

WORKPLAN CMD(h) 2007

February 2007

Introduction

2006 was the first full year of operation of the Coordination Group for Mutual Recognition and Decentralised procedures-Human (CMD(h)), set up under the revised EU pharmaceutical legislation for the examination of any question relating to the marketing authorisation of a medicinal product in two or more Member States, in accordance with the mutual recognition procedure (MRP) or the new decentralised procedure (DCP).

The tasks and functioning of the group have been outlined in the Rules of Procedures, which were adopted by the Group and endorsed by the European Commission.

A Summary of activities in 2006 has been published on CMD(h) website.

In the first year of the CMD(h), the main topics on the Agenda were implementation of the New legislation and update of Guidance papers to take into account New legislation. The new Decentralised procedure and 60 day-referrals to CMD required many discussions and New Guidance papers.

The 60 day-referrals took a considerable amount of time in the meetings and resources from national agencies. But it stimulated also discussions on how to achieve a more harmonised approach with regard to data requirements, assessment of the dossier and harmonisation of SPC's and PL. A major achievement was that the CMD(h) has agreed that a deviation in indications (more or fewer) in the generic product from the national reference product in the CMS is not considered to be, per se, an appropriate reason to refuse licensing a medicinal product .

Priorities in 2007

The work done in 2006 has created a solid basis for the new procedures under the new legislation. The CMD(h), as a group, has shown that they can take responsibility for scientific and regulatory questions. In 2007 the CMD(h) will build on this and concentrate on improvement of existing procedures.

In 2007 the CMD(h) will concentrate on the following points:

- 1) Active participation of all members of the group. In order to create general consensus in the agreements reached and avoid repetition of discussions on the same topics, all CMD(h) members are encouraged to participate in the referral discussions, also in applications in which they are not involved as RMS and CMS.

- 2) Improvement and evaluation of existing procedures. 2 new Working groups are set up, to evaluate the Decentralised procedure and Validation issues /National requirements in MR/DC procedures.
- 3) Reduction in number of referrals (see also below)
- 4) Readability tests; better guidance for industry and harmonisation in assessment of user tests
- 5) Strengthening cooperation with PhVWP
- 6) Transparency; Update of information and better structure of information on CMD(h) website has priority.
- 7) Further development of a Scientific Memory Database to keep track of CMD(h) agreements.
- 8) A new Working Group, set up to facilitate MS implementation of the Paediatric Regulation. Continuation of EU Worksharing procedure in assessment of paediatric data and publication of Paediatric public assessment reports.

Referrals

105 Mutual recognition Procedures and 1 Decentralised Procedure were referred to the CMD(h) in 2006. The CMD(h) was able to reach agreement in 71% of the referrals and 29% was referred to CHMP. The success rate of the outcome of CMD(h) discussions is considered very good, taking into account that this was the first year of CMD(h) working with the new Mandate to discuss any scientific and regulatory question.

As the referrals take many resources from competent authorities and companies, the aim is to reduce the number of referrals. However, it is also acknowledged that it is the task of CMD to be a platform for scientific discussions if there are different views between the Member States.

The following is suggested to reduce the number of referrals:

- The results of agreements reached in the CMD(h) should be applied in the assessment of new applications. There is still the need for a Scientific Memory of the CMD(h) where the outcome of discussions can be stored and made accessible for all national experts;
- General questions are sent to CHMP Working Parties and agreements should be followed;
- Discussion in Working Parties on the update of Guidelines and training of assessors
- Start discussions between Member States earlier in the procedures and involve CMD(h) earlier in the discussions
- The commitment of all the National agencies to follow the agreements made in the CMD(h)

Working groups

CTS

Full support of all procedures MRP, DCP and referrals is needed.

SPC harmonisation

The Subgroup has selected a first list of products. Industry has been consulted and feedback will be discussed.

Joint CMD(h) /PhVWP Working Group

The work of this WG started in 2006 and is important to create a forum for discussion on issues of common interest.

The CMD(h) has adopted a paper on communication between PhVWP and CMD(h). This exchange of information will help to implement new safety information in a consistent manner and facilitate the national implementation of safety warnings in the same timeframe.

The ongoing projects such as synchronisation of PSUR submissions need close monitoring to make the Work sharing successful.

Transparency

CMD(h) has increased their transparency in the press releases by providing more information on the outcomes of the referral discussions. CMD(h) will follow general agreements made in the Working group of HMA together with EMEA.

The information on the Website needs to be updated. The new HMA website will help to improve structure and quality of information. This has a high priority and should be implemented before 1st April.

With regard to the publication of PARs and product information in MRI - Product Index, the CMD(h) will try to ensure the timely availability of these documents on the website.