ECONOMIC AND SOCIAL
CONSULTATIVE ASSEMBLY

1992

Foward towards a European policy on medicinal products

EUROPEAN COMMUNITIES

ECONOMIC AND SOCIAL COMMITTEE

EN

Brussels 1991

ECONOMIC AND SOCIAL
CONSULTATIVE ASSEMBLY

Forward towards a European policy on medicinal products

EUROPEAN COMMUNITIES

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Brussels, September 1991

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Preface

As the Europe of 1993 draws closer, we face a possible delay in the harmonization of the pharmaceuticals market. Significant differences remain in a sector which is important in public health terms and of strategic significance for the European economy.

The welter of proposals for Directives which the EC Commission has only recently adopted bears witness to the contrast between the irreversible advance of the European unification process and the delay in harmonizing the pharmaceuticals sector.

The main reasons for the delay are to be found in the resistance occasioned by the radically different situations in the individual Member States : Europe's schools of medical thought differ in their historical, cultural and therapeutic traditions, and this has led to differing approaches to health protection.

Differences are also created by the tendency of national authorities to introduce legislation which paradoxically often treats medicine simply as an economic item which generates expenditure, rather than as a vital tool for improving our quality of life.

The situations pertaining in the individual Member States reflect the prevalence (and alternation) of these two approaches. National legislation has thus lacked the continuity and the strategic overview needed to give the sector the certainties it requires.

Public authorities' alternately "permissive" and "repressive" use of their significant powers of control has also affected the sector's manufacturing decisions, and the resultant uncertainty has affected investment. Scientific research has suffered particularly, and this has had a direct impact on the availability of effective drugs for new emerging diseases.

A body of Community legislation that places the interests of the patient at the forefront, though without ignoring the public cost aspect, is indeed needed. But, we must not underestimate the importance of the industrial aspects.

Community measures are needed to help Europe's pharmaceutical companies to remain competitive, especially against their rivals, in the United States and Japan. The emphasis must be on quality, which can only be improved by coordinating and boosting the fundamental role played by scientific research.

Of particular interest to industry is the ESC's call for the opening of EC research programmes to in-company industrial research, which is an important link between the university-research and the final application stages.

In passing judgement on the programme of Directives, one has to weigh the cautious wording of some provisions and the weakness of some of the practical indications against the complexities of the harmonization process which lies ahead. It must also be remembered that we are not, as in the past, dealing solely with general indications, but with key areas of the "pharmaceutical system", so radical changes are inevitable.

The programme put forward by the Commission covers many areas of the drug production and distribution chain. Specific provisions are laid down for wholesale distribution and for package labelling and leaflets. Supply of drugs is dealt with in the proposal on "legal status". A later proposal on the advertising of medicinal products for human use regulates the advertising of prescription and over-the-counter drugs to the general public, doctors and health professionals.

The proposal to create a supplementary protection certificate for medicinal products aroused particular interest in the industry. The proposal addresses the need to improve patent protection, currently governed by the European Patents Convention which covers all products.

The length of time that a patent remains protected is subject to gradual "erosion", owing to the time taken by the administrative procedures and the need to check the product's quality, efficacy and safety.

The supplementary certificate certifies industrial property ownership and extends the basic patent. It is valid for a maximum period of 16 years from the date on which the drug was authorized for marketing, and allows an extension of the basic patent for a maximum period of ten years.

While the Directives listed above will all have a growing influence on the EC pharmaceuticals system, the most radical development is the proposal for a Regulation laying down Community procedures for the authorization and supervision of medicinal products.

The proposal concerns the setting-up of an agency which the Commission intends should become the real regulator of the EC market.

In addition to taking over many tasks hitherto carried out by the Member States, the agency is increasingly to play a central role in coordinating and monitoring the quality, efficacy and safety of drugs marketed in the Community.

The proposal is currently the subject of a complex political debate; some circles go so far as to question the need for a centralized assessment body. The ESC has adopted an Opinion on the subject, for which I was Rapporteur. The Opinion welcomes the proposal and comes out in favour of establishing a centralized evaluation agency.

Whilst supporting the general thrust of the proposal, the ESC makes a number of general and specific comments. The main points made concern the central role of the Committee for Proprietary Medicinal Products (CPMP) within the agency. The ESC proposes that the CPMP be strengthened by a multidisciplinary scientific contribution guaranteeing balanced representation of the various schools of medical thought in the Community.

The Opinion outlines the health protection and industrial policy tasks which should be assigned to the agency. Such a totally new system will have to be phased in over a period whose duration is difficult to determine in advance. In order to ensure that the process goes smoothly and to facilitate the completion of the new structures, existing instruments should be retained during the transitional period until the new EC instruments have got through any teething troubles.

Harmonization of the authorization procedures has formed the central feature of the debate.

The ESC considers that continued use of the national procedure is justified, as it offers a guarantee for smaller firms producing drugs solely for the domestic market. Moreover,the national procedure will form the basis for the decentralized EC procedure.

The ESC recognizes that the new procedures are made necessary by the failure of the "multi-state" procedure, which has been very unevenly applied by the Member States.

The decentralized procedure is a step forward from the "multi-state" procedure and offers a gradual move to the European market for firms which wish to reach this wider market.

Debate has focused on the centralized procedure, which leads to an authorization immediately valid in all Member States. The ESC considers the procedure too restrictive in scope: there are some fields of pathology in which there is always a need for effective, highly innovative drugs, and where gradual introduction of the centralized procedure would appear warranted.

For such drugs, the ESC considers that wider use of the centralized procedure would be in the interests both of patients and of firms, although it should remain optional. The procedure would have the advantage of giving all EC patients immediate access to innovative drugs, while offering firms a prestigious label which would help them penetrate markets outside the EC.

The dual nature of the European pharmaceutical system is evident even from this brief analysis.

It offers industry a unique opportunity, but it also harbours risks.

Everything will depend on how well the businesses which have to operate within the new system adapt to the new rules and trading conditions.

In the Committee's view, the proposals reflect a cautious gradual, approach which is nevertheless ambitious in intention. The innovative features are tempered by a whole host of safeguard clauses placed at the disposal of the Member States. These clauses could seriously encumber the procedures and delay real free movement of medicinal products within the Community, which is necessary if consumers are to be guaranteed equal access to these products and there is to be equal protection of public health and safety.

The Committee's recommendations are designed to make the procedures more efficient and transparent, taking account of the social aspects of the pharmaceuticals sector and the need to focus on the interests of the consumer (and thus the needs of the patient, who should be the prime beneficiary of the drug).

SERGIO COLOMBO

OPINION

of the Economic and Social Committee on the Proposal for a Council Directive on the wholesale distribution of medicinal products for human use

(COM (89) 607 final - SYN 229)

On 8 February 1990 the Council decided to consult the Economic and Social Committee, under Article 100a of the Treaty establishing the European Economic Community, on the

Proposal for a Council Directive on the wholesale distribution of medicinal products for human use
(COM(89) 607 final - SYN 229).

The Section for Industry, Commerce, Crafts and Services, which was responsible for preparing the Committee's work on the subject, adopted its Opinion on 6 June 1990. The Rapporteur was Mr ROLÃO GONÇALVES.

At its 278th Plenary Session (meeting of 4 July 1990), the Economic and Social Committee adopted unanimously the following Opinion:

* * *

1. Introduction

1.1. As the link between the manufacturer and the retailer of medicinal products, the wholesaler is a key element in the distribution chain of these vital goods.

1.2. The wholesaler must provide a swift, efficient and highly economic service, without this under any circumstances jeopardizing the quality of the product.

1.3. The handling, storage and transport arrangements must ensure that the products are distributed where and when required and are of the same quality as they were when they left the factory, whether this be inside or outside the Community.

1.4. Arrangements are also needed for the withdrawal of products from the market when the relevant authorities feel that this must be done in the interests of patient safety.

1.5. As a general measure, a code of conduct must be drawn up for wholesalers, modelled on those in existence in other areas of the medicinal products sector. This code could either be adopted voluntarily by wholesalers or could be based on harmonization laid down by the Community in the public interest. The completion of the internal market at the start of 1993 will increase intra-EC trade, and thus makes action particularly necessary.

1.6. The market in medicinal products has various special features: the consumer does not generally choose the prescription, and in many cases the product is paid for by a third party. These factors work against market transparency, particularly in cases where there is an exclusive supplier. Distribution is only one link in the chain from production to consumption, and it may be affected by externalities.

2. The principles behind the proposal

2.1. The proposal forms part of the package of measures contained in the 1985 White Paper for completing the internal market. It has three main aims:

—to adapt the responsibilities of wholesalers to the new conditions governing cross-frontier trade over a wider economic area;

—to perfect the arrangements for withdrawing medicinal products efficiently and rapidly from the single Community market when necessary;

—to step up the fight against counterfeit products, which will become a greater problem with the expansion of the market.

2.2. The Commission's proposal, whose objectives cover both economic and safety aspects, states that:

—wholesalers must be registered, and must adhere to certain administrative requirements;

—wholesalers must follow certain rules in their work and must have suitable storage premises manned by qualified staff;

—wholesalers must keep detailed records of their transactions and stocks, conduct checks on these records and make them available to the competent authorities.

2.3. Whilst taking account of national public health laws and certain specific circumstances within Member States, the proposal aims to harmonize the present systems so that they can operate within a frontier-free market.

3. General Comments

3.1. The Committee endorses the aims of the Commission proposal, subject to the following comments.

3.2. The economies of scale brought by the internal market should cut costs. If there is free competition, this must ultimately lead to a drop in consumer prices. The Committee considers it essential not to jeopardize this goal with red tape which would generate additional structural expenditure, affecting costs and thus limiting the scope for reducing retail prices. Steps will also have to be taken to counter any developments which could threaten the transparency of the market.

3.3. The desire to speed up stock rotation - dictated by the need to improve financial management - has been the reason for the rapid computerization of the wholesale sector. However, lack of information and finance means that computerization is not yet widespread, particularly among smaller firms in the most disadvantaged Member States. The Committee asks for this to be borne in mind. It must also be ensured that the new administrative rules (especially the keeping of records) are phased in gradually, with the backing of financial programmes (TEDIS).

3.4. The Committee is concerned about a confluence of activities in certain Member States, in the form of either upstream expansion by the retail trade or downstream expansion by wholesalers. This is likely to reduce the transparency of the marketing chain and limit the free competition which is necessary at each stage, to the detriment of the consumer or of whoever is paying for the products.

3.5. Rules on wholesale distribution should not threaten imports and exports from/to third countries when these can help satisfy personal health needs and lessen price differences between regions. Experience has shown that third-country trade can be reconciled with the higher quality standards demanded of medicinal products.

3.6. Community legislation on medicinal products should remain flexible, by adapting to socio-economic trends and taking account of traditional habits in the Member States whilst not forgetting the general principles of free competition and the elimination of monopolies.

3.7. The Committee draws the Commission's attention to the need for Member States to set up monitoring mechanisms to ensure that procedures are followed uniformly throughout the Community, in order to prevent discrepancies which could give rise to unfair competition.

3.8. The Committee recognizes the seriousness of the problems referred to by the Commission with regard to the need to withdraw faulty or counterfeit medicines from the market. It therefore calls for public programmes involving all interested parties, from manufacturers to consumers, with support from the relevant national and Community authorities.

4. Specific comments

4.1. Preamble

The Committee suggests that the Commission include a recital highlighting the abiding concern of Community pharmaceutical legislation to accord priority to the achievement of a high level of protection, in line with Article 100a(3) of the Treaty.

4.2. Article 1(2)

The Committee considers that the definition of "wholesale distribution of medicinal products" is incomplete and could generate confusion, particularly as the proposal takes the form of a Directive which Member States will have to translate into national law. At the very least, the text should be made more precise by amending "all activities" to read "all **commercial** activities" and adding **"to any bodies other than the final consumer**" after "supplying".

4.3. Article 3

The end of Article 3(1) should be amended to read "... medicinal products **for human use**".

The Committee suggests the addition of the following new points:

"8. Branches of authorized wholesalers shall be required to meet the conditions laid down in Article 5 as if they were independent establishments.

9. Manufacturers who supply retailers directly with products not manufactured by themselves shall be required to meet the same conditions as wholesalers."

4.4. Article 4

A new Article 4(2) should be inserted, to read as follows:

"2. Failure to take a decision within the period referred to in Article 4(1) shall for all legal purposes be interpreted as signifying the provisional granting of the authorization referred to in Article 3(1)."

It would also be advisable to adopt similar provisions in the Member States of manufacture and distribution.

The existing Article 4(2) would then become Article 4(3).

4.5. Article 5

To avoid serious distortions of competition, the Committee considers it vital that the requirements for obtaining authorization should be specified more clearly, with a view to closer harmonization between Member States. The Committee therefore proposes:

—in point (a), the addition of the following: "..., and appropriate procedures to ensure that they are handled and transported correctly;"

—in point (b), the addition of the following: "qualified personnel **who have had appropriate technical training** and meet ...;"

—the addition of the following new points d, e, f and g:

"d) they must have appropriate repackaging facilities, as required for holders of a manufacturing authorization (Article 16 of Directive 75/319/EEC);

e) they must have appropriate facilities for the storage of dangerous and inflammable products;

f) they must have appropriate facilities and equipment for the storage of medicinal products which have to be stored at a particular temperature;

g) they must have a sufficient stock of the medicinal products habitually prescribed in the area they serve."

4.6. **Article 6(b)**

The Committee is surprised that there is no mention of any authorization for wholesalers to obtain supplies from manufacturers. It therefore recommends that "who are themselves in possession of the authorization" be amended to read: "who are in possession either of a manufacturing authorization or the authorization ...".

4.7. **Article 6 (e)**

The words "no minimo" ("at least") in the Portuguese version of the first sentence should be deleted. (Translator's note: the English version of the Commission document omits this phrase.) Inclusion of the phrase "at least" brings a danger that stiffer conditions could be set, and this would distort competition between Member States.

The Committee also questions the feasibility and point of referring to the production batch number "for each transaction ... received or dispatched" except when "the delivery is destined for a retailer".

4.8. **Article 9**

The Committee proposes that the text of this Article be transferred to a new Article 8(3).

4.9. **Article 10**

The Committee thinks that the qualifying phrases ("if appropriate" ... "in that case") should be deleted, and that the Commission should take a firmer and more concrete stance. At all events, the Committee should be consulted on any such proposal.

Done at Brussels, 4 July 1990.

The Chairman of the Economic and Social Committee	The Secretary-General of the Economic and Social Committee
Alberto MASPRONE	Jacques MOREAU

OPINION

of the Economic and Social Committee
on the
Proposal for a Council Directive concerning the legal status for the supply of medicinal products for human use

(COM(89) 607 final - SYN 230)

On 8 February 1990 the Council decided to consult the Economic and Social Committee, under Article 100a of the Treaty establishing the European Economic Community, on the

Proposal for a Council Directive concerning the legal status for the supply of medicinal products for human use
(COM(89) 607 final - SYN 230).

The Section for Protection of the Environment, Public Health and Consumer Affairs, which was responsible for preparing the Committee's work on the subject, adopted its Opinion on 5 June 1990. The Rapporteur was Mr COLOMBO.

At its 278th Plenary Session (meeting of 4 July 1990) the Economic and Social Committee adopted the following Opinion by 96 votes to 12, with 9 abstentions:

* * *

1. Introduction

1.1. The Committee notes that the Commission has drafted a proposal which takes as its base "a high level of protection ... concerning health, safety, environmental protection and consumer protection" as envisaged in Article 100a(3) of the Treaty.

1.2. The present proposal establishing harmonized conditions for the issue of medicinal products to patients is without doubt a further step towards the completion of the internal market.

The proposal is designed to eliminate differences in Member States' legislation and implementing criteria for the supply of medicinal products to patients, and, in particular, medicines not subject to medical prescription. It does not cover matters relating to who exactly is authorized to prescribe or distribute medicines.

Here the Committee suggests the insertion in the preamble of a new recital to read as follows:

"Whereas the protection of public health requires that the dispensing of medicinal products should always be supervised by a professionally and legally qualified health specialist, given the potential risks of these products' indiscriminate use;"

1.3. The Commission sets two basic preconditions for allowing a medicinal product to be sold over the counter (OTC):

— it is safe to use because its effects and toxicity are well known;

— it is used to treat minor ailments which are easily identifiable by the user and do not justify a medical consultation.

1.4. Article 4 of the proposal lays down the cases where a prescription must be supplied, listing eight possible risk factors which make medical control necessary.

1.5. Among these, the risk factor "novelty of the active principle" (also mentioned in Article 3(2)) is of particular importance. It is rightly felt that a new chemical substance should not be supplied without prescription until adequate information about it is available.

1.6. Article 2 of the proposal divides prescription drugs into four categories. For category a) products, the prescription may be renewed during a limited period; for category b) products, the prescription may not be renewed; and category c) covers products on special prescription (containing a psychotropic or narcotic substance).

1.7. Category d) covers products on restricted prescription, reserved for use in hospitals or by certain specialists.

Several Member States already use this category, as the administration of complex or high-risk drugs calls for specific controls by specialist bodies.

2. General comments

2.1. On the relevant categories of medicinal products, the Committee would make the following comments:

2.2. Some parts of Article 4, which deals with prescription drugs, may prove difficult to interpret, and could be interpreted differently by individual Member States. This would be at odds with the aims of the Directive, which seeks to group products together uniformly.

2.3. The Committee considers that OTC medicinal products perform a practical social function. This being the case, the formulation of a single EC-wide criterion for defining OTC medicines is to be welcomed.

2.4. The Committee is concerned at the frequent references to decisions to be taken by "competent authorities" at Community level, when there is no definition of these authorities[1].

2.5. In conclusion, the structure of the Directive can be endorsed as providing useful clarification for national authorities which authorize drugs for marketing.

2.6. However, the Committee stresses the need for close links between the Directives concerning medicinal products currently under preparation and, more particularly, with the other Directives scheduled in the Commission's 1990 work programme.

3. Comments on the individual Articles

3.1. **Article 1(2)**

The differing situations in the Member States as regards the right to prescribe medicinal products could create problems here. The Committee therefore asks that efforts be made with reasonable speed as warranted by the present situation, to clarify and harmonize such rights.

The Committee also proposes the addition of a third indent, to read as follows:

"-'Pharmaceutical activity': any act of dispensing medicinal products, in accordance with the requirements of the legislation of each Member State."

3.2. **Article 2**

Article 2(a) and (b)

While endorsing the aims of this Article, the Committee feels that the formula proposed by the Commission could prove difficult to implement in practice. A simpler soluton might be to merge paragraphs (a) and (b), and make a more clear-cut division between renewable and non-renewable prescriptions.

However, such a solution is complicated by the existence of the Council of Europe lists.

(1) The nature and scope of the competent institutional body have still to be determined at Community level.

Article 2(c)

Replace "medicinal products on special prescription" by "medicinal products containing a quantity exceeding a specific level of a substance classified as a psychotropic ....".

3.3. **Article 3**

Article 3(2)

A clear scientific definition must be given of the term "new chemical entity", to be understood as a new chemical and/or biological entity.

Article 3(3)

The annual list should highlight any medicines being transferred from one category to another.

A further point should be added to this Article, to read as follows:

"5) Should the legal status for the supply of a medicine be determined or altered independently of the marketing authorization procedure or its renewal every five years, the competent authorities in the Member States shall substantiate and publish decisions taken on the basis of Article 2 or the present Article. Procedures for appeal against such decisions shall be established and brought to the attention of the persons authorized to market the product."

This procedure is designed to ensure the fullest possible information and prior consultation among the organizations representing the various interests concerned, thereby guaranteeing that it is based on sound scientific premises and takes account of prevailing social conditions.

3.4. **Article 4**

Article 4(1)

The term "indirect risk" to human health needs further clarification. Moreover, the criteria need to be spelt out in more detail to stop Member States interpreting the words "safety in use" differently (as they do at present).

Article 4(1)(a)

The term "preclinical" should be deleted as it is impossible at that stage to determine the risks to human health.

Article 4(2)

In order to put the two categories of medicines on a more equal footing, the Committee suggests that Article 4(2) form a separate Article:

"Article 5 — Medicinal products which ... a medicinal consultation."

The remaining Articles should be renumbered accordingly.

Done at Brussels, 4 July 1990.

The Chairman of the Economic and Social Committee	The Secretary-General of the Economic and Social Committee
Alberto MASPRONE	Jacques MOREAU

N.B.: Appendices overleaf.

APPENDIX I

to the Opinion of the Economic and Social Committee

The following amendments were rejected during the debates, but received at least 25% of the votes cast.

Point 1.2. - Third paragraph

Delete from "Here the Committee ..." to the end of the suggested recital.

Voting

For: 28
Against: 78
Abstentions: 8

Point 3.1. Article 1(2)

Delete the second paragraph: "The Committee ... of each Member State".

Voting

For: 28
Against: 73
Abstentions: 14

APPENDIX II

to the Opinion of the Economic and Social Committee

The following members, present or represented, voted in favour of the Opinion.

Mr/Mrs/Miss

ALEXOPOULOS
ARENA
ARETS
ATAIDE FERREIRA
BAGLIANO
BERGER
BERNASCONI
BERNS
BERTON
BLESER
BODDY
BOISSEREE
BORDES-PAGES
BOS
BREDIMA-SAVOPOULOU
BROICHER
Vasco CAL
CALVET CHAMBON
CHRISTIE
COLLAS
COLOMBO
CALVES CONDE
CORELL AYORA
CORTOIS
COYLE
van DAM
DECAILLON
DELLA CROCE
VAN DIJK
DOS SANTOS
ELSTNER
ETTY
EULEN
FORGAS
FRANDI
GARDNER
GAYETOT
GREDAL
GREEN
HAAS
HAGEN
HILKENS
HOUTHUYS
JASCHICK
JENKINS
JESUS SEQUEIRA
KAARIS
KENNA
KIRCHFELD
de KNEGT
KRÖGER
LAPPAS
LARSEN
LIVERANI
LÖW
LUCHETTI
MACHADO VON TSCHUSI
MADDOCKS
MAINETTI
MANTOVANI
MARGOT
MATTEOLI
MAYAYO BELLO
MEYER HORN
MORSELLI
MOURGUES
NIELSEN P.
NIERHAUS
NOORDWAL
de NORMANN
PARDON
PEARSON
PELLETIER R.
PERRIN-PELLETIER
PETERSEN
PROUMENS
QUEVEDO ROJO
RANGONI-MACHIAVELLI
RIBIERE
ROBINSON
ROLÃO GONÇALVES
ROUZIER
SALMON
SANTILLAN CABEZA
SCHADE-POULSEN
SCHNITKER
SCHOEPGES
SCHWEITZER
SMITH A.R.
SMITH L.J.
TELLES
TIEMANN
TIXIER
TUKKER
VIDAL
YVERNEAU

The following members, present or represented, voted against the Opinion.

Mr/Mrs/Miss

ASPINALL
BEALE
BENTO GONÇALVES
FLUM
FRESI
LUSTENHOUWER
MORELAND
MUHR
STORIE-PUGH
STRAUSS
TAMLIN
WILLIAMS

The following members, present or represented, abstained:

Mr/Mrs/Miss

CAMPBELL
CEYRAC
DODD
van EEKERT
HOVGAARD JAKOBSEN
NIEUWENHUIZE
PETROPOULOS
VANDEN BROUCKE
WAGNER

OPINION

of the Economic and Social Committee
on the
Proposal for a Council Directive on the labelling of medicinal products for human use and on package leaflets

(COM(89) 607 final - SYN 231)

On 8 February 1990 the Council decided to consult the Economic and Social Committee, under Article 100A of the Treaty establishing the European Economic Community, on the

Proposal for a Council Directive on the labelling of medicinal products for human use and on package leaflets
(COM(89) 607 final - SYN 231).

The Section for Protection of the Environment, Public Health and Consumer Affairs, which was responsible for preparing the Committee's work on the subject, adopted its Opinion on 5 June 1990. The Rapporteur was Mr HILKENS.

At its 278th Plenary Session (meeting of 4 July 1990) the Economic and Social Committee adopted the following Opinion by a majority vote, with ten abstentions:

* * *

The Committee approves the Draft Directive subject to the following comments.

1. Introduction

1.1. It should be pointed out that the Commission's proposal to provide the consumer with more complete and comprehensible information by means of labelling and leaflets is required by Article 100A(3), which states that "The Commission in its proposals ... concerning health, safety, environmental protection and consumer protection, will take as a base a high level of protection." The Committee is pleased to note that the Commission studied this question when drafting its proposal.

1.2. The Committee notes that the Commission proposal is to be seen in the context of the completion of the Internal Market. For both public health and economic reasons a higher degree of regulation is undoubtedly required in the medicinal products market than in many other sectors of the economy. This applies particularly to information for patients with regard to pharmaceutical products.

1.3. The Commission proposal follows on from Directives 65/65/EEC and 75/319/EEC and the amendments thereto in Directive 89/341/EEC which regulate respectively labelling and the information which leaflets must contain. The proposed Directive lays down detailed requirements for labelling and package leaflets.

1.4. Generally speaking it should be pointed out that this approach is also consistent with new social trends regarding the provision of information. As far as medicines are concerned, this means that in a modern society an ever increasing number of people insist on being informed in readily understandable language of the effects, advantages and disadvantages of medicines.

1.5. The Committee notes that the Commission's Draft Directive was drawn up after intensive consultations with all interested parties, including consumers. In view of the preceding comments (Points 1.1. and 1.4.) the Committee urges the Commission to extend the dialogue initiated here in the field of medicinal products to other regulations and not to forget the consumer's role in this process.

In this connection the Committee would refer to the Commission proposal still being drawn up on the information to be supplied to doctors, pharmacists and other medical experts.

2. General comments

2.1. With regard to patient leaflets, the Committee would refer to its Opinion of 2 June 1988[1] in which it urged the Commission to hold consultations with the consumer organizations with a view to establishing adequate rules on the content and form of patient leaflets.

The Committee is pleased that so many of the points on which consensus was achieved in the course of those consultations are to be found in the proposed Directive (Art. 8). The Committee urges the Commission to incorporate the remaining points in Article 8, i.e. the points with regard to the legal status and the pharmacology of the medicinal product.

2.2. The Committee wonders whether the Commission's aims would not be served by laying down guidelines for the wording of leaflets for which the manufacturer is responsible. This would have a twofold purpose:

a) to make the job easier for those responsible for writing package leaflets;

b) to make the presentation of leaflets more uniform.

The Committee points out that some Member States already apply such guidelines.

In the Committee's view the guidelines referred to in Article 13 of the proposed Directive are too narrow and should be widened to cover all aspects of patient leaflets.

2.3. The Committee would even go one step further and urge that, with a view to ensuring that product information corresponds as closely as possible to the actual needs of patients, manufacturers of identical products listed in the official monograph of the European Pharmacopoeia be required to use a standard leaflet, since the active ingredients in the products are the same and have virtually the same bioavailability.

2.4. The Committee urges the Commission to ensure that representatives of consumers and all other interested parties are involved in the drafting of guidelines for patient leaflets. In addition, it must be possible to take action if, after evaluation, a patient leaflet appears to be unsatisfactory.

3. Specific comments

3.1. **Article 3**

3.1.1. **Sub-paragraph (d)**

The Committee would like to see the Commission append to the Directive, besides the excipients, a list of E-Number substances, including and highlighting those which induce hypersensitivity reactions. These hypersensitivity reactions must be confirmed by independent scientific evidence.

3.1.2. The Committee urges the Commission to examine the feasibility of using pictograms as a means of informing patients. Such a method could be considered in particular for psychotropics and narcotics as defined in the UN Convention. EC pictograms for potentially dangerous dependency-producing psychotropics and narcotics should be made mandatory for the whole Community. The use of different colours for different doses of the same product is recommended. Finally, the normal side-effects of medicines must be mentioned, along with any special warnings about driving.

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(1) OJ No C 208 of 8 August 1988

3.2. **Article 4**

3.2.1. **Paragraph 1, 2nd indent**

The English version should read "quantity of active **ingredients**" instead of "quantity of active constituents".

3.2.2. **Paragraph 2**

The Committee feels that, both in order to prevent this exception finding ever broader application and in view of the need to provide basic information on small packages, the common name of the product, the quantities of active ingredients and the batch number should appear on the product packaging.

3.3. **Article 6**

3.3.1. **Paragraph 2**

The Committee approves the provisions set out in Article 6(2) regarding price labelling, reimbursement and legal status. The Committee urges the Commission to include in the Directive an obligation on the part of chemists to have information available on arrangements concerning reimbursement and prices.

3.4. **Article 8**

3.4.1. **Paragraph 1a) - third indent**

This indent should be reworded as follows:

"- pharmaco-therapeutic group, if there exists a term easily comprehensible for the patient, supplemented by 'OR FAILING THIS THE THERAPEUTIC CHARACTERISTICS'."

3.4.2. **Paragraph 1b)**

Insert after "the therapeutic indications": "the pharmacological properties".

3.4.3. **Paragraph 1d)**

It is pointed out that antidotes do not exist for all medicinal products. Furthermore, in the case of overdoses antidotes may be administered only under medical supervision.

3.4.4. **Paragraph 1e)**

Patients should be invited to communicate any undesirable effect not only of new medicinal products but of all medicinal products to their doctor or pharmacist.

3.4.5. **Paragraph 2**

The Committee would point out that in its Opinion of 2 June 1988[2] it stated that:

"it is vital that the leaflet provide the patient with all necessary information on the medicine. While every effort should be made to avoid alarming the patient, this must clearly not be at the expense of the clarity and completeness of the information."

3.4.6. **Paragraph 3**

Regarding pictograms, see the comments under 3.1.2.

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(2) OJ No. C 208 of 8 August 1988

3.5. **Article 12**

3.5.1. **Paragraph 1**

The correct application of this Directive is of considerable importance for public health; hence the Committee feels that the imposition of adequate penalties, both general and financial, by the competent authorities of a Member State should be made mandatory where the provisions of this Directive are not observed.

3.6. **Article 13**

See Point 2.2. which urges that the guidelines be widened. They should also be mandatory.

Done at Brussels 4 July 1990.

The Chairman of the Economic and Social Committee	The Secretary-General of the Economic and Social Committee
Alberto MASPRONE	Jacques MOREAU

OPINION

of the

Economic and Social Committee

on the

Proposal for a Council Directive
on advertising of medicinal products for human use

(COM(90) 212 final - SYN 273)

On 21 June 1990 the Council decided to consult the Economic and Social Committee, under Article 100a of the Treaty establishing the European Economic Community, on the

Proposal for a Council Directive on advertising of medicinal products for human use
(COM(90) 212 final - SYN 273).

The Section for Protection of the Environment, Public Health and Consumer Affairs, which was responsible for preparing the Committee's work on the subject, adopted its Opinion on 4 December 1990. The Rapporteur was Mr COLOMBO.

At its 282nd Plenary Session (meeting of 19 December 1990), the Economic and Social Committee adopted the following Opinion with no dissenting votes and one abstention:

* * *

1. Preliminary comments

1.1. The proposal represents a further step in the Commission's drive to harmonize the pharmaceutical sector and eliminate barriers to the free movement of medicinal products in the run-up to an internal market, ensuring a high level of protection of public health.

1.2. The proposal forms part of the programme announced in the 1985 White Paper on completing the internal market. It follows the proposals (discussed in the respective Committee Opinions[1] on:

— wholesale distribution of medicinal products for human use;

— legal status for the supply of medicinal products for human use;

— labelling and package leaflets of medicinal products for human use.

1.3. The proposal seeks to harmonize the rules on advertising of medicinal products to the general public, doctors, and health professionals.

1.4. This is an important matter - the pharmaceutical industry spends considerable sums on advertising to the general public, promotion to health professionals and medicinal information.

1.5. The products of this sensitive sector are designed to improve human health and it is reasonable to introduce Community legislation, without prejudice to the general rules laid down in Directive 84/450/EEC on misleading advertising and Directive 89/552/EEC on television broadcasting.

1.6. All Member States have specific legislation on pharmaceutical advertising.

1.7. Analysis of the situation in the Member States shows significant points of convergence, but also discrepancies as regards both authorization and the systems and levels of advertising control. Community harmonization is thus needed.

1.8. Member States' legislation on the information provided to health professionals presents fewer divergencies. This is partly because of the existence of deontological codes of conduct at both national and EC level, which can provide a useful point of reference.

1 OJ No. C 225 of 10 September 1990.

2. General Comments

2.1. The Committee endorses the need for and structure of the proposed Directive, subject to the comments and recommendations which follow.

2.2. Advertising to the public and to health professionals is treated separately because different messages are being conveyed and because current legislation in the two areas differs. While it is common practice in the Member States to include the two areas in a single legal instrument, the Committee is concerned that failure to draw a precise distinction between advertising to the public and information/promotion to health professionals could give rise to ambiguities.

2.3. The ban on public advertising of prescription drugs deserves particular endorsement. However, the Committee notes the concern expressed in its Opinion on legal status of medicines, as regards the latitude allowed the Member States in the classification of prescription and OTC drugs. Differing interpretations of the classification criteria would have an effect on the authorization of advertising to the public.

2.4. The Committee notes the importance of proper health education in order to ensure the "rational use" of medicinal products which advertising is supposed to encourage under the terms of Article 2(3) of the present proposal.

2.5. Although advertising can be an information vehicle, it is not the main one. In no way can it replace the information on the product's labelling and in the package leaflet, nor that provided by health professionals.

2.6. Lastly, the Committee asks the Commission to examine possible ways and fora for achieving closer harmonization of the instruments and bodies responsible for pharmaceutical advertising.

3. Specific comments

3.1. **Definitions - Article 1(3)**

3.1.1. The definition of advertising in Article 1(3) includes information and promotion for health professionals. There is a danger here of confusing proper scientific information activity with improper incentives to prescribe a particular drug.

3.1.2. For example, it has to be determined whether attendance at congresses is a form of illicit pressure, or whether these provide an updating necessary for the doctor's further training and are potentially in the patient's interest.

3.1.3. The vague reference to "invitations ... to congresses" in the third indent of Article 1(3) should therefore be deleted, as it seems to imply that any information or training initiatives aimed at health professionals are a form of commercial incitement.

3.2. **Article 2(3)**

The term "rational use" seems rather vague. The Committee suggests the wording "appropriate correct use".

3.3. **Article 4**

3.3.1. In the interests of improved consumer protection, the Committee is concerned at the alternative offered in the second indent, between (a) inclusion of "the information necessary for correct usage of the medicinal product, such as indications for use and special precautions" and (b) a mere "invitation to read the package leaflet carefully".

3.3.2. The package leaflet is of the utmost importance if the consumer is to be fully informed. Advertisements should always include a reminder to read the leaflet. However, it will only be read after the medicine has been purchased; patients could make the wrong purchase if no explicit counter-indications are provided.

3.3.3. Lack of space is no excuse for not providing vital information in a clear and legible form, even if it is not advisable to include a welter of technical and scientific details in advertising targetted to the general public.

3.3.4. However, where the vital information is available on the outer pack, the Committee accepts that, in the case of medicines for which no special precautions are necessary a message to read the label and or the package leaflet is the best alternative means.

3.4. **Article 5(d)**

Drug advertising directed at children should be banned outright. The words "solely or mainly" could offer a loophole for getting round this ban.

3.5. **Chapter III - Wording of the title**

The term "advertising" is an oversimplification for describing the complex promotional and information activity aimed at health professionals. The title should include a reference to information activity.

3.6. **Article 3(2)**

This Article should specify that the list of prohibited therapeutic indications is indicative and not exhaustive.

3.7. **Article 8(1)**

3.7.1. Although it is not possible to give a full definition of a "medical sales representative" in a Directive on drug advertising, the fact remains that the definition given is very vague ("shall be given adequate training and shall have sufficient scientific knowledge") considering the responsibilities which these representatives have.

3.7.2. Provision should be made to ensure that representatives have had higher education and special training and refresher courses from the company, the health authorities or universities on the scientific, legal and deontological aspects of the profession. The position of the medical sales representative within the pharmaceutical business also requires clarification.

3.7.3. These points are important because representatives are required to provide information on the products and promptly report any side effects.

3.8. **Article 8(3)**

3.8.1. It should be specified that the feedback to the company provided by the medical sales representative is not the same as the fourth stage of clinical trials and is subject to different regulations. The information covered by the present Article is provided free of charge by the doctor during normal talks with the sales representative.

3.8.2. Moreover, neither this feedback nor stage four can replace a general drug monitoring service as envisaged by the WHO.

3.9. **Article 9**

3.9.1. Clarification is needed of the term "insignificant intrinsic value" in Article 9(1) The Committee suggests the following wording:

"objects whose value is not sufficient to induce the health professional to prescribe the drug other than in accordance with good clinical practice."

3.9.2. If the reference to congresses in Article 1(3) (definitions) is not deleted, the Committee proposes that a clause be inserted in Article 9 to exclude from the ban refresher conferences held solely to inform and train health professionals. The pharmaceutical industry's work in this area should not be discouraged.

3.10. **Article 10**

3.10.1. The maximum of two free samples (obviously per product) per year seems very rigid. It appears to conflict with the need for doctors to familiarize themselves with new drugs and learn to use them better. Furthermore, Article 10(b) requires the doctor to make a written request for the samples, thus assuming direct responsibility for them. The doctor should be given a wider margin of discretion.

3.10.2. The list of products of which samples may not be provided should include thermolabile or otherwise easily perishable products. Representatives do not have proper premises or facilities for storing samples correctly - and these samples are fully-fledged medicinal products.

3.11. **Article 11**

3.11.1. The proposal should identify the body which is to monitor advertising and the relation between image and content of the message, particularly where this exceeds the bounds of proper information and constitutes an incentive to use a particular drug.

3.11.2. It is necessary to harmonize the monitoring systems of the Member States, which range from specific authorization bodies to self-policing arrangements. The free movement which will soon be achieved by the Single Market makes Commission consideration of this point particularly important.

3.11.3. The moves to draw up a European Code of Practice in this sector are to be welcomed. The European pharmaceutical industry has so far only drawn up a code for drugs promotion to health professionals, and this does not lay down sufficient implementing guarantees.

3.11.4. The Committee asks the Commission to investigate possible ways and fora for dealing with this matter at Community level.

3.12. **Article 12**

The in-company scientific service must be headed by a health specialist offering a maximum guarantee of professional skills and legal responsibility. The existence of such a service does not of course preclude the existence of (or indeed, the need for) other information channels for health professionals, such as national or European-level data banks.

3.13. **Article 13**

3.13.1. Further consideration is needed of the clause (Article 13(1)) allowing marketing authorizations to be suspended if the Directive is not observed.

3.13.2. If drugs of proven therapeutic value and novelty had to be withdrawn, this would unfairly deprive patients of a vital drug.

3.13.3. It seems right to impose financial and legal penalties if a company commits a serious offence.

3.13.4. However, the punishment should be in keeping with the severity of the risks engendered for human health.

Done at Brussels, 19 December 1990.

The Chairman of the Economic and Social Committee	The Secretary-General of the Economic and Social Committee and Consumer Affairs
François STAEDELIN	Jacques MOREAU

OPINION

of the Economic and Social Committee on the Proposal for a Council Regulation (EEC) concerning the creation of a supplementary protection certificate for medicinal products

(COM(90) 101 final - SYN 255)

On 3 May 1990, the Council decided to consult the Economic and Social Committee, under Article 100a of the Treaty establishing the European Economic Community, on the

Proposal for a Council Regulation (EEC) concerning the creation of a supplementary protection certificate for medicinal products (COM(90) 101 final - SYN 255).

The Section for Industry, Commerce, Crafts and Services, which was responsible for preparing the Committee's work on the subject, adopted its Opinion on 9 January 1991. The Rapporteur was Mr HILKENS.

At its 283rd Plenary Session (meeting of 30 January 1991), the Economic and Social Committee adopted the following Opinion by with 81 votes in favour and 5 abstentions.

* * *

Whilst essentially endorsing the Commission proposal and the greater protection for the European pharmaceuticals industry for which it provides, the Committee would make the following observations and suggestions.

1. Introduction

1.1. This proposal, which is based on Article 100a of the EEC Treaty, falls within the framework of a Community health policy or, more specifically, of an internal market for medicinal products.

1.2. In assessing the draft, all the consequences of the proposed legislation must be taken into account. The pharmaceuticals sector and market exhibit certain peculiarities which affect both producers and consumers.

1.3. On the supply side, the need for extensive research makes patent protection necessary. Effective patent protection is, however, subject to gradual "erosion" owing to the numerous tests called for by the application dossier. On the demand side, medicinal products are of crucial importance for public health and therefore rate highly on the scale of consumer preferences, even though, at least in the case of prescription drugs, the decision to purchase does not rest with the consumer himself.

1.4. The Regulation is intended to ensure greater protection for innovation in the pharmaceuticals sector. The best means of providing such protection is through patents. Although under the European Patent Convention which covers all products including pharmaceuticals, patent protection is generally granted for 20 years in Europe, the numerous, obligatory (physio-chemical, biological or micro-biological, toxicological, pharmacological and clinical) tests reduce the exclusive exploitation period to only 8-12 years in the case of pharmaceuticals. This situation is the result of administrative procedures which are recognized as necessary precautions for the marketing of medicinal products. Furthermore, the effect of brand loyalty over longer exploitation periods should not be underestimated in the case of many products.

1.5. In outlining the content and scope of its proposal, the Commission makes clear that the purpose of the draft Regulation is to restore the effective period of patent protection so as to encourage innovation in the Community's pharmaceuticals industry while at the same time avoiding discrimination visvis other industrial sectors. Another aim is to close the gap between the Community and the USA/Japan with regard to patent protection for basic innovations in the pharmaceuticals industry.

2. Broad outlines of the proposal for a Regulation

2.1. The proposal assumes that research is vital, both for the pharmaceuticals industry itself and for society as a whole. Accordingly, in Europe the industry allocates between 10 and 15% of its turnover for pharmaceuticals research on a self-financing basis. The patent protection system is therefore of crucial importance, since it makes it possible to recoup research investment during a period of exclusive exploitation, thereby securing the self-financing process and guaranteeing future research.

2.2. Over the last ten years, the level of the European pharmaceuticals industry's research - expressed as its share of the total number of molecules developed - has declined from 65% to 40%. This situation could enable competitors, particularly in the US and Japan, to increase their market share further at Europe's expense.

2.3. The principal aims of the proposed Regulation relate to the efficient operation of the internal market, the improved competitiveness of Community industry and the promotion of research and development in the health field.

2.4. The proposed certificate will be issued by national patent offices at the request of the holder of a national or European patent (the "basic" patent) in respect of a product authorized to be marketed in the country concerned. It does not protect the expired patent in its entirety, but only the basic innovation which has also been authorized to be placed on the market.

3. General comments

3.1. The Committee recognizes that, in the interests of health protection, the marketing of medicinal products in the Community must be subject to stringent quality and therapeutic requirements. It therefore approves of the existing Community authorization procedures and those still to be introduced. Patent protection for innovation in the Community pharmaceuticals industry can also be said to contribute to health protection.

3.2. Whilst the Committee is aware that the Single European Act states (in Declaration No. 4) that the Commission should give precedence to the use of a Directive under Article 100a, it nevertheless believes that the Commission is correct in preferring the use of a Regulation in this instance and endorses the proposal. It is important that all Member States implement the extended period of a patent simultaneously: a Regulation can achieve this, but the legislation to enact the requirements of a Directive in each Member State can be of indeterminate duration.

3.3. The Committee thinks that the additional period of patent protection provided by the proposed certificate should also be looked at.

A fair solution would be to align on US and Japanese patent protection laws so as to safeguard the competitive position of the Community's pharmaceuticals industry worldwide.

3.4 The Committee calls on the Commission to examine all the economic consequences of the proposal, with particular reference to the duration of the protection certificate.

3.4.1. The interests of generics producers, who have an influence on price competition in a number of market segments, must also be borne in mind (generic medicinal products are pharmaceuticals which contain the same chemically active principle as proprietary products - i.e. having chemical and therapeutic equivalence and the same bioavailability - and which are marketed after the proprietary products' protection has expired). In this connection, a balance must be maintained between the interests of this industry and pharmaceuticals research.

3.4.2. The Committee urges the Commission to verify whether the direct interests of generics producers will be damaged by the transitional provisions set out in Article 13(2) of the proposal.

3.5. The Committee thinks that consideration must also be given to the scope of the proposed Regulation. Thus, the concept of a "basic patent" used, inter alia, in Article 3 appears to bear no relation in most cases to the concept of a "basic innovation". Since, in its view, the Regulation should be restricted to pharmaceutical discoveries which genuinely involve a basic innovation, the Committee urges the Commission to lay down explicit criteria to this end.

3.6. The introduction of the supplementary protection certificate would seem likely to produce a sharp increase in the cost of, and expenditure on, medicinal products, particularly if the scope of the Regulation were to be broadly defined. This increased burden will be borne by consumers and health-insurance schemes. On the basis of a number of general conditions, the Commission puts this overall increase at 1% of the total turnover in medicinal products in the first year. The Committee calls on the Commission to take account of these factors and introduce appropriate measures to deal with them.

3.7. The Committee proposes that, after the Regulation has been in force for five years, the Commission should draw up an evaluation report on which the European Parliament and the Economic and Social Committee may comment.

Done at Brussels, 30 January 1991.

The Chairman of the Economic and Social Committee	The Secretary-General of the Economic and Social Committee
François STAEDELIN	Jacques MOREAU

OPINION

of the

Economic and Social Committee

on the

Proposal for a Council Regulation (EEC) laying down Community procedures for the authorization and supervision of medicinal products for human and veterinary use and establishing a European Agency for the Evaluation of Medicinal Products

Proposal for a Council Directive amending Directives 65/65/EEC, 75/318/EEC and 75/319/EEC in respect of medicinal products

Proposal for a Council Directive amending Directives 81/851/EEC and 81/852/EEC in respect of veterinary medicinal products

Proposal for a Council Directive repealing Directive 87/22/EEC on the approximation of national measures relating to the placing on the market of high Otechnology medicinal products particularly those derived from biotechnology

(COM(90) 283 final - SYN 309 to 312)

On 3 December 1990, the Council decided to consult the Economic and Social Committee, under Article 100a of the Treaty establishing the European Economic Community, on the

Proposal for a Council Regulation (EEC) laying down Community procedures for the authorization and supervision of medicinal products for human and veterinary use and establishing a European Agency for the Evaluation of Medicinal Products

Proposal for a Council Directive amending Directives 65/65/EEC, 75/318/EEC and 75/319/EEC in respect of medicinal products

Proposal for a Council Directive amending Directives 81/851/EEC and 81/852/EEC in respect of veterinary medicinal products

Proposal for a Council Directive repealing Directive 87/22/EEC on the approximation of national measures relating to the placing on the market of high technology medicinal products particularly those derived from biotechnology (COM(90) 283 final - SYN 309 to 312)

The Section for Protection of the Environment, Public Health and Consumer Affairs, which was responsible for preparing the Committee's work on the subject, adopted its Opinion on 4 June 1991. The Rapporteur was Mr COLOMBO.

At its 288th Plenary Session (meeting of 4 July 1991), the Economic and Social Committee adopted the following Opinion unanimously:

* * *

1. Preliminary comments

1.1. The Committee welcomes the Commission proposals, and in particular the proposal to set up a European Agency for the Evaluation of Medicinal Products; this marks the culminating point in the major package of measures to harmonize the market in medicinal products.

1.2. The importance of the Agency lies in the remit and role which will be assigned to it. Alongside this remit - outlined below - the Agency will also act as guarantor for the implementing arrangements of the other Directives currently being adopted (wholesale distribution, legal status, labelling and advertising, patents), on most of which the Committee has already issued Opinions[1].

1.3. These earlier proposals, although an undeniable step forward on the road to Community harmonization, leave room for differing interpretations at national level of certain key points.

1.4. Any such differing interpretations would impede real free movement of medicinal products within the Community, which is necessary if consumers are to be guaranteed equal access to these products and there is to be equal protection of public health and safety.

1.5. In industrial terms, EC legislation must safeguard and improve the competitiveness of Community products. Their quality is already high, and can be further improved by coordinating and boosting the fundamental role played by scientific research.

1.6. While we should endorse the aim of safeguarding and supporting the EC's pharmaceuticals industry by means of harmonized authorization procedures, account must also be taken of the social aspects of the pharmaceuticals sector, and the need to make procedures as transparent as possible. The experience gleaned by Member States' health insurance systems can be of particular help here.

1 OJ C 225 of 10 September 1990, OJ C 60 of 8 March 1991 and OJ C 69 of 18 March 1991.

1.7. It is not enough simply to state that the interests of the consumer (and thus the needs of the patient who should be the prime beneficiary of the drug) are paramount; this intention must be given concrete legitimation by setting up a specific forum where these interests can be voiced.

1.8. Lastly, in the run-up to a People's Europe with free movement, the Community cannot shirk the question of harmonization of drug pricing and reimbursement systems. The significant divergences which still persist in this field will appear increasingly unacceptable as the EC drug authorization system gets under way. The Committee notes that the Commission is working on this problem, and urges it to analyze the various systems and draw up proposals at an early opportunity.

1.9. The present proposals, examined in greater detail below, seem to reflect a cautious gradual approach which is nevertheless ambitious in intention.

1.10. The innovative features are tempered by a whole host of safeguard clauses placed at the disposal of the Member States. These clauses could seriously encumber the procedures and delay real free movement of medicinal products within the Community.

1.11. The recommendations which follow are designed to make the procedures more efficient and ensure a smooth transition to the new system.

2. Character, scale and duties of the Agency

2.1. The Agency has aroused the expectations and keen attention of the entire EC health and pharmaceuticals sectors. This in itself is an indication of the key role which the Agency is to play in this sensitive sector.

2.2. The proposed structure will mean the strengthening of the existing Committee for Proprietary Medicinal Products and Committee for Veterinary Medicinal Products (CPMP/CVMP). This strengthened role should lead to the creation of a structure guaranteeing independent assessment, balanced representation of experts from the Member States and of the various biological and medical "schools of thought" in the Community, and a multidisciplinary scientific contribution.

2.3. The tasks of the Agency will be gradually extended during a transitional period under which national procedures are to remain in force until 1996, alongside a centralized procedure for certain categories of drug, and the phasing-in of new EC procedures for the registration of medicinal products.

2.4. Initially, the Agency's main task will be to coordinate, assess and monitor the activity of the Member States. Only where disputes arise will the Agency be able to enforce a binding arbitration procedure.

2.5. However, the Agency will later assume wider responsibilities in the fields of public health protection and industrial policy with respect to medicinal products.

2.6. The Agency's main duties in the **public health** field will be to provide:

— scientific EC-level evaluation of authorization applications which require the centralized procedure or are brought to arbitration;

— a guarantee that new medicinal products meet rigorous EC quality, safety and efficacy requirements;

— better coordination of the withdrawal or restriction of drugs in the event of a serious threat to health;

— identical published information valid throughout the Community (as requested by the Committee in its Opinion on labelling and package leaflets)[2];

— an ambitious commitment to bolster the Community's preclinical and clinical research facilities;

— coordination of inspections and pharmacovigilance;

— an assessment of the health hazards of residues of veterinary medicinal products in foodstuffs.

2.7. In the field of industrial policy, the Agency should offer valuable support for EC businesses by:

— preparing EC Guidelines on the presentation and content of authorization applications, drawing on the experience already gained in this area;

— laying down a standard, simple (in administrative and linguistic terms) format for applications;

— observance of specified time-limits for the issue of marketing authorizations for new products;

— protecting the applicant's confidentiality, thanks to the deposit of a single file;

— offering the possibility of preliminary advice on the tests to be carried out;

— enhancing the status of Community-produced medicines on export markets (authorizations will guarantee high therapeutic value).

2.8. The Agency is also to adopt simple, transparent procedures backed by objective assessment criteria to guarantee the applicant that data will be treated in confidence. The applicant will be allowed to appeal to the various responsible authorities if the authorization is refused.

2.9. Lastly, the Agency is to tackle matters of particular Community interest, such as the pooling of expertise, harmonization of scientific evaluations and harmonized management of EC authorizations with a view to the Single Market.

2.10. As regards pharmacovigilance in particular, the Committee considers it vital for information to be as transparent and well-publicized as possible. Instruments should be set up for EC-level collection and rapid transmission of data.

3. Comments on the authorization procedures

3.1. Harmonization of the authorization procedures is the central feature of the package, and will form the linchpin of the future EC pharmaceuticals market.

1 OJ C 225 of 10 September 1990, OJ C 60 of 8 March 1991 and OJ C 69 of 18 March 1991.

3.2. The Commission's cautious handling of the authorization procedures is understandable. Account has to be taken of the fact that although EC-wide free movement of drugs brings a need for new regulations, the fragmented regulatory system which already exists cannot be dismantled overnight; it must be amended rationally and gradually.

3.3. Such a totally new system will require a transitional period whose duration is difficult to determine in advance. An overhasty transition could jeopardize the effectiveness of the new instruments. In order to ensure that the process goes smoothly and to facilitate the completion of the new structures, existing instruments should be retained during the transitional period until the new EC instruments have got through any teething troubles.

3.4. At all events, in the interests of the consumer, the procedures must obviously all meet rigorous quality, efficacy and safety criteria.

3.5. **The national procedure**

3.5.1. Continued use of national procedures is justified, as it offers a guarantee for smaller firms producing drugs solely for the domestic market who do not wish their authorization to be extended to other Member States.

3.5.2. Moreover, the national procedure will form the basis for the decentralized EC procedure discussed below.

3.6. **Decentralized EC procedure**

3.6.1. As the "multi-state" procedure has failed in practice because it has been very unevenly applied by the Member States, the Commission has devised two complementary procedures for regulating free movement of drugs within the Community.

3.6.2. The decentralized procedure is based on mutual recognition, whereby authorization in one Member State is subsequently extended to other States. Under this procedure the decision-taking powers of the Member States remain virtually unchanged, although the Agency acquires the role of arbiter.

3.6.3. This is a step forward from the "multi-state" procedure, as it establishes clearer time-limits and allows firms to decide for themselves how many further authorizations to request.

3.6.4. The procedure offers a gradual move to the European market for firms which wish to reach this wider market.

3.6.5. However, the procedure is less advantageous for the patient/consumer, as it could mean that new drugs take longer to reach the market, and does not guarantee their availability in all Member States.

3.6.6. Furthermore, recourse to the Agency's arbitration should not become the standard practice. Its rulings should be binding in all Member States and not, as presently envisaged, simply in the Member State opposing the application. This would prevent needless proliferation of applications to the Agency by the Member States.

3.6.7. Lastly, Member States must be prevented from opposing applications on any grounds other than efficacy, quality and safety. This is important in order to avoid disguised forms of protectionism which would impede the establishment of a real Single Market.

3.7. **The centralized procedure**

3.7.1. The second procedure is a centralized one leading to an authorization which is immediately valid in all Member States. Decision-taking power is concentrated in the European Drugs Agency.

3.7.2. The Annex to the proposed Regulation (SYN 309, page 112) states that for drugs intended for direct human use, the centralized procedure is:

— obligatory only for products developed by means of certain biotechnological processes;

— optional for those developed by means of other biotechnological processes, or by means of highly technological and innovative processes.

3.7.3. The Committee wonders whether this distinction properly protects the interests of either the "passive consumer" (i.e. the patient) or the "active consumer" (the doctor who prescribes the drug and is thus the real promoter of its consumption).

3.7.4. Moreover, there are some fields of pathology in which there is always a need for effective, highly innovative drugs. Anti-cancer drugs are not the only important example where gradual introduction of the centralized procedure would appear warranted.

3.7.5. The procedure should however remain optional for these categories of drug, and the bureaucratic procedures should be simplified, while rigidly adhering to the criteria laid down.

3.7.6. Drugs subject to this procedure will naturally enjoy a high "scientific status" and prestigious label, which will also help them in markets outside the EC.

3.7.7. The centralized procedure would also have three practical advantages:

— **all** EC patients would have immediate access to the above-mentioned innovative drugs, without having to experience the lengthy delays which the authorization procedure in the individual Member States would inevitably entail;

— it would make the best possible use of specialist skills, preventing twelve groups of people from having to examine substances which could be examined perfectly thoroughly by one single (and thus larger) group of experts of high and unquestionable international standing;

— there would be an **a priori** guarantee that, because industry's preclinical and clinical research had to meet more rigorous standards, manufacturers would only put forward drugs of a fully proven innovative nature in technical and/or medical and biological terms.

3.7.8. The Committee therefore asks the Commission to consider the case for gradually extending optional use of the centralized procedure to other categories of drug.

3.8. Veterinary medicinal products

3.8.1. The above criteria also apply to the authorization of veterinary medicinal products. However, greater centralization might be desirable in the case of medicinal products for animals intended for human consumption, in view of the Community interests at stake (residues, movement of food products, etc.). For drugs administered to domestic pets such as cats and dogs, on the other hand, the aim should be automatic mutual recognition without recourse to central arbitration.

3.8.2. The Committee views with concern the reference to the CAP in connection with the authorization of veterinary medicinal products (fourth recital of the Regulation establishing the Agency). The Agency is concerned with the quality, safety and efficacy of drugs, and does not seem the appropriate place for political and economic judgments. Its remit should be confined to public health considerations.

4. Structure and scientific quality

4.1. The key role which the Agency is to play in the assessment process means that it must be completely neutral and independent, and that its monitoring functions must be multidisciplinary. The Agency's technical and scientific structure must provide balanced representation of experts from the various Member States, and the different disciplines must be fully represented on the assessment committees.

4.2. The Committee endorses the Commission's decision to set up a light central structure, relying heavily on national experts operating in their regular places of activity. The Committee also appreciates the intention (Articles 50 to 52) to ensure the scientific independence of the Agency and the impartiality of its experts, and to avoid interference from industry and intervention by the national authorities which would be incompatible with assessment duties.

4.3. The establishment of a European college of experts based on national lists endorsed and updated by the Member States, as laid down in Article 51, appears vital. These lists, which should be made public, should mention the experts' academic and technical qualifications, along with details of their research work and publications, and should include the declaration of other interests mentioned in Article 52.

4.3. If the centralized procedure proves its worth as a swift and competent system, the number of central staff could gradually be increased by recruitment from national bodies.

Done at Brussels, 4 July 1991.

The Chairman of the Economic and Social Committee	The Secretary-General of the Economic and Social Committee and Consumer Affairs
François STAEDELIN	Jacques MOREAU

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