

8 June 2020

# BVA submission to the Public Bill Committee: Medicines and Medical Devices Bill 2019-21

## 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.

## Introduction

2. We welcome the opportunity to provide evidence on the Medicines and Medical Devices Bill 2019-21. This legislation should be used to develop a new and innovative regulatory system, rooted in safety, quality and efficacy, which aims to attract companies to authorise and commercialise products in the UK, preferably ahead of the remainder of the EU.
3. The Bill is enabling legislation to allow the UK's existing medicines and medical devices regulatory frameworks to be updated, following EU Exit, without the need to introduce subsequent primary legislation. Part 2 of the Bill confers a delegated power to amend or supplement the Veterinary Medicines Regulations 2013 which consolidate all regulations relating to veterinary medicines into a single set of regulations governing the animal health industry.

## Updating Veterinary Medicines Regulations

4. The Bill sets out the circumstances under which the appropriate authority (the Secretary of State, and in Northern Ireland DAERA acting alone or jointly with the Secretary of State) could amend or supplement the VMRs. We strongly support the three factors which must be considered:
  - the safety of veterinary medicines in relation to animals, humans and the environment;
  - the availability of veterinary medicines (for animal use, whilst remaining under veterinary control);
  - the attractiveness of the relevant part of the United Kingdom as a place in which to develop or supply veterinary medicines.
5. We would like to see a regulatory and legislative framework that ensures the UK is an attractive location for pharmaceutical R&D with the focus on new product development. Measures to align the UK with EU systems should avoid the introduction of greater bureaucracy.
6. The ability to trade animals and products of animal origin with fewer barriers, and associated costs should also be considered. For example, Maximum Residue Limits (MRLs) for substances in medicinal products destined for use in food animals are established by the EU according to Regulation No 470/2009. These MRLs underpin trade in animals and animal products. If in the future, UK authorities diverge from the EU MRLs this could impact on the ability to trade in animal products without testing for residue levels at the border.

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## Manufacturing and marketing authorisation

7. Currently, there are three channels for the authorisation of veterinary medicines in the UK:
  - National authorisation by the Veterinary Medicines Directorate (VMD) when an applicant has applied to the UK only, and has no desire or intention to license and commercialise the product in any other Member State.
  - Centralised procedure, under which an applicant submits a dossier to the European Medicines Agency (EMA) and a product is then licensed for use throughout the EU.
  - Mutual recognition or decentralised procedure by which an applicant submits a dossier to one Member State which undertakes the authorisation. In this third procedure, other Member States may approve the product by mutual recognition of the original marketing authorisation.
8. Only a small percentage of veterinary medicines are authorised through the centralised EMA process, and those will become nationally authorised when the UK leaves the EU, preventing the need for re-authorisation at a UK level.
9. In order to protect public safety and in doing so support trade with the EU, the legislation must be used to establish a national authorisation procedure on the same scientific and evidence based technical requirements as currently adopted by the EU, firmly rooted in the standards set for quality, safety and efficacy, in order to facilitate submissions to both processes.

## The Cascade

10. Veterinary medicines are authorised for specific conditions and species. If, however, there is “no suitable veterinary medicine authorised in the UK for the specific condition in the animal being treated”, vets apply the Cascade, which is a risk-based decision tree setting out the steps, in descending order of suitability. The veterinary medicines cascade must be maintained, and the UK should seek opportunities to simplify it.
11. There is an opportunity for VMD to review the cascade to consider whether it is possible to allow greater flexibility regarding the use of medicinal products licensed elsewhere in the EU, and those of other partners within the International Cooperation on Harmonisation of Technical Requirements for Registration of Veterinary Medicinal Products (VICH). In order to remain as one of the leading agencies in Europe and beyond and have an influential voice in global veterinary regulatory affairs, the UK should seek full membership of VICH.

## Classification and prescription of veterinary medicines

12. There are four different categories of authorised veterinary medicine, each with varying controls regarding who can prescribe and supply the medicine. The categories are:
  - Prescription-only Medicine – supplied only by a Veterinarian; abbreviated to POM-V;
  - Prescription-only Medicine – this category may be supplied by a Veterinarian, Pharmacist, Suitably Qualified Person (SQP); abbreviated to POM-VPS;
  - Non-Food Animal – these are medicines for companion animals and may be supplied by a Veterinarian, Pharmacist, Suitably Qualified Person; abbreviated to NFA-VPS; and,

- Authorised Veterinary Medicine – General Sales List; abbreviated to AVM-GSL. These medicines have no supply restrictions in the VMR.

13. We strongly support the commitment to engage with the veterinary profession on any potential changes to prescribing. Ensuring responsible prescribing by appropriately trained and regulated professionals is essential for animal health and welfare and public health, and to protect against irresponsible prescribing and use which can contribute to a growth in resistance.
14. While a voluntary registration scheme for the supply of veterinary medicines over the internet, run by the VMD, is currently in operation, Subsection (1)(h) could, according to the Explanatory Notes, enable mandatory registration to be introduced. We would support further exploration of mandatory registration as a route to better protecting animal health and welfare and supporting consumer confidence.

## Pharmacovigilance

15. The VMD is responsible for monitoring the safety and efficacy of a medicine after it has been authorised. This includes monitoring, and receiving reports of adverse events, a summary of which is published in the Veterinary Pharmacovigilance in the UK Annual Review. It is essential that we continue to share intelligence in relation to adverse events and have access to international reporting after the Transition Period.

## New EU Regulations

16. Two EU Regulations, put forward as part of legislative package on improving animal and human health, entered into force on 27 January 2019 and will apply from 28 January 2022, after the Transition Period has ended
  - Regulation (EU) 2019/4 on the ‘manufacture, placing on the market and use of medicated feed’, aims to ensure that medicated feed can only be manufactured from specifically authorised veterinary medicines and by approved manufacturers. EU wide residue limits for veterinary medicines in ordinary feed are also established at a limit which aims to avoid the development of antimicrobial resistance.
  - Regulation (EU) 2019/6 on ‘veterinary medicinal products’ aims to make more medicines available in the EU to treat and prevent diseases in animals through simplifying procedures for obtaining a marketing authorisation and reviewing incentives for breakthrough medicines.

We support Clause 9(2) of the Bill which provides the means to make “corresponding or similar provision” to both these EU regulations.

## Medical Devices

17. Although we recognise that Part 3 Medical Devices currently only relates to medical devices for the field of human healthcare, remote animal health and welfare services and remote health monitoring is a field of rapid growth. Opportunities to regulate such devices with regard to safety and efficacy, and set standards for production, should be considered.