NOAH
Supporting the future of animal health

A thriving **animal health sector** through the revised Great Britain **Veterinary Medicines Regulations**

The GB Veterinary Medicines Regulations Review (VMR) presents an opportunity for our animal health sector to thrive. **The current 2013 VMR regulatory framework is no longer fit for purpose.**

NOAH, representing 97% of the UK animal medicines market, **welcomes much in the revised VMR proposals. Time must be allocated for the VMR legislation to be laid before Parliament and approved.**

Nevertheless, in our submission to the Veterinary Medicines Directorate (VMD) public consultation, we suggest several changes to the VMR proposals. If left unchanged, **some of the draft proposals could have an adverse impact on the availability of veterinary medicines in GB and a knock-on risk to animal and public health, animal welfare and sustainability.**

Regulatory burden

The proposals will only partially achieve the consultation's aim to reduce regulatory burden where possible. NOAH proposes changes that will enable the Regulations to achieve their stated aim. Many companies manage the GB animal health sector as part of the wider European market meaning that Britain will benefit from closer alignment to EU requirements on some aspects of regulation. For example, even minor divergence from the EU approach in labelling and packaging requirements can create a negative administrative burden and adversely affect product availability.

Access to veterinary medicines

The classification and distribution system for GB veterinary medicines (indeed, across all of the UK) achieves a balance between appropriate control and animal owner accessibility, giving farmers and pet owners appropriate options for advice and supply.

Decisions on product classification and whether a prescription from a vet is required or not can be made case-by-case by the regulators as part of the benefit/risk assessment. The draft proposals require all future immunological products such as vaccines to be classified as prescription-only medicines and available only from vets; this proposal is not appropriate as availability from other professionals (SQPs) for appropriate products can improve accessibility and hence animal health and welfare.

Innovation and responsible use

The finalised VMRs should be future-proofed to reflect developments and advances in the veterinary medicines sector to allow for and promote innovation.

The current UK systems of advertising and communication, including the ability of companies to carry out disease awareness educational campaigns, aimed at professional keepers of animals, should continue.

Antimicrobial resistance

NOAH supports the proposals in the draft VMR revision. It recognises the past and ongoing commitment of the livestock and veterinary sector, which has helped achieve a 55% reduction in antibiotic use in food producing animals in the UK since 2014. The proposals in the revised VMR will support and build on that success.

Conclusion

NOAH agrees with many of the proposals in the draft GB VMRs and wishes to see the new Regulations laid and passed. Some changes are needed to prevent negative outcomes for the animal health sector and ensure the regulations protect the availability, safety, efficacy, quality, and production of GB veterinary medicines.

We would welcome the opportunity to discuss our response to the consultation in more detail.

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Background

Regulatory burden

The proposals as written will only partially achieve the consultation's aim to reduce regulatory burden where possible. NOAH proposes changes that will enable the Regulations to achieve their stated aim. Many companies recognise the UK as part of the wider European market meaning the UK will benefit from closer alignment. Even minor divergence can create a critical burden.

- Crucially, full alignment with EU labelling and package leaflet requirements is needed to make joint labelling and packaging a realistic proposition. Failure to do so will reduce the competitiveness of the UK's products overall, add to the administrative burden and costs for animal health companies and risk the availability of vet medicines in the UK.

- The current divergence in the technical requirements will require GB specific data for Marketing Authorisation Applications. Without full alignment on data requirements and the manner in which these data are presented, GB could be an unviable market and products could be in the EU and in NI years before GB.

Access to veterinary medicines

The classification and distribution system for veterinary medicines in Great Britain (indeed, in the UK) achieves a balance between control and accessibility, giving farmers and pet owners appropriate options for advice and supply. The current proposals would limit certain new products such as immunologicals (vaccines) to prescription by the vet only.

- Decisions and assessments on product classification can be made on a case-by-case basis as part of the authorisation procedure for individual products with the VMD classifying products as POM V where the particular features of a product deem that necessary.
- Requiring all future immunological products to be classified as prescription-only medicine by vets is not appropriate. Wider availability of some such products would support animal health and welfare and access through suitably qualified persons could be appropriate for some products in the future.

Innovation and responsible use

The finalised VMRs should be developed and applied in a manner that reflects developments and technical advances in the veterinary medicines sector and are future-proofed as much as possible to allow for new developments and innovations.

The current UK systems of advertising, including the ability of companies to carry out disease awareness educational campaigns, should continue. The suggested change to only permit advertising of immunologicals to professional keepers of animals would negatively affect the awareness of disease prevention and treatment among animal owners.

This proposal would also limit the ability of animal health companies to communicate about new, novel therapies that might be developed in the future.

- Awareness of products available can contribute to the reduction in antibiotic use. The use of teat sealants at drying off is one measure that has helped to reduce the use of antibiotic dry cow therapy in the dairy sector. The use of non-steroidal anti-inflammatory medicines can help animal welfare through the provision of pain relief and can also reduce usage of antibiotics, for example, as an option for the treatment of toxic mastitis in dairy cows.
- The ability to educate farmers, who are professionals running businesses, through advertising and educational CPD events assists with correct use and drives improved animal welfare, for example, through companies being able to educate and encourage greater uptake of anti-inflammatory pain killers.

Antimicrobial resistance

NOAH supports the proposal in the VMR revision. It recognises the commitment of the livestock and veterinary sector the commitment of the livestock and veterinary sector, for example through the work of the RUMA Alliance (Responsible Use of Medicines in Agriculture) and indeed, through the development of NOAH's own Livestock Vaccination Guideline and AMBP (Animal Medicines Best Practice) training, which have helped achieve a 55% reduction in antibiotic use in food producing animals since 2014. We believe the proposals in the revised VMR will support and build on that success.

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