



Report from the meeting held on 20 January 2003

General issues:

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

- MRFG Recommendation on Implementation of Article 30 Decisions for Generic Products

MRP statistics 2002

Statistics regarding new applications in the MRP in the year 2002 according to the 5-level classification will be available on the Heads of Agencies Website by the end of January 2003.

Applications in CTD format in the MRP

Marketing authorisation holders are reminded that the CTD format will be mandatory for all applications which will be submitted after 1 July 2003.

Simultaneous applications for marketing authorisation in different Member States

If identical applications are submitted in different Member States, companies are strongly recommended to state this in the application form accordingly. Companies are reminded, that in such cases Article 17 paragraph 2 of Directive 2001/83/EC is applied. A relevant SOP is published on the Heads of Agencies Website (http://heads.medagencies.com/mrfg/docs/sops/sim_application.pdf).

Meeting schedule

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

Annex 1

Joint CPMP/ MRFG working group on harmonisation of SPCs:

The group decided to start cooperation with EMACOLEX, to discuss future legislation concerning the harmonisation of SPCs.

On 7 January 2003 the European Commission triggered two new referrals. Pre-referral discussions will begin in February for four new products.

Mutual Recognition Monitoring

The MRFG noted that 46 new mutual recognition procedures were finalised during the month of December 2002, as well as 198 type I and 53 type II variations.

The status as of 31st December 2002 and for the period 1995–2002 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
2002	420	106	2104	224	527	223	2 N.A. and 7 variations

The global status since 1st January 1995 is as follows (further detailed statistics can be found at the MRFG website):

Years	Procedures from New applications finalised	Procedures from Type I variations finalised	Procedures from Type II variations finalised	Arbitrations referred to CPMP
1995	10	16	17	1 N.A.
1996	84	49	73	1 N.A. and 1 variation
1997	146	101	163	1 N.A. and 1 variation
1998	182	339	222	1 N.A. and 4 variations
1999	228	671	301	2 N.A. and 2 variations
2000	306	1007	320	3 N.A. and 2 variations
2001	443	1487	474	1 N.A. and 3 variations
2002	420	2104	527	2 N.A. and 7 variations
1995-2002	1819	5774	2097	12 N.A. and 20 variations

50 new procedures (regarding 111 products) started in December 2002. The categories of these procedures are as follows:

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

12 known active substances (already authorised in at least one member state), including **3** multiple applications and **2** repeat use.

27 abridged applications including **10** multiple applications and **6** repeat use.

The new procedures started this month relate to 17 full dossiers, 16 generics, 6 bibliographic applications and 11 for different use, route or dose.

The procedures consisted of 49 chemical substances and 1 biological – blood product¹.

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47 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.
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Number of countries involved in the new applications procedures started in December 2002

Reference Member State (number of products involved in the procedure)	Number of CMSs involved in the procedure
BE (1)	1
BE (1)	5
DE (1)	2
DE (1)	14
DE (3)	16
DE (3)	5
DE (3)	14
DE (1)	16
DE (1)	1
DE (1)	1
DE (1)	16
DK (1)	4
DK (2)	5
DK (2)	1
DK (1)	3
DK (1)	4
DK (3)	5
DK (3)	5
DK (3)	1
DK (3)	1
DK (3)	1
ES (1)	5
FI (1)	3
FI (5)	2
FI (5)	1
FI (5)	1
FI (5)	9
FI (5)	2
FI (2)	3
FI (2)	1
FR (1)	9
FR (1)	3
FR (1)	5
IT (2)	1
NL (5)	9
NL (3)	16
NL (3)	2
NL (3)	6
NL (3)	2
NL (4)	11
SE (1)	11
SE (1)	11
SE (1)	11
SE (1)	8
SE (1)	16
UK (1)	12
UK (3)	1
UK (3)	1
UK (2)	4
UK (1)	1

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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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<http://heads.medagencies.org/>*