EUROPEAN COMMISSION

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Dear President,

The Commission would like to thank the Sénat for its Opinion on the proposal for a Regulation on the manufacture, placing on the market and use of medicated feed and repealing the Directive 90/167/EEC {COM(2014) 556 final} and on the proposal for a Regulation on veterinary medicinal products {COM(2014) 558 final}.

The Commission would like to make the following remarks on the comments related to the proposal for a Regulation on veterinary medicinal products ("the proposed Regulation").

Concerning the public health risk of antimicrobial resistance, this proposal is part of the action plan against the rising threats from antimicrobial resistance. The Commission in its 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.

The proposed Regulation includes new rules for on-line sales in view of making end-users able to recognise legal internet retailers across the Union. Further implementing measures including the administrative and practical details would be developed by the Commission and the Member States in that view. In order to take into account the sales practices at national

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level Member States are given a certain level of flexibility in the proposed Regulation. 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 it can be either by a veterinarian or in a pharmacy.

Regarding the import of veterinary medicines, the Commission's proposal contains a number of provisions among which the possibility to suspend imports of veterinary medicinal products in the event of non-compliance with the obligations applying for the manufacturing authorisation holders.

However, the proposal does not regulate the imports of animals and animal-by-products, as these remain outside the scope of the proposal for a regulation on veterinary medicinal products.

The four marketing authorisation procedures have been maintained but have been adapted with a view to making the procedures more effective and to giving stakeholders the indispensable legal certainty. The introduction of a simple vote majority rule in the process of the coordination group review procedure (Article 49 of the proposal) is one of the measures proposed to achieve this objective. The possibility to trigger a Union interest referral procedure is maintained (Articles 84 – 87 of the proposal). In accordance with this procedure, a Member State can refer its concerns regarding the safety, quality and efficacy of a veterinary medicinal product to the European Medicines Agency. The final decision on the referral is adopted by the Commission in form of implementing acts.

The Commission would like to stress that the revision of the legislation on veterinary medicinal products aims at increasing availability of veterinary medicinal products and reducing administrative burden, while at the same time maintaining the highest standards for public health, animal health and environmental safety.

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

The Commission hopes that these clarifications address the issues raised by the Sénat and looks forward to continuing our political dialogue in the future.

Yours faithfully,

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First Vice-President

Vytenis Andriukaitis
Member of the Commission