Veterinary medicinal products

2014/0257(COD) - 25/10/2018 - Text adopted by Parliament, 1st reading/single reading

The European Parliament adopted by 583 votes to 16, with 20 abstentions, a legislative resolution on the proposal for a regulation of the European Parliament and of the Council on veterinary medicinal products.

The European Parliament's position adopted at first reading under the ordinary legislative procedure amended the Commission proposal as follows:

Purpose: the Regulation shall establish rules for the placing on the market, manufacturing, import, export, supply, distribution, pharmacovigilance, control and the use of veterinary medicinal products. It shall set **high standards of quality, safety and efficacy for veterinary medicinal products** in order to meet common concerns as regards the protection of public and animal health and of the environment. At the same time, it shall harmonise the rules for the authorisation of veterinary medicinal products and the placing of them on the Union market.

It shall not apply to veterinary medicinal products which have not undergone an industrial process such as, for example, non-processed blood.

Marketing authorisations: a veterinary medicinal product may only be placed on the market when a marketing authorisation for that product has been granted by a competent authority or by the Commission. Authorisations may only be granted to applicants established in the Union. Decisions to grant, **refuse, suspend, revoke or amend** a marketing authorisation shall be made public.

Exemptions may be granted for veterinary medicinal products for animals that are exclusively pets, provided that these medicinal products are not subject to a veterinary prescription.

Decisions to grant marketing authorisations: a marketing authorisation for a veterinary medicinal product shall be valid for an unlimited period. By way of derogation, a marketing authorisation for a limited market shall be valid for five years.

Where the application concerns an antimicrobial veterinary medicinal product, the competent authority or the Commission, as applicable, may require the marketing authorisation holder to conduct post-authorisation studies in order to ensure that the benefit-risk balance remains positive given the potential development of antimicrobial resistance.

A marketing authorisation shall be refused if: (i) the applicant has not sufficiently demonstrated efficacy on the target species; (ii) the risks to public or animal health or the environment are not sufficiently addressed; (iii) the medicinal product is an antimicrobial veterinary medicinal product presented for use as a **performance promoter to accelerate the growth or increase the yield of treated animals**; (iv) the active substance contained in the medicinal product meets the criteria to be considered persistent, bioaccumulative and toxic or very persistent and very bioaccumulative.

Responsibilities of marketing authorisation holders: the marketing authorisation holder shall be responsible for the placing on the market of his veterinary medicinal product. The designation of a representative shall note relieve the marketing authorisation holder of legal liability. In particular, the authorisation holder shall:

- ensure, within the limits of its responsibilities, an appropriate and continuous supply of its veterinary medicinal products;
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- ensure that the summary of product characteristics, package leaflet and labelling is kept up to date with current scientific knowledge;
- not place generic veterinary medicinal products and hybrid veterinary medicinal products on the Union market until the period of the protection of technical documentation for the reference veterinary medicinal product has elapsed;
- record in the product database the dates when its authorised veterinary medicinal products are placed on the market, information on the availability for each veterinary medicinal product in each relevant Member State and, as applicable, the dates of any suspension or revocation of the marketing authorisations concerned;
- record in the product database the annual volume of sales for each of its veterinary medicinal products.

Prudent use of antibiotics: given that resistance to antimicrobial drugs for human and veterinary use is a growing health problem in the EU and worldwide, the amended text emphasised the need to **limit the veterinary use of critically important antimicrobial agents** to the prevention or treatment of life-threatening human infections and to encourage and facilitate the development of new antimicrobials.

According to the amended text:

- antimicrobial drugs shall only be used for **prophylactic purposes** (as a preventive measure) in **well-defined cases** of treatment of an animal or a limited number of animals, if the risk of infection is very high or if the consequences of such infection can have serious consequences. Antibiotic drugs shall only be used for prophylactic purposes in **exceptional cases** and only for a specific animal;
- antimicrobial drugs should only be used for **metaphylaxis** (e. g. to treat a group of animals, one of which shows signs of infection) if there is a **high risk of spreading** an infection or infectious disease in a group of animals and no other solution exists.

Veterinarians shall always issue a veterinary prescription when supplying a veterinary medicinal product subject to a veterinary prescription only and not administering it themselves. Whenever the veterinarians administer such medicinal products themselves it shall be left up to national provisions to specify whether a veterinary prescription needs to be issued. However, veterinarians shall always keep records of the medicinal products that they have administered.

The amended text provides that **third country** operators will have to comply with certain basic conditions relating to antimicrobial resistance for animals and products of animal origin exported to the Union. It also provides incentives to encourage **research and innovation**, in particular on antimicrobials.