



Report from the meeting held on 22 September 2003

General Issues

Position Paper on Repeat Use of the MRP

The final revised “Position Paper on Repeat Use of the MRP” was adopted at the September meeting and will be published on the Website. The document now contains a paragraph on “Special case – simplified CADREAC procedure”.

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

The revised version of the “Best Practice Guides for the Submission and Processing of Variations in the Mutual Recognition Procedures” has been published on the MRF G website.

The BPGs are applicable only as of 1st October 2003 with the entry into force of the new Variation Regulation (EC) 1084/2003. All information about the numbering system for the new Variation procedures can be found in this document.

Mutual Recognition Monitoring

The MRFG noted that **69** new mutual recognition procedures were finalised during the months of July and August 2003, as well as **628** type I and **185** type II variations.

The status as of 31 August 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	267	190	1834	376	487	220	2 N.A. and 2 Variations

150 new procedures (regarding **402** products) started in July and August 2003. The categories of these procedures are as follows:

3 new active substances consisted of 2 chemical substances and 1 biological vaccine.

16 known active substances (already authorised in at least one member state), including **2** multiple and **2** repeat uses.

123 abridged applications; including **36** multiple applications and **1** repeat use.

8 line extension application and

The new procedures started related to **17** full dossiers, **99** generics, **6** bibliographic applications, **1** informed consent, 1 fixed combination and **26** other.

The procedures consisted of **145** chemical substances, **2** biological-vaccine and **2** biological blood product and **1** other¹.

142 of these procedures were prescription-only medicinal products in the reference Member State and **8** 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 July and August 2003

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

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Reference Member State (number of products involved in the procedure)	Number of CMSs involved in the procedure
FI (5)	1
FI (3)	15
FI (3)	8
FI (3)	3
FI (4)	2
FI (4)	1
FI (4)	2
FI (4)	6
FI (4)	6
FI (4)	1
FR (2)	8
FR (1)	1
FR (1)	9
FR (1)	8
NL (1)	12
NL (1)	1
NL (1)	1
NL (1)	3
NL (1)	4
NL (2)	10
NL(2)	1
NL (2)	1
NL (2)	11
NL (3)	11
NL (3)	10
NL (4)	4
NL (2)	1
NL (2)	1
NL (2)	1
NL (1)	6
NL (2)	8
NL (2)	5
NL (2)	1
NL (2)	1
NL (2)	1
NL (2)	3
NL (2)	2
NL (2)	8
NL (1)	14
NL (4)	7
SE (1)	4
SE (1)	1
SE (1)	16
SE (2)	2
SE (4)	3
SE (1)	1
SE (2)	2
SE (1)	2
SE (1)	3
SE (1)	7
SE (2)	1
SE (2)	1
SE (2)	1
SE (2)	1
SE (2)	1
SE (4)	3
SE (4)	2
SE (4)	1
SE (4)	1
SE (4)	4
SE (1)	13
UK (2)	5
UK (3)	1

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Reference Member State (number of products involved in the procedure)	Number of CMSs involved in the procedure
UK (3)	5
UK (1)	3
UK (1)	6
UK (1)	7
UK (5)	5

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/>