

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

**SUMMARY OF ACTIVITIES IN 2005**

**Web Sites:**

Heads of Medicines Agencies for human medicines

<http://heads.medagencies.com/>

European product index

<http://mri.medagencies.com/prodidx/>

EMA/CMD(h) SECRETARIAT (E-MAIL)

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The Mutual Recognition Facilitation Group (MRFG), in operation over the last 10 years to coordinate and facilitate the operation of the mutual recognition procedure, held its final meeting in October 2005.

The group was composed of delegates from the EU, Iceland and Norway. Observers from the European Commission and accession countries also participated in the meetings. The Group reported to the Heads of Medicines Agencies for human medicines.

In November 2005, the MRFG was replaced by the Co-ordination Group for Mutual Recognition and Decentralised Procedures – Human, CMD(h), set up in the new legislation for the examination of any question relating to marketing authorisation of a medicinal product in two or more Member States in accordance with the mutual recognition procedure or the new decentralised procedure.

The MRFG met nine times in 2005. Mrs. Truus Janse-de Hoog chaired the meetings on behalf of the Luxembourg presidency in the first half of 2005 and Ms. Shirley Norton during the UK presidency in the second half of the year until the final meeting of the MRFG in October 2005. Press releases with statistics and adopted documents were published monthly on the Heads of Medicines Agencies website. Two informal meetings were held in 2005 in Luxembourg and in Dorking, UK.

The preparation for the implementation of the new pharmaceutical legislation and arrangements for the new Co-ordination Group were permanent items on the agendas of the MRFG meetings. The MRFG published a Q&A document outlining practical considerations on the implementation of the new legislation to medicinal products for human use authorised or applied via the mutual recognition procedure or the new decentralised procedure.

The MRFG published guidance on the new Decentralised procedure, the 60 days pre-referral procedure in case of disagreement between MS in a MRP/DCP, the new requirements for patient information, assessment and approval of the PL and labelling in the MRP/DCP, the public assessment report, guideline on submission of renewals in the MR/DC procedures, etc.

The MRFG worked in close collaboration with the EMEA in the development of guidance for the authorisation and supervision of medicinal products for human use in line with the provisions of the new EU pharmaceutical legislation.

Following the endorsement by the Heads of Medicines Agencies of the proposal for work sharing in the assessment of paediatric data, the MRFG agreed on a Best Practice Guide, which has been published on the Heads of Medicines Agencies website.

In view of the experience gained with recent urgent safety restrictions, the MRFG worked on the update of the Urgent Safety Restriction – Member States Standard Operating Procedure in close liaison with the PhVWP.

In addition, the MRFG continued to develop and update new guidance papers to assist marketing authorisation holders and national competent authorities and to answer questions from Interested Parties.

The Co-ordination Group for Mutual Recognition and Decentralised Procedure held its inaugural meeting in November 2005.

The activities included an informative session to Interested Parties on the new decentralised procedure, the referral procedure to the CMD(h) in case of disagreement between MS in a MRP/DCP and a session of questions and answers, followed by speeches from major contributors to the EU Pharmaceutical Regulatory System and a reception.

Mrs. Truus Janse-de Hoog was elected Chairperson of the CMD(h) for a term of three years. The Vice-Chair was Ms. Shirley Norton for the duration of the term of the UK presidency of the Council of the European Union.

The CMD(h) adopted the Rules of Procedure for the Co-ordination Group for Mutual Recognition and Decentralised Procedure, which were sent to the European Commission for a favourable opinion, as provided for in Article 27(3) of Directive 2001/83/EC, as amended.

The arrangements for conducting the CMD(h) business, the preparation of the work plan for the CMD(h) and the timelines for the update of MRFG guidance documents, to reflect the new pharmaceutical legislation and to consider, where appropriate the new decentralised procedure were some of the items on the agendas of the CMD(h) meetings.

A number of MRFG/CMD(h) subgroups meetings were held during 2005.

The Subgroup on CTS, dealing with the Mutual Recognition Procedures tracking system, met 6 times in 2005.

An updated version of the CTS software, incorporating tracking of the decentralised procedure, was deployed on 1 November 2005 to all Member States.

The Variation Sub-group met once in 2005 to continue discussions on an harmonised approach in the assessment of variations, submitted in accordance with the Commission Regulation (EC) No 1084/2003. The Sub-group agreed an updated version of the Questions & Answers list for the submission of variations according to Commission Regulation (EC) No 1084/2003, which was adopted by the MRFG and published on the HMA website.

The Sub-group on Article 17 and 18 procedures, set up in 2004 to discuss the triggering of the MRP for pending applications in new Member States on 1 May 2004, met twice in 2005.

The Joint MRFG/QRD Working Group on Patient information, set up to consider the new legal requirements for patient information met 3 times in 2005. A workshop was organised to discuss the structure and content of package leaflets in different Member States, in order to develop a harmonised view regarding the assessment of the PL in the MRP/DCP.

The Working Group developed a Concept paper – Achieving harmonised patient information to assist Marketing Authorisation Holders with the new requirements of harmonised labelling and package leaflets for marketing authorisations granted in accordance with the MRP/DCP, which was adopted by the MRFG and published on the HMA website.

The joint Pharmacovigilance Working Party/ MRFG Working Group met 3 times in 2005, twice with Interested Parties mainly to discuss the synchronisation of PSUR submissions and the PSUR work-sharing project.

In view of the role of the Coordination group to lay down a list of medicinal products for which a harmonised SPC should be drawn up, in accordance with Article 30(2) of Directive 2001/83/EC, as amended, a Sub-Group with representatives from the CMD(h), CHMP, EMEA and EC was set up. The CMD(h) endorsed, at its inaugural meeting, the mandate of the CMD(h) Sub-group on harmonisation of SPCs, which has been published on the HMA website. The Sub-Group on harmonisation of SPCs met 3 times in 2005 mainly to discuss the criteria for selection of products for SPC harmonisation and to consider the comments received from Interested Parties.

The EMEA supported the chairpersons, the MRFG/CMD(h) and the respective subgroups in their activities, including the organisation of a meeting for the transition of the presidency and the inaugural meeting of the Co-ordination Group for Mutual Recognition and Decentralised Procedures – Human, CMD(h).

The secretariat was also in charge of answering the questions received at the EMEA from Interested Parties in relation to the Mutual Recognition Procedure/new Decentralised Procedure, in liaison with the Chairperson.

The number of new applications and variations finalised in 2005 has increased compared to 2004. In addition, there was an increase in the number of arbitrations for type II variations and a decrease in the number of arbitrations for new applications.

The decrease in the number of arbitrations for new applications might be partially explained by the new provision in the revised pharmaceutical legislation, according to which in case of disagreement between MS for a MRP or DCP, the points of disagreement are referred to the CMD(h).

From 30 October 2005 until the end of 2005, 10 procedures were referred to the CMD(h) in accordance with Article 29(1) of Directive 2001/83/EC, as amended.

Statistical information on applications under the mutual recognition procedure and the new decentralised procedure is provided by the EMEA and presented in the monthly MRFG/CMD(h) press releases.

	<b>Total submitted in 2005*</b>	<b>Under evaluation in 2005*</b>	<b>Ended positively in 2005*</b>	<b>Referrals to CHMP in 2005</b>	<b>Referrals to CMD(h) in 2005</b>
New applications MRP	826	137	954	2	10
New applications DCP	31	9	N/A	N/A	N/A
Type-IA variations	4681	404	4044	N/A	N/A
Type-IB variations	2299	372	1944	0	N/A
Type-II variations	2050	855	1509	7	N/A

\*The numbers include multiple procedures as stated at 31 December 2005.

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