

Trio Presidency of the Council of the European Union
France, Czech Republic and Sweden

DECLARATION ON ANTIMICROBIAL RESISTANCE

On 07 March 2022, the French Presidency of the Council of the European Union (EU) organised a High-Level One Health Ministerial Conference on Antimicrobial Resistance (AMR) during which the Trio Presidency of the Council of the EU (France, Czech Republic and Sweden) presented this Declaration.

The Trio Presidency places special emphasis on the fight against AMR in the EU.



SUMMARY

The Trio Presidency of the Council of the European Union (EU) calls on the European Union and its Member States to strengthen their action and cooperation at European and international level with regards to the fight against antimicrobial resistance (AMR), one of the main global public and animal health threats. This notably includes:

- Strengthening the existing cooperation with international organisations;
- Advocating for actions against AMR to be central in the ongoing negotiations on the International Health Regulations (IHR) and within the multilateral initiatives on health emergencies, such as the upcoming international agreement instrument on pandemics;
- Advocate for, and support international implementation of relevant standards from OIE, IPPC and Codex Alimentarius;
- Reinforcing the collaboration and synergy between the relevant services of the European Commission (EC).

The Trio Presidency reaffirms its support to the objectives set up in the 2017 EU One Health Action Plan, as well as its commitment to strong and multidisciplinary actions within a *One Health* approach at European and national level, as recommended in the 2015 WHO Global Action Plan on AMR. The French, Czech and Swedish Presidencies also acknowledges the recent outputs of the 2017-2021 European joint action on antimicrobial resistance and healthcare-associated infections (EU-JAMRAI), coordinated by France, and seek to build on the EU-JAMRAI's momentum, key results and recommendations.

The Trio Presidency calls on the EU and its Member States to focus on the unmet needs to address urgently in order to step up the fight against AMR, including but not limited to:

- The strong need for ambitious **AMR-related, evidence-based, education initiatives**, taking into account the *One Health* approach.
- The need for enforced **Infection Prevention and Control (IPC)** measures in human and animal health and **biosecurity measures** in animal health across the EU.
- The crucial need to **increase preventative measures regarding animal health**, such as improved animal husbandry, biosecurity and vaccination as relevant.
- The cooperation between all concerned parties at all levels, including between national authorities and the private sector, is also crucial.
- The essential development of **European standards, guidance and indicators** to improve antimicrobial stewardship (AMS), IPC and biosecurity practices with a *One Health* approach. The project of a possible common ambitious AMR framework or agreement at EU level might be explored and discussed. The tools provided in EU regulations on veterinary medicinal products and on transmissible animal diseases should be part of such initiatives.
- The design and the implementation of ***One Health* monitoring and surveillance systems** for antimicrobial use and AMR, with account taken to existing systems, critical to follow AMR trends and take measures to limit the associated risks.

- Ensuring the **availability of antibiotics**, both for humans and animals by improving the accessibility and availability of high quality authorised medicines.
- The necessity to **address health market failures**, strengthen the value chain in the health sector and support the development of health innovations at the European level.

The Trio Presidency welcomes the Commission's intention to put forward an AMR policy initiative for the end of 2022. AMR is an issue that we expect to be high on the Council's agenda during the Trio Presidency.

TRIO PRESIDENCY DECLARATION ON ANTIMICROBIAL RESISTANCE

Antimicrobial resistance (AMR), in particular bacterial resistance to antibiotics, is one of the main global public health threats, as highlighted by the World Health Organization (WHO)¹.

In the EU, the estimated burden of infections with antibiotic-resistant bacteria in humans has increased since 2007² and infections due to multidrug-resistant bacteria are now responsible for an estimated 33 000 deaths per year. Tackling AMR requires urgent reinforced multi-sectoral action, as it has a direct impact on human health, animal health and on the environment, and therefore carries a heavy economic burden.

Coordinated efforts across the EU are required to tackle AMR. No country can succeed on its own.

- **1.** The Trio Presidency places special emphasis on the importance of fostering a *One Health* approach in tackling AMR, taking into account the complexity of the interface of human, animal and environmental health.
- **2.** We call on the EU and its Member States to build on and strengthen the existing cooperation between, on the one hand WHO, Food and Agriculture Organization of the United Nations (FAO), World Organisation for Animal Health (OIE), United Nations Environment Programme (UNEP), and, on the other hand International Plant Protection Convention (IPPC), to develop and implement long-term, sustainable solutions to reduce the spread and impact of AMR in humans, animals, plants, food and the environment.
- **3.** Significant progress has already been made. In 2017, the European Commission launched the European One Health Action Plan against Antimicrobial Resistance, following the Council Conclusions of 17 June 2016. Since then, the Commission, EU agencies and Member States have conducted many actions within the framework of the 2017 EU One Health AMR Action Plan. The 2019 Council Conclusions on the next steps towards making the EU a best practice region in combatting AMR suggested further actions.
- **4.** AMR being a global cross-border health and development threat, we believe actions against AMR should be strengthened in the International Health Regulations (IHR) and included in the collective pandemic preparedness and response initiatives to health emergencies, such as in the upcoming international agreement instrument on pandemics, and further addressed in other relevant international organisations.

International standards on monitoring and prudent use of antibiotics for animals have been developed by the OIE and the Codex Alimentarius. The standards of OIE are in a process to be updated. The EU should advocate for, and support, implementation of these standards internationally and call on the IPPC to encourage the reduction of the use of antimicrobial products for plant health purposes.

- **5.** The Trio Presidency is committed to action and supports an update of the 2017 EU One Health AMR Action Plan to strengthen the fight against AMR. As AMR needs to be addressed in a comprehensive *One Health* perspective, further reinforcing the collaboration and synergy

¹ [Antimicrobial resistance \(who.int\)](https://www.who.int/antimicrobial-resistance)

² Cassini A. et al (2019). The Lancet, 19:1.

between the relevant services of the European Commission (EC) should be considered. Member States authorities are also encouraged to develop and update their national action plans on AMR, as appropriate.

- **6.** Tackling AMR requires strong and multidisciplinary actions in a *One Health* approach from the EU and its Member States, as recommended in the 2015 WHO Global Action Plan on AMR, in order to:

- (i) Improve awareness and understanding of AMR through effective communication, education and training;
- (ii) Strengthen the knowledge and evidence base through interoperable surveillance systems and coordinated, collaborative and multidisciplinary research;
- (iii) Reduce the incidence and burden of infections (both community-acquired and healthcare-associated) through effective Infection Prevention and Control (IPC) measures in human and veterinary medicine as well as biosecurity measures in veterinarian medicine;
- (iv) Increase preventative measures regarding animal health, such as improved animal husbandry, biosecurity and vaccination as relevant, by cooperation between all concerned parties at all levels, including between national authorities and the private sector;
- (v) Optimize the responsible use of antimicrobial medicines (i.e. AntiMicrobial Stewardship (AMS));
- (vi) Develop new antimicrobials, vaccines, alternatives to antimicrobials, diagnostic methods, and other interventions addressing unmet needs, as well as maintain availability of existing antimicrobials.

- **7.** The Trio Presidency reaffirms its support to the objectives set up in the 2017 EU One Health Action Plan:

- (i) Making the EU a best practice region with better evidence, better coordination and surveillance, and better control measures, which should serve primarily as tools to assist Member States to tailor their national strategy to fight against AMR to their local conditions, taking feasibility and added burden into account;
- (ii) Boosting research, development and innovation by closing current knowledge gaps, providing novel solutions and tools to prevent and treat infectious diseases, and improving diagnosis in order to control the spread of AMR;
- (iii) Intensifying EU efforts worldwide to shape the global agenda on AMR and the related risks in an increasingly interconnected world.

Additionally, the Trio Presidency affirms its support to the objectives set up in the *Farm to Fork* strategy, in particular the objective of the reduction of overall EU sales of antimicrobials for farmed animals and in aquaculture by 50% by 2030. The Trio remains aware of the challenge of this EU objective. We believe that the significant decrease achieved in some Member States before the *Farm to Fork* strategy should also be taken into account. We believe such objectives will contribute to truly make the EU a best practice region.

- **8.** We acknowledge the recent outputs of the 2017-2021 European Joint Action on antiMicrobial Resistance and healthcare-Associated Infections (EU-JAMRAI), coordinated by France, which

strengthened the collaboration between Member States and highlighted remaining gaps that still need to be urgently addressed in the field of AMR. Hence, we will seek to build on the EU-JAMRAI's momentum, key results and recommendations. We welcome the inclusion of a new joint action focusing on the implementation of AMR measures by Member States in the 2022 EU4Health programme.

- **9.** While we acknowledge that tackling AMR needs a global multifaceted strategy addressing all the objectives listed above, we are focussing thereafter on the unmet needs and key actions on AMR, which we consider should be *urgently* addressed by Member States and the European Commission.
- **10.** We commend the **educational tools** developed by the EU-JAMRAI to support Member States as well as scientific, educational and awareness-raising communities, and we support the inclusion of further educational initiatives in the upcoming joint action on AMR. We believe there is a strong need for ambitious AMR-related education initiatives, taking into account the *One Health* approach, targeting children and teenagers primarily through inclusion in school education and curricula, which will make use of valuable existing tools and develop new educational resources. We encourage to do so at national level and encourage the Commission to also facilitate this work at EU level, making these resources accessible to all Member States. For instance, we appreciate the tools produced by EU initiatives such as the e-Bug program aiming at supporting teachers to educate children and teenagers. We also encourage the implementation of actions to increase awareness among parents and childhood professionals around this issue. The 2021-2027 EU work programme on health (EU4Health) might help support these actions.
- **11.** The COVID-19 pandemic as well as zoonotic and non-zoonotic outbreaks in the animal population, have brought into strong focus the **importance of Infection Prevention and Control (IPC)** in human and animal health as well as of improved animal husbandry and strengthened **biosecurity measures** in animal health and food production. Reducing the incidence of both community-acquired and healthcare-associated infections in human and veterinary medicine or improving animal husbandry and biosecurity practices contributes to reducing AMR. We therefore recognize the need for enforced IPC measures across the EU. The EU One Health AMR Action Plan as well as the national action plans should include actions to reinforce IPC measures, targeting in particular bacterial and viral infections. The EU4Health work programme as well as the European Commission's Farm to Fork Strategy and Regulation (EU) 2016/429 on transmissible animal diseases might help reinforce IPC and biosecurity actions.
- **12.** To improve Antimicrobial Stewardship (AMS), Infection Prevention and Control (IPC) and biosecurity practices with a *One Health* approach, we urge the European Commission to facilitate the development of **European standards, guidance and indicators**. These standards, guidance and indicators should take into account the necessity of implementation strategies based on behavioural science evidence, with the aim for continuous quality improvement using collected data for action, and in accordance with the objectives of the European Commission's *Farm to Fork* Strategy. As recommended by the EU-JAMRAI and the 2019 Council Conclusions on the next steps towards making the EU a best practice region in combatting AMR, we recommend in particular:
 - (i) **Core competencies**³ that may be used as a reference in the EU for the undergraduate and postgraduate training of professionals in human and animal health. There is also a need to implement mentorship and observership programmes on IPC and AMS³ in human and

³ EU-JAMRAI, D4.4 "Report on sustainability plan", 2021. https://eu-jamrai.eu/wp-content/uploads/2021/03/EUjamrai_D4.4_Report-on-sustainability-plan_WP4_MoH_20210225.pdf

veterinarian medicine as well as biosecurity in veterinarian medicine. The EU4Health work programme and the Better Training for Safer Food (BTSF) EU Training Programme on AMR might help support these actions.

- (ii) Standardized **core elements**⁴ for AMS, biosecurity and IPC programmes. These would guide implementation at national and facility levels, both in human and animal health, and would represent the minimum reference framework for all Member States. EU4Health and the BTSF EU Training Programme on AMR might also help support this action. European agencies such as European Centre for Disease prevention and Control (ECDC), European Medicines Agency (EMA) and European Food Safety Authority (EFSA) could be mandated by the European Commission to develop such guidance.
- (iii) We call the European Commission on developing further as relevant the existing set of common **indicators on AMR and antimicrobial consumption** developed by ECDC, EFSA and EMA, and to broaden their scope to monitor progress made against shared objectives across the EU⁵. This should be done both at the European level (within the existing and future EU One Health action plan) and at the Member State level (national action plans).

This need has already been mentioned by the EU-JAMRAI and was listed within the 2019 Council Conclusions on the next steps towards making the EU a best practice region in combatting AMR. We believe it is crucial to develop a set of such key indicators *with associated targets* (e.g. on AMS, biosecurity and IPC programs, antibiotic usage, including quantity and appropriateness, and AMR) for the human and animal health sectors, that also integrate environmental issues (with common *One Health* indicators when possible), that might be used by Member States on a voluntary basis. European agencies such as ECDC, EMA and EFSA could also be mandated by the European Commission to develop such guidance.

- (iv) Facilitating the routine collection of data and indicators on the **appropriateness of antibiotic usage** in particular, both at national and European level in humans and animals, is urgently needed, since almost all available data currently focus only on quantity and volume of use.

- **13. Monitoring and reporting** such standards and indicators will contribute to improving the level of preparedness and response measures to cross-border health threats across the EU, in line with the Proposal for a Regulation of the European parliament and the Council on serious cross-border threats to health and repealing Decision No 1082/2013/EU, as well as the ECDC's new mandate. The project of a possible **common ambitious AMR framework or agreement at EU level** might be explored and discussed, thus facilitating the discussions around a global agreement on access and use, mentioned in the Mission Letter to Commissioner Stella Kyriakides⁶.
- **14.** The design and the implementation of *One Health monitoring and surveillance systems* for antimicrobial use and AMR are critical to follow AMR trends and take measures to limit the

⁴ EU-JAMRAI, Policy brief "The need to develop core elements at the European level on IPC and AMR", 2021. https://eu-jamrai.eu/wp-content/uploads/2021/03/201022_EUJAMRAI_policy-brief_WP4_core-elements.pdf

⁵ EU-JAMRAI, Policy brief "The need to develop indicators and targets for AMR action plans in the EU", 2021. https://eu-jamrai.eu/wp-content/uploads/2021/03/201022_EUJAMRAI_policy-brief_WP4_indicators.pdf

⁶https://ec.europa.eu/commission/commissioners/sites/default/files/commissioner_mission_letters/mission-letter-stella-kyriakides_en.pdf

associated risks. The WHO⁷ guidelines, the OIE standards⁸, the *Codex alimentarius*⁹ standards as well as the regulation (EU) 2019/6 of the European Parliament and of the Council of 11 December 2018 on veterinary medicinal products and Regulation (EU) 2016/429 of the European parliament and of the Council of 9 March 2016 on transmissible animal diseases might help support this action, together with the EU4Health programme.

Monitoring and surveillance programmes should cover all sectors in a *One Health* approach and limit gaps in data. The EU-JAMRAI highlighted the lack of surveillance of AMR for diseased animals as compared to existing clinical surveillance data in human health. The Trio Presidency reaffirms its support to the development of the European network of AMR surveillance in diseased animals (EARS-Vet) in the upcoming joint action on AMR and healthcare-associated infections.

As already identified by the Joint Interagency Antimicrobial Consumption and Resistance Analysis (JIACRA), data generated from monitoring and surveillance programmes should be analysed in a cross-sectorial manner. The EU agencies should contribute further to the harmonization and interoperability of national and regional systems, in support of the European Commission and the Member States.

As identified in 2021 by EMA¹⁰ and EFSA¹¹ and in order to estimate the burden of AMR in the environment, we recognize the need for more research on the role played by the environment in the emergence and spread of AMR, and of strengthened surveillance of AMR in the European environment. Both EMA and EFSA have underlined the knowledge gaps concerning respectively the risks of AMR in the environment due to the use of antimicrobials in veterinary medicine towards human and animal health, and concerning the role played by the environment in the emergence and spread of AMR through the food chain.

As concluded by the Commission in the 2019 Communication on an EU Strategic Approach to Pharmaceuticals, pollution caused by pharmaceuticals is an emerging problem with well-documented evidence of risks to the environment and, particularly in relation to antimicrobial resistance, to human health. Further, the Commission states that while there are still substantial knowledge gaps to be filled, there is sufficient evidence that action should be taken to reduce the risk from pharmaceuticals in the environment. The upcoming revisions of legislative acts such as the Industrial Emissions Directive and the Urban Wastewater Directive as well as the pharmaceutical legislation, offer a window of opportunity to address this issue and take action against AMR in the environment.

- **15.** We welcome the opportunities in the **EU regulations adopted in 2019 on veterinary medicinal products** and the **2020 EU pharmaceutical strategy** to combat AMR. For instance, the upcoming reform of the pharmaceutical legislation will introduce measures to restrict and optimise the use of antimicrobial medicines and foster innovation for the development of innovative antimicrobials. In addition, the European Commission should facilitate unit dispensing of antibiotics across the EU, as recommended in the 2017 EU AMR One Health action

⁷ [WHO guidelines for the use of antimicrobials important for human medicine in food-producing animals: note for guidance. World Health Organization.](#)

⁸ [Terrestrial Animal Health Code : Chapter 6.9. « Monitoring of the quantities and usage patterns of antimicrobial agents used in food-producing animals » ; Chapter 6.7-6.11 in the Terrestrial Code \[Terrestrial Code Online Access - OIE - World Organisation for Animal Health\]\(#\)](#)

[Aquatic Animal Health Code : Chapter 6.3. « Monitoring of the quantities and usage patterns of antimicrobial agents used in aquatic animals » Chapter 6.1-6.5 in the Aquatic Code \[Aquatic Code Online Access - OIE - World Organisation for Animal Health\]\(#\)](#)

⁹ [Codex Guidelines on integrated monitoring and surveillance of foodborne antimicrobial resistance \(CXG 94-2021\)](#)

¹⁰ https://www.ema.europa.eu/en/documents/scientific-guideline/reflection-paper-antimicrobial-resistance-environment-considerations-current-future-risk-assessment_en.pdf

¹¹ <https://efsa.onlinelibrary.wiley.com/doi/epdf/10.2903/j.efsa.2021.6651>

plan. The EU4Health work programme might help support this action. The EMA should also be mandated by the European Commission to work on this.

We welcome the tools provided in Regulation (EU) 2019/6 on veterinary medicinal products, as well as Regulation (EU) 2016/429 on transmissible animal diseases. For instance, adherence to Article 107 of the former will support a more prudent use of antimicrobials medicinal products in animals, and implementation of the responsibilities for biosecurity of the latter has potential to improve animal health and reduce the need for antimicrobials in animal production.

We also welcome the new regulation on veterinary medicinal products, which provides that imported food of animal origin into the EU does not come from animals that have received any antimicrobials medicinal products used to promote growth or to increase yields or are reserved for the treatment of certain infections in humans.

- **16.** The **availability of antibiotics** should be ensured, both for humans and animals. It is a priority at Trio and European level. We wish to be part of the continuity of the ambitions expressed during the Slovenian Presidency, aimed at improving the accessibility and availability of high quality authorised medicines, in particular where there may be a lack of commercial interest, as in the case of antimicrobials. The evidence-based repurposing of already approved, off-patent antimicrobials should be explored further to treat patients and animals in areas of unmet needs. We support the ambitions of the 2020 EU pharmaceutical strategy, the new mandate of the EMA and appreciate the work of the Antimicrobial Advice Ad Hoc Expert Group (AMEG) on the categorization of antimicrobials as for use in animals. The adoption in October 2021 of the European Commission delegated regulation establishing the criteria for the designation of antimicrobials to be reserved for the treatment of certain infections in humans, thus forbidding their use for animal health, is an important step that we welcome. The upcoming publication of the list of those antimicrobials will be a real step forward towards the goals expressed here. We are committed to secure the supply of antibiotics and call for the integration of this topic of great concern in the upcoming international instrument on pandemics.
- **17.** We welcome the creation of the Health Emergency Preparedness and Response Authority (**HERA**), a European structure aiming at improving preparedness and response to serious cross-border threats in the area of medical countermeasures and welcome the integration of AMR in HERA's scope of activities. We recognize that HERA represents an important tool for addressing the challenge of antimicrobial resistance, taking into account the *One Health* approach.
 - (i) We welcome that HERA will be in charge of ensuring sufficient supply of the relevant medical countermeasures (MCMs) and developing new countermeasures against existing, emerging or unknown pathogens and cross-border threats.
 - (ii) We highlight the need for HERA to focus on accelerating the research and development of new AMR-related MCMs and to implement appropriate operational, funding and support mechanisms to bring and maintain new and old AMR-related MCMs on the market.
 - (iii) In the context, we stress the need for HERA to support enhanced public-private cooperation and partnerships, in synergy with Horizon Europe partnerships, in the field of science and clinical research to jointly combat AMR.
- **18.** We congratulate the Joint Programming Initiative on Antimicrobial Resistance (JPI-AMR) initiative on its impressive outputs and call for the Horizon Europe program to further strengthen the support to *One Health* AMR including via the planned *One Health* AMR partnership. We urge the European Commission to reinforce and expand the EU *One Health* research efforts on AMR, especially on antibiotic resistance, and to launch Research Chairs on AMR.

- **19.** The COVID-19 pandemic has shed light on the importance of a resilient European industry and open strategic autonomy when it comes to health. We thus acknowledge the necessity to address health market failures, strengthen the value chain in the health sector and support the development of health innovations at the European level. A possible contribution to these objectives could be the launch of a health Important Project of Common European Interest (IPCEI). We also support the *One Health* Approach initiated at global level by international organisations in order to work together in order to prevent the spread of serious zoonosis and future pandemics.
- **20.** We recognize that AMR affects all countries, but that the burden is disproportionately higher in low-income and middle-income countries.¹² We therefore commit to strengthen our support to low- and middle-income countries, in cooperation with WHO, OIE, FAO and UNEP on one hand, and with IPPC on the other hand, with initiatives such as the AMR Multi-Partner Trust Fund (AMR MPTF) where donations support the implementation of national action plans against AMR, or the One Health High Level Expert Panel (OHHLEP), proposed by France with the support of Germany and set up by WHO, FAO, OIE and UNEP in May 2020.
- **21.** We welcome the Commission's intention to put forward an AMR policy initiative for the end of 2022. AMR is an issue that we expect to be high on the Council's agenda during the Trio Presidency.

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¹² The Lancet 2022. [https://doi.org/10.1016/S0140-6736\(21\)02724-0](https://doi.org/10.1016/S0140-6736(21)02724-0)