COMMISSION OF THE EUROPEAN COMMUNITIES

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SECOND COMMISSION REPORT TO THE COUNCIL ON THE FUNCTIONING OF THE COMMITTEE FOR PROPRIETARY MEDICINAL PRODUCTS AND ITS IMPACT ON THE DEVELOPMENT OF INTRA-COMMUNITY TRADE (1979)

Second Commission report on the functioning of the Committee for Proprietary Medicinal Products and its impact on the development of intra-Community trade

(1979)

Council Directive 75/319/EEC relating to proprietary medicinal products (OJ L 147 of 9 June 1979) provides, in Article 15(1), that "the Commission shall report to the Council annually on the operation of the procedure laid down in this Chapter (Committee for Proprietary Medicinal Products) and its effects on the development of intra-Community trade".

This report covers the year 1979.

I. THE FUNCTIONING OF THE COMMITTEE FOR PROPRIETARY MEDICINAL PRODUCTS

1. Membership

(a) Committee

The terms of office of the members were renewed as from 1 December 1979.

The membership of the Committee was not changed as regards the full members.

Dr. JONES, Principal Medical Officer, Medicines Division, was appointed an alternate member for the United Kingdom.

It was resolved that the Chairman and Vice-Chairmen of the Committee would remain in their office (cf. Annex I).

(b) Groups of experts

The membership of the groups of experts has varied according to the items on the agenda. A list of the participants in these groups is given in Annex II.

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2. Functioning

The Committee met six times, on the following dates: 20 February 1979, 13 and 14 March, 19 and 20 April, 7 and 8 June, 11 and 12 September, 14 November.

The "Safety of Drugs" panel met three times, i.e., on 16 and 17 January 1979, 3 and 4 April and 3 and 4 December.

The "Efficacy of Drugs" panel also met three times, i.e.,on 13 and 14 February 1979, 3 and 4 April and 3 and 4 December.

The "Medicinal Products of Plant Origin" panel met on 12 March 1979.

3. Opinions of the Committee

3.1 Opinions on the basis of Article 11 of Directive 75/319/EEC

Until 31 December 1979 two opinions were delivered by the Committee. Furthermore, two new applications for marketing authorization were forwarded, pursuant to Article 9 of Directive 75/319/EEC. The procedure in the case of these two new applications had not been completed by the end of the period covered by this report.

In spite of this very limited experience, the following facts emerged:

- not all manufacturers presented the particulars in conformity with the plan adopted by the Committee for Proprietary Medicinal Products and reproduced in the booklet published by the Commission of the European Communities in 1978 under the title "The rules governing medicaments in the European Community", page 57 et seq. This caused loss of time at the level of both national and Community examination;

- it is difficult, in the absence of guidelines prepared by the panels of experts of the Committee, to achieve complete harmonization of the therapeutic indications, contra-indications, warnings and side-effects, since different national attitudes have been adopted

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for various products of a similar nature and that it would therefore be difficult to justify at national level an abrupt change of doctrine for a particular case;

- supervision of the stability period brought to light divergent attitudes: certain authorities accept accelerated studies, others only accept real-time trials;

- certain authorities contacted the applicant during the 120 days of examination and thus have additional information which the other authorities do not possess;

- the time-limits laid down in Articles 10 and 11 of the abovementioned Directive are very short, even if it has been possible to comply with them in this case;

- the time for sending files by post to all the Member States specified has never been less than one month.

3.2 Opinion on the basis of Article 12 of Directive 75/319/EEC

On the basis of the abovementioned Article 12, the Committee was asked for an opinion concerning clofibrate.

All the delegations, except one, stated that clofibrate would remain on their respective markets subject to limitation of the indications, the formulation of revised warnings and contra-indications and special information for the medical profession.

Subsequently, all the national authorities adopted an attitude identical to that reported above.

3.3 Opinion on the basis of Article 14 of Directive 75/319/EEC

The Committee was consulted on and duly examined the following medicines for problems of interest to the Community: Alclofenac, Aminophenazone and derivatives, Benperidol, Biguanides (Buformine, Metformine, Phenformine), Chloramphenicol, Clioquinol, Dinoprostone, Furazolidone, Hydrazinophtalazine, Inosine, Methapyrilene, Noramidopyrine, Triazolam.

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4. Activity of the expert panels

The three panels of experts set up in accordance with Article 13 of the Committee's rules of procedure continued their work.

4.1 The panel on "Safety of Drugs", chaired by Dr J.P. GRIFFIN, has completed the drafting, after consultation with national authorities and private associations and examination of their comments, of the following guidelines:

- single dose toxicity studies;
- repeated dose toxicity studies;
- reproduction studies;
- carcinogenicity studies;
- inhalation toxicity studies;
- pharmacokinetics.

A guideline on the mutagenicity tests has still to be revised in the light of the comments received.

4.2 The panel on "Efficacy of Drugs", chaired by Dr M.N.G. DUKES, has completed the drafting, after consultation with national authorities and private associations and examination of their comments, of a guideline on fixed combinations of medicines. After a final revision, the same procedure will be applied to the note on anti-inflammatory preparations.

The following guidelines are being prepared or are at the planning stage:

- antiepileptics/anticonvulsants;
- bioavialability;
- cardiac glycosides;
- human pharmacokinetics;
- antianginal agents;
- oral contraceptives (tests);
- oral contraceptives (information for users);
- antihypertensive agents;
- hypoglycemic agents;

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- antiarrhythmic agents;
- medicines used over a long period;
- local corticoids;
- peripheral vasodilators;
- antimicrobial agents;
- medicines and pregnancy;
- diuretics;
- contrast media.

4.3 The panel on "Medicinal Products of Plant Origin", chaired by Professor B. SCHNIEDERS, considered it advisable, before proceeding further, to collect bibliographical data on the quality, efficacy and harmlessness of plants and preparations based on plants.

4.4 After the adoption of these guidelines by the Committee for Proprietary Medicinal Products, it will rest with the Commission to give them the appropriate legal form.

5. Other activities of the Committee

5.1 The Committee has amended or clarified the notice to the manufacturers and importers of proprietary medicinal products published in OJ N° C 302 of 15 December 1977, with regard to the following three points:

- the languages in which certain parts of the file can be supplied;

- the countries which request that the file be accompanied by samples of the proprietary product;

- the fact that the national registration fees remain applicable as laid down by the national laws.

5.2 The Committee expressed its opinion on the desirability of drawing up a Community model of a data sheet which would be used to summarize the marketing authorization and which could also be used for other purposes, e.g., medical information. It has prepared a list of the essential information to be stated on this sheet.

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5.3 The Committee also assessed the situation with regard to drug monitoring and considered that there should be more systematic mutual information on any potential danger. An early-warning system has been introduced for this purpose.

5.4 The system laid down in Article 33 of Directive 75/319/EEC for notifying decisions adopted by the competent authorities has been improved. A special treatment has been instituted for marketing authorizations concerning new substances, salts or esters, new routes of administration, new combinations, important new indications and new dosages and for refusals and revocations of MAs, the prohibition of supply and withdrawal from the market.

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II. DEVELOPMENT OF INTRA-COMMUNITY TRADE

The data are taken from the Analytical Tables of Foreign Trade - NIMEXE 1978 - published by the Statistical Office of the European Communities.

The statistics are given in European units of account (EUA).
Table 6 can be used for conversion to national currencies.

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1. a) Imports of medicaments for clinical and veterinary medicine (Value: 1 000 EUA) (Chapter 30.03 of the Common Customs Tariff)

Origin	EUR 9	DE	FR	IT	NE	B - L	UK	IR	DA
1978									
Intra-Com.	1.033.581	259.912	46.684	102.069	207.398	211.527	104.854	56.828	44.309
Extra-Com.	413.783	150.263	8.186	40.991	51.578	65.500	63.026	2.091	32.353

1. b) Percentage of intra-Community imports in total imports of medicaments

72 %	63 %	85 %	71 %	80 %	76 %	62 %	96 %	58 %

2. a) Imports of medicaments packaged for retail sale (value: 1 000 EUA)

Origin	EUR 9	DE	FR	IT	NE	B - L	UK	IR	DA
1978									
Intra-Com.	737.600	156.543	30.444	63.570	168.815	146.571	82.148	51.384	38.126
Extra-Com.	195.957	79.673	4.733	23.085	23.018	19.425	25.451	1.747	29.918

2. b) Percentage of intra-Community imports in total imports of medicaments packaged for retail sale

- 1974	81 %	73 %	82 %	77 %	92 %	89 %	73 %	91 %	58 %
- 1978	79 %	66 %	87 %	73 %	88 %	88 %	76 %	97 %	56 %

2. c) Percentage of medicaments packaged for retail sale in total Community medicaments imports

In 1978 medicaments packaged for retail sale accounted for 64.5 % of medicaments imported by the Community. This figure is slightly lower compared with those for previous years, which were marked by a constant increase in the relevant figure since 1974 (66 % in 1977, 65 % in 1976, 64 % in 1975, 63 % in 1974).

If only intra-Community imports are considered, packaged medicaments account for 71.3 % of the total intra-Community imports of medicaments (69.3 % in 1974 and 1975, 71 % in 1976, 72.4 % in 1977).

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3. a) Exports of medicaments for clinical and veterinary medicine (Value: 1 000 EUA) (Chapter 30.03 of the Common Customs Tariff)

Destination	EUR 9	DE	FR	IT	NE	B - L	UK	IR	DA
1978									
Intra-Com.	1.032.774	223.292	172.214	56.511	120.084	207.413	187.139	24.632	38.489
Extra-Com.	1.853.801	545.064	373.354	118.514	111.628	109.537	494.305	9.513	91.856

3. b) Percentage of intra-Community exports in total exports of medicaments

36 %	29 %	32 %	32 %	52 %	65 %	27 %	72 %	30 %

4. a) Exports of medicaments packaged for retail sale (Value: 1 000 EUA)

Destination	EUR 9	DE	FR	IT	NE	B - L	UK	IR	DA
1978									
Intra-Com.	796.544	191.593	119.016	35.583	81.730	193.308	122.424	15.235	36.655
Extra-Com.	1.555.042	444.373	339.726	104.475	93.487	99.789	381.268	7.073	84.852

4. b) Percentage of intra-Community exports in total exports of medicaments packaged for retail sale

- 1974	32 %	33 %	24 %	26 %	39 %	65 %	24 %	57 %	17 %
- 1978	34 %	30 %	26 %	25 %	47 %	66 %	24 %	68 %	30 %

4. c) Percentage of medicaments packaged for retail sale in total Community exports of medicaments

In 1978, medicaments packaged for retail sale accounted for 81.4 % of the medicaments exported by the Community.

5. Development of trade in medicaments packaged for retail sale (index 100 in 1974)

	DE	FR	IT	NE	B - L	UK	IR	DA
Indices in 1978								
Imports								
intra-Com.264	331	141	209	162	242	191	216	
extra-Com.368	235	173	361	172	202	67	238	
Exports								
intra-Com.163	301	324	368	224	293	639	405	
extra-Com.197	203	238	219	218	238	334	195	

6. Value of the European unit of account (EUA)

1 EUA =	DM	FF	Lit	Hfl	BF	UKL	IRL	DKr
1978	2,55607	5,73983	1080,216	2,75409	40,0611	0,663910	0,663888	7,01946

7. Comments

It is, of course, unnecessary to assess the effects of the Committee's procedure on the development of intra-Community trade, in view of the fact that it has been used so little.

ANNEX I

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