COMMISSION OF THE EUROPEAN COMMUNITIES

Brussels, 14.11.1997
COM(97) 581 final

Classification for the supply of medicinal products for human use

Commission Report to the Council on the application of Directive 92/26/EEC

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1. Introduction

The 1985 White Paper identified the harmonisation of conditions for the supply of medicinal products to patients, as being necessary for the completion of the internal market in the pharmaceutical sector. In this context Directive 92/26/EEC was proposed by the Commission in 1989 and adopted by the Council in March 1992. During the discussions which took place prior to its adoption, it was recognised that a progressive approach would be required to clearly identify the fundamental principles which should govern the role of the Community in this area, while recognising that the legislation would need to be refined and developed over time.

To enable account to be taken of the progress achieved following its implementation and to provide a means for refining and developing the legislation, Article 6 provides for a report (accompanied if necessary by appropriate proposals) on the application of this Directive, within 4 years of its adoption, (i.e. by March 1996).

The deadline for its implementation by the Member States was 1 January 1993 but this was delayed in many Member States such that its implementation was spread from December 1992 through to December 1994. Consequently, this report was also delayed.

In 1994, in preparation for this report, Informations Médicales Statistiques S.A. (IMS) were contracted to carry out a study which would analyse the degree of convergence of national decisions following the implementation of the Directive on the one hand, and on the other hand, the analysis of the persistent obstacles which go against the adoption of coherent decisions and thus hinder the proper functioning of the single market.

[1] Council Directive 92/26/EEC of 31 March 1992 concerning the classification for the supply of medicinal products for human use, O.J. L 113, 30.4.1992 p.5

2. Application of Directive 92/26/EEC

The Directive's implementation into national law has been carried out by all the Member States. They all use the classification system set out in the Directive which consists of two main categories, non-prescription and prescription-only. However within each of these main categories there are optional sub-categories which vary from one Member State to the next.

Non prescription medicines

The notion of non-prescription medicines is univocal. Within this category certain Member States have created the sub-category of medicinal products for self-medication. However, certain Member States, (for example Austria), do not acknowledge the notion of self-medication.

The Directive is silent with regard to the outlets through which non-prescription medicines are available. Finland, Austria, Denmark, Germany, Ireland, Sweden and The U.K. distinguish between the outlets: i.e. availability for general sale and the availability in pharmacies only. Availability for general sale, only relates to certain non-prescription medicines. In The Netherlands there are two outlets for the sale of non-prescription medicines: pharmacies and authorised druggists. In the other seven Member States [2]all medicines are available only in pharmacies.

There is nothing to prevent any medicinal product which is non-prescription from being prescribed, although it may not necessarily be reimbursed.

Prescription-only medicines

The notion of prescription medicines is also univocal. Nevertheless, differences can be noted when considering the prescriber's right to prescribe all or only certain medicinal products. The criteria applicable to this classification have been implemented in all Member States.

The sub-categories for prescription-only medicines in Article 2(2) are optional. The Directive provides that - *'The competent authorities may fix sub-categories for medicinal products which are available on medical prescription only. In that case, they shall refer to the following classification:*

(a) medicinal products on renewable or non-renewable prescription
(b) medicinal products subject to special medical prescription
(c) medicinal products on restricted medical prescription reserved for use in certain specialised areas'.

Implementation of these sub-categories has only been carried out only to the extent that it was deemed necessary in terms of national health services or the rational use of medicines. The nature of the State funded health services in certain Member States has significantly influenced the implementation of the first sub-category. In this context, certain medicinal products have been subjected to a renewable prescription classification which enables the pharmacist to repeat the supply of certain prescribed medicines. When the implementation is examined in relation to the national regulations in force and their interpretation through national practices, it becomes evident that the situation in each Member State differs for these optional parts of the Directive:-

[2] (France, Spain, Italy, Greece, Portugal, Belgium & Luxembourg)

- All Member States have legislative provisions for making certain medicinal products available only on 'special medical prescription'; within the meaning of the second sub-category, at least with regard to psychotropic substances.
- Eleven Member States[3] have implemented the 'renewable' sub-category; Germany, U.K, The Netherlands and Portugal have not.
- Eleven Member States[4] have implemented the third sub-category of 'restricted'; Austria, Sweden, The Netherlands and The U.K. have not.

So far, the operation of the centralised Community procedure (Council Regulation 2309/93) has not brought about the implementation of these sub-categories in all Member States.

National lists

Articles 5(1) and 6(1) provide for these lists:-

Article 5(1) - *'The competent authorities shall draw up a list of the medicinal products subject on their territory to medical prescription, specifying, if necessary, the category of classification. They shall update this list annually.'*

Article 6(1) - *'Within two years of adoption of this Directive, the Member States shall communicate the list referred to in Article 5(1) to the Commission and to the other Member States, when requested by the latter'*

These lists do not exist in all the Member States. Substance lists or lists of exemption according to pharmaceutical form or dosage are used in certain countries even if they do not correspond to the same end. However the majority of the 15 Member States (in accordance with Articles 5(1) and 6(1)) have sent lists, to the Commission, of medicinal products which are prescription-only medicines. Although such lists have been sent, the presentation format is not necessarily analogous and does not necessarily contain the same rubrics.

As outlined in the paragraph entitled 'Annual Lists' on page 8, the format for these lists needs to be standardised and they could be used to draw up a list of products restricted to prescription-only throughout the Community.

3. Non-prescription/Self-medication

Following a long historical period during which the evolution of professional medical services sometimes appeared to be rendering self-medication superfluous, at least in developed countries, there is now a growing trend towards self-medication. Recognition of the responsibility of the individual for his or her own health, and of the fact that recourse to medical care for minor ailments is often unnecessary, has contributed to this development. More recently, the actions of governments everywhere to curtail the costs of state-funded treatment is seen as a factor which may result in increased self-medication.

The Commission in its Communication on the framework for action in the field of public health, published in November 1993, states that this trend towards self-medication must be accompanied by a strengthening of information measures, if it is not to have an adverse effect on people's health. It considers further that giving people more choice and responsibility must also involve ensuring that they are equipped to make sensible choices.

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[3] (Austria, Belgium, Denmark, Finland, France, Greece, Ireland, Italy, Luxembourg, Spain, Sweden)

[4] (Belgium, Denmark, Finland, France, Germany, Greece, Ireland, Italy, Luxembourg, Portugal, Spain,)

For the medicinal products switched from prescription-only to non-prescription (i.e. for self-medication) the provision of patient information is particularly important. Council Directive 92/27/EEC[5] requires "the use of clear and understandable terms for the patient which are legible and which are in the official language of the Member State where the product is placed on the market". Furthermore the Commission has recently drafted guidelines, (as provided for in article 12 of Directive 92/27/EEC), on the readability and excipients in the label and package leaflet.

The Communication also states that self-medication is of particular benefit in the treatment of minor ailments. It emphasises that the public must be made aware of the need to consult a doctor if symptoms persist or doubts exist. It outlines how, after initial diagnosis and prescription, self-medication becomes possible with the doctor delegating control while retaining an advisory role. The Communication considers that information in all these cases must be easily accessible and understandable and that both pharmacists and doctors have an important role to play as far as self-medication is concerned.

- There is still considerable variation throughout the EU as to the non-prescription status of many medicinal products, with the result that some medicines are prescription-only in one Member State and available without prescription in another Member State. Directive 92/26/EEC clearly states the criteria to be used to classify a medicinal product within the non-prescription class. These criteria make clear that a prescription shall only be necessary if the product:
- Is likely to present a danger if used without medical supervision;
- Is frequently, and to a wide extent, incorrectly used;
- may cause an action or a side effect which needs to be investigated;
- Is normally prescribed by a doctor to be administered parenterally.

These criteria were expected to bring the classification, of medicinal products, in the Member States closer to each other. This expectation was reinforced by the obligation on national authorities to examine, as appropriate, the classification of a medicinal product at least on the occasion of the five-year renewal of the marketing authorisation (as required by Article 5(2) of Directive 92/26/EEC). This examination of the classification, by the competent authorities on the occasion of the five-yearly renewal, is usually provoked by proposals made by the marketing authorisation holder. In some Member States the marketing authorisation holders are cautious about switching legal status from prescription-only to non-prescription because of the possibility that the medicinal product concerned will lose its reimbursement status in the State funded health service.

Differences, between Member States, in the classification of medicinal products have decreased since the adoption of Directive 92/26/EEC. However, it is generally felt that the level of harmonisation achieved is not yet satisfactory. This may be due to the fact that Member States have been late in implementing this Directive, but it also probably reflects more fundamental differences in their approaches to self-medication.

4. Switching legal status

At present each Member State has different procedures for considering the switch of a medicinal product from prescription-only to non-prescription.

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[5]Council Directive 92/27/EEC on the labelling of medicinal products for human use and on package leaflets of 31 March 1992, O.J. No. L 113 30. 4. 1992 p.8

Following the adoption of the Directive 92/26/EEC, efforts have been made at national level to improve the procedures for change of the legal status from prescription to non-prescription, (i.e. switching). In several Member States, however, the impact of this Directive has been minor. In these Member States, neither the authorities nor the marketing authorisation holders changed their previous practices significantly, therefore there has been hardly any change with regard to the legal status of the medicinal products. As mentioned already, the risk of losing reimbursement by the State funded health service is frequently a factor which discourages marketing authorisation holders from applying to switch legal status from prescription-only to non-prescription.

On the 28 March 1996, the Council of Ministers adopted a 'Council Resolution designed to implement the outlines of an industrial policy for the pharmaceutical sector in the European Union'[6]. This Resolution states that it would be appropriate to tighten the common classification system in Directive 92/26/EEC, so that there is a clearer distinction between prescription and non-prescription medicinal products.

The European Parliament adopted a resolution on industrial policy for the pharmaceutical sector on 16 April 1996[7]. It calls for the establishment of transparent procedures which define the method by which prescription medicines can be transferred (i.e. switched) to non-prescription status.

Therefore to move forward with EU harmonisation of medicinal products restricted to prescription-only and of medicinal products available without prescription, it is now necessary to establish criteria and procedures for switching prescription-only medicinal products to supply without a prescription. These criteria and procedures should take the form of a Commission guideline (to be approved by the Pharmaceutical Committee). Within the framework of the criteria already set out in the Directive for non-prescription and prescription-only medicines, the guideline would outline the supporting scientific data required to demonstrate that the product (at a specified dosage and for specific indications) may safely be supplied without a prescription and thus be available for self-medication. The guideline would also outline the administrative procedures and timetables which would apply.

Some Member States (e.g. Portugal and Spain) require the name of the medicinal product to be changed when a product, which was previously prescription-only, becomes available without a prescription. It appears that this requirement is not entirely based on safety, quality or efficacy considerations but is sometimes linked to concerns that advertising of a non-prescription medicine which has the same name as a prescription medicine may increase the prescribing of the prescription-only product and this impacts on the state funded health service. Data available, so far, from industry, does not support this concern

5. Prescription-only medicines

Article 3 of Directive 92/26/EEC sets out the criteria for restricting the supply/legal status of a medicinal product to prescription-only. A medicinal product classified as prescription-only may be available on prescription, without further restriction, or it may be available on prescription with further restriction, as provided for by the sub-categories for prescription-only ⟨in Article 2(2)⟩.

The three sub-categories:-

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[6] O.J. C 136 8 May 1996 p.4
[7] O.J. C 141 13 May 1996 p.63

"medicinal products on renewable or non-renewable medical prescription"
"medicinal products subject to special medical prescription"
"medicinal products on restricted medical prescription, reserved for use in certain specialised areas",
are optional and this means that whatever the level of harmonisation achieved for prescription-only products this will be limited by the extent to which the sub-categories are used. However all of the Member States have legal provisions which give effect to the second sub-category *"medicinal products subject to special medical prescription"*, at least with regard to psychotropic substances.

The third sub-category, *"medicinal products on restricted medical prescription, reserved for use in certain specialised areas"*, must remain optional, at present, because four Member States (Austria, The Netherlands Sweden and The UK) do not use it. However, for medicinal products authorised by the Community, in line with article 13.3 of Council Regulation No. 2309/93 [8], which states: "Some products may be authorised only for use in hospitals or for prescription by some specialists", the following interpretations are used:-

use in hospital/use in certain specialised areas, may be taken to include use within a framework providing hospital-type care;

prescription by some specialists/restricted medical prescription, may be taken to include:- that the prescription, or the initial prescription only must be by a specialist.

The designation of the specialist shall take into account the progress made under Directive 93/16/EEC[9] in harmonising Member States' terminology for medical specialists.

The first sub-category, *"medicinal products on renewable/non-renewable medical prescription"*, must also remain optional, at present, because four Member States (Germany, The Netherlands, Portugal and The U.K.) do not have this sub-category; although in The U.K. there is the possibility to repeat the supply,(for prescriptions issued outside the scope of the State funded health service). This sub-category has different interpretations in the Member States who have it, as illustrated in the table overleaf.

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[8] Council Regulation No. (EEC) 2309/93 of 22 July 1993 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Agency for the Evaluation of Medicinal Products, O.J. No. L 214 24. 8. 1993 p.1

[9] Council Directive 93/16/EEC of 5 April 1993 to facilitate the free movement of doctors and the mutual recognition of their diplomas, certificates and other evidence of formal qualifications, O.J. L 165 of 7.7.1993 p.1

Member States' interpretations of the sub-category renewable/non-renewable

Renewable[10]		Non-renewable	
On the basis of one medical prescription the supply of the quantity prescribed may be repeated, unless the prescriber has specified to the contrary on the prescription.	On the basis of one medical prescription the supply of the quantity prescribed may only be repeated for the number of times/over the period of time specified by the prescriber on the prescription.	On the basis of one medical prescription the supply of the quantity prescribed may not be repeated unless the prescriber has specified to the contrary.	On the basis of one medical prescription the supply of the total quantity prescribed may not be repeated.
Austria	Belgium	Austria	Belgium
France	Denmark	France	Denmark
Ireland	Finland	Ireland	Italy
Italy[11]	Greece	Sweden	Luxembourg
	Luxembourg		Spain
	Spain		Portugal
	Sweden		Greece
	U.K.		

[10] In Portugal renewable prescription is provided for by the legislation but has not yet been put into operation

[11] In Italy prescriptions do not include any statement concerning renewable or non-renewable

6. Annual Lists

According to Articles 5 and 6 of Directive 92/26/EEC, each Member State is obliged to provide, annually, a list of the medicinal products which they have classified as prescription-only. These lists should be used to draw up, in consultation with the Pharmaceutical Committee, a Community list of medicinal products which are restricted to prescription-only throughout the Community. This Community list could then, in consultation with the Pharmaceutical Committee, be revised annually, in the light of the lists submitted annually by the Member States. There should be a standard format to be followed by Member States when submitting these annual lists of medicinal products which are restricted to prescription-only. The Commission will draw up a guideline for the presentation and submission of these lists, by telematic means.

7. The centralised procedure for a Community marketing authorisations

The Community decision (in accordance with Council Regulation 2309/93) concerning the marketing authorisation for a medicinal product contains: the legal status in Annex 2, the label text in Annex 3 and the summary of product characteristics in Annex 1.

For a medicinal product authorised by the Community the legal status is elaborated having regard to this Directive (which is invoked in Council Regulation No. 2309/93) and to article 13.3 of Council Regulation No. 2309/93. The legal status thus elaborated forms part of the Commission Decision. Due to the disharmony amongst the Member States in their national provisions for legal status (in particular for the sub-categories of prescription-only medicines) the expression of the legal status, for restricting the supply of a medicinal product authorised by the Community, in the label text in the Commission Decision (and thus on the label of medicinal products authorised by the Community) is limited at present to the main category in Article 2(1) of Directive 92/26/EEC, i.e. prescription-only.

It would make the Commission decision more transparent if, the additional restrictions to supply, beyond prescription-only, which appear in annex 2 of the decision but which do not appear on the Community label text (in annex 3), were included in the summary of product characteristics (viz. Directive 65/65/EEC[12] article 4a (5.4) as introduced by Dircetive 83/570/EEC[13]).

Nevertheless Member States have to find suitable ways to allow the marketing authorisation holder of a centrally authorised product to fulfil all of the conditions laid down in the Commission Decision granting the marketing authorisation. Thus, when the legal status in the Commission Decision includes one of the optional sub-categories, then the Member States who have not implemented this sub-category must provide an administrative, legal or practical framework that will allow the marketing authorisation holder to put the medicinal product(s) (concerned by this Decision) on their market under the specific condition(s) provided for by the legal status in the Decision.

In accordance with article 5.2 of Directive 92/27/EEC[14], Member States may require the legal status for supply to the patient, (in accordance with Directive 92/26/EEC), to

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[12] Council Directive 65/65/EEC of 26 January 1965 on the approximation of provisions laid down by law, regulation or administrative action relating to medicinal products, O.J. L 22 of 9.2.1965 p.369/65

[13] Council Directive 83/570/EEC of 26 October 1983 amending Directives 65/65/EEC, 75/318/EEC and 75/319/EEC on the approximation of provisions laid down by law, regulation or administrative action relating to proprietary medicinal products, O.J. L 332 of 28.11.83 p. 1

[14] Council Directive 92/27/EEC of 31 March 1992 on the labelling of medicinal products for human use and on package leaflets, O.J. L 113 of 30.4.1992 p.8

appear on the label. So, for a medicinal product authorised by the Community, a Member State may require further information concerning the legal status, in addition to the main category, to appear on the label; e.g. mention of the sub-categories, where relevant. Any further information concerning the legal status must be in accordance with annex 2 of the decision.

Subject to approval by the Community competent authority which is normally the European Commission, this further information is to be accommodated on the label in a boxed area ('blue box') which is used for other optional labelling items, not relevant to all Member States.

8. The mutual recognition procedures for national marketing authorisations

Council Directive 75/319/EEC[15] provides that an application can be made for the mutual recognition of national marketing authorisations and Articles 10,11,12,13 and 14 of this Directive provide a means for harmonisation (including arbitration if necessary) at Community level of national marketing authorisations leading to a Community Decision. To date the legal status of the medicinal product concerned has not been included, however, there seems to be no legislative obstacle to doing so.

The exclusion of legal status from the mutual recognition procedures is due firstly to the fact that the sub-categories for prescription-only are optional in the Member States and secondly, these optional sub-categories for prescription-only are sometimes interpreted differently in each Member State, due to the absence of clear definitions.

The proposals concerning guidelines for switching, could, given time, facilitate the inclusion of legal status in the mutual recognition procedures.

9. General Conclusions and Proposals

The implementation of Directive 92/26/EEC was spread from December 1992 to December 1994. These delays in implementation, together with the fact that the optional parts of the Directive were not implemented in all Member States, account for some of the non-convergence which still exists.

Although individual market profiles have changed in the period 1992-95, the effect has been relatively small in overall terms and further initiatives should be considered:-
EU harmonisation of medicinal products restricted to prescription-only
and
EU harmonisation of medicinal products available without prescription i.e. for self-medication.

National procedures need to be adapted and aligned with the Directive's overall strategy, which is to provide uniform criteria for the supply of medicinal products throughout the Community.

The optional nature of the sub-categories, for prescription-only medicines need to be addressed. The interpretation of these sub-categories also needs to be harmonised.

The Directive's provision for monitoring harmonisation, which is the Member State's lists of medicinal products restricted to prescription-only, should be retained and used to draw up a Community list of prescription-only medicines. The Commission will provide guidance on the presentation and submission of these lists by telematic means. As part of the inevitable ongoing review of the guidelines on switching, it would also be useful if Member States were to draw up similar lists for non-prescription products which could then be used to draw up a Community list of non-

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[15] Council Directive 75/319/EEC of 20 May 1975 on the approximation of provisions laid down by law, regulation or administrative action relating to medicinal products, O.J.No. L 147 9. 6. 1975 p.13

prescription products. As a first step towards achieving this, it is proposed that the Commission draw up guidelines to improve the comparability of the Member States' lists and thus within four years this should allow a Community list of non-prescription medicinal products to be drawn up.

Article 71 of Council Regulation 2309/93 provides for a general report (in 2001) on the experience acquired as a result of the operation of the centralised and mutual recognition procedures. In view of the anticipated progress towards harmonisation (e.g. the development of 'switching' guidelines), it is reasonable to expect that within four years (i.e. by 2001) it should be possible to include legal status for all medicinal products in the mutual recognition procedures.

This report could be updated at the time of publication of the general report (in 2001), referred to above, so that the progress towards the harmonisation of the legal status of medicinal products throughout the Community could continue to be monitored.

ISSN 0254-1475

COM(97) 581 final

DOCUMENTS

EN 05 15 17

Catalogue number : CB-CO-97-599-EN-C

ISBN 92-78-27385-6

Office for Official Publications of the European Communities

L-2985 Luxembourg