

Report from the meeting held on 26 June 2000

The MRFG noted that 10 new mutual recognition procedures were finalised during the month of May 2000, as well as 65 type I and 27 type II variations.

The status as of 31st May 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	73	96	338	71	101	145	1 N.A.

26 new procedures (regarding 42 products) started in May 2000. The categories of these procedures are as follows:

5 new active substances (first authorisation in the European Community after RMS approval), including **3** multiple applications and **1** repeat use.

5 known active substances (already authorised in at least one member state), including **1** multiple application and **3** repeat use.

14 abridged applications including **1** multiple application and **1** repeat use.

2 line extension applications.

The new procedures started this month relate to 9 full dossiers, 3 informed consent applications, 1 bibliographic application, 10 generics, 1 fixed combination, and 2 for different use, route or dose.

The procedures consisted of 25 chemical substances and 1 blood products¹.

22 of these procedures were prescription-only medicinal products in the reference Member State and 4 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 May 2000

Reference Member State (number of products involved in the procedure)	Number of CMSs involved in the procedure
DE (1)	5
DE (2)	1
DE (1)	4
DK(2)	7
FI (1)	2
FR (1)	11
FR (1)	11
FR (1)	8

Reference Member State (number of products involved in the procedure)	Number of CMSs involved in the procedure
IR (1)	5
IR (3)	2
IR (1)	1
NL (1)	6
NL (1)	16
NL (1)	7
NL (1)	8
SE (3)	1
SE (3)	1
SE (3)	1
SE (2)	1
SE (1)	1
UK (4)	1
UK (1)	8
UK (1)	1
UK (1)	10
UK (1)	15
UK (4)	2

General issues

Scientific/Regulatory recommendations given to the applicants by MSs

The Member States have noticed that applicants often contact several national agencies for scientific/regulatory recommendations and advice on borderline products prior to submitting the application. In order for Member States to be aware of the recommendations given by other competent authorities, the Group agreed on a set of information to be shared between the Member States.

SOP on Urgent Safety Restrictions

The SOP on Urgent Safety Restrictions was formally adopted by the MRFG and will be published on the MRFG website.

Harmonisation of generic medicinal products

The MRFG considered problems related to the disharmony between the SPC of the brand leader and the generic medicinal products. Within the MRP this often causes partial withdrawals of the dossier from the CMSs.

The MRFG discussed the possibility of harmonisation of generic medicinal products and respective brand leaders via Article 11 procedure.

TSE related requirements in Directive 75/318/EEC as amended by Directive 1999/82/EEC – implications on MRP

According to the above mentioned Directive the applicants/Marketing Authorisation Holders (MAHs) have to demonstrate compliance of their products with the requirements stated in the Note for guidance on minimising the risk of transmitting Animal Spongiform Encephalopathy agents via medicinal products. For existing Marketing Authorisations this needs to be done by 1 March 2001 and for new applications for Marketing Authorisations lodged by 1 July 2000.

The model declaration of compliance with the Annex to the above mentioned Directive has been published on the Internet on the EC-Enterprise DG's website. In order not to delay initiation of the MRP, the MRFG agreed that for products that have already been approved in the RMS for the subsequent MR-procedures the CMSs would accept those products as regards to TSE requirements under the same conditions as in the RMS.

Those applications for marketing authorisations submitted in the CMSs after 1 July 2000 should also be mentioned by the applicants in Part B of the Annexes for pending applications that have been published on the EC-Enterprise DG's website.

Change of the Presidency

The June MRFG meeting was the last under the Portuguese Presidency. France will take over the Chairmanship as of July 2000. Prof. Jean-Michel Alexandre will be the next chairman.

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:

*Dr. António MELO GOUVEIA
Head of the Medicines Division
INFARMED
Parque de Saude de Lisboa
Avenida do Brasil, n° 53
P - 1700 LISBOA*

*Phone: + 351 21 798 7201
Fax: + 351 21 798 7217
e-mail: Melo.gouveia@infarmed.pt*

From 1st July 2000:

*Prof. Jean-Michel ALEXANDRE
Agence Française de Sécurité
Sanitaire des Produits de Santé
143-147 Bd. Anatole France
F-93285 Saint-Denis Cedex
FRANCE*

*Phone: + 33.1.5587.3299
Fax: + 33.1.5587.3292
e-mail: fr-h.eudranet@fr-h.eudra.org*

*Or you could visit the **MRFG web site** at the EUROPEAN NATIONAL MEDICINES AUTHORITIES WINDOW:*

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