

MINUTES

CMDh meeting with representatives of Interested Parties

21 June 2010

17.00-19.00, EMA, Room 2G

Chairperson: Mrs. Truus Janse-de Hoog

	Action
1. Agenda of the meeting	
Agenda Rev.1	
The agenda was adopted.	
2. Member States' resources in the Mutual Recognition and Decentralised Procedures/CMDh contribution to Task force on resources	
<p>The CMDh informed the Interested Parties (IP) that discussions on how to improve DCP are still ongoing at CMDh, HMA Task Force on resources and Working Party on Future of CMDh. A broad range of issues are under focus:</p> <ul style="list-style-type: none"> • Role of RMS in the start of the procedure • Assessment Reports • Transparency of slots and booking systems • Clock stops • Decision making process • National requirements • E-submissions • Common portal for submissions <p>The CMDh will give an input to the HMA Strategy paper II meeting in July.</p> <p>EGA gave a positive feedback on the Common request form for RMS but stressed that the information requested is often not compatible with the state of development of the products. EGA also gave examples of reasons for slot cancellation (e.g. mergers and acquisitions leading to duplicated projects) and presented possible solutions such as introducing booking fees or increasing the visibility of available slots per therapeutic area through a centralised database. EGA indicated that the overall impression is that there has been no significant improvement in the slot booking situation.</p> <p>EFPIA welcomed the actions taken by CMDh and HMA to increase transparency on slot booking and the number of agencies volunteering as RMS but agreed that there is still room for improvement. EFPIA noted that the agreed MRP/DCP guidelines are not followed and highlighted several issues at different time during MRP/DCP that lead to MRP/DCP prolongation such as the need to consult national committees whose timelines are not aligned with DCP.</p>	

	Action
<p>AESGP indicated that slot time booking is still a major concern and presented metrics obtained via a survey, on the use of DCP by the self-medication sector. In conclusion, the national route is still preferred.</p> <p>The CMDh noted that the proposal from EGA and EFPIA to have companies reconfirming the slots 3 months in advance is current practice but does not prevent cancellations.</p> <p>Following the point raised by EFPIA on e-submissions, IPs were invited to report any discrepancies found in the national requirements to CMDh.</p>	IP
3. Decentralised Procedure: clock-stop	
<p>The CMDh presented the new rules for clock-stop that were introduced in the SOP on DCP in January 2010. The changes aim at reducing the delay for restarting the procedure and at improving the predictability of the procedure for NCA and applicants. Feedback from applicants and NCA is needed to evaluate the effectiveness of the new rules. The CMDh has started to monitor procedures in clock-stop every 3 months and to request feedback from RMS.</p> <p>EGA referred to the results of the survey discussed under section 6 A.O.B showing important differences between RMSs when handling clock-stops.</p> <p>The survey conducted by AESGP showed that 6-month long clock stops can be expected (180 days) with data ranging from 80 to 660 days.</p> <p>The CMDh expressed the wish to get practical examples of DCP with very long clock-stops for MS to identify the cases and confirmed that they will monitor duration of clockstops and adherence to the revised SOP.</p>	IP
4. Variations: first experiences with worksharing and Art.5 procedures	
<p>The CMDh presented an overview of the experience gained during the first 6 months following the implementation of the new Regulation on variations and indicated that an electronic application form will soon be available.</p> <p>The CMDh reiterated that the classification guideline should be carefully checked before a request for classification in accordance with Art. 5 is sent to the CMDh and that when one or more of the conditions established in the Annex to this Guideline for a minor variation of type IA are not met, the concerned change may be submitted as a type IB variation unless the change is specifically classified as a major variation of type II.</p> <p>AESGP presented their experience with type IAIN variations which are supposed to be submitted within 14 days after implementation and explained that based on the current definition of the implementation, the 14-days deadline is too restrictive and may not be met. AESGP proposed to have a longer submission timeframe e.g. 6 months.</p> <p>EGA expressed the wish to get more background on the Art.5 recommendations published on the CMDh website in order to evaluate the applicability of the recommendations to new cases. EGA asked whether consequential variations are still allowed as some MS do not accept them anymore and request grouped variations with more expensive fees and noted that for IB, validation time is not always respected.</p>	

		Action
	<p>EFPIA welcomed the CMDh BPG on variations but suggested to find a more pragmatic approach for grouping as some MS stick to the examples given in Annex III. EFPIA informed that a new survey is being prepared to be circulated to the Industry end of November 2010, the results of which will be presented beginning 2011.</p> <p>The CMDh informed IP that the issues raised in the presentations are known and are being discussed in the CMDh subgroup on variations.</p>	
5.	Press release & publication of presentations on website	
	<i>[Post-meeting note: IP accepted that presentations given during the meeting could be published on the CMDh website]</i>	
6.	A.O.B.	
	<i>Issues encountered with type IA implementation</i>	Discussion
	This topic proposed by AESGP was discussed under section 4 on variations.	
	<i>Results of the EGA survey on DCP</i>	Discussion
	<p>EGA presented the results of a survey conducted among generic companies on DCP to evaluate the implementation of the new DCP since January 2010. The results show that the validation phase is an issue: the validation process is not transparent when compared to CP which takes 14 days and allows for issues to be solved after validation.</p> <p>The results relating to clock-stops were discussed under section 3.</p> <p>Regarding the national phase, important variations were observed between MSs and between procedures within a same MS, even after exclusion of the extremely long procedures from the counting. In some MSs a slight tendency towards a quicker process was observed in 2010 when compared with 2009.</p> <p>The late submission of the translations by the applicant is a critical point. However, no correlation has been observed between a timely submission of translations and the timely granting of MA. A possible link between delays in granting of MA and quality issue with translations is being investigated.</p> <p>Delays during national phases are considered as a major inconvenient of DCP.</p>	
	<i>Practical elements of Art.30 harmonisations</i>	Discussion
	<p>EFPIA presented proposals aiming at saving resources and obtaining a consistent and timely implementation of Art.30 outcome / switch to the MRP process.</p> <p>EFPIA asked for a Best Practice Guide or SOP containing agreed common rules to be published on the CMDh website and requested that further clarification is given via the Q&A published on the CMDh website.</p> <p>The CMDh indicated that discussions are ongoing that will take into account the presented proposals.</p>	EMA

	Action
<i>Paediatric Art.45/46 WS procedures</i>	Discussion
For Art.46, EFPIA asked for a common process for submission of data regardless of whether products are centrally approved or MRP/DCP.	
EFPIA informed the CMDh of a survey to be circulated to companies shortly asking about their experiences with Paediatric Regulation. Results will be available 1Q2011.	
The CMDh informed IP that a meeting dedicated to the Paediatric Regulation will be organised with IP in September.	
<i>How to make MRP/DCP more attractive for the self medication sector</i>	Discussion
AESGP presented metrics obtained via a survey, on the use of DCP by the self-medication sector under section 2.	

The chair thanked all participants for their contributions. As the time for the meeting was limited it was not possible to discuss into detail all the points raised, but they will be taken into account in the ongoing discussions in the CMDh and various working groups.

ANNEX I: LIST OF PARTICIPANTS

- CMDh Members

- AESGP
 - Glenn Carpenter
 - Ari Alfred (GSK)
 - Helen Darracott (PAGB)
 - Christelle Anquez-Traxler (AESGP)

- EFPIA
 - Isabelle Stöckert (Bayer Healthcare)
 - Paloma de Miguel
 - Craig Johnson (Lilly)
 - Xavier Lllaurado
 - Angelika Joos (Merck)

- EGA
 - Caroline Kleinjan (Sandoz)
 - Helen Staresinic
 - Tom Manussen
 - Beata Stepniewska (EGA)