

MEDICINAL PRODUCTS FOR HUMAN USE

Mutual Recognition

EXTRACT

from the

THIRD GENERAL REPORT ON THE ACTIVITIES OF THE EUROPEAN AGENCY FOR THE EVALUATION OF MEDICINAL PRODUCTS 1997

Adopted by the Management Board on 3 December 1997

3.5 Mutual recognition

The mutual recognition or decentralised procedure is the second and complementary part of the single Community system which is being established in Europe with co-operation between the Member States, the EMEA and the European Commission.

The mutual recognition procedure has made considerable progress during 1997. The use of the procedure in 1997 was:

Mutual recognition procedure	Total submitted in 1997*	Under evaluation in 1997*	Ended positively in 1997*	Arbitrations in 1997*
New applications	190	51	147	1
Type I variations	139	16	99	0
Type II variations	215	66	152	1

* The number includes multiple procedures (total = 244)

The number of applications both submitted and completed has risen significantly during 1997, compared with 10 procedures completed in 1995 and 84 in 1996. The very low level of arbitrations is another encouraging feature. The adoption of the Best Practice Guide in September 1996 and its subsequent endorsement by the Heads of Agencies has helped to improve the time both for initiating a mutual recognition procedure and the granting of national marketing authorisations.

The development of a complementary best practice guide by the European Federation of Pharmaceutical Industries' Associations has been particularly welcomed and this should help to improve the procedure further.

The Mutual Recognition Facilitation Group (MRFG) continues to meet at the EMEA in parallel with the meetings of the CPMP. The MRFG met under the chairmanship of Dr Truus Janse-de Hoog of the Netherlands from January to September 1997 and Dr David Jefferys of the United Kingdom for the remainder of the year until June 1998. The MRFG and the Member States have been particularly grateful for the support of the EMEA in providing meeting rooms for the Group and for the break-out sessions. The EMEA has also provided the Secretariat to support the MRFG. The recent decision of the Commission to attend the MRFG meetings has also been valuable.

In 1997 a total of 84 break-out sessions were organised by reference Member States and held at the EMEA. The MRFG has agreed a protocol for the handling of break-out sessions and is currently undertaking a diagnostic review of the best uses of these meetings.

One issue of concern is the frequency of withdrawals of applications from individual Member States during the mutual recognition procedure. This may be a feature of the transition period which will resolve itself next year, but it is being closely monitored and the reasons for withdrawal are being analysed. During the year the MRFG has elaborated a validation report form, a response document form and a procedure for handling post-authorisation commitments.

The introduction of the tracking system 'EudraTrack' in October was a significant step forward. It should allow more statistical information to be generated which can be made available in the published monthly MRFG report and will also improve the monitoring of the procedure. During the year the MRFG significantly expanded its press release and is now making available more information on its deliberations and on the operation of the system.

During the year an increasing number of Member States acted as reference Member State and nine 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 August 1995 to December 1997*		
	Number	Percentage
New active substance	77	31.5%
Generics	45	18.4%
Line extensions	29	11.9%
Fixed combination	20	8.2%
OTC	6	2.6%

Herbal	2	0.8%
Others	65	26.6%

* The number includes multiple procedures (total = 244)

It is encouraging to see the wide range of applications now using the mutual recognition procedure, also that similar applications are using both Community procedures.

The MRFG has identified several areas where there is a need for existing CPMP guidelines to be updated or new guidance to be elaborated. These requests have been put to the CPMP to be addressed by its Working Parties. The issues identified by the MRFG for further work include the areas of hormone replacement therapy, paediatric medicines, oncology products, anti-infectives and revision of the guidance on bioequivalence testing. The MRFG has developed a procedure with the European vaccine manufacturers for handling influenza vaccines through the mutual recognition procedure for the influenza season 1998-99.

Significant issues remain to be addressed in the mutual recognition procedure but good progress has been achieved during 1997. 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 two years.