



EUROPEAN COMMISSION
HEALTH AND CONSUMERS DIRECTORATE-GENERAL

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

Brussels, 21/11/2018

NTA H

Notice to Applicants

Medicinal products for human use

Meeting on 29 November 2018

AGENDA (Version 02)

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

Meeting of the drafting subgroup on Chapter 2

9:45 - 10:30, Meeting room AB-0.20

(Only participation of the previously appointed subgroup members is required.)

NTA Group Plenary meeting

10:30 – 18:00, Meeting room AB-4D

1. Adoption of agenda of the meeting
2. Adoption of minutes of the last meeting on 5 June 2018
3. Volume 2A (human) - Chapter 1 - Marketing authorisation
4. Volume 2C (human) - Guidelines on the categorisation of new applications versus variations applications
5. Volume 2C (human) - Guidelines on the excipients in the labelling and package leaflet
6. Allergens from source materials in the Product Information
7. Volume 2A (human) - Chapter 2 – Mutual Recognition
8. Volume 2B (human) - Electronic Application Forms
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

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