Veterinary medicinal products

2014/0257(COD) - 11/12/2018 - Final act

PURPOSE: to adopt new rules on veterinary medicinal products with a view to ensuring a high level of protection of human and animal health and the environment and the proper functioning of the internal market.

LEGISLATIVE ACT: Regulation (EU) 2019/6 of the European Parliament and of the Council on veterinary medicinal products and repealing Directive 2001/82/EC.

CONTENT: the Regulation lays down rules for the placing on the market, manufacturing, import, export, supply, distribution, pharmacovigilance, control and use of veterinary medicinal products. It sets high standards of quality, safety and efficacy of veterinary drugs. At the same time, it harmonises the rules on the authorisation of veterinary medicinal products and their placing on the Union market.

Marketing authorisations

The new rules clarify and simplify the procedures for granting a marketing authorization for new medicines, which reduces the administrative burden for businesses, especially small businesses. Member States will have to take the necessary measures to advise SMEs on compliance with the requirements of the Regulation.

A veterinary medicinal product shall be placed on the market only when a competent authority or the Commission, as applicable, has granted a marketing authorisation for that product. A marketing authorisation for a veterinary medicinal product shall only be granted to an applicant established in the Union. It shall be valid for an unlimited period of time. Decisions to grant, refuse, suspend, revoke or amend by way of a variation a marketing authorisation shall be made public.

A marketing authorisation will be refused if, in particular:

- the benefit-risk balance of the veterinary medicinal product is negative;

- the applicant has not provided sufficient information on the quality, safety or efficacy of the veterinary medicinal product;

- the veterinary medicinal product is an antimicrobial veterinary medicinal product presented for use as performance enhancer in order to promote the growth of treated animals or to increase yields from treated animals;

- the risk for public health in case of development of antimicrobial resistance or antiparasitic resistance outweighs the benefits of the veterinary medicinal product to animal health

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.

Improving the operation of the pharmacovigilance system

Holders of marketing authorisations will be responsible for continuously carrying out pharmacovigilance in order to ensure the continuous evaluation of the benefit-risk balance of the veterinary medicinal products they place on the market. They will, in particular:

- collect reports on suspected adverse events relating to their veterinary medicinal products;

- ensure that the summary of product characteristics, package leaflet and labelling is kept up to date with current scientific knowledge, and

- record in the product database the dates when its authorised veterinary medicinal products are placed on the market, and, as applicable, the dates of any suspension or revocation of the marketing authorisations concerned.

Member States competent authorities will have the power to carry out inspections, including unannounced inspections, at all stages of the production, distribution and use of veterinary medicinal products. To ensure a harmonised approach to controls throughout the Union, the Commission will be able to carry out audits in the Member States to verify the functioning of national control systems.

Prudent use of antimicrobials

The new rules provide that certain critical antimicrobials are reserved for the treatment of certain infections in humans so that their effectiveness is preserved.

Furthermore, the Regulation provides a better framework for the use of antimicrobial agents to prevent their prophylactic (as a preventive measure) and metaphylactic use (for example to treat a group of animals, one of which presents signs of infection):

- antimicrobial medicinal products should not be used for prophylaxis other than in well-defined cases for the administration to an individual animal or restricted number of animals when the risk for infection is very high or its consequences are likely to be severe. Antibiotic medicinal products should not be used for prophylaxis other than in exceptional cases only for the administration to an individual animal;

- antimicrobial medicinal products should be used for metaphylaxis only when the risk of spread of an infection or of an infectious disease in a group of animals is high and where no appropriate alternatives are available.

A veterinary prescription for an antimicrobial medicinal product for metaphylaxis shall only be issued after a diagnosis of the infectious disease by a veterinarian. It shall be issued only after a clinical examination or any other proper assessment of the health status of the animal or group of animals by a veterinarian.

The Regulation also improves the protection of European consumers against the risk that antimicrobial resistance will spread through imports of animals and animal products.

ENTRY INTO FORCE: 27.1.2019.

APPLICATION: from 28.1.2022.