



Report from the meeting held on 21 July 2003

General Issues

Position Paper on Repeat Use of the MRP

The Group agreed on a wording which will be integrated in the “Position Paper on Repeat Use of the MRP” in order to include the case of simplified CADREAC procedure:

“Although the normal timeframe for the repeat-use procedure is 90 days, in the case of existing marketing authorisations for the identical product granted via the ‘simplified CADREAC procedure’ this period may be reduced to 30 days with the agreement of all member states involved in the procedure. Agreement means that the new member states can accept the current MR-SPC in the repeat use without any comments and are therefore prepared to grant a marketing authorisation. If all MSs involved in the repeat-use procedure will inform the RMS between day 25 and day 29 at the latest, the RMS will finalise the procedure at day 30.”

The final revised “Position Paper on Repeat Use of the MRP” will be adopted at the September meeting.

Best Practice Guides for the Submission and Processing of Variations in the Mutual Recognition Procedures

A final version of the “Best Practice Guides for the Submission and Processing of Variations in the Mutual Recognition Procedures” were adopted by the MRFG after minor changes following consultation of Industry.

The Best Practice Guides will be published on the MRFG website. It should be noted that given that the BPGs are applicable only as of 1st October 2003 when the new Variation Regulation (EC) 1084/2003 comes into force, both the new BPGs and the old guidance documents relating to the old Variation Regulation will have to coexist for a few months on the website. To this purpose the expiry date of the soon to be outdated documents and the new BPGs will be made clearly identifiable on the website.

Application of the Variation Regulations

The European Commission confirmed that the Variations will be handled under the new or the old Regulation according to the date of submission.

Mutual Recognition Monitoring

The MRFG noted that **36** new mutual recognition procedures were finalised during the month of June 2003, as well as **238** type I and **79** type II variations.

The status as of 30th June 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	198	109	1206	381	302	293	2 N.A. and 2 Variations

41 new procedures (regarding **87** products) started in June 2003. The categories of these procedures are as follows:

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

34 abridged applications; including **12** multiple applications and **1** repeat use.

1 line extension application and

2 new active substances.

The new procedures started related to **5** full dossiers, **30** generics, **2** bibliographic applications, **2** informed consents and **2** other.

The procedures consisted of **39** chemical substances, **1** biological-vaccine and **1** biological blood product¹.

38 of these procedures were prescription-only medicinal products in the reference Member State and **3** were 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 June 2003

Reference Member State (number of products involved in the procedure)	Number of CMSs involved in the procedure
DE (4)	12
DE (1)	4
DE (1)	14
DK (2)	1
DK (4)	10
DK (2)	8
DK (2)	8
FI (1)	3
FI (1)	1
FI (1)	1
FI (1)	1
FI (1)	2
FI (1)	1
FI (1)	6
FR (5)	1
NL (3)	1
NL (2)	10
NL (2)	11
SE (4)	1
SE (2)	1

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Reference Member State (number of products involved in the procedure)	Number of CMSs involved in the procedure
SE (2)	7
SE (2)	1
SE (2)	1
SE (2)	7
SE (2)	8
SE (2)	1
SE (2)	1
SE (2)	3
UK(1)	3
UK(1)	1
UK(3)	8
UK(2)	11
UK(1)	4
UK(2)	5
UK(2)	4
UK(2)	1
UK(2)	1
UK(2)	1
UK(3)	5
UK(4)	3
UK(4)	1

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/>