



EUROPEAN COMMISSION
HEALTH AND CONSUMERS DIRECTORATE-GENERAL

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

Brussels,

NTA H+V

Notice to Applicants

Medicinal products for veterinary and human use

Meeting on 28 November 2016

10.00 – 18.00

Address: Berlaymont, 200 Rue de la Loi, 1040 Brussels,
Room Walter Hallstein,
1040 Brussels

AGENDA

- 1. Adoption of draft agenda**
- 2. Adoption of draft minutes of the meeting on 7 June 2016**
- 3. Notice to Applicants discussion (human part)**
 - 3.1. Volume 2B Electronic Application Forms for initial MA, variations and renewals (specific proposals for amendments)
 - 3.2. Volume 2A (human) – Chapter 1 - Marketing authorisation
 - 3.3. Volume 2A (human) - Chapter 2 – Mutual Recognition
 - 3.4. Volume 2A (human) – Chapter 3 – Union Referral Procedures
- 4. Common European Single Submission Portal (CESSP)**
 - 4.1. Presentation of CESSP and implications for the Electronic Application Form
 - 4.2. Discussion on NTA group's involvement
- 5. Notice to Applicants discussion (veterinary part)**
 - 5.1. Update on Volume 6A (veterinary) – Chapters 1 to 3.
 - 5.2. Volume 6A (veterinary) – Chapter 6 (for discussion)
- 6. AOB**