

# **BVA response to: Revised guideline on safety and residue data requirements for pharmaceutical veterinary medicinal products intended for minor use or minor species (MUMS)/limited market**

## **Who we are**

1. The British Veterinary Association (BVA) is the national representative body for the veterinary profession in the United Kingdom. With over 18,000 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 and the wellbeing of the profession.

## **Our response**

2. We strongly support the intention behind this revised guideline, to stimulate the research, development and innovation of new veterinary medicines intended for minor uses or minor species (MUMS). The development of new veterinary medicines for minor species would be a positive outcome for animal health and animal welfare.
3. As noted within the consultation document, the CVMP has worked on this issue since 1998, and attempted to incentivise the development of veterinary medicinal products indicated for MUMS/limited markets. An assessment of how successful the current policy has been in incentivising the development of new products would have been beneficial. From our position in the United Kingdom it would seem to have had a limited effect in stimulating new market authorisations. However, we are aware that this may have had more effect elsewhere.
4. The document provides considerable detail concerning how the guidelines will be relaxed. The guidelines are largely clear and coherent. They provide a welcome balance between relaxing barriers to the development of new market authorisations and maintaining appropriate quality, safety and efficacy.
5. There is a lack of licensed medicinal products across a range of minor species including farm animals (e.g. goats and camelids) and most small and exotic pets. This can have a significant impact on the health of these animals because of medicine being used in ways that are ineffective or have safety concerns. The Goat Veterinary Society notes that there is a lack of licenced medicines available within the goat sector and delivering new products that are licensed for goats would benefit animal health and welfare. However, goat milk and meat are niche products in the UK that rely on a reputation for safety and quality. Any risk that there would be undesirable medicine residues would be harmful to producers and that must be taken into consideration when marketing authorisations are applied for. However, we believe that this concern is addressed within the detail of the guidelines.
6. One area where there could be a stronger evidence base would be to ascertain dose rates that are both effective and safe. At present, there is a greater emphasis on finding a safe dose rather than the most effective dose. This can mean that the dose rates can be too low to be effective. This can lead to practitioners being encouraged to under dose analgesia, which is a welfare issue. An improved evidence base could provide dose rates that are simultaneously effective and safe.

7. The slightly reduced standards that will be required to obtain a marketing authority in MUMS situations may possibly increase the number of adverse reactions in the animals involved. It must be stressed that in the case of such an occurrence, the veterinary surgeon finding these reactions must report them immediately to the appropriate national authority to avoid any potential compromising of animal welfare.
8. The factors that lead to the development of new veterinary medicines for any species or disease depends on many factors, and regulatory oversight is only one of them. Therefore, while we support the proposals, they must form part of a wider joined-up approach. It will be essential to work with industry, to establish and address other factors limiting the development of new veterinary medicines for MUMS situations.