

MINUTES

CMD(h) meeting with representatives of Interested Parties

16 November 2009
17.00-19.00, EMEA, Room 2A
Chairperson: Mrs. Truus Janse-de Hoog

	Title	Resp. Action
1.	Agenda of the meeting	
	<p>Agenda rev.0</p> <p>The agenda has been adopted with the addition of a topic on paediatrics issues under the section A.O.B.</p>	
2.	Member States' resources in the Mutual Recognition and Decentralised Procedures/CMD(h) contribution to Task force on resources (SE)	
	<p>The CMDh reported from the CMDh contribution to the Task force on resources:</p> <p>The number of finalised DCP has multiplied by more than five between 2007 and 2009. In order to face increasing workload, measures were taken to evaluate the future workload, identify areas for improvement and propose new approaches to make a better use of available resources.</p> <p>A questionnaire was circulated to NCAs to gather information on resources, needs for training and assessment performed by CMSs.</p> <p>A list of expiry of data exclusivity for nationally and centrally authorised products has been established to evaluate the workload until 2011: no reduction of the number of DCP is expected until 2011.</p> <p>In addition, national requirements have been reduced (15 MSs without national requirements in September 2009 versus 6 MSs in 2007) and a common booking form for RMS has been developed and published which is used by 18 MSs.</p> <p>In order to reduce parallel assessment, a risk-based approach is promoted at both HMA and CMDh level and a feedback form has been developed to be used by CMSs to give feedback to the RMS on the AR. MSs will use this feedback form for a pilot period of 6 months starting on 1st November 2009.</p> <p>Clock-stops are closely monitored by the CMDh, proposals for improvement will follow.</p> <p>The HMA Task force on Training will identify training needs for assessors.</p>	

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<p>Discussions are ongoing regarding a central repository to store and share assessment reports between NCAs, however some MSs are facing legal hurdles due to national laws.</p> <p>The HMA Task Force on resources that was initially supposed to merge with the Strategic group will continue to operate separately and report to the HMA and in strategic matters give input to HMA strategic group.</p> <p>A common portal for applications is being discussed but legal and technical problems have to be analysed and solved.</p> <p>In conclusion, resources have to be saved where possible and have to be used more efficiently however, it will be essential to get more resources from HMA.</p> <p>EGA mainly commented on the slot-booking situation:</p> <p>Industry expressed mixed views on the slot-booking process.</p> <p>More transparency is needed on the capacity for each MS to act as RMS and on timeslots made available by cancellations that could be used by Industry. It should be noted that no short-notice (< 6 month notice) timeslots are available.</p> <p>Companies have difficulties to start RUP or MRP even if the strategy was previously agreed with RMS.</p> <p>Companies reported difficulties to obtain a timeslot in certain MSs and some of them ended with no slot even in MSs with a longer slot-booking system. More transparency would be appreciated regarding the rules that are applied by each MS for timeslots allocation.</p> <p>In order to improve the system, EGA proposed to establish reserve lists by therapeutic class with applications ready for submission for MSs to use in case of cancellations</p> <p>The feedback on the common booking form is positive however, it was noted that the information requested in the form is often not yet defined at the time the form should be submitted.</p> <p>EGA reported that generally, industry has seen no improvement regarding parallel assessment.</p> <p>EFPIA welcomed the actions taken for a better use of resources and expressed same views as EGA on timeslot booking. EFPIA supported the twinning concept for the training of new MSs. EFPIA proposed to take this one step further towards workshare supporting new RMSs with review resources from more experienced Member States as this would allow more countries to participate already now.</p>	

EFPIA indicated that while good progress was made on transparency of national requirements, also in publication on the CMDh website, the expectation of industry is that individual Member States now adapt legislations wherever possible to reduce the remaining differences that still hinder validation. EFPIA dwelled on the fact that the current MRP life cycle processes for marketing authorisation holders to expand marketing authorisations were extremely complex and resource intensive for industry and regulators. Simplification of these life cycle processes (such as harmonisation of MRP and national authorisations, repeat use, informed consent and handling of duplication authorisations) would free significant resources for innovations and new procedures. Several proposals were made where more flexibility would be required and where the new Variation Regulation would offer opportunities to pursue this further.

AESGP welcomed the progress on reduction of national requirements but reported mixed experiences with timeslots, depending on MSs.

AESGP raised the following points:

- Validations are handled according to different timetables and can take several months in case the legal basis is discussed. AESGP proposed that CMDh considers providing advices to MSs based on experience gained, to help agencies taking a common approach on legal basis.
- A more harmonised approach should be taken on clock-stops duration and management.
- The timelines to handle the national phase of procedures is too long and represents a big challenge for companies.

Regarding timeslots and transparency, the CMDh noted that to improve transparency, the criteria for timeslot allocation were published on some NCA's websites but legal limitations are encountered concerning the criteria for giving a slot. The CMDh explained that in some MSs there were more submitted applications than time and/or resources to allocate and that NCAs also try to distribute timeslots between companies. NL noticed that experiences of publication of cancellations on the website have proved to be successful and in addition a newsletter can be subscribed to via the website.

The CMDh acknowledged that there was still room for improvement on validation issues and it was suggested to bring the emerging issues to CMDh for discussion earlier in the process.

The CMDh stressed that more information is needed from industry to plan resources. It was also noted that a better cooperation/communication between applicants and RMSs was needed.

EFPIA was of the view that optimising life-cycle management would help saving resources.

The CMDh Chair proposed to meet within 6 months to continue the discussion on resources in MRP/DCP.

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3.	Electronic submissions (AT)	
	<p>EFPIA recommended the adoption of eCTD as the only electronic submission format in the MRP/DCP, the transition from NeeS to eCTD being decided by companies depending on lifecycle stage and complexities of each product. Industry's default position is that the supply of a baseline (at least Module 3) should not be required for existing applications but applicants should be allowed to make the decision on a case by case basis.</p> <p>EFPIA noted that it was complex to produce and maintain applications because of different national requirements and that industry needed a reliable source of information in English. More transparency was requested on the status on the e-submissions implementation.</p> <p>AESGP raised concerns about the costs involved, particularly for small and medium size companies that have no in-house structure to deal with e-submissions.</p> <p>EGA also noted that applicants need to know where to find information on which format is currently accepted in which MS and when MS not accepting e-submissions will be ready. Applicants also need an up-to-date overview of national requirements.</p> <p>EGA welcomed the proposal to handle translations out of e-CTD and questioned whether translations submitted with variations could also be out of e-CTD.</p> <p>EGA was of the view that although national requirements were reduced there were still many requirements with no clear added value from an e-CTD point of view. EGA noted that the creation of local portals is in contradiction with the objective to have one central portal and stressed the need for a clear roadmap for the next major updates of e-CTD and electronic application form implementation.</p> <p>The CMDh gave a presentation on the implementation status of e-submission in the MSs.</p> <p>The CMDh acknowledged that the implementation process was slower than expected and informed IPs that a roadmap was being prepared in collaboration with HMA to address MS accepting paperless applications, target dates for MS that are not ready, the need to have a review tool as of January 2010 and recommendation to use e-CTD as of January 2010 for MRP/DCP. A deadline for mandatory e-CTD submissions for human MRP/DCP, is currently under discussion.</p> <p>The published table on national requirements will be regularly updated; any discrepancies or additional requirements that may be identified by industry should be sent to the CMDh secretariat for internal check and update of the table when relevant.</p> <p>Several hurdles encountered by industry have been identified. A good collaboration has been established with industry and the Agency through various working group and proposals to simplify the process for e-CTD users were put forward to HMA for approval. The CMDh Best Practice Guide is being updated to reflect the agreed changes and comments received from industry; a new version will be published by the end of 2009/early 2010.</p> <p>The CMDh acknowledged that there was an increasing number of specific portals but indicated that all of them would be linked to the EU portal.</p>	

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	<p>EFPIA proposed to update the table of requirements more often to reflect quick and frequent changes.</p>	
4.	Variation Regulation Sub-group & Overview of developed and revised documents (NL/DE)	
	<p>The CMDh presented the activities of the EMEA/CMD subgroup on variation regulation and its activities in 2009. The following topics were addressed:</p> <ul style="list-style-type: none"> - the rules for the transition period, - the revised CMDh Best Practice Guide on variation was published but may have to be further amended following the publication of the final variation guidelines by the European Commission. - the application form and corresponding user guide are being revised - “one Marketing Authorisation” has been defined as “all strengths and pharmaceutical forms of a medicinal product” for grouping and worksharing purposes as MSs have different definitions. - the new numbering system; - the Q&A on variation published on the CMDh website will be updated. <p>The group will continue to meet in 2010 and will revise the documents based on experience gained.</p> <p>EFPIA welcomed the progress and wished that all MS choose to apply the same approach for national procedures. EFPIA informed the CMDh and other IP that a survey was being prepared to evaluate the number of variations and how often worksharing/grouping would be used.</p> <p>The CMDh Chair expressed the wish to work together on surveys and proposed to further discuss it.</p> <p>EGA highlighted that it was important for EGA members that timelines defined in the SOP are respected and supported EFPIA’s view that changes should be implemented at the same time for nationally authorised products. EGA raised the following points for consideration:</p> <ul style="list-style-type: none"> - Companies expressed concerns about rejection of type IA variations when products are on the market. EGA suggested that experienced MSs share their experience with others to avoid unnecessary withdrawals. - Further clarification is needed on the process for upgrading type IB to type II. Especially it should be clarified if companies have to withdraw the application and resubmit. - Applicants see no advantage in using WS because of the timelines applied. Shortening the timelines would make it more attractive. <p>EGA informed the CMDh that a survey was being prepared and that they would liaise with CMDh to prepare the questions.</p> <p>The CMDh Chair proposed to discuss concerns raised within the subgroup on variations.</p>	

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5.	SOP on Decentralised Procedure (FR/NL)	
	<p>The CMDh presented the proposals for revision and improvement of the SOP on DCP.</p> <p>Applicants are advised to follow the rules for allocating timeslot and to use the common request form and to use the template for the cover letter published on the CMDh website for submission of the dossier.</p> <p>Proposals have been made to raise validation issues such as questions on the legal basis at the next CMDh meeting, to simplify assessment step I, to improve clock-stop periods, to facilitate early discussion during step II assessment and to address the particular situation where the RMS has a negative opinion at the end of the procedure.</p> <p>In particular it is proposed to simplify the end of Step I by deleting the possibility to close at Day 120 and to have only 2 possibilities remaining: the procedure can be positively finalised at Day 105 or in the absence of consensus, the procedure will be stopped at Day 105. However, after the re-start of the procedure at Day 106, possibility to close the procedure at any time-point during Step II.</p> <p>For the applicant: maximum time allowed for submission of the response document. If it is not expected to receive the response document in due time, the applicant will be requested to withdraw the application.</p> <p>For the RMS: maximum time to provide a feedback about the draft response. This feedback will include a proposed date for the restart of the procedure, excepted in specific situations where the restart of the procedure will depend on the resolution of other issues.</p> <p>Following the opinion received from the EU Commission: At the end of the procedure, if the RMS concludes that the product is not approvable: the RMS includes information in the FAR on the outstanding issues and closes the procedure. No referral to CMDh will follow even if other CMSs are not in agreement with the RMS.</p> <p>EGA presented the 3 major issues identified and made proposals for improvement:</p> <p>Validation can take up to 3 months and RMSs allow questions from CMSs received after day 14. RMSs are requested to keep to the defined 14 days validation period.</p> <p>Restarting the procedure after the clock-stop is a problem as RMSs want to assess the draft responses which could take a month or more. In order to simplify the process, EGA proposed that applicants submit their responses within 90 days in parallel to all MSs and to apply a revised a timetable for step II assessment. EGA also proposed to exclude the break out session as none has been organised so far.</p> <p>Regarding the national phase, EGA reported that despite applicants having submitted translations within the defined timeline, significant delays (up to 12 months) were experienced in some countries and that national contacts were requested by some MSs. EGA asked MSs to keep to the 30 days for granting MA provided applicants have sent the translations within 5 days, and to accept EU contacts.</p>	

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<p>EFPIA highlighted that the major competitive advantage of the DCP is only achieved when the procedure can be early closed at day 120. EFPIA also noted that BoS have not proved to be very useful, and it was of the utmost importance that the CMDh take up their role as consensus finding body as early as possible in the procedure.</p> <p>EFPIA commented on the proposal outlined that a deadline to limit clock-stops could follow the same rules as for the centralised procedure. EFPIA emphasised the results of its survey presented in July to CMD(h) that showed that a significant obstacle of the DCP/MRP procedures is the national implementation times.</p> <p>AESGP confirmed that there was a lot of issues with clock-stop phases as various national issues were raised at this stage such as name or environmental risk assessment, slowing the process. AESGP asked to speed up the national phase.</p> <p>The CMDh Chair noted that it would not be easy to change much in the timetable because of the wording in the legislation.</p>	
<p>6. Press release & publication of presentations on website</p>	
<p>Question to IP on whether presentations can be published on the CMDh website.</p>	
<p>IP accepted that presentations of the meeting are published on the website together with the minutes.</p>	
<p>7. A.O.B.</p>	
<p>Issues with implementation of outcomes of work-sharing procedure for assessment of studies submitted according to Art. 45 of Paediatric Regulation EC/1901/2006</p>	
<p>The CMDh expressed its disappointment regarding the implementation of wordings agreed in the context of Art 45. worksharing assessments as procedure require a lot of efforts and resources but innovators do not implement in a timely manner. A more proactive approach is requested from companies.</p>	
<p>Some NCAs will give guidance on national products and RMSs will take the lead for MRP/DCP products.</p>	
<p>The CMDh is working on further guidance for assessors and industry following the paediatric workshop for assessors held in July 2009. Further guidance will be published.</p>	
<p>EFPIA asked about the experience with the procedure on Interactions on safety warnings agreed in PhVWP and expressed the wish to receive more information on the joint CMDh/PhVWP Working Group and to have the originator being involved in the discussions.</p>	
<p>The CMDh Chair explained that there was a procedure in place for interaction and communication between PhVWP and CMDh and that CMDh was getting the reports from PhVWP after PhVWP agreement. The CMDh publishes the recommended PhVWP wording and the implementation timelines.</p>	
<p>More information on the process may be found in the press release of PhVWP.</p>	

ANNEX I: LIST OF PARTICIPANTS

- CMD(h) Members

- AESGP
 - Hubertus Craz
 - Eric Teo
 - Helen Darracott

- EFPIA
 - Isabelle Stöckert
 - Paloma de Miguel
 - Andrew Marr
 - Marianne Poulmaire

- EGA
 - Susan De Stasio
 - Remco Munnik
 - Tom Manussen
 - Beata Stepniewska