EUROPEAN COMMISSION
HEALTH AND CONSUMERS DIRECTORATE-GENERAL

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

Brussels, 26/11/2018
NTA H+V

Notice to Applicants

Medicinal products for human and veterinary use

Meeting on 05 June 2018

Minutes

The meeting covered parts of the NTA concerning medicinal products for human use and also veterinary medicinal products.

1. **Adoption of draft agenda**
   The Agenda for the meeting was adopted as proposed.

2. **Adoption of draft minutes of the meeting on 29 November 2017**
   The minutes of the last meeting of the NTA group were adopted.

3. **Volume 6A (veterinary) - Chapter 1 - Marketing Authorisation and Chapter 3 - Union Referral Procedures**
   Following the discussion during the November 2017 NTA meeting further proposed changes to Chapter 1 and Chapter 3 were discussed at this meeting. New versions of Chapter 1 and Chapter 3 will be circulated after the meeting for written comments.

4. **Volume 2C (veterinary) - Guideline on the packaging information of veterinary medicinal products authorised by the Community**
   It was agreed to remove from the Guideline the information that is already available either on the website of EMA or CMDv. The information that will be kept in the Guideline will be updated. CMDv and the QRD group will be informed about the development.

5. **Volume 2A (human) – Chapter 1 – Marketing authorisation**
   The proposed revisions of Chapter 1 were discussed, including the issues of conditions or restrictions regarding the supply and use in the assessment of applications for centrally authorised products; products authorised under Article 10(1) and subsequently amended to include a new indication, strength, pharmaceutical form or route of administration; one year period of protection for new indications of well-established substances; variations and extensions; transfer of marketing authorisation of a reference medicinal product after the bioequivalence study of a future generic application was completed.

The proposed revisions of Chapter 1 were partly agreed at the meeting and partly postponed for further discussion at a future meeting.

6. **Volume 2A (human) – Chapter 2 – Mutual Recognition**

As previously agreed by the NTA group, the parts of the text that concern general principles of mutual recognition and decentralised procedures will be maintained within the Notice to Applicants. The parts of the text concerning rather more technical or operational issues should be moved to the existing or new CMDh guidance documents and updated within that framework. A small drafting group composed of NTA members was set up and met in the margins of the NTA plenary meeting. During the NTA plenary the drafting reported on the progress made and the next steps. The text of Chapter 2 was divided into several "work packages". Specific drafting suggestions will be prepared and progress will be presented at the next NTA meeting.

7. **Volume 2C (human) – Guidelines on the categorisation of new applications versus variations applications**

A report on progress made by the CMDh Working Party on Variations Regulation was presented at the meeting, including the latest draft of the revised Guidelines. The work should continue, with the input from the CMDh Working Party on Variations Regulation and the QRD group and a consolidated version should be presented at the next NTA meeting.

8. **Volume 2C (human) – Guidelines on the excipients in the labelling and package leaflet**

The NTA group was informed about the latest development. The revised version of the main text of the Guidelines, as previously agreed by the NTA group, was published on the Commission website in March 2018. In order to facilitate updates of the technical Annex, the link to the Annex appears on the Commission NTA website but the text of the Annex appears on the website of the EMA. The Commission and the NTA group are being regularly consulted and they must agree on any update of the Annex before it is published.

9. **Information on the update of Questions and Answers related to UK's withdrawal from the Union**

The NTA group was informed about preparations of an upcoming update of the Questions and Answers documents.

10. **Information on the Commission Study on the experience acquired as a result of the operation of centralised and decentralised marketing authorisation procedures.**

The NTA group was informed about this ongoing study that was launched at the end of May 2018 and should be completed within 12 months.

11. **AOB**

11.1. Scope of the centralised procedure – Homeopathic MP and recombinant DNA technology

The issue of the scope of the centralised procedure with regard to homeopathic products was discussed and should be further followed up in the future.

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