



Plenary sitting

B9-0327/2022

14.6.2022

MOTION FOR A RESOLUTION

pursuant to Rule 112(2) and (3) of the Rules of Procedure

on the draft Commission implementing regulation designating antimicrobials or groups of antimicrobials reserved for treatment of certain infections in humans, in accordance with Regulation (EU) 2019/6 of the European Parliament and of the Council
(D080741/01 – 2022/2693(RSP))

Committee on the Environment, Public Health and Food Safety

Members responsible: Tiemo Wölken, Nicolae Ștefănuță, Martin Häusling, Anja Hazekamp

European Parliament resolution on the draft Commission implementing regulation designating antimicrobials or groups of antimicrobials reserved for treatment of certain infections in humans, in accordance with Regulation (EU) 2019/6 of the European Parliament and of the Council (D080741/01 – 2022/2693(RSP))

The European Parliament,

- having regard to the draft Commission implementing regulation designating antimicrobials or groups of antimicrobials reserved for treatment of certain infections in humans, in accordance with Regulation (EU) 2019/6 of the European Parliament and of the Council (D080741/01),
- having regard to Regulation (EU) 2019/6 of the European Parliament and of the Council of 11 December 2018 on veterinary medicinal products and repealing Directive 2001/82/EC, and in particular Article 37(5) thereof¹,
- having regard to Article 11 of Regulation (EU) No 182/2011 of the European Parliament and of the Council of 16 February 2011 laying down the rules and general principles concerning mechanisms for control by Member States of the Commission's exercise of implementing powers²,
- having regard to Rule 112(2) and (3) of its Rules of Procedure,
- having regard to the motion for a resolution of the Committee on the Environment, Public Health and Food Safety,
- A. whereas antimicrobial resistance (AMR) is a serious challenge for human and animal health, in the Union and globally;
- B. whereas based on data from 2015, in the Union 33 000 people die each year due to AMR³, which is an increase of more than 30 % compared to the estimated 25 000 deaths for 2007⁴;
- C. whereas, globally, AMR was estimated to be responsible for 700 000 deaths per year in 2015⁵, and inaction is projected to cause ten million annual deaths globally by 2050⁶,

¹ OJ L 4, 7.1.2019, p. 43.

² OJ L 55, 28.2.2011, p. 13.

³ <https://www.ecdc.europa.eu/en/news-events/33000-people-die-every-year-due-infections-antibiotic-resistant-bacteria>

⁴ European Centre for Disease Prevention and Control/European Medicines Agency Joint Technical Report, 'The bacterial challenge: time to react - A call to narrow the gap between multidrug-resistant bacteria in the EU and the development of new antibacterial agents', September 2009, https://www.ecdc.europa.eu/sites/default/files/media/en/publications/Publications/0909_TER_The_Bacterial_Challenge_Time_to_React.pdf

⁵ Commission communication of 29 June 2017, 'A European One Health Action Plan Against Antimicrobial Resistance (AMR)', COM(2017)0339.

⁶ 'Tackling drug-resistant infections globally', The Review on Antimicrobial Resistance, May 2016, https://amr-review.org/sites/default/files/160525_Final%20paper_with%20cover.pdf

more deaths than those due to cancer;

- D. whereas the use of antimicrobials in medicinal products that are used in animals accelerates the emergence and spread of resistant micro-organisms and compromises the effective use of the already limited number of existing antimicrobials to treat human infections;
- E. whereas Regulation (EU) 2019/6 lays down rules for the placing on the market, manufacturing, import, export, supply, distribution, pharmacovigilance, control and use of veterinary medicinal products;
- F. whereas the legal basis of Regulation (EU) 2019/6 is Article 114 and Article 168(4), point (b), of the Treaty on the Functioning of the European Union (TFEU); whereas legislative proposals based on Article 114 TFEU are to take as a base a high level of health protection; whereas Article 168(4), point (b), TFEU provides for measures in the veterinary and phytosanitary fields which have as their direct objective the protection of public health;
- G. whereas according to Recital 41 of Regulation (EU) 2019/6, antimicrobial resistance to medicinal products for human use and veterinary medicinal products is a growing health problem in the Union and worldwide that requires urgent and coordinated intersectoral action in accordance with the 'One Health' approach; whereas according to that Recital, such action includes 'actions to restrict the use in animals of antimicrobials that are of critical importance for preventing or treating life-threatening infections in humans';
- H. whereas according to Recital 46 of Regulation (EU) 2019/6, '[i]n order to preserve as long as possible the efficacy of certain antimicrobials in the treatment of infections in humans, it may be necessary to reserve those antimicrobials for humans only. It should be possible, therefore, to decide that certain antimicrobials, following the scientific recommendations of the [European Medicines] Agency, should not be available on the market in the veterinary sector. When making such decisions on antimicrobials, the Commission should also take into account available recommendations on the matter provided for by the European Food Safety Authority (EFSA) and other relevant Union agencies, which in turn also take into account any relevant recommendations from international organisations, such as the World Health Organization (WHO), the World Organisation for Animal Health (OIE), and the Codex Alimentarius';
- I. whereas the Commission has furthermore stated that 'the EU will lead the way in reducing antimicrobial use in animals through concrete action. In particular, the EU will reserve certain critical antimicrobials for human use so that we reduce antimicrobial resistance and guarantee a last line of defence to protect human health'⁷;
- J. whereas under Article 37(3) of Regulation (EU) 2019/6, a marketing authorisation for an antimicrobial veterinary medicinal product is to be refused if the antimicrobial is reserved for treatment of certain infections in humans ('human-reserved antimicrobials' or 'HRAM');

⁷ Letter of 15 September 2021 by Health Commissioner Stella Kyriakides to Pascal Canfin, Chair of the Committee on the Environment, Public Health and Food Safety.

- K. whereas, on 26 May 2021, the Commission adopted a delegated regulation establishing the criteria for the designation of HRAM pursuant to Article 37(4) of Regulation (EU) 2019/6⁸;
- L. whereas the Commission has stated in that context that ‘[a] key measure is to reserve certain antimicrobials for human medicine only, banning their uses in veterinary medicine’⁹;
- M. whereas, on 19 April 2022, the Commission published the draft Commission implementing regulation, which designates antimicrobials or groups of antimicrobials reserved for treatment of certain infections in humans, and which is to be adopted pursuant to Article 37(5) of Regulation (EU) 2019/6;
- N. whereas the draft Commission implementing regulation designates 18 antibiotics, 18 antivirals and one antiprotozoal, all of which are already not authorised for veterinary use;
- O. whereas the draft Commission implementing regulation thus fails to ‘reserve’ any antimicrobials or groups of antimicrobials for treatment of certain infections in humans which are actually authorised for veterinary purposes and thus fails to preserve the efficacy of essential antimicrobials for the treatment of certain infections in humans;
- P. whereas the draft Commission implementing regulation is therefore not compatible with the aim and content of Regulation (EU) 2019/6;
- Q. whereas the WHO established a ranking of critically important antimicrobials for human medicine¹⁰; whereas the WHO ranking is based on two criteria, the combination of which leads to the classification of ‘critically important antimicrobials for human use’ (‘CIA’; i.e. 17 out of 35 groups), and another three prioritisation criteria, the combination of which leads to the identification of the ‘highest priority critically important antimicrobials for human use’ (‘HP CIA’; i.e. five out of 35 groups: cephalosporins 3rd, 4th and 5th generation, glycopeptides, macrolides and ketolides, polymyxins and quinolones)¹¹;
- R. whereas the draft Commission implementing regulation designates glycopeptides and two types of cephalosporins (ceftazidime and ceftazidime/avibactam) that are HP CIA, but as stated in Recital N, these are already not authorised for veterinary use in the Union;
- S. whereas the fact that substances that are designated by the draft Commission implementing regulation can no longer be authorised outside their marketing

⁸ Commission Delegated Regulation (EU) 2021/1760 of 26 May 2021 supplementing Regulation (EU) 2019/6 of the European Parliament and of the Council by establishing the criteria for the designation of antimicrobials to be reserved for the treatment of certain infections in humans (OJ L 353 of 6.10.2021, p. 1).

⁹ Commission factsheet of September 2021 on the Commission Regulation/AMR/Reservation of antimicrobials for humans, https://www.martin-haeusling.eu/images/Veterinary_medicines_factsheet_EU_commission_sep21.pdf

¹⁰ Critically Important Antimicrobials for Human Medicine, 6th Revision 2018, WHO, <https://apps.who.int/iris/bitstream/handle/10665/312266/9789241515528-eng.pdf>

¹¹ WHO list of Critically Important Antimicrobials for Human Medicine (WHO CIA list), <https://apps.who.int/iris/bitstream/handle/10665/325036/WHO-NMH-FOS-FZD-19.1-eng.pdf?sequence=1&isAllowed=y>

authorisation for veterinary purposes does not qualify as a relevant reduction of their use, as such off-label use is only possible in exceptional cases pursuant to Articles 112, 113 and 114 of Regulation (EU) 2019/6, and such exceptional treatment of the animals concerned can hardly be seen as a major cause of AMR;

- T. whereas the fact that substances that are designated by the draft Commission implementing regulation can no longer be authorised for use in animals or products of animal origin to be imported into the Union is of very limited relevance, as only very few of the substances designated by the draft Commission implementing regulation are actually authorised for veterinary use in third countries;
- U. whereas moreover only addressing the use in third countries of a few substances that are not authorised in the Union is tantamount to saying that the problem of AMR is solely created in third countries, which is manifestly wrong;
- V. whereas Articles 112, 113 and 114 of Regulation (EU) 2019/6 allow the off-label use of veterinary and human medicinal products for veterinary purposes as an exception, only under certain conditions; whereas Article 107(5) of Regulation (EU) 2019/6 however explicitly rules out the application of those articles as regards HRAM; whereas in light of Article 37(3) and Article 107(5) of Regulation (EU) 2019/6, the current provisions of that Regulation prohibit the use of HRAM for any veterinary purposes without exception;
- W. whereas the risk of creating resistances is, however, far more significant in group treatment of food-producing animals as compared to the treatment of individual animals;
- X. whereas it would be desirable to distinguish between group treatment and individual treatment to achieve the objective of preserving the efficacy of HRAM in the most effective way without causing an undue adverse effect on individual animal health;
- Y. whereas specific derogations for individual treatment of animals with HRAM should be adopted via an amendment of Regulation (EU) 2019/6;
- 1. Considers that the draft Commission implementing regulation exceeds the implementing powers provided for in Regulation (EU) 2019/6 as the draft Commission implementing regulation is not compatible with the aim and content of Regulation (EU) 2019/6;
- 2. Considers that the draft Commission implementing regulation fails to achieve a high level of protection of human health by failing to reserve any antimicrobials which are currently authorised for veterinary use for treatment of infections in humans only, and thus fails to preserve their efficacy for treatment of infections in humans;
- 3. Calls on the Commission to withdraw its draft implementing regulation and to submit a new draft to the committee in line with the criteria and the recommendations of the WHO to reserve highest priority critically important antimicrobials for human use only;
- 4. Calls on the Commission to accompany the new implementing act with a legislative proposal to amend Article 107(5) of Regulation (EU) 2019/6 to allow the off-label

veterinary use of HRAM for the treatment of individual, clinically ill animals (i.e. companion animals, zoo animals, wild animals or food-producing animals) under certain conditions;

5. Considers that such a derogation should only apply (a) to the treatment of individual animals with a clinically diagnosed serious, life-threatening disease which, if inappropriately treated, would lead to significant morbidity or significant mortality, and for which no alternative treatment, alternative farm management strategies or improved animal husbandry techniques to prevent, treat or control the disease are available, and (b) provided that an antibiotic susceptibility test has been conducted prior to treatment, unless the health condition of the animals concerned requires immediate treatment;
6. Considers that new antimicrobials developed for human use should not be subject to that derogation;
7. Considers that the designation to be adopted pursuant to Article 37(5) of Regulation (EU) 2019/6 and the amendment of that Regulation as referred to in paragraphs 4 and 5 of this resolution should be applicable at the same time;
8. Calls on the Commission to step up efforts in tackling the connections between human health, animal health and environmental protection, and explore ways to reinforce the application of the 'One Health' approach in Europe, starting by taking action on the inappropriate and excessive use of antibiotics in humans and for animals;
9. Instructs its President to forward this resolution to the Council and the Commission, and to the governments and parliaments of the Member States.