

CO-ORDINATION GROUP FOR MUTUAL RECOGNITION AND DECENTRALISED PROCEDURES – HUMAN (CMD(h))

WORKPLAN 2008

January 2008

INTRODUCTION

The Coordination Group for Mutual Recognition and Decentralised procedures –Human (CMD(h)) was 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 CMD(h) started its activities in November 2005.

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.

Two years after the introduction of the revised Mutual Recognition procedure (MRP) and Decentralised procedure (DCP), it can be concluded that both procedures function well. Applicants have shown a growing interest in the Decentralised procedure. The DCP was evaluated in 2007 and further evaluation will be performed in Q3 2008. It is expected that at that time approximately 1000 procedures have been finalised. The concerns of industry on the availability of resources at the National Competent Authorities needs further discussion, especially at the level of HMA, but CMD(h) is willing to contribute to this discussion in order to find ways of making the best use of available resources.

The Working group on validation issues/national requirements, started at the end of 2006 has already contributed to the reduction in the number of national requirements and has provided guidance for applicants on e.g. common grounds for invalidation/delaying of validation, Member States recommendation and template for the cover letter for new applications, etc. This group will continue in 2008 with the aim to achieve a more harmonised approach with validation of dossiers, including electronic submissions.

The percentage of applications referred to CMD(h) in 2007 was far below the numbers of the first year 2006, but a further reduction should be possible in 2008. Information on the outcome of discussions in CMD(h) and CHMP on referred products is considered important. Further discussion is needed on how transparency on the agreements made in CMD(h) and CHMP can be increased.

PRIORITIES 2008

For 2007 the CMD(h) agreed on priorities in the work plan. Some of the priorities are maintained for 2008.

For 2008 the following priorities have been defined:

- 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 scientific and regulatory discussions, even in applications in which they are not involved as RMS and CMS.

- 2) Improvement and evaluation of existing procedures. The Working group on validation issues/national requirements will continue to achieve further reduction in number of national requirements in the MRP/DCP and to reach a similar understanding between MSs on 'level' of validation.

It has been decided to evaluate the Decentralised procedure again in Q3 2008.

- 3) Evaluation of functioning of the CMD(h), two years after the start of the group with broad mandate.
- 4) Readability tests: finalisation of Guidance documents and a harmonised approach in requirements for testing and accepting bridging data.
- 5) To contribute to a successful implementation of Paediatric Regulation.
- 6) To contribute to a successful implementation of Variation Regulation.
- 7) To contribute to the Public consultation of the new legislative proposals 'Strategy to better Public Health by strengthening and rationalising EU Pharmacovigilance'.
- 8) To contribute to a truly mutual recognition by Member States with a focus on a targeted approach and elimination of full parallel assessment by CMSs.
- 9) Increase transparency for industry on the outcome of referral discussions in CMD(h) and CHMP by publication of information and organisation of meetings with interested parties.

ORGANISATIONAL MATTERS

The meeting calendar and relevant procedure dates have been published on CMD(h) website.

Membership renewal and chair elections:

CMD(h) members are nominated for a period of 3 years, which is renewable. From 30 October 2008 onwards the first renewals or new nominations are due. The secretariat is keeping track of the expiry dates, whilst the Member States are responsible for sending in renewals or new nominations in time.

The term of the chairperson is also a period of 3 years and is renewable once. Elections for the position of chairperson will be held in the November meeting.

EVALUATION CMD (h)

The CMD(h) started in November 2005 with a broad mandate given in Art 27 of Dir 2001/83/EC, as amended, for examination of any question related to marketing authorisations of a medicinal product in two or more Member States. The Rules of Procedure have been adopted and are published on CMD(h) website. The CMD(h) agreed also on a document Function and tasks for CMD(h) in February 2006. After two years it is important to conduct an evaluation on how the Group is functioning in view of agreed mandate and new responsibilities and discuss how further improvement in the operation of the group can be achieved.

A working group will prepare a questionnaire to explore Member States views. The outcome of the evaluation will be reported to the Heads of Medicines Agencies.

REFERRALS

The percentage of applications referred to CMD(h) in 2007 is lower than in the first year.

The percentage of applications referred to CMD(h) is approximately 10% for MRP and 6.5% for DCP. In 26% of the referrals finalised by the CMD(h) in 2007 no agreement could be achieved and the products were referred to CHMP.

The number of referrals can be further reduced, especially in the Decentralised procedure. Discussions in the CMD(h) could start earlier around the clock stop. This will allow the Member States to start the scientific discussions earlier and discuss potential options to come to consensus.

It is important that the CMD(h) will continue to be a platform for scientific discussions, if there are different views between the Member States. The CMD(h) should also discuss different standards in assessment and stimulate harmonised interpretation of Guidelines. Cooperation with the CHMP Working parties (Quality, Safety, Efficacy, and Pharmacokinetic Sub-group) has been successful in answering general questions and giving further clarification on Guidelines. This cooperation is very important in developing a harmonised approach also between different procedures (CP, MRP, DCP) and keeping informed on new developments that are considered to be 'state of the art'. This will help to avoid future referrals, but also to agree on common standards in assessment of dossiers.

The recommendations formulated to reduce the numbers of referrals in 2007 are still valid for 2008:

- 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

The following permanent or ad hoc Working groups are in place:

CTS Working Group (Hum+Vet)

It is expected that the tracking system in CTS for paediatric applications in accordance with Art. 45 and 46 of the Paediatric Regulation will be in place Q1 2008.

Validation issues/national requirements

The Group will continue to discuss how to come to a more harmonised approach in validation of dossiers, including electronic submissions.

SPC harmonisation

A new list of products for SPC harmonisation in 2008 will be sent to the European Commission.

Joint CMD(h)-PhVWP Working Group

The agreed procedure on Interactions on safety warnings agreed in PhVWP will be followed and regular meetings of the working group are foreseen in 2008.

The group will work together to advise the European Commission on 'Strategy to better protect Public Health by strengthening and rationalising EU Pharmacovigilance' and focus on fast and simple procedures for implementation of safety information in SPC and PL.

The ongoing project of synchronisation of PSUR submissions and work sharing will be followed.

CMD(h)-EMEA Sub-group on Paediatrics

All paediatric data, submitted in accordance with Art 45 and 46 of the Paediatric Regulation, will be assessed in an EU Work sharing procedure. The Working Group has already provided Guidance to industry on format and type of data to be submitted. The group will follow the process and Work sharing procedure after the submission of information on paediatric data at latest by 26 January 2008 for data submitted according to Art. 45. If appropriate meetings with interested parties can be arranged.

CMD(h)-GCP Inspectors

This group was a new initiative to work closer together in the development of New Guidance papers and create a platform for exchange of information between Inspectors Working Group and CMD(h). The first discussions on the Guideline on the organisation of GCP inspections in the Decentralised procedure took place in 2007. The first Draft of the Guideline should be released in Q1 2008. Other discussions will take place on exchange of information between Inspectors and Regulators and a common approach with regard to outcome of GCP inspections of CRO's involved in conducting bioequivalence trials.

TRANSPARENCY

CMD(h) website

Updating of CMD(h) website was considered as one of the priorities in 2007. After the launch of the new HMA website the CMD(h) subgroup has discussed proposals for a better structure of the information. This work will be finalised Q1 2008.

CMD(h) has increased transparency, especially with regard to the information on reasons and outcome of CMD(h) referrals. Further discussion is needed on how transparency on the agreements made in CMD(h) and CHMP can be increased.

A first joint meeting with EGA was organised in 2007 to discuss together with Inspectors and the Pharmacokinetic Experts the outcome of discussions with regard to bioequivalence and GCP after CMD(h) referrals.

Such opportunities will be used again in 2008 to give interested parties more feedback on general questions and outcome of discussions in CMD(h) referrals.

After the successful second Workshop together with EMEA/QRD on the assessment of Readability test it was agreed also to organise in 2008 a meeting with interested parties to discuss two years experience with Readability testing.

VARIATION REGULATION

CMD(h) has discussed the Commission's proposals on the update of the Variation regulation. This will be continued in 2008 with a focus on the foreseen enhanced role of CMD(h) such as with work sharing and in Type II procedures in which RMS and CMSs could not agree on the outcome of Variation procedures in MRP/DCP.

THE SECRETARIAT

The support of CMD(h) secretariat is extremely important for the functioning of CMD(h). It includes amongst others organisation of the meetings, drafting Agenda and Minutes, follow-up actions, coordination of referrals and liaison with other committees and Working Parties. In view of the increase in number of procedures and activities increase in administrative staff has been requested to EMEA.