



## FUNCTION AND TASKS FOR CMD(h)

*February 2006*

Directive 2001/83/EC as amended by 2004/27/EC sets up a co-ordination group, named CMD(h), to examine any question related to marketing authorisations through mutual recognition or decentralised procedures. The CMD(h) had its first meeting on 14 November 2005 and has made up its own rules of procedure. The rules of procedure entered into force on 20 February 2006 after a favourable opinion by the European Commission and have been made public.

### **TASKS SPECIFIED IN LEGISLATION**

The Directive provides direction for the work of CMD(h) in the following articles.

#### **Article 27 (1)**

A coordination group should be set up for the examination of any question relating to marketing authorisation of medicinal product in two or more Member states.

#### **Article 29 (1) and (3)**

In the case of disagreement between Member States on the grounds of potential serious risk to public health, the application will be considered by the CMD(h) and MS will use their best endeavours to reach agreement on the action to be taken.

In the case of an unsolved disagreement in a specific procedure, the matter must be referred to the CHMP for arbitration.

#### **Article 30 (2)**

In order to promote harmonisation of marketing authorisations across the Community, the CMD(h) will lay down a list of products where the SPC needs to be harmonised taking into account the proposals from Member States.

## **MANDATE FOR CMD(h)**

The Heads of Medicines Agencies (HMA) has endorsed a mandate for the CMD(h):

The mandate of the CMD(h) is:

1. To address procedural, regulatory and scientific issues arising from the mutual recognition and decentralised procedures.
2. To consider points of disagreement raised by a Member State in relation to the assessment report, SPC, labelling and package leaflet of a medicinal product on the grounds of potential serious risk to public health within a mutual recognition or decentralised procedure.
3. To facilitate the establishment of dialogue between Member States, in general through meetings and concerning particular procedures through oral explanations and to provide a forum to discuss any difficulties in dialogue and seek to overcome such difficulties.
4. To control the practical application of a “potential serious risk to public health taking account of:
  - guidelines to be adopted by the Commission that provide a definition;
  - the legal grounds for refusal/suspension/revocation of an application/marketing authorisation in accordance with Articles 26 and 116 of Directive 2001/83/EC.
5. In order to promote harmonisation of marketing authorisations across the Community, to lay down a list of products where the SPC needs to be harmonised taking into account proposals from Member States. This will be done on an annual basis.
6. To facilitate the resolution of procedural, regulatory and scientific issues arising from variation and renewal procedures, with a view to maintain harmonisation of a marketing authorisation following a mutual recognition or the completion of a decentralised procedure or following a referral.
7. To identify issues which will be referred to the Commission, the Pharmaceutical Committee, HMA, and other appropriate bodies.
8. In close liaison with the Pharmacovigilance Working Party (PhVWP) of CHMP, to ensure best practice for risk management of marketing authorisations granted through the mutual recognition or decentralised procedure. Specifically, the CMD(h) and the PhVWP, will have joint responsibility for the efficient processing of periodic safety update reports (PSURs) across Member States, making provision for work sharing when applicable, and co-ordinating the synchronisation of birth dates if necessary.
9. To undertake tasks concerning the overall management of the mutual recognition and decentralised procedures, maintaining close interaction with HMA.

To make the CMD(h) function as intended the members must try to reach agreement on issues arising during MRPs and DCPs; therefore the members will need to have sufficient authority from their MS.

Members should bring back to their agency the background for agreements in the CMD(h). Such feedback is important to reach a harmonised interpretation of directives, guidelines etc.

## **ROLE OF CMD(h)**

The scope for the work of CMD(h) is not only new application for medicinal products but by analogy will be followed also for renewals, extension and variations. The procedure described in article 29 (CMD(h) referral) is applicable for new applications, extensions and renewals. In addition, the applicant has the right to request an oral explanation before the CMD(h), if felt appropriate.

The CMD(h) will develop and keep updated standard operation procedures (SOPs), guidelines and recommendations for use by Member States and applicants/marketing authorisation holders. The CMD(h) will present a harmonised view on the interpretation and implementation of directives and regulations in order to facilitate handling and finding solutions.

## **DISAGREEMENTS IN PROCEDURES**

The CMD(h) will undertake the necessary discussion to resolve scientific problems related to specific procedures, see also SOP on disagreements in procedures.

The CMD(h) will consider oral and/or written explanations from applicants. The aim is to solve the majority of issues and avoid arbitrations. Every effort should be made to reach an agreement and refer to CHMP only in exceptional cases.

The CMD(h) will identify and communicate to the EMEA when necessary the need for modification or development of new guidelines or any particular areas requiring the establishment of ad hoc groups, which shall not overlap already existing ones.

The CMD(h) will reach a common understanding of the Commission guideline on potential serious risk to public health, which members could communicate within their agencies. This agreed understanding should form the basis for referring a product application to arbitration.

General scientific issues that relate more broadly to medicinal products may be referred to the CHMP and its working parties for advice needed to reach a timely decision.

The expertise of the Committee on Herbal medicinal Products may also be used by CMD(h).

## **HARMONISATION OF SPCs**

The CMD(h) is obliged to lay down a list of medicinal products for which a harmonised SPC should be drawn up. This list should take account of proposals from Member States and the list shall be forwarded to the Commission once a year. The views from the interested parties shall be taken into account. A subgroup of CMD(h) could be used to prepare the list and to communicate with interested parties, EMEA and the Commission.

## **PHARMACOVIGILANCE**

It is a priority for CMD(h) to cooperate with PhVWP to take forward recommendations in relation to risk management strategies for products approved through national procedures, In this regard a joint CMD(h)/PhVWP sub-group has been established with a mandate to cover issues such as the Best Practice Guide for effective CMD(h)/PhVWP liaison, development of a crisis management plan and work sharing of PSURs. The mandate will be subject to review and updating as the need arises.

## **PRODUCT INFORMATION**

CMD(h) will encourage and facilitate the approval of SPCs that reflect the highest scientific standards of work. The perspective of users will be taken into account when agreeing patient information, and CMD(h) will strive to improve the quality of package leaflets and follow agreed principles reflected in the Commission's guideline on readability (currently subject to revision).

## **WORKING PARTIES**

When necessary, the CMD(h) may decide to create ad-hoc working parties for permanent or temporary purposes such as the CTS group to work with the CTS User Group and to encompass work on special projects, e.g. a database for regulatory memory and Product Information Management, SPC harmonisation, PhVWP/CMD, etc. Members of a working party and its chairperson will be appointed by the CMD(h).

The CMD(h) shall adopt the mandate and objectives of each working party and the duration of their activity. The activity of the working parties shall not overlap the work in existing working parties instead CMD(h) should cooperate with other working parties at European level.