29 September 2018

Submission of comments on Guideline on the summary of product characteristics (SPC) for veterinary medicinal products containing antimicrobial substances

Comments from:

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<th>Name of organisation or individual</th>
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<td>British Veterinary Association (BVA)</td>
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Please note that these comments and the identity of the sender will be published unless a specific justified objection is received.

When completed, this form should be sent to the European Medicines Agency electronically, in Word format (not PDF).
1. General comments

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**Who we are**

1. The British Veterinary Association (BVA) is the national representative body for the veterinary profession in the United Kingdom. With over 17,000 members, our primary aim is to represent, support and champion the interests of the United Kingdom’s veterinary profession. We, therefore, take a keen interest in all issues affecting the profession, including animal health and welfare, public health, regulatory issues and employment matters.

**Introduction**

2. We welcome the opportunity to respond to this consultation on the second revision of the guideline on the Summary of Product Characteristics (SPC) for antimicrobial products. The UK veterinary profession is concerned by the implications of the development of antimicrobial resistance. Each use of antimicrobials increases the risk of selection for resistant bacteria and other micro-organisms, so we must ensure the use of antimicrobials is responsible across human and animal health.

**Presentation of information**

3. BVA welcomes the emphasis placed on changing
prescribing behaviour, which is found within the revised guidelines. We would ask that additional consideration is given to how the proposals will impact on behaviour. We are concerned that the proposals may provide an excess of information for vets, which would be counterproductive. To encourage a behaviour, it is important for an intervention to be Easy, Attractive, Social and Timely (EAST).¹ These principles for applying behavioural insights are based on the work of the Behavioural Insights Team and a large body of evidence on what influences behaviour.²

4. It is absolutely correct to provide vets with the material necessary to make informed decisions in the interest of animal health, animal welfare and wider public health: including the maintenance of antimicrobials. However, the level of detail in an SPC should be relevant to the end user.

5. In particular, we note that the proposals for the PDynamic section will present a large amount of data. This information will be of use to veterinary surgeons but be impractical in a clinical setting where decision making can be time limited. Furthermore, inclusion of “relevant pharmacokinetic parameters such as Vd, Cmax, Tmax, elimination half-life, clearance, bioavailability and area under the concentration

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¹ Behavioural Insights Team, EAST Four simple ways to apply behavioural, 2014 <https://www.behaviouralinsights.co.uk/publications/east-four-simple-ways-to-apply-behavioural-insights/>

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| (To be completed by the Agency) | curve (AUC)” may also be inappropriate. Such data will be important for specialists who advise primary care practitioners and should be made available, however the SPC is the wrong place for this. 6. BVA agrees with the emphasis placed on behaviour change within the document. To further this ambition within the scope of this consultation we would suggest a very clear indication of:  
  • the class of antibiotic the particular active(s) belong to.  
  • whether the product is a time dependent or a concentration antimicrobial | (To be completed by the Agency) |

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