

MINUTES

CMDh meeting with representatives of Interested Parties

20 June 2011

16.30-18.00, EMA, Room 4A

Chairperson: Mrs. Truus Janse-de Hoog

| | Title | Resp. Action |
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| 1. | Agenda of the meeting | |
| | Agenda Version 1 | |
| | The agenda of the meeting was adopted with an additional item proposed by AESGP under A.O.B. | |
| 2. | Improvement of DCP | |
| | <p>SE introduced the topic and the idea to have a small group between CMDh/HMA and the Task Force on resources with involvement of trade associations to discuss the improvement of the DCP. The group should stay small in order to have a better follow-up of actions.</p> <p>The trade associations welcomed the idea and the invitation to participate.</p> <p>More information will be provided at a later stage.</p> <p>EGA presented the outcome of a survey on the DCP among members. A similar survey has been conducted last year and it has been repeated after the revision of the SOP on DCP. The survey focused on validation, restart of the clock-stop and the national phase. Suggestions for improvements were made in all three areas.</p> <p>DK noted that for the validation the timelines are very tight and sometimes cannot be kept if discussions with the applicant take place. A quick response by the applicant would help in some cases to reduce the validation time.</p> <p>SE noted that with regard to e-validation, discussions are ongoing and it is the intention that in the future the RMS will perform the technical validation in MRP/DCP.</p> <p>Interested Parties were reminded to forward to the CMDh any national requirements that they encounter and that are not listed on the CMDh website. The group was informed that Chapter 7 of the NtA Volume 2A will be taken over by the CMDh from the EC in the future.</p> <p>With regard to the restart of the clock, UK stated that sometimes the clock is not restarted because further discussion with the applicant takes place in order to resolve remaining issues. Once the clock is restarted there would be no room for further discussion.</p> | |

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| | AESGP also commented on the long clock-stops, the role of the RMS and new national requirements. | |
| 3. | Slot booking and cancellation | |
| | <p>FR summarised the CMDh position. Currently up to 50% of booked slots are cancelled, which creates problems from NCAs in planning their resources. Possible options for improvement were presented.</p> <p>EGA presented a policy agreed by their members including a commitment to inform NCAs in advance of their plans (announcement of cancellations 3 months in advance). EGA supported the idea of slot booking fees and presented other proposals for improvement.</p> <p>FR noted that the main reason for cancellations are that the dossier is not ready, change in registration policy and double bookings. The avoidance of double bookings should be included in the EGA policy. EGA commented that a quicker feedback to applicants on the booked slot would be helpful.</p> <p>EFPIA appreciated the EGA policy and supported the idea to discourage double booking. EFPIA will discuss internally the possibility of booking fees.</p> <p>It was noted that it would be difficult to fix an appropriate level for booking fees.</p> <p>AESGP noted that cancellations are extremely rare in the self-care sector. Generally, pre-submission meetings with the RMS 6 month prior to submission are preferred for non-prescription medicines. This makes possible to gage interest from the potential RMS and to discuss regulatory strategy concerning legal status and time slot.</p> <p>It was proposed to discuss a common code of conduct between Interested Parties and NCAs at the next HMA task force on resources.</p> <p>EGA noted that not all companies are members of EGA and would therefore not have agreed on the policy.</p> | |
| 4. | National translations | |
| | <p>EGA presented feedback on questions regarding the quality of translations and presented proposals for improvement of the situation.</p> <p>It was noted that the proposals will be further discussed in the CMDh. The participants were informed that the CMDh plans to work on a guidance document on high quality translations.</p> | |

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| 5. | DDPS declaration form | |
| | <p>Updated declaration form & guidance document</p> <p>NL presented an update of the DDPS declaration form and the related guidance. In the future only one signature of the applicant on behalf of the future MAH is required.</p> <p>The intention of the declaration form is to facilitate the procedure and has to be considered as transitional measure before the new legal framework comes into place.</p> <p>It was clarified that a missing declaration form would not be a reason for invalidation.</p> <p>EGA noted that in some MSs the DDPS is approved independent of a procedure number.</p> <p>It was clarified that in this case the date and the version number should be given.</p> | |
| 6. | Press release & publication of presentations on website | |
| | <p>The meeting will be mentioned in the CMDh press release.</p> <p>All parties agreed that their presentations can be published on the CMDh website.</p> | |
| 7. | A.O.B. | |
| | <p>Purely national procedures for well-established herbal medicines / AESGP</p> <p>AESGP asked if the CMDh Q&A addressing purely national procedures for well-established herbal medicines could be re-published in virtue of the 1998 Commission Communication (98/C229/03) which foresees the possibility for well-established medicines to continue to use purely national procedures provided the SmPC has not been harmonised. Hence purely national applications should remain possible for well-established herbal medicines. Some AESGP members recently saw their application for a MA for a well-established medicine on basis of a bibliographic application turned down and were advised to start MRP/DCP.</p> <p>DE noted that the well-established use principle was introduced at a time when the old substances were not harmonised, but the situation has changed in the meantime.</p> <p>The Q&A has been removed as it was in contradiction with the NtA. No final conclusion in this regard has been reached yet.</p> | |

Participants:

Representatives from CMDh

Representatives from EGA

Representatives from EFPIA

Representatives from AESGP