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via e-mail to the members of the ENVI Committee

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Drug resistance – criteria for identifying antimicrobial medicines reserved for treating humans

Dear Members of the ENVI Committee,

The emergence and spread of antimicrobial resistance is considered one of the greatest threats to human health. With the scrutiny of the delegated act "Drug resistance – criteria for identifying antimicrobial medicines reserved for treating humans", it is currently in your hands in the ENVI Committee to make a decisive difference in addressing this threat. As a broad coalition of organisations from the fields of human medicine as well as environmental and animal protection, we urge you to ensure that the most important antimicrobials (Highest Priority Critically Important Antimicrobials for Humans, **HP CIA**) are reserved exclusively for the medical treatment of humans:

- HP CIAs, according to the World Health Organisation (WHO), comprise five classes of antimicrobials that are increasingly needed in human medicine for serious infections. Their efficacy must no longer be compromised by their use in food-producing animals.

- Resistance to HP CIA is already spreading. It has been shown that it can spread very quickly from animal husbandry to humans and the environment.

- Bans in some Member States show that antimicrobials of the HP CIA groups are not necessary in livestock farming.

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Exclusion of HP CIAs from animal husbandry because of their increasing importance for humans

The delegated act in question serves to concretise one of the most urgent objectives of Regulation (EU) 2019/6 on veterinary medicinal products, namely the identification of antimicrobials that are indispensable for human medical use and should therefore remain reserved for the treatment of humans. In this respect, an internationally decisive list already exists: the "Highest Priority Critically Important Antimicrobials" (HP CIA) list determined by the World Health Organization (WHO).[1] In the European Union, the ketolides and glycopeptides of these antimicrobial classes are already no longer authorised for veterinary use.[2] Such a ban must also apply to the other antimicrobial classes listed by WHO as HP CIA.

Colistin, for example, from the class of polymyxins, is of utmost importance for human health. Among other uses, it is critically important in the treatment of cystic fibrosis, serving as a highly effective antimicrobial.[3] Recent studies also show that colistin is increasingly needed in intensive care units[4] – as a highly valuable antimicrobial for the medical treatment of humans in the 21st century.[5] The antimicrobials of the other four classes of the HP CIA are also essential medicines that safeguard human health – and especially that of our children.[6]

Existing resistances and transmission routes

There is already evidence of resistance and in some countries co-resistance to fluoroquinolones, cephalosporins, macrolides as well as polymyxins – and thus to all of the HP CIA used in veterinary medicine.[7] The spread of such resistances and the transmission from farm animals to humans and the environment can be extremely rapid, as officially indicated for colistin by the EMA.[8]

The direct threat to humans posed by antimicrobial resistance from livestock farms is particularly evident in the case of poultry meat: Since years, numerous studies have shown that poultry meat in particular is contaminated with pathogens resistant to antimicrobials, including HP CIA.[9] By

[1] World Health Organization (WHO), Critically important antimicrobials for human medicine, 6th revision, 2019.

[2] European Medicines Agency (EMA), Categorisation of antibiotics in the European Union, 2020.

[3] Heijerman et al., „Inhaled medication and inhalation devices for lung disease in patients with cystic fibrosis: A European consensus", Journal of Cystic Fibrosis, Volume 8, Issue 5, p. 295-315, 2009.

[4] Lepape et al., "European intensive care physicians' experience of infections due to antibiotic-resistant bacteria", Antimicrob Resist Infect Control 9:1, 2020.

[5] Nation and Li, "Colistin in the 21st century", Current Opinion in Infectious Diseases 22(6), p. 535-543, 2009.

[6] See fn. 1, p. 26: "3rd and higher generation cephalosporins are one of few available therapies for serious Salmonella spp. and E. coli infections […], particularly in children", same with macrolides.

[7] European Food Safety Authority (EFAS) and European Centre for Disease Prevention and Control (ECDC), The European Union Summary Report on Antimicrobial Resistance in zoonotic and indicator bacteria from humans, animals and food in 2018/2019, 2021.

[8] European Medicines Agency (EMA), „Countries should reduce use of colistin in animals to decrease the risk of antimicrobial resistance", Press release, 27/07/2016.

[9] See, e.g., Benning, "Chicken meat tested for resistance to Critically Important Antimicrobials for Human Medicine.
Ranking of EU chicken meat companies according to contamination by antibiotic-resistant pathogens" (Study), Germanwatch e. V., 2020.

exporting meat, the European Union also exports resistant pathogens to other countries – and vice versa when importing meat products into Europe.[10] Another transmission route is the direct entry of antimicrobial-resistant pathogens from animal husbandry into the environment.[11]

Need to close loopholes in the drafted delegated act

In order to maintain the effectiveness of the HP CIA for human medical therapies, the delegated act must set out clearly formulated criteria in this regard. The draft now published by the European Commission and submitted to you lacks such clarity. Criterion C in particular threatens to become a dangerous loophole for further high use of HP CIA in animal husbandry:

According to this criterion, antimicrobials can only be reserved for humans if they are not considered essential for animal health. This does not do justice to the special importance of HP CIA for human health. It also disregards the devastating consequences that can be foreseen due to the further spread of resistance, especially against these antimicrobials.

Avoidance options and alternatives with regard to HP CIAs

In order to avoid unnecessary use of antimicrobials in general, an antibiotic susceptibility test prior to use is the required professional practice. Thanks to modern precise diagnostics, animals can generally be treated without broad spectrum antimicrobials. The different diagnostic instruments determine whether antimicrobials are effective at all and which antimicrobials are effective in the case of infection. For example, mastitis pathogens in dairy cattle can often be treated successfully without HP CIAs or even without antimicrobials altogether if the causes of infection are carefully diagnosed.[12] However, there are no binding rules on diagnostics before the use of antimicrobials in EU veterinary legislation.

Furthermore, animal group treatment in particular poses an unacceptable risk and must be safely excluded for antimicrobials of the HP CIA groups. And not least, significant improvements in the breeding, keeping and feeding of animals are essential for animal health. Here, the EU rules do not yet correspond to the ethically justifiable animal husbandry rules demanded by society throughout Europe.

For effective and strong protection of human health and the environment

The WHO itself suggests, “antimicrobials classified as highest priority critically important for human medicine should not be used for treatment of food-producing animals with a clinically diagnosed infectious disease"[13]. As the EU is already committed to the WHO antimicrobial resistance strategy,

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[10] See, e.g., Rabello et al., “Antimicrobial Resistance in Farm Animals in Brazil: An Update Overview”, Animals 10(4), p. 552, 2020: “However, in the last few years, colistin-resistant E. coli is becoming more common.”

[11] Koutsoumanis et al., “Role played by the environment in the emergence and spread of antimicrobial resistance (AMR) through the food chain”, EFSA Panel on Biological Hazards (BIOHAZ), EFSA Journal 19(6):6651, 2021.

[12] Nobrega et al., “Critically important antimicrobials are generally not needed to treat nonsevere clinical mastitis in lactating dairy cows: Results from a network meta-analysis”, Journal of Dairy Science 103(11), p. 10585-10603, 2020; Malcata et al., “Point-of-care tests for bovine clinical mastitis: what do we have and what do we need?”, Journal of Dairy Research 87 (S1), 60–66, 2020.

[13] World Health Organization (WHO), WHO guidelines on use of medically important antimicrobials in food-producing animals, p. 20, 2017.

it should not allow contradictions with WHO recommendations in the present delegated act. Some EU countries already regulate HP CIA in animal husbandry, where they are hardly used any more. In Denmark, for instance, fluoroquinolones and cephalosporins of third and fourth generation are virtually no longer used in animal farming – and colistin has not been used at all since 2017.[14] There is no evidence that animal health in Denmark has deteriorated as a result.

Please act!

Dear Members of the ENVI Committee, do not miss this unique opportunity to vote against the drafted delegated act and to make sure that it is strengthened, so that it will effectively serve in its intended purpose. An expert opinion from Germany has recently shown that the exclusion of HP CIA from animal husbandry is perfectly compatible with EU law.[15] Whether such a necessary exclusion is actually implemented now depends on your vote. We encourage you to use your influence to address one of the most imminent threats to the environment and human health.

Yours sincerely,

Ärzte gegen Massentierhaltung n.e.V. (Doctors against Factory Farming)

Cystic Fibrosis Europe

Deutsche Umwelthilfe e.V. (Environmental Action Germany)

Germanwatch e.V.

Greenpeace e.V.

Mukoviszidose e.V. - Bundesverband Cystische Fibrose

Pestizid Aktions-Netzwerk e.V. (PAN Germany)

Tierärzte für verantwortbare Landwirtschaft e.V.

[14] European Medicines Agency (EMA), Sales of veterinary antimicrobial agents in 31 European countries in 2018, 2020; Statens Serum Institut (SSI) and National Food Institute, Technical University of Denmark (DTU Food), DANMAP 2019 - Use of antimicrobial agents and occurrence of antimicrobial resistance in bacteria from food animals, food and humans in Denmark, 2020.

[15] Bruhn, Rechtsgutachten zum umfassenden Verbot des Einsatzes von Reserveantibiotika in der nahrungsindustriellen Tierhaltung, legal opinion on behalf of Ärzte gegen Massentierhaltung e. V. (Doctors Against Factory Farming), 2021.