EUROPEAN COMMISSION
HEALTH AND CONSUMERS DIRECTORATE-GENERAL

Health systems and products
Medicines: policy, authorisation and monitoring

NTA H+V

Notice to Applicants

Medicinal products for veterinary and human use

Meeting on 9 November 2015

Minutes

1. Adoption of Agenda

The Agenda for the meeting was adopted as proposed. Two additional points were introduced under any other business: applications in accordance with Article 10b of Directive 2001/83/EC for substitution indications and a potential electronic application form for homeopathic medicinal products.

2. Notice to Applicants discussion

2.1. Volume 6A (Veterinary sector)

The substantial review of Chapter 1 and Chapter 3 were discussed in order to update the text of these Chapters and also to reflect relevant changes made recently in Volume 2A (Human sector). It was agreed that the members will provide their written comments on these Chapters by 8 January 2016.

2.2. Volume 2B (Human sector) – Module 1.2 Homeopathic Application Form

A proposal for the revised version of the Homeopathic Application Form was presented and discussed. The purpose of this new version is to consolidate changes made recently in the general Application Form, the homeopathic Application Form published on the HMA website in 2014 and to accommodate various comments received from the NTA members. The proposed revision was agreed in principle, but specific drafting will be agreed after the meeting.

2.3. Volume 2C (Human sector) - Guideline on the Excipients in the Label and Package Leaflet of Medicinal Products for Human Use

A proposal for the revised version of the "core" text of the Guideline was presented and discussed. Once the revised version is agreed by the NTA group it will be submitted for public consultation. The proposed revisions were agreed in principle, but specific drafting will be agreed after the meeting.

2.4. Volume 2A (Human sector) – Chapter 1 Marketing authorisation

Following the major review of Chapter 1 in July 2015, it was discussed what further revisions in Chapter 1 may be required. The review of the following sections was discussed in particular: 2.4.4 Suspension of marketing authorisation, 3.3 Procedure for homeopathic medicinal products, 5.3.1.1 Reference medicinal product, 5.3.1.3 Reference medicinal product not harmonised in the EU, 5.4 Applications according to Article 10a of Directive 2001/83/EC, 6.1.3 Data exclusivity and market protection for applications submitted before the implementation of the amended legislation. Where agreement was reached on specific wording this will be included in the next review of Chapter 1. On issues where no agreement has been reached yet, these will be discussed further at the following NTA meetings.

2.5. Volume 2A (Human sector) – Chapter 3 Union Referral Procedures
The review of the notification forms for referral procedures (Annex of Chapter 3) was discussed. The proposed revisions were agreed in principle, but specific drafting will be agreed after the meeting. In addition, the potential review of the core text of Chapter 3 was also discussed in particular with regard to the scope of the referral procedures. This issue may be followed up at one of the future NTA meetings.

2.6. Work plan of the NTA working group – topics for next meetings
The working group members were invited to send their proposals for topics for the future NTA meetings to the Commission after this meeting.

3. AOB

3.1. The issue of applications in accordance with Article 10b of Directive 2001/83/EC for substitution indications was discussed. This may be followed up at one of the future NTA meetings.

3.2. The issue of a potential electronic application form for homeopathic medicinal products was discussed. It was clarified that even after the introduction of the mandatory use of the general electronic application form, for homeopathic medicinal products the paper form will still remain available.

* * *