EUROPEAN COMMISSION
HEALTH AND CONSUMERS DIRECTORATE-GENERAL

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

Brussels, 29/11/2017

NTA H+V

Notice to Applicants

Medicinal products for human and veterinary use

Meeting on 29 November 2017
10.00 – 18.00

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

AGENDA (Version 02)

1. Adoption of draft agenda
2. Adoption of draft minutes of the meeting on 7 June 2017
3. Questions and Answers related to the UK's withdrawal from the EU
4. Volume 2A (human) - Chapter 1 - Marketing authorisation
5. Volume 2B (human) - Electronic Application Forms
6. Volume 2A (human) - Chapter 3 – Union Referral Procedures
7. Volume 2A (human) - Chapter 2 – Mutual Recognition
8. Volume 2C (human) - Guidelines on the excipients in the labelling and package leaflet
9. Volume 2C (human) - Guidelines on the categorisation of new applications versus variations applications
10. Volume 6A (veterinary) - Chapter 1 - Marketing authorisation and Chapter 3 – Union Referral Procedures
11. Volume 6B (veterinary) - Electronic Application Forms
12. Volume 6A (veterinary) - Chapter 2 – Mutual Recognition
13. Volume 6C (veterinary) - Guideline on the packaging information of veterinary medicinal products authorised by the Community
14. Volume 8 (veterinary) - Maximum residue limits guidelines (MRLs)
15. AOB