Veterinary medicinal products

2014/0257(COD) - 29/02/2016 - Committee report tabled for plenary, 1st reading/single reading

The Committee on the Environment, Public Health and Food Safety adopted the report by Françoise GROSSETÊTE (EPP, FR) on the proposal for a regulation of the European Parliament and of the Council on veterinary medicinal products.

The committee recommended that Parliament make the following amendments to the Commission proposal:

Antibacterial resistance for humans only: the Committee agreed with the Commission that in order to preserve as long as possible the efficacy of certain antimicrobials in the treatment of infections in humans, those antimicrobials should be reserved for humans only. 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, the Commission will designate antimicrobials or groups of antimicrobials reserved for treatment of certain infections in humans.

Prophylactic use of medicines: Members considered that the routine prophylactic and metaphylactic 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.

Innovation: to encourage research into new antimicrobials, Members advocate incentives, including:

- 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 data protection for redevelopment of veterinary medicinal products states that where the data protection period has elapsed, any applicant may apply for a data protection period for additional innovations to existing veterinary medicinal products, which shall amount to **two years for an additional species and one year for an additional indication**, additional pharmaceutical form or new withdrawal period.

Any **new studies and trials**, submitted by the applicant for a marketing authorisation for an existing antimicrobial veterinary medicinal product no longer covered by any protection period shall benefit from a stand-alone period of protection of four years, provided that they fulfil certain conditions.

Animals under the care of veterinary professionals: the committee 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: Members tightened the rules on sales online. **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.

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.