

Annex

Request for a joint ECDC, EFSA and EMA scientific opinion on a list of outcome indicators as regards surveillance of antimicrobial resistance and antimicrobial consumption in humans and food-producing animals

I. BACKGROUND

Antimicrobial resistance (AMR) – the process whereby microbes evolve to resist the action of antimicrobial medicines, thus making them ineffective – is increasing worldwide, with an estimated 700,000 deaths per year globally. In the EU alone it is estimated that AMR claims over 25,000 deaths a year and incurs over 1.5 billion euros of healthcare and productivity losses¹. As a global, economic and societal challenge, tackling the emergence of AMR requires the adoption of a multisectoral ‘One Health’ approach.

Combating AMR is a priority for the European Commission (EC). Surveillance of AMR and antimicrobial consumption is essential to have comprehensive and reliable information on the development and spread of drug-resistant bacteria, to measure the impact of measures taken to reduce AMR and to monitor progress. Such data provide insights to inform decision-making and facilitate the development of appropriate strategies and actions to manage AMR at European, national and regional levels. In 2001 the EC launched the Community strategy against antimicrobial resistance², proposing monitoring the evolution and the effects of interventions through the establishment/strengthening of accurate surveillance systems on AMR and on the consumption of antimicrobial agents in the human and veterinary sectors. In 2011, the 5-year Action Plan against the rising threats from antimicrobial resistance³ introduced a set of measures to further strengthen surveillance, monitoring and data collection, improving the scope and coverage both in the human and veterinary sectors.

In the EU, monitoring and surveillance of AMR and antimicrobial consumption are currently coordinated by the three EU agencies operating in the areas of human health, food safety and pharmaceuticals: the European Centre for Disease Prevention and Control (ECDC), the European Food Safety Authority (EFSA) and the European Medicines Agency (EMA).

These three agencies collect data from Member States and other reporting countries through diverse networks:

- The European Antimicrobial Resistance Surveillance Network (EARS-Net)⁴, coordinated by ECDC, provides European reference data on antimicrobial resistance in humans for public health purposes;
- The European Surveillance of Antimicrobial Consumption Network (ESAC-Net)⁵, coordinated by ECDC, collects and analyses data on antimicrobial consumption in humans both in the community and in the hospital sector;

¹http://ecdc.europa.eu/en/publications/Publications/0909_TER_The_Bacterial_Challenge_Time_to_React.pdf

² COM (2001) 333 final

³ COM (2011) 748

⁴<http://ecdc.europa.eu/en/activities/surveillance/EARS-Net/Pages/index.aspx>

- The Healthcare-Associated Infections Surveillance Network (HAI-Net)⁶, coordinated by ECDC, is responsible for the European point prevalence survey of HAI and antimicrobial use in acute care hospitals, the European surveillance of surgical site infections, the European surveillance of HAI in intensive care units and the repeated prevalence surveys of HAI and antimicrobial use in European long-term care facilities;
- The Food-and-Waterborne Diseases and Zoonoses Network (FWD-Net)⁷, coordinated by ECDC, provides antimicrobial resistance data for diseases that are acquired by humans through the consumption of food, water or contact with animals;
- The Scientific Network for Zoonosis Monitoring Data⁸, coordinated by EFSA, collects and analyses data on antimicrobial resistance in zoonotic and commensal indicator bacteria from food, food-producing animals and food derived thereof in accordance with the EU legislation;
- The European Surveillance of Veterinary Antimicrobial Consumption (ESVAC)⁹, coordinated by EMA, collects and analyses information on how antimicrobial medicines for animal use are sold across the European Union and European Economic Area countries.

The collaboration between ECDC, EFSA and EMA resulted in 2015 in the first joint inter-EU agencies report on the integrated analysis of the consumption of antimicrobial agents and occurrence of antimicrobial resistance in bacteria from humans and food-producing animals, or Joint Interagency Antimicrobial Consumption and Resistance Analysis (JIACRA) Report¹⁰. The intensification of the cooperation on surveillance of AMR and antimicrobial consumption, building on the expertise and previous joint publications on related subjects, has enabled the report to present data in a harmonised and transparent way.

The recent evaluation of the 2011 5-year Action Plan against the rising threats from antimicrobial resistance highlighted that the EU achieved better coordination in the area of monitoring and surveillance of AMR, which resulted for instance in an enhanced harmonisation of monitoring in zoonotic and commensal indicator bacteria in the targeted food-producing animal species. However, the evaluation also called for further strengthening of monitoring and surveillance of AMR and AMR-related activities, in particular by developing expertise on methodologies, indicators and instruments to monitor trends in resistant infections and antimicrobial consumption and the effectiveness of policy interventions both in the human and veterinary sectors.

⁵ <http://ecdc.europa.eu/en/activities/surveillance/ESAC-Net/Pages/index.aspx>

⁶ http://ecdc.europa.eu/en/healthtopics/Healthcare-associated_infections/HAI-Net/Pages/HAI-Net-surveillance-network.aspx

⁷ http://ecdc.europa.eu/EN/HEALTHTOPICS/FOOD_AND_WATERBORNE_DISEASE/fwd-network/Pages/fwd-network.aspx

⁸ <http://www.efsa.europa.eu/en/data/networks>

⁹ http://www.ema.europa.eu/ema/index.jsp?curl=pages/regulation/document_listing/document_listing_000302.jsp&mid=WC0b01ac0580153a00

¹⁰ <http://ecdc.europa.eu/en/publications/Publications/antimicrobial-resistance-JIACRA-report.pdf>

Finally, the Council conclusions on the next steps under a 'One Health' approach to combat antimicrobial resistance¹¹, adopted by the Council on 17 June 2016, call upon the Member States to have in place before mid-2017 national action plans against AMR based on the 'One Health' approach and including measurable goals to reduce infections in humans and animals, the use of antimicrobials in the human and veterinary sectors and antimicrobial resistance in all domains.

In order to support the EU and Member States in their efforts to address AMR including the establishment of measurable goals to reduce infection by key drug-resistant microorganisms in humans and food-producing animals, to improve the appropriateness of the use of antimicrobials in the human and veterinary sectors and to combat AMR in all domains, the European Commission would like to establish a list of harmonised outcome indicators that would assist the EU and Member States to assess, in a clear and simple way, the progress made in the implementation of their action plans against AMR.

II. TERMS OF REFERENCE

The European Commission therefore requests the ECDC, EFSA and EMA to jointly propose a list of outcome indicators suitable for monitoring and detecting reductions of relevant magnitude in the levels of key drug-resistant microorganisms in humans, food-producing animals and food derived thereof and in antimicrobial consumption in humans and food-producing animal species.

The list of outcome indicators should be provided together with a succinct rationale for the election behind each indicator.

These indicators should meet the following requirements:

- Their number should be limited to a maximum of 15 indicators, ideally divided into primary and secondary indicators. The list of primary indicators should establish a bare minimum, i.e. the indicators which monitoring is considered essential to assess the progress made in the implementation of Member States' action plans against AMR. The list of secondary indicators should consist of indicators which monitoring is highly recommended to strengthen the assessment of the performance of national action plans against AMR. We suggest a maximum of 5 primary indicators and 10 secondary indicators.
- They should be suitable to estimate progress made towards a reduction in bacterial resistance to key antimicrobials in humans and animals in accordance with WHO, AMEG and OIE definitions, as well as improvements in the appropriateness and need for the use of antimicrobials in the EU and the Member States.
- They should be robust and take into account the 'One Health' approach in order to track and compare improvements in the human and veterinary sectors for the EU as a whole and for individual Member States.

¹¹ <http://www.consilium.europa.eu/en/press/press-releases/2016/06/17-epsco-conclusions-antimicrobial-resistance/>

- Each indicator on resistance should ideally specify the bacteria, the population concerned (human or animal), the antimicrobial substance (using where possible the ATC codes), the recommended protocol (if existing) and the reporting unit. Each indicator on consumption should ideally specify the antimicrobial class (using where possible the ATC codes), the sector (community or hospital for human level) and the reporting unit.
- They should be built wherever possible upon data already collected through the afore-mentioned different networks in order not to create additional administrative burden for Member States and preferably in line with international standards taking particular account of indicators proposed by WHO and OIE.
- They should remain pertinent and comparable for a sufficient period of time (e.g. at least 5 years) in order to reliably measure temporal trends.