



Report from the meeting held on 17 November 2003

Mutual Recognition Monitoring

The MRFG noted that **50** new mutual recognition procedures were finalised during the months of October 2003, as well as **243** type I variations and **71** type II variations.

The status as of 30 September 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	363	220	2302	241	627	220	8 N.A. and 1 Variation

39 new procedures (regarding **95** products) started in October 2003. The categories of these procedures are as follows:

2 known active substances (already authorised in at least one member state),

33 abridged applications; including 18 multiple applications,

4 line extension application and

the new procedures started related to **6** full dossiers, **32** generics, and **1** other.

The procedures consisted of **37** chemical substances and **2** biological vaccine products¹.

All of these procedures were prescription-only medicinal products² in the reference Member State.

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 October 2003

Reference Member State (number of products involved in the procedure)	Number of CMSs involved in the procedure
AT (1)	3
AT (1)	14
AT (1)	1
AT (1)	1
AT (1)	1
AT (1)	1
DE (2)	1
DE (2)	1
DE (2)	1
DK (2)	7
DK (3)	4

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Reference Member State (number of products involved in the procedure)	Number of CMSs involved in the procedure
DK (1)	1
DK (2)	1
FI (2)	2
FI (2)	3
FI (2)	6
FI (4)	11
FI (4)	1
FI (4)	1
FI (4)	1
FI (4)	1
FI (4)	1
FI (4)	5
FI (4)	6
FI (2)	1
FI (4)	3
FI (4)	1
FI (4)	1
FI (2)	1
IR (3)	1
NL (1)	12
NL (2)	6
NL (2)	2
NL (2)	1
NL (2)	1
UK (1)	15
UK (3)	2
UK (4)	12
UK (1)	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/>