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 human use

Meeting on 12 May 2014

Minutes

1. Adoption of draft agenda
The agenda was adopted.

2. General information
The group was informed that as from now on the agenda and minutes will be published on the DG SANCO website.

3. Notice to Applicants discussion

3.1. 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 for the next meeting in November 2014.

3.2. Volume 2A- Chapter 3 Union Referral Procedure

The review of chapter 3 of volume 2A was endorsed by the group.
(post-meeting note, the document was published on 26 May 2014).

3.3. Future of Volume 2A – Chapter 4 Centralised procedure

The possibility to withdraw chapter 4 and transfer some parts of it into chapter 1 was discussed. It was agreed that further reflection on this point was necessary.

3.4. Volume 2B and 6B: application forms renewal and variations: latest changes to be published in paper and on-line

The review of the applications forms for renewal and variations of human and veterinary marketing authorisations was agreed. The publication of the paper and electronic versions will be done simultaneously on 10 June on the Commission services website and the EMA gateway for e-submission.
(post-meeting note, the document was published on 10 June 2014).

4. AOB

No further point was added.