



Report from the meeting held on 15 December 2003

General Issues

MRFG expert group on the core SPC for HRT

The expert group met on 15 December to take up the work of updating the core SPC. Good progress was made and a draft revised core SPC will be circulated to MRFG members and then posted on the MRFG website on Friday 19 December 2003.

Applicant's Response Document

An updated document was adopted and will be published on the website.

Core SPC for influenza vaccines

The harmonised core SPC for influenza vaccines was corrected to take into account the age range of the 'Note for Guidance on Harmonisation of Requirements for Influenza Vaccine'. The new revised text will be published on the website.

Change in the EU-Presidency

The December 2003 MRFG meeting was the last one under the Italian presidency. Ireland will take over the presidency in January 2004. Dr. Caitriona Fisher will be the next MRFG chairperson and she should be contacted in the future in case of any questions regarding the MRP.

Meeting schedule

The next MRFG meeting will be held on 19 January 2004.

Merry Christmas and a Happy New Year!

Καλά Χριστούγεννα και ευτυχισμένο το καινούριο έτος !!

Buon Natale e Felice Anno Nuovo!

Mutual Recognition Monitoring

The MRFG noted that **90** new mutual recognition procedures were finalised during the month of November 2003, as well as **126** type I variations, **66** type IA variations, **48** type IB variations and **62** type II variations.

The status as of 30 November 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 IA variations finalised	Procedures from Type IB variations finalised	Procedures from Type II variations finalised	Arbitrations referred to CPMP
2003	453	176	2428	66	48	669	5 N.A.* and 3 Variations

* the figures of arbitrations from New Applications published last month were incorrect. No new arbitrations from New Applications were referred to the CPMP during the month of October 2003.

52 new procedures (regarding **110** products) started in November 2003. The categories of these procedures are as follows:

3 new active substances (first authorisation in the European Community after RMS approval), of which **1** is classified as repeat use.

7 known active substances (already authorised in at least one member state), of which **2** are classified as repeat use.

41 abridged applications; including **16** multiple applications and **2** repeat use.

1 line extension application.

The new procedures started related to **6** full dossiers, **29** generics, **5** bibliographic applications and **12** for different use, route or dose.

The procedures consisted of **47** chemical substances, **1** herbal medicinal product, **1** biological-other, **1** biological-vaccine, **2** biological blood products¹.

48 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 November 2003

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

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Reference Member State (number of products involved in the procedure)	Number of CMSs involved in the procedure
ES (2)	2
ES (1)	2
FI (2)	6
FI (2)	1
FI (2)	2
FI (2)	2
FI (2)	2
FI (2)	2
FR (2)	16
IE (1)	1
IE (6)	4
NL (1)	1
NL (2)	1
NL (2)	1
NL (2)	1
NL (2)	2
NL (1)	10
NL (3)	2
NL (3)	9
NL (3)	2
NL (3)	1
NL (3)	4
NL (3)	11
NL (3)	1
NL (3)	1
NL (3)	1
NL (2)	2
NL (2)	2
NL (2)	2
NL (2)	1
NL (2)	2
NL (2)	2
SE (5)	5
SE (2)	1
UK (1)	10
UK (1)	10
UK (1)	9
UK (1)	15

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:

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