



Report from the meeting held on 17 February 2003

General issues:

The following new documents will be published on the MRFG website:

- Guidance paper and Templates for the mutual recognition assessment report in the CTD format

Meeting schedule

The next MRFG meeting will be held on 17 March 2003.

Annex 1

Joint CPMP/ MRFG working group on harmonisation of SPCs:

No meeting was held in February.

Mutual Recognition Monitoring

The MRFG noted that 32 new mutual recognition procedures were finalised during the month of January 2003, as well as 164 type I and 39 type II variations.

The status as of 31st January 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	32	97	164	245	39	237	1 N.A.

29 new procedures (regarding 44 products) started in January 2003. The categories of these procedures are as follows:

3 new active substances, classified as repeat use.

10 known active substances (already authorised in at least one member state), including **1** multiple application and **2** repeat use.

11 abridged applications including **3** multiple applications and **2** repeat use.

The new procedures started this month relate to 7 full dossiers, 10 generics, 5 bibliographic applications, 2 fixed combinations and 5 for different use, route or dose.

The procedures consisted of 26 chemical substances, 2 biological- vaccines and 1 biological –other¹.

28 of these procedures were prescription-only medicinal products in the reference Member State and 1 was 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 January 2003

Reference Member State (number of products involved in the procedure)	Number of CMSs involved in the procedure
DE (1)	1
DK (3)	1
DK (1)	5
DK (1)	3
DK (1)	1
DK (1)	1
DK (1)	1
DK (1)	1
DK (1)	3
DK (1)	1
DK (1)	1
ES (1)	6
ES (1)	4
FI (1)	8
FR (2)	9
FR (2)	14
FR (1)	11
NL (1)	9
NL (1)	1
NL (1)	1
SE (2)	1
UK (5)	1

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Reference Member State (number of products involved in the procedure)	Number of CMSs involved in the procedure
UK (2)	4
UK (1)	13
UK (1)	14
UK (2)	1
UK (4)	3
UK (1)	5
UK (2)	4

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 by 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/>