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 7 June 2016

Minutes

1. Adoption of Agenda

The Agenda for the meeting was adopted as proposed with the exception of the point concerning Volume 2A (human) – Chapter 2 – Mutual Recognition that was removed from the agenda.

2. Minutes of meeting on 9 November 2015

The minutes of the last meeting of the NTA group were adopted.

3. Notice to Applicants discussion

3.1. Volume 6A (veterinary) - Chapter 1

It was agreed in principle to proceed with the review of Chapter 1. It will be finalised after the meeting.

3.2. Volume 6A (veterinary) - Chapter 2

It was agreed that this Chapter should be removed from the NTA website provided that the information is included on the CMDv website. This will be verified after the meeting.

3.3. Volume 6A (veterinary) - Chapter 3

It was agreed in principle to proceed with the review of Chapter 3. It will be finalised after the meeting.

3.4. Volume 6A (veterinary) - Chapter 4

Following the previous agreement the group was informed that this Chapter was removed from the NTA website.

3.5. Volume 6C (veterinary) - Guideline on the packaging information of veterinary medicinal products

An NTA subgroup agreed to check if all the elements in the NTA were included in the QRD. If so, deletion of the section was agreed in principle. The subgroup agreed to discuss this after the next QRD meeting.

3.6. Volume 6C (veterinary) - Proposals for a Guideline on the change in classification for the supply of veterinary medicinal products
As there is currently no harmonisation of classification in Member States, it was agreed to leave this section apply just for centrally authorised products with a Q&A on EMA website.

3.7. Volume 2B (human) - Module 1.2 Homeopathic Application form
The revised version of the Homeopathic Application form was agreed in principle subject to minor editorial changes to be finalised in writing after the meeting.

3.8. Volume 3 (human) - Guideline on the Excipients in the Label and Package Leaflet of Medicinal Products for Human Use
The revised version of the Guideline was agreed. It will be now submitted by the Commission services for public consultation before the final adoption.

3.9. Volume 2A (human) – Chapter 1 - Marketing authorisation
The revised version of Chapter 1 was agreed in principle subject to editorial changes to be finalised in writing after the meeting.

3.10. Volume 2A (human) – Chapter 3 - Union Referral Procedures
The revised version of the Annex to Chapter 3 (notification forms) was agreed. It will be submitted for the final review by the Commission services before publishing on the NTA website.

4. AOB

4.1. Mailing list
It was agreed that after the meeting each Member State will provide two contact email addresses that can be used as a back-up mailing list in case of technical difficulties with the Eudra mail system.

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