EUROPEAN COMMISSION
HEALTH AND CONSUMERS DIRECTORATE-GENERAL

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

Brussels,
SANCO/D/5/BM/ddg1

NTA H+V

Notice to Applicants

Medicinal products for veterinary human use

Meeting on 14 November 2014

Minutes

1. Adoption of draft agenda

One point was added regarding interpretation in connection with informed consent legal basis at the request of one Member State.

2. Notice to Applicants discussion

2.1. Volume 2A – Chapter 1 Marketing authorisation

The review of the following sections was discussed: 2.3 Notion of 'global marketing authorisation', 5.4 applications according to Article 10a of Directive 2001/83/EC, 5.5 application according to Article 10b of Directive 2001/83/EC, 6.3 one year of protection for new indications of well-established substances and Annex I definition of new active substance.

The Commission services will present to the group a new drafting of Chapter 1 in view of the discussion in view of internal consultation.

2.2. Volume 2B – Module 1.2 Application form

The review of the application form, in order to take into account the changes in the application form was discussed.

The Commission services will present to the group a new drafting of Chapter 1 in view of the discussion in view of internal consultation.

2.3. Volume 2B - Module 1.2 Homeopathic Application form

Commission services explained that two different versions of the document exist on the NTA website and the HMA. The NTA version, available on NTA website

should be the “official” one. Commission services will propose a new version to NTA members in order to take into account the changes introduced in the HMA version, when relevant.

2.4. Volume 3 - Guideline on the Excipients in the Label and Package Leaflet of Medicinal Products for Human Use
The CHMP is in the process of finalising the assessment for some of existing entries and new entries. The guideline will then need to be updated in order to take into account these new assessments. It was highlighted that one of the crucial point to be discussed for each entry by the NTA is the time for implementation.

2.5. Future of Volume 2A – Chapter 4 Centralised procedure
The NTA agreed to delete this chapter, point of interests will be transferred to chapter 1.

2.6. Volume 6 State of play regarding NTA for veterinary sector

The group agreed that the webpage for the NTA Volume 6 (Notice to applicants and regulatory guidelines for medicinal products for veterinary use) could be updated to modify and delete obsolete links (General information regarding veterinary medicinal products authorised centralised and nationally contained in Volume 6A, Chapter 7 and Volume 6C – Regulatory guidelines).

Action post meeting: this was done as well as some format changes to improve readability (November 2014)

The group also agreed that the vet NTA need some updating. In particular, the following texts merit discussion with views to preparing a revised text: Vol 6A Chapter, Vol 6A Chapter 3, Vol 6 C Guideline on the packaging information of veterinary medicinal products authorised by the Community ("blue box").
It was also agreed that Vol 6A Chapter 6 requires further discussion at a next meeting as to whether or not it may be updated or an be deleted.
It was agreed that Vol 6A Chapter 2 could be deleted

It was agreed that the latest version of Vol 6B presentation and contents of the dossier could be circulated to the group.

3. AOB

Some legal issues regarding informed consent application were discussed, in particular the possibility to have it as reference medicinal product. Further discussion will occur in the context of the review of chapter 1.