



Report from the meeting held on 24 April 2003

General issues:

Processing of renewals in the post referral phase

Following an Article 30 or 31 referral, the MAHs are strongly recommended to select and contact an RMS immediately in order to plan the procedures ahead, including renewals and variations and to resolve relevant issues.

Starting date of the data exclusivity period

The interpretation of the European Commission on this item is as follows:

The requirement for the use of 'essential similarity' is stated in Article 10.1 a) iii). It requires that the medicinal product, to which essential similarity is claimed, is authorised within the Community, in accordance with Community provisions in force, for not less than 6 years, respectively 10 years.

The starting date of the data exclusivity period is the date of the first approval in the European Union.

Therefore an application relying on Article 10.1. a) iii) can only be validated and processed after expiry of the data exclusivity time of 6/10 years in the EU.

In case that the reference product is not authorised in the Community yet, but only in an applicant country, then the 6/10 year protection period counts from the accession of the applicant country to the Community.

Annex 1

Joint CPMP/ MRFG working group on harmonisation of SPCs:

Taking into consideration the discussions during the interlinking meeting of EMACOLEX and the SPC harmonisation working group, it was decided to prepare a report, which will be presented to the HoA at their next meeting in May.

Meeting schedule

The next MRFG meeting will be held on Monday 19 May 2003.

Mutual Recognition Monitoring

The MRFG noted that **49** new mutual recognition procedures were finalised during the month of March 2003, as well as **220** type I and **34** type II variations.

The status as of 31st March 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	104	85	545	329	109	297	1 N.A.

34 new procedures (regarding **87** products) started in March 2003. The categories of these procedures are as follows:

2 new active substances, classified as repeat use.

4 known active substances (already authorised in at least one member state), including **1** repeat use.

22 abridged applications including **5** multiple applications.

6 Line extension applications, including **2** repeat use.

The new procedures started related to **7** full dossiers, **24** generics, **2** bibliographic applications and **1** for different use, route or dose.

The procedures consisted of **32** chemical substances, **1** biological- blood product and **1** biological- other¹.

31 of these procedures were prescription-only medicinal products in the reference Member State and **3** 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 March 2003

Reference Member State (number of products involved in the procedure)	Number of CMSs involved in the procedure
AT (2)	4
AT (2)	2
DE (2)	11
DE (4)	1
DE (1)	3
DK (3)	1
DK (1)	1
DK (1)	1
DK (2)	1
DK (4)	1
DK (3)	1
DK (3)	4
DK (3)	4
DK (3)	3
DK (2)	2
DK (1)	3
DK (2)	1
DK (4)	5
DK (3)	1
DK (4)	11

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Reference Member State (number of products involved in the procedure)	Number of CMSs involved in the procedure
DK (4)	12
DK (4)	5
DK (4)	1
DK (3)	3
NL (1)	1
NL (3)	5
SE (2)	1
SE (1)	1
SE (2)	4
SE (2)	16
UK (3)	1
UK (4)	6
UK (1)	5
UK (2)	4

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:

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