Report from the meeting held on 21 June 1999

The MRFG noted that 14 new mutual recognition procedures were finalised during the month of May 1999, as well as 63 type I and 26 type II variations.

The status as of 31 may 1999 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
1999	44	61	299	87	121	135	1 var.

20 new procedures (regarding 41 products) started in May 1999. The categories of these procedures are as follows:

New active substance[1]	Line extensions[2]	Fixed combinations	Generics	Herbal products[3]	OTC[4]	Blood-products	Immuno-logicals	Others[5]
0	1	1	10	0	0	0	0	8

1. When in one of the involved Member States it concerns a new active substance according to the definition in the Notice to Applicants Part IIA;
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 previous six categories.

Each application can be classified in only one category.

Number of countries involved in the started new applications procedures in May 1999:

Reference Member State (number of products involved in the procedure)	Number of CMSs involved in the procedure
DE(1)	14
DK(1)	1
DK(4)	2
DK(2)	13
DK(2)	3
DK(4)	1
DK(4)	3
FR(1)	8
NL(1)	8
NL(1)	3
NL(1)	8
NL(1)	10
NL(2)	5
NL(2)	5
NL(2)	1
SE(1)	14
SE(1)	14
UK(5)	14
UK(1)	8

General Issues.

- The document "Applications under Annex II of Regulation (EC) No. 541/95 in Mutual Recognition Procedures, Member States Recommendations", (including "line extensions") has been adopted and will be published on the Heads of Agencies Website as indicated below.
- The MRFG agreed that a pilot phase in the work on Mutual Recognition SPC (MR-SPC) could start in July 1999.
- Comments concerning specific products in the MRP index should be generally addressed to the reference member state directly. In addition, comments regarding the product name and marketing authorisation holder should be addressed directly to the respective concerned member state.
- As already stated in the Break-out session protocol, the latest time for the confirmation of a break-out session should be the Wednesday before the plenary MRFG meeting via the RMS.
- The June MRFG meeting was the last under German Presidency. Finland will take over the Chairmanship from the beginning of July 1999. Dr. Veijo Saano will be the next chairman. He should be contacted in future for details of the MRFG procedure.

All documents mentioned in this press realease 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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