

**POSITION PAPER ON THE PRESENT TRANSPARENCY POLICY
OF THE COORDINATION GROUP FOR MUTUAL RECOGNITION
AND DECENTRALISED PROCEDURES – HUMAN (CMD(h))**

February 2007

Introduction

The CMD(h) is composed of members of the agencies of medicinal products in EU member states (MS) plus the three EFTA states Iceland, Lichtenstein and Norway, the latter due to the European Economic Area Agreement. A representative from the European Commission attends the meetings. The CMD(h) handles questions on interpretation of legal requirements of European legislation and guidelines related to applications for marketing authorisations for medicinal products submitted via the Mutual Recognition (MRP) or Decentralised Procedures (DCP).

The aim of the CMD(h) is to present a harmonised view on the interpretation of Pharmaceutical legislation and ensure consistency of standards and good quality decision making across the EU. Furthermore, CMD(h) aims for consensus, in the CMD(h) referral procedures, by trying to solve disagreements in specific MRP/DCP application procedures where an agreement was not reached during the earlier phase of the procedure.

The European legislation places certain requirements on national medicines agencies to ensure that the public will have access to relevant information pertaining to the process of accepting new medicinal products. Agencies are therefore working to establish rules so that these requirements as far as possible can be met with a common approach.

For groups such as the CMD(h) there is no specific transparency requirement in the legislation. It is however, important for the CMD(h) also to be transparent in its work and decision making. The group is therefore following closely the discussions presently taking place in different fora and will, whenever relevant and feasible, follow decisions being made regarding transparency and access to information.

Present practice

The CMD(h) is currently practicing transparency and openness to its activities mainly through its press releases (monthly reports), Questions and Answers, guidance documents covering a broad area of subjects and the MRI-Product Index. Furthermore its composition, Rules of Procedure, functions and tasks have been published. The published information is found on the website of the CMD(h): <http://www.hma.eu/cmdh.html>

The CMD(h) also shares the view expressed in the EMEA paper “Principles to be applied for the Deletion of Commercially Confidential Information for the Disclosure of EMEA documents”

Press releases

The CMD(h) is issuing press releases after its monthly meetings and after its informal meetings. The press release discloses matters which may be of interest to industry, health personnel or the public. The information released pertains to matters where decisions have been made and the result can be made public. Decisions are much related to papers stating positions, standard operating procedures, best practice guides etc. and to industry guidance. The documents themselves are then placed on the website of the CMD(h).

The press release also contains information on the referrals to the CMD(h), according to Article 29(1) of Directive 2001/83/EC, as amended, where the referral phase is completed at CMD(h) level such as: Name of the medicinal product, name of the active substance, pharmaceutical form, procedure no, name of the concerned member states of the procedure (the CMS), legal basis for the application, reason for referral to the CMD(h), date of Day 60 (end of referral phase to CMD(h)), outcome of the referral phase: agreement reached or further referral to the CHMP. Lately the press release also contains information explaining, in the case of agreement, how this was achieved.

The press release will also give statistics showing the numbers of applications in different categories, thus illustrating the activity within the different areas of mutual assessment and recognition of applications for marketing authorisations and the variations of these.

Furthermore there is information regarding positively concluded procedures where new active substances have been through an assessment or recognition procedure. The information given includes: Name of the medicinal product, name of the active substance, name of the holder of the marketing authorisation, accepted indication, procedure no and Day 90/Day 210 (end of procedure)

Questions and answers

The CMD(h) will regularly publish Questions and Answers to ensure that guidance given to interested parties is transparent and the result of a common CMD(h) approach.

Guidance documents

As need arise CMD(h) develops, updates and publishes position papers and a broad range of guidance documents. The majority of the papers are published for consultation with interested parties before final adoption. This is again in order to be transparent and open about CMD(h) activities.

MRI-Product Index (European Product Index)

This index contains medicinal products which have been granted a marketing authorisation through the Mutual Recognition or the Decentralised procedures. It gives some key information including the member states which have been included in the procedure and thus should have the product on their market. It was developed to make visible to the public which medicinal products have been the subject of a mutual recognition. This is the web address: <http://www.hma.eu/mri.html>

The Public Assessment Reports following the completion of MR and DC procedure applications will be made publicly available on the MRI-Product Index.