EUROPEAN COMMISSION
HEALTH AND CONSUMERS DIRECTORATE-GENERAL

Health systems and products
**Medicinal products – authorisations, European Medicines Agency**

Brussels, 01/06/2018

NTA H+V

# Notice to Applicants

# Medicinal products for human and veterinary use

**Meeting on 5 June 2018**
10.00 – 18.00

Address: Conference Centre "Albert Borschette", Room AB-4C, Rue Froissart 36, 1040 Brussels

## AGENDA (Version 02)

1. Adoption of draft agenda
2. Adoption of draft minutes of the meeting on 29 November 2017
3. Volume 6A (veterinary) - Chapter 1 - Marketing authorisation and Chapter 3 – Union Referral Procedures
4. Volume 6C (veterinary) - Guideline on the packaging information of veterinary medicinal products authorised by the Community
5. Volume 2A (human) - Chapter 1 - Marketing authorisation
6. Volume 2A (human) - Chapter 2 – Mutual Recognition
7. Volume 2C (human) - Guidelines on the categorisation of new applications versus variations applications
8. Volume 2C (human) - Guidelines on the excipients in the labelling and package leaflet
9. Information on the update of Questions and Answers related to UK's withdrawal from the Union
10. Information on the Commission Study on the experience acquired as a result of the operation of centralised and decentralised marketing authorisation procedures
11. AOB
    11.1. Scope of the centralised procedure - Homeopathic MP

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