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**NOTE**

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From: General Secretariat of the Council  
To: Permanent Representatives Committee

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Subject: Proposal for a Regulation of the European Parliament and of the Council  
on veterinary medicinal products  
*- Confirmation of the final compromise text with a view to agreement*

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1. On 16 September 2014, the Commission submitted the above mentioned proposal to the European Parliament and to the Council.
2. The proposal is based on Articles 114 and 168(4)(b) TFEU and it lays down rules for the placing on the market, manufacture, import, export, supply, pharmacovigilance, control and use of veterinary medicinal products with the general objective of safeguarding public health, animal health, food safety and the environment. It is part of a package comprising two other proposals<sup>1</sup>.

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<sup>1</sup> Documents 13196/14 (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 ) and 13240/14 (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).

3. On 21 January 2015, the European Economic and Social Committee adopted its opinion. The Committee of the Regions informed the institutions on 19 November 2014 that it would not issue an opinion.
4. On 10 March 2016, the European Parliament adopted 285 amendments without voting on a legislative resolution.
5. On 20 December 2017, Coreper approved a negotiation mandate<sup>2</sup>. Based on that initial mandate, five informal trilogues were held (31 January, 26 February, 22 March, 19 April and 15 May 2018).
6. On 25 May 2018, Coreper approved a revised negotiation mandate<sup>3</sup> which addresses the issues which were still outstanding at the negotiations. A sixth trilogue was held on 5 June 2018 based on that revised mandate. At that trilogue, a tentative agreement was reached between co-legislators on the compromise text as set out in the Addendum 1 to this note.
7. In the light of the above, Coreper is invited to:
  - confirm its agreement on the compromise text as set out in the Addendum 1 to this note;
  - authorise the Presidency to send a letter to the Chair of the European Parliament's Committee on Environment, Public Health and Food Safety (ENVI), confirming that, should the European Parliament adopt its position at first reading, in accordance with Article 294(3) of the Treaty, in the form set out in the Addendum 1 to this note (subject to revision by the lawyer-linguists of both institutions), the Council would, in accordance with Article 294(4) of the Treaty, approve the European Parliament's position and the act shall be adopted in the wording which corresponds to the position of the European Parliament.

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<sup>2</sup> 15296/17 ADD1 REV1.

<sup>3</sup> 8883/18 ADD1 REV1.