



Brussels, 7 June 2017

NTA H+V

## Notice to Applicants

### Medicinal products for veterinary and human use

Meeting on 28 November 2016

### Minutes

#### 1. Adoption of draft agenda

The Agenda for the meeting was adopted as proposed.

#### 2. Adoption of draft minutes of the meeting on 7 June 2016

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

#### 3. Notice to Applicants discussion (human part)

##### 3.1. 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. For the initial marketing authorisation it was agreed that after the meeting the Member States will provide written comments on the explanatory background document. Once agreement is reached in principle on the points to be amended in the application form a revised version of the application form itself will be circulated to the NTA working group for further discussion and agreement. For the variations and renewal application forms, a revised version of the applications forms with the proposed amendments will be circulated after the meeting directly, without the need to provide comments on the explanatory background document first.

##### 3.2. 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; Article 10(3) hybrid applications and Article 10a applications for fixed combinations for substitution indications. A revised version of Chapter 1 reflecting the discussion will be submitted to the NTA working group after the meeting for further discussion and agreement.

##### 3.3. Volume 2A (human) - Chapter 2 – Mutual Recognition

The potential future revision and update of Chapter 2 was discussed. Two options were discussed: to review the whole Chapter 2 or to move the text concerning general principles of MR/DC procedures to Chapter 1 and for the more specific guidance on MR/DC procedures to refer to the specific guidance available on the CMDh website. The NTA working group was open to consider both options and the issue will be further discussed at the next meeting.

#### **3.4. Volume 2A (human) – Chapter 3 – Union Referral Procedures**

The proposed revisions of Chapter 3 were discussed at the meeting. The outstanding issues should be finalised after the meeting.

### **4. Common European Single Submission Portal (CESSP)**

#### **4.1. Presentation of CESSP and implications for the Electronic Application Form.**

The NTA working group was informed by the CESSP project representative about the state of play of the project.

#### **4.2. Discussion on NTA group's involvement**

Efficient collaboration between the CESSP project, the NTA working group and the CMDh/v during the development phase of CESSP is needed as a number of changes in the electronic application forms will possibly need to be implemented. It is important that an efficient process for review and approval of those changes is in place. It was discussed in particular how to manage technical changes, content-based changes and "border-line" changes of the electronic application form in the future. The respective procedures of each type of changes were agreed.

### **5. Notice to Applicants discussion (veterinary part)**

#### **5.1. Update on Volume 6A (veterinary) – Chapters 1 and 3**

The revised versions of Chapters 1 and 3 were discussed and agreed. They will be submitted for the final review by the Commission Legal Service before publishing on the NTA website.

#### **5.2. Volume 6A (veterinary) – Chapter 6**

The discussion on possible revisions of Chapter 6 will continue at one of the future meetings.

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