



Report from the meeting held on 24 May 2004

General Issues

Documents: Simultaneous applications (Article 17 paragraph 2 of Directive 2001/83/EC) Member States Operating Procedure and Triggering of Mutual Recognition by Member States (Article 18 of Directive 2001/83/EC)

In view of the enlargement on 1 May 2004, an updated version of each document has been adopted by the group and is currently available on the website under the headings Application for MRP and General Information on the MRP, respectively.

MRFG Best Practice Guides for the Submission and Processing of Variations in the Mutual Recognition Procedure

An updated version of Chapter 5, to include information on the implementation of variations affecting the SPC, label and leaflet, has been adopted by the group and will be published on the website.

Implementation of the Commission Decision after a referral procedure

The SPC of the finalised referral for pravastatin has been published on the EMEA website (www.emea.eu.int/hums/human/referral/referral.htm) and the SPC of the recently finalised referral for simvastatin will also be published on the EMEA website.

Meeting schedule

The next MRFG meeting will be held on 21 June 2004.

Mutual Recognition Monitoring

The MRFG noted that **42** new mutual recognition procedures were finalised during the month of April 2004, as well as **6** type I variations, **242** type IA variations, **140** type IB variations and **75** type II variations.

The status as of 30th April 2004 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 |
|------|--|---|---|--|--|--|-------------------------------|
| 2004 | 175 | 258 | 42 | 920 | 647 | 305 | 1 N.A |

97 new procedures (regarding **211** products) started in April 2004. The categories of these procedures are as follows:

1 new active substance (first authorisation in the European Community after RMS approval), classified as repeat use.

9 known active substances (already authorised in at least one member state).

85 abridged applications including **39** multiple applications and **2** repeat use.

2 line extension applications.

The new procedures started related to **9** full dossiers, **76** generics, **1** bibliographic application, **1** fixed combination and **10** for different use, route or dose.

The procedures consisted of **96** chemical substances and **1** biological-vaccine¹.

95 of these procedures were prescription-only medicinal products in the reference Member State and **2** procedures were classified as a Non-prescription (including OTC) medicinal product².

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 April 2004

| Reference Member State (number of products involved in the procedure) | Number of CMSs involved in the procedure |
|---|--|
| AT (1) | 1 |
| AT (1) | 1 |
| AT (1) | 1 |
| AT (1) | 1 |
| AT (1) | 1 |
| DE (2) | 3 |
| DE (1) | 1 |
| DE (2) | 6 |
| DK (1) | 11 |
| DK (4) | 2 |
| DK (4) | 2 |
| DK (1) | 13 |
| DK (3) | 7 |
| DK (3) | 1 |
| DK (3) | 2 |
| DK (3) | 1 |
| DK (3) | 3 |
| DK (2) | 1 |
| DK (2) | 1 |

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| 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) | 1 |
| DK (3) | 1 |
| FI (2) | 2 |
| FI (4) | 1 |
| FI (3) | 15 |
| FI (3) | 1 |
| FI (3) | 1 |
| FI (3) | 1 |
| FI (3) | 1 |
| FI (1) | 1 |
| FI (1) | 4 |
| FI (3) | 8 |
| FI (3) | 1 |
| FI (2) | 6 |
| FI (2) | 1 |
| FI (2) | 1 |
| FI (3) | 5 |
| FI (3) | 3 |
| FI (3) | 1 |
| FI (3) | 6 |
| FI (3) | 7 |
| FI (3) | 1 |
| FI (3) | 12 |
| FI (3) | 1 |
| FI (3) | 1 |
| FI (3) | 1 |
| FI (3) | 4 |
| FI (3) | 6 |
| FI (1) | 16 |
| FI (2) | 8 |
| FI (2) | 7 |
| FI (2) | 2 |
| FI (2) | 11 |
| FI (2) | 1 |
| FI (3) | 8 |
| FI (3) | 1 |
| FI (3) | 12 |
| FI (3) | 1 |
| FI (3) | 1 |
| FI (3) | 1 |
| FI (3) | 1 |
| FI (3) | 2 |
| FI (3) | 1 |
| FI (1) | 1 |
| FI (1) | 1 |
| FI (1) | 1 |
| FI (3) | 1 |
| FI (2) | 13 |
| FI (2) | 6 |
| FR (1) | 3 |
| IT (1) | 6 |
| IT (1) | 8 |
| NL (1) | 12 |
| NL (3) | 7 |
| NL (1) | 8 |
| NL (1) | 2 |
| NL (1) | 1 |
| NL (3) | 1 |
| NL (1) | 2 |
| NL (2) | 5 |
| SE (3) | 3 |

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| Reference Member State (number of products involved in the procedure) | Number of CMSs involved in the procedure |
|---|--|
| SE (1) | 1 |
| SE (2) | 1 |
| SE (2) | 2 |
| SE (2) | 1 |
| SE (1) | 16 |
| SE (3) | 2 |
| SE (1) | 15 |
| SE (1) | 1 |
| UK (1) | 2 |
| UK (1) | 9 |
| UK (1) | 9 |
| UK (1) | 6 |
| UK (3) | 4 |
| UK (3) | 7 |

All documents mentioned in this press release can be found at the MRFG website at the European Medicines Authorities Windows under the heading *MRFG Guidance*.

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/>*