

MINUTES

CMDh meeting with representatives of Interested Parties

15 November 2010
17.00-18.30, EMA, Room 2A
Chairperson: Mrs. Truus Janse-de Hoog

1.	Agenda of the meeting
	Agenda Version 1
	The agenda of the meeting was adopted.
2.	CMDh contribution to Task Force on resources
	<p>BE opened the discussion on the topic of national closing time. It was noted that for the correct understanding of statistics it would be important to know how the 30 days for the national phase are calculated (When is the start date? Is a clock-stop applied?).</p> <p>SE noted that availability of slots does not seem to be a big issue for industry anymore, but NCAs are experiencing a lot of cancellations of booked slots, which has an impact on the efficiency of the system.</p> <p>EGA stated that problems with BE studies or a changed market situation can lead to cancellation of slots. As a result of the current situation, EGA wants to tackle the problem by writing a code of conduct addressing cancellation and postponement of procedures and when to notify these. EGA also has no objection towards a booking fee. It is envisaged to finalise the code of conduct within the next 2-3 months.</p> <p>EGA also noted that the visibility of last-minute slots is not clear yet for each MS and a mixed model with long-term and short-term slots was proposed.</p> <p>Some MSs stated that up to 40-50% of the slots are cancelled and one of the reasons is double booking in different MSs. A code of conduct would be appreciated.</p> <p>With regard to the DCP, EGA has recognised an improvement on validation. However, the time for restart of the procedure and the time for the national phase vary across MSs.</p> <p>For the electronic validation the problems increase.</p> <p>A discussion with the CMDh on transparency as to what is considered good/bad quality of translations would be appreciated.</p> <p>It was also noted that not all MSs provide PARs.</p> <p>PT informed the group that they have published quality criteria for translations in PT, which are accepted by industry and provide a way of working together. The document will be shared with CMDh.</p> <p>AESGP supported a lead role of the RMS in certain fields, particularly in ensuring the timelines, consolidation of questions and postponing national issues to the national phase. It was also noted that not all MSs are acting as RMS yet and training on the RMS role should be considered.</p>

EFPIA stated that a slot cancellation only takes place if a project becomes nonviable. A postponement can happen if there is a change in the development of a product. EFPIA supported the idea of a code of conduct.

In their presentation, EFPIA proposed a more coordinated approach between CMDh and EMA on the implementation of changes to the DDPS. The presentation also addressed the improved situation on eSubmissions.

UK supported the EFPIA suggestions on DDPS changes, but also noted that the pharmacovigilance legislation will bring changes in this area.

As a follow-up from the meeting in June 2010, AESGP presented the outcome of a survey on time slots. Although the number of replies was limited, it was noted that the companies mainly used their slots. However the number of requested slots exceeded the number of granted slots. The transparency and the process of slot booking have been improved, but a central EU booking system would be preferable. A pre-submission meeting also presents a successful alternative before slot booking.

With regard to the calculation of the 30 days for the national closing time, EGA stated that for their statistics they have asked their members for the closure date and the date of issuing of the MA. No information was given on clock-stops.

The EGA members have informed that the translations are submitted within 5 days.

EGA proposed to grant the MA based on the commitment to provide the translations before marketing as practiced by some MSs.

3. Variations

EFPIA asked for the possibility to allow grouping of type IA variations across RMSs. Also the worksharing procedure should be simplified, i.e. quicker procedure for duplicate procedures and shortened timetable for worksharing procedures including only one type IB variation. The administrative burden should be reduced by removing national specific requirements in MRP. EFPIA also proposed to revise the Article 5 procedure to make it more attractive.

EGA informed the group that companies are facing problems with grouping, i.e. disagreement with published grouping examples and non-allowance of consequential changes anymore. As there are problems receiving the grouping numbers, EGA proposed to compile a list of contact points for each MS.

EGA also raised concerns regarding the validation time and made the group aware of the reluctance of industry to implement type IA variations before approval by the NCAs.

DE gave a presentation on behalf of the CMDh addressing the questions previously raised. The group was informed that there is no definition of 'immediate notification' so far. The number of single type IA variation submissions has been reduced due to the introduction of grouped IAs. However, the overall number of individual variations has further increased. Further examples of groupings have been published and more will be published early 2011. Only limited experience with worksharing has been gained so far, but further simplification of the procedure is foreseen.

A procedure to allow grouping of type IAs for products with different RMSs has to be discussed in the future.

4.	Practical elements for harmonisation after Art.30 referral procedure
	<p>EFPIA proposed that renewal dates for MRP after a referral procedure and repeat-use MRP should follow the renewal as determined by the RMS. Also for duplicates the renewal dates of the original MA should be followed. In order to reduce workload, no assessment would be needed for duplicate informed consent applications of products undergoing an Art. 30 referral as they are based on the same data set.</p> <p>EGA stressed the importance to have agreed translations available.</p> <p>DE informed the group that the CMDh paper ‘Recommendation for Mutual Recognition Procedure after finalisation of a referral procedure with a positive decision by the EC’ is under revision and an update will be published soon. The implementation would very much depend on the flexibility of the involved MAH.</p> <p>The Chair acknowledged the need to discuss requests for national renewals in order to find a harmonised approach.</p>
5.	Active Substance Master Files
	<p>AT informed Interested Parties about the ongoing discussions between CMDh, EMA, EDQM and QWP to centralise the ASMF assessment for ASMFs going through DCP and CP, including a central database and an EU numbering system.</p> <p>As first step, the ASMF AR has already been separated from the AR of the medicinal product. In the future a meeting of the ASMF group with Interested Parties including APIC is planned.</p> <p>EGA informed that a centralised ASMF assessment based on the CEP model is also part of the EGA vision 2015.</p>
6.	National switch of product when part of a European procedure – impact on labeling
	<p>AESGP gave a presentation on the problems faced for a national switch of products in EU procedures and the impact on labelling.</p> <p>AESGP proposed to agree on a prescription and a non-prescription subset of the product information during the procedure.</p> <p>UK informed Interested Parties that the topic has also been discussed as one topic of the WP on the future of CMDh and the recommendations of the CMDh have been endorsed by HMA. The need to agree on a way forward was acknowledged and a meeting with Interested Parties on the topic is foreseen in the future.</p> <p>EGA noted that generic companies also face problems with different MAs for prescription and non-prescription status.</p>
7.	Results of an AESGP survey on Certificates of Pharmaceutical Products (CPPs)
	<p>AESGP presented the results of a survey on CPPs.</p> <p>AESGP noted that there is a great variability in timelines for the issuing of CPPs across MSs and proposed a 6 weeks period as reasonable target timeline for the issuing.</p> <p>It was noted that the CMDh would not be correct group to address the issue.</p> <p>AESGP was asked to forward the request to HMA.</p>

8.	Press release & publication of presentations on website
	No objections were raised to publish the presentations on the CMDh website. The minutes will be circulated as soon as they are available and published after agreement.
9.	A.O.B.
	The next meeting of the CMDh with Interested Parties is planned for Q2 2011.

LIST OF PARTICIPANTS

- **CMDh Members**

- **AESGP Representatives**
 - Ari Alfred
 - Christelle Anquez-Traxler
 - Tracey Atkins
 - Helen Darracott

- **EFPIA Representatives**
 - Isabelle Clamou
 - David Jefferys

- **EGA Representatives**
 - Caroline Kleinjan
 - Beata Stepniewska