



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

30 April 2019

Submission of comments on '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 - Categorisation of antimicrobials' (EMA/CVMP/CHMP/682198/2017)

Comments from:

Name of organisation or individual

German Federal Chamber of Veterinary Surgeons "Bundestierärztekammer (BTK)"

Please note that comments will be sent to the **ICH M10 EWG** for consideration in the context of Step 3 of the ICH process.



1. General comments

Stakeholder number	General comment (if any)
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(To be completed by the Agency)

BTK welcomes very much the updated AMEG classification; finding it a very clear, evidence-based and well developed document. We especially welcome that AMEG moved away from only looking at the public health risk (based on WHO listing) and instead considered additional criteria such as indications in veterinary medicines ('need for this product'), animal health and welfare aspects, route of administration and availability of alternatives in veterinary medicine.

We regret that despite the overwhelming evidence of difference in AMR risk profiling, the route of administration was not fully utilised and was not used further in the risk categorisation as it was felt to be 'too complex and the difficult to evidence'. BTK strongly feels, that seen the route of administration makes such a difference in risk towards public health, that this should be taken stronger into account.

We welcome the categorisation to go from 3 to 4 categories (with the extra category C - 'Caution'), allowing for refinement of the risk and for avoiding a too restrictive approach by placing too many antimicrobials in the highest risk category. It could be worth to further divide some of the antimicrobials in the same class when their risk profile differs.

BTK welcomes that after adoption an Infograph and other communication materials will be developed. This was certainly lacking for the first AMEG classification, which was very hard to retrieve. Good communication is essential to inform veterinarians about this classification so that they can act accordingly (line 143).

2. Specific comments on text

Line no.	Stakeholder no.	Comment and rationale; proposed changes
141		<p>Comment: Category A: We suggest in the table to add for Category A before summing up all antimicrobials that these are all antimicrobials not authorised in veterinary medicine.</p> <p>In addition, also in Category 1, typo - the first cephalosporins need to be removed in 'Cephalosporins, Other cephalosporins and penems (ATC code J01DI)'</p> <p>Proposed change (if any): Add at beginning of Category 1 before listing the antimicrobials: Antimicrobials not authorised in veterinary medicine, such as ... and remove double cephalosporins.</p>
200-201		<p>Comment: "restrictions on one class alone might not have the desired impact because of co-selection of AMR." This is a very important, factual statement that has been missed in the legislation.</p>
532-534		<p>Comment: "Nevertheless resistance can persist in the absence of antimicrobial use (Enne et al., 2001). 532 If this is the case (or in cases of co-resistance), reduction of consumption of a certain substance, in 533 both veterinary and human medicine, will not necessarily lead to consequent reduction in AMR." This is a very important, factual statement that has been missed in the legislation.</p>
688 - 692		<p>Comment: BTK suggests to insert a 5th criterion: namely route of administration. It is contradictory to first explain in the text how important this criteria is (which we totally support) and afterwards to say we do not include it because it is 'too complex'. At least use it for the antimicrobials for which it is most relevant e.g. the 3 and 4th generation cephalosporins are mainly used parentally or locally (e.g. intramammary).</p> <p>Proposed change: insert 5th criterion, route of administration and use this criterion for more antimicrobials than fusidic acid.</p>
735-741		<p>Comment: The possibility to very exceptionally use Category A products for companion animals under the cascade is welcome. This use is extremely minimal but in some cases necessary.</p>
769		<p>Comment: need to specify that the antimicrobial alternative must be available. Some countries have also a limited number of</p>

Line no.	Stakeholder no.	Comment and rationale; proposed changes
		<p>authorised products or/and alternative products might be unavailable e.g. when there is a shortage. Therefore it is worth adding 'when available'</p> <p>Proposed Change: 'These antimicrobials should only be used when there is no available substance in Category D that would be effective.'</p>
807		<p>Comment: Please recognise the national difference in available alternatives and the different epidemiological situations.</p> <p>Proposed Change: Add '...and the availability of alternatives antimicrobials in veterinary medicine, which may depend according to the country and local epidemiological situation'.</p>

Please add more rows if needed.