

## Report from the meeting held on 10 April 2000

The MRFG noted that 22 new mutual recognition procedures were finalised during the month of March 2000, as well as 80 type I and 17 type II variations.

The status as of 31<sup>st</sup> March 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	41	57	206	83	58	138	--

28 new procedures (regarding 61 products) started in March 2000. The categories of these procedures are as follows:

New active substance <sup>1</sup>	Line extensions <sup>2</sup>	Fixed comb.	Generics	Herbal products <sup>3</sup>	OTC <sup>4</sup>	Blood products	Immuno-logicals	Others <sup>5</sup>
4	5	1	15	0	0	0	0	3

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 March 2000:

Reference Member State (number of products involved in the procedure)	Number of CMSs involved in the procedure
AT (4)	10
AT (4)	10
AT (4)	10
DE (4)	11
DE (3)	12
DE (1)	5
DE (1)	15
DK (4)	14
DK (1)	2
DK (2)	6
DK (3)	1
DK (3)	1
DK (1)	9
DK (3)	2

Reference Member State (number of products involved in the procedure)	Number of CMSs involved in the procedure
DK (4)	1
FI (3)	10
FI (1)	5
FI (2)	1
FI (1)	1
IT (2)	2
NL (1)	8
NL (1)	5
NL (1)	2
NL (1)	2
NL (1)	3
SE (2)	1
UK (1)	5
UK (1)	1

**General issues**

- **Note for guidance on the Pharmacodynamic section of the SPC for antibacterial medicinal products**

The MRFG agreed that recommendations in the note for guidance made for section 5.1 should as of now also be followed in the SPC of antibiotics going through MRP.

- **Marketing Authorisation through Mutual Recognition in EFTA countries**

A harmonisation of several different marketing authorisations can be generally achieved by a referral according to article 11 of Directive 75/319/EEC.

In addition, the Repeat Use MR-procedure is a tool by which a Marketing Authorisation Holder, with an existing national marketing authorisation in NO/IC (or any MS), can easily obtain a ‘Marketing Authorisation through Mutual Recognition’ for the same medicinal product, provided that for this medicinal product an initial MR procedure had been successfully completed. If an MR procedure has not preceded, a normal MR procedure (first use) may be used.

The MRP, first or repeat use, can be used regardless of the products already on the market, provided that the MAH submits a separate application. The concerned country would then request the AR from the initial RMS and start e.g. a repeat use procedure (with reference to the ‘MRFG position paper on repeat use of the Mutual Recognition’). Once this procedure has been successfully completed, the existing national authorisations may have to be revoked or withdrawn or the name of the product may have to be changed in order to avoid 2 different SPCs for the same product on the same market. However, this would be decided at national level.

- **Joint MRFG/EFPIA survey**

The MRFG, upon request by trade associations, would like to remind the pharmaceutical companies, to send completed questionnaires rapidly back to the respective contact point at the trade associations.

- **Guideline on Renewals**

The MRFG noted the new Guideline on Renewals which was published on the European Commission-Enterprise DG Website.

**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/>*