COMMISSION OF THE EUROPEAN COMMUNITIES

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Brussels, 28 January 1981

Proposal for a

COUNCIL DIRECTIVE

concerning the coordination of provisions laid down by law, regulation or administrative action in respect of certain activities in the field of pharmacy

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Proposal for a

COUNCIL DIRECTIVE

concerning the mutual recognition of diplomas, certificates and other evidence of formal qualifications in pharmacy, including measures to facilitate the effective exercise of the right of establishment relating to certain activities in the fields of pharmacy

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Draft

COUNCIL DECISION

setting up an Advisory Committee on Pharmaceutical Training

(submitted to the Council by the Commission)

EXPLANATORY MEMORANDUM

INTRODUCTION

1. These proposals, which are based on Articles 49 and 57 of the EEC Treaty, are designed to facilitate the mobility of one of the last great professions in the field of health. In this connection, the Council has already adopted Directives with the same aim in the case of doctors[1], nurses[2], dentists[3], veterinary surgeons[4] and midwives[5].

2. As early as 1969[6] and 1972[7] the Commission submitted to the Council proposals concerning pharmacists, but these initial proposals have since all been withdrawn by the Commission.

Some were withdrawn because they were no longer applicable; this was the case in particular (as a result of the decisions of the Court of Justice in the Reyners 2/74 and Van Binsbergen 33/74, which stated that Articles 52 and 59 of the EEC Treaty were directly applicable) with the proposals designed to abolish discriminations based on nationality[8]. The others were withdrawn owing to the Commission's new policy concerning the approximation of national laws - as developed from 1974 onwards. The harmonization of laws, which is not an aim in itself but an instrument for achieving European integration, must be used only where necessary for the development of the common market[9].

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(1) Council Directives of 16 June 1975, OJ No L 167 of 30 June 1975.

(2) Council Directives of 27 June 1977, OJ No L 176 of 15 July 1977.

(3) Council Directives of 25 July 1978, OJ No L 233 of 24 August 1978

(4) Council Directives of 23 December 1978, OJ No L 362 of 23 December 1978.

(5) Council Directives of 21 January 1980, OJ No L 33 of 11 February 1980.

(6) OJ No C 54 of 28 April 1969.

(7) COM(72) 1375 final, not published in the OJ.

(8) In the special case of the proposal for a directive concerning the coordination of provisions laid down by law, regulation or administrative action in respect of self-employed activities in the manufacture of medicinal products (OJ No C 54 of 28 April 1969, page 35), the withdrawal is justified by the fact that the content of this proposal has been largely incorporated by the Council in its Directive 75/319/EEC of 20 May 1975 on the approximation of provisions laid down by law, regulation or administrative action relating to proprietary medicinal products (OJ No L 147 of 9 June 1975).

(9) cf. in particular OJ, Debates of the European Parliament, No 171, February 1974, page 45 et seq.

The proposals put forward by the Commission in 1969 and 1972 did not meet these restrictive criteria and doubtless not all the proposed provisions were necessary merely in order to achieve the fundamental freedom embodied in the Treaty, which the free movement of persons constitutes, insofar as these provisions were intended to make the exercise of the profession of pharmacist subject to the same rules throughout the Community. For this purpose, they provided for a wide measure of coordination of the conditions of practice (e.g. the establishment of the pharmacist's monopoly of the retail sale of medicinal products, the pharmacist's ownership of the medicinal products he stocks and the geographical distribution of dispensaries as well as for coordination, specified in great detail, of the conditions of pharmacists' training (e.g. the laying down in the case of each basic subject of the number of hours to be devoted to theoretical training on the one hand and to practical training on the other)).

3. The present proposals appear to be more modest in scope than those put forward by the Commission in 1969 and 1972, but they are certainly better adapted to the present state of Community integration; they are confined to the measures necessary to facilitate the free movement of pharmacists within the Community; they nevertheless include the definition of the standard minimum requirements as to the exercise of the profession with regard both to the pharmacists' field of activity and to the conditions of his training.

These proposals do not imply any renunciation of further development in fields such as the monopoly of dispensing medicinal products, the geographical distribution of dispensaries or, yet again, the ownership of medicinal products, but this coordination should develop within the framework of an integrated Community health policy.

I. Proposal for a Council directive concerning the coordination of provisions laid down by law, regulation or administrative action in respect of certain activities in the field of pharmacy

This proposal ensures the approximation of the national laws which is necessary if confidence is to reign between Member States in regard to the qualifications and competence of migrant professional persons. For this purpose it defines not only the characteristics which pharmaceutical training must have in all the Member States but also the pharmacist's field of activity, which is the raison d'être of such training.

Article 1

This Article specifies the activities access to which must be accorded in all Member States to holders of a pharmacist's diploma, subject to the additional requirement, in the case of certain activities, of an in-service training period or professional experience.

It is not, however, an exhaustive list of all the activities to which the pharmacist has access.

Thus this provision covers only the activities which the "general" pharmacist must be entitled to exercise in each Member State; it disregards the activities open to the pharmacist who has supplemented his initial training with special training (e.g. activities pertaining to analyses in the field of medical biology). In other words, this Article does not rule out the possibility that a Member State may extend on its territory the pharmacist's range of activities; the coordination envisaged is a minimum coordination the aim of which, having regard to the status of specialist in medicinal products attributed to the pharmacist, is to characterize the profession at European level by specifying its essential functions.

For all that, the Directive will not create for the benefit of the pharmacist any professional monopoly for any of the activities specified in this Article. The maintenance or the introduction of such monopoly will, at this stage, continue to be entirely a matter for the Member States.

Article 2

This Article lays down the minimum conditions to be satisfied by university diplomas awarded in the Member States for pharmacists.

In accordance with the Council Resolution of 6 June 1974[1] and the preceding Council Directives concerning the Health professions, minimum qualitative and quantitative criteria are resorted for the purpose of approximating the laws of the Member States. Hence the Directive specifies on the one hand the knowledge which the pharmacist's training must ensure in all the States (see paragraph 1) and, on the other hand, the minimum duration of the training course (see paragraph 2), together with the list of basic subjects (cf. paragraph 3) which appear to be indispensable for acquiring this knowledge.

The aim of the coordination is by no means to lay down a single system of training considered ideal in the abstract, but to determine the common denominator of training courses which is necessary in order that each Member State may have confidence in the training provided in the other Member States. This explains, for instance, the flexibility of the provisions adopted with regard to the in-service training course in a dispensary; such a course appeared to be indispensable for the pharmacist's training, but it was found that its duration could vary within certain limits without any adverse effect on the quality of the training. Likewise, no attempt is made to quantify the hours to be devoted to the teaching of each basic subject or to give a breakdown as between theoretical and practical training.

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(1) OJ No C 98 of 20 August 1974.

This approach appeared to be the only one possible for reconciling the necessary assurances which the migrant professional person must offer with observance of the Member States and national traditions.

Nevertheless, the proposed approximation by no means amounts to a levelling down of training standards, and several Member States will have to modify the pharmacists' training course as at present organized on their territories. This will mainly involve lengthening the period of theoretical and practical training and extending its duration of in-service training (see attached synoptic table of the conditions of training of pharmacists in the Member States).

II. Proposal for a Council directive concerning the mutual recognition of diplomas, certificates and other evidence of formal qualifications in pharmacy

This proposal has a twofold aim. Firstly, it draws the appropriate conclusions from the approximation of the laws of the Member States that is to be achieved by the previously examined proposal for a directive by ensuring recognition in all the Member States of the training courses which meet the minimum criteria laid down. Secondly, apart from the field of training, the proposal contains a number of provisions intended also to facilitate effective exercise of the right of establishment.

Chapter 1: Scope

Article 1 defines the range of activities affected by the recognition of diplomas, and hence the activities in the host country open to the holder of a reconized diploma. The activities in question are not merely those referred to in the first proposal for a directive (see Article 1 of that proposal), but all the activities in the host country open to the holder of a national pharmacist's diploma.

This solution was at first criticized on the grounds that it leads to the situation whereby the fact of crossing a frontier may extend the openings so available to the migrant professional person. It was finally adopted, however, because the differences between the field of activity open to "general" pharmacists in the various Member States will be of little significance in view of the coordination achieved and will concern only secondary activities as compared with the essential functions of the profession.

Another solution was sometimes suggested: it would have consisted in limiting the openings available to the migrant professional person to those activities he is entitled to exercise in the State from which he comes. This approach would have destroyed the unity of the profession in the host country. Furthermore, it would have cast doubt on the pharmacist's professional conscience since one of the common principles of pharmacists' professional ethics is that the pharmacist shall perform only acts for which he considers he is sufficiently competent.

Chapter II: Diplomas, certificates and other evidence of formal qualifications in pharmacy

Article 2: This Article obliges each Member State to recognize pharmacists' diplomas which are awarded by other Member States and which meet the minimum qualitative and quantitative criteria laid down by the first directive.

Article 3: This Article constitutes a technical provision; it lists the diplomas awarded in each Member State which will be granted recognition.

Article 4: The achieved minimum coordination of the pharmacist's field of activity (see Article 1 of the first proposal for a directive) does not preclude Member States from requiring, in addition to the pharmacist's diploma, the completion of a period of in-service training or professional experience as a condition of access to a particular activity, e.g. post-graduate in-service training course in preparation for a position as head of a dispensary. But to leave to the host Member State, which has instituted such an in-service training course the option of requiring the completion thereof on its own territory, would have very considerably restricted the possibilities of migration for the professional persons concerned; Article 4 counters this danger by requiring the host Member State to recognize as equivalent to the completion of such a course the exercise of the relevant activities for an equal period in the Member State of origin. In this way the proposal reconciles the Member States' freedom to organize activities with the requirements of professional mobility within the Community.

Chapter III: Established rights

In accordance with the invariable practice of the Council in the field of mutual recognition of diplomas, Article 5 conditionally ensures the recognition of pharmacists' diplomas providing evidence of training commenced before the directive came into effectiveness though they do not meet all the minimum criteria laid down in Article 2 of the first directive.

This provision does not stem from a legal necessity but gives effect to a fundamental political choice, that of not depriving a priori any professional person of the benefit of free movement.

This generosity concerning the past is a quid pro quo for the effort made for the future with regard to the approximation of training courses in the Member States; furthermore, it is not boundless, since diplomas which do not meet all the qualitative and quantitative requirements will have to be accompanied by a certificate attesting to professional practice over a period of at least three years.

Chapter IV: Use of academic title

While drawing the appropriate conclusions from the mutual recognition of diplomas, Article 6 sets out the conditions under which the migrant professional person will be entitled to make use of his academic title in the host country. Indeed, the most important thing is that the migrant person may practise in the host country with the professional qualification which is used there, so that equality between all professional people is ensured (see Article I3 below); nevertheless, the attachement of a profesional person to his academic titles should not be disregarded. The purpose of Article 6 is therefore to secure for the migrant the right to make use of them provided that, when necessary, the precautions required in order to avoid mistakes detrimental to third parties are taken.

Chapter V: Provisions to facilitate the effective exercise of the right of establishment

1. The differences between training courses in the Member States usually necessitate prior coordination of the study courses in order that the mutual recognition of diplomas may come about. On the other hand, the discrepancies in the national laws relating to the other conditions governing the right to engage in and practise a profession, especially requirements as the good character and physical or mental health, do not give rise to the same apprehensions on the part of the Member States. Consequently, harmonization of these requirements does not appear to be strictly necessary; more flexible measures can be proposed on the basis of the principle that the host Member State will consider it sufficient, with regard to its own rules on good repute and good character, if the migrant professional person satisfies the conditions governing the right to engage in and pursue activities in the Member State of origin.

.../...

This general principle, which was proposed by the Commission in the early sixties, was first countenanced by the Council as early as 1964 in connection with industrial, commercial and craftsmen's activities and then confirmed, with its rules of application improved, in connection with the Health professions as from 1975.

The provisions of this Chapter are comparable to those included in the earlier Directives relating to the professions. One difference should be noted, however: the proposed measures concern solely the establishment of pharmacists and are not intended also to facilitate the provision of services. The reason for this is that, in the case of the pharmaceutical profession, the provision of services within the meaning of Articles 59 and 60 of the EEC Treaty appears to be quite exceptional.

2. Articles 7 to 12 lay down the procedure for the admission of the beneficiary to the profession in the host country.

Since it is a question requirements as to good character, a distinction is made between the migrant who has not exercised the activities of a pharmacist in the Member States from which he comes (Article 7) and the professional person who is already practising his profession in the Member State of origin and who wishes to settle in another Member State (Article 8).

In the first case, the fact that the applicant while practising his profession in the country from which he comes.

In both cases, the host Member State's power of assessment is limited. That a State nevertheless retains the possibility of penalizing (by refusing admission) serious matters which have previously occurred on its territory and for which the applicant was responsible. Similarly, the directive does not prevent the host Member State from imposing on its territory - without increasing their severity - professional penalties, which temporarily or permanently prevent the applicant from pursuing his activity in the Member State from which he comes.

The effectiveness of the proposed system largely depends both on the host Member State's confidence in the information received and on the diligence of the host Member State's authorities in investigating the applications. In order to satisfy the first requirement, the

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directive provides that the certificates and documents must be issued by authorities and bodies authorized to do so by the Member State from which the applicant comes (see Articles 7, 8 und 9) and stipulates the term of validity of such documents (Article 10).
These safeguards make it possible to require host Member States to examine the files at the earliest opportunity, and in any case not later than three months after the application has been made (Article 11).

3. Articles 13 and 14 specify certain rights and duties of the migrant professional person.

The mutual recognition of diplomas implies that no distinction should be made between national diplomas and diplomas of other Member States as regards the professional effects relating to either of these categories of diploma in the host Member State. The consequence of this basic principle is that the holder of a diploma recognized by the host Member State must be able to use the professional title appertaining in that State to the corresponding national dipoma (Article 13). While enjoying all the professional rights attached to the corresponding national diploma, the migrant professional person is subject to all the obligations resulting from the pursuit of activities in the host country and, in particular, those deriving from the health and social security laws and professional ethics.

It is therefore indispensable to provide for the Member States' obligation to make it easy for migrant professional persons to obtain information on the social and legal aspects of the profession. Member States are encouraged to set up appropriate information centres for this purpose.

Similarly, the host Member State's competent authorities shall see to it that, where necessary, the attention of the migrant pharmacist is drawn to the need to improve his linguistic knowledge, in particularly by informing him of the existence of language courses, and that he is warned of the penalities he may incur if he is guilty of professional misconduct due to inadequate linguistic knowledge (Article 14).

.../...

Chapter VI: Final provisions

Activities in the field of pharmacy which are subject to regulations as regards qualification and standards of good repute in the Member States are not generally subject to a different system according to whether the professional person practises in a self-employed or employed capacity (see the example of assistant pharmacists). In these circumstances it is particularly advisable to grant the benefit of this directive to employed pharmacists to whom freedom of movement of persons is applicable (Article 17).

III. Draft Council decision setting up an Advisory Committee on Pharmaceutical Training

The various Articles of the draft decision do not appear to need enlarging in any particular way, but it does seem useful to set out the general principles on which the draft is based.

The Directives already adopted by the Council which relate to the professions and likewise these proposed directives are the starting points. Although they are indispensable if confidence between Member States is to reign, they do not provide a definitive answer to the need to ensure a comparably high level of training courses in the Community.

The systems of the automatic recognition of national certificates, either existing or to come, for instance in the field of the EEC type approval of motor vehicles, seeds, plants and meats, are generally based on an extremely advanced harmonization of the conditions of issue of national certificates; on the other hand, in the present proposals for directives, the indispensable confidence required in systems of recognition is ensured by a few general provisions. This original quality of the method employed results from the fact that the harmonization concerns the field of education and culture and touches upon the independence of the universities and the teaching profession. In return, this method necessitates constant and concrete assessment of the realities covered by fixed general criteria; it should be constantly ascertained whether, during the development of syllabuses and teaching methods, the harmonization is still adequate to maintain the links between national training courses which have been created by the mutual recognition of diplomas. Furthermore, the latitude allowed the Member States by the minimum character of the qualitative and quantitative criteria, which enables them to arrange

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training courses of a higher level than that stipulated by the coordination Directive, also calls for regular examination; for the recognition of diplomas would indeed be threatened if considerable differences between the levels of training were to be caused and maintained beyond the prescribed minima. These are the reasons why it seems indispensable to set up a committee responsible for ensuring a comparably high level of training.

Specifically, it will be possible for the complementary approximation of training courses to be achieved by resorting, where necessary, to the legal instruments provided for by the EEC Treaty, but it will also be possible to ensure this by the voluntary concerted action of the Member States and, through them, of the universities, taking as their basis the opinions and recommendations of the Committee (see Article 2). It is therefore indispensable that the opinions and recommendations reflect a sufficiently large consensus of all the parties concerned if they are to be subsequently implemented. It is consequently of prime importance to associate with the work of the Committee the competent government departments, teaching establishments and the pharmaceutical profession (see Article 3).

Lastly, it should be noted that since this decision is of an institutional nature it has no addressee.

ANNEX 1

SYNOPTIC TABLE OF THE CONDITIONS OF TRAINING
OF PHARMACISTS IN THE MEMBER STATES AS AT
1 JANUARY 1980

	BELGIUM	Fed.Rep. GERMANY	DENMARK	FRANCE	IRELAND	ITALY	LUXEMBOURG	NETHERLANDS	UNITED KINGDOM	GREECE
Period of theoretical and practical studies	4.5 yrs	3.5 yrs	4 yrs	4.5 yrs	4 yrs	5 yrs[1] or 3.5 yrs[2]	4.5 yrs	6 yrs[3] and 2 mths 6 yrs and 8 mths	3 yrs[4] or 4 yrs[5]	4 yrs
In-service training period	6 mths	1 yr	11 mths	6 mths	1 yr	6 mths	9 mths	4 mths	12 mths	1 yr
Total duration	5 yrs	4.5 yrs	5 yrs	5 yrs	5 yrs	5.5 yrs[1] or 4 yrs[2]	5 yrs and 3 mths	6.5 yrs or 7 yrs	4 yrs[4] or 5 yrs[5]	5 yrs

[1] Laurea in chimica e tecnologia farmaceutica

[2] Laurea in farmacia

[3] According to the universities

[4] In England and Wales

[5] In Scotland and Northern Ireland

PROPOSAL FOR A COUNCIL DIRECTIVE CONCERNING THE COORDINATION OF PROVISIONS LAID DOWN BY LAW REGULATION OR ADMINISTRATIVE ACTION IN RESPECT OF CERTAIN ACTIVITIES IN THE FIELD OF PHARMACY

THE COUNCIL OF THE EUROPEAN COMMUNITIES,

HAVING regard to the Treaty establishing the European Economic Community, and in particular Articles 49 and 57 thereof ,

HAVING regard to the proposal from the Commission ,

HAVING regard to the Opinion of the European Parliament ,(1)

HAVING regard to the Opinion of the Economic and Social Committee ,(2)

WHEREAS persons who hold a diploma, certificate or other university qualification in pharmacy are for that reason specialists in the field of medicinal products and, in principle, must have access in all the Member States to a minimum range of activities in that field ; whereas in defining that minimum range, this Directive does not have the effect of limiting the activities accessible in the Member States to pharmacists, in particular with regard to medical biology analyses, and does not give them any monopoly, creation of a monopoly continuing to be a matter for the Member States alone ;

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(1) OJ No

(2) OJ No

WHEREAS, moreover, this Directive does not ensure coordination of all conditions of access to and pursuit of activities in the field of pharmacy ; whereas in particular, the geographical distribution of dispensaries and the monopoly of dispensing medicinal products continue, at this stage, to be matters for the Member States ;

WHEREAS the coordination of the conditions for the pursuit of these activities as envisaged by this Directive does not exclude any subsquent coordination, including that of the abovementioned conditions;

WHEREAS, with a view to achieving mutual recognition of diplomas, certificates and other evidence of formal qualifications in pharmacy, as required by Council Directive 8 / /EEC of concerning the mutual recognition of diplomas, certificates and other evidence of formal qualifications in pharmacy, including measures to facilitate the effective exercise of the right of establishment, relating to certain activities in the field of pharmacy[1], the broad comparability of training courses in the Member States enables coordination in this field to be confined to the requirement that minimum standards be observed, thus leaving the Member States freedom of organization as regards teaching;

WHEREAS certain Member States require or are contemplating requiring that access to a position involving responsibility for a dispensary be conditional upon the completion of an in-service training course subsequent to the award of the pharmacist's diploma; whereas such an in-service training course, although it seems to be a factor in the improvement of the protection of public health, is not commonly held at present ; whereas it is nevertheless advisable not to exclude a generalized extension of this system in future, after examination of the advantages it would be likely to entail;

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(1) See page of this Official Journal

WHEREAS this Directive does not prevent the Member States from requiring supplementary conditions of training for access to activities not included in the coordinated minimum range of activities ; whereas for this reason the host Member State which lays down such conditions may subject thereto nationals of Member States who hold one of the diplomas referred to in Article 3 of Directive 8/ /EEC;

WHEREAS the coordination envisaged by this Directive covers professional qualifications ; whereas as regards such qualifications most Member States do not at present distinguish between professional persons who pursue their activities as employed persons and those who are self-employed ; whereas for this reason, it appears necessary to extend the application of this Directive to employed professional persons ;

HAS ADOPTED THIS DIRECTIVE

Article 1

1. Member States shall ensure that holders of a diploma, certificate or other university qualification in pharmacy which meets the conditions laid down in Article 2 shall be entitled at least to access to the activities mentioned in the following paragraph and to exercise such activities subject, where "appropriate", to the requirement of an in-service training period or additional professional experience.

2. The activities referred to in paragraph 1 are :

- the activities of a person responsible for the preparation of the pharmaceutical form of medicinal products ;

- the activities of a person responsible for the manufacture and testing of medicinal products ;

- the activities of a person in charge of a laboratory for testing medicinal products ;

- the activities of a person responsible for the storage, preservation and distribution of medicinal products at the wholesale stage ;

- the activities of a person responsible for preparing and dispensing medicinal products in dispensaries on a retail basis ;

- the activities of a person responsible for preparing and dispensing medicinal products for patients in hospitals ;

- activities involving the dissemination of scientific information on medicinal products to the medical and pharmaceutical professions.

ARTICLE 2

Member States shall subordinate the award of the diplomas, certificates and other qualifications referred to in Article 1 to the following minimum conditions :

1. Training leading to the award of the diploma, certificate or other qualification shall ensure :

a) adequate knowledge of the starting materials used in pharmacy, of medicines and of products, whether they be chemical products or products of natural origin including micro-organisms and viruses ;

b) adequate knowledge of pharmaceutical technology and the physical, chemical and biological testing of medicinal products ;

c) adequate knowledge of the action and metabolism of medicinal products and toxic substances and the use of medicinal products ;

d) adequate knowledge of the conditions associated with the practice of pharmaceutical activities.

2. The diploma, certificate or other qualification shall testify to the completion of a course of training covering a period of at least five years and comprising :

- at least four years of full-time theoretical and practical training, in a university or in an advanced institute of a level recognized as equivalent thereto ;

- at least six months of in-service training in a dispensary.

However, if at the time of the adoption of this Directive two courses of training co-exist in a Member State, one of which lasts five years and the other four years, the diploma, certificate or other qualification testifying to the completion of the four-year course of training, shall be considered to fulfill the condition concerning duration referred to in the first subparagraph provided the diplomas, certificates or other qualifications testifying to the completion of the two courses of training are recognized as equivalent by that State.

3. The course of training referred to in paragraph 2 shall comprise as a minimum theoretical and practical training in the following basic subjects :

Plant and animal biology ;
Experimental physics ;
General and inorganic chemistry ;
Organic chemistry ;
Analytical chemistry ;
Pharmaceutical chemistry, including analysis of medicinal products ;
General and applied (medical) biochemistry ;
Anatomy and physiology ; concepts of semiology ;
Microbiology ;
Pharmacology ;
Pharmaceutical technology ;
Toxicology ;
Pharmacognosy (materia medica) : study of the composition and the effects of the active principles of natural substances of vegetable and animal origin ;

Legislation and deontology

The balance between theoretical and practical training shall, in respect of each subject, give sufficient importance to theory to maintain the university quality of the training.

ARTICLE 3

This Directive shall also apply to nationals of Member States who, in accordance with Council Regulation (EEC) N° 1612/68 of 15 October 1968 on freedom of movement for workers within the Community(1), are pursuing or will pursue, as employed persons, one of the activities referred to in Article 1 of Directive 8 / /EEC.

1) OJ N° L 257, 19.10.1968, p.2.

ARTICLE 4

1. Member States shall take the measures necessary to comply with this Directive before ..... (1) . They shall forthwith inform the Commission thereof.

2. Member States shall communicate to the Commission the texts of the main provisions of national law which they adopt in the field covered by this Directive.

ARTICLE 5

Where a Member State encounters major difficulties in certain fields when applying this Directive, the Commission shall examine these difficulties in conjunction with that State and shall request the opinion of the Pharmaceutical Committee set up by Council Decision 75/320/EEC (2).

Where necessary, the Commission shall submit appropriate proposals to the Council.

ARTICLE 6

This Directive is addressed to the Member States.

Done at

For the Council

The President

(1) The date should correspond to a period of 18 months from the date of adoption of the Directive by the Council.
(2) OJ N° L 147 9. 6. 1975, p. 23

PROPOSAL FOR A COUNCIL DIRECTIVE CONCERNING THE MUTUAL RECOGNITION OF DIPLOMAS, CERTIFICATES AND OTHER EVIDENCE OF FORMAL QUALIFICATIONS IN PHARMACY, INCLUDING MEASURES TO FACILITATE THE EFFECTIVE EXERCISE OF THE RIGHT OF ESTABLISHMENT RELATING TO CERTAIN ACTIVITIES IN THE FIELD OF PHARMACY

THE COUNCIL OF THE EUROPEAN COMMUNITIES,

HAVING regard to the Treaty establishing the European Economic Community, and in particular Articles 49 and 57 thereof,

HAVING regard to the proposal from the Commission,

HAVING regard to the Opinion of the European Parliament (1),

HAVING regard to the Opinion of the Economic and Social Committee (2),

WHEREAS, pursuant to the Treaty, all discriminatory treatment based on nationality with regard to establishment and provision of services is prohibited as from the end of the transitional period ; whereas the principle of such treatment based on nationality applies, in particular, to the grant of any authorization required for the practise of certain activities and also to registration with or membership of professional organizations or bodies ;

WHEREAS it nevertheless seems desirable that certain provisions be introduced to facilitate the effective exercise of the right of establishment ;

WHEREAS, pursuant to Article 54(3)(h) of the Treaty, the Member States required not to grant any form of aid likely to distort the conditions of establishment;

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1) O J No

2) O J No

WHEREAS Article 57(1) of the Treaty provides that directives be adopted for the mutual recognition of diplomas, certificates and other evidence of formal qualifications ;

WHEREAS, in view of the present disparities in training in pharmacy given in the Member States it is necessary to lay down certain coordinating provisions to enable the Member States to introduce mutual recognition of diplomas, certificates and other evidence of formal qualifications ; whereas such coordination has been established by Council Directive 8/ /EEC of , concerning the coordination of provisions laid down by law, regulation or administrative action in respect of some activities in the field of pharmacy (1) ;

WHEREAS in certain Member States access to certain activities in the field of pharmacy is, apart from the award of the diploma, certificate or other qualification, subject to the completion of a period of in-service training or the requirement of additional professional experience ; whereas, since there is as yet no identity of views among the Member States on this point, it is advisable, in order to obviate any difficulties, to recognize as a sufficient condition appropriate practical experience of equal duration acquired in another Member State ;

WHEREAS, with regard to the possession of a formal certificate of training, since a directive on the mutual recognition of diplomas does not necessarily imply equivalence in the training covered by such diplomas, the use of such qualifications should be authorized only in the language of the Member State of origin or of the Member State from which the foreign national comes ;

WHEREAS, to facilitate the application of this Directive by the national authorities, Member States may require the persons satisfying the conditions of training required by this Directive to provide, together with the formal certificates of training, a certificate from the competent authorities of his country of origin or of the country from which he comes stating that these certificates of training are those covered by the Directive ;

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1) See page of this Official Journal

WHEREAS this Directive does not affect the provisions laid down by law, regulation or administrative action in the Member States which prohibit companies from practising certain activities or impose on them certain conditions for such practice ;

Whereas it is difficult to assess the extent to which rules aimed at facilitating freedom of pharmacists to provide services could at present be appropriate; whereas, in these conditions, it is not advisable to adopt such rules for the time being ;

WHEREAS, with regard to good character and good repute, a distinction should be drawn between the requirements to be satisfied on first taking up the profession and those to be satisfied to practise it ;

WHEREAS, as far as the activities of employed persons are concerned, Council Regulation (EEC) Nº 1612/68 of 15 October 1968 on freedom of movement for workers within the Community[1] lays down no specific provisions relating to good character or good repute, professional discipline or use of title for the professions covered ; whereas, depending on the individual Member State, such rules are or may be applicable both to employed and self-employed persons ; whereas the activities subject in the Member States to possession of a diploma, certificate or other evidence of formal qualification in pharmacy are pursued by both employed and self-employed persons, or by the same persons in both capacities in the course of their professional caree; whereas, in order to encourage as far as possible the free movement of those professional persons within the Community, it therefore appears necessary to extend this Directive to employed persons,

HAS ADOPTED THIS DIRECTIVE :

(1) OJ Nº L 257, 19.10.1968, p. 2

Chapter I : Scope

Article 1

This Directive applies to activities, access to and practice of which is subject to conditions of professional qualification in one or more Member States, and which are open to holders of one of the diplomas, certificates or other qualifications in pharmacy listed in Article 3.

Chapter II : Diplomas, certificates and other evidence of formal qualifications in pharmacy

Article 2

Each Member State shall recognize the diplomas, certificates and other qualifications awarded to nationals of Member States by other Member States in accordance with Article 2 of Directive 8 / /EEC and listed in Article 3, by giving to such qualifications, as far as the right to take up and pursue the activities in a self-employed capacity is concerned, the same effect in its territory as to those diplomas, certificates and other qualifications, listed in the same Article, which it itself awards.

Article 3

The diplomas, certificates and other evidence of formal qualifications referred to in Article 2 are the following :

a) in Germany

1. the State examination certificates for pharmacists awarded by the competent authorities of the Länder ;

2. certificates from the competent authorities of the Federal Republic of Germany stating that the diplomas awarded after 8 May 1945 by the competent authorities of the German Democratic Republi are recognized as equivalent to that referred to under point 1 above;

b) in Belgium

the legal diploma in pharmacy awarded by the faculties of medicine and pharmacy of the universities, by the central examining board or by the State examining boards for university education.

c) in Denmark

the "farmaceutisk Kandidateksamen" certificate.

d) in France

The State diploma in pharmacy awarded by the universities.

e) in Greece

(The Pharmacy faculty diploma awarded by the Pharmacy faculty of a University)

f) in Ireland

The certificate of Registered Pharmaceutical Chemist.

g) in Italy

the diploma or certificate giving the right to practise pharmacy, obtained by passing a State examination.

h) in Luxembourg

the State pharmacy diploma awarded by the State examining board.

i) in the Netherlands

the university pharmacy certificate.

j) in the United Kingdom

the certificate of Registered Pharmaceutical Chemist.

Article 4

Where, in a Member State, access to or practice of one of the activities referred to in Article 1 is subject not only to the possession of a diploma, certificate or other qualification mentioned in Article 3 but also to the accomplishment of in-service training or the requirement of additional professional experience, that State shall accept as sufficient evidence in this respect a certificate issued by the competent authorities of the person's country of origin or of the country from which he comes, attesting that he has pursued the said activities for an equal period in his country of origin or in the country from which he comes.

Chapter III : Established rights

Article 5

The diplomas, certificates and other university qualifications in pharmacy which were awarded to nationals of Member States by Member States and which do not satisfy all the minimum training requirements laid down in Article 2 of Directive 8 / /EEC shall be treated as diplomas satisfying these requirements if:

- they are evidence of training which was completed before the implementation of the said Directive, or

- they are evidence of training which was completed after but which was commenced before the implementation of the said Directive ;

and, in each case, if:

- they are accompanied by a certificate stating that their holders have been effectively and lawfully engaged in one of the activities referred to in Article 1 (2) of Directive 8/ /EEC in a Member State for at least three consecutive years during the five years preceding the award of the certificate, provided this activity is regulated in that State.

Chapter IV : Use of academic title

Article 6

1. Without prejudice to Article 13, host Member States shall ensure that nationals of Member States who fulfil the conditions laid down in Articles 2, 4 and 5 have the right to use the lawful academic title and, where appropriate, the abbreviation thereof, of their Member State of origin or of the Member State from which they come, in the language of that State. Host Member States may require this title to be followed by the name and location of the establishment or examining board which awarded it.

2. If the academic title used in the Member State of origin, or in the Member State from which a foreign national comes, can be confused in the host Member State with a title requiring in that State additional training which the person concerned has not undergone, the host Member State may require such a person to use the title employed in the Member State of origin or the Member State from which he comes in suitable wording to be indicated by the host Member State.

Chapter V : Provisions to facilitate the effective exercise of the right of establishment

Article 7

1. A host Member State which requires of its nationals proof of good character or good repute when they take up for the first time any of the activities referred in Article 1 shall accept as sufficient evidence, in respect of nationals of Member States, a certificate issued by a competent authority in the Member State of origin or in the Member State from which the foreign national comes, attesting that the requirements of the Member State as to good character or good repute for taking up the activity in question have been met.

2. Where the Member State of origin or the Member State from which the foreign national comes does not require proof of good character or good repute of persons wishing to take up the activity in question for the first time, the host Member State may require of nationals of the Member State of

origin or of the Member State from which the foreign national comes an extract from the judicial record or, failing this, an equivalent document issued by a competent authority in the Member State of origin or the Member State from which the foreign national comes.

3. If the host Member State has detailed knowledge of a serious matter which has occurred outside its territory and which is likely to affect the taking up within its territory of the activity concerned, it may inform the Member State of origin or the Member State from which the foreign national comes.

The Member State of origin or the Member State from which the foreign national comes shall verify the accuracy of the facts if they are likely to affect the taking up of the activity in question in that Member State. The authorities in that State shall decide on the nature and extent of the investigations to be made and shall inform the host Member State of any consequential action which they take with regard to the certificates or documents they have issued.

4. Member States shall ensure the confidentiality of the information which is forwarded.

Article 8

1. Where, in a host Member State, provisions laid down by law, regulation or administrative action are in force laying down requirements as to good character or good repute, including provisions for disciplinary action in respect of serious professional misconduct or conviction for criminal offences and relating to the pursuit of any of the activities referred to in Article 1, the Member State of origin or the Member State from which the foreign national comes shall forward to the host Member State all necessary information regarding measures or disciplinary action of a professional or administrative nature taken in respect of the person concerned, or criminal penalties imposed on him when pursuing his profession in the Member State of origin or in the Member State from which he came.

2. If the host Member State has detailed knowledge of a serious matter which has occurred outside its territory and which is likely to affect the pursuit within its territory of the activity concerned, it may inform the Member State of origin or the Member State from which the foreign national comes.

The Member State of origin or the Member State from which the foreign national comes shall verify the accuracy of the facts if they are likely to affect in that Member State the pursuit of the activity in question. The authorities in that State shall decide on the nature and extent of the investigations to be made and shall inform the host Member State of any consequential action which they take with regard to the information they have forwarded in accordance with paragraph 1.

3. Member States shall ensure the confidentiality of the information which is forwarded.

Article 9

Where a host Member State requires of its own nationals wishing to take up or pursue any of the activities referred to in Article 1, a certificate of physical or mental health, that State shall accept as sufficient evidence thereof the presentation of the document required in the Member State of origin or in the Member State from which the foreign national comes.

Where the Member State of origin or the Member State from which the foreign national comes does not impose any requirements of this nature on those wishing to take up or pursue the activity in question, the host Member State shall accept from such national a certificate issued by a competent authority in that State corresponding to the certificates issued in the host Member State.

Article 10

The documents referred to in Articles 7, 8 and 9 may not be presented more than three months after their date of issue.

Article 11

1. The procedure for authorizing the person concerned to take up any of the activities referred to in Article 1, pursuant to Articles 7, 8 and 9, must be completed as soon as possible and not later than three months after presentation of all the documents relating to such person, without prejudice to delays resulting from any appeal that may be made upon the completion of this procedure.

2. In the cases referred to in Articles 7(3) and 8(2), a request for re-examination shall suspend the period stipulated in paragraph 1.

When consulted, the Member State of origin or the Member State from which the foreign national comes shall give its reply within three months.

On receipt of the reply or at the end of the period, the host Member State shall continue with the procedure referred to in paragraph 1.

Article 12

Where a host Member State requires its own nationals wishing to take up or pursue one of the activities referred to in Article 1 to take an oath or make a solemn declaration and where the form of such oath or declaration cannot be used by nationals of other Member States, that Member State shall ensure that an appropriate and equivalent form of oath or declaration is offered to the persons concerned.

Article 13

Where in a host Member State, the use of the professional title relating to one of the activities referred to in Article 1 is regulated, nationals of Member States who fulfil the conditions of professional qualification laid down in Articles 2, 4 and 5 shall use the professional title of the host Member State which in that State corresponds to those conditions, and shall use the abbreviated title.

Article 14

1. Member States shall take the necessary measures to enable the persons concerned to obtain information on the health and social security laws and, where applicable, on the professional ethics of the host Member State.

For this purpose, Member States may set up information centres from which such persons may obtain the necessary information. The host Member States may require the persons concerned to contact these centres.

2. Member States may set up the centres referred to in paragraph 1 under the aegis of the competent authorities and bodies which they shall designate within the period laid down in Article 18(1).

3. Member States shall see to it that, where appropriate, the persons concerned acquire, in their own interest and in that of their customers, the linguistic knowledge necessary for the practice of their profession in the host country.

Chapter VI : Final provisions

Article 15

In the event of justified doubts, the host Member State may require of the competent authorities of another Member State confirmation of the authenticity of the diplomas, certificates and other qualifications issued in that other Member State and referred to in Chapters II and III, and also confirmation of the fact that the person concerned has fulfilled all the training requirements laid down in Directive 8 / /EEC.

Article 16

Within the time limit laid down in Article 18(1), Member States shall designate the authorities and bodies competent to issue or receive the diplomas, certificates and other qualifications as well as the documents and information referred to in this Directive, and shall forthwith inform the other Member States and the Commission thereof.

Article 17

This Directive shall also apply to nationals of Member States who, in accordance with Regulation (EEC) No 1612/68, are pursuing or will pursue as employed persons one of the activities referred to in Article 1.

Article 18

1. Member States shall bring into force the measures necessary to comply with this Directive before .....(1). They shall forthwith inform the Commission thereof.

2. Member States shall communicate to the Commission the texts of the main provisions of national law which they adopt in the field covered by this Directive.

Article 19

Where a Member State encounters major difficulties in certain fields when applying this Directive, the Commission shall examine these difficulties in conjunction with that State and shall request the opinion of the Pharmaceutical Committee set up under Council Decision 75/320/EEC(2).

Where necessary, the Commission shall submit appropriate proposals to the Council.

Article 20

This Directive is addressed to the Member States.

Done at,

For the Council

The President

(1) The date should correspond to a period of 18 months from the date of adoption of the Directive by the Council.

(2) OJ No L 147, 9.6.1975 p.23

DRAFT COUNCIL DECISION

setting up an Advisory Committee on Pharmaceutical Training

THE COUNCIL OF THE EUROPEAN COMMUNITIES,

HAVING regard to the Treaty establishing the European Economic Community,

HAVING regard to the draft decision submitted by the Commission,

WHEREAS, in its resolution of 6 June 1974 concerning the mutual recognition of diplomas, certificates and other evidence of formal qualifications[1], the Council declared itself in favour of the establishment of advisory committees ;

WHEREAS, in the context of the mutual recognition of diplomas, certificates and other evidence of formal qualification in pharmacy, it is important to ensure a comparable standard of training ;

WHEREAS, to contribute to the achievement of this objective, it is desirable to set up an Advisory Committee to advise the Commission,

HAS DECIDED AS FOLLOWS :

Article 1

An Advisory Committee on Pharmaceutical Training, hereinafter called the "Committee", shall be set up to assist the Commission.

(1) OJ No C 98, 20.8.1974, p.1.

Article 2

1. The task of the Committee shall be to help to ensure a comparably high standard of pharmaceutical training in the Community.

2. It shall carry out this task in particular by the following means :

   - exchange of comprehensive information as to the training methods and the content, level and structure of theoretical and practical courses provided in the Member States ;

   - discussion and consultation with the object of developing a common approach to the standard to be attained in the training of pharmacists and, as appropriate, to the structure and content of such training ;

   - keeping under review the adaptation of pharmaceutical training to developments in pharmaceutical science and teaching methods.

3. The Committee shall communicate to the Commission and the Member States its opinions and recommendations including, when it considers it appropriate, suggestions for amendments to be made in the Articles relating to pharmaceutical training in Council Directives 8/ /EEC[1] and 8/ /EEC[2].

4. The Committee shall also advise the Commission on any other matter which the Commission may refer to it in relation to pharmaceutical training.

Article 3

1. The Committee shall consist of three experts from each Member State, as follows :

   - one expert from the practising pharmaceutical profession;

   - one expert from the Faculties of pharmacy of the universities ;

   - one expert from the competent authorities of the Member State.

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(1) See page of this Official Journal
(2) See page of this Official Journal

2. There shall be an alternate for each member. Alternates may attend the meetings of the Committee.

3. The members and alternates described in paragraphs 1 and 2 shall be nominated by the Member States. The members referred to in the first and second indents of paragraph 1 and their alternates shall be nominated upon the proposal of the practising pharmaceutical profession and the faculties of pharmacy of the universities. The alternate members thus nominated shall be appointed by the Council.

Article 4

1. The term of office for a member of the Committee shall be three years. After the expiry of this period the members of the Committee shall remain in office until replacements have been provided for or until their term of office is rene

2. The term of office of a member may end before expiry of the period of three years in the event of the resignation or death of the member, or of his being replaced by another person, in accordance with the procedure laid down in Article 3. The appointment of a new member shall be for the remainder of the term of office.

Article 5

The Committee shall elect a chairman and two vice-chairmen from among its members. It shall adopt its own rules of procedure. The agenda for meetings shall be drawn up by the chairman of the Committee in consultation with the Commission.

Article 6

The Committee may set up working parties and call upon and allow observers or experts to assist it in connection with all the special aspects of its work.

Article 7

The secretariat of the Committee shall be provided by the Commission.

Done at .
For the Council
The President

Annex 2

Financial record for the 1983 budget

1. Relevant budget heading

Article 251. Administrative expenditure for an Advisory Committee on pharmaceutical training.

2. Legal basis

Articles 52 to 66 of the EEC Treaty.

Council Resolution of 6 June 1974.

3. and 4. Description and justification of project

The purpose of the Advisory Committee to be set up is to ensure an equally high level of training for pharmacists in all the Member States of the Community.

The Advisory Committee should fulfil this task in two ways:

(i) by transmitting Opions and Recommendations to the Commission enabling the Commission, if so desired, to submit to the Council proposals for amending the Directives relating to pharmacists;

(ii) by transmitting Opinions and Recommendations to the Member States thereby prompting them to take concerted action on the training of pharmacists.

This qualitative approach is in keeping with that already adopted by the Council for the other health professions (doctors, dentists, nurses, mid-wives and veterinary surgeons) and reflects one of the guidelines outlined in the Council Resolution of 6 June 1974 relating to the mutual recognition of diplomas, certificates and other qualifications.

5. Financial implications of project on intervention appropriations:

does not apply.

6. Financial implications on appropriations for staff and routine administration

6.1. Staff required for implementation of this project alone: the work of the Advisory Committee on pharmaceutical training is essentially the same as that of the Advisory Committee on medical training and the Advisory Committee on training in nursing.

Experience gained in the administration of these committees and of the Committee of Senior Officials on Public Health shows that the administration of each Committee takes up half the time of:

- one a 5/4 grade official
- one B 3/2 grade official
- one C 5/4 grade official.

.../...

6.2. Appropriations required of this staff

36 850 EUA per year

6.3. Appropriations required for administration

63 036 EUA per year[1]

6.4. Method of calculation for 6.3

Sixty members and alternates for 2 two-day meetings in Brussels (20 government representatives - 40 private members)	EUA	32 690
Three one-day meetings for three working parties made up of 12 members (4 government representatives - 8 private members)	EUA	26 334
Four meetings attended by four members in each case to visit training institutions for pharmacists in the Member States of the Community (1 government representative - 3 private members)	EUA	4 012
TOTAL	EUA	63 036

7. and 8. Does not apply.

9. Type of control to be applied

The Commission will provide the secretariat services of this Committee and will help to convene meetings and draw up agendas.

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[1] Based on data from October 1980.