



**B9-0424/2021**

8.9.2021

## **MOTION FOR A RESOLUTION**

pursuant to Rule 111(3) of the Rules of Procedure

on the Commission delegated regulation 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 (C(2021)03552 – 2021/2718(DEA))

**Committee on the Environment, Public Health and Food Safety**

Member responsible: Martin Häusling

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**European Parliament resolution on the Commission delegated regulation 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 (C(2021)03552 – 2021/2718(DEA))**

*The European Parliament,*

- having regard to the Commission delegated regulation 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 (C(2021)03552),
  - having regard to Article 290 of the Treaty on the Functioning of the European Union,
  - 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<sup>1</sup>, and in particular Articles 37(4) and 147(7) thereof,
  - having regard to Rule 111(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 AMR<sup>2</sup>, which is an increase of more than 30 % compared to the estimated 25 000 deaths for 2007<sup>3</sup>;
- C. whereas globally, AMR was estimated to be responsible for 700 000 deaths per year in 2015<sup>4</sup>, and inaction is projected to cause ten million annual deaths globally by 2050<sup>5</sup>, more deaths than those due to cancer;
- D. whereas the ‘One Health approach’ is a multisectoral approach which recognises that

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<sup>1</sup> OJ L 4, 7.1.2019, p. 43.

<sup>2</sup> <https://www.ecdc.europa.eu/en/news-events/33000-people-die-every-year-due-infections-antibiotic-resistant-bacteria>

<sup>3</sup> 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](https://www.ecdc.europa.eu/sites/default/files/media/en/publications/Publications/0909_TER_The_Bacterial_Challenge_Time_to_React.pdf)

<sup>4</sup> Commission communication of 29 June 2017, ‘A European One Health Action Plan Against Antimicrobial Resistance (AMR)’, COM(2017)0339.

<sup>5</sup> ‘Tackling drug-resistant infections globally’, Review on Antimicrobial Resistance, May 2016, [https://amr-review.org/sites/default/files/160525\\_Final%20paper\\_with%20cover.pdf](https://amr-review.org/sites/default/files/160525_Final%20paper_with%20cover.pdf)

human health is connected to animal health and to the environment, and that actions to tackle threats to health must take into account those three dimensions<sup>6</sup>;

- E. 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;
- F. whereas, studies from 2017 have estimated that in absolute terms 73 % of all antimicrobials sold globally are used in animals raised for food<sup>7</sup>; whereas in relative terms, humans and animals use comparable amounts of antimicrobials, but given that the biomass of animals raised for food exceeds by far the biomass of humans, new resistant mutations are more likely to arise in animals<sup>8</sup>;
- G. whereas the European Food Safety Authority reported on 8 April 2021 that resistance levels are still high in bacteria causing foodborne infections<sup>9</sup>;
- H. whereas an inter-agency report of 11 June 2021 on integrated analysis of consumption of antimicrobial agents and occurrence of antimicrobial resistance in bacteria from humans and food-producing animals in the EU/EEA found that ‘[f]or certain combinations of bacteria and antimicrobials, resistance in bacteria from humans was associated with resistance in bacteria from food-producing animals which, in turn, was related to antimicrobial consumption in animals’; whereas the report concludes that ‘[o]verall, the findings suggest that further interventions to reduce AMC [antimicrobial consumption] will have a beneficial impact on AMR, which underlines the need to promote prudent use of antimicrobial agents in conjunction with infection control, prevention of infection and other relevant measures in both humans and food-producing animals’ and that [t]he high levels of AMC and AMR still being reported in animals and humans from several countries show that these interventions should be reinforced<sup>10</sup>;
- I. 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;
- J. whereas under Article 107(1) of Regulation (EU) 2019/6, antimicrobial medicinal products are not to be applied routinely or used to compensate for poor hygiene, inadequate animal husbandry or lack of care, or to compensate for poor farm

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<sup>6</sup> See Article 2(5) of Regulation (EU) 2021/522 of the European Parliament and of the Council of 24 March 2021 establishing a Programme for the Union’s action in the field of health (‘EU4Health Programme’) for the period 2021-2027, and repealing Regulation (EU) No 282/2014 (OJ L 107, 26.3.2021 p. 1).

<sup>7</sup> Tiseo, K., Huber, L., Gilbert, M., Robinson, T.P., Van Boeckel, T.P., ‘Global Trends in Antimicrobial Use in Food Animals from 2017 to 2030’, *Antibiotics* (Basel), 2020 Dec; 9(12): 918, <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7766021/>

<sup>8</sup> Van Boeckel, T.P., Glennon, E.E., Chen, D., Gilbert, M., Robinson, T.P., Grenfell, B.T., et al., ‘Reducing antimicrobial use in food animals’, *Science* 29 Sep 2017: Vol. 357, Issue 6358, pp. 1350-1352, <https://science.sciencemag.org/content/357/6358/1350>

<sup>9</sup> <https://www.efsa.europa.eu/en/news/resistance-levels-still-high-bacteria-causing-foodborne-infections>

<sup>10</sup> Third joint inter-agency report on integrated analysis of consumption of antimicrobial agents and occurrence of antimicrobial resistance in bacteria from humans and food-producing animals in the EU/EEA, EFSA Journal 2021;19(6):6712, <https://www.efsa.europa.eu/en/efsajournal/pub/6712>

management;

- K. 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');
- L. whereas Article 37(4) of Regulation (EU) 2019/6 obliges the Commission to adopt delegated acts establishing the criteria for the designation of HRAM in order to preserve the efficacy of those antimicrobials;
- M. whereas, on 26 May 2021, the Commission adopted a delegated regulation establishing the criteria for the designation of HRAM;
- N. whereas it is of paramount importance that the correct criteria be chosen, as they set the basis for the list of HRAM to be designated by the Commission by means of implementing acts pursuant to Article 37(5) of Regulation (EU) 2019/6;
- O. 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 under certain conditions; whereas Article 107(6) of Regulation (EU) 2019/6 allows the Commission to restrict off-label use; whereas there are no provisions in Regulation (EU) 2019/6 allowing the use of HRAM for any veterinary purposes;
- P. whereas under Article 118(1) of Regulation (EU) 2019/6, operators in third countries are not to use HRAM in respect of animals or products of animal origin exported from third countries to the Union; whereas there are significant such imports from third countries, in particular from Brazil (beef) and Thailand (poultry)<sup>11</sup>; whereas those countries are major users of antimicrobials<sup>12</sup>; whereas the designation of HRAM will therefore set an important international standard;
- Q. whereas globally, 93 000 tonnes of antimicrobials were estimated to be used in food-producing animals in 2017, and that amount is expected to rise by 11,5 % in 2030<sup>13</sup>;
- R. whereas according to the latest report of the European Surveillance of Veterinary Antimicrobial Consumption ('ESVAC report'), a project organised by the European Medicines Agency (EMA), 6 500 tonnes of antimicrobial veterinary medicinal products were sold in 31 European countries in 2018 (EU 28 plus Iceland, Norway and Switzerland)<sup>14</sup>;
- S. whereas pharmaceutical forms suitable for group treatment (oral solutions, premixes,

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<sup>11</sup> In the first three quarters of 2018, more than 1 million tonnes of meat were imported from third countries, <https://www.topagrar.com/markt/news/eu-fleischimporte-gestiegen-10133494.html>

<sup>12</sup> Tiseo, K., Huber, L., Gilbert, M., Robinson, T.P., Van Boeckel, T.P., 'Global Trends in Antimicrobial Use in Food Animals from 2017 to 2030', *Antibiotics* (Basel), 2020 Dec; 9(12): 918, <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7766021/>

<sup>13</sup> idem.

<sup>14</sup> EMA, European Surveillance of Veterinary Antimicrobial Consumption, 'Sales of veterinary antimicrobial agents in 31 European countries in 2018', 2020, [https://www.ema.europa.eu/en/documents/report/sales-veterinary-antimicrobial-agents-31-european-countries-2018-trends-2010-2018-tenth-esvac-report\\_en.pdf](https://www.ema.europa.eu/en/documents/report/sales-veterinary-antimicrobial-agents-31-european-countries-2018-trends-2010-2018-tenth-esvac-report_en.pdf)

oral powders) accounted for 88 % of total sales and those intended for treatment of individual animals (injectable preparations, other preparations) accounted for 12 % of total sales [figures rounded];

- T. whereas tablets, which are almost exclusively given to companion animals, only account for about 1 % of total sales;
- U. whereas the World Health Organization (WHO) established a ranking of critically important antimicrobials for human medicine<sup>15</sup>; 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)<sup>16</sup>;
- V. whereas according to the ESVAC report, HP CIA accounted for 14 % of total sales of antimicrobial veterinary medicinal products in the Union, and notable variations in the proportion of the use of HP CIA were observed between countries (no specific information on macrolides);
- W. whereas according to the ESVAC report, variations in reported sales and in sales patterns for 2018 between the 31 countries are likely to be due in part to differences in the composition of the animal population, production systems and prescription guidelines or habits in the different countries;
- X. whereas in line with Article 37(6) of Regulation (EU) 2019/6, the Commission consulted EMA for scientific advice with regard to the establishment of criteria for HRAM<sup>17</sup>; whereas EMA, unlike the WHO, proposed a third criterion for the designation of HRAM (‘low importance to animal health’);
- Y. whereas the Commission delegated regulation sets out three different criteria for the designation of HRAM, all of which need to be met for antimicrobials to be designated as HRAM;
- Z. whereas the first criterion is ‘high importance for human health’ (Part A of the Annex to the Commission delegated regulation), with three subcriteria;
- AA. whereas that criterion closely matches the first criterion of the WHO (‘sole or last resort antimicrobial or essential component of limited alternatives to treat serious, life-

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<sup>15</sup> Critically Important Antimicrobials for Human Medicine, 6th Revision 2018, WHO, <https://apps.who.int/iris/bitstream/handle/10665/312266/9789241515528-eng.pdf>

<sup>16</sup> WHO list of Critically Important Antimicrobials for Human Medicine (WHO CIA list), <https://www.who.int/foodsafety/publications/WHO-CIA-list-6flyer-EN.pdf?ua=1>

<sup>17</sup> EMA, ‘Advice on implementing measures under Article 37(4) of Regulation (EU) 2019/6 on veterinary medicinal products – Criteria for the designation of antimicrobials to be reserved for treatment of certain infections in humans’, 31 October 2019, [https://www.ema.europa.eu/en/documents/regulatory-procedural-guideline/advice-implementing-measures-under-article-374-regulation-eu-2019/6-veterinary-medicinal-products-criteria-designation-antimicrobials-be-reserved-treatment-certain\\_en.pdf](https://www.ema.europa.eu/en/documents/regulatory-procedural-guideline/advice-implementing-measures-under-article-374-regulation-eu-2019/6-veterinary-medicinal-products-criteria-designation-antimicrobials-be-reserved-treatment-certain_en.pdf)

threatening diseases'), with the addition of a subcriterion for addressing an unmet medical need, which is welcome;

- AB. whereas the second criterion is 'risk of transmission of resistance' (Part B of the Annex to the Commission delegated regulation), with a distinction made between antimicrobials authorised for use in animals and those not authorised for use in animals; whereas this criterion requires not only evidence of an actual emergence, dissemination and transmission of resistance for antimicrobials authorised for use in animals, and a potential for emergence, dissemination and transmission of resistance for antimicrobials not authorised for use in animals, but also that the transmission is 'significant' (for antimicrobials authorised for use in animals) or 'likely be significant' (for antimicrobials not authorised for use in animals);
- AC. whereas the requirement to show 'significant' transmission deviates from the second criterion laid down by the WHO, which explicitly states that transmission of resistant bacteria or their genes does not need to be demonstrated (let alone be significant), but that it is 'sufficient that the potential for such transmission exists';
- AD. whereas the requirement to show significant transmission therefore sets a far higher threshold for the designation of HRAM as compared to the WHO;
- AE. whereas the Commission delegated regulation also lays down several factors relevant to 'triggering significant transmission' of resistance, but without any further specification or quantification;
- AF. whereas consideration of those additional factors without any further specification or quantification leaves substantial uncertainty with regard to the designation of HRAM, an uncertainty that is likely to lead to further discussion and controversies, thus potentially hindering the designation of HRAM;
- AG. whereas the third criterion is 'non-essential need for animal health' (Part C of the Annex to the Commission delegated regulation), with three subcriteria; whereas the WHO does not have any such criterion in its ranking of CIA or HP CIA;
- AH. whereas it is very peculiar that the essential, life-saving measure of reserving certain last resort antimicrobials for humans should be conditional on there being a 'non-essential need for animal health'; whereas imposing such a condition unduly places concerns linked to animal health above human health;
- AI. whereas, without prejudice to this fundamental general concern about Part C, it is appropriate to discuss the subcriteria thereof, which will illustrate further specific concerns;
- AJ. whereas the first subcriterion of Part C would allow an antimicrobial to be designated as HRAM if there is 'no robust evidence of the need for the antimicrobial or group of antimicrobials in veterinary medicine';
- AK. whereas conversely, this means that if there is robust evidence of the need for this antimicrobial in veterinary medicine in general, irrespective of the severity of the disease and the consequences of inappropriate treatment, the first subcriterion would not

be fulfilled, thus requiring one of the other subcriteria to be fulfilled to allow HRAM to be designated;

- AL. whereas this reinforces the concern that the Commission delegated regulation unduly makes the designation of HRAM, i.e. sole or last resort antimicrobials or essential components of limited alternatives to treat serious, life-threatening diseases of humans, subject to a veterinary perspective;
- AM. whereas the second subcriterion of Part C would allow an antimicrobial to be designated as HRAM if inappropriate treatment of animals that suffer from serious, life-threatening infections would lead to significant morbidity or significant mortality, or would have a major impact on animal welfare or public health, but ‘adequate alternative medicinal products’ are available for the treatment of those infections in the animal species concerned;
- AN. whereas the second subcriterion only takes into account the availability of alternative medicinal products, but does not consider alternative farming practices or animal husbandry techniques that could prevent, treat or control the infections;
- AO. whereas the failure to reflect the provisions of Article 107(1) of Regulation (EU) 2019/6 in the second subcriterion represents a serious legal incoherence and takes an unduly narrow pharmaceutical-centred approach to the prevention, treatment and control of such infections, all the more so given that it is well-known that HP CIA such as colistin are, for example, used to treat post-weaning diarrhoea following early weaning of piglets, for which however a whole array of alternative measures exist for prevention or treatment<sup>18</sup>, including later weaning<sup>19</sup>;
- AP. whereas it is important to highlight that, in this regard, the Commission delegated regulation deviates from the advice from EMA, which in addition to ‘alternative treatment’ explicitly refers to the fact that ‘alternative management strategies other than the use of antimicrobials exist to prevent, treat or control such infections’ in the context of the third criterion;
- AQ. whereas the second subcriterion is also problematic because the lack of alternative medicinal products for treating a serious infection of one single animal species would be enough grounds for not designating an antimicrobial as HRAM, which in turn could lead to its use also in other animal species where it is not similarly relevant, and thereby increase the risk of AMR;
- AR. whereas it is not appropriate to make the generic designation of HRAM dependent on specific infections in specific animal species;
- AS. whereas the third subcriterion of Part C would allow an antimicrobial to be designated as HRAM if inappropriate treatment of animals that suffer from serious, life-threatening

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<sup>18</sup> [https://www.researchgate.net/publication/317093483\\_Post\\_weaning\\_diarrhea\\_in\\_pigs\\_Risk\\_factors\\_and\\_non-colistin-based\\_control\\_strategies](https://www.researchgate.net/publication/317093483_Post_weaning_diarrhea_in_pigs_Risk_factors_and_non-colistin-based_control_strategies)

<sup>19</sup> Faccin, J.E.F., Laskoski, F., Hernig, L.F., Kummer, R., Lima, G.F.R., Orlando, U.A.D., Gonçalves, M.A.D., Mellagi, A.P.G., Ulguim, R.R., Bortolozzo, F.P., ‘Impact of increasing weaning age on pig performance and belly nosing prevalence in a commercial multisite production system’, Journal of Animal Science, Volume 98, Issue 4, April 2020, skaa031, <https://doi.org/10.1093/jas/skaa031>

infections would lead to limited morbidity or limited mortality and there was scientific evidence showing an overriding public interest in not using it;

- AT. whereas the third subcriterion should be assessed in the context of the first two subcriteria of Part A, which require that inappropriate treatment has to lead to ‘significant debilitating morbidity or significant mortality’ in humans to allow a sole or last resort or an essential component of limited treatment alternatives to be designated as HRAM;
- AU. whereas in other words, in the event of ‘limited morbidity or limited mortality’ in animals as compared to ‘significant debilitating morbidity or significant mortality’ in humans in the event of inappropriate treatment, one would still have to show an overriding public health interest to reserve this antimicrobial for humans;
- AV. whereas the third subcriterion clearly illustrates the skewed priorities in the Commission delegated regulation;
- AW. whereas the Commission is unable to say which antimicrobials would be reserved for humans based on the criteria in the Commission delegated regulation, which in turn raises important questions about the list of HRAM likely to be adopted;
- AX. whereas the Commission was merely obliged to ‘take into account’ the scientific advice of EMA when adopting the criteria for the designation of HRAM, but is perfectly free to base such criteria on the scientific ranking established by the WHO, an international organisation that is explicitly referred to in Recital 46 of Regulation (EU) 2019/6;
- AY. whereas the WHO also adopted guidelines on use of medically important antimicrobials in food-producing animals<sup>20</sup>;
- AZ. whereas the WHO suggests in those guidelines: (a) that critically important antimicrobials should not be used for control of the dissemination of a clinically diagnosed infectious disease within a group of food-producing animals, and (b) that highest priority critically important antimicrobials should not be used for treatment of food-producing animals with a clinically diagnosed infectious disease;
- BA. whereas the empowerment of the Commission to adopt criteria for the designation of HRAM is a general empowerment to preserve the efficacy of certain antimicrobials for treatment of certain infections in humans;
- BB. 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;
- BC. whereas it would be desirable to distinguish between those different applications to achieve the objective of preserving the efficacy of HRAM in the most effective way without causing an undue adverse effect on animal health; whereas, however, the empowerment in Regulation (EU) 2019/6 does not provide for the possibility to make

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<sup>20</sup> <https://apps.who.int/iris/bitstream/handle/10665/259240/WHO-NMH-FOS-FZD-17.4-eng.pdf?sequence=1>



such a distinction;

- BD. whereas the criteria for designating HRAM can and should therefore be established solely on the basis of considerations related to human health and the potential for transmission;
- BE. whereas specific derogations for individual treatment of animals with HRAM should be adopted via an amendment of Regulation (EU) 2019/6;
1. Objects to the Commission delegated regulation;
  2. Instructs its President to forward this resolution to the Commission and to notify it that the delegated regulation cannot enter into force;
  3. Considers that the Commission delegated regulation:
    - (a) sets the bar for the designation of HRAM unduly high,;
    - (b) leaves important issues undefined;
    - (c) gives undue consideration to animal health concerns in its criteria; and
    - (d) therefore significantly deviates from the WHO criteria for the designation of (highest priority) critically important antimicrobials for human use and the WHO guidelines on use of medically important antimicrobials in food-producing animals;
  4. Considers that the Commission delegated regulation is therefore not sufficiently protective of human health;
  5. Calls on the Commission to submit a new delegated act in line with the criteria and the recommendations of the WHO to reserve highest priority critically important antimicrobials for human use only;
  6. Calls on the Commission to accompany the new delegated act with a legislative proposal to amend Regulation (EU) 2019/6 to set the conditions for the treatment of individual animals with HRAM by way of derogation from Article 37(3) of that Regulation;
  7. Considers that such a derogation should only apply 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 should only apply subject to an antibiotic susceptibility test being required prior to treatment;
  8. Instructs its President to forward this resolution to the Council and to the governments and parliaments of the Member States.