



Report from the meeting held on 20 October 2003

General Issues

Best practice guide for the exchange of regulatory and administrative information regarding orphan medicinal products between the EMEA and national competent authorities

The Best practice guide for the exchange of regulatory and administrative information regarding orphan medicinal products between the EMEA and national competent authorities was adopted and will be published on the website.

Processing of Renewals in the post-Referral phase and Recommendation for Mutual Recognition Procedure after finalisation of an arbitration procedure with a positive opinion by the CPMP and a positive Decision by the EU Commission

The documents 'Recommendation for Mutual Recognition Procedure after finalisation of an arbitration procedure with a positive opinion by the CPMP and a positive Decision by the EU Commission' and 'MRFG Best Practice Guide for handling Renewals in the Mutual Recognition Procedure' Rev. 2 were adopted and will be published on the website

Guidance on submission dates for applicants of the MRP for the year 2004

The document was adopted and will be published on the website.

Mutual Recognition Monitoring

The MRFG noted that **46** new mutual recognition procedures were finalised during the months of September 2003, as well as **225** type I variations and **69** type II variations.

The status as of 30 September 2003 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
2003	313	234	2059	378	556	195	5 N.A. and 1 Variation

90 new procedures (regarding **202** products) started in September 2003. The categories of these procedures are as follows:

4 new active chemical substances.

15 known active substances (already authorised in at least one member state), including **2** multiple and **1** repeat uses.

61 abridged applications; including **32** multiple applications and **1** repeat use.

10 line extension application and

The new procedures started related to **17** full dossiers, **51** generics, **9** bibliographic applications, **3** fixed combinations and **10** other.

The procedures consisted of **87** chemical substances, **1** biological-other and **2** biological blood products¹.

84 of these procedures were prescription-only medicinal products in the reference Member State and **6** 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 September 2003

Reference Member State (number of products involved in the procedure)	Number of CMSs involved in the procedure
BE (1)	7
DE (1)	4
DE (1)	1
DE (1)	3
DE (1)	4
DE (4)	7
DK (3)	13
DK (2)	3
DK (2)	2
DK (2)	1
DK (2)	3
DK (1)	1
DK (1)	1
DK (1)	1
DK (1)	3
DK (1)	1
DK (1)	1
DK (2)	2

Report from the MRFG meeting held in October 2003

Reference Member State (number of products involved in the procedure)	Number of CMSs involved in the procedure
DK (2)	1
DK (2)	1
DK (2)	1
DK (2)	2
DK (2)	3
DK (2)	7
DK (2)	9
DK (2)	1
DK (2)	7
DK (2)	1
DK (3)	1
FI (1)	6
FI (1)	12
FI (2)	3
FI (1)	2
FI (1)	1
FI (1)	1
FI (2)	12
FI (2)	1
FI (2)	10
FI (2)	1
FI (2)	1
FI (1)	7
FI (2)	3
FI (2)	2
FI (2)	1
FI (2)	1
NL (3)	6
SE (2)	2
SE (1)	1
SE (1)	15
SE (1)	1
SE (2)	7
SE (1)	2
SE (1)	1
SE (1)	1
SE (2)	11
SE (1)	10
SE (3)	3
SE (4)	5
SE (4)	10
SE (4)	10
SE (4)	3
SE (4)	2
SE (4)	2
SE (4)	1
SE (6)	16
SE (1)	3
SE (2)	10
SE (2)	1
Se (2)	1
SE (6)	3
SE (4)	1
SE (4)	1
SE (4)	2
SE (4)	1
SE (4)	1
SE (4)	1
SE (4)	1
SE (4)	1
SE (4)	3
SE (4)	3
SE (4)	1
SE (6)	1

Report from the MRFG meeting held in October 2003

Reference Member State (number of products involved in the procedure)	Number of CMSs involved in the procedure
SE (1)	1
SE (1)	1
UK (2)	1
UK (1)	11
UK (1)	11
UK (1)	1
UK (40)	14
UK (1)	16

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 from the presiding chair of the MRFG:

*Dr. Silvia Fabiani
Ministero della Salute
Direzione Generale della Valutazione dei
Medicinali e della Farmacovigilanza
Via della Civiltà Romana, 7
00144 – Roma
ITALY*

*Phone: + 39 06 5994 3495
Fax: + 39 06 5994 3646
e-mail: s.fabiani@sanita.it*

*Or you could visit the **MRFG web site** at the EUROPEAN NATIONAL MEDICINES AUTHORITIES WINDOW:
<http://heads.medagencies.org/>*