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From:	Secretary-General of the European Commission, signed by Ms Martine DEPREZ, Director
date of receipt:	26 May 2021
To:	Mr Jeppe TRANHOLM-MIKKELSEN, Secretary-General of the Council of the European Union
No. Cion doc.:	C(2021) 3552 final ANNEX
Subject:	ANNEX to the Commission delegated regulation 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

Delegations will find attached document C(2021) 3552 final ANNEX.

Encl.: C(2021) 3552 final ANNEX



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ANNEX

ANNEX

to the

Commission delegated regulation

**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**

ANNEX

Criteria for the designation of the antimicrobials which are to be reserved for treatment of certain infections in humans

PART A: CRITERION OF HIGH IMPORTANCE TO HUMAN HEALTH

1. The antimicrobial or group of antimicrobials meets this criterion if any of the following applies:
 - (a) it is the sole or last-resort antimicrobial or group of antimicrobials available in a patient management treatment approach for serious, life-threatening infections in humans which, if inappropriately treated, would lead to significant debilitating morbidity or significant mortality;
 - (b) it is an essential component of the limited treatment alternatives available in a patient management treatment approach for serious, life-threatening infections in humans which, if inappropriately treated, would lead to significant debilitating morbidity or significant mortality;
 - (c) it is an antimicrobial or a group of antimicrobials, which is authorised in the Union for the treatment of serious microbial infections in patients with limited treatment options, indicating that the antimicrobial or the group of antimicrobials considered is recognised as addressing an unmet medical need related to antimicrobial resistance.
2. Factors considered responsible for limited treatment alternatives for patients, as referred to in point 1(b), include:
 - the virulence and antimicrobial resistant phenotype(s) of the microorganisms causing infection, including multidrug resistance;
 - the characteristics of the patients (for example, immunocompromised, paediatric, elderly) and disease (for example, site of infection concerned) under treatment;
 - the proportion of patients requiring treatment and the impact on healthcare services.

PART B: CRITERION OF RISK OF TRANSMISSION OF RESISTANCE

1. The antimicrobial or group of antimicrobials meets this criterion if any of the following applies:
 - (a) for an antimicrobial or group of antimicrobials authorised for use in animals, scientific evidence, including epidemiological evidence where available, exists showing that:
 - there is an actual emergence, dissemination and transmission of resistance to this antimicrobial or group of antimicrobials, or induction of cross-resistance or co-selection of resistance to other antimicrobials, and
 - transmission of such resistance from animal sources to humans is significant and linked to the use of this antimicrobial or group of antimicrobial in animals, whether it occurs through microorganisms resistant to the antimicrobial or group of antimicrobials considered or through the transmission of genes conferring resistance to the antimicrobial or group of antimicrobials considered.

- (b) for an antimicrobial or group of antimicrobials not authorised for use in animals, scientific evidence exists showing that:
 - there is the potential for emergence, dissemination and transmission of resistance to this antimicrobial or group of antimicrobials or potential for inducing cross-resistance or co-selection of resistance to other antimicrobials, and
 - this transmission from animal sources to humans would likely be significant and linked to the use of this antimicrobial or group of antimicrobials in animals, whether it would occur through microorganisms resistant to the antimicrobial or group of antimicrobials considered or through the transmission of genes conferring resistance to the antimicrobial or group of antimicrobials considered.
- 2. Factors triggering significant transmission of resistance between animals and humans linked to the use of an antimicrobial or group of antimicrobials in animals include:
 - use selects for resistance, cross-resistance or co-selection of resistance to antimicrobials that are crucial for human medicine;
 - transmission of resistance occurs by vertical as well as horizontal transmission;
 - transmission of resistance involves zoonotic pathogens;
 - transmission can take place by different routes of exposure;
 - transmission occurs through a number of different animal species.

PART C: CRITERION OF NON-ESSENTIAL NEED FOR ANIMAL HEALTH

- 1. The antimicrobial or group of antimicrobials meets this criterion if any of the following applies:
 - (a) there is no robust evidence of the need for the antimicrobial or group of antimicrobials in veterinary medicine;
 - (b) the antimicrobial or group of antimicrobials is used to treat serious, life-threatening infections in animals which, if inappropriately treated, 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;
 - (c) the antimicrobial or group of antimicrobials is used to treat serious, life-threatening infections in animals which, if inappropriately treated, would lead to limited morbidity or limited mortality and there is scientific evidence showing an overriding public health interest in not using it.
- 2. The provisions laid down in point 1 apply when the antimicrobial or group of antimicrobials considered is either of the following:
 - (a) an antimicrobial or group of antimicrobials present within authorised veterinary medicinal products;
 - (b) an antimicrobial or group of antimicrobials present within medicinal products authorised for use in humans, that may be administered to animals outside the terms of their marketing authorisation.