



Report from the meeting held on 19 May 2003

General issues:

EU Enlargement

Following the decision of the European Commission and the HoA, the MRFG has invited the Candidate Countries to nominate representatives to attend their monthly meetings as observers. The nominated representatives of four CEEC countries, which were present at the meeting were welcomed by the Chair. It is expected that all Candidate Countries would be represented in future meetings.

Annex 1

Joint CPMP/ MRFG Working Group on Harmonisation of SPCs:

The progress report of the working group, outlining the current situation and the perspectives of the SPC harmonisation exercise will be presented to the HoA at their meeting on the 28 May 2003 in Athens.

Meeting schedule

The next MRFG meeting will be held on Monday 23 June 2003.

Mutual Recognition Monitoring

The MRFG noted that **31** new mutual recognition procedures were finalised during the month of April 2003, as well as **228** type I and **41** type II variations.

The status as of 30th April 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	135	100	773	292	150	338	1 N.A.

42 new procedures (regarding **90** products) started in April 2003. The categories of these procedures are as follows:

2 new active substances, including **1** repeat use.

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

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

1 Line extension applications, classified as repeat use.

The new procedures started related to **7** full dossiers, **27** generics, **2** bibliographic applications and **1** for different use, route or dose.

The procedures consisted of **39** chemical substances, **2** biological- blood product and **1** biological- other¹.

36 of these procedures were prescription-only medicinal products in the reference Member State and **6** 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 April 2003

Reference Member State (number of products involved in the procedure)	Number of CMSs involved in the procedure
AT (3)	2
AT (1)	1
DE (1)	5
DE (1)	2
DE (1)	10
DE (3)	1
DK (4)	2
DK (3)	1
DK (3)	1
DK (3)	1
DK (3)	1
DK (3)	1
FI (2)	3
FI (2)	1
FI (2)	7
FI (4)	3
FI (1)	1
FI (1)	1
FI (1)	1
FR (3)	11

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Reference Member State (number of products involved in the procedure)	Number of CMSs involved in the procedure
FR (1)	8
FR (1)	9
FR (1)	6
IT (1)	16
NL (1)	16
NL (1)	1
NL (1)	14
NL (3)	1
NL (3)	1
NL (3)	1
NL (3)	2
NO (3)	2
SE (5)	7
SE (5)	1
UK (3)	2
UK (2)	6
UK (2)	6
UK (1)	12
UK (2)	5
UK (1)	4
UK (1)	10
UK (1)	7

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/>*