EUROPEAN COMMISSION
HEALTH AND CONSUMERS DIRECTORATE-GENERAL

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

Brussels, 21/11/2017
NTA H

Notice to Applicants

Medicinal products for human use

Meeting on 7 June 2017

Minutes

The meeting covered only the part of the NTA concerning medicinal products for human use. Issues concerning only veterinary medicinal products were not discussed at meeting.

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

2. **Adoption of draft minutes of the meeting on 28 November 2016**
   The minutes of the last meeting of the NTA group were adopted.

3. **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; Article 10(3) hybrid applications; global development of biosimilars; Article 10a applications for fixed combinations for substitution indications.

   A revised version of Chapter 1 agreed at the meeting will be submitted after the meeting to the Commission Legal Service and once approved, it will be prepared for publication.

4. **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.

   Concerning the application forms for variations and renewals the proposed changes were agreed in principle, subject to few minor or editorial changes to be finalised after the meeting. Revised versions of these two applications forms will be circulated after the meeting for the final written approval.

   Concerning the application form for initial marketing authorisations a revised version will be prepared taking into account comments made at the meeting and will be further discussed at the next NTA meeting.

5. **Volume 2A (human) – Chapter 3 – Union Referral Procedures**
   The proposed revisions of Chapter 3 were discussed at the meeting. A new revised version will be prepared taking into account comments made at the meeting and will be submitted for approval at the next NTA meeting.

6. **Volume 2A (human) - Chapter 2 – Mutual Recognition**
   With regard to the revision of Chapter 2 it was agreed by the NTA 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. After the meeting agreement to this approach will be sought also form the CMDh. If the approach is agreed by the CMDh a small drafting group should be established from the NTA group members that would (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.

7. **Volume 2C (human) - Guidelines on the excipients in the labelling and package leaflet**
   The NTA group was informed that on 27 February 2017 the Commission launched a targeted stakeholder consultation on the draft revised Guidelines on the excipients in the labelling and package leaflet. The document has been published on the Commission website and the consultation closed on 22 May 2017. At the meeting it was agreed that a small expert group will be established with the assistance of EMA to analyse the stakeholders' contributions and to prepare revised version of the Guideline for the next NTA group meeting.

8. **Volume 2C (human) - Guidelines on the categorisation of new applications versus variations applications**
   The NTA group agreed that work should be started on updating this Guideline. A draft will be submitted to the CMDh Working Party on Variations Regulation that would attempt to present a proposal for the updated version for the next NTA group meeting.

9. **Specific questions and answers related to UK's withdrawal from the Union**
   The Commission informed the NTA group about the document "Questions and Answers related to the United Kingdom's withdrawal from the European Union with regard to the medicinal products for human and veterinary use within the framework of the Centralised Procedure" that was published on the Commission and EMA website on 31 May 2017. On the same day CMDh published on its website a similar document concerning nationally authorised medicinal products.

10. **Any Other Business**

    10.1. Regulatory data protection for studies included in applications for fixed combinations

    At the request of a NTA group member the issue of regulatory data protection for studies included in a dossier of an authorised product which are subsequently used in another application for fixed dose combinations was discussed.

* * *