicators are selected that provide information on more specific issues, e.g. the proportion of penicillin-resistant and macrolide-resistant *Streptococcus pneumoniae*. Furthermore, several indicators are based on the World Health Organization (WHO) classification of

critically important antimicrobials (WHO 2017).

## EPHA response

EPHA welcomes the indicators and considers them to be an important development as a step toward aligning surveillance and developing targets to reduce AMR prevalence and antimicrobial use across Europe. The joint work of ECDC, EFSA and EMA is valuable for the assessment of national action plans and to track their progress. It also provides a good example of interdisciplinary work and sharing of expertise and competencies between European scientific bodies. As Vytenis Andriukaitis, European Commissioner for Health and Food Safety, highlighted:

*“I therefore very much welcome (...) setting out indicators that address both the human and animal sectors, in line with the EU Action Plan’s One Health approach. Without these*



*indicators we would not be able to assess our progress in tackling the serious health threat posed by AMR”*

Further, EPHA supports the reconsideration of indicators at least every five years, ideally more frequently. This approach ensures the flexibility to keep up with emerging public health threats and changes over time.

However, the Joint Scientific Opinion by ECDC, EFSA and EMA falls short in some aspects, namely covering all aspects of the One Health approach, supporting harmonised methodologies and establishing reduction targets.

## Current gaps in the proposed list of outcome indicators

### **One Health approach:**

The Commission requested indicators that monitor the implementation of One Health action plans on AMR. Yet the proposed indicators are restricted to humans and the following species of food-producing animals: broilers, pigs, turkeys and calves (whereas monitoring of the latter two is only required by countries with meat-production over a defined threshold). The opinion states that the reason for excluding other food-producing animals, companion animals and AMR in food, stem from insufficient information. Further, indicators are lacking that evaluate the progress made in fighting AMR in the environmental sector; in water, soil and air. This is likely to be attributed to a similar lack of information. However, there is sufficient evidence that these factors pose a serious AMR threat, and it is therefore

important to develop the information required to develop indicators in these areas.

The WHO recently proposed indicators as regards awareness of AMR, evidence-based policy-making, effective prevention measures in all One Health domains and research and development (WHO 2017a). For the Global Antimicrobial Resistance Surveillance System (GLASS), WHO specifically developed 17 indicators for monitoring and evaluating GLASS including public health priorities targeted for surveillance, surveillance structure, core and support functions and quality and outputs of the surveillance system (WHO 2015).

**RECOMMENDATION:** More information on the occurrence of AMR in the environment, in agriculture, and in the food chain is needed to establish standards and, eventually, more meaningful indicators. The monitoring of these additional areas would enable the Member States and the EU to better evaluate their One Health Action Plans. As requested by the European Commission, the ECDC, EFSA and EMA also need to further align their indicators to the indicators proposed by the WHO.

### **Same indicators - different methodologies:**

The evaluation of the previous five-year EU action plan recommended the development of expertise on surveillance methodologies, indicators and instruments (European Commission 2016). Whereas common indicators are proposed, methodologies and instruments remain the sovereignty of Member States. However, European legislation has attempted to harmonise the methods of data



collection and reporting to some extent, through introducing mandatory reporting.

The occurrence of AMR (limited for reporting purposes to eight bacterial species) in humans is reported by countries to the EARS-Net (European Antimicrobial Resistance Surveillance Network) in a standardised protocol. Additionally, ECDC collects data as part of a case-based data sets for two diseases. Also, the reporting of AMR in food-producing animals is regulated at a European level with the Member States reporting to EFSA on a yearly basis. In general, the monitoring and reporting of AMR in food-producing animals and food is mandatory for Member States, however, the requirement of monitoring and the sample size depends on the production level (ECDC, EFSA & EMA 2015). Data on AMC in humans is collated by ECDC through the ESAC-Net (European Surveillance of Antimicrobial Consumption Network). Countries report data to ECDC either based on sales, reimbursement data or both. The data on AMC in food-producing animals is obtained on a voluntary basis whereas the methods of quantifying AMC in animals depend on the objective. Sales data is obtained either from marketing authorisation holders, wholesalers, pharmacies or feed mills.

In 2010, the European Surveillance of Veterinary Antimicrobial Consumption (ESVAC) project introduced a harmonised and standardised system. Difficulties remain in the collection of data on AMC by animal species because often, antimicrobial products are authorised for several species. Therefore, a method was developed to monitor the consumption in

animal species by combining sales data with other information. However, it still needs to be validated at country level and over time (ECDC, EFSA, & EMA, 2017 p10). Although tremendous efforts were made in harmonising methods, the methodologies of data collection still differ within the European Union.

**RECOMMENDATION:** ECDC, EFSA and EMA should continue to work on the harmonisation of methodologies within and between Member States. A guideline for implementing the proposed indicators should be made available. Standardised data enables the comparison of trends and progress between countries.

***Lack of follow-up measures:***

The data, required for measuring the indicators is already collected by Member States. Hence, monitoring and reporting systems of Member States can remain unchanged. The Joint Opinion states that the indicators' proposed aim is to monitor progress at the national and EU-level, but they are neither intended to be used for benchmarking between the Member States nor for monitoring specific interventions. Further, the opinion states that the "definition and possible setting of targets at EU level for the reduction of AMC and of occurrence/prevalence of antimicrobial-resistant bacteria are beyond the scope of this opinion" (ECDC, EFSA, & EMA 2017, p9).

**RECOMMENDATION:** The Joint Scientific Opinion by ECDC, EFSA and EMA should be followed-up with measures in three areas:

1. Common methodologies are needed that allow for a comparison of the progress





made in the Member States, enable benchmarking and, therefore, highlight best practices.

2. Country-specific indicators should be recommended to enable the evaluation of national data considering relevant animal populations, diseases and patient groups, behaviours related to antimicrobial use, and interventions. With regard to the evaluation of the effectiveness of national or local interventions, it is important to provide Member States with further assistance and resources.

3. The ECDC, EFSA and EMA should continue to support the Member States and the European Union to develop realistic and achievable targets at EU- and Member States level. The Joint Scientific Opinion on a list of outcome indicators by ECDC, EFSA and EMA serves as a valuable starting point in target-setting.

**Additional considerations:** Another challenge in the development of indicators is consideration of the appropriateness of AMC. Differences in disease patterns and prescription patterns may not always be reflected by quantitative indicators. Indicators develop and adjust over time, hence they should be able to detect the incidence of health threats, as well as long-term changes. The lifelong prevention of communicable and non-communicable diseases results in an improved overall health. This in turn reduces consumption of pharmaceuticals, the frequency of contacts with healthcare facilities and potentially the risk of infections – all favourable circumstances for a reduction in AMR.

## Conclusion

The indicators proposed by ECDC, EFSA and EMA are a valuable initiative in the fight against AMR in the European Union. However, they are not enough on their own. Further assistance and resources are needed to ensure coherent and meaningful use of the indicators across Member States. This paper proposes areas of potential action, such as further incorporation of One Health elements, harmonisation of methodologies, and follow-up measures such as benchmarking and target-setting. ECDC, EFSA and EMA should continue to support the Member States and the European Commission by developing instruments and methods for benchmarking and target setting. This may increase the pressure on the Member States and the EU to reallocate resources and to successfully tackle AMR.



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A scanning electron micrograph (SEM) showing a dense cluster of rod-shaped bacteria, likely Escherichia coli, against a black background. The bacteria are shown in various orientations, some individually and some in small groups. The surface of the bacteria appears textured with fine details.

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