sante.ddg2.g.5(2019)6173616

Standing Committee on *Veterinary Medicinal Products* 30 September 2019

CIRCABC Link: https://circabc.europa.eu/w/browse/69ea7490-8cab-41a1-9aa3-b7bfb74bac91

AGENDA

Section A <u>Information and/or discussion</u>

- **A.01** Opening and adoption of the agenda.
- **A.02** Update on the state of play of the implementation of the new Regulation on veterinary medicinal products.
- **A.03** EMA advice on the implementing acts (IAs) to be adopted 12 months before entry into application of the new Regulation on veterinary medicinal products:
 - a) Advice on implementing measures under Article 60(1) of Regulation (EU) 2019/6 on veterinary medicinal products Scientific recommendation on the list of variations not requiring assessment; (JP)
 - b) Advice to the European Commission on the Union Product Database. (LG)
- **A.04** Ongoing work on scientific advice for IAs update from EMA on the expert working groups' activities and progress:
 - good pharmacovigilance practice; (JP)
 - pharmacovigilance system master file (PSMF); (JP)
 - format for the collection of data on antimicrobial medicinal products used in animals; (JS)
 - list of antimicrobials or groups of antimicrobials reserved for treatment of certain infections in humans; (JS)
 - good distribution practice (GDP) for veterinary medicinal products; (LG)
 - good distribution practice (GDP) for active substances used as starting material in veterinary medicinal products. LG)

A.05 AOB.