

1) What is happening in this review?

In 2004 the European Veterinary Medicines Directive controlling the authorisation, supply and use of animal medicines in Europe was revised. In the UK, the Veterinary Medicines Regulation which implemented this at a national level came into force in 2005, and this Regulation has been updated regularly since. The revoking and remaking of the Veterinary Medicines Regulations 2009 (VMR 2009, SI 2297) is undergoing scrutiny as part of the Government initiative for better regulation. This legislation is still in force. It is expected that the updated legislation will come into force in October 2011.

Now the European regulatory legislation governing veterinary medicines is to be reviewed by the European Commission. It will propose revised legislation which will be considered in detail by the European Council and MEPs (the Co-Decision process) which will, when agreement is reached, be adopted and applied in the 27 EU Member States. This will shape the regulatory framework for the research, development and authorisation of new animal medicines, and will control how animal medicines are distributed to those who protect both farm animals and pets from disease.

The draft regulations are expected in 2012, and the final legislation is expected to be adopted in 2014.

2) Why is it happening?

The animal medicines industry recognises the importance of a robust regulatory system controlling animal medicines. This ensures that the people using medicines to benefit the health and welfare of animals, and those eating food derived from livestock, can have confidence that medicines have been assessed for safety, quality and efficacy and are being used safely and correctly.

There is a standard clause in new European legislation for it to be reviewed after 10 years. However, the European animal health industry, through its federation IFAH-Europe, identified areas in the current Directive that, they felt, were impinging on companies' ability to bring new medicines to the market to treat and prevent disease. Also the regulations were overly burdensome in relation to keeping existing medicines, which have been assessed, on the market. National inconsistencies

in relation to the authorisation process also cause difficulties.

As a result, IFAH-Europe gained support of members of the European Parliament to address these problems, and the review process has started slightly earlier than expected.

The European Commission has been gathering information in preparation for the publication of new draft legislation. This review provides an opportunity to explore the best way forward to improve the availability of animal medicines, and to introduce 'better regulations' in line with the European Commission's principles.

3) What are the issues that will be considered?

The whole of the Directive is under consideration, but there are eight key issues for focus:

- Data exclusivity – this area will address data protection of intellectual property
- Authorisation procedure- how medicines are assessed by the regulatory authorities before they are placed on the market
- Packaging and labelling- self explanatory
- Pharmacovigilance and monitoring- the reporting of suspected adverse reactions
- The distribution channel – how products are sold and supplied from the company to the end user.
- Authorised use and cascade use
- Harmonisation of already authorised products- currently some products are authorised in some countries, but not in others, and the terms of the authorisation for identical products may differ.
- New needs and challenges- the development of new, innovative animal disease solutions.

4) What are NOAH & IFAH-Europe looking for?

The animal health industry is looking for simplified procedures leading to a true single market for animal medicines in Europe. NOAH and IFAH Europe are promoting the 1-1-1 Concept; one dossier, one scientific assessment, and one decision to license a product for use in all 27 Member States, so that veterinary surgeons across Europe could have access to every medicine available in the European Union.

A further issue is that currently data protection provisions are insufficient, leading to a lack of investment in product development by companies. Research and innovation is a direct victim of the current complex authorisation procedures and lack of data protection. Companies who invest substantial budgets into developing medicines must ensure their investment is viable. There must be a sufficient return on investment in order for them to justify this substantial cost. A discouraging regulatory environment makes them wary of investing in smaller market segments such as rare diseases, minor species (animals not commonly kept), and small Member States, which of course impacts on animal welfare and public health. A severe drop in innovation output was observed after the implementation of the 2004 European Directive, indicating a negative impact on companies. So, the industry is looking for this situation to be reversed through the provision of adequate data protection for companies to obtain a return on investment.

In addition it is likely that the review will consider the distribution of animal medicines and their promotion. The animal medicines industry believes that each member state's system of distribution has developed to best meet the needs of that particular country. In Denmark, for example, veterinary surgeons cannot supply medicines (they are only available through pharmacies) whereas in Germany medicines are only available through the vet.

All medicines for farm animals are 'prescription only'. In the UK this classification is sub-divided, allowing other Suitable Qualified Persons (SQPs) to prescribe and supply certain medicines to prevent and treat disease and parasite infestation in farm animals. Farmers are legally responsible for ensuring the livestock they raise to provide food are well looked after, healthy and the produce is free from harmful residues. In the UK they are therefore not considered as 'members of the general public' so the UK permits promotion of animal medicines to farmers, as well as to those who can prescribe medicines, to educate them and keep them informed about the medicines available for treatment of their animals. NOAH wishes to see the ability to retain the UK 2 tier distribution system for medicines for food producing animals and the ability to promote medicines to farmers included within the new European regulations.

5) Are there any threats to the UK system?

The main threat relates to the reclassification of certain animal medicines – particularly to the UK's ability to split the prescription-only category into POM-V (to be prescribed only by a veterinary surgeon and supplied on prescription by a vet or a pharmacist) and POM-VPS (to be prescribed by a veterinary surgeon, SQP or pharmacist and supplied by these groups in accordance with the prescription). The removal of the POM-VPS category would make all medicines POM-V. While this is wholly appropriate for many medicines, for example antimicrobials, it is difficult to see the benefits for others, including antiparasitics, and easy to see a potential negative welfare impact arising from reduced medicine availability, as a consequence of any changes to the distribution system.

This change would have a significant effect on the supply system and the availability of medicines to professional farmers wishing to prevent disease in their animals.

In addition, a change in the ability of companies to communicate direct to farmers would impact on their knowledge about how best to treat disease and best practice on responsible use.

While they are not a target as the focus is on public health, a complete harmonisation of distribution from Europe could even have the potential to impact on companion animal medicines, as the NFA-VPS classification is a UK system. NOAH needs to keep a watching brief on this.

6) What can be done?

At this stage there are no firm proposals from the Commission. By the end of 2011 more details should be emerging.

Within Europe, IFAH-Europe will be working with the Commission to communicate its thoughts on how the regulations can be improved. Each national association will be ensuring that elements of controls within their member state that work well can be retained – or improved, within the regulatory package.

NOAH will also work in the UK, alongside our colleagues, involved in the production of food from British livestock, to ensure UK MEPs and members of the UK parliament are kept up to date with these issues, and can carry forward these views as discussions on the new regulations enter the co-decision process.

NOAH has devoted a section on its website to information on the Review, and will be looking to develop further tools to assist in discussions.