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establishing a list of antimicrobials which shall not be used in accordance with Articles 112 and 113 of Regulation (EU) 2019/6 of the European Parliament and of the Council or which shall only be used in accordance with those Articles subject to certain conditions

(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 107(6) thereof,

Whereas:

(1) Regulation (EU) 2019/6 lays down rules for use of veterinary medicinal products, including the requirement to use them in accordance with the terms of their marketing authorisations. Where there is no veterinary medicinal product authorised or available in a Member State for a species or for an indication, veterinarians may, in particular to avoid causing unacceptable suffering, under their direct responsibility use medicinal products outside the terms of their marketing authorisations in accordance with the rules laid down in Articles 112, 113 or 114 of that Regulation, as applicable to the animal species concerned.

(2) Article 107(6), first subparagraph, of Regulation (EU) 2019/6 provides for the possibility to establish, by means of implementing acts, and taking into consideration scientific advice of the European Medicines Agency (the 'Agency'), lists prohibiting the use of certain antimicrobials in accordance with Articles 112, 113 and 114 of that Regulation or restricting the use of certain antimicrobials in accordance with Articles 112, 113 and 114 of that Regulation only subject to certain conditions.

(3) Article 114(3) of Regulation (EU) 2019/6 provides for the establishment, by means of implementing acts, of a list of substances used in veterinary medicinal products authorised in the Union for use in food-producing terrestrial animal species or substances contained in a medicinal product for human use authorised in the Union in accordance with Directive 2001/83/EC of the European Parliament and of the Council ([2]) or Regulation (EC) No 726/2004 of the European Parliament and of the Council ([3]), which may be used in food-producing aquatic species in accordance with Article 114(1) of Regulation (EU) 2019/6.

(4) Article 115(5) of Regulation (EU) 2019/6 provides for the establishment, by means of implementing acts, of a list of substances which are essential for the treatment of equine species, or which bring added clinical benefit compared to other treatment options available for equine species and for which the withdrawal period for equine species shall be six months.

(5) In order to ensure legal certainty for the competent authorities, veterinarians, animal keepers and economic operators concerned, as well as coherence between the provisions of this Regulation and the implementing acts to be adopted under Articles 114(3) and 115(5) of Regulation (EU) 2019/6, food-producing aquatic species and equine species should be excluded from the scope of this Regulation.

([1]) OJ L 4, 7.1.2019, p. 43, ELI: http://data.europa.eu/eli/reg/2019/6/oj.

([2]) Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use (OJ L 311, 28.11.2001, p. 67, ELI: http://data.europa.eu/eli/dir/2001/83/oj).

([3]) Regulation (EC) No 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency (OJ L 136, 30.4.2004, p. 1, ELI: http://data.europa.eu/eli/reg/2004/726/oj).

(6) On the basis of the criteria laid down in Article 107(6), second subparagraph, of Regulation (EU) 2019/6, the Agency evaluated antimicrobials and groups of antimicrobials that have potential veterinary use in the Union ([4]), taking into consideration the latest available scientific evidence, Regulation (EC) No 470/2009 of the European Parliament and of the Council ([5]) and Commission Regulation (EU) No 37/2010 ([6]). The Agency also considered information collected from an 'open call for data' ([7]) in which interested parties were invited to submit information on the uses and availability of antimicrobials in the Union to treat serious infections in animals, including uses outside the terms of a marketing authorisation, and used as reference various categorisations of antimicrobials developed by international organisations or by the Agency.

(7) The antimicrobials and groups of antimicrobials included in the Annex to Commission Implementing Regulation (EU) 2022/1255 ([8]) are prohibited for any use in animals, including uses in accordance with Articles 112 and 113 of Regulation (EU) 2019/6. Therefore, the Agency did not evaluate those antimicrobials.

(8) The Agency examined the various cases of use in accordance with Articles 112 and 113 of Regulation (EU) 2019/6. This included use for indications, animal species or via routes of administration not included in the terms of the marketing authorisation of veterinary medicinal products, use of medicinal products for human use authorised in accordance with Directive 2001/83/EC or Regulation (EC) No 726/2004, use of veterinary medicinal products prepared extemporaneously in accordance with the terms of a veterinary prescription and use of veterinary medicinal products authorised in a third country for the same animal species and same indication.

(9) The Agency considered that the use of some antimicrobials in accordance with Articles 112 and 113 of Regulation (EU) 2019/6 in the cases where therapeutic needs require that a medicinal product be used via routes of administration not included in the terms of its marketing authorisation could significantly increase the antimicrobial resistance risks. To help mitigate those risks a condition was proposed to restrict the use of those antimicrobials to individual animals only.

(10) In accordance with Article 113(4) of Regulation (EU) 2019/6, only active substances allowed in accordance with Regulation (EC) No 470/2009 and any acts adopted on the basis thereof can be used for the purposes of that Article. The conditions imposed by this Regulation should therefore be without prejudice to that provision.

(11) Taking into consideration the Agency's advice, the use of certain antimicrobials in accordance with Articles 112 and 113 of Regulation (EU) 2019/6 should be subject to certain conditions, including, in certain instances, a ban to use them in specific species.

([4]) Scientific advice under Article 107(6) of Regulation (EU) 2019/6 for the establishment of a list of antimicrobials which shall not be used in accordance with Articles 112, 113 and 114 of the same Regulation or which shall only be used in accordance with these articles subject to certain conditions (EMA/CVMP/151584/2021, 15 June 2023).

([5]) Regulation (EC) No 470/2009 of the European Parliament and of the Council of 6 May 2009 laying down Community procedures for the establishment of residue limits of pharmacologically active substances in foodstuffs of animal origin, repealing Council Regulation (EEC) No 2377/90 and amending Directive 2001/82/EC of the European Parliament and of the Council and Regulation (EC) No 726/2004 of the European Parliament and of the Council (OJ L 152, 16.6.2009, p. 11, ELI: http://data.europa.eu/eli/reg/2009/470/oj).

([6]) Commission Regulation (EU) No 37/2010 of 22 December 2009 on pharmacologically active substances and their classification regarding maximum residue limits in foodstuffs of animal origin (OJ L 15, 20.1.2010, p. 1, ELI: http://data.europa.eu/eli/reg/2010/37(1)/oj)

([7]) Background information and a partial summary report on the findings of the open call are presented in Section 4. of the Annex of EMA 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-rev, 25 May 2022)

([8]) Commission Implementing Regulation (EU) 2022/1255 of 19 July 2022 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 (OJ L 191, 20.7.2022, p. 58, ELI: http://data.europa.eu/eli/reg_impl/2022/1255/oj).

(12) Regulation (EU) 2016/429 of the European Parliament and of the Council ([9]) provides for the possibility to impose prohibitions and restrictions on the use of veterinary medicinal products for the prevention and control of certain diseases. Under Regulation (EC) No 2160/2003 of the European Parliament and of the Council ([10]), the use of veterinary medicinal products may be prohibited as part of national control programmes. In addition, Article 107(7) of Regulation (EU) 2019/6 allows Member States to adopt measures further restricting or prohibiting the use of antimicrobials in animals on their respective territories if the administration of such antimicrobials to animals is contrary to the implementation of a national policy on prudent use of antimicrobials. This Regulation should therefore apply without prejudice to any such national measures and to the provisions laid down in those Regulations or any acts adopted on the basis thereof.

(13) In its scientific advice, the Agency recommended that the use of certain antimicrobials in accordance with Articles 112 and 113 of Regulation (EU) 2019/6 should be based on the results of prior target pathogen identification and antimicrobial susceptibility testing demonstrating that the antimicrobial concerned is likely to be effective and that preferable antimicrobials in accordance with the Categorisation of antibiotics in the European Union of the European Medicines Agency ([11]) would not be effective. However, it is not always possible in practice for the veterinarian to base the choice of an antimicrobial for use in accordance with those articles on such identification and susceptibility testing. In these cases, the veterinarian responsible should be able to demonstrate why the use of a certain antimicrobial could not be based on such identification and susceptibility testing. In cases where the animals' condition necessitates that the veterinarian starts using the antimicrobial concerned without delay, the veterinarians responsible should be allowed to start using the antimicrobial concerned before the results of target pathogen identification or antimicrobial susceptibility testing are known. To ensure prudent use of antimicrobials, the choice of antimicrobial should be adapted, if needed, after the results of such identification and susceptibility testing become available.

(14) Where an antimicrobial is already authorised for use in cattle, sheep for meat production, pigs, chickens, dogs or cats, the extent of the additional exposure to that antimicrobial due to use in other animals is likely to be relatively small. In addition, there are fewer antimicrobial veterinary medicinal products authorised for use in sheep, including sheep for meat production. Therefore, in order to not disadvantage the sectors of those animals, for which there are less available antimicrobials and to ensure availability of antimicrobials for and to maintain the welfare of animals other than cattle, pigs, chickens, dogs or cats, the condition for target pathogen identification and antimicrobial susceptibility testing should not be imposed on the use in accordance with Articles 112 or 113 of Regulation (EU) 2019/6 in those animals, where the antimicrobial concerned is contained in a veterinary medicinal product authorised in the Union for use in cattle, sheep for meat production, pigs, chickens, dogs or cats.

(15) In order to allow competent authorities, veterinarians, animal keepers and economic operators concerned the necessary time to adapt to the requirements of this Regulation, its application should be deferred.

(16) The list of antimicrobials and related restrictions laid down in this Regulation should be kept under continual review 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 resistance or changes in availability or patterns of antimicrobial use, as well as the marketing authorisation of new veterinary medicinal products or medicinal products for human use.

(17) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on Veterinary Medicinal Products,

([9]) Regulation (EU) 2016/429 of the European Parliament and of the Council of 9 March 2016 on transmissible animal diseases and amending and repealing certain acts in the area of animal health ('Animal Health Law') (OJ L 84, 31.3.2016, p. 1, ELI: http://data.europa.eu/eli/reg/2016/429/oj).

([10]) Regulation (EC) No 2160/2003 of the European Parliament and of the Council of 17 November 2003 on the control of salmonella and other specified food-borne zoonotic agents (OJ L 325, 12.12.2003, p. 1, ELI: http://data.europa.eu/eli/reg/2003/2160/oj).

([11]) European Medicines Agency Categorisation of antibiotics in the European Union; Answer to the request from the European Commission for updating the scientific advice on the impact on public health and animal health of the use of antibiotics in animals of 12 December 2019 (EMA/CVMP/CHMP/682198/2017).

HAS ADOPTED THIS REGULATION:

Article 1

Scope

This Regulation applies to the use of antimicrobials in accordance with Articles 112 and 113 of Regulation (EU) 2019/6 in animals other than those of equine species.

Article 2

Conditions on the use of antimicrobials in accordance with Articles 112 and 113 of Regulation (EU) 2019/6

1. The antimicrobials or groups of antimicrobials listed in the Annex shall be used subject to the conditions applicable to them as specified therein.

2. The conditions applicable to the respective antimicrobials or groups of antimicrobials listed in the Annex shall be cumulative.

3. The conditions set out in the Annex shall apply without prejudice to the application of:

(a) Article 113(4) of Regulation (EU) 2019/6;

(b) any measures adopted in accordance with Article 107(7) of Regulation (EU) 2019/6;

(c) any restrictions on the use of antimicrobials or groups of antimicrobials imposed by Regulation (EU) 2016/429 or Regulation (EC) No 2160/2003 and any acts adopted on the basis thereof.

Article 3

Condition for prior target pathogen identification and antimicrobial susceptibility testing

1. It shall be deemed that the performance of prior target pathogen identification or antimicrobial susceptibility testing is not possible where the veterinarian responsible can demonstrate that such identification or susceptibility testing is not possible.

2. Where the clinical condition of the animal necessitates that the veterinarian starts using the antimicrobial concerned before the results of target pathogen identification and antimicrobial susceptibility testing are available, the veterinarian responsible may use the antimicrobial concerned before those results become available.

In this case the veterinarian shall demonstrate that the choice of the antimicrobial concerned was based on relevant information indicating that the antimicrobial concerned is likely to be clinically effective and that preferable antimicrobials would not be clinically effective, including the animal's clinical condition or medical history, epidemiological information and knowledge of antimicrobial susceptibility of the target pathogen at farm, local or regional level. The veterinarian shall adapt the choice of antimicrobial, if needed, based on the results of target pathogen identification or antimicrobial susceptibility testing once they become available.

3. Prior target pathogen identification and antimicrobial susceptibility testing shall not be required where the antimicrobial concerned is contained in a veterinary medicinal product authorised in the Union for cattle, sheep for meat production, pigs, chickens, dogs or cats and is to be used in accordance with Articles 112 or 113 of Regulation (EU) 2019/6 in animals other than cattle, pigs, chickens, dogs or cats.

Article 4

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 8 August 2026.

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

Done at Brussels, 18 July 2024.

For the Commission
The President
Ursula VON DER LEYEN

ANNEX

Antimicrobials or groups of antimicrobials	Conditions on the use in accordance with Articles 112 and 113 of Regulation (EU) 2019/6
Aminopenicillins in combination with beta-lactamase inhibitors	(1) In the cases of use of aminopenicillins in combination with beta-lactamase inhibitors for indications not included in the terms of the marketing authorisation of a medicinal product authorised in the Union and containing those antimicrobials, the veterinarian responsible shall prescribe those antimicrobials based, where possible, on prior target pathogen identification and antimicrobial susceptibility testing. The antimicrobial susceptibility testing shall demonstrate that: (a) aminopenicillins in combination with beta-lactamase inhibitors are likely to be clinically effective; (b) preferable antibiotics in accordance with the Categorisation of antibiotics in the European Union of the European Medicines Agency, or in accordance with stricter rules applicable in the Member State concerned, would not be clinically effective. (2) Aminopenicillins in combination with beta-lactamase inhibitors shall not be used in accordance with Article 113 of Regulation (EU) 2019/6 in poultry.
Third- and fourth-generation cephalosporins	(1) In the cases of use of third- or fourth-generation cephalosporins for indications not included in the terms of the marketing authorisation of a medicinal product authorised in the Union and containing those antimicrobials, the veterinarian responsible shall prescribe those antimicrobials based, where possible, on prior target pathogen identification and antimicrobial susceptibility testing. The antimicrobial susceptibility testing shall demonstrate that: (a) third- or fourth-generation cephalosporins are likely to be clinically effective; (b) preferable antibiotics in accordance with the Categorisation of antibiotics in the European Union of the European Medicines Agency, or in accordance with stricter rules applicable in the Member State concerned, would not be clinically effective. (2) The use shall be limited to administration to individual animals only. This condition shall not apply to the use in accordance with Article 112 of Regulation (EU) 2019/6 in aquatic animals kept in closed water tanks. (3) Third- and fourth-generation cephalosporins shall not be used in accordance with Article 113 of Regulation (EU) 2019/6 in poultry. (4) In the cases of treatment of salmonellosis in animals other than poultry, the use in accordance with Article 113 of Regulation (EU) 2019/6 shall be limited to injectable medicinal products administered to individual animals with potentially life-threatening infections.
Polymyxins	(1) In the cases of use of polymyxins for indications not included in the terms of the marketing authorisation of a medicinal product authorised in the Union and containing those antimicrobials, the veterinarian responsible shall prescribe those antimicrobials based, where possible, on prior target pathogen identification and antimicrobial susceptibility testing. The antimicrobial susceptibility testing shall demonstrate that: (a) polymyxins are likely to be clinically effective;

	(b) preferable antibiotics in accordance with the Categorisation of antibiotics in the European Union of the European Medicines Agency, or in accordance with stricter rules applicable in the Member State concerned, would not be clinically effective. (2) For salmonellosis, polymyxins shall not be used in accordance with Article 113 of Regulation (EU) 2019/6 in poultry. (3) For salmonellosis in animals other than poultry, veterinary medicinal products, which are authorised for oral administration to groups of animals, may be used in accordance with Article 113 of Regulation (EU) 2019/6 for treatment of individual animals only. (4) In each of the following cases the administration of the medicinal product shall be limited to individual animals only: (a) use of a veterinary medicinal product in accordance with Article 112 or 113 of Regulation (EU) 2019/6 via a route of administration not included in the terms of its marketing authorisation; (b) use of a medicinal product for human use authorised in accordance with Directive 2001/83/EC or Regulation (EC) No 726/2004; (c) use of a veterinary medicinal product prepared extemporaneously in accordance with the terms of a veterinary prescription.
Amphenicols	In the cases of use of amphenicols for indications not included in the terms of the marketing authorisation of a medicinal product authorised in the Union and containing those antimicrobials, the veterinarian responsible shall prescribe those antimicrobials based, where possible, on prior target pathogen identification and antimicrobial susceptibility testing. The antimicrobial susceptibility testing shall demonstrate that: (a) amphenicols are likely to be clinically effective; (b) preferable antibiotics in accordance with the Categorisation of antibiotics in the European Union of the European Medicines Agency, or in accordance with stricter rules applicable in the Member State concerned, would not be clinically effective.
Quinolones (including fluoroquinolones)	(1) In the cases of use of quinolones (including fluoroquinolones) for indications not included in the terms of the marketing authorisation of a medicinal product authorised in the Union and containing those antimicrobials, the veterinarian responsible shall prescribe those antimicrobials based, where possible, on prior target pathogen identification and antimicrobial susceptibility testing. The antimicrobial susceptibility testing shall demonstrate that: (a) quinolones (including fluoroquinolones) are likely to be clinically effective; (b) preferable antibiotics in accordance with the Categorisation of antibiotics in the European Union of the European Medicines Agency, or in accordance with stricter rules applicable in the Member State concerned, would not be clinically effective. (2) For salmonellosis, quinolones (including fluoroquinolones) shall not be used in accordance with Article 113 of Regulation (EU) 2019/6 in poultry. (3) For metaphylaxis of salmonellosis, quinolones (including fluoroquinolones) shall not be used in accordance with Article 113 of Regulation (EU) 2019/6 in animals other than poultry.

	(4) In the cases of treatment of salmonellosis in animals other than poultry, the use of quinolones (including fluoroquinolones) in accordance with Article 113 of Regulation (EU) 2019/6 shall be limited to injectable medicinal products administered to individual animals with potentially life-threatening infections. (5) In each of the following cases the administration of the medicinal product shall be limited to individual animals only: (a) use of a veterinary medicinal product in accordance with Article 112 or 113 of Regulation (EU) 2019/6 via a route of administration not included in the terms of its marketing authorisation; (b) use of a medicinal product for human use authorised in accordance with Directive 2001/83/EC or Regulation (EC) No 726/2004; (c) use of a veterinary medicinal product prepared extemporaneously in accordance with the terms of a veterinary prescription.
Rifamycins except rifaximin	(1) The veterinarian responsible shall prescribe rifamycins except rifaximin, based, where possible, on prior target pathogen identification and antimicrobial susceptibility testing. The antimicrobial susceptibility testing shall demonstrate that: (a) rifamycins are likely to be clinically effective; (b) preferable antibiotics in accordance with the Categorisation of antibiotics in the European Union of the European Medicines Agency, or in accordance with stricter rules applicable in the Member State concerned, would not be clinically effective. (2) The use shall be limited to administration to individual animals for treatment of mycobacteria or multidrug-resistant staphylococci only in combination with other antimicrobials likely to be clinically effective.
Rifaximin	In the cases of use of medicinal products, other than veterinary medicinal products authorised in the Union, the veterinarian responsible shall prescribe rifaximin, based, where possible, on prior target pathogen identification and antimicrobial susceptibility testing. The antimicrobial susceptibility testing shall demonstrate that: (a) rifaximin is likely to be clinically effective; (b) preferable antibiotics in accordance with the Categorisation of antibiotics in the European Union of the European Medicines Agency, or in accordance with stricter rules applicable in the Member State concerned, would not be clinically effective.
Substances used solely to treat tuberculosis or other mycobacterial diseases	(1) The veterinarian responsible shall prescribe substances used solely to treat tuberculosis or other mycobacterial diseases, based, where possible, on prior target pathogen identification and antimicrobial susceptibility testing. The antimicrobial susceptibility testing shall demonstrate that: (a) those substances are likely to be clinically effective; (b) preferable antibiotics in accordance with the Categorisation of antibiotics in the European Union of the European Medicines Agency, or in accordance with stricter rules applicable in the Member State concerned, would not be clinically effective. (2) The use shall be limited to administration to individual animals only.

Riminofenazines	(1) The veterinarian responsible shall prescribe riminofenazines, based, where possible, on prior target pathogen identification and antimicrobial susceptibility testing. The antimicrobial susceptibility testing shall demonstrate that: (a) riminofenazines are likely to be clinically effective; (b) preferable antibiotics in accordance with the Categorisation of antibiotics in the European Union of the European Medicines Agency, or in accordance with stricter rules applicable at the Member State concerned, would not be clinically effective. (2) The use shall be limited to administration to individual animals only for treatment of mycobacteria only.
Pseudomonic acids	(1) The veterinarian responsible shall prescribe pseudomonic acids, based, where possible, on prior target pathogen identification and antimicrobial susceptibility testing. The antimicrobial susceptibility testing shall demonstrate that: (a) pseudomonic acids are likely to be clinically effective; (b) preferable antibiotics in accordance with the Categorisation of antibiotics in the European Union of the European Medicines Agency, or in accordance with stricter rules applicable in the Member State concerned, would not be clinically effective. (2) Pseudomonic acids may only be used where the following conditions are met: (a) the medicinal product is to be used for the treatment of infections with methicillin-resistant *Staphylococcus aureus* or methicillin-resistant *Staphylococcus pseudintermedius*; (b) the use of veterinary medicinal products authorised for the treatment for staphylococcal infections via the topical route of administration has not been clinically effective; (c) the medicinal product is to be administered to individual animals; (d) the medicinal product is to be administered via the topical route of administration. (3) Pseudomonic acids shall not be used for routine decolonisation of methicillin-resistant *Staphylococcus aureus* or methicillin-resistant *Staphylococcus pseudintermedius*.
Remdesivir	Remdesivir may only be used in accordance with Article 112 of Regulation (EU) 2019/6 for the treatment of feline infectious peritonitis.
Echinocandins	(1) The veterinarian responsible shall prescribe echinocandins based, where possible, on prior target pathogen identification and antimicrobial susceptibility testing. The antimicrobial susceptibility testing shall demonstrate that those antimicrobials are likely to be clinically effective. (2) Echinocandins may only be used where the following conditions are met: (a) the medicinal product is to be administered to individual animals; (b) the medicinal product is to be used for the treatment of invasive aspergillosis or candidiasis; (c) the medicinal product is to be administered as a last resort.
Amphotericin B	In the case of treatment of leishmaniasis, or of other diseases in animals in regions where leishmaniasis is endemic, amphotericin B may be used only as a last resort.