

MINUTES

CMDh meeting with representatives of Interested Parties

14 November 2011
17.00-19.00, EMA, Room 4B
Chairperson: Peter Bachmann

	Title	Resp. action
1.	Agenda of the meeting	
	The agenda of the meeting was adopted.	
2.	E-submissions – technical validation	
	<p>AESGP gave a presentation on their comments on the revision of the document “Procedural Advice – Automatic validation in MR/Repeat-use/DC Procedures”.</p> <p>This was followed by a presentation from SE on the outcome of the public consultation of the above mentioned document.</p> <p>The revision will introduce a RMS-led technical validation as the main point. CMSs will rely on the technical validation done by the RMS. Applicants need to check CDs/DVDs for readability to identify burning problems. It was noted that in general, problems with technical validation seem to decline.</p> <p>The timelines for technical validation and the use of CTS are still subject to further discussion within the CMDh.</p> <p>It was stressed that the changed procedure should apply to eCTD and NeeS. There will also be further discussion on the submission date for technical validation with regard to data exclusivity.</p> <p>Applicants are encouraged to technically validate their submissions in advance with the appropriate and publicly available validation tools. A technical validation by the applicant on behalf of the RMS will not yet be an option.</p> <p>The intention is to extend the procedure to all submission types after successful implementation for new MAAs.</p> <p>EFPIA expressed their concerns regarding a prolongation of the validation time for technical validation by further 7 days. With regard to eCTD and NeeS, the intention should be to harmonise module 1 without national requirements.</p> <p>The Chair noted that the reduction of national requirements is an ongoing process. Despite a lot has been achieved already, the CMDh is working on a further reduction of national requirements.</p> <p>The group was informed that further discussion on the document in the CMDh is needed. A final document might be ready early 2012.</p>	

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3.	Implementation of the outcome of paediatric worksharing	
	<p>The Chair stated that there are currently problems with the implementation of safety issues as a consequence of the outcome of paediatric worksharing in existing MA.</p> <p>AT gave a presentation on their national experience with the implementation. Only 24% of MAHs have submitted a variation to implement the outcome without additional request letter from the NCA. 88% of MAHs submitted a variation after being reminded. The remaining 3 MAHs were either insolvent or the product was about to be withdrawn.</p> <p>MAHs are reminded to follow the BPG and immediately submit variations following publication of PARs to implement the proposed changes to the product information, especially in the case of safety related issues.</p>	
4.	HMA Task Force meeting with Stakeholders on DCP/MRP improvements	
	<p>SE reported that, as announced in the last meeting with Interested Parties, the new initiative has been launched. A small group of CMDh members and industry representatives has been created to discuss specific steps for the further improvement of the MRP/DCP. The initiative is in line with the HMA strategy paper and the goals of the WP on the future of CMDh. There was broad agreement from the industry that the priorities were: 1/ national phase, 2/ clock stop and 3/ validation. From the CMDh point of view, cancellation of slots is a priority as well.</p> <p>The group is currently assessing priorities for improvement. The next meeting is intended to take place early 2012 (probably February) to tie in with the HMA meeting.</p>	
5.	Chapter 7 transfer from EC to CMDh	
	<p>The EMA gave a presentation on the transfer of parts of Chapter 7 of the NtA to the CMDh website following a request from the EC.</p> <p>The CMDh is currently nominating Rapporteurs for each section. The Rapporteur will then look into the information and update it accordingly for publication on the CMDh website. For some sections the information might already be available on the CMDh website.</p> <p>IP were asked to comment on the initiative before June 2012 which would be the target date for the inclusion of the procedural guidance on the CMDh website.</p>	IP

	Title	Resp. action
6.	ASMF	
	Update on the project and further activities	
	Questions on closed and open parts	
	<p>Currently work is ongoing on the development of an EU ASMF numbering system and on a revision of the ASMF guideline and the annexes. Further practical guidance will be developed on “Issuing of the ASMF number” and “How to use the ASMF-AR”.</p> <p>APIC welcomed the initiative and the approach to work together. APIC will provide comments on the Annexes of the ASMF guideline once they are published for public consultation.</p> <p>Following a comment from EGA, AT clarified that EDQM is involved in the project and that there will be a vice versa access to the ASMF AR repository and the CEP AR database. This is planned for mid 2012.</p> <p>EGA was in favour of having a fast procedure. The procedure should also allow submission of changes during the assessment, if possible.</p> <p>It was noted that the comments will be taken into account when drafting the procedure. However, in order for the procedure to work in practice, not too much flexibility can be allowed at the start.</p> <p>EFPIA also supported the initiative and put forward some questions.</p> <p>The following feedback was given:</p> <ul style="list-style-type: none"> • An ASMF repository is kept in mind for the future. For the time being it will be an ASMF AR repository. • Within the current legal framework a totally independent assessment has not yet been discussed. The assessment will have to be linked to a MA application and the assessment will be product specific. A change in legislation is currently not within the scope of the WG. • National procedures are included in principle, however, not in the first step as some issues need to be solved first, e.g. languages. • Biologicals are out of the scope of the project as legally no ASMF is possible. • A step by step approach has to be taken. Details will be discussed later. 	
7.	Press release & publication of presentations on website	
	The participants agreed to a publication of the presentations on the CMDh website. The meeting will be mentioned in the CMDh press release.	
8.	A.O.B.	
	N/A	

Participants:

Representatives from CMDh

Representatives from EGA

Representatives from EFPIA

Representatives from AESGP

Representatives from APIC