

Council of the European Union

> Brussels, 28 February 2020 (OR. en)

6341/20

FIN 127 SAN 63 VETER 16 AGRI 67 PHARM 3

'I/A' ITEM NOTE

From:	General Secretariat of the Council
To:	Permanent Representatives Committee/Council
No. prev. doc.:	14538/19 FIN 774 SAN 486 VETER 99 AGRI 572 PHARM 50 14539/19 FIN 775 SAN 487 VETER 100 AGRI 573 PHARM 51
Subject:	Draft Council conclusions in response to the European Court of Auditors' Special Report No 21/2019: "Addressing antimicrobial resistance: progress in the animal sector, but this health threat remains a challenge for the EU" - Adoption

 On 15 November 2019, <u>the European Court of Auditors</u> published Special Report No 21/2019 entitled "Addressing antimicrobial resistance: progress in the animal sector, but this health threat remains a challenge for the EU"¹.

Under the rules laid down in the Council conclusions on improving the examination of special reports drawn up by the Court of Auditors², <u>the Permanent Representatives Committee</u> on 4 December 2019 instructed the Working Party of Public Health to examine, with the appropriate involvement of the Working Party of Agriculture Counsellors/Attachés (Agri - Veterinary matters), the report in accordance with those rules³.

¹ This special report is available in 23 EU languages on the Court's website: <u>www.eca.europa.eu</u>.

² Doc. 7515/00 + COR 1.

³ Doc. 14539/19.

- 3. <u>The two Working Parties</u> examined the report at a meeting on 14 January 2020, at which representatives of the European Court of Auditors presented their main findings.
- 4. Based on that examination, <u>the Presidency</u> prepared a set of draft Council conclusions⁴, that was circulated to delegations.
- Following informal consultations, two revised sets of draft Council conclusions were prepared⁵ and circulated to delegations. As a result, tentative agreement was reached on the draft Council conclusions set out in the <u>Annex</u> to this note.
- 6. Consequently, <u>the Permanent Representatives Committee</u> is invited to confirm the agreement reached at Working Party level and to recommend to <u>the Council</u> to adopt, as an "A" item at one of its forthcoming meetings, the draft Council conclusions set out in the <u>Annex</u> to this Note.

⁴ WK 1140/2020

⁵ See documents WK 1140/2020 REV1 and WK 1140/2020 REV 2.

Draft Council conclusions on the European Court of Auditors' Special Report No 21/2019: "Addressing antimicrobial resistance:

progress in the animal sector, but this health threat remains a challenge for the EU"

THE COUNCIL OF THE EUROPEAN UNION:

- STRESSES that antimicrobial resistance (AMR) is a very serious global health threat, the mitigation of which urgently requires measures at the Member State, European Union and international levels, and in this context RECALLS the recently adopted Council conclusions of 14 June 2019⁶ on the next steps towards making the EU a best practice region in combating antimicrobial resistance;
- Against this background WELCOMES the Special Report of the European Court of Auditors No 21/2019: "Addressing antimicrobial resistance: progress in the animal sector, but this health threat remains a challenge for the EU" and the conclusions and recommendations therein;
- UNDERLINES that the Member States have the main responsibility for public health policies and that EU action in this area should be designed to complement and support the Member States' activities;

⁶ OJ C 214, 25.6.2019

- 4. STRESSES the importance of the EU rules on monitoring and reporting on the sales and use of antimicrobials and on AMR in the veterinary field, and in this context REFERS to the new EU legislation on veterinary medicinal products⁷ and medicated feed⁸, which requires more prudent use of antimicrobials and regulates data collection on sales and use of antimicrobial veterinary medicinal products, thereby contributing to the fight against AMR, and RECALLS the undertaking by the Commission⁹ to explore the possibilities for supporting this data collection in the Member States;
- 5. TAKES NOTE of the main findings of the Court presented in the Special Report and of its recommendations to the Commission to strengthen the response to AMR, in particular through better support to Member State national action plans, by promoting better monitoring and the prudent use of antimicrobial veterinary medicinal products, and finally by strengthening strategies for boosting AMR research in the EU;
- 6. WELCOMES the Commission's reply to the findings of the Court and the initiatives already taken to implement those recommendations, in particular those providing comprehensive support to the One Health approach in the Member States to address the problem of AMR, regularly reviewing AMR outcome indicators, evaluating EU financial investment in AMR research and innovation, and providing a number of push mechanisms for innovative medicinal products;
- 7. WELCOMES the Commission's commitment to identifying actions to be taken to address the potential risks to public health from pharmaceutical residues in the environment, hence to contribute to the Union's action on combatting AMR, as stated in the Commission's Communication of 11 March 2019¹⁰ on the European Union Strategic Approach to Pharmaceuticals in the Environment;

⁷ OJ L 4, 7.1.2019, p. 43–167

⁸ OJ L 4, 7.1.2019, p. 1–23

⁹ Doc. 13921/18 ADD 1

¹⁰ COM (2017) 339 final of 29.6.2017

- 8. DRAWS THE ATTENTION TO the significant support and guidance provided by the European Centre for Disease Prevention and Control, the European Food Safety Authority, the European Medicines Agency and the Joint Action on Antimicrobial Resistance and Healthcare-Associated Infections (JAMRAI) in addressing AMR;
- 9. CALLS UPON the Commission and the Member States to continue to cooperate closely to reduce the burden of AMR through:
 - full implementation of the actions set out in the 2017 One Health Action Plan against AMR¹¹;
 - further improvement of the collection of surveillance data on and monitoring of antimicrobial use and AMR;
 - better use of the outcome indicators developed to assist the Member States in measuring their progress in fighting AMR;
- 10. CALLS UPON the Commission to:
 - further promote the monitoring and prudent use of antimicrobial veterinary medicinal products through support to the Member States in developing systems that comply with the data collection requirements of the new EU legislation on veterinary medicinal products;
 - continue promoting implementation in the Member States of results of the EU funded projects carried out by JAMRAI and OECD;
 - identify existing funding opportunities to better support the sustained implementation by the Member States of policies related to AMR, based on the One Health approach;
 - strengthen support of research and development of new antimicrobials, alternative treatments and vaccines through EU funding and incentives, while evaluating in a comprehensive way its support to AMR research;

¹¹ OJ C 214 of 25.6.2019

- develop a strategy for its support to AMR research in the context of global and European funding programmes and initiatives, to ensure sustainability of activities across programming periods and, if appropriate, strengthen the involvement of the pharmaceutical industry, including SMEs, and other relevant stakeholders in the development of new antimicrobials and treatments;
- examine, in close cooperation with the Member States, how to address the problem of withdrawals from the market of existing products, the mechanisms that affect the continuity of supply of antimicrobials and market failures hindering the development of new treatments and antimicrobials;
- assess the option of integrating the monitoring of AMR occurrence in the environment into existing environmental monitoring schemes in order to collect robust evidence to underpin further policy making, in particular, when implementing the Strategic Approach to pharmaceuticals in the environment;
- WELCOMES the regular reporting by the Commission on progress in the implementation of the 2017 One Health Action Plan against AMR, in particular on completed actions and results in the field.