EUROPEAN COMMISSION
HEALTH AND CONSUMERS DIRECTORATE-GENERAL

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

Brussels, 05/06/2018
NTA H+V

Notice to Applicants

Medicinal products for human use

Meeting on 29 November 2017

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 7 June 2017**
   The minutes of the last meeting of the NTA group were adopted.

3. **Questions and Answers related to the UK's withdrawal from the EU**
   The NTA group was informed about a planned update of the Q&As related to the UK's withdrawal from the EU. The content of this update was discussed and explained in detail.

4. **Volume 2A (human) – Chapter 1 - Marketing authorisation**
   The proposed revisions of Chapter 1 were discussed, including the issues of naming of generics of centrally authorised products; generic applications of reference medicinal products granted under exceptional circumstances; data exclusivity according to Article 10(1) of Directive 2001/83 and market exclusivity according to Article 8 of Regulation (EC) No 141/2000; reliance on pre-clinical and clinical data contained in the dossier of a mono-component product in a subsequent application for a fixed dose combination

   The proposed revisions of Chapter 1 were partly agreed at the meeting and partly will be circulated after the meeting for written approval.

5. **Volume 2B Electronic Application Forms for initial MA, variations and renewals (specific proposals for amendments)**
   Specific proposals for amendments to the electronic application forms for the initial marketing authorisation, variations and renewals were presented and discussed.

   The proposed amendments of the application forms were agreed. All three forms will be submitted for the preparation of the next release of the electronic application forms

(eAFs). Once the new release of the eAFs becomes available later this year the agreed versions of application forms in pdf format will be published on the NTA website for information purposes only.

6. **Volume 2A (human) – Chapter 3 – Union Referral Procedures**
   The proposed revisions of Chapter 3 were circulated before the November NTA meeting. No comments have been received in writing before the meeting. The NTA group members were invited to provide written comments by 6 January 2017. If no comments are received by this deadline the document will be deemed agreed and prepared for publication.

7. **Volume 2A (human) - Chapter 2 – Mutual Recognition**
   It was previously agreed by the NTA group that 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. This approach was agreed also by the CMDh. NTA group members were invited to express their interest to participate in a small drafting group that should (1) start identifying parts of the text to be moved to the CMDh guidance and (2) start working on proposals for updates of Chapter 2. Expression of interest should be submitted by email after the meeting.

8. **Volume 2C (human) - Guidelines on the excipients in the labelling and package leaflet**
   Following the targeted stakeholders consultation on the draft revised guideline the NTA group requested a small expert group to assess the stakeholders' contributions received. On the basis of this assessment a revised version of the guideline has been prepared and submitted for the NTA group agreement. The revised version was agreed.

9. **Volume 2C (human) - Guidelines on the categorisation of new applications versus variations applications**
   The NTA group previously agreed that work should be started on updating this Guideline the CMDh Working Party on Variations Regulation. A report on progress made by the CMDh Working Party on Variations Regulation was presented at the meeting. On the basis of the report the NTA group agreed that the Working Party on Variations Regulation should continue the discussions on a proposal for the updated version of the guideline and should present its proposals at the next NTA group meeting.

10. **Volume 6A (veterinary) - Chapter 1 - Marketing authorisation and Chapter 3 – Union Referral Procedures**
    In Chapter 1 the proposed changes, mainly on "hybrid" veterinary medicinal product were agreed on. For Chapter 3, the proposed new wording was discussed and it was agreed that the Commission will first submit it for comments to CMDv before concluding the discussion in the NTA group.

11. **Volume 6B (veterinary) - Electronic Application Forms**
    The update of the eAF was discussed and agreed on.

12. **Volume 6A (veterinary) - Chapter 2 – Mutual Recognition**

It was agreed that Chapter 2 will be deleted from the Notice to Applicants. Therefore a dedicated chapter on the Mutual Recognition and Decentralised Procedure is no longer included in the NTA. The CMDv provides relevant information and guidance for companies and individuals regarding the Mutual Recognition and Decentralised Procedures. General Information on Mutual Recognition and Decentralised Procedure relating to former Chapter 2 of the Notice to Applicants as well as details of the procedures can be found on the CMDv website: http://www.hma.eu/156.html

13. **Volume 6C (veterinary) - Guideline on the packaging information of veterinary medicinal products authorised by the Community**
    The Commission proposed to delete the guideline from the NTA Volume 6C as most of the information are to be found on the EMA and CMDv websites. However, no final decision was taken since more detailed discussion is still needed.

14. **Volume 8 (veterinary) - Maximum residue limits guidelines (MRLs)**
    The Commission proposed to delete the NtA Volume 8, with the effect from the date when the third implementing act (Commission Regulation (EU) on the methodological principles for the risk assessment and risk management recommendations referred to in the Regulation (EC) No 470/2009) is published in the Official Journal of the European Union (OJ). This was agreed.

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