Press release

FOR IMMEDIATE RELEASE

Industry and regulators review the changing landscape for veterinary medicines in Europe

Munich, 1 February 2019; AnimalhealthEurope and Klifovet held the first public conference to examine in-depth the contents of the new EU Regulation on Veterinary Medicinal Products, published in the EU Official Journal on 7 January 2019.

As the objectives of the new Regulation were shared by both regulators and industry alike, delegates were keen to share their views as to whether the objectives of the review of the legislation had been met. These objectives were to reduce administrative burden arising from compliance with EU legislation, to stimulate innovation in the sector, to further facilitate the EU single market, to improve the availability of animal medicines, and to address the public health risk arising from antibiotic resistance.

The new Regulation brings some significant changes to the way animal medicines are regulated in the EU. Speakers from the national competent authorities presented the main changes in three key areas:

1. pre-authorisation processes (such as registration procedures, packaging and labelling);
2. post-authorisation processes (such as the variations procedure and pharmacovigilance); and
3. manufacturing, distribution, retail and controls (such as inspections).

Industry delegates presented their views of the impact of these main changes: on the ability of companies to innovate; on the objective to reduce administrative burden; on product development; and on product registration and registration maintenance processes.

"***Companies are naturally interested to find out what the main changes are, how this will impact their daily lives in regulatory affairs, and how it will affect company business plans,***" said Rick Clayton, Technical Director at AnimalhealthEurope. "***In particular companies will be looking at how the new regulation will affect their ability to innovate and bring new veterinary medicinal products to the market.***"

In a separate session, the delegates also heard how the work on the new Regulation has not come to an end with its publication on 7 January. The work now begins in earnest on the next phase – implementation of the new Regulation. There is an enormous amount of work to do, particularly in the first 3 years, which is the transition period before the new rules become applicable in January 2022. Not only are there a high number of Implementing Acts and Delegated Acts to be prepared, agreed and published, but an enormous effort will also be necessary to put in place all the support IT infrastructure that is required.

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This includes electronic portals and three new EU databases, covering products, manufacturing and pharmacovigilance.

Ivo Claassen, Head of Veterinary Medicines at the European Medicines Agency, reported that the EMA had been given a mandate from the European Commission to prepare scientific advice on the implementing measures. "***Preparing these implementing measures will be a complex task and will need an aggressive workplan, as the EMA advice on the drafting of the first batch of these implementing measures must be delivered within 7 months,***" *said Mr Claassen.* "***It is not just the number of measures involved, but also the complexity of the topics and their inter-dependence.***"

This heavy workload comes at a difficult time, with the EMA relocating to Amsterdam during this period, and with the loss of UK experts from the EU regulatory network.

- ENDS -

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Notes for Editors:

- Regulation (EU) 2019/6 on veterinary medicinal products was published in the Official Journal on 7 January 2019.
- The conference also included a session on the new Regulation 2019/4 on medicated feed, which was published at the same time and is also of direct interest to many animal health companies.
- More information on the event can be found on AnimalhealthEurope's website, including the full programme.
- AnimalhealthEurope represents twelve of Europe's leading manufacturers of animal medicines and twenty national associations. Covering 90% of the European Market, the animal health industry enables more than 293,000 direct and indirect jobs (incl. veterinarians), ensures that over a billion animals in Europe - both livestock and companion animals - stay healthy, while providing solutions for 10 million livestock farmers and 80 million pet-owning households across Europe.
- Event organising partner, KLIFOVET AG, based in Munich, Germany is a full service Contract Research and Development Organisation (veterinary CRO) for the Animal Health and Nutrition Industry.