FEDERATION OF VETERINARIANS OF EUROPE

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CRITERIA FOR THE DESIGNATION OF ANTIMICROBIALS RESERVED FOR HUMANS

FVE Input

Background:

- Regulation 2019/6 on veterinary medicinal products lays down in article 37(4) that the Commission shall adopt a **delegated act** laying down criteria for the designation of antimicrobials reserved for *treatment of certain infections in humans*, in order to preserve the efficacy of these antimicrobials.
- On a later stage, on the basis of the above delegated act, art 37(5) says that the Commission shall adopt an **implementing act** to designate antimicrobials or groups of antimicrobials reserved for treatment of certain infections in humans.

Criteria FVE suggests to include:

(a) Evidence that the use of the antimicrobial agent or antimicrobial class in animals is causing substantial measurable antimicrobial resistance in humans, and;
(b) Evidence that the antimicrobial agent or antimicrobial class is one of the sole treatments for a certain serious infection in humans, and;
(c) Availability of alternative treatments for certain infections in humans, and;
(d) Evidence that measures have been taken to restrict the use in human medicine for the antimicrobial agent or antimicrobial class that is banned for use in animals, and;
(e) Evidence that alternative therapeutic treatments are available for animals, and;
(f) Evidence that lack of this antimicrobial agent or antimicrobial class will not cause serious risk to animal health, animal welfare, environment and public health.

Considerations:

- Infections due to antibiotic-resistant bacteria are threatening modern health care and the ability of veterinarians to treat bacterial infections in animals.
- FVE and the whole European Veterinary Profession, combat antimicrobial resistance while ensuring the continuing availability of drug medications essential for human and animal health, since many years. As veterinarians, we oversee the prudent and responsible use of antimicrobials in animals, thereby helping to minimize the emergence and spread of antimicrobial resistance, and maximize their efficacy.
- In the last decade, antibiotic use in animals has gone down substantially. The latest ESVAC report[1], published in October 2018, shows that sales of antibiotics for use in animals in Europe fell by 20% between 2011 and 2016. All EU countries have agreed on a national one health action plan and are committed to further reduce antimicrobial use and especially the use of important antimicrobials (CIA's). In some countries, through the reduction in antibiotic use in animals, antimicrobial resistance in animal pathogens have also started to decrease. Unfortunately, antibiotic consumption in humans is not yet going down.
- Recent research estimates that the use of antibiotics in animals contributes to the human antimicrobial burden for only a small part (EFFORT, Wageningen[2]). It is clear that the human antibiotic burden is mostly caused by human antibiotic use, and similarly for animals. As such, banning certain antibiotics for animals will have little effect on the human antibiotic burden. The 2018 Lancet study[3] concludes that in Europe infections with antibiotic-resistant bacteria predominantly occur in hospitals and other health-care settings (63,5% of infections, 74,9% of the DALY's).
- In respect to companion animals, dogs and cats live in close proximity with their owner providing opportunity for interspecies transmission of resistant bacteria and their resistance genes in either direction. In the strategies to combat AMR, regulators need to consider the risks of both problems by not over-restricting use of antibiotic classes. Antimicrobials should be used as little as possible, but be available in case of need to treat serious zoonotic infections.
- FVE believes that the most effective way to fight antimicrobial resistance is: to ensure prudent and responsible use, use as much possible the bacterial culture and antibacterial susceptibility testing (AST), and by focusing much more on the prevention of disease to avoid treatments. Animals are sentient beings and deserve treatment too. The inability to treat susceptible infection has serious implications for animal health and animal welfare and potentially for public health (Zoonotic pathogens can be bacterial, viral, or fungal, and they represent 70% of

[1] https://www.ema.europa.eu/documents/report/sales-veterinary-antimicrobial-agents-30-european-countries-2016-trends-2010-2016-eighth-esvac_en.pdf
[2] https://www.wur.nl/en/newsarticle/Chance-of-ESBL-contamination-via-livestock-farming-is-small.htm
[3] https://www.thelancet.com/journals/laninf/article/PIIS1473-3099(18)30605-4/fulltext

all human diseases). Therefore, we are against banning authorised antimicrobials for animals without any scientific argument and science-based.

- A complete ban of currently authorised antimicrobial agent or antimicrobial class would have as consequences that certain bacterial infections can no longer be treated and that some animals will have to be euthanised or eradicated. On top of the financial and emotional problems to farmers, to companion animal owners this would be devastating!
- FVE believes much more impact can be made by ensuring that important antibiotics such as defined in the latest AMEG categorisation proposal class B, should only be used upon after bacterial culture and antibacterial susceptibility testing (AST), and as a last resource. Mass/group treatment of animals should also be replaced as much as possible by individual treatment. In addition, FVE believes that through further ensuring 'prevention is better than cure', good housing and management to reduce environmental challenges and stress, correct nutrition and diets, good level of biosecurity, vaccination, among others might reduce further the use of antimicrobials. Similarly, in human medicines, better hygiene and disease prevention, especially in hospitals, is needed.
- To **conclude**: banning is not a solution for animal health care nor the miracle to reduce the human antimicrobial burden. To combat antimicrobial resistance (AMR), we have to continue working on ***Reduction, Replacement and the Re-thinking*** of the use of antimicrobials in animals and humans (as defined by the EFSA/EMA RONAFA Joint Scientific Opinion[4]).

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[4] https://www.efsa.europa.eu/en/efsajournal/pub/4666