



Report from the meeting held on 10th and 11th October 2005

Final meeting of the Mutual Recognition Facilitation Group

The October meeting was the final meeting of the Mutual Recognition Facilitation Group. This Group was an informal group established by the member states in March 1995 to coordinate and facilitate the operation of the mutual recognition procedure.

The new legislation sets up a formal Group, the Coordination group, 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 Coordination group for the mutual recognition and decentralised procedure – human, to be known as CMD(h), will start its activities in November 2005. Practical arrangements for the transition from the MRFG to the CMD(h) have been agreed at the October meeting.

The MRFG would like to thank all MRFG members, past and present, and Interested Parties for the contribution, over the last 10 years, to the success of the MRFG.

General Issues

Guideline on the processing of renewals in the mutual recognition and decentralised procedures

The MRFG has considered the comments received on the Guideline on the processing of renewals in the mutual recognition and decentralised procedures following the consultation procedure. The final Guideline will be published shortly on the website.

Decentralised procedure – Member States' Standard Operating Procedure

The MRFG has finalised the Decentralised procedure – Member States' SOP, taking account of the comments received following the consultation procedure. The final SOP for the Decentralised procedure will be published on the website.

Disagreement in procedures – referral to CMD

The MRFG has considered the comments received from Interested Parties on the CMD SOP – Disagreement in procedures – referral to CMD. The final SOP will be published on the website to coincide with the Notice to Applicants updated chapters.

Guidance document – Information to be submitted by the Member State of the European Reference Product

The MRFG has agreed a guidance document on the information to be transmitted by the Competent Authority of the Member State of the European reference product to the Competent Authority of the Member State where an application has been submitted, in accordance with Article 10(1) of Directive 2001/83/EC, as amended, when the reference medicinal product is not authorised in that Member State. The Guidance document will be published on the website for information.

Usage patent common statement in the Package Leaflet

The MRFG, having taken account of views of the EMEA/CHMP Working Group with Patient Organisations, has agreed a statement to be included in the Package Leaflet of generic medicinal products for indication(s) or dosage form(s) of the reference medicinal product covered by patent law, in accordance with Article 11 of Directive 2001/83/EC, as amended.

The MRFG has agreed to publish the proposed statement for a 4-week consultation period with Interested Parties.

Any comments or proposals on the proposed statement for the PL should be sent by 10 November 2005 coordinated where possible by trade associations, to the CMD(h) secretariat (sonia.ribeiro@emea.eu.int).

Annotated QRD template for MR/DC procedures

The MRFG, in collaboration with the QRD, has adapted the annotated QRD product information template for medicinal products for human use with guidance suitable for use in the Mutual Recognition and Decentralised procedures. The adapted MRP/DCP QRD annotated template will be published on the website. The 'clean' version of the template for completion by applicants will be found on the EMEA website.

Standard Operating Procedure for Article 61(3) changes to patient information

The MRFG has agreed a procedure to maintain the harmonisation of labelling and package leaflet of medicinal products approved via the decentralised or mutual recognition procedure concerning changes not connected with the summary of product characteristics, in accordance with Article 61(3) of Directive 2001/83/EC, as amended.

The SOP and the notification form will be published on the website.

The intention of the Group is to review the procedure in 3 months, in light of experience and initial comments received from Interested Parties (to be sent by 10 November 2005 to the CMD(h) secretariat (sonia.ribeiro@emea.eu.int)).

Best Practice Guide for the Public Assessment Report in the Decentralised and Mutual Recognition Procedure

The MRFG has agreed a Best Practice Guide for the Public Assessment Report in the Decentralised and Mutual Recognition Procedure, to comply with the requirements set out in Article 21(4) of Directive 2001/83/EC, as amended. The Best Practice Guide will be published on the website for a 4-week consultation period with Interested Parties.

Any comments on the BPG should be sent by 10 November 2005 coordinated where possible by trade associations, to the CMD(h) secretariat (sonia.ribeiro@emea.eu.int).

Best Practice Guide for the Mutual Recognition Procedure & Procedure for Automatic Validation of MR Procedures for New Applications

The MRFG has agreed an updated BPG for the Mutual Recognition Procedure, to take account of the new legislation and to include a flow chart for the mutual recognition procedure.

The Procedure for Automatic Validation of MR Procedures for New Applications has also been updated.

Any comments on the draft updated documents should be sent by 10 November 2005 coordinated where possible by trade associations, to the CMD(h) secretariat (sonia.ribeiro@emea.eu.int).

Guidance on submission dates for Applicants of the Decentralised and Mutual Recognition Procedures

A Guidance document on submission dates for Applicants of the Decentralised procedure and an updated Guidance document on submission dates for Applicants of the Mutual Recognition Procedure, to include dates for 2006 and 2007, has been adopted by the Group and will be published on the website.

Urgent Safety Restriction – Member States' Standard Operating Procedure

The Urgent Safety Restriction – Member States' Standard Operating Procedure has been updated by the MRFG, in collaboration with the PhVWP. As a consequence the Variations Best Practice Guide has been updated and the amended version will be published on the website.

Any comments on the draft updated Urgent Safety Restriction SOP should be sent by 10 November 2005 coordinated where possible by trade associations, to the CMD(h) secretariat (sonia.ribeiro@emea.eu.int).

New Questions and Answers on the implementation of the new legislation

The MRFG has agreed 4 new Q&A to address applications for marketing authorisation for generic medicinal products for indications within the mandatory scope of the centralised procedure; timing in a MR/DC procedure for consultation with target patient groups for the PL; information on marketing of medicinal products; and withdrawals in MR/DC procedures. The updated Q&A document will be published on the website.

Working group meeting on harmonisation of SPCs

The working group met in October to continue the preparatory discussions on the role of the Coordination group to promote harmonisation of authorisations for medicinal products in the Community and to consider the timing and process for selection of medicinal products for SPC harmonisation.

Meeting schedule

The inaugural CMD(h) meeting will be held on 14th and 15th of November 2005.

Mutual Recognition Monitoring

The MRFG noted that **89** new mutual recognition procedures were finalised during the month of September 2005, as well as **336** type IA variations, **180** type IB variations and **186** type II variations.

The status as of 30th of September of procedures under mutual recognition is as follows:

Year	Procedures from New applications finalised	Procedures from New applications in process	Procedures from Type IA variations finalised	Procedures from Type IB variations finalised	Procedures from Type II variations finalised	Arbitrations referred to CHMP
2005	782	221	3006	1440	1065	2 N.A. 6 Var.

72 new procedures (regarding **136** products) started in September 2005. The categories of these procedures are as follows:

1 new active substance classified as repeat use.

17 known active substance (already authorised in at least one member state) including **4** multiple applications and **3** repeat use.

52 abridged applications including **14** multiple applications and **10** repeat use.

2 line extension applications.

The new procedures started related to **7** full dossiers, **45** generics, **10** bibliographic applications, **3** fixed combinations, and **7** for different use, route or dose.

The procedures consisted of **70** chemical substances, **1** biological-vaccine and **1** biological-other¹.

70 of these procedures were prescription-only medicinal products in the reference Member State and **2** procedures were classified as a Non-prescription (including OTC) medicinal products².

1. As considered by RMS.

2. In this category products are classified as prescription-only or Non-prescription (OTC) products when the RMS has approved them accordingly, although the legal status is not part of the Mutual Recognition Procedure.

Number of countries involved in the new applications procedures started in September 2005

Reference Member State (number of products involved in the procedure)	Number of CMSs involved in the procedure
AT (2)	9
CZ (1)	9
CZ (4)	6
DE (1)	1
DE (1)	10
DE (1)	3
DE (2)	11
DK (1)	5
DK (1)	1
DK (2)	2
DK (3)	7
DK (3)	9
DK (2)	13
ES (1)	4
FI (5)	15
FI (5)	6
FI (5)	3
FI (1)	1
FI (1)	4
FI (2)	1
FI (2)	1
FI (2)	5

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Reference Member State (number of products involved in the procedure)	Number of CMSs involved in the procedure
FI (1)	13
FI (2)	8
FI (2)	1
FR (1)	2
FR (2)	22
FR (2)	20
FR (1)	3
HU (1)	6
HU (1)	7
HU (1)	2
HU (1)	9
HU (1)	4
HU (1)	1
HU (1)	1
IT (1)	2
IT (1)	3
NL (2)	10
NL (1)	8
NL (1)	5
NL (2)	2
NL (4)	1
NL (2)	9
NL (1)	4
NL (2)	2
NL (3)	3
PT (2)	6
PT (2)	9
SE (4)	6
SE (2)	15
SE (2)	6
SE (2)	5
SE (1)	1
SE (1)	1
SE (1)	1
SE (1)	13
SE (2)	12
SE (2)	1
UK (4)	12
UK (1)	5
UK (2)	11
UK (2)	2
UK (2)	12
UK (1)	4
UK (1)	16
UK (1)	6
UK (2)	7
UK (2)	2
UK (4)	1
UK (6)	12
UK (2)	16

All documents mentioned in this press release can be found at the MRFG website at the European Medicines Authorities Windows under the heading *MRFG Guidance*.

Information on the above mentioned issues can be obtained from the presiding chair of the MRFG:

Ms. Shirley Norton

Phone: + 44 207084 2390

Medicines and Healthcare products Regulatory Agency

Fax: + 44 207084 2293

1 Nine Elms Lane – Market Towers

e-mail: Shirley.norton@mhra.gsi.gov.uk

London SW8 5NQ

United Kingdom

*Or you could visit the **MRFG web site** at the EUROPEAN NATIONAL MEDICINES AUTHORITIES WINDOW:*

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