# European Animal Health Industry Calls for Performant New Set of Rules to Improve Availability of Veterinary Medicines Across Europe and Encourage Innovation in Animal Disease Prevention and Control

PEER REVIEWED

The European institutions are now in the throes of reshaping the regulatory environment for veterinary medicines and medicated feed with the revised legislation currently on the agenda of the European Parliament.

Moments such as these only occur once a decade, sometimes even longer, so now is the time to be bold in our policy-making. We need to seize this moment to make the rules governing our products more efficient by cutting red tape, simplifying rules, and ensuring a true single market to encourage innovation, while maintaining high levels of safety and quality.

There is a need for a major reduction in administrative tasks and full implementation of the single market. As a proportion of turnover, the administrative burden on the veterinary medicines sector stands at 13 % versus just 6 % for the human medicines sector. According to the European Commission this amounts to a massive EUR 538 million per year.

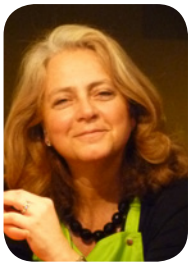
Europe has one of the world's most stringent licensing systems for controlling medicines with an unusually high administrative burden associated with the licensing of veterinary medicines. The disproportionate costs of product maintenance and insufficient data protection, coupled with increasing data requirements, have had a direct impact on innovation with companies in Europe having fewer new products in the pipeline.

Overall the industry is encouraged by the current discussions but there is room for improvement in a number of key areas to further harmonise rules that would ultimately allow for increased innovation to develop much-needed medicines that safeguard not only animal, but also human, health.

One such improvement is a reduction of the administrative tasks associated with the marketing authorisation. The Commission has made several proposals, such as opening up the 'centralised' procedure to any product (currently restricted to innovative and 'biotech' products). A centralised procedure that would result in a single marketing authorisation for Europe is much more efficient than a multiple member state system such as the current mutual recognition procedure which, unsurprisingly, results in multiple national authorisations.

A risk-based approach to the variations procedure is another improvement that should be considered. The variations system should keep all the necessary paperwork well up to date. In conjunction with this, if we can continually monitor the safety of the product in the marketplace with an efficient pharmacovigilance system, then there is no need to follow a fixed five-year time-point to review the benefit:risk of the product.

Reducing the red tape goes hand-in-hand with the need for an improved legal framework for periods of protection of technical documentation that will encourage investments to meet the demand for new and innovative medicines to protect both people and animals from future disease outbreaks and combat emerging animal diseases. If there is no data protection there is little or no incentive to make the significant investments needed into R&D. This also seriously hampers the competitiveness and indeed the future for all players in an already relatively small medicines market.



**Roxane Feller** is Managing Director of IFAH-Europe, the representative body of manufacturers of veterinary medicines, vaccines and other animal health products in Europe. With membership covering 90 % of the European Market, it is a resilient and innovative sector with strong investments in Europe. IFAH-Europe's member companies invest over €400 million in research and development each year. The sector employs some 50,000 people in Europe.

IFAH-Europe promotes a single market in veterinary medicines across the EU ensuring the availability of medicines to protect the health and welfare of animals.
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