

Minutes

CMD(h) meeting with representatives of Interested Parties

13 November 2006

17.00-19.00, EMEA, Room 4B

Chairperson: Mrs. Truus Janse-de Hoog

The Chair of the CMD(h) welcomed the representatives from AESGP, EFPIA and EGA to the meeting with the CMD(h) and invited the participants to introduce themselves.

1. Adoption of Agenda

The agenda of the meeting was adopted.

2. The Decentralised Procedure (DCP) and the Mutual Recognition Procedure (MRP), including communication of outcome of referrals in the CMD(h)

EGA gave a presentation on the following key issues of the DCP/MRP, identified by EGA Members:

- Significant delays for obtaining a submission of application's date (6 months to one year);
- Limited availability of RMS (currently only 9 MSs are being used as RMS);
- Delays in the validation period (average of 30 days), lack of a clear start /finish validation phase and need for harmonisation of what should be checked at validation phase;
- Delays on the restart of the DCP, due to the need to submit draft answers for pre-assessment by the RMS;
- The proposal to facilitate earlier closures of DCP in assessment phase II.

With regard to the delays on the restart of the DCP, due to the need to submit draft answers for pre-assessment by the RMS, the CMD(h) advised Interested Parties to use RMS resources in the best way and focus on the difficult questions raised instead of submitting the full draft answers for RMS review.

It was noted that Applicants are advised to have early discussions with the RMS on how to submit the replies to the questions.

The CMD(h) informed Interested Parties that it is possible to have an early closure of DCP, if there is agreement between all the involved MSs. It was noted that some DCP have been closed before day 210.

It was agreed to reflect this information in the update of the DCP SOP.

With regard to the MRP, EGA mentioned the delays for updating the AR, to start repeat-use MRP and delays in receiving Day 50 comments.

With regard to the outcome of CMD(h) referrals, EGA asked the CMD(h) to publish policy decisions made during the procedures, as these might have implications for other applications.

Interested Parties were informed that the CMD(h) has identified some areas for review, in relation to the DCP.

The CMD(h) has set up a working group to evaluate the Decentralised Procedure and to consider the need for the revision of the DCP SOP, as experience is gained for each part of the procedure.

Interested Parties were invited to send comments/proposals in relation to the Decentralised procedure to the attention of the CMD(h) secretariat (sonia.ribeiro@emea.europa.eu) by 1 February 2007, for early consideration by the CMD(h).

With regard to the outcome of referrals to CMD(h), Interested Parties were informed that the CMD(h) acknowledged the need to be more transparent on how agreements have been reached and would reflect this approach in the information provided in the CMD(h) press releases.

Interested Parties were asked to inform National Competent Authorities if they are delayed with the submission of applications, as this might have implications on the possibility to act as RMS for other applications.

With regard to validation issues, Interested Parties were informed that the CMD(h) has compiled validation issues raised within the MRP/DCP and set up a working group to analyse validation issues and national requirements within the framework of the decentralised and mutual recognition procedures.

The intention of the CMD(h) would be to come back in some months with information to Interested Parties on validation issues and national requirements.

AESGP asked the CMD(h), for MR renewals, to avoid requesting documents not mentioned in the Guideline on the processing of renewals in the mutual recognition and decentralised procedures.

The Chair proposed to take into account also renewals when discussing national requirements.

3. Usage patents – Implementation within the framework of the MRP/DCP

EGA informed the Group that they had sent a letter to the CMD(h) in July 2006, asking for clarification of certain practicalities on the implementation of usage patents and in the meantime the CMD(h) had published a Q&A document on usage patents.

EGA welcomed the approach from the CMD(h) regarding usage patents and the leading role of the applicant to inform NCA on usage patents, that will be carved out at national level.

EGA asked for confirmation of the following:

- Subsequent variations are based on the full SPC;
- The complete SPC/PL is published with the PAR at national level;
- The alignment of the product information after expiry of the usage patent is done by a notification/variation (but not a type II).

The CMD(h) gave a presentation on usage patents in MRP/DCP. The concept is that MSs will disregard patent situation during the procedure and recognise the full SPC/PL.

MSs will rely on Applicants to inform them of usage patents that might apply and will grant the national license of the medicinal product without the patented indications and/or dosage forms.

After expiry of a patent, the MAH should inform the NCA via the appropriate national procedure that could differ between MSs, to bring the MA in line with the one agreed in the MRP/DCP.

The CMD(h) informed Interested Parties that the complete EN SPC/PL is published with the PAR in the MRI-Product Index.

With regard to the product information published at national level it was mentioned that this is a decision of the respective NCA, but it is most likely that it will be the approved SPC and PL in the respective language without the patented indications.

With regard to whether the subsequent variations should be based on the full dossier, this issue would be further considered by the CMD(h).

It was proposed that the involved MSs should recognise, but not approve the variations in case it deals with information covered by patent law in the respective MS.

EFPIA was of the view that the proposal for the wording in Blue Box, to explain to patients why therapeutic indication(s) or dosage form(s) may be lacking in the PL could encourage patent infringement.

It was mentioned that some MSs have been using the wording for several years and that MSs have to balance intellectual property rights against their duty to protect public health.

4. Package leaflet – Experience with consultation with target patients groups

EGA gave a presentation on user testing addressing the following issues:

- Timing of user testing and events that will trigger a user test;
- Mechanisms to take user test results and improve/update QRD template and the need for a common understanding of QRD;
- The need to publish bridging guidance and the proposal from EGA to work with NCAs on this issue;
- The acceptance of user testing in any EU language with the submission of the report in EN;
- Issue of a certificate of passing user test for the PL, recognised across EU.

EGA added that it would be important to have the same standard of assessment across EU, to have faster feedback and approval times and that Companies are willing to cooperate to achieve the aim that patients always receive the same leaflet for the same product.

EGA proposed to work with the CMD(h) to ensure that the time and effort put into user testing improves the safe use of medicines by patients.

EGA would provide comments on the draft guideline on the readability of the label and package leaflet of medicinal products for human use.

The CMD(h) invited Interested Parties to send in proposals for other methods for user consultation.

The CMD(h) informed Interested Parties of the workshop on user consultation, organised by the EMEA and CMD(h) on 23 October 2006 NL, which focused on the lay out and design of a good package leaflet, the review of user testing reports and the assessment of justification for not performing user testing.

The CMD(h) acknowledged the need for common standards on the assessment of user testing and for guidance regarding justifications for not performing user testing and informed Interested Parties that the outcome of the workshop on user consultation would be further discussed in the CMD(h) and reflected in the format of Q&As.

The proposed Q&As would seek to further clarify the timing of user testing and the need for user testing with harmonisation of the PL, renewals, etc.

The CMD(h) confirmed the acceptance of user testing in any EU language with the submission of the report in EN.

The CMD(h) welcomed EGA proposal to have the same product information for identical medicinal products.

5. Implementation of e-CTD in the Decentralised and Mutual Recognition Procedures

EFPIA gave a presentation on the implementation of the eCTD in MRP&DCP.

EFPIA referred to the HMA agreement that all NCAs should be in a position to accept eCTD as official submission (without paper) from end 2009 and asked for the CMD(h) help to address some of the issues.

EFPIA mentioned that there has been little uptake of eCTD in MRP and DCP so far because of the complex processes and proposed to find a way and forum to agree on common interpretation of eCTD standards.

EFPIA explained the proposals for best practice in the lifecycle management in the MRP and DCP and the need for a central repository.

EFPIA asked for the CMD(h) endorsement of the principles and proposed to work with the members of the TIGes, NtA interlinking group to formalise the FAQ that define an accepted, best-practice methodology for lifecycle management in the MRP and DCP.

EFPIA asked also for the CMD(h) support for the principle of a central repository, allowing for a single location for all MSs with all sequences.

EFPIA was of the view that the eCTD uptake in MRP/DCP would be facilitated by clear guidance on best practice for handling eCTD in the procedures, by focusing on common interpretation of eCTD standards and processes and by progressing towards a common repository. EFPIA requested the CMD(h) support in achieving these objectives.

EGA gave also a presentation on electronic submissions in MRP/DCP.

EGA was of the view that business processes need to be clearly defined and that for smaller companies an on-line eCTD tool could increase eCTD readiness. EGA added that generic industry is not ready for XML application form and proposed to have a single tool for creation of XML application forms, updated at the same time as the NtA.

EGA pointed out that guidance for electronic submissions is not consistent across Countries and is required for non-eCTD electronic submissions and proposed to find a common solution, e.g. the creation of a single portal accessible for all NCAs and Applicants. EGA proposed to have a harmonised target date for eCTD mandatory date.

The CMD(h) acknowledged its role to discuss eCTD implementation in the MRP and DCP within the CMD(h).

It was noted that all NCAs should be able to accept eCTD by the end of 2009. However, it is not mandatory for Applicants to use the eCTD.

The CMD(h) informed Interested Parties that they had already addressed to the HMA the need for a central repository to be available to all MSs, which had been forwarded for discussion at the level of the Telematics Steering Committee.

Representatives of Interested Parties mentioned that it would be very important to avoid that NCA set up different IT systems that deviate from common standards.

It was mentioned that a sub-group within TIG was set-up to produce guidance for non eCTD submissions, to have a common way of submitting non eCTD submissions. The working group would hold its first meeting in the following week.

The Chair supported the proposal to agree on common standards and proposed that MS work closely together and with other groups and that the CMD(h) should be regularly updated in the areas where the input of the CMD(h) might be important.

With regard to the central repository, it was proposed to get further information on the questionnaires from the TIG on this issue.

In reply to a question on how to get the CMD(h) endorsement of the EFPIA proposals, the Chair proposed to include eCTD in the agenda of the CMD(h) meeting and to agree on a CMD(h) member to take the Rapporteurship for the eCTD and to involve the TIG.

6. A.O.B

The Chair thanked Interested Parties for the presentations and the several points raised and informed them that the EMEA would prepare the minutes of the meeting that would be published on the Heads of Medicines Agencies website.

Participants

- CMD(h) Members

- AESGP
Christelle Anquez-Traxler
Diane Poole
Lieven Costers

- EFPIA
Christine-Lise Julou
Hilary Jones
Andrew Marr
Geoff Williams

- EGA
Beata Stepniewska
Caroline Kleinjan
Mary Smillie
Susan De Stasio