Veterinary medicinal products

2014/0257(COD) - 10/09/2014 - Legislative proposal

PURPOSE: to ensure a high level of public health protection, high standards of quality and safety of veterinary medicinal products and the optimal functioning of the internal market.

PROPOSED ACT: Regulation of the Council and the European Parliament.

ROLE OF THE EUROPEAN PARLIAMENT: the European Parliament decides in accordance with the ordinary legislative procedure and on an equal footing with the Council.

BACKGROUND: in 2001, all the rules on production, marketing, distribution and use were consolidated in a veterinary medicines code (Directive 2001/82/EC); this was followed by Regulation (EC) No 726/2004.

The current EU legislation on veterinary medicinal products provides the legal environment on authorisation, production, marketing, distribution and use of veterinary medicinal products. It brought some harmonisation to the procedures and rules required to place veterinary medicinal products on the EU market.

However, the Commission considers that there is evidence that the existing provisions do not deliver a functioning internal market:

- diverging or incomplete transposition of the rules and the existence of numerous national requirements imply that companies are confronted with different rules and interpretation in countries and have also led to different levels of public and animal health protection;
- that needs of the veterinary sector differ substantially from those of the human sector in relation to medicines: in the veterinary sector there are many different animal species, which creates both a fragmented market and the need for major investments in order to extend the authorisation of medicines existing for one animal species to another;
- the price-setting mechanisms in the veterinary sector follow a completely different logic. Consequently, prices for veterinary medicines are typically substantially lower than for medicinal products for human use;
- the size of the animal pharmaceutical industry is only a small fraction of the size of the pharmaceutical industry for human medicines.

The Commission considers that it is critically important to have a single market for veterinary medicinal products. The current confined and fragmented markets do not allow the pharmaceutical sector to have a positive return on investments for developing new products for certain animal species.

The ambition to improve the availability of medicines in the Union and the functioning of the internal market and market competition can only be carried out at EU level.

IMPACT ASSESSMENT: the consultation and a study, An assessment of the impact of the revision of veterinary pharmaceutical legislation, formed the basis of an impact assessment carried out for the Commission between November 2009 and June 2011. The Commissions Impact Assessment Board (IAB) released its final opinion in September 2013.

CONTENT: the revision of Directive 2001/82/EC and other legislation on veterinary medicinal products seek to put in place, while safeguarding public health, animal health, food safety and the environment, an up-to-date, proportionate body of legislation tailored to the specificities of the veterinary sector.

Specific objectives aim to:

- expand the market beyond the top four animal species,
- simplify procedures for obtaining a marketing authorisation in multiple national markets,
- review data requirements in marketing authorisation procedures,
- simplify post authorisation requirements,
- review incentives for breakthrough medicines.

The proposal also tackles the issue of antimicrobial resistance and introduces provisions to minimise risks to public health arising from the use of antimicrobials in veterinary medicine.

BUDGETARY IMPLICATION: the costs for the EMA for implementing and applying the new rules are entirely covered by fees charged to industry. Therefore, the proposal is not expected to have any financial impact on the budget of the EU.

The additional resource needs for EMA are approximately 8 staff plus expenditure for meetings, translation, IT, etc. The level of fees, their structure and modalities and exceptions will be set at a later stage by the Commission by way of implementing acts.

DELEGATED ACTS: the proposal contains provisions empowering the Commission to adopt delegated acts in accordance with Article 290 of the treaty on the Functioning of the European Union.