



EUROPEAN COMMISSION

Health and Food Safety Directorate General

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**Standing Committee on Plants, Animals, Food and Feed**  
**Section *Veterinary Medicinal Products***  
**14 DECEMBER 2018**

*CIRCABC Link:* <https://circabc.europa.eu/w/browse/15d1ee97-3ef4-48ef-a36c-58adc23451ce>

<b>AGENDA</b>
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**Section A**     **Information and/or discussion**

**A.01** Opening and adoption of the agenda. (CS)

**A.02** Draft Regulation on Veterinary Medicinal Products – overview and roadmap for implementation (role of the Standing Committee). (CS)

**A.03** Draft mandates to EMA on scientific advice for implementing acts. (JP + LG)

A.03.1. IAs to be adopted 12 months before entry into application of the new Regulation :

- establishing a list of variations not requiring assessment;
- measures and practical arrangements for veterinary medicinal product database.

A.03.2. IAs to be adopted by the date of application of the new Regulation :

- good pharmacovigilance practice;
- pharmacovigilance system master file (PSMF).

**A.04** A.O.B. (CS)