COMMISSION OF THE EUROPEAN COMMUNITIES

COM(82) 787 final

Brussels, 3 December 1982

FOURTH COMMISSION REPORT TO THE COUNCIL

ON THE FUNCTIONING OF THE COMMITTEE FOR PROPRIETARY MEDICINAL PRODUCTS

COM(82) 787 final

I. INTRODUCTION

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

   This Fourth Report(**) covers in particular the Committee's activities from July 1981 to September 1982.

2. The Committee's procedure, which permits the holder of a marketing authorization to send an application for marketing authorization to at least five other Member States by way of the Member State which granted the authorization, is still in reality an exceptional procedure when compared with the filing of separate applications in each Member State.

   Nevertheless, the 28 applications received in five years, above all since the end of 1980, are useful pointers on the way towards the free movement of medicinal products.

3. Cooperation within the Committee between those responsible at national level for marketing authorizations has developed further, especially as regards the exchange of information on the side effects of medicines (drug monitoring). The increasing part played by the Committee in the coordination of national decisions on marketing authorizations, as provided for in Articles 12 and 14 of Directive 75/319/EEC, is the most encouraging aspect of its current operation.

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(*) OJ No L 147, 9.6.75

(**) The file references of the three previous reports are COM(79)59, 22.2.79; COM(80)149, 31.1.80; and COM(81)363, 13.7.81.

4. The experience gained within the Committee makes a useful contribution to the discussions which have been held by the Council's experts since November 1981 on the proposal(*) for the amendment of Directives 65/65/EEC, 75/318/EEC and 75/319/EEC. The Commission has involved itself in these discussions in order to ensure that the new procedure for the recognition of authorizations that is being proposed to manufacturers remains attractive and is not weighed down with measures which are likely to be no more successful than the present procedure.

   The Committee's experience will in part be beneficial to the activities of the future Committee for Veterinary Medicinal Products set up by Council Directive 81/851/EEC(**) which, together with Directive 81/852/EEC(**), will henceforth govern marketing authorization for veterinary medicines.

5. The development of intra-Community trade in medicinal products between 1975 and 1981 is shown in Annex I. From 1981 onwards, Greece is included. In 1981, intra-Community trade continued to account for the greater part (70.5 %) of the total imports by Member States. The balance of trade in medicinal products between the Community and non-member countries is still in substantial surplus.

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(*) OJ No C 355, 31.12.80

(**) OJ No L 317, 6.11.81

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

1. General

It should be remembered first of all that the procedure provided for in Articles 9 to 11 of Directive 75/319/EEC is not a Community registration procedure for medicinal products. It is a special means of submitting application dossiers which is intended to make it easier to obtain marketing authorization in five or more Member States, on the basis of an authorization obtained in one Member State in accordance with the criteria set out in the directives relating to proprietary medicinal products. During the period for examination of applications, which is 120 days as in the case of the normal national procedure provided for in Directive 65/65/EEC, the Member States can issue reasoned objections on which the Committee has to give its non-binding opinion within 60 days. At the end of this Community consultation phase, the Member States concerned reach a decision on the marketing authorization, applying the same criteria as in the purely national procedures and complying with Articles 30 to 36 of the EEC Treaty and with the Directives(**) relating to proprietary medicinal products.

2. Applications filed in accordance with the Committee's procedure

2.1 Filing of applications

Since the second half of 1980 the number of applications has been growing steadily if a little slowly. Some applications concern several different presentations (dosage form or strength) of the same active principle, and therefore, strictly speaking, several proprietary medicinal products.

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(*) OJ No 22, 9.2.65

(**) Directives 65/65/EEC and 75/319/EEC cited above;
Directive 75/318/EEC, OJ No L 147, 9.6.75 (tests of medicinal products);
Directive 78/25/EEC, OJ No L 11, 14.1.78 (colouring agents).

	1978	1979	1980	1981	1982 (9 months)	TOTAL (Sept. 82)
Number of applications	2	2	7	7	10	28
Number of proprietary medicinal products (or presentations)	5	2	12	11	14	44

These 28 applications forwarded to the Committee cover 179 national applications for authorization, which is an indication that the geographical spread of recent applications has widened. The index for the number of countries per application has risen from 5.875 in July 1981 to 6.4 in September 1982, the minimum number of Member States permitted under the procedure being five.

As a rule the firms, in agreement with the Member State which has notified the Committee, take it upon themselves to send the dossier to the Member States which the application concerns and to the secretariat of the Committee. In view of the considerable size of some of the dossiers, the time taken for filing the application depends on how it is routed; the quickest way is for the firm itself to file the application.

The secretariat is informed by telex or telephone by the countries receiving the applications, in order that it may fix the date when the 120-day period for examination of the dossiers is to start as soon as they have arrived in all the countries concerned.

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2.2 The countries concerned

The 28 applications recorded (September 1982) show that a gradual diversification is taking place as regards the origin and destination of applications.

Out of 28 applications at September 1982	B	D	DK	F	GR	IRL	IT	LUX	NL	UK
Number of applications filed by the country	4	3	5	5	0	0	0	0	0	11
Number of applications made to the country	23	17	18	12	5	16	21	26	25	13
Total = "participation index"	27	20	23	17	5	16	21	26	25	24

Only five countries have forwarded applications: these are, above all, the United Kingdom, followed by France, Denmark, Belgium and Germany. More effort should perhaps be made in the other Member States to inform the manufacturing companies of the opportunities offered by the Committee's procedure.

The countries to which applications are made are chiefly those with relatively small markets, namely Luxembourg, the Netherlands, Belgium and Denmark. Firms have a tendency to file separate applications, for example in the United Kingdom, France and Germany, before making use of the Committee's procedure to apply in the other Member States. Moreover, medicinal products are often registered in the United Kingdom and in Ireland simultaneously.

The total of the two figures to some extent provides an index of the "participation" of each Member State in the procedure, both as an applicant and as a recipient. This "participation index" is clearly very similar for all the Member States except Greece, which has only recently joined.

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2.3 The firms concerned

The Committee's procedure takes place prior to the granting of marketing authorizations, and in the applicants' interest the names of the firms and medicinal products concerned are therefore not made public. It should be noted, however, that the 28 applications are more or less equally shared between major multinationals and medium-sized undertakings.

It is also worth taking a look at the original nationality of the undertakings or the groups to which they belong, on the basis of the information available and on the understanding that this concept might give cause for discussion. It goes without saying that the applicant firms are all established within the territory of the Community.

Origin of group	USA	DK	F	B	SWEDEN	UK	D	NL
Number of applications	8	7	5	3	2	1	1	1
Number of firms	7	3	5	1	2	1	1	1

2.4 The products

The applications cover a wide variety of product types:

- 4 non-steroid anti-inflammatory agents
- 3 antibiotics
- 3 analgesics
- 3 antihypertensives
- 1 anti-anginal agent
- 1 oral contraceptive
- 1 anaesthetic solution
- 1 anti-osteoclastic (Paget's disease)
- 1 potassium
- 1 calcium
- 1 antitussive syrup

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- 1 antidyspeptic
- 1 anti-smoking drug
- 1 anti-glaucoma collyrium
- 1 glucocorticoid-based nasal spray
- 1 powder for varicose ulcers
- 1 occlusive gel for surgical use
- 1 topical solution for the treatment of herpes
- 1 solution for warts

2.5 Presentation of dossiers

One significant advantage of the Committee's procedure lies in the relaxation of the language rules set out in a notice(*) to applicants, which is not always sufficiently known.

It should be remembered on the one hand that the largest part of the dossier, i.e. that concerning the analytical, toxicological and pharmacological tests and clinical trials, is accepted in English by all the Member States except France, and in French by all Member States except Germany, the United Kingdom and Ireland.

The "pharmaceuticals" dossier, on the other hand, which concerns the composition, the method of preparation and the manufacturer's routine checks, is accepted in English by all the Member States except France, Germany and Italy, and in French by all the Member States except Denmark, Germany, Italy and the United Kingdom.

A conventional order of presentation of the dossiers, recommended by the Committee for Proprietary Medicinal Products, makes the task of the Committee and of the manufacturers easier.

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(*) OJ No C 162, 2.7.1980

3. Opinions of the Committee

The case provided for in Article 10.1 of Directive 75/319/EEC where, in the absence of any objections, the Committee is not required to give its opinion, has not so far arisen.

Assessing the benefits to be expected from a therapeutic drug as against its actual or potential risks is a difficult and complex task for the national authorities, who are anxious to elicit as many guarantees as possible before granting marketing authorization.

3.1 Reasoned objections

The frequency of the initial objections raised within the 120 days against the applications indicates that the Member States have so far taken a very cautious approach. The national authorities tend always to want more information than is available in the dossier which served as the basis for the authorization given by the original Member State in accordance with the Directives.

The information is often already in the possession of the applicant but he has not seen fit to pass it on in full.

There have therefore been numerous questions regarding the analytical part of the dossier. These relate to:

- the impurities resulting from the method of synthesizing the active principle;
- the exact specifications of starting materials not referred to in the European or relevant national Pharmacopoeia;
- precise nature of the container;
- checks carried out during manufacture;
- specificity of the method of quantitative determination of the active principle in the finished product;
- details of the stability tests.

Directives 75/318/EEC and 75/319/EEC require the submission of summaries and an expert opinion on the analytical, pharmacological/toxicological and clinical parts of the dossier, and these are not always provided. Clear presentation and clear conclusions would undoubtedly help to reduce the number of these objections.

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Other objections are of a more serious nature, calling for tests additional to those applied for the purpose of the original authorization. Some of these tests, such as the carcinogenicity test, might take several years to complete. A situation like this can arise when the original authorization was granted several years previously but the opinion of the experts has since moved towards tighter requirements. Firms are therefore recommended to update their dossiers so as to adapt them to the scientific requirements prevailing when they make their new application.

In a few cases difficulties have arisen owing to the small therapeutic interest of products which do not lend themselves to controlled clinical testing. It would seem preferable to refrain from putting through this procedure products which have only marginal indications and the need for which might be disputed.

3.2 The adoption of opinions

In spite of the organizational problems encountered, particularly as regards the rapid translation and dissemination of objections, the Committee has always managed to deliver its opinions within the sixty days allowed.

The 21 opinions rendered by the Committee up to September 1982 break down as follows:

- 10 favourable opinions, 8 of which were unanimous;
- 6 unfavourable opinions;
- 5 divided opinions, without majority.

In view of the frequency of the objections received, the predominance of favourable opinions illustrates the very active part played by the Committee, which, after discussion, succeeds in removing many of the objections.

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Even in its favourable opinions the Committee indicates to the manufacturer those points in the dossier which still have to be clarified in order to satisfy the requirements of the directives on marketing authorization. Invariably, the need is for more precise details in the analytical part of the dossier or for amendments to the general information or the package insert.

If a favourable opinion is not unanimous, the conflicting views are stated as well.

Unfavourable opinions adopted by the Committee as a whole tend to call into question not so much the products themselves as substantial gaps in dossiers which have been submitted without having been brought up to date.

The divided opinions and, moreover, the conflicting views expressed in some of the Committee's favourable opinions, bear witness to the multiplicity of choice in public health matters. Any medicinal product has its inherent risks and there is no sure criterion for fixing the level of risk acceptable to each Member State with due regard to the therapeutic advantage hoped for. The Commission, for its part, makes sure that the opinions expressed keep within the bounds of the Treaty and the Community directives.

3.3 Action to be taken on the Committee's opinions

When favourable opinions contain reservations, marketing authorizations cannot as a rule be granted within the time limit of 30 days from notification of the Committee's opinion.

The time taken by manufacturers to reply to the questions of the national authorities on the grounds of the opinion of the Committee is itself very variable and is sometimes beyond the Committee's control if the manufacturer does not see fit to send it a copy of his reply to the national authorities concerned.

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As a remedy for these drawbacks, on receipt of the Committee's opinion the Member States notify it of the action they intend to take. The Committee then keeps a regular check on the progress of applications which are pending, until the final decision is taken as to authorization or refusal.

On the basis of 18 initial opinions of the Committee - corresponding to 105 applications for marketing authorization and 77 in principle favourable positions of individual members - 40 marketing authorizations have already been granted.

In the purely national marketing authorization procedure the usual time limits for examination are suspended whenever, as is very often the case, the authorities want additions to the dossier (Article 4(c) of Directive 75/319/EEC). In like manner, applications which have been the subject of an opinion from the Committee receive the same treatment as purely national ones, but are assured of direct Community supervision of their progress.

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III. COOPERATION WITHIN THE COMMITTEE

1. General

The Committee for Proprietary Medicinal Products meets about once every two months, depending on the deadlines resulting from the filing of applications for marketing authorization transmitted by way of the Committee's procedure.

Since July 1981, meetings have taken place on 7 and 8 July, 6 and 7 October and 8 and 9 December 1981 and on 6 and 7 April, 8 and 9 June and 7 and 8 September 1982.

The organization and work of the Committee's secretariat are a growing burden on the Commission. To give an example, in 1981 the Committee for Proprietary Medicinal Products alone required the translation of some 450 pages of scientific texts.

2. Composition of the Committee

The term of office of the Chairman and the members is three years. The Chairman may be re-elected once only.

In the first 6 years of the Committee's existence Mr. Léon Robert took the Chair for two terms, having previously taken part as the Luxembourg representative in virtually all the initiatives and official meetings in the field of pharmaceuticals that had taken place in Europe since 1947, including in particular the European Pharmacopoeia, the Commission of which he had chaired. He was supported in his task by his two Deputy Chairmen, Professor Duilio Poggiolini, Director-General of the Italian Pharmaceutical Service, and Mr. Nicolaas Bel, Head of the Pharmaceuticals and Veterinary Medicinal Products Division of the Commission of the European Communities.

At the meeting of September 1982 Dr. Teijgeler, President of the College ter Beoordeling van Geneesmiddelen in the Netherlands, was elected Chairman of the Committee for Proprietary Medicinal Products.

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The present composition of the Committee is given in Annex II.

3. Exchange of information within the Committee

Since 1980 a system of information exchange has been set up in order to enable the Member States the better to meet their obligations under Articles 30 and 33 of Directive 75/319/EEC.

A network of national correspondents has been formed and is constantly updated so that it can receive by telephone or telex information or questions on medicinal products, especially in cases of emergency (Annex III). Although the network is not often used it was considered very important to keep it in operation, and a similar system was set up on an informal basis between 45 countries, including the Member States of the Community, at the second meeting of ICDRA (the International Conference of Drug Regulatory Authorities), organized by the Italian Minister of Health in April 1982 under the patronage of the World Health Organization.

Since 1980, systematic notifications to the Committee of authorizations, withdrawals, refusals and suspensions of medicinal products have numbered about 5 500, a common form being used for this purpose. The Commission has redistributed some 2 600 of these notifications to the Member States for information and to the Council of Europe to help in updating Resolution AP(77)1 on medicinal products available only on prescription.

After the new system of notifications has been in operation for two years the Committee plans to establish more selective criteria for the dissemination of information among the Member States.

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4. Drug monitoring

At each of its meetings the Committee discusses questions relating to the quality, safety or efficacy of particular medicinal products, as required by Articles 12 and 14 of Directive 75/319/EEC.

The discussion mainly concerns the side effects of certain medicaments: information available, investigations in progress, conclusions of scientific symposia or procedures for hearing the firms concerned. This allows the national authorities to know in advance the steps which the other Member States intend to take.

The Members of the Committee have made it a habit to consult each other before taking important decisions on refusals, withdrawals or suspensions.

Since July 1981, particular attention has been paid to medicinal products containing the following active principles: noramidopyrine, sodium methanesulphonate, phenazone, propyphenazone, emepronium bromide, oxyphenisatine, aristolochic acid, insoluble salts of bismuth, phenacetin, progestagens, benoxaprofene, fenbufene, tienilic acid, penfluridol, dexamethasone, hydrocortisone, association of chloramphenicol with tetracyclin, etretinate, bisoxatine, ticlopidine, suxibuzone, association of benzylpenicillin with kanamycin, tiaramide, feprazone, gold salts, ACTH, nitrofurans, anorexiants, preparations based on Bac. subt., benzyl alcohol for preserving injection solutions, amphoprinol, amrinone, benfluorex.

5. Committee's panels of experts

Under Article 13 of its rules of procedure, the Committee has so far set up three working parties as and when the need has arisen.

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The Working Party on Medicinal Products of Plant Origin, chaired by Professor Schnieders, has not met again, chiefly because of the differences of opinion among members of the Committee as to the tasks to be assigned to it. Professor Schnieders has, however, sent the members of the Working Party a good deal of documentation resulting from studies carried out by an ad hoc committee of the Bundesgesundheitsamt.

The Working Party on the Safety of Drugs, chaired by Dr. Griffin, has held no further meetings, because the notes for guidance which it produced to the studies on single-dose toxicity, repeated-dose toxicity, reproduction, carcinogenesis, pharmacokinetics and metabolism in animals from the safety standpoint are annexed to a proposal for a Recommendation(*) that is still being discussed in the Council. The working paper on mutagenicity (III/630/78 rev. 2) will be brought up to date by the Working Party as the Council's discussions progress.

The Working Party on the Efficacy of Drugs, chaired by Dr. Dukes, met on 12 and 13 October 1981 and on 24 and 25 February 1982 and made appreciable progress towards completing twelve notes for guidance which are in various stages of the process of written consultation with the national authorities and the pharmaceutical industry, as can be seen in Annex IV. The Working Party's programme covered a total of 15 subjects, the first of which, namely fixed combination products, is likewise annexed to the proposal for a Council Recommendation(*), and the last two, namely corticoids for topical use and antidysrhythmics, have made very little progress. Work has been suspended for the time being since the departure of Dr. Dukes for the European Regional Office of the WHO.

A consultation meeting was held on 6 September 1982 with experts from the pharmaceutical industry (European Federation of Pharmaceutical Industries' Associations) to deal in particular with the notes for guidance prepared by the Working Party on the Efficacy of Drugs.

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(*) OJ No C 355, 31.12.80, pp 6-30

IV. CONCLUSION

The Committee for Proprietary Medicinal Products has helped to institutionalize the dialogue between the representatives of the Member States who are responsible for the marketing of medicinal products and between them and the departments of the Commission.

Although Community legislation on medicinal products is for the most part already in existence, the individual measures taken in this field by each of the Member States now have to be brought into line.

In this respect the Committee is a privileged instrument for the harmonization of national policies with regard to medicinal products.

Despite the fact that the Committee's role is limited to that of a consultative body acting on behalf of the Commission and the Member States, the importance of its work is now internationally recognized, particularly since the two international conferences of authorities responsible for medicinal products (I.C.D.R.A.) that were held under the aegis of the World Health Organization in 1980 and 1982.

A Working Party on the Quality of Drugs may be set up in the near future to aid the Committee in its discussions on the analytical part of the dossiers which it is called upon to examine.

The Commission feels that the Committee could play an increasing part in coordinating the review of old medicinal products, the registration dossiers on which will have to be brought into conformity with the Directives by 1990.

LIST OF ANNEXES

INTRA AND EXTRA COMMUNITY TRADE

(Medicines for human and veterinary use,
Chapter 30.03 of the Common Customs Tariff)

1. IMPORTS, in millions ECU, C.C.T. Chapter 30.03

Import year	EEC	D	F	IT	NL	B-L	UK	IRL	DK	GR
1975	782	196	18	91	142	184	79	32	40	--
% intra EEC	74 %	67 %	83 %	72 %	87 %	79 %	59 %	90 %	59 %	
1976	1.034	258	21	117	199	230	107	42	56	--
% intra EEC	72 %	62 %	77 %	71 %	87 %	77 %	59 %	87 %	60 %	
1977	1.189	326	35	112	217	240	143	49	67	--
% intra EEC	73 %	63 %	87 %	73 %	84 %	76 %	65 %	97 %	64 %	
1978	1.447	410	55	143	259	277	168	59	77	--
% intra EEC	72 %	63 %	85 %	71 %	80 %	76 %	62 %	96 %	58 %	
1979	1.648	482	65	154	281	301	210	71	82	--
% intra EEC	72 %	65 %	78 %	72 %	80 %	76 %	65 %	98 %	59 %	
1980	1.849	540	101	182	296	322	231	87	90	--
% intra EEC	72 %	63 %	74 %	73 %	82 %	75 %	69 %	98 %	60 %	
1981	2.247	599	163	226	299	340	334	108	101	78
% intra EEC	70,5 %	60 %	77 %	71 %	82 %	68 %	68 %	98 %	58 %	55 %

2. EXPORTS, in millions ECU, C.C.T. Chapter 30.03 (UK 1981 not available)

Export year	EEC	D	F	IT	NL	B-L	UK	IRL	DK	GR
1975	1.786	518	344	116	126	171	427	16	79	--
% intra EEC	33 %	31 %	26 %	27 %	49 %	66 %	23 %	59 %	24 %	
1976	2.184	642	407	137	179	220	475	22	100	--
% intra EEC	33 %	31 %	26 %	34 %	48 %	65 %	24 %	65 %	24 %	
1977	2.551	708	472	172	211	266	573	29	120	--
% intra EEC	33 %	28 %	28 %	30 %	51 %	63 %	24 %	72 %	24 %	
1978	2.887	768	546	175	232	317	681	34	130	--
% intra EEC	36 %	29 %	32 %	32 %	52 %	65 %	27 %	72 %	30 %	
1979	3.136	862	649	187	237	334	675	45	147	--
% intra EEC	37 %	29 %	33 %	33 %	53 %	64 %	34 %	71 %	32 %	
1980	3.801	992	828	221	278	394	868	49	171	--
% intra EEC	35 %	30 %	29 %	31 %	52 %	59 %	29 %	69 %	32 %	
1981	--	1.193	919	291	306	466	--	58	219	25
% intra EEC		30 %	31 %	26 %	53 %	58 %		67 %	33 %	6 %

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Tél.: (1) 720.21.88

CCE / CEC

a) M. Nicolaas BEL

Chef de la Division
"Pharmacie, médicaments vétérinaires"
Commission des Communautés européennes
D.G. III/A-3
Tél.: (2) 2351891
Télex: 21877 COMEU B

b) M. Fernand SAUER

Administrateur
Commission des Communautés européennes
D.G. III/A-3
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COMMISSION
DES
COMMUNAUTES EUROPEENNES

Direction générale du
marché intérieur et des
affaires industrielles

octobre / October 1982

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

COMITE DES SPECIALITES PHARMACEUTIQUES

COMMITTEE FOR PROPRIETARY MEDICINAL PRODUCTS

ETAT MEMBRE
MEMBER STATE

BELGIQUE

PERSONNES RESPONSABLES DE L'INFORMATION
PERSONS RESPONSIBLE FOR INFORMATION
} Directive 75/319/CEE EEC

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)564.10.64 Télex: 25768	(1) (2) (3)
Mad. ROLAND, N. Inspecteur	- " -	(2)564.10.48 564.11.48	(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

ETAT MEMBRE
MEMBER STATE

D E N M A R K

PERSONNES RESPONSABLES DE L'INFORMATION
PERSONS RESPONSIBLE FOR INFORMATION
} Directive 75/319/CEE EEC

Nom et Fonction Name and Function	Adresse Address	Teleph. & Telex	Type d'information (*) Type of information (*)
Mr. H.O. Andersen Sekretariatschef	Sundhedsstyrelsen Frederikssunds-vej 378, DK-2700 Brønshøj	(02) 94.37.73 Telex: 35333 ipharm	(1) (2) (4)
Mrs. Agnete Kjærvig Afdelingsleder	- " -	(02) 94.37.73 Telex: 35333 ipharm	(1) (2)
Bodil Strøh Head of Medicines Supply Section	National Board of Health St. Kongensgade 1 DK-1264 København K Danmark	(01) 14.10.11	(2) (3)
Jens Overø Head of Medicines Division	- " -		

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ETAT MEMBRE
MEMBER STATE

BUNDESREPUBLIK DEUTSCHLAND

PERSONNES RESPONSABLES DE L'INFORMATION
PERSONS RESPONSIBLE FOR INFORMATION
} Directive 75/319/CEE EEC

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 Seestraße 10 D-1000 BERLIN 65	(30) 450.20 Telex: 183310	1, 2, 4	8117829
Dir. u. Prof. Dr. J. Schuster Coordination of registration of drugs	- " -	- " -	1	
Dir. u. Prof. Dr. G. Stille Head, Department experim./clinical pharmacology	- " -	- " -	1	
Dir. u. Prof. Dr. P. Schönhöfer Head, Department Drug monitoring	- " -	- " -	2, 4	
Dr. K. Feiden Ministerialrat	Bundesministerium für Jugend, Familie und Gesundheit, Postf. 200490 D-5300 Bonn 2	(228) 338 251	3	
Dr. Chr. Gaudich Regierungsdirektorin		(228) 338 335 Telex: 8-85 517	3	

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ETAT MEMBRE
MEMBER STATE

F R A N C E

PERSONNES RESPONSABLES DE L'INFORMATION
PERSONS RESPONSIBLE FOR INFORMATION
} Directive 75/319/CEE EEC

Nom et Fonction Name and Function	Adresse Address	Teleph. & Telex	Type d'information (*) Type of information (*)
Pierre GRECH Chef de Service Adjoint au Directeur	Ministère de la Santé Direction de la Pharmacie et du Médicament 1, place de Fontenoy F-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	- " -	567.55.44 Poste 55.04 Ligne directe: 306.59.47	1, 2, 3, 4
		Télex: SANTSEC 2500 11 F	

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ETAT MEMBRE
MEMBER STATE

G R E C E

PERSONNES RESPONSABLES DE L'INFORMATION
PERSONS RESPONSIBLE FOR INFORMATION
} Directive 75/319/CEE EEC

Nom et Fonction Name and Function	Adresse Address	Teleph. & Telex	Type d'information (*) Type of information (*)
Prof. U. Marcelou-Kinti Vice-President (Mrs.) of KEEF	K E E F Voulis St. 4 Athens 125	(00301) 32.47.711	1, 2, 4
Mrs. G. Melissaratou Pharmacien Director	Ministry of Social Services Aristotelous 17 Athens	(00301) 52.37.483 Telex: 215927 Y.K.Y.P. GR	3
Mrs. E. Vardacosta Head, Directorate of pharmaceuticals and pharmacies	Ministry of Social Services Aristotelous 17 Athens	(00301) 52.27.360	1, 2
Miss A. Varveri Head, Section of Studies and Proposals (EEC, FDA, WHO)	State Laboratory for the control of pharmaceuticals Voulis St. 4 Athens 125	(00301) 32.34.953 or 32.30.648	3, 4

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ETAT MEMBRE
MEMBER STATE

IRELAND

PERSONNES RESPONSABLES DE L'INFORMATION
PERSONS RESPONSIBLE FOR INFORMATION
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Nom et Fonction Name and Function	Adresse Address	Teleph. & Telex	Type d'information (*) Type of information (*)
Dr. A. SCOTT Medical Director	National Drugs Advisory Board Charles Lucas House 63-64 Adelaide Road Dublin 2	76.49.71 - 7 Telex: 90542	1, 2, 3, 4

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

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

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ETAT MEMBRE
MEMBER STATE

I T A L I A

PERSONNES RESPONSABLES DE L'INFORMATION
PERSONS RESPONSIBLE FOR INFORMATION
} Directive 75/319/CEE EEC

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) 592.58.63 (6) 592.58.24 Telex: 610453 MINSAN I	1, 2, 3, 4
Dr. Romano CAPASSO Consigliere Ministeriale	- " -	(6) 592.58.28	1, 2, 3, 4

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MEMBER STATE

LUXEMBOURG

PERSONNES RESPONSABLES DE L'INFORMATION
PERSONS RESPONSIBLE FOR INFORMATION
} Directive 75/319/CEE EEC

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

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

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ETAT MEMBRE
MEMBER STATE

NETHERLANDS

PERSONNES RESPONSABLES DE L'INFORMATION
PERSONS RESPONSIBLE FOR INFORMATION
} Directive 75/319/CEE EEC

Nom et Fonction Name and Function	Adresse Address	Teleph. & Telex	Type d'information (*) Type of information (*)
Drs. R.A. Drost, inspecteur	Ministerie van Volksgezondheid, College ter beoordeling van geneesmiddelen Case postale 5811 2280 HV Rijswijk (ZH)	(70) 94.95.05 Télex: 32691	1
Dr. C.A. Teijgeler, Voorzitter	Ministerie van Volksgezondheid, College ter beoordeling van geneesmiddelen Case postale 439 2260 AK Leidschendam	(70) 20.92.60 Télex: 32362 v m nl	2 + 3
Drs. R.H.B. Meyboom, inspecteur	- " -	- " -	4

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ETAT MEMBRE
MEMBER STATE

UNITED KINGDOM

PERSONNES RESPONSABLES DE L'INFORMATION
PERSONS RESPONSIBLE FOR INFORMATION
} Directive 75/319/CEE EEC

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 + 3
Dr. R. PENN Principal Medical Officer	- " -	ext. 3143 or 3146	4

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COMMISSION DES C.E.
COMMISSION OF THE E.C.

PERSONNES RESPONSABLES DE L'INFORMATION
PERSONS RESPONSIBLE FOR INFORMATION
} Directive 75/319/CEE EEC

Nom et Fonction Name and Function	Adresse Address	Teleph. & Telex	Type d'information (*) Type of information (*)
Mr. N. BEL Chef de Division	Commission des Communautes européennes D.G. III/A-3 Rue de la Loi 200 B-1049 Bruxelles	(2) 235.18.91 ou (2) 235.18.90 (secrétariat) ou (2) 235.69.35 (secrétariat) Télex: 21877 COMEU B	1, 2, 3, 4
Mr. F. SAUER Administrateur	- " -	- " - (2) 235.51.80 ou (2) 235.69.35 (secrétariat)	1, 2, 3, 4

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March 1982

COMMITTEE FOR PROPRIETARY MEDICINAL PRODUCTS

PROGRESS REPORT ON EFFICACY GUIDELINES

Stages: 1	2	3	4	5	6	7	8	9
Fixed combinations	III/115/79	01-78	.....	.....	.....	.....	11-78	O.J.E.C.31-12-80 C355
Cardiac glycosides	III/635/78	11-78	12-78	.....	.....	06-80	11-80	
Or.contr.clinical	III/571/79	03-79	06-79	02-80	05-80	06-80	11-80	
Or.contr.inform.	III/572/79	03-79	06-79	02-80	05-80	06-80	11-80	
Antihypertensive	III/1667/79	05-80	05-80	.....	.....	.....	.....	(OMS/WHO text)
Long-term use	III/602/81	12-81	01-82					
N.St.Anti-Inflam.	III/601/81	01-78	.....	10-81	12-81	01-82		
Antiepileptic	III/634/78	04-78	06-78	10-81	12-81	01-82		
Bioavailability	III/573/79	03-79	06-79	10-81	12-81	01-82		
Pharmacokin.in man	III/603/81	12-81	01-82					
Antianginal	III/1261/78	11-78	12-78	02-82				
Ischaemia in the limbs	III/1270/81	12-81	01-82					
Antimicrobial	III/1666/79	05-80	05-80	02-82				
Topical corticoïds	III/225/82							
Antidysrhytmic								

1. = Subject of instruction to the working party
2. = Reference No. of draft actively prepared by working party
3. = Draft submitted to CPMP
4. = Draft forwarded to national agencies and industry for first comments
5. = Rediscussion of comments in the working party
6. = Revised version before CPMP
7. = Draft circulated to national agencies and industry
8. = Approval by CPMP
9. = Adoption and publication