COMMISSION OF THE EUROPEAN COMMUNITIES

COM(81) 363 final

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THIRD COMMISSION REPORT TO THE COUNCIL ON THE FUNCTIONING OF THE COMMITTEE FOR PROPRIETARY MEDICINAL PRODUCTS

COM(81) 363 final

Third Commission report to the Council on the functioning of the Committee for Proprietary Medicinal Products

I. INTRODUCTION

1. Council Directive 75/319/EEC* establishing the Committee for Proprietary Medicinal Products provided, in Article 15(1), that the Commission should report to the Council annually on the operation of that Committee's procedure and its impact on the development of intra-Community trade.

Essentially, the Committee's procedure makes it possible for the holder of a marketing authorization in one Member State to file an application for authorization in respect of the same proprietary product in at least five other countries. Should one or more countries consider that such authorization cannot be granted, the objections are submitted to the Committee, which expresses a non-binding opinion.

2. The Committee's setting-up and running-in period, in 1977 and 1978, was the subject of an initial report**.

During 1979, the period covered by the Second Report***, the Committee meetings were the means of promoting cooperation between the national authorities, especially in the field of drug monitoring. Simultaneously, the Committee's three groups of experts were pursuing their work on the safety and efficacy of medicines and on plant-based products.

Nevertheless, by the end of 1979, the procedure had been used only twice, with two Committee opinions emerging.

3. This Third Report covers the year 1980 and the first half of 1981.

An increasing number of applications involving the use of the Committee's procedure were filed from the second half of 1980, but the vast majority of the opinions were not adopted until 1981.

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* OJ N° L 147, 9.6.75

** COM(79)59, 22.2.79

*** COM(80)149, 31.3.80

owing to the normal effect of the periods allowed for the procedure. It was therefore advisable to wait until 1981, so as to have a minimum amount of experience with this procedure and be able to arrive at a first assessment of its functioning. By the end of 1980, the Commission had already supplied information on the status of the Committee's procedure and its inadequacies in its report* to the Council on the approximation of laws relating to proprietary medicinal products. This report supported proposals** the main purpose of which is to secure mutual recognition of marketing authorizations, in particular through a change in the Committee's procedure.

4. Under such circumstances, assessment of the procedure's specific effects on the development of intra-Community trade remains purposeless. The statistics concerning the development of intra-Community trade in medicinal products between 1975 and 1980 are set out in Annex I. Intra-Community imports of medicinal products account for nearly three-quarters of the Community's total drug imports. It does not appear as though this high proportion can be exceeded. Almost two-thirds of exports go to non-member countries. The trade balance is in substantial surplus, as imports from outside the Community amount to scarcely a quarter of the volume of exports to non-member countries.

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* COM(80)789, 28.11.80

** Proposal for a Council Directive amending Directives 65/65/EEC, 75/318/EEC and 75/319/EEC and proposal for a Council Recommendation concerning tests relating to the placing on the market of proprietary medicinal products, OJ N° C 355, 31.12.80.

II. FUNCTIONING OF THE PROCEDURE PROVIDED FOR IN ARTICLES 9 - 11 OF DIRECTIVE 75/319/EEC

Various observations are called for as a result of consideration of the successive stages in the procedure for applications for marketing authorization, as provided in Articles 9 - 11 of Directive 75/319/EEC, which were made by a Member State, at the request of a manufacturer, to at least five other Member States.

1. FILING OF APPLICATIONS

Each application may relate to one or more proprietary medicinal products containing the same active substance in several pharmaceutical or dosage forms.

The number of applications filed has considerably increased since the second half of 1980.

Number of applications	1978	1979	1980 1st half	1980 2nd half	1981 1st half	TOTAL (JUNE 1981)
Filing of applications	2	2	1	6	5	16
Number of proprietary medicinal products	5	2	3	9	9	28

Some applications are accompanied by voluminous data and they reach the various countries concerned only after some delay, which, in two cases out of sixteen, has exceeded 45 days. In order to reduce this delay, the Committee has agreed that the applicant can be instructed by the country of origin to lodge himself a copy of the dossier with the countries concerned and the Committee's Secretariat.

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2. PRESENTATION OF THE DOSSIER

All the recent dossiers are in conformity with the presentation scheme recommended by the Committee.

This standard presentation exempts the applicant from complying with the various national forms of presentation, but also, and in particular, it considerably facilitates the Committee's proceedings.

Another appreciable advantage of the Committee's procedure is the possibility of employing languages other than the national language for the most voluminous parts of the scientific literature. In a notice* of July 1980 to applicants, certain countries stated which languages they could accept. Thus, in the case of a dossier in English, and even more in that of one in both English and French, only the general information on the product, the label and the package insert will, as a general rule, have to be translated. This obviates long, expensive and possibly dubious translations of some thousands of pages of each dossier.

ACCEPTABLE LANGUAGES ACCORDING TO THE NOTICE	BE	BRD	DK	FR	GR (3)	IR	IT	LUX	NL	UK
ENGLISH pharmaceutical dossier (1)	+	-	+	-	+	+	-	+	+	+
tests (2)	+	+	+	-	+	+	+	+	+	+
FRENCH pharmaceutical dossier (1)	+	-	-	+	+	+	-	+	+	-
tests (2)	+	-	+	+	+	-	+	+	+	-
GERMAN pharmaceutical dossier (1)	+	+	-	-	±	+	-	+	+	-
tests (2)	+	+	+	-	±	-	-	+	+	-

(1) Pharmaceutical dossier: composition, method of preparation and manufacturer's control methods (Art. 4(3), (4), (7), Directive 65/65/EEC)

(2) Analytical, toxicological and pharmacological tests and clinical trials (Art. 4(8), Directive 65/65/EEC :

(3) Particulars provided by the Greek member of the Committee.

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*OJ N° C 162, 2.7.80

3. MEMBER STATES INVOLVED IN THE COMMITTEE'S PROCEDURE

New drugs are generally first introduced in the United Kingdom, France and Germany. The Committee's procedure is therefore relatively little used vis-à-vis these three countries, where proprietary products are generally already being marketed when the procedure is initiated. Most of the applications forwarded to the Committee have been filed by the United Kingdom. This is partly accounted for by the fact that the original particulars and documents in English can be used directly in most of the other countires. It may be observed that, whereas the procedure requires that the applicant solicit at least five States, the average number has hitherto been less than six (5.875 to be exact).

Out of 16 applications at June 1981	BE	BRD	DK	FR	GR	IR	IT	LUX	NL	UK
Number of applications introduced by the country	3	1	3	0	0	0	0	0	0	9
Number of applications made to the country	12	8	12	7	0	9	10	15	15	6

4. NATIONAL EXAMINATION WITHIN 120 DAYS

As soon as receipt of an application by all the countries concerned has been confirmed, the Committee's Secretariat informs the national authorities by telex of the commencement of the prescribed maximum period of 120 days for the examination of the file. The applications examined hitherto have all been the subject of reasoned objections within the meaning of Article 10(2) of Directive 75/319/EEC. Usually such objections come from all the countries to which the applications are sent; those made upon expiry of the 120-day time-limit are not taken into account. The pledge that this time-limit will be complied with is an appreciable advantage for manufacturers.

The Committee hopes that in future national authorities will make a clear distinction between objections of substance, which require in-depth discussion by the Committee, and mere requests for clarification or linguistic amendments, which can be satisfied through direct contact with applicants before the Committee actually meets.

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5. OPINIONS OF THE COMMITTEE

The Committee has not yet been in a position to inform any Member State that, as provided in Article 10(1) of Directive 75/319/EEC, where no objections have been notified, the MA applied for should be granted. By May 1981 it had delivered eleven opinions within the 60 days referred to in Article 11(1) of this Directive, two of them being in 1979, two in 1980 and seven since the beginning of 1981.

Contrary to the fears expressed by the pharmaceutical industry, the Committee has not aggregated the demands of all its members. So far from this, it has been careful to assume moderate attitudes, securing the withdrawal of many objections during discussions.

Since dialogue between the applicant and the Committee has not yet been provided for in the current procedure, there remain a few analytical points to be clarified or a few amendments to be made in the general information or the package insert. The Committee mentions this in its opinion so that a manufacturer may give a single, comprehensive reply.

In the interests of companies concerned, it is not possible to quote the names of the medicines subjected to the procedure. It may be noted, however, that the Committee unanimously decided to adopt six favourable and two unfavourable opinions. The unfavourable opinions were due to inadequacies in the files as regards proof of the harmlessness and efficacy of the drugs.

Three other favourable opinions were adopted by the majority of the Committee members; one, three and four Committee members respectively were not wholly satisfied with the documents and particulars submitted.

6. ACTION TAKEN ON THE COMMITTEE'S OPINIONS

It is mandatory for the Member States to state their positions within 30 days of receiving the Committee's opinion.

More often than not they have, within this short time-limit, only been able to inform the Committee that they were preparing to comply with the opinion expressed. Authorization can then be granted only when the manufacturer

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has been able to submit the additional information requested by the Committee or when he has agreed to amend his package insert.

In the short term there is no prospect of the texts of national package leaflets being standardized, even if agreement can be obtained in the Committee on the main indications or other essential data of authorization.

In the case - a rarer occurrence - of a proposal to refuse a product, the manufacturer must be given the opportunity to exhaust all the possibilities offered by appeal proceedings at national level, which are often long-drawn-out. The Committee keeps itself regularly informed of the subsequent development of the procedure at national level. The Commission, for its part, watches very closely this stage of the implementation of the Committee's opinions in order to prevent unwarranted delays.

The Committee has also expressed the wish that any substantial changes made in the file once the product has been authorized be brought to its notice either by the manufacturer or by the national authorities in order, as far as possible, to keep a single file for each of the proprietary products in respect of which the Committee's procedure has been followed.

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III. COOPERATION WITHIN THE COMMITTEE

1. GENERAL

Cooperation between the national authorities through the instrumentality of the representatives within the Committee for Proprietary Medicinal Products continues to intensify. Among the subjects dealt with are strengthening of the information exchange system, drug monitoring, follow-up of the work of the panels of experts, and certain views concerning the implementation of the Directives.

The Committee for Proprietary Medicinal Products held six meetings in 1980, namely, on 24 January, 4 - 5 March, 2 April, 13 - 14 May, 9 September and 11 - 12 November. During the first half of 1981 the Committee met three times, i.e., on 10 - 11 February, 10 - 11 March and 11 - 12 May.

There have been some changes in the membership of the Committee. The Danish representatives are now Mr ANDERSEN, member, and Mrs KYLLINGSBAEK, deputy, while the French representatives are Mr GRECH, member, and Professor ALEXANDRE, deputy. Professor STILLE has been appointed the German representative's deputy.
Greece has appointed as its representatives on the Committee Professor VARONOS, member, and Mrs MELISSARATOU, deputy.
A list of the present members of the Committee is given in Annex II.

2. INFORMATION EXCHANGE SYSTEM

The exchange of information on medicines provided for by Directive 75/319/EEC has increased. Very simple procedures have been introduced in order to optimize the use of this information, without forcing either government departments or the Commission to create new instruments for this purpose.

Pursuant to Article 33 of Directive 75/319/EEC, all national measures relating to marketing authorizations for medicines must be brought to the attention of the Committee immediately. The common notification form (cf. Annex III) recommended by the Committee has been employed by all Member States since July 1980. It enables the Committee's secretariat

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to pass on to national authorities the most important data reportet by a Member State: new drugs (substance, dosage, new form or indications), refusals, cases of prohibition of a proprietary medicinal product and its withdrawal from the market. Up to now, approximately 2 000 forms of this type have been sent in to the Committee, which has forwarded about 800 to the appropriate government departments. Furthermore, this information is used by the Council of Europe for the purpose of updating Resolution AP (77)1 on drugs subject to medical prescription.

A list of national correspondents (Annex IV), which is regularly updated, has been drawn up to permit rapid exchange of accurate information in the following fields:

- decisions authorizing marketing (Article 33, Directive 75/319/EEC);
- withdrawal of batches, prohibition of supply (Article 28, Directive 75/319/EEC);
- manufacture, inspection (Article 30, Directive 75/319/EEC);
- drug monitoring (Articles 12 and 14, Directive 75/319/EEC).

3. DRUG MONITORING

Certain medicines have been the subject of special discussion by the Committee, which has reviewed their quality, safety or efficacy. Without formally referring to Articles 12 or 14 of Directive 75/319/EEC, Committee members have formed the habit of raising topical questions or presenting measures which their national authorities contemplate adopting.

More particularly, the following active principles have been dealt with: aristolochid acid; clioquinol; clonidine; dicycloverine; dinoprost; dinoprostone; difemerine furazolidone; Haemoresin(R); lynoestrenol; medroxyprogesterone; methapyrilene; nalidixic acid; noramidopyrine; oxetorone; sulfinpyrazone; tienilic acid; tipepidine; triazolam; valproic acid. Urgent measures taken at national level can be immediately communicated to the correspondents mentioned above.

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4. COMMITTEE'S PANELS OF EXPERTS

Pursuant to Article 13 of its rules of procedure, the Committee set up three panels of experts.

The Working Party on Medicinal Products of Plant Origin, chaired by Professor SCHNIEDERS, has not met since 1979 as it is awaiting the results of studies being carried out at national level, notably in Germany.

The Working Party on the Safety of Drugs, chaired by Dr GRIFFIN, completed its work in December 1979 and its proposals have been incorporated in the abovementioned proposal for a Council Recommendation of 4 December 1980. Nevertheless, it met on 9 June 1980 to revise the project relating to mutagenic potential, which will be formally submitted when the proposal for including the mutagenesis test in Directive 75/318/EEC has been adopted by the Council.

The Working Party on the Efficacy of Drugs, chaired by Dr DUKES, met four times in 1980, e.e., on 11 - 12 February, 21 - 22 April, 16 - 17 June and 29 - 30 September and once during the first half of 1981, namely on 22 - 23 June.
The draft concerning fixed combinations of drugs has been incorporated in the proposal for a Recommendation of 4 December 1980.
The studies concerning cardiac glycosides and oral contraceptives have been completed. Considerable differences of opinion have emerged regarding the clinical trials which have to be carried out in the case of drugs intended for use in long-term treatment, such as nonsteroid anti-inflammatory agents, antiepileptics and antianginal agents. The status of the work of this panel is presented in a table, which appears in Annex V.

The consultation procedures are far advanced. The main object of the work of the Committee's experts is to try to avoid, in some fields which have priority, differences in the implementation by the national authorities of the provisions of Directive 75/318/EEC, which relate to the standards and procedures in respect of the testing of medicines. This work entails a very onerous consultation procedure, which it is advisable to mention at this point. The priority subjects are determined by the Committee for Proprietary Medicinal Products by agreement with the Pharmaceutical Committee. The national authorities appoint the experts they consider best qualified to take part in the work. During the stage in which the projects are being drawn up,

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these government experts usually consult various experts of their choice in the universities or the pharmaceutical industry. When a project is considered by the panel to have made adequate progress, it is submitted to the Committee for Proprietary Medicinal Products. Once the Committee has provisionally accepted the text presented, it forwards it for comment to the national authorities, who then consult the parties concerned at national level. Simultaneously, the Commission sends the project to the representatives of the European pharmaceutical industry. The observations obtained are then studied by the panel of experts over a period of six to ten months and a definitive draft is submitted to the Committee for Proprietary Medicinal Products for adoption. The Commission and, where appropriate, the Council decide in due course upon the action to be taken on these various projects.

At a joint meeting of the experts in the working parties and experts representing the European pharmaceutical industry on 10 June 1980, a certain concurrence of views emerged at the technical level. However, the pharmaceutical industry has on several occasions regretted that it had not been formally consulted when these projects were first being drawn up. The Committee has not yet considered it advisable to admit the industry's representatives to the working parties.

5. COMMENTS ON THE IMPLEMENTATION OF THE DIRECTIVES

In the course of its work, the Committee has been faced with various questions raised by the national authorities during the implementation of the provisions of Directives 65/65/EEC, 75/318/EEC and 75/319/EEC which are directly connected with the examination of applications for authorization.

In the first instance, these reflections conduce to more uniform implementation of these Directives. Thus it was that the Committee defined its position regarding the question whether certain preparations possessed the characteristics of medicines or proprietary medicinal products. It has also studied the national requirements for identification of colouring agents in finished products. The work of the panels on safety and efficacy has served to bring closer together the points of view of the national experts concerning the implementation of Directive 75/318/EEC as regards pharmacological and toxicological tests and clinical trials, while highlighting the various differences of opinion. Furthermore, this work has greatly facilitated the adoption of the Committee's opinions on applications submitted in accordance with the procedure laid down in Article 9 of Directive 75/319/EEC.

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In the medium term, certain comments may prompt the Commission, if it considers it worth-while, to make proposals for improving the present Directives, after consulting the Pharmaceutical Committee.

For instance, it is not easy to interpret Article 4(8) of Directive 65/65/EEC, which makes provision for certain exemptions concerning the admission of the results of pharmacological and toxicological tests and clinical trials. Some authorities accept an abridged dossier if the drug is well known. The Committee has enquired about the practices in force in the Member States because it has itself had to define its position when two abridged applications submitted in accordance with its procedure have been examined.

In addition, the Committee has taken note of post-marketing-surveillance pilot projects. They concern clinical trials carried out after marketing and intended, in very special cases, to enable the volume of the initial application file to be reduced in order not to deprive patients for too long of a drug that is valuable but exerts certain rare side-effects which perhaps can be detected only as a result of a great number of observations.

Finally, the Committee has acquainted itself with the new problems relating to the testing of substances manufactured by means of bioengineering processes bringing genetic manipulation techniques into play.

ANNEXE I

ECHANGES INTRA- ET EXTRACOMMUNAUTAIRES

(Médicaments à usage humain et vétérinaire, Chapitre 30.03 du T.D.C.)

1. IMPORTATIONS, en millions d'UCE, T.D.C. Chapitre 30.03

Année d'importation	EUR. 9	DEUT.	FR	IT	NL	B-L	UK	IREL.	DK
1975	782	196	18	91	142	184	79	32	40
% intra CEE	74 %	67 %	83 %	72 %	87 %	79 %	59 %	90 %	59 %
1976	1.034	258	21	117	199	230	107	42	56
% intra CEE	72 %	62 %	77 %	71 %	87 %	77 %	59 %	87 %	60 %
1977	1.189	326	35	112	217	240	143	49	67
% intra CEE	73 %	63 %	87 %	73 %	84 %	76 %	65 %	97 %	64 %
1978	1.447	410	55	143	259	277	168	59	77
% intra CEE	72 %	63 %	85 %	71 %	80 %	76 %	62 %	96 %	58 %
1979	1.648	482	65	154	281	301	210	71	82
% intra CEE	72 %	65 %	78 %	72 %	80 %	76 %	65 %	98 %	59 %
1980 *)	1.849	540	101	182	296	322	231	87	90
% intra CEE	72 %	63 %	74 %	73 %	82 %	75 %	69 %	98 %	60 %

2. EXPORTATIONS, en millions d'UCE, T.D.C. Chapitre 30.03

Année d'exportation	EUR 9	DEUT.	FR	IT	NL	B-L	UK	IREL.	DK
1975	1.786	518	344	116	126	171	427	16	79
% intra CEE	33 %	31 %	26 %	27 %	49 %	66 %	23 %	59 %	24 %
1976	2.184	642	407	137	179	220	475	22	100
% intra CEE	33 %	31 %	26 %	34 %	48 %	65 %	24 %	65 %	24 %
1977	2.551	708	472	172	211	266	573	29	120
% intra CEE	33 %	28 %	28 %	30 %	51 %	63 %	24 %	72 %	24 %
1978	2.887	768	546	175	232	317	681	34	130
% intra CEE	36 %	29 %	32 %	32 %	52 %	65 %	27 %	72 %	30 %
1979	3.136	862	649	187	237	334	675	45	147
% intra CEE	37 %	29 %	33 %	33 %	53 %	64 %	34 %	71 %	32 %
1980 *)	3.801	992	828	221	278	394	868	49	171
% intra CEE	35 %	30 %	29 %	31 %	52 %	59 %	29 %	69 %	32 %

*) Chiffres provisoires

ANNEXE II

LISTE DES MEMBRES DU COMITE DES SPECIALITES PHARMACEUTIQUES

COMMITTEE FOR PROPRIETARY MEDICINAL PRODUCTS

Président / Chairman :

M. Léon ROBERT — 18, rue J.P. Koenig, L-1865 Luxembourg, Tél.: (352) 260.76

Vice-Présidents / Deputy Chairmen :

1. Prof. Duilio POGGIOLINI — Direttore Generale del Servizio Farmaceutico, Ministero della Sanità

2. M. Nicolaas BEL — Chef de Division à la Direction générale du Marché intérieur et des Affaires industrielles - III/A-3, Commission des Communautés européennes

LISTE DES MEMBRES / LIST OF MEMBERS

a) Représentants / Representatives :

b) Suppléants / Deputies :

BELGIQUE

a) M. Ben HUYGHE — Inspecteur Général, Inspection générale de la Pharmacie, Ministère de la Santé publique, Cité Administrative, Quartier Vésale, 1010 Bruxelles, Tél.: 564.10.64, Télex: 25.798

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ANNEXE III FORMULAIRE COMMUN DE NOTIFICATION DES DECISIONS NATIONALES

COMMITTEE FOR PROPRIETARY MEDICINAL PRODUCTS

NOTIFICATION UNDER ARTICLE 33

State of origin _____

Product reference numbers _____

_____

_____

1. Name of the Product: _____

2. Name of the licence holder: _____

_____

3. Qualitative and quantitative particulars in terms of its active ingredients

_____

_____

_____

_____

4. Pharmaceutical form _____

_____

5. Method and route of administration _____

_____

6. ☐ Notification only - copy to other Member States not required
(Product with established use)
Marketing Authorization granted: Date _____

OR

7. ☐ To be brought to the attention of other Member States.

Marketing Authorization granted

Date _____

- 1.1 ☐ New drug substance, salt or ester
- 1.2 ☐ New route of administration
- 1.3 ☐ New combination
- 1.4 ☐ Major new use
- 1.5 ☐ New dosage form
- 1.6 ☐ Other

Other Action

Date _____

- 2 ☐ Refused
- 3 ☐ Revocation
- 4 ☐ Cancellation of 2 above
- 5 ☐ Prohibition of supply (Article 28)
- 6 ☐ Withdrawn from market (Article 28
- 7 ☐ Cancellation of 5 above
- 8 ☐ Cancellation of 6 above

8. Reasons for action (where appropriate)

ANNEXE IV

LISTE DES CORRESPONDANTS NATIONAUX POUR LES ECHANGES D'INFORMATIONS PREVUS PAR LA DIRECTIVE 75/319/CEE

LIST OF NATIONAL CORRESPONDENTS FOR EXCHANGES OF INFORMATION AS PROVIDED BY DIRECTIVE 75/319/EEC

ECHANGE D'INFORMATIONS
EXCHANGE OF INFORMATION } Directive 75/319/CEE EEC

COMITE DES SPECIALITES PHARMACEUTIQUES

COMMITTEE FOR PROPRIETARY MEDICINAL PRODUCTS

Président / Chairman:

Mr. Léon ROBERT

18, rue J.P. Koenig
L-1865 Luxembourg

Téléphone: (352) 260.76

COMMISSION
DES
COMMUNAUTES EUROPEENNES

Direction générale du marché intérieur et des affaires industrielles

ETAT MEMBRE
MEMBER STATE

BELGIQUE

PERSONNES RESPONSABLES DE L'INFORMATION
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Nom et Fonction Name and Function	Adresse Address	Teleph. & Telex	Type d'information (*) Type of information(*)
Mr. VAN HERPE, G. Conseiller	Ministère de la Santé publique et de la Famille Inspection générale de la Pharmacie Rue Montagne de l'Oratoire, 10 B-1010 Bruxelles	(2)564.10.29 (2)564.10.62 Télex: 25768	(1) (2) (3)
Mad. ROLAND, N. Inspecteur	- " -	(2)564.10.40	(4)
Mad. THYS, I. Pharmacien	- " -	(2)564.10.46	(4)
Mr. MEYER, P. Pharmacien	- " -	(2)564.10.47	(4)

(*) 1.) autorisations de mise sur le marché / marketing authorizations

2.) retrait de lot, interdiction de délivrance / batch withdrawal, prohibition of supply

3.) autorisation de fabrication, inspections / manufacturing authorization, inspection

4.) pharmacovigilance / drug monitoring

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DENMARK

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Nom et fonction Name and function	Adresse Address	Teleph. & Telex	Type d'information (*) Type of information(*)
H.C.Andersen Sekretariatschef	Sundhedsstyrelsen Frederikssunds-vej 378., 2700 Brønshøj, Danmark.	(02) 94 37 73 Telex 35333 ipharm	1. 2. 3. 4.
Helga Kyllingsbæk Lic. pharm.	- " -	(02) 94 37 73 Telex 35333 ipharm	1. 2. 3. 4.

(*) 1.) autorisations de mise sur le marché / marketing authorizations

2.) retrait de lot, interdiction de délivrance / batch withdrawal, prohibition of supply.

3.) autorisation de fabrication, inspections / manufacturing authorization, inspection

4.) pharmacovigilance / drug monitoring

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Nom et fonction Name and function	Adresse Address	Teleph. & Telex	Type d'information (*) Type of information(*)	Teleph. privat
Dir. u. Prof. Dr. B. Schnieders Head of Institute	Institut für Arzneimittel des Bundesgesundheitsamtes Stauffenbergstraße 13 D-1000 BERLIN 30	(30) 26.37.203/04 Telex 1 83 310	1, 2, 4	811.78.29
Dir. u. Prof. Prof. Dr. G. Stille Head, Department Experim./clinical Pharmacology	- " -	26.37.311/312	1	826.45.76
Dir. u. Prof. Prof. Dr. P.Schönhöfer Head, Department Drug monitoring	- " -	26.37.248/249	2, 4	
Dir. u. Prof. Dr. Schuster Coordination of registration of drugs	- " -	26.37.288	1	
Dr. K. Feiden Ministerialrat	Bundesministerium für Jugend, Familie und Gesundheit, Postf. 200 D-5300 Bonn 2	(2221) 83.42.65	3	
Dr. Chr. Gaudich Regierungsdirektorin		490 83.43.35 Telex: 8-85 517	3	

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MEMBER STATE

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Nom et Fonction Name and Function	Adresse Address	Teleph. & Telex	Type d'information (*) Type of information(*)
Pierre GRECH Adjoint au Directeur	Ministère de la Santé et de la Sécurité Sociale Direction de la Pharmacie et du Médicament 1, place de Fontenoy 75700 - PARIS	567.55.44 Poste 54.92 Ligne directe 306.59.48	1.2.3.4.
Yvonne CHAVAUDRET Pharmacien chargé du bureau des Affaires Internationales	Même adresse	567.55.44 Poste 55.04 Ligne directe 306.5947 --- Télex : SANTSEC 2500 11 F	1.2.3.4.

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GRECE

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Nom et Fonction Name and function	Adresse Address	Teleph. & Telex	Type d'information (*) Type of information(*)
Prof. D. Varonos Exp.-Pharm. Head, Dep. of Pharmacology, Athens University	Department of Experim.Pharmacology Athens University Goudi 609, Athens	Tél.: (00301) 77.90.841 Télex: 215927 Y.K.Y.P. GR.	1, 2, 4
Mrs. G. Melissaratou Pharmacien	Ministry of Social Services Artisotelous 17 Athens	(00301) 52.37.483	3

(*) 1.) autorisations de mise sur le marché / marketing authorizations

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Nom et Fonction Name and Function	Adresse Address	Teleph. & Telex	Type d'information (*) Type of information(*)
Dr. A. SCOTT, Mrs. Medical Director	National Drugs Advisory Board 57C Harcourt Street Dublin 2	Dublin 68.10.98 68.14.11 78.28.86 Telex: 4894 Department of Health, For the attention of N.D.A.B.	(1) (2) (3) (4)

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Direction générale du marché intérieur et des affaires industrielles

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ITALIA

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Nom et Fonction Name and Function	Adresse Address	Teleph. & Telex	Type d'information (*) Type of information(*)
Prof. Duilio POGGIOLINI Direttore Generale del Servizio Farmaceutico	Ministero della Sanità Servizio Farmaceutico Viale della Civiltà Romana, 7 00144 ROMA EUR	(6) 592.5863 (6) 592.5824 Télex: 610453 MINSAN I	(1) (2) (3) (4)
Dr. Romano CAPASSO Chimico Superiore	idem	(6) 592.5828	idem

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LUXEMBOURG

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Nom et Fonction Name and Function	Adresse Address	Teleph. & Telex	Type d'information (*) Type of information(*)
Mad. LOUTSCH-WEYDERT, J.	Inspection des Pharmacies 28, bd. Joseph II Luxembourg	47.55.01 Télex: 2546 SANTE LUX	(1) (2) (3) (4)

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MEMBER STATE — NETHERLANDS

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Nom et Fonction Name and Function	Adresse Address	Teleph. & Telex	Type d'information (*) Type of information(*)
Drs. R.A. Drost, inspecteur	Case postale 5811 2280 HV Rijswijk (ZH)	070 - 94.95.05 Télex 32691	(1)
Dr. C.A. Teijgeler, Voorzitter	Case postale 439 2260 AK Leidschendam	070 - 20.92.60 Télex 32362 v m nl	(2) + (3)
Drs. R.H.B. Meyboom, inspecteur	idem	idem	(4)

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UNITED KINGDOM

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Nom et fonction Name and function	Adresse Address	Teleph. & Telex	Type d'information (*) Type of information(*)
		Telex 883669 Telephone (1) 720.21.88	
Mr. W. CROSTON Principal Licensing Officer	DHSS Market Towers 1 Nine Elms Lane London SW8 5NQ	ext. 3413	1
Mr. R. BAKER Superintending Medicines Inspector	- " -	ext. 3353 or 3354	2 and 3
Dr. R. PENN Principal Medical Officer	- " -	ext. 3143 or 3146	4

(*) 1.) autorisations de mise sur le marché / marketing authorizations

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COMMISSION OF THE E.C.

PERSONNES RESPONSABLES DE L'INFORMATION
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Nom et Fonction Name and Function	Adresse Address	Teleph. & Telex	Type d'information (*) Type of information(*)
Mr. N. BEL Chef de Division	Commission des Communautés européennes D.G. III/A-1 Rond Point Schuman 3 B-1049 Bruxelles	(2) 735.00.40 (2) 735.80.40 (2) 735.80.30 ext. 1891 Télex: 21877 COMEU B	1, 2, 3, 4
Mr. P. DUPRAT Administrateur principal	- " -	- " - ext. 3524/6935	
Mr. F. SAUER Administrateur	- " -	- " - ext. 5180/6935	

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ANNEXE V

COMMITTEE FOR PROPRIETARY MEDICINAL PRODUCTS

PROGRESS REPORT ON EFFICACY GUIDELINES

1. Subject of instruction to the working group	2. Ref. nº of draft actively prep.by working group	3. Draft submitted to CPMP	4. Draft forwarded to national agencies for comments	5. Rediscussion of comments in the working group	6. Revised version before CPMP	7. Approval by CPMP	8. Adoption and publication
Fixed combinations	III/115/79 (ex 1387)	01-78			11-78	11-78	
Non-steroid. anti-inflamm.	III/115/79 (ex 1388)	01-78		since 78			
Antiepileptic	III/634/78	04-78	06-78	02-80	05-80		
Cardiac Glycosides	III/635/78	11-78	11-78			11-80	
Bioavailability	III/573/79	11-78	06-79				
Pharmacokin.in man	III/1665/79						
Antianginal	III/1261/78	11-78	11-78				
Or.contr.clinical	III/571/79	02-79	06-79	02-80	05-80	11-80	
Or.contr.informat.	III/572/79	02-79	06-79	02-80	05-80	11-80	
Antihypertensive	III/1667/79	05-80	05-80	.....	.....	.....	(OMS/WHO text)
Antihyperglycaemic							
Antiarrhythmic							
Long-term use							
Topical corticoids							
Peripheral circulat.	III/1664/79						
Antimicrobial drugs	III/1666/79	05-80	05-80				
Pregnancy	III/654/79						
Diuretics							
X-ray contrast							