



**EUROPEAN COMMISSION**  
HEALTH AND CONSUMERS DIRECTORATE-GENERAL

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

Brussels, 02/06/2017

**NTA H**

## **Notice to Applicants**

### **Medicinal products for human use**

**Meeting on 7 June 2017**

10.00 – 18.00

Address: Conference Centre "Albert Borschette", Room AB-3C, Rue Froissart 36, 1040  
Brussels

#### **AGENDA (Version 02)**

1. Adoption of draft agenda
2. Adoption of draft minutes of the meeting on 28 November 2017
3. Volume 2A (human) – Chapter 1 - Marketing authorisation
4. Volume 2B Electronic Application Forms for initial MA, variations and renewals (specific proposals for amendments)
5. Volume 2A (human) – Chapter 3 – Union Referral Procedures
6. Volume 2A (human) - Chapter 2 – Mutual Recognition
7. Volume 2C (human) - Guidelines on the excipients in the labelling and package leaflet
8. Volume 2C (human) - Guidelines on the categorisation of new applications versus variations applications
9. Specific questions and answers related to UK's withdrawal from the Union
10. AOB
  - 10.1. Regulatory data protection for studies included in applications for fixed combinations