

MINUTES
Meeting with EGA on Work-sharing for patient consultation

London, Tuesday 19 June 2007
9.00-10.00, Room 2G
Chairperson: Ms. Shirley Norton

Ms. Shirley Norton, UK CMD(h) Member welcomed the representatives from EGA to the meeting with the CMD(h) to discuss their proposal for a work-sharing initiative for patient consultation and invited the participants to introduce themselves.

1. Agenda of the meeting

The agenda of the meeting was adopted.

2. Proposal for work-sharing initiative for patient consultation

The Chairperson noted that the proposal for package leaflet user testing work sharing initiative across Europe tabled at the meeting was not the updated version discussed at the Informal CMD(h) meeting in Bonn, Germany and proposed to circulate the version discussed at the Informal EMEA meeting.

- **Overview from EGA**

The Chairperson invited EGA to give a brief overview of their work-sharing proposal.

EGA informed the Group of the main benefits of the initiative, i.e. patients would receive more consistent and better quality product information and the workload for Industry and National Competent Authorities would be reduced by avoiding the need to repeat assessment of user tests.

EGA proposed that National Competent Authorities recognise the assessment of the package leaflet carried out by each other.

- Feedback from Informal CMD(h) discussion
 - The Chairperson informed EGA of the feedback from the discussions at the informal CMD(h) meeting, e.g.:
 - The CMD(h) supported in principle the proposal from EGA for package leaflet user testing work-sharing initiative across Europe;
 - The CMD(h) was of the view that this work-sharing initiative would only be possible if the product information is harmonised between MSs;
 - The CMD(h) acknowledged the need to make a distinction between requirements in UK and in other MSs, as user testing is not a requirement for old medicinal products in some MSs;
 - The CMD(h) continue to consider how MSs assess results of user testing, with a view to optimising the process and applying results of user testing in a consistent manner;
 - The CMD(h) acknowledged that the purpose of the initiative would be to improve the quality of the package leaflet for the benefit of patients and did not endorse the proposal for a certificate of passing user testing;
 - The EGA was reminded that the leaflet was the subject of approval whereas the user test (or other data demonstrating compliance with article 59(3)) was supporting data and not subject to approval.

The Chairperson informed EGA that the revision of the Readability Guideline had been agreed at the level of the Notice to Applicants subject to input of Legal Services. A key aspect of the Guideline was whether the questions asked within a user test were appropriate and tested for safety messages.

3. Development of guidance to support extending use of test results to related products

The UK bridging study guidance on consultation with target patient groups was tabled as a background document, for information.

The EGA representatives welcomed the proposal from the CMD(h) to develop further guidance to support extending use of test results to related products.

The Chairperson explained the principle that a justification is needed to demonstrate that a user testing performed for another product is considered relevant for the specific product applied for.

EGA informed the Group that they had not received feedback from National Competent Authorities on the situations where bridging studies had been accepted and asked if the UK guidance was considered acceptable by other National Competent Authorities.

It was clarified that UK bridging study guidance had been developed for the UK.

The Chairperson of the CMD(h) mentioned that a training session for MSs to share experience with bridging studies and to discuss how to apply bridging study guidance could be organised.

EGA informed the Group that sharing of user testing results was already taking place following a UK industry initiative and that all pre-requisites for the work-sharing initiative were in place. EGA added that the work-sharing scheme was open to any Company willing to participate, regardless of whether they were members of the British Generic Manufacturers Association (BGMA) or not.

The Chairperson of the CMD(h) was of the view that it would be useful to identify in the EGA list of products to be part of the work-sharing scheme, the products which were in the MRP/DCP and thus could benefit most from this work-sharing initiative, as they have harmonised patient information.

However, it was acknowledged that the work-sharing initiative could also apply to nationally authorised medicinal products with similar product information.

The Chairperson of the CMD(h) was also of the view that it would be beneficial to involve the RMS in the discussions on the user test options for MRP/DCP products.

EGA replied that the majority of user tests performed had been generated as part of European procedures and agreed to identify in their list of products to be part of the work-sharing scheme, the products which are in the MRP/DCP. EGA

4. Next steps and timeframe

The Group agreed to develop guidance to support extending use of test results to related products.

The guidance would consider content issues, e.g. how user tests address key messages of safe use for the patient, and design and format issues.

It was noted that it would be possible to discuss this initiative further in a meeting with EGA or in a meeting with representatives from all Trade Associations.

5. Press Release

The Group agreed to include a general statement in the CMD(h) June EMEA 2007 press release to encourage Industry to participate in this work-sharing initiative.

EGA would also to consider how to communicate this initiative to the EGA exterior.

Participants

- Representatives from CMD(h)
- Representatives from EGA
 - Mary Smillie
 - Alex Harris
 - Michael Borek
 - Paul Fleming