COM(2014) 558	**1st Reading EP started in October 2014**
Lead committee: ENVI	**Opinion committee: AGRI**

REGULATION ON VETERINARY MEDICINES

TOPIC: BACKGROUND INFORMATION

What and when:

COM(2014) 558 proposal for a Regulation on veterinary medicinal products was submitted to the European Parliament in October 2014. The legislation covers both the data requirements and the marketing authorisation procedures for the placing of a veterinary medicinal product on the market. It also covers manufacturing, labelling, sales/distribution and in-market safety surveillance (pharmacovigilance).

What are the Commission's objectives?

- To increase the availability of veterinary medicines
- To reduce administrative burden for companies and regulators
- To stimulate competitiveness and innovation
- To improve the functioning of the internal market
- To address the public health risk of antimicrobial resistance

What is at stake?

- Animal health and welfare
- Availability of a wide range of veterinary medicines across Europe
- Innovation in new medicines to prevent and treat animal diseases
- Sustainability of the European Animal Health Industry

What does this impact?

- One World One Health (control of zoonoses, i.e. infectious diseases which pass between animals and humans) and food security
- Ability to respond (rapidly) to emerging animal diseases
- Agriculture – sustainable food production and prevention of losses from disease
- Medicines for our companion animals

What are the main issues for industry?

The COM proposal partly addresses the issues, *and makes good proposals in some chapters,* but in two key chapters it does not go far enough to meet the objectives:

- Stimulating innovation (e.g. with protection of scientific documentation from use by third parties for reasonable periods of time) and stimulating research into new antibiotics.
- Improving the functioning of the internal market through harmonisation of product information and the possibility of obtaining a pan-European licence for existing veterinary medicinal products.

The main issues for support and amendment are explored in more detail in separate information sheets. Some background information is provided overleaf.

P.T.O.

Background:

Similar to human medicines, veterinary medicines have to be authorised before they can be placed on the market. Data must be provided to prove quality of manufacture and safety (to animals, users and the environment) as well as clinical efficacy. In addition, for products for food-producing animals data must be provided on consumer safety.

However, the human medicines and the veterinary medicines markets are very different in terms of levels of resources and benefit/risk scenarios. So while the 'principles' should remain consistent, the way of implementing those principles must be fully adapted to the conditions of the veterinary medicines sector.

The defining features of the veterinary sector are:

- A wide variety of **species/subpopulations**, each having specific needs, different physiologies and pathologies. A product developed for a cow is unlikely to be suitable for a cat. Separate product developments must take place for each species.
- **Market size**: the veterinary medicines market is **1/40th** the size of the human medicines market. Thus both resource-use and the registration system must be highly efficient.
- **Additional data** must be provided for user, consumer and environmental protection.
- The **price-setting mechanisms** follow a completely different logic since animal owners pay the full cost of treatment - there is **no state healthcare** system. Accordingly the prices for veterinary medicines are much lower and there are far fewer generics.
- The agricultural sector is **sensitive to costs**, such as the price of medicines.

The above results in very different drivers for investment in the veterinary medicines sector.

There are 4 routes to obtain a marketing authorisation for a veterinary medicine:

- **Centralised procedure**: goes via the European Medicines Agency and results in a pan-European authorisation.
- Decentralised procedures where two or more member states (MS) are involved:
  1) **Decentralised Procedure** for new products
  2) **Mutual Recognition Procedure** if an authorisation already exists in one MS
- **National procedure**: goes via the National Competent Authority, if a single national authorisation is required.

More information on the marketing authorisation procedures can be found at
http://www.ifaheurope.org/regulatory-affairs/bringing-veterinary-medicines-to-market.html
and an infographic on what the administrative burden consists of can be found at
http://www.ifaheurope.org/regulatory-affairs/efficient-regulation.html

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IFAH-Europe (International Federation for Animal Health Europe) is the federation representing manufacturers of veterinary medicines, vaccines and other animal health products in Europe. It represents both corporate members and national animal health associations in Europe. These associations comprise both local medium-size enterprises (SMEs) and international companies. IFAH-Europe's membership covers 90% of the European market for veterinary products. IFAH-Europe is a member of the EPRUMA platform for Responsible Use of Medicines in Animals (www.epruma.eu)

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