EUROPEAN COMMISSION

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Dear President,

The Commission would like to thank the Senato della Repubblica for its Opinion on the proposal for a Regulation of the European Parliament and of the Council on veterinary medicinal products {COM(2014)558 final} and on the proposal for a Regulation of the European Parliament and of the Council amending Regulation (EC) No 726/2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency {COM(2014)557 final}.

The Commission welcomes the detailed observations and suggestions made by the Senato della Repubblica. The Commission would like to make the following remarks on the comments related to the above mentioned proposals.

On the proposal for a Regulation of the European Parliament and of the Council on veterinary medicinal products {COM(2014)558 final}:

Concerning the rules on prescription and sale of medicinal products by veterinarians, the proposal on veterinary medicinal products does not change the current rules allowing the prescription and supply of veterinary medicines by veterinarians. The Commission's proposal does not interfere with the national rules of the supply of veterinary medicines. The professional situation of veterinarians in Member States varies significantly therefore this is and should remain an issue to be dealt with at national level.

The proposal includes new rules for on-line sales of veterinary medicinal products in view of making end-users able to recognise legal internet retailers across the Union. Further implementing measures including the administrative and practical details should be developed by the Commission and the Member States in that view. In order to take into account the sales practices at national level Member States are given in the proposal a certain level of flexibility. In fact, the organisation of the retail of veterinary medicines including the retail at distance vary between the Member States, if in certain Member States veterinary medicines can only be sold in pharmacy, in others they can be either sold by a veterinarian or in a pharmacy.

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With a view to combatting the development of resistance, the proposal is part of the action plan against the rising threats from antimicrobial resistance. The Commission proposal aims to ensure a prudent use and to preserve critical antimicrobials for the treatment of human infections. In that regard, a number of specific provisions have been introduced in the proposal allowing the control of the use of antimicrobials. There will be the possibility to take decisions refusing marketing authorisations when the product is an antimicrobial presented for use to promote the growth of treated animals or if the antimicrobial is reserved for treatment of certain infections in humans. In addition, the retail of antimicrobials by veterinarians should only be possible for animals which are under their care, and only in the amount required for the treatment concerned. The Commission believes that these provisions are more appropriate to tackle the problem of antimicrobial resistance than a complete ban. Measures restricting the use of veterinary antimicrobials in the Union should also be considered in the context of cooperation with third countries and international organisations addressing antimicrobial resistance in order the ensure consistency with their activities and policies.

On the rules on the use of homeopathy in veterinary field the Commission proposes to establish a special, simplified registration procedure and to provide specific provisions for labelling for certain homeopathic veterinary medicinal products which are placed on the market without therapeutic indications. Immunological homeopathic products would not be able follow the simplified registration procedure as immunologicals may initiate a response at a high dilution rate.

On the proposal for a Regulation of the European Parliament and of the Council amending Regulation (EC) No 726/2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency {COM(2014)557 final}:

As regards the delegation of powers to the Commission to lay down rules concerning the limitation, duration, time-limits and conduct of the imposition of fines or periodic penalty payments to the holders of marketing authorisations, the maximum amounts of these penalties and the conditions and methods for their collection, the Commission would like to point out that such rules are laid down in the Commission Regulation (EC) No 658/2007 of 14 June 2007 concerning financial penalties for infringement of certain obligations in connection with marketing authorisations granted under Regulation (EC) No 726/2004 of the European Parliament and of the Council. In its proposal the Commission aims to adapt the Regulation (EC) No 726/2004 to the requirements set out by the Treaty of Lisbon regarding the delegation of powers. To this end, the powers conferred on the Commission in the proposal to adopt implementing acts are in compliance with Article 291 TFEU and Regulation (EC) 182/2011.

As to the financial impact of the proposed acts, the Commission's proposals contain rules to ensure that the tasks and activities attributed to the European Medicines Agency are adequately funded. Nonetheless, those provisions do not affect the right of Member States to charge fees for activities and tasks at national level.

The points made above are based on the initial proposal presented by the Commission which is currently in the legislative process involving both the European Parliament and the Council in which your government is represented.

The Commission hopes that these comments address the concerns raised by the Senato della Repubblica and looks forward to continuing our political dialogue.

Yours faithfully,

Frans Timmermans
First Vice-President

Vytenis Andriukaitis
Member of the Commission