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COMMISSION

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COMMISSION DELEGATED REGULATION (EU) …/...

of XXX

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

(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 DELEGATED REGULATION (EU) …/...

of XXX

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

(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(4) thereof,

Whereas:

(1) Regulation (EU) 2019/6 of the European Parliament and of the Council aims to enhance the internal market and increase the availability of veterinary medicinal products, while guaranteeing the highest level of public and animal health and environmental protection. In particular, it aims to contain the spread of antimicrobial resistance with concrete measures to promote a prudent and responsible use of antimicrobials in animals, in line with the 'One Health' approach[2].

(1) Although the efficacy of all antimicrobials is important to preserve public health, some antimicrobials are deemed more crucial than others, based on being preferred options for the treatment of serious infections in humans and the availability or lack of alternative treatment options. When antimicrobial resistance develops to an antimicrobial agent used to treat a specific infection for which there are no treatment alternatives and that resistance spreads, the consequences to public health are significant and potentially life-threatening. Human health, animal health and the environment are interlinked and are all essential parts of the 'One Health' approach, thus antimicrobial management in one sector may affect antimicrobial resistance in the other sectors.

(2) Article 37(4) of Regulation (EU) 2019/6 requires the Commission to adopt delegated acts establishing criteria that will allow the Commission to determine which antimicrobials or groups of antimicrobials should be reserved for human use.

(3) Various international organisations and countries have developed criteria for specifying or ranking the importance of antimicrobials or antimicrobial classes for human and veterinary medicine. Those criteria were developed for use in risk management strategies related to antimicrobial use in human healthcare settings and animal use. Prioritising critically important antimicrobials for humans is a valuable tool to support an evidence-based approach to risk management.

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1 OJ L 4, 7.1.2019 p. 43.

2 Commission Communication of 29 June 2017 on a European One Health Action Plan against Antimicrobial Resistance (COM(2017)0339).

(4) The criteria to determine which antimicrobials are to be reserved for human use should be clear and pertinent whilst reflecting the latest scientific evidence. Pursuant to Article 37(6), the Commission received advice from the European Medicines Agency ('the Agency') on 31 October 2019[3]. The Agency's advice has taken account of expert opinions from national competent authorities, the European Food Safety Authority and the European Centre for Disease Prevention and Control. In the context of the preparation of that advice, a scientific workshop involving members of the Agency's expert group and international organisations was organised in Brussels on 14 June 2019. The workshop allowed participants to exchange views and share expertise from a global perspective on the topic of how to establish such criteria. The outcome of those discussions was taken into consideration by the Agency's expert group in completing its advice and the Commission has taken into account that advice in accordance with Article 37(6) of Regulation (EU) 2019/6.

(5) While a number of countries within and outside the Union have implemented measures to restrict the use of certain antimicrobials, few have specific legislation for banning their use in veterinary medicine. Banning the use of an antimicrobial in animals is one of the most severe risk management measures that can be taken, thus such measures should be taken cautiously. Whenever possible, other existing risk management measures should be favoured, such as improving animal husbandry, biosecurity and herd or flock management, making a better use of vaccination and restricting the use of antimicrobials to specific circumstances.

(6) Antimicrobials to be used only for treatment of certain infections in humans should be designated on the basis of sound criteria. Those criteria should allow to identify those antimicrobials that are of high importance to preserve human health and that should therefore be considered for use in human medicine exclusively. The criteria should also enable to identify those antimicrobials, whose use in animals could accelerate the spread of antimicrobial resistance, or present a risk thereof, by allowing for the transmission of resistance, which may include cross-resistance or co-selection of resistance to other antimicrobials, from animals to humans. Finally, the criteria should allow to identify antimicrobials that do not represent an essential need for animal health, and whose absence of use in veterinary medicine would not lead to any significant negative impact on animal health.

(7) While assessing whether an antimicrobial could be reserved for the treatment of certain infections in humans, it is important to determine whether its absence of use in veterinary medicine would result in significant morbidity or significant mortality or would have a major impact on animal welfare and public health. In the latter case, the availability of adequate alternative medicinal products for the treatment of the diseases concerned in the animals species concerned should be considered.

(8) When considering the use of alternative medicinal products instead of certain antimicrobial medicinal products, it is important that those products are adequate and available. Such alternatives should be authorised medicinal products in suitable formulations for the treatment of the disease in the animal species requiring treatment. Their use should lead to a lower risk to public health in terms of antimicrobial resistance than the antimicrobial medicinal product it aims to replace.

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[3] 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 (EMA/CVMP/158366/2019)

(9) In exceptional cases where there is scientific evidence showing an overriding public health interest, the criterion of non-essential need to animal health should envisage the possibility for an antimicrobial to be reserved for human use, even if no alternative medicinal product is available for veterinary medicine, provided that not using such an antimicrobial would only result in limited morbidity or limited mortality. In such exceptional cases, the fulfilment of the other two criteria (high importance to human health and risk of transmission of resistance) should be still required for such an antimicrobial to be reserved for human use.

(10) Article 152(1) of Regulation (EU) 2019/6 indicates that existing products authorised in accordance with the previous legislation is to be deemed to be authorised in accordance with the Regulation, with the exception of authorisations of veterinary medicinal products containing antimicrobials that have been reserved for human use only. The criteria in the present act apply to antimicrobials that have not yet been authorised for the veterinary market but also apply to antimicrobials in existing veterinary medicinal products.

(11) It is recognised that the necessary available evidence to assess the fulfilment of the criteria may vary depending on the marketing authorisation status of the antimicrobial or group of antimicrobials considered: (1) authorised in human medicine only; (2) authorised in veterinary medicine only; (3) authorised both in human and veterinary medicine; (4) authorised neither in human nor veterinary medicine. For that reason, the available evidence should be taken into account while applying the criteria.

(12) This Regulation should apply from 28 January 2022 in accordance with Article 153(2) of Regulation (EU) 2019/6,

HAS ADOPTED THIS REGULATION:

Article 1

1. The criteria for the designation of antimicrobials to be reserved for the treatment of certain infections in humans are set out in the Annex.

2. An antimicrobial or a group of antimicrobials shall meet all three criteria set out in Parts A, B and C in the Annex in order to be designated as reserved for treatment of certain infections in humans.

Article 2

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 28 January 2022.

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