



EUROPEAN COMMISSION
HEALTH AND CONSUMERS DIRECTORATE-GENERAL

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

NTA H+V

Notice to Applicants

Medicinal products for veterinary and human use

Meeting on 7 June 2016

10.00 – 18.00

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

AGENDA

1. Adoption of draft agenda

2. Notice to Applicants discussion

- 2.1. Volume 6A (veterinary) - Chapter 1
- 2.2. Volume 6A (veterinary) - Chapter 2
- 2.3. Volume 6A (veterinary) - Chapter 3
- 2.4. Volume 6A (veterinary) - Chapter 4
- 2.5. Volume 6C (veterinary) - Guideline on the packaging information of veterinary medicinal products – possible update
- 2.6. Volume 6C (veterinary) - Proposals for a Guideline on the change in classification for the supply of veterinary medicinal products

- 2.7. Volume 2B (human) - Module 1.2 Homeopathic Application form
- 2.8. Volume 3 (human) - Guideline on the Excipients in the Label and Package Leaflet of Medicinal Products for Human Use
- 2.9. Volume 2A (human) – Chapter 1 - Marketing authorisation
- 2.10. Volume 2A (human) – Chapter 3 - Union Referral Procedures
- 2.11. Volume 2A (human) – Chapter 2 – Mutual Recognition (to be confirmed)

3. AOB