

# Mutual recognition of medicinal products for human use

## Report 1998

### Extract from EMEA report 1998

The mutual recognition or decentralised procedure is the second European Community licensing system that is being established in Europe with co-operation between the Member States.

The mutual recognition procedure has made considerable progress during 1998. The use of the procedure in 1998 was:

Mutual recognition procedure	Total submitted in 1998*	Under evaluation in 1998*	Ended positively in 1998*	Arbitrations in 1998*
New applications	183	30	179	1
Type I variations	482	152	327	--
Type II variations	344	147	204	4

\* [figures as at 18 December 1998]

The number of applications both submitted and completed has risen during 1998, compared with 10 procedures completed in 1995, 84 in 1996 and 147 in 1997. The very low level of arbitrations is another encouraging feature.

The Mutual Recognition Facilitation Group (MRFG) continues to meet at the EMEA every month on Monday of the CPMP week. The MRFG met under the chairmanship of Dr David Jefferys of the United Kingdom from January to June 1998 and Dr Christa Wirthumer-Hoche of Austria from July to December 1998. The MRFG and the Member States were particularly grateful for the support of the EMEA in providing meeting rooms for the Group and for the break-out sessions. The EMEA also provided the Secretariat to support the MRFG. The participation of the Commission during the MRFG meetings was very valuable. Observers from Iceland and Norway attended the MRFG from January 1998 in order to prepare for their full participation in the mutual recognition system from early in 1999.

During 1998, the MRFG concentrated upon improving the performance of the procedure. In order to avoid delays an automatic validation procedure for new application was introduced from 1 May 1998 for a six-month trial period. The great success of the trial meant that this was continued as an established part of the procedure from November and at the same time an automatic validation procedure was introduced to cover all type II variations.

The group undertook a major review of the operation of break-out sessions and the clarification phase. This was discussed in depth at an informal meeting of the MRFG organised in May during the UK Presidency. Following this, the Best Practice Guide was modified in July 1998 so that the deadline for comments from concerned Member States has been changed from day 60 to day 55 in order to increase the time for the clarification phase. Other changes were made to the break-out protocol document and a series of initiatives were put into place by the Member States to improve this part of the procedure.

In 1998 a total of 64 break-out sessions were organised by reference Member States and held at the EMEA. The MRFG reviewed the protocol for the handling of break-out sessions in order to improve the outcome of these meetings for clarification of serious public health concerns. It is important to mention that in 1998 there was a decrease of 48 percent in the number of break-out sessions for new applications compared to the period 1995 to 1997.

The frequency of withdrawals of applications from individual Member States during the mutual recognition procedure is still an issue of concern, but also this number of partial withdrawals decreased in 1998 by about 40 percent compared to the number during the transition period.

Version 3 of the tracking system, 'EudraTrack', for monitoring of the mutual recognition procedure became fully operational on 1 November 1998.

During the year an increasing number of Member States acted as reference Member State and nearly all Member State have now undertaken this important role. The number of finalised procedures by type is given in the table:

Total number of finalised procedures by type in 1998*		
	Number	Percentage
New active substance	35	19.6
Generics	45	25.1
Line extensions	26	14.5
Fixed combination	22	12.3
OTC	5	2.8
Herbal	1	0.6
Others	45	25.1

\* The number includes a total of 179 multiple procedures

In order to classify the products in a more detailed way two additional categories were identified, namely for blood products and vaccines since November 1998. It is encouraging to see the wide range of applications now using the mutual recognition procedure.

In 1998 there was for the first time the annual update of mutually recognised licenses of influenza vaccines via the fast track procedure. Based on the first experience this procedure proved to be very successful. It worked well taken into account the adherence to the agreed timetable in general, the final approval dates and the positive outcome of all requested annual updates.

A major emphasis during the year was to increase the visibility of the mutual recognition procedure. The press release instituted in July 1997 has become a regular feature with increased statistical information and increased feedback. This is now published on the MRFG Internet site (<http://heads.medagencies.org>). Additional statistical information and standard operating procedure are also published on the website along with a list of contact points. It is intended that a product index of mutual recognition procedures will be made available on the site early in 1999 and will be followed slightly later by the publication of summary of product characteristics of products which have been through mutual recognition.

A major workshop on transparency in the mutual recognition procedure was hosted by the UK in September 1998. Proposals are currently under discussion to increase transparency in the mutual recognition system and the possible development of mutual recognition public assessment reports.

Following the release of the 'Commission communication on the community marketing authorisation procedures for medicinal products', (OJ C 229, 22.7.1998, p.4) the Group had in-depth discussions on the document in order to clarify the situation and created several standard operating procedures, which are available on the MRFG website for information.

Significant issues remain to be addressed in the mutual recognition procedure but good progress was achieved during 1998. The close co-operation between all the stakeholders in the system provides an encouraging platform for the rapid expansion in the number of procedures, which can be expected over the next years.