



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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Veterinary Medicines Division

Open call for data on use of antimicrobials in animals

Regulation (EU) 2019/6 on veterinary medicinal products, which sets the future regulatory framework for veterinary medicines, provides a wide range of concrete measures to fight antimicrobial resistance and to promote the prudent use of antimicrobials. Such measures include, in particular, the possibility to reserve certain antimicrobials for treatment of certain human infections only, in order to preserve their efficacy (Article 37(5))¹.

In accordance with the new Regulation, 'antimicrobial' means any substance with direct action on micro-organisms used for treatment or prevention of infections or infectious diseases, including antibiotics, antivirals, antifungals and antiprotozoals.

The European Commission has asked the European Medicines Agency to provide scientific advice on how these provisions could best be addressed in forthcoming additional legislation.

Under certain conditions the Regulation also allows medicinal products to be used outside the terms of their marketing authorisation, often referred to as 'cascade use', when no suitable authorised product is available². However, in the specific case of antimicrobials, Article 107(6) makes provisions for a list of antimicrobials that may not be used under the cascade, or may only be used subject to certain conditions.

In order to support the European Medicines Agency in the preparation of its scientific advice, the CVMP invites all interested parties, such as pharmaceutical industry, veterinarians, professional groups, learned societies, governmental institutions as well as EU and EEA Member States to submit information on cascade use of antimicrobials in animals and any scientific evidence of an impact on public and animal health that the CVMP should consider.

¹ The EMA has already provided advice on implementing measures on Criteria for the designation of antimicrobials to be reserved for treatment of certain infections in humans (Article 37(5))
https://www.ema.europa.eu/en/documents/regulatory-procedural-guideline/advice-implementing-measures-under-article-374-regulation-eu-2019/6-veterinary-medicinal-products-criteria-designation-antimicrobials-be-reserved-treatment-certain_en.pdf

² 'Cascade use' is permitted under certain specific circumstances (Article 10 and 11 of Directive 2001/82/EC and Articles 112, 113, and 114 of Regulation (EU) 2019/6). For example, owing to the variety of veterinary species and conditions, there are often no medicines available that have been authorised to treat rarer conditions or less common species. In this case it is permitted to use a medicine authorised for another species or condition, in particular to avoid animal suffering. However, in the case of antimicrobials there are concerns that this type of prescription could increase the risk to animal or public health due to antimicrobial resistance.

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Below are the questions that we kindly ask you to respond to by filling in the questionnaire:
<https://ec.europa.eu/eusurvey/runner/OpenCallUseofantimicrobialsinanimals>.

Please note, that these questions relate to EU practices, only.

Please provide details of your area of work (e.g. veterinarian and type of practice, industry, professional body) and country where you are located at the top of the template. Please note that your responses will be considered anonymously. The data collected will be used to inform the advice provided to the Commission on the Implementing Acts under the new Regulation 2019/6. It may be included in the report in an aggregated format.

The call is open until 6 March 2020.

Question 1

Please advise which antimicrobials (**label or 'cascade use'**) are used to treat **serious life-threatening infections in animals** for which **no or only few authorised* alternative antimicrobial treatment options** are available. For each antimicrobial use quoted, please detail the animal species, the indication, alternative treatment options (if available) and the consequences if the antimicrobial used would no longer be available.

*'Authorised' means a veterinary medicinal product that has a marketing authorisation ('licence') in Europe to treat specified diseases and animal species.

1. Antimicrobial substance and formulation
2. Animal species
3. Disease/indication
4. Is this label or 'cascade use'?
5. Existing alternatives
6. Consequences of unavailability of this antimicrobial

Question 2

Please provide any scientific evidence (e.g. scientific publication) or experience from your personal practice (e.g. due to lack of availability of medicines) over the last five years of the **use in animals** of antimicrobials that have **only been authorised in human medicine** (See Annex).

1. Antimicrobial substance and formulation
2. Animal species
3. Disease/indication
4. Frequency of use (e.g. the number of times this 'cascade use' was applied per week, month or year)
5. Extent of use (the number of animals that were treated on each occasion.)
6. Are there alternative treatment options (including non-antimicrobial alternatives) for animals?

7. If the antimicrobial or formulation would no longer be available for 'cascade use' what would be the consequences for animal health and welfare, or food safety and food security, or human health (e.g. potential zoonotic disease transmission)?

Question 3

Please provide any scientific evidence (e.g. scientific publication) or experience from your personal practice (e.g. due to lack of availability of medicines) over the last five years of the use of any **veterinary antimicrobial substances** or **formulations** in **animal species for which they are not authorised**.

1. Antimicrobial substance and formulation
2. Animal species
3. Disease/indication
4. Frequency of use (e.g. the number of times this 'cascade use' was applied per week, month or year)
5. Extent of use (the number of animals that were treated on each occasion.)
6. Are there alternative treatment options (including non-antimicrobial alternatives) for animals?
7. If the antimicrobial or formulation would no longer be available for 'cascade use' what would be the consequences for animal health and welfare, or food safety and food security, or human health (e.g. potential zoonotic disease transmission)?

Question 4

Please provide any scientific evidence (e.g. scientific publication) or experience from your personal practice (e.g. due to lack of availability of medicines) over the last five years of the use of **any veterinary antimicrobial substances** or **formulations for indications for which they are not authorised**

1. Antimicrobial substance and formulation
2. Animals species
3. Disease/indication
4. Frequency of use (e.g. the number of times this 'cascade use' was applied per week, month or year)
5. Extent of use (the number of animals that were treated on each occasion.)
6. Are there alternative treatment options (including non-antimicrobial alternatives) for animals?
7. If the antimicrobial or formulation would no longer be available for 'cascade use' what would be the consequences for animal health and welfare, or food safety and food security, or human health (e.g. potential zoonotic disease transmission)?

Annex

Antibiotic classes which are not authorised in veterinary medicine in the European Union

(Source: EMA/CVMP/CHMP/682198/2017)

AMEG Categories	Antibiotic class, subclasses	Example of antibiotic(s)
Category A ("Avoid")	Aminopenicillins	mecillinam, pivmecillinam
	Carbapenems	meropenem, doripenem
	Other cephalosporins [§] and penems (ATC code J01DI), including combinations of 3rd-generation cephalosporins with beta-lactamase inhibitors	ceftobiprole, ceftaroline, ceftolozane-tazobactam, faropenem
	Glycopeptides	vancomycin
	Glycylcyclines	tigecycline
	Ketolides	telithromycin
	Lipopeptides	daptomycin
	Monobactams	aztreonam
	Oxazolidinones	linezolid
	Penicillins: carboxypenicillins and ureidopenicillins combinations with beta-lactamase inhibitors	piperacillin-tazobactam
	Phosphonic acid derivatives	fosfomicin
	Pseudomonic acids	mupirocin
	Rifamycins (except rifaximin)	rifampicin
	Riminofenazines	clofazimine
Streptogramins	pristinamycin, virginiamycin	
Sulfones	dapsone	
	Drugs used solely to treat tuberculosis or other mycobacterial diseases	isoniazid, ethambutol, pyrazinamide, ethionamide

[§] Other than 1st-, 2nd-, 3rd- and 4th-generation