EUROPEAN
COMMISSION

Brussels, XXX
SANTE/10220/2022 feedback
(POOL/E5/2022/10220/10220-EN feedback.docx)
[…](2022) XXX draft

COMMISSION IMPLEMENTING REGULATION (EU) …/...

of XXX

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

(Text with EEA relevance)

This draft has not been adopted or endorsed by the European Commission. Any views expressed are the preliminary views of the Commission services and may not in any circumstances be regarded as stating an official position of the Commission.

COMMISSION IMPLEMENTING REGULATION (EU) …/...

of XXX

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

(Text with EEA relevance)

THE EUROPEAN COMMISSION,

Having regard to 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[1], and in particular Article 37(5) thereof,

Whereas:

(1) Regulation (EU) 2019/6 sets a broad range of concrete measures to fight antimicrobial resistance and to promote a more prudent and responsible use of antimicrobial medicinal products in animals, including very strict rules on their veterinary prescription for prophylactic and metaphylactic use. That Regulation also recalls that antimicrobial medicinal products should not be administered routinely nor used to compensate for poor hygiene, inadequate animal husbandry, lack of care or to compensate for poor farm management.

(2) Certain antimicrobial medicinal products or groups of antimicrobial medicinal products should be reserved for treatment of certain infections in humans, with a view to better preserve their efficacy for human medicine and to supporting the fight against antimicrobial resistance, which is a major threat to global health.

(3) The antimicrobial medicinal products or groups of antimicrobial medicinal products to be reserved for treatment of certain infections in humans are to be designated on the basis of the criteria set for this purpose in Commission Delegated Regulation (EU) 2021/1760[2].

(4) The European Medicines Agency ('the Agency') evaluated[3] antimicrobials and groups of antimicrobials used in medicinal products authorised in Member States and in third countries. It identified which antimicrobials and groups of antimicrobials fulfilled the criteria set in Delegated Regulation (EU) 2021/1760, taking into consideration the latest available scientific evidence. The Agency's advice is based, in accordance with

[1] OJ L 4, 7.1.2019, p. 43.

[2] 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, 6.10.2021, p. 1).

[3] Advice on the designation of antimicrobials or groups of antimicrobials reserved for treatment of certain infections in humans - in relation to implementing measures under Article 37(5) of Regulation (EU) 2019/6 on veterinary medicinal products (EMA/CVMP/678496/2021, 16 February 2022)

Article 37(6) of Regulation (EU) 2019/6, on the joint opinion of experts in human medicine and of experts in veterinary medicine from national competent authorities, the European Food Safety Authority, the European Centre for Disease Prevention and Control and the Agency itself, as well as of external experts on human infectious diseases from learned societies and academia.

(5) Pursuant to the Agency's advice, several antibiotics, several antivirals and one antiprotozoal fulfilled the criteria established under Delegated Regulation (EU) 2021/1760 and should therefore be reserved for the treatment of certain infections in humans. Pursuant to the Agency's advice, none of the antifungals evaluated met those criteria.

(6) The antimicrobials and group of antimicrobials listed in this Regulation should not be used in veterinary medicinal products. Thus, marketing authorisation applications for veterinary medicinal products that contain any of the antimicrobials or groups of antimicrobials listed in this Regulation should be refused. In addition, existing marketing authorisations of veterinary medicinal products containing such antimicrobials or groups of antimicrobials should cease to be valid.

(7) Veterinary medicinal products are sometimes administered to animals through medicated feed. The use of veterinary medicinal products that contain antimicrobials or groups of antimicrobials listed in this Regulation in medicated feed should not be possible.

(8) Moreover, medicinal products that contain any of the antimicrobials or groups of antimicrobials listed in this Regulation should not be used in animals, even under the conditions set in Articles 112, 113 and 114 of Regulation (EU) 2019/6.

(9) With a view to giving veterinarians, owners of animals and economic operators concerned the necessary time to adjust to the consequences referred to above, this Regulation should apply six months after its entry into force.

(10) The list of antimicrobials or groups of antimicrobials to be reserved for treatment of certain infections in humans, as provided for in this Regulation may be reviewed, as necessary, in the light of new scientific evidence or emerging information, including the emergence of new diseases, changes in the epidemiology of existing diseases, changes in antimicrobial drug resistance or changes in availability or patterns of antimicrobial use.

(11) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on Veterinary Medicinal Products referred to in Article 145 of Regulation (EU) 2019/6,

HAS ADOPTED THIS REGULATION:

Article 1

Antimicrobials or groups of antimicrobials designated as reserved for treatment of certain infections in humans

1. The antimicrobials and groups of antimicrobials listed in the Annex shall not be used in veterinary medicinal products or medicated feed.

2. The use in animals of medicinal products for human use that contain any of the antimicrobials or groups of antimicrobials listed in the Annex is prohibited.

Article 2

Entry into force and application

This Regulation shall enter into force on the twentieth day following that of its publication in the *Official Journal of the European Union*.

It shall apply from [OP please insert the date = 6 months after the date of entry into force of this Regulation].

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Brussels,

For the Commission
The President
Ursula VON DER LEYEN