



## **Report from the meeting held on 23 June 2003**

### **General Issues:**

#### Updated Best Practice Guides published for consultation:

The following MRFG Best Practice Guides have been updated to give detailed procedural guidance on the new Variation Regulation and have been published on the Heads of Agencies website for consultation. Notifications have been sent to the pharmaceutical trade associations EGA, EFPIA and AESGP at time of publication. Any response is kindly requested through the pharmaceutical trade associations and should be forwarded via email to the EMEA/MRFG Secretariat ([mrp@emea.eu.int](mailto:mrp@emea.eu.int)) by the 1 July 2003:

#### **CHAPTER 1**

MRFG Best Practice Guide for the allocation of the Mutual Recognition Variation Number for Type I Notifications and Type II Variations

#### **CHAPTER 2**

Procedure for the Automatic Validation of Mutual Recognition Procedures for Variations

#### **CHAPTER 3**

MRFG Best Practice Guide for the Processing of Type IA Minor Variations (Notifications) in the Mutual Recognition Procedure

#### **CHAPTER 4**

MRFG Best Practice Guide for the Processing of Type IB Minor Variations (Notifications) in the Mutual Recognition Procedure

#### **CHAPTER 5**

MRFG Best Practice Guide for the handling of Variations in the Mutual Recognition Procedure: Type II Variations

#### **CHAPTER 6**

MRFG Standard Operating Procedure: Urgent Safety Restriction

#### Applications in CTD format in the MRP

Following the publication of Annex I to Dir. 2001/83, MAHs are strongly recommended to submit the new applications in the CTD format after the 1<sup>st</sup> July 2003, when they request member states to become RMS for MRPs after national approval.

The CTD format is also strongly recommended for MRP variations submitted after the 1<sup>st</sup> July 2003.

#### Change in the EU-Presidency

The June 2003 MRFG meeting was the last one under the Greek presidency. Italy will take over the presidency in July 2003. Sylvia Fabiani will be the next MRFG chairperson and she should be contacted in the future in case of any questions regarding the MRP.

#### Meeting schedule

The next MRFG meeting will be held on 21 July 2003.

## Mutual Recognition Monitoring

The MRFG noted that **27** new mutual recognition procedures were finalised during the month of May 2003, as well as **195** type I and **73** type II variations.

The status as of 31<sup>st</sup> May 2003 of procedures under mutual recognition is as follows:

Year	Procedures from New applications finalised	Procedures from New applications in process	Procedures from Type I variations finalised	Procedures from Type I variations pending	Procedures from Type II variations finalised	Procedures from Type II variations pending	Arbitrations referred to CPMP
2003	162	104	968	348	223	287	2 N.A. and 1 Variation

**31** new procedures (regarding **74** products) started in May 2003. The categories of these procedures are as follows:

**9** known active substances (already authorised in at least one member state), including **2** repeat use.

**21** abridged applications, including **9** multiple applications.

**1** Line extension application.

The new procedures started related to **2** full dossiers, **21** generics, **4** bibliographic applications and **4** fixed combinations.

The procedures consisted of **31** chemical substances<sup>1</sup>.

**28** of these procedures were prescription-only medicinal products in the reference Member State and **3** were Non-prescription (including OTC) medicinal products<sup>2</sup>.

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.

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Number of countries involved in the new applications procedures started in May 2003

Reference Member State (number of products involved in the procedure)	Number of CMSs involved in the procedure
DE (1)	13
DE (1)	2
DE (1)	4
DE (1)	1
DE (1)	1
DK (4)	2
DK (8)	4
DK (1)	1
ES (2)	2
NL (3)	1
NL (3)	1
NL (3)	3
NL (3)	1
NL (3)	2
NL (3)	5
NL (3)	1
NL (3)	1
NL (3)	1
NL (3)	9
NL (3)	2
NL (3)	5

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Reference Member State (number of products involved in the procedure)	Number of CMSs involved in the procedure
NL (3)	1
NL (1)	3
NO (3)	8
NO (2)	6
NO (3)	3
NO (2)	3
SE (1)	1
UK (1)	1
UK (3)	15

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

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

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*Or you could visit the **MRFG web site** at the EUROPEAN NATIONAL MEDICINES AUTHORITIES WINDOW:  
<http://heads.medagencies.org/>*