

## Veterinary medicines regulatory review 2012: “one-one-one is a win-win-win for all”

Brussels, 16 June 2011 – A significantly revised legislation governing the authorisation of veterinary medicinal products is expected in 2012. IFAH-Europe, the federation representing the European animal health industry, organised the first public “big debate” about the future legislation for all parties involved<sup>(1)</sup>. All agreed that a simplification of the legislation is needed and had a lively exchange about the consequences this review will have for the future of animal health in Europe.

Opening the conference, European Commissioner for Health and Consumer Policy John Dalli explained that the review that is currently taking place is an opportunity for the European Commission to apply its “better regulation” principles: *“The ongoing review of the veterinary medicinal products legislation exemplifies our SMART Regulation programme. We hope to finally achieve a single EU market for veterinary medicines and to simplify the marketing authorisation procedures. We see strong possibilities to make a good contribution to the reduction of the administrative burden for national competent authorities, veterinarians and manufacturers – in other words a win-win-win situation.”*

What are the major drivers behind the review? First, a lack of a genuine European single market for veterinary medicinal products, leading to at times incongruous situations: veterinarians on one side of a border might not have access to the same products as veterinarians on the other side of that border.

Second, market authorisation processes across the European Union are complex, with national inconsistencies and interpretations, creating a very high administrative burden for both regulators and the industry. There was a very strong call at the IFAH-Europe conference for simplification to one single marketing authorisation procedure in the EU and for all existing and future marketing authorisations to be European authorisations and therefore valid in all Member States.

Third, the 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. A discouraging regulatory environment makes them wary of investing into smaller market segments such as rarer diseases, less common animals, small Member States. This has critical and direct consequences on animal welfare and public health. A severe drop in innovation output was observed after the implementation of the latest European Directive, indicating a negative impact on companies.

*“I found the debate today with all stakeholders very encouraging. There is very strong alignment on the issues, their causes and the basic principles of the solutions. We have heard a number of proposals today and if they all came to fruition in a revised legislation could make a tremendous impact on the improved availability of veterinary medicinal*

*products in Europe. Our ambition is to create a single market, so that veterinarians in every Member State have access to every medicine available”,* said Jochen Wieda, Chairman of IFAH-Europe.

(1) The audience gathered animal health professionals and European institutions, farmers, veterinarians, animal owners and the pharmaceutical industry, but also Members of the European Parliament, European Commission and national authorities

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Notes for editors:

### **IFAH-Europe**

IFAH-Europe is the representative body of manufacturers of veterinary medicines, vaccines and other animal health products in Europe. It promotes a single market in veterinary medicines across the EU ensuring the availability of medicines to protect the health and welfare of animals. For further information on IFAH-Europe and on the conference, including its programme and a video report, please visit [www.ifaheurope.org](http://www.ifaheurope.org)

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