

Recommendations for the Dutch Council Conclusions on Antimicrobial Resistance

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EPHA recommendations for the Draft Council Conclusions on the next steps under a One Health approach to combat Antimicrobial Resistance

Key priorities for the Dutch Presidency Council Conclusions:

- Ensure that the European Union (EU) and the national AMR policies reinforce each other and contribute to public health. The policies should, based on the national context, contain ambitious targets for the reduction of using antimicrobials, e.g. through an emphasis on preventative treatment (for infectious diseases). Moreover, they should demonstrate a strong focus on infection prevention and on maintaining health and well-being at population level, using a variety of tools (e.g. vaccination, exploring alternatives to antibiotics).
- Require prudent use of antimicrobials in all areas of the One Health approach, by removing opportunities to supply and consume antimicrobials unnecessarily (including the phasing out of routine prophylactic use of antibiotics), and by enabling better comparison and benchmarking between Member States in all sectors. This can be achieved through enhanced coordination at EU level and inter-sectoral collaboration, transfer of good practices, ensuring accurate enforcement of relevant legislation, eliminating perverse financial incentives, and combatting illegal Internet, over-the-counter and off-label sales. At the same time, the access to affordable, safe and suitable medicines and diagnostic tools must be ensured.
- Close existing data gaps by enabling the compilation of comprehensive and comparable data across Europe, and call for mandatory data reporting by Member States.
- Educate the public and health professionals to overcome common misconceptions about AMR and antimicrobials, and clearly define and emphasise the role of the latter in empowering individuals to practise prudent use.

EPHA welcomes the Dutch Presidency's continued support for expanding European collaboration and action on antimicrobial resistance (AMR), including the establishment of the European Union (EU) One Health Network that would bring together Member States and stakeholders representing human health, animal health, and the physical



environment, as well as health professionals, farmers, industry, patients, and public health interests to discuss the various dimensions of AMR and decide on joint measures. Good governance, clearly defined responsibilities, inclusiveness and transparency are important elements for the Network to succeed. It is also crucial that national governments take responsibility for undertaking rigorous monitoring and enforcements activities. Such oversight is a prerequisite if aspirations for improved stewardship are to be delivered.

EPHA is concerned that the **urgency and severity of the global AMR threat** has not sufficiently registered among policymakers, health professionals, concerned sectors (pharmaceuticals, agriculture, food, medical devices) or the general public at European and national level. This means that the understanding of AMR and its consequences to the individual, to the whole population, to the environment and to health systems remains low and under-discussed at the public level. As a result, common misconceptions about resistance and about the use of antimicrobials remain, and it seems notoriously difficult to change routines and behaviours, especially when it comes to the over-prescription and -consumption of antimicrobials.

Hence it is crucial to ensure that **awareness-raising and communication campaigns** about AMR, financed by both national and European funds, take place continuously throughout the year in all Member States, and not only around the European Antibiotic Awareness Day. They should focus more decidedly on a holistic approach to AMR to make all stakeholders, including the general public, understand the causes and consequences of AMR, and what can be done to tackle it. AMR is already recognised by the World Health Organisation as a global, cross-border health threat, and the EU has a particularly important role to play in taking leadership at the global level. EPHA is in a position to lend important support in this area through its AMR campaign.

Raising awareness among the European and global public is clearly a dimension that needs to be strengthened in order to stimulate behavioural change, and it is equally important to create political will to implement policies and initiatives that can really make a difference. EPHA thus proposes **taking a comprehensive and coherent public health approach to AMR** that focuses strongly on ensuring that good practices are shared and adopted across the European Union, supported by concrete and binding targets for antimicrobial reductions in human and veterinary medicine.

EPHA is looking forward to strong Council Conclusions by the Dutch Presidency in order to ensure that AMR remains high on the EU agenda and to **boost inter-sectoral work on AMR by creating new mechanisms for collaboration** between Member States while also involving Europe's global partners. Given the status quo, it is of utmost importance that AMR is made more tangible, as something that affects everybody, so that stakeholders in all relevant sectors realise that action is no longer an option, but an imperative, urgent and non-negotiable necessity; AMR is no longer just a future threat, it is here and now and only shows signs of increasing in intensity.

Hence EPHA recommends that the Dutch Presidency's Council Conclusions on AMR

CALL UPON THE MEMBER STATES TO:

1. develop national action plans (and update existing ones) before mid-2017 following a clear timeline, in line with the WHO Global Action Plan objectives, taking on a One



Health approach. The plans should be accompanied by data on causes, prevalence and impacts of AMR. Furthermore, they should:

- a. ensure that all AMR measures and actions are taken in the interest of public health;
 - b. ensure that AMR is an inter-sectoral priority at national and regional level, and be developed in consultation with all relevant public sector actors including ministries and agencies, the private sector and civil society;
 - c. ensure that surveillance data are comprehensive, coherent and comparable to monitor the implementation and progress of national action plans, and to use them to identify best practice between Member States;
 - d. include a mechanism for the implementation of national action plans and monitoring of their progress following the **WHO manual for developing national action plans on AMR**;
 - e. stipulate how enforcement is organised and ensured in the Member States;
 - f. include targeted campaigns to raise awareness and strengthen antimicrobial stewardship, for healthcare professionals, patients, consumers, and farmers; and set out with clarity and precision the roles of different healthcare professionals in driving improved use of antimicrobials;
 - g. include binding and non-binding measures to improve the prudent use of antimicrobials in human health, e.g. remove circumstances in which antimicrobials can be easily obtained, ensure a robust system is in operation to guarantee the appropriate supply of antimicrobials, ensure the provision of preventative measures, and step up vaccination programmes;
 - h. include binding targets to reduce the use of antimicrobials in the human and veterinary sector, reduce resistance in all domains and reduce infections in human and animals. These targets should be tackled via **SMART formulated actions** adapted to the Member States' national situations. These targets could include e.g. the number of HCAs acquired by patients in healthcare settings;
 - i. include binding and non-binding measures to improve the prudent use of antimicrobials in animal health; eradicate the practice of routine preventive use of antimicrobials in animal farming while simultaneously enhancing farm animal welfare and health through good husbandry;
 - j. include binding and non-binding measures to reduce the use of veterinary antimicrobials that are of critical importance to human health;
 - k. **identify and address weaknesses in national surveillance systems** and make improvements according to the **characteristics of a good surveillance system to be set by the Commission**. Include in the characteristics at least the quality of surveillance data on resistance and use of antimicrobials in humans, animals and the environment to be reported to relevant EU agencies (ECDC, EMA, EFSA);
2. ensure that national action plans are ready for presentation to the EU One Health Network on AMR by mid-2017;
 3. hold each other accountable for the implementation of public health measures in the national plans;



4. frame AMR as a **health security issue**, e.g. via the EU Health Security Committee;
5. adopt and implement legislation that will support the actions and measures included in the national action plans on AMR;
6. negotiate with the pharmaceutical industry and other partners to set effective measures and/or incentives to minimise overuse and unnecessary use of existing antimicrobials while ensuring affordable access to the public for appropriate use; strengthen industry recognition that there is a global AMR crisis;
7. set priorities and ensure the development and delivery of **new antimicrobials and diagnostic tools that are affordable, accessible and suitable** and are used responsibly; and the management of intellectual property to ensure open knowledge sharing and improve further innovation from research;
8. strengthen commitment to the Joint Programming Initiative on AMR, to articulate and coordinate national research priorities and put in place measures to support their implementation;
9. encourage all relevant partners including national Regulatory Authorities, to **explore new models for research and development** to deliver new antimicrobials, whilst upholding the highest standards to assure patient safety;
10. develop diagnostic tools and ensure their use in the human and veterinary sector as a means to enable appropriate prescription of antimicrobials;
11. **strengthen laboratory infrastructure** with, e.g. state-of-the-art diagnostic tools, for improved surveillance and epidemiological research.

CALL UPON THE MEMBER STATES AND THE COMMISSION TO:

1. work closely together in the preparation of a new EU Action Plan on AMR by taking into account the WHO Global Action Plan, the outcome of the evaluation of the current Action Plan, relevant national and international documents (e.g. the UK Review on AMR reports, G7 declaration, transferable good practices of national action plans) and the conclusions of the EU Ministerial One Health Conference of 10 February 2016. The new EU Action Plan should propose new initiatives for their implementation and for the reporting to the Council.

It should include the following elements to strengthen the One Health approach:

- a. the environmental dimension should be strengthened by:
 - i. introducing binding global supply chain standards, including environmental criteria into Good Manufacturing Practice to be applied by pharmaceutical companies producing antimicrobials;
 - ii. include environmental data in monitoring and surveillance;
 - iii. **making Environmental Risk Assessment a mandatory part of the marketing authorisation process for antimicrobials, including old products that have never been tested;**
 - iv. ensuring that the Commission's Pharmaceuticals in the Environment strategy sets binding limits for their presence (residues) in ground and surface water;



- b. the animal health dimension should be strengthened by:
 - i. ensuring the provisions of the Veterinary Medicinal Products Regulation and the Regulation on Animal Health are supported by implementation guidelines for veterinarians, farmers and animal keepers;
 - ii. **incentivise veterinarians and farmers to no longer treat animals prophylactically or metaphylactically** (e.g. by implementing alternatives for ensuring animal welfare by improving living conditions, providing healthy feed and strengthening hygiene measures);
 - iii. improving collection of comparable data on use of antimicrobials in the agricultural sector throughout Europe, per animal species. This should also cover testing meat for the presence of resistant and susceptible bacteria;
 - iv. ensuring the highest possible standards of animal welfare by ensuring stocks with suitable genetic diversity, densities that reduce the risk of disease transmission and isolation of sick animals from herds to improve infection control);
- c. the human health dimension should be strengthened by:
 - i. improving systems for comparable data collection on antimicrobial use in human health throughout Europe, **including qualitative data on the reasons for continued demand and availability** (cultural, socioeconomic and behavioural aspects);
 - ii. making available EU Guidelines for prudent use of antimicrobials in human health;
 - iii. investing in and making best use of new technology, including rapid diagnostic testing and eHealth tools, to enable more effective treatment decisions for patients, better infection control and (self-) monitoring;
- d. all dimensions of One Health can be strengthened by:
 - i. creating a more holistic monitoring and surveillance system for AMR, e.g. by expanding the compilation of ECDC data across Europe for better knowledge of the real extent of AMR, infection control and antimicrobial stewardship;
 - ii. emphasising on both student and professional level the importance of healthcare workforce training, including consistent training in microbiology, antibiotic pharmacotherapy and drug development related topics;
 - iii. **placing greater emphasis on maintaining health as a prevention** against infection and thereby reducing the need for antimicrobials;
 - iv. making best use of ICT and social media tools for communicating AMR and its implications to maximum effect, and by incorporating them in targeted awareness campaigns.



It should also include the following goals and targets:

- a. ensure the implementation of good management practices on antimicrobial use and infection control are in place in both the human and veterinary sector; enable comparison between countries and regions to encourage the adoption of successful good practices in all Member States;
 - b. **remove financial incentives** for individuals (e.g. health and animal health professionals) and institutions to unnecessarily use antimicrobials on farms (e.g. by improving livestock living conditions, instead of using antimicrobials prophylactically) and in human health, by emphasising prudent use and supply of antimicrobials;
 - c. strengthen legislation and combat illegal practices related to the trade and use of antimicrobials, including **illegal over-the-counter and Internet sales and off-label uses**;
 - d. develop and align surveillance systems in humans, food, animals and environment on AMR at EU level;
 - e. the spread of AMR in humans, animals and the spread in the environment within the EU shall decrease in the next five years (compared to 2015);
 - f. the differences between Member States in use of antimicrobials in human, animal and environmental health shall decrease in the next five years (compared to 2015); and for all MS, the antimicrobial usage should decrease over the next five years;
 - g. have in place effective prevention, hygiene and infection control measures to **combat healthcare associated infections** in the EU over the next five years (compared to 2015);
 - h. **set characteristics for the monitoring system required to obtain adequate and comparable data** on resistance and antimicrobial uses across Europe;
2. promote coordination and cooperation between Member States, between MS and the Commission, and between the different relevant sectors of the One Health approach within the framework of a One Health-AMR network to be facilitated by the EC. The governance structure of the network must be transparent and inclusive, and ideally equipped with binding decision-making powers;
 3. set up measures to further restrict the use and promote the prudent use of veterinary antimicrobials, including **phasing out preventive use of antimicrobials and restrictions on the use of antimicrobials that are of critical importance to human health**, e.g. mandatory susceptibility testing before the use of those antimicrobials;
 4. set up a country-to-country assessment system and peer review schemes to evaluate improvements;
 5. define a common EU approach and lead global discussions on AMR, especially on the implementation of the WHO GAP, the FAO and the OIE Resolutions on AMR and the implementation and updating of the intergovernmental standards related to AMR published by Codex Alimentarius and the OIE;
 6. establish a European multi-disciplinary strategy commission to define a prioritised multidisciplinary R&D agenda on new antimicrobials, alternatives and diagnostics



based on public health, animal health and environmental needs and taking into account the gaps analysis in this domain;

- a. emphasise in this research agenda the need for an increased collaboration between teaching faculties and researching institutes;
 - b. include the possibility for research projects to be directly linked to antibiotic development, and to be a focal point for synergetic activities between universities and research institutes;
 - c. include in the research strategy a biological aspect: the exploration of mechanisms that can boost the immune system. Antimicrobial infections are often the result of two biological factors: the exposure to a microbe and a person's susceptibility;
7. investigate the potential of alternative methods to prevent infectious diseases as well to treat infectious diseases in humans and animals, so as to reduce the need for antimicrobials;
 8. actively discuss and, when possible, implement a new business model for bringing new antimicrobials to the market, in which investment costs are de-linked from sales volumes;
 9. support, in close cooperation between the Member States and the Commission, the proposals to put AMR on the agenda of the UN General Assembly in Sep 2016, in order to involve all Heads of State and all relevant UN organisations;
 10. **empower ECDC with an enhanced mandate and an appropriate budget** to make country specific and European recommendations on improving antimicrobial stewardship, based on the data it receives and analyses.

CALL UPON THE COMMISSION TO:

1. demonstrate Europe's added value by establishing and coordinating new mechanisms for the Member States and all other relevant AMR stakeholders to come together:
 - a. support the development, assessment and implementation of new national action plans against AMR and the review of existing ones;
 - b. facilitate **a One Health-AMR network including**, among others, civil society, patient and health professional organisations, representatives of public health, the food and agricultural sector;
 - c. ask the network to compile, disseminate and discuss good practices already implemented in the MS, coupled with concrete advice on how to achieve them;
 - d. ask the network to report to the Council, European Parliament and European Commission at least once a year on the developments pertaining to the implementation of the EU Action Plan;
 - e. encourage MS and the network to explore the role of European joint procurement of high-value antimicrobials to ensure their preservation;



2. assume a global leadership role by ensuring that the decisions of the network are used to encourage action against AMR at global level, e.g. via a global AMR observatory that would ensure coherence of data collection and policy action;
3. provide Member States and regions with targeted technical, educational and financial support through available EU programmes and Structural Funds;
4. focus more attention on **researching alternatives to antimicrobials**, including CAM modalities, traditional healthcare, vaccination and phage therapy;
5. establish a harmonised approach to prevent introduction and spread of emerging AMR in the food chain which has a potential impact in public health (e.g. carbapenem resistance); ensure appropriate food safety monitoring practices;
6. develop as a matter of priority specific delegated acts under the Animal Health Regulation including infection prevention measures, good management practices in animal husbandry, and harmonised surveillance systems in animal pathogens;
7. actively promote and defend in multilateral and bilateral dialogues, and in agreements between the EU and its counterparts, and **further develop EU standards and policies on AMR in accordance with the precautionary principle**, especially:
 - a. the importance of infection prevention, **vaccination coverage**¹, prudent use of antimicrobials and strengthening the awareness of the risks of AMR;
 - b. the ban on the use of antimicrobials as growth promoters in livestock farming;
 - c. the phasing out of the routine preventive use of antimicrobials in veterinary practice;
 - d. the phasing out of the use in veterinary practice of antimicrobials that have not yet been authorised in veterinary medicine in the EU and that are critically important for the prevention and treatment of life-threatening infections in humans;
 - e. **introduce CAP conditionalities**, including an update of the cross-compliance legislations reflecting the need for higher animal health- and welfare standards, and the conversion of the direct payment system into f. development-payments. Together, these would provide a legislative and financial incentive for farmers to improve their farming practices, as so to reduce the need for antimicrobials and thus reduce the development of AMR;
 - f. investigate the current use of alternatives in food production, with a view to wider use and integrate alternatives across the whole animal food industry;
8. **stress the human side of AMR** by conducting research into consumer behaviour, farmer and health-worker attitudes, and into social aspects of AMR including the public attitude and (inter)national prescribing practices;
9. ensure that all relevant Directorate-Generals of the Commission collaborate effectively to tackle AMR in an effective way.

¹ Draft Council conclusions on vaccinations as an effective tool in public health (15090/14)
<http://register.consilium.europa.eu/doc/srv?l=EN&f=ST%2015090%202014%20INIT>

About EPHA

EPHA is a change agent – Europe's leading NGO advocating for better health. We are a dynamic member-led organisation, made up of public health NGOs, patient groups, health professionals, and disease groups working together to improve health and strengthen the voice of public health in Europe. EPHA is a member of, among others, the Social Platform, the Health and Environment Alliance (HEAL), the EU Civil Society Contact Group and the Better Regulation Watchdog.

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