

Report from the meeting held on 13 March 2000

The MRFG noted that 16 new mutual recognition procedures were finalised during the month of February 2000, as well as 65 type I and 20 type II variations.

The status as of 29th February 2000 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
2000	19	52	126	63	41	118	--

7 new procedures (regarding 11 products) started in February 2000. The categories of these procedures are as follows:

New active substance ¹	Line extensions ²	Fixed comb.	Generics	Herbal products ³	OTC ⁴	Blood products	Immuno-logicals	Others ⁵
0	0	0	6	0	0	0	1	0

1. When in one of the involved Member States it concerns a new active substance according to the definition in the Notice to Applicants Volume IIA; the number given includes multiple applications and repeat use procedures.
2. Line extensions are those applications which extend a range of products, e.g. an additional strength, or a new pharmaceutical form from the same Marketing Authorisation Holder;
3. In this category products are classified as herbals when the RMS has considered them as herbal product;
4. In this category products are classified as OTC products when the RMS has approved it for OTC use, although the legal status is not part of the Mutual Recognition Procedure;
5. When the product is not classified in the other eight categories.

Each application can be classified in only one category.

Number of countries involved in the new applications procedures started in February 2000:

Reference Member State (number of products involved in the procedure)	Number of CMSs involved in the procedure
DE (3)	6
DE (3)	6
DE (1)	14
DK (1)	11
NL (1)	9
NL (1)	4
NL (1)	3

General issues

- **MR-related documentation to be submitted by applicants to the EMEA:**
Applicants are reminded to limit the documentation to be submitted to the EMEA (MRFG support) to those currently listed in the Notice to Applicants (Chapter II): notification of an application, in case of arbitration a full copy of the dossier as submitted in the MR-procedure, for arbitrations relating to variations an updated full dossier and documentation related to the relevant respective variations. In addition, the applicants shall submit notifications of withdrawals.

- **MR-SPC for influenza vaccines: amendment regarding Gullain Barré Syndrome (GBS) and Thiomersal**

The MRFG agreed to amend the MR-SPC for influenza vaccines regarding GBS and Thiomersal. The revised MR-SPC is published on the Heads of Agencies Website. Applicants may update their product information accordingly through one single type II variation.

- **Meeting with interested parties:**

The MRFG plenary meeting was followed by a meeting with interested parties. In the future this forum will be more used to discuss identified issues necessitating clarification from both sides. The MRFG presented the new classification of Eudra Track subtypes which will translate to a new format of statistics presented in the MRFG Press Release. The MRFG invited interested parties to present additional proposals for improvement of the information given in the MRFG Press Release. The MRFG presented the progress made in the projects on withdrawal reports and MR-SPC. The MRFG will further consider industry's proposal regarding timing of variations of MR authorised Medicinal Products and simplified procedures to update marketing authorisations in EFTA countries regarding MR-authorisations.

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/>