

Veterinary medicinal products

2014/0257(COD) - 10/03/2016 - Text adopted by Parliament, partial vote at 1st reading/single reading

The European Parliament adopted amendments to the proposal for a regulation of the European Parliament and of the Council on veterinary medicinal products.

The matter has been referred back to the committee. The vote on the legislative resolution has been postponed to a subsequent sitting.

The main elements adopted in plenary are as follows:

Aim: this Regulation aims at ensuring a high level of protection of both animal and human health while securing the protection of the environment. Therefore, the precautionary principle should be applied.

Member States may impose stricter conditions, justified on grounds of public health, animal health and environmental protection, for the use and retail of veterinary medicinal products on their territory, provided that these conditions are proportionate to the risk and do not unduly restrict the functioning of the internal market

Antibacterial resistance: in order to preserve as long as possible the efficacy of certain antimicrobials in the treatment of infections in humans, Members considered it necessary to reserve those antimicrobials for humans only. The Commission shall, by means of implementing acts and taking into consideration the scientific advice of the Agency as well as the work already carried out by the WHO, designate antimicrobials or groups of antimicrobials reserved for treatment of certain infections in humans.

Therefore, the Union should be active in advocating the creation of an international strategy to combat antimicrobial resistance, in line with the recent Global Action Plan adopted by the WHO.

Use of prophylactic and metaphylactic medicines: Members considered that the routine prophylactic (preventive) and metaphylactic (mass medication of a group of animals to eliminate or minimize an expected outbreak of disease) use of antimicrobials on groups of food-producing animals should be brought to an end. Disease should be prevented not by routine recourse to antimicrobials but by good hygiene, husbandry and housing and sound management practices.

Routine prophylactic use of antimicrobials is therefore prohibited. Prophylactic use of antimicrobial veterinary medicines will only be permitted on single animals and when fully justified by a veterinarian in exceptional indications, of which a list shall be drafted by the Agency.

Metaphylactic use of antimicrobial veterinary medicines will be restricted to use in clinically-ill animals and to those single animals that are identified as being at a high risk of contamination, to prevent further spread of the disease in the group.

According to the amended text, antimicrobial veterinary medicines shall not under any circumstances serve to improve performance or compensate for poor animal husbandry.

Research and innovation: to encourage research into new antimicrobials, Parliament advocated the following incentives:

- longer periods of protection for technical documentation on new medicines;
- commercial protection of innovative active substances, and
- protection for significant investments in data generated to improve an existing antimicrobial product or to keep it on the market.

A new article on the period of protection of new data packages related to existing veterinary medicinal products stipulated that any new studies and trials, submitted by the applicant for a marketing authorisation to the competent authorities for an existing veterinary medicinal product no longer covered by any protection period shall benefit from a stand-alone period of protection of four years under certain conditions.

Animals under the care of veterinary professionals: Parliament narrowed the definition of persons entitled to retail veterinary medicines and states that persons qualified to prescribe veterinary medicinal products in accordance with applicable national law shall retail antimicrobial products only for animals which are under their immediate care, subject to an appropriate veterinary diagnosis and examination of the animals concerned, and only in the amount required for the treatment concerned. In the case of food-producing animals, the continuation of the treatment with antimicrobial products shall be decided based on a renewed clinical examination by a veterinarian

On-line sales: antimicrobials, psychotropic and biological or immunological veterinary medicinal products may not be offered on the internet. Other products may be sold online under strict criteria e.g that the veterinary medicinal products and the prescriptions comply with the law of the destination Member State.

The Commission shall adopt guidelines supporting the Member States in the development of a harmonised system of digital prescription across the Union, including measures for controlling cross-border veterinary prescriptions.

Environmental protection: no later than six months before the date of application of the Regulation, the Commission must present a report on a feasibility study of a substance-based review system ('monographs') and other potential alternatives for the environmental risk assessment of veterinary medicinal products, to be accompanied, if appropriate, by a legislative proposal.