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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 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 *- Progress report*

I. INTRODUCTION

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

- a proposal for a Regulation of the European Parliament and of the Council on veterinary medicinal products[1] accompanied by an impact assessment[2];
- 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] accompanied by an impact assessment[2];

[1] doc.13289/14 + ADD 1+ADD 2+ADD 3
[2] For both proposals, the Impact assessment was presented and discussed at the first meeting of the Working Party.
[3] doc. 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].

2. The present report will focus on the state of play of the examination of the first two proposals. These proposals are respectively based on Article 114 and Article 168(4)(b) TFEU for the first one and on Article 43 and 168(4) TFUE for the second one (Ordinary legislative procedure in both cases).

3. While having the objective to safeguard public health, animal health, food safety and the environment, the aim of the proposal on veterinary medicinal products 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; and
- address the public health risk of antimicrobial resistance.

The overall objective of the proposal on medicated feed is to review the current legislation[5] to ensure the highest degree of animal health and welfare and public health as well as a better functioning of the internal market and the competitiveness of the livestock sector with respect to the use of medicated feed.

[4] doc.13240/14

[5] Council Directive 90/167/EEC of 26 March 1990 laying down the conditions governing the preparation, placing on the market and use of medicated feedingstuffs in the Community

4. The European Parliament has designated Ms. Grossetête (EPP, FR) rapporteur for the proposal on veterinary medicinal products and Ms. Clara Eugenia Aguilera García (S&D, ES) rapporteur for the one on medicated feed. The European Parliament's lead committees for each of the proposal are respectively the committee for the Environment, Public Health and Food Safety (COMENVI) and the committee for the Agriculture and the rural development (COMAGRI). They both plan to adopt their opinion in February 2016.

5. The European Economic and Social Committee delivered its opinion on 21 January 2015 on both proposals. On 19 November 2014, the Committee of Regions informed the Council that it would not issue an opinion on the proposal on medicated feed; its opinion on the proposal on veterinary medicinal products is not yet available.

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

7. In the Council, these proposals are being respectively examined by the working party of veterinary experts (animal health)[7] and by the working party on agricultural questions (feedingstuffs).

[6] Doc 16096/14; doc 16818/14

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

II. STATE OF PLAY

A. Proposal on veterinary medicinal products

After seventeen days of meetings, under the Italian, Latvian and Luxembourg Presidencies[8], the first technical reading through of the proposal was concluded by the Luxembourg Presidency.
The proposal was generally welcomed. However many delegations highlighted the need to ensure high consistency with the other two proposals of the package that are examined by different Council working parties and that are also advancing at different pace.

Among the concerns expressed on this proposal, the following points have been highlighted;

- validity of the marketing authorisation of veterinary medicinal products which has currently a validity of 5 years but would have in future an unlimited validity;
- the qualification of the person authorised to prescribe veterinary medicinal products and the recognition of the veterinary prescription throughout the European Union;
- new rules on off-label use of medicinal products for veterinary or human use which would not follow the existing 'cascade' principles and which are set separately for food producing animals of aquatic species;

[8] Meetings under the Italian Presidency (9 October, 11 November 2014), the Latvian Presidency (28 January, 24 February, 12&13 March, 22 April, 20 May and 18 June 2015) and the Luxembourg Presidency (13&14 July, 14 September, 12&13 October, 10 and 30 November 2015)

- the specific rules to minimise antimicrobial resistance and in particular the restriction on the use of antimicrobial veterinary medicinal products for food producing animals and the empowerment to the Commission to establish a list of 'critical' antimicrobial medicinal products prohibited for use in veterinary medicine.
- new rules on pharmacovigilance relaxing in particular marketing authorisation holder from submitting the so called Periodic Safety Update Reports (PSURs) .
- data requirements (quality, safety and efficacy) for different types of applications for granting a marketing authorisation to a veterinary medicinal product and the harmonisation of Summary of Product Characteristics (SPCs)
- Union databases on veterinary medicinal products, pharmacovigilance, manufacturing and wholesale distribution.
- the establishment and role of the Committee for Veterinary Medicinal Products (CVMP) and of the Coordination group in the centralised, decentralised and mutual recognition procedures for marketing authorisation of veterinary medicinal products.

B. Proposal on medicated feed

After four days of meetings under the Italian and the Latvian Presidency[9], the first technical examination of the proposal was concluded under the Latvian Presidency. The latter prepared a first redrafted text[10], on which discussions started at a working party meeting on 19 June 2015.

The Luxembourg Presidency finalised the technical examination of the first redrafted text during three working party meetings[11] and elaborated a second redrafted text[12], which will be presented at the working party meeting on 9 December 2015.

The second redrafted document sets out clear and harmonized rules for feed business operators and control authorities on the manufacture, placing on the market and use of medicated feed in all the Member States. The text has been fine tuned in order to avoid the repetition of existing legal provisions and to ensure legal clarity.

The Presidency has devoted particular attention to the fight against antimicrobial resistance, which will be tackled through a number of measures, and notably: the introduction of a specific prescription for medicated feed; compulsory measures to avoid cross-contamination; the setting of maximum limits for active substances of veterinary medicinal products in non-target feed.

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9 Meetings under the Italian Presidency (10October 2014 and 12 November 2014); under the Latvian Presidency (27 January 2014 and 23 February 2015).

10 Doc. 9713/15.

11 On 15.7.2015, 10.10.2015 and 28.10.2015.

12 Doc. 14534/15.

III. CONCLUSION

Given the comments made by several delegations on the close links between the proposals on medicated feed and on veterinary medicinal products and taking into account the different pace of examination of the two proposals, the Luxembourg Presidency invited the working party of agricultural attachés to provide guidance on their handling. The working party considered at its meeting on 3 November 2015 that a package approach should be maintained, to ensure consistency between the two proposals.

The first examination of the proposal on veterinary medicinal products was extremely detailed. It will allow to start the redraft of the text and to prepare for the next steps of the examination, in particular with regard to the provisions that are closely linked to the proposal on medicated feed.

The substantive work carried out on the proposal on medicated feed will serve as a solid basis for concluding discussions on this proposal in Council, once the discussions on the proposal on veterinary medicinal products will have reached a more advanced stage.