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REPORT

From:	Presidency
To:	Council
Subject:	Proposal for a Regulation of the European Parliament and of the Council on veterinary medicinal products *- Progress report*

I. INTRODUCTION

1. On 16 September 2014, the Commission submitted a legislative package to the European Parliament and the Council, comprising three proposals[1]:

- a proposal for a Regulation of the European Parliament and of the Council on veterinary medicinal products[2] (based on Articles 114 and 168(4)(b) TFEU);
- a proposal for a Regulation of the European Parliament and of the Council on the manufacture, placing on the market and use of medicated feed and repealing Council Directive 90/167/EEC[3] (based on Articles 43 and 168(4)(b) TFEU);

[1] The first two proposals listed were accompanied by impact assessments which were presented and discussed at the first meetings of the relevant working parties.
[2] 13289/14 + ADD 1 + ADD 2 + ADD 3.
[3] 13196/14 + ADD 1-3.

- a proposal for a Regulation of the European Parliament and of the Council amending Regulation (EC) N° 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[4] (based on Articles 114 and 168(4)(b) TFEU).

2. The present report will focus on the state of play of the examination of the first proposal, namely the proposal for a Regulation on veterinary medicinal products.

3. While having the general objective of safeguarding public health, animal health, food safety and the environment, the specific aim of that proposal is to put in place a set of rules tailored to the specificities of the veterinary sector and aiming in particular to:
   - increase the availability of veterinary medicinal products;
   - reduce administrative burdens;
   - stimulate competitiveness and innovation;
   - improve the functioning of the internal market;
   - address the public health risk of antimicrobial resistance.

4. The European Parliament has designated the Committee on the Environment, Public Health and Food Safety (ENVI) as the lead committee and Ms Grossetête (EPP, FR) as the rapporteur for the proposal. ENVI adopted its opinion on 17 February 2016, and the plenary subsequently adopted 285 amendments on 10 March 2016[5]. The European Parliament has not yet voted on the legislative resolution, thereby allowing for the possibility to conclude a first-reading agreement between the institutions.

5. The European Economic and Social Committee delivered its opinion on 21 January 2015 and the Committee of the Regions informed the institutions on 19 November 2014 that it would not issue an opinion on the proposal.

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[4] 13240/14.
[5] 6875/16.

6. Two national parliaments delivered opinions[6] on the application of the principles of subsidiarity and proportionality with regard to this proposal.

7. In the Council, the proposal is being examined by the Working Party of Veterinary Experts (Animal Health)[7].

II. STATE OF PLAY

During the current trio Presidency the Council started the **second technical reading** of the Commission's proposal for a Regulation on veterinary medicinal products. After 31 days of Council Working Party meetings under the Netherlands, Slovak and Maltese presidencies, almost all provisions of this proposal have been redrafted at least twice and have been thoroughly examined. An additional four days of meetings at expert level are planned before the end of the Maltese Presidency.[8]

The objectives of the Commission proposal were generally supported by delegations. However, many of the proposed provisions were generally deemed as needing to be clarified, strengthened and/or complemented with additional provisions. By so doing, the Council Working Party has worked towards providing the proposed Regulation the level of detail necessary to ensure a smooth transition towards its implementation, while also safeguarding the current level of animal health, public health and environmental protection.

The delegations have emphasised that the proposed **annexes** provide an insufficient level of technical detail and would require considerable work to reach a text that provides the same level of certainty as that provided by the current Directive.

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6 16096/14; 16818/14.

7 Given the nature of the subject, in addition to animal health experts working on veterinary medicines, experts in pharmaceuticals are also welcome to attend the meetings.

8 The Council Working Party is planning to meet for four additional days of meetings on the 8-9 and 28-29 June 2017.

The Maltese Presidency continued building on the momentum garnered by its trio partners by prioritising the main provisions of the proposed regulation. In doing so, all efforts were employed to initially complete the **second technical reading** and then consolidate technical discussions with a view to bring to completion**, as far as possible,** the **examination** of the Commission proposal at technical level.

To advance the Council's examination of this proposal the Maltese Presidency adopted a topic-based approach that ensured the continued consistency between the different provisions of the proposed Regulation. Furthermore, the Presidency's efforts regarding the main provisions of the proposal sought to ensure that the main proposed changes in the Regulation are made achievable through a more coherent and implementable text.

With this approach, considerable effort was placed on the provisions related to the use of veterinary medicinal products (including antimicrobials), pharmacovigilance and manufacturing and wholesale distribution.

Improvements to the proposed framework to regulate the use of **antimicrobials** on animals have been developed to support the growing efforts to reduce the risk of antimicrobial resistance, in particular by strengthening the legal provisions on prudent use of veterinary medicines. New dedicated provisions on the correct use of antimicrobials on animals for prophylactic and metaphylactic purposes were introduced with that aim in mind, thereby ensuring these practices are used prudently. Delegations generally supported the framework proposed to regulate and strengthen provisions on prudent use of antimicrobials.

Extensive discussions were held to understand Member States' preferences on the **use of medicinal products on animals outside of the terms of their marketing authorisation ('cascade use')**. Based on these discussions, the Presidency strived to clarify this important section and its provisions and reintroduced a tiered system for a cascade that maintains the general availability of therapeutic options for veterinarians.

With regard to **pharmacovigilance,** the Presidency extensively revised the whole section dedicated to the reporting and recording of adverse events of veterinary medicines, i.e. when the products are found to have a reduced efficacy and/or safety. The Presidency compromise suggestion sought to deliver a workable and risk-based pharmacovigilance system that operates on a real-time basis, through rapid transmission of, primarily, pharmacovigilance data and options for risk management, with a clear delineation of responsibility for all users. Delegations generally supported the idea that the marketing authorisation holder (MAH) should be responsible for ensuring a favourable risk-benefit balance for its veterinary medicine and that an active obligation to inform the competent authorities of any changes to the risk-benefit balance or the emergence of new risks should be maintained. The proposal that the MAH should report the results of the 'signal management process' in the pharmacovigilance database at least annually also met with general approval.

On **manufacturing,** the relevant provisions of the proposal were considerably strengthened to require the high manufacturing standards currently in place to be maintained, while also allowing the possibility for environmental and animal welfare aspects to be considered. There was general support for making the principles of 'good manufacturing practice' and related requirements mandatory for all manufacturers of veterinary medicinal products.

With regard to **wholesale distribution** there was also general support for introducing harmonised authorisation requirements to ensure compliance with the principles of 'good distribution practice' and related requirements. By strengthening controls on veterinary medicinal products along the supply chain, cross-border cooperation on control and enforcement will be enhanced.

III. CONCLUSION

The Maltese Presidency will hold additional expert level meetings to discuss this proposal on 8-9 and 28-29 June, at which the examination of the redrafted texts will continue.

To complete the **technical examination**, further work will in particular be required on the 'harmonisation of summary of product characteristics'. In addition, a solution still needs to be found for the proposed annexes, which in the proposed form do not ensure continuity with the current regulatory framework.