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Working Documents

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DOCUMENT 1-485/83

REPORT

drawn up on behalf of the Legal Affairs Committee

on the proposals from the Commission of the European Communities to the Council (Doc. 1-934/80 - COM(81) 4 final)

for

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

II. a 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

and a

draft Council decision

setting up an Advisory Committee on Pharmaceutical Training

Rapporteur: Mr K. Malangré

By letter of 19 February 1981 the President of the Council of the European Communities requested the European Parliament to deliver an opinion, pursuant to Article 57 of the EEC Treaty, on the proposals from the Commission of the European Communities to the Council for

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

and a

draft Council decision setting up an Advisory Committee on Pharmaceutical Training.

On 27 February 1981 the President of the European Parliament referred these proposals to the Legal Affairs Committee as the committee responsible and to the Committee on Budgets for an opinion.

At its meeting of 18 March 1981 the Legal Affairs Committee appointed Mr Malangré rapporteur.

At its meetings of 29/30 April and 19/20 October 1982 the committee considered the Commission's proposals and a working document drawn up by the rapporteur.

As a result of the contribution to the debate made by the Commission's representative at its meeting of 29/30 April 1982 the chairman requested him to submit to the committee in written form his speech and the statistical information which he had drawn up, if possible supplemented by further data (see PE 78.747).

On 22 June 1982 this speech and additional statistics relating to pharmacies in the various Member States were forwarded to the members of the Legal Affairs Committee (Notice to Members No. 22/82 - PE 78.898).

At its meeting of 19/20 October 1982, the committee continued its deliberations on the basis of a working document prepared by Mr Malangré (PE 77.316) and the documents supplied by the Commission and annexed to Notice No. 22/82 (PE 78.898).

In the light of this debate, Mr Malangré prepared a draft report (PE 77.316/rev) which was considered by the committee at its meeting of 15/16 February 1983.

At its meeting of 25/26 May 1983, the committee voted on a number of amendments. However, the vote was adjourned when some inconsistencies came to light in the adopted text.

At its meeting of 15/16 June 1983, the committee agreed to the proposal by its rapporteur to resume consideration of the matter on the basis of a revised report.

At its meeting of 20/21 June 1983 the committee decided by 12 votes to 0 with 2 abstentions to recommend to Parliament that it approve the proposals for directives and the draft decision as amended by the amendments below (pp. 6 - 9).

The committee then adopted the motion for a resolution as a whole by 13 votes to 0 with 1 abstention.

The following took part in the vote: Mrs Veil, chairman:

Mr Luster, vice-chairman; Mr Malangré, rapporteur; Mr Dalziel, Mr Geurtse, Mr Gontikas, Mr Goppel, Mr Janssen van Raay, Mr Megahy, Mr Sieglerschmidt, Mr Tyrrell, Mrs Vayssade, Mr Vetter and Mr Vie.

The opinion of the Committee on Budgets is attached (p. 34).
This report was tabled on 27 June 1983.

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The Legal Affairs Committee hereby submits to the European Parliament the following amendments to the Commission's proposals and motion for a resolution together with explanatory statement:

TEXT PROPOSED BY THE COMMISSION
OF THE EUROPEAN COMMUNITIES¹

AMENDMENTS TABLED BY THE LEGAL
AFFAIRS COMMITTEE

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

Preamble and recitals unchanged

Article 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.

AMENDMENT No. 1

Article 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, and subject to the provisions of Article 2(2) of Directive 8/ EEC on the mutual recognition of diplomas.

Paragraph 2 of Article 1 unchanged.

Articles 2 to 6 unchanged.

¹ For complete text see
OJ No. C 35 of 18.2.1981, p. 3

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

AMENDMENT NO. 2

First 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

Preamble unchanged.

1st to 6th recitals unchanged

AMENDMENT NO. 3

New recital to follow 6th recital:

WHEREAS although the coordination of training and the mutual recognition of diplomas are of an objective nature, it is clearly impossible to extend the effect of recognition to access to the exercise of the activities of self-employed persons in the field of pharmacy, so far as the opening of new pharmacies is concerned: whereas the difficulties in the legislation of the Member States on this latter matter - in some cases, heavy restrictions are placed on such openings and in others, there is complete freedom in this respect - might in fact, if recognition of diplomas in pharmacy were extended to the right to open a new pharmacy, lead to unbalanced emigration of pharmacists from countries in which there is geographical distribution of pharmacies to countries where there is complete freedom to set up pharmacies;

Seventh to twelfth recitals unchanged

HAS ADOPTED THIS DIRECTIVE:

Article 1 unchanged

AMENDMENT No. 4

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 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 referred to in Article 1 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.

further, each Member State need not
recognize these diplomas for the opening
of new pharmacies open to the public.

Articles 3 to 20 unchanged

DRAFT COUNCIL DECISION

OF

setting up an Advisory Committee on
Pharmaceutical Training

Text unchanged.

MOTION FOR A RESOLUTION

closing the procedure for consultation of the European Parliament on the proposals from the Commission of the European Communities to the Council for

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

and a draft Council decision setting up an Advisory Committee on Pharmaceutical Training

The European Parliament,

- having regard to the proposals from the Commission of the European Communities to the Council¹,
 - having been consulted by the Council pursuant to Article 57 of the EEC Treaty (Doc. 1-934/80),
 - having regard to the report of the Legal Affairs Committee and the opinion of the Committee on Budgets (Doc. 1-485/83),
 - having regard to the votes on the Commission's proposals for directives and draft decision,
1. Notes that the present Commission proposals fall short of the provisions previously submitted by it;
 2. Notes that the Commission has also been unable to submit proposals for freedom to provide services with regard to activities in the field of pharmacy;

¹ OJ No. C 35 of 18.2.1981, page 3

3. Notes the failure to make progress in the important and complicated field of the harmonization of the market in pharmaceutical products;
4. Recognizes that the Commission's decision not to provide for the geographical distribution of dispensaries, and instead to allow the varying national provisions on the right of establishment to stand, is based on valid, practical considerations;
5. Notes that, while harmonisation of the national conditions relating to the right of establishment is a requirement for the freedom of establishment of all self-employed pharmacists, nonetheless such harmonisation is not necessary to permit freedom of establishment for the vast majority of self-employed pharmacists who establish themselves by purchase;
6. Takes the view, therefore, that the Commission proposals can be endorsed, but that Member States should be permitted not to apply the provisions relating to recognition to self-employed pharmacists seeking to establish themselves in new pharmacies;
7. Requests the Commission, therefore, to monitor the situation following the adoption of these proposals and to submit further proposals in due course to permit unrestricted freedom of establishment in all Member States;
8. Views the Commission's present proposals, therefore, as merely a first step towards the achievement of freedom of establishment and freedom to provide services for activities in the field of pharmacy;
9. Considers in this respect that the Advisory Committee on Pharmaceutical Training should play an important part in the formulation of further-reaching proposals;
10. Welcomes the intended harmonization of training, final examinations and evidence of formal qualifications;
11. Approves the proposals subject to the amendments which have been adopted;
12. Requests the Commission to include these amendments in its proposals, pursuant to Article 149(2) of the EEC Treaty;

13. Instructs its President to forward to the Council and Commission, as Parliament's opinion, the Commission's proposals as voted by Parliament and the corresponding resolution together with the committee's report.

EXPLANATORY STATEMENTPart 1 Synopsis of previous proposals submitted by the Commission concerning the right of establishment in respect of certain activities in the field of pharmacy

1. In order properly to assess the significance of the proposals to facilitate the exercise of the right of establishment relating to certain activities in the field of pharmacy¹, forwarded by the Commission to the Council by letter of 3 February 1981, it is necessary to refer back to the earlier proposals on the same subject submitted by the Commission in 1969 and 1972 and later withdrawn, and to highlight the major differences which distinguish them from the present proposals.

I. The Commission's 1969 proposals

2. In March 1969 the Commission submitted seven proposals for directives and one recommendation designed to implement the provisions of the EEC Treaty concerning the free movement of persons and freedom of establishment for companies in the entire field of pharmacy (including the manufacture and retailing of pharmaceuticals by self-employed persons).

These included the following proposals:

- (1) proposal for a directive on the coordination of certain provisions laid down by law, regulation or administrative action in respect of the retail sale of medicinal products by self-employed persons²,
- (2) proposal for a directive on the mutual recognition of the diplomas, certificates and other formal qualifications of pharmacists³,
- (3) proposal for a directive on the coordination of certain provisions laid down by law, regulation or administrative action in respect of the activities of self-employed pharmacists⁴.

¹ COM(81) 4 final, OJ No. C 35, 18.2.81, p. 3

² OJ No. C 54, 28.4.1969, p. 44

³ OJ No. C 54, 28.4.1969, p. 48

⁴ OJ No. C 54, 28.4.1969, p. 50

3. Those proposals were based on Articles 57 and 66 of the EEC Treaty and covered all the activities of pharmacists, including monitoring and control, industrial manufacture of pharmaceuticals, laboratory research and dispensing work in a pharmacy. They were the first of their kind to make detailed provisions in the area of the mutual recognition of diplomas.

The following requirements were laid down:

- possession of a diploma or certificate fulfilling the entrance requirement for studying pharmacy at an institution of higher education in one of the Member States;
- at least four and a half years theoretical and practical training, consisting of at least 3,500 hours and covering a specific curriculum;
- at least six months in-service training in a dispensary.

For anyone wishing to engage in and pursue activities in a factory, laboratory or dispensary, there was a further requirement of at least one year's practical training carried out on a full-time basis under the direction of an approved pharmacist. Special provisions were laid down in respect of the exercise of certain activities in the area of pharmaceutical analysis.

4. On 18.11.1970 the European Parliament adopted, on the basis of a report by the Legal Affairs Committee (rapporteur: Mr Ditttrich)¹ a resolution² in which it welcomed the Commission's proposals to eliminate the existing obstacles to freedom of establishment and freedom to provide services, approved them as a whole, and called on the Commission to adopt a number of amendments³.

5. The report of the Legal Affairs Committee welcomed the fact that for reasons of public health, the Commission proposed to authorize the sale of medicinal products in pharmacies only. It considered, however, that this dispensing monopoly should come into effect only after a transitional period of 10 years.

¹ Document 142/70-71

² OJ No. C 143, 3.12.1970, p. 22

³ The amendments did not concern the proposals for directives which are of relevance here

6. The Legal Affairs Committee expressed regret that the directive on coordination did not contain provisions relating to the geographical distribution of pharmacies. It recognized, however, that this matter raised complex questions, some of them, as in the Federal Republic of Germany, of a constitutional nature. The European Parliament recommended that a solution be found to the problem of the geographical distribution of pharmacies as soon as possible¹.

In discussions in the Legal Affairs Committee the Commission spoke in favour of finding an early solution to this problem so that the question of the right of establishment in the field of pharmacy could be regulated in its entirety. It undertook to submit, by October 1970, a report which would serve as a basis for further proposals for directives providing for the attainment of freedom of establishment in respect of pharmacies².

The Legal Affairs Committee was in favour of the proposals concerning the liability of dispensing chemists and the question of ownership of equipment and medicinal products and suggested certain exceptions to the latter proposal.

With regard to the pharmacist's right of establishment in another Member State, the committee - and Parliament in its resolution³ - recommended an appropriate transitional period of at least six months.

The Legal Affairs Committee regarded the proposal for a minimum course of four and a half years practical and theoretical training together with at least six months in-service training as an adequate basis for recognition of a pharmacist's right to engage in and pursue activities and also as a minimum requirement with regard to the mutual recognition and coordination of training.

¹ OJ No. C 143, 3.12.1970, p. 23 (paragraph 6)

² See Doc. 142/70-71, p. 42 (paragraph 32)

³ OJ No. C 143, 3.12.1970, p. 23

II. The Commission's 1972 proposals

7. In November 1972 the Commission submitted the following proposals for directives which had been promised in 1970:

- (1) proposal for a directive on the coordination of certain laws, regulations and administrative provisions concerning the retail sale of medicinal products by self-employed persons,
- (2) proposal for a directive concerning the attainment of freedom of establishment and freedom to provide services in respect of the retail sale of medicinal products by self-employed persons¹.

These proposals complemented the seven proposals for directives submitted in 1969, as called for by the European Parliament², and were designed to bring about freedom of establishment in respect of the retail sale of pharmaceuticals by self-employed pharmacists by resolving the problems connected with the geographical distribution of pharmacies.

The first directive was also based on Articles 57 and 66 of the EEC Treaty, whereas the second directive took Articles 54(2) and (3), 63(2) and (3) and 66 of the EEC Treaty as its legal basis.

The proposals for directives submitted in 1972 were therefore intended primarily to regulate the geographical distribution of pharmacies, 'since otherwise the achievement of freedom of establishment will cause an abnormal influx of applicants, particularly from countries which restrict the number of dispensaries, into the Member States where dispensaries may be freely set up'³.

8. The European Parliament considered these proposals in the light of the report of the Legal Affairs Committee (rapporteur: Mr Vernaschi) and the opinion of the Committee on Public Health and the Environment (draftsman: Mr Walkhoff⁴) and, in its resolution of 13.6.1974⁵, called on the Commission to withdraw its proposals and to prepare new proposals,

¹ COM(72) 1375 final (= Document 102/74)

² Resolution of 18.11.1970, OJ No. C 143, 3.12.1970, p. 23

³ See COM(72) 1375 final, p. 2

⁴ Document 102/74

⁵ OJ No. C 76, 3.7.1974, p. 48

'providing for full and effective freedom of establishment and freedom to provide services in the retail sale of the pharmaceuticals sector, while nevertheless safeguarding public health.'¹

9. As was made clear in the explanatory statement of the Legal Affairs Committee and, in particular, in the opinion of the Committee on Public Health and the Environment², the European Parliament considered that the Commission's proposals would result not in liberalization but rather in restriction of the freedom of establishment. It adopted the view that the proposed regulation of geographical distribution combined with the monopolistic position of pharmacists would grant dispensing chemists an unjustifiably privileged status.

10. The Legal Affairs Committee expressly recommended abandoning the principle of controlled geographical distribution of pharmacies since it believed that freedom of establishment and freedom to provide services could be brought about only through the liberalization of national legislation and not by imposing restrictions on distribution³.

11. In its opinion, the Committee on Public Health and the Environment was opposed to granting pharmacists a privileged and monopolistic position since the present-day nature of their work (sale of primarily ready-made preparations, transfer of responsibility for production to the pharmaceutical manufacturer) did not justify such exaggerated protection.

III. Withdrawal of the Commission's proposals

12. By decision of 8 December 1976, the Commission expressly withdrew three of the directives⁴ contained in the package on harmonization in the pharmaceutical sector (production and sales)⁵ submitted in 1969, including the two directives of interest here concerning:

¹ EP resolution, paragraph 2, OJ No. C 76, 3.7.1974, p.48

² See Doc. 102/74, in particular pages 15 and 20-22

³ Doc. 102/74, p. 15, paragraphs 19 and 20

⁴ OJ No. C 26, 3.2.1977, pp. 5 and 6

⁵ OJ No. C 54, 28.4.1969 (see paragraph 2)

- the mutual recognition of the diplomas, certificates and other formal qualifications of pharmacists;
- the coordination of certain provisions laid down by law, regulation or administrative action in respect of the activities of self-employed pharmacists.

The proposals were withdrawn on the grounds that the Council had not reached a decision and that they were no longer of topical interest.

13. At the same time, however, the Commission announced that it would be submitting new proposals to the Council in the course of 1977 on:

'the coordination of minimum training requirements and mutual recognition of qualifications for pharmacists'¹.

These proposals were forwarded by the Commission to the Council on 3 February 1981².

14. The 1969 proposals also ceased to apply as a result of the decisions of the European Court of Justice in Cases 2/74 (Reyners)³ and 33/74 (van Binsbergen)⁴ which stated that following the expiry of the transitional period, Articles 52 and 59 of the EEC Treaty (right of establishment and freedom to provide services) were directly applicable. On 24 July 1974 the Commission withdrew its 1972 proposals⁵.

Since 1974 the Commission has adopted a new policy with regard to harmonization measures to bring about freedom of establishment and freedom to provide services. The Commission's aim in following this restrictive policy is to submit proposals for the attainment of freedom of movement only insofar as these are necessary for the development of the common market. The Commission appears not to have applied this criterion in the case of its 1969 and 1972 proposals. The intention at that time was to propose a uniform

¹ OJ No. C 26, 3.2.1977, p. 5

² See paragraphs 1 and 15 et seq.

³ Case 2/74, ECR 1974, 631

⁴ Case 33/74, ECR 1974, 1299

⁵ By decision of the Commission, not published

structure for the profession, covering both the exercise of activities (geographical distribution of pharmacies, monopoly of retail sales, ownership of medicinal products and the liability of the pharmacist) and professional training¹.

IV. The Commission's new 1981 proposals

15. The proposals² forwarded by the Commission to the Council on 3 February 1981 reflect this new restrictive policy.

The Commission bases its new proposals solely on Articles 49 and 57 of the EEC Treaty and thus confines itself to the right of establishment. It expressly excludes any facilitation of the provision of services since it considers that the profession of pharmacist represents an exceptional case in terms of the provision of services within the meaning of Articles 59 and 60 of the EEC Treaty. The Commission considers it difficult to judge at present whether measures designed to facilitate the provision of services by pharmacists would serve a useful purpose and considers such provisions inappropriate for the moment³.

16. The Commission therefore proposes only measures designed to promote mutual confidence in the qualifications and competence of pharmacists coming from other Member States through the approximation of national laws.

The directive on coordination first specifies the fields of activity to which holders of suitable qualifications must be granted access and then lays down the minimum conditions which the training leading to these qualifications must satisfy (at least four years training at an institution of higher education and six months in-service training). The Commission chooses not to make detailed specifications regarding the content of the training and hopes that the minimum requirements will increase mutual confidence.

¹ See Introduction to COM(81) 4, pp. 2 and 3

² COM(81) 4 final

³ As stated in the explanatory memorandum to the proposal for a directive on mutual recognition, COM(81) 4 final, p. 10

17. The proposed directive on mutual recognition also defines the range of activities to which this mutual recognition applies. This allows a pharmacist moving to another country to exercise all the activities open to pharmacists in the host country. The measures do not affect the application of national provisions, the nature of the profession of pharmacist in each individual country remains the same and is not subject to harmonization.

The proposal for a directive also specifies in detail the diplomas, certificates and other evidence of formal qualifications, including the in-service training completed in the country of origin, which must be recognized.

In line with the directives on mutual recognition already adopted, the directive stipulates that the professional title of the host Member State must be used¹, and includes a language requirement².

18. In the provisions to facilitate the effective exercise of the right of establishment (Articles 7-14 of the directive on mutual recognition) the basic principle applied by the Commission is that a pharmacist seeking to exercise his activities must conform to the requirements laid down by the host country. The host country should recognize a certificate issued in the country of origin attesting to the applicant's reliability. Each country should inform the other if they have any knowledge of serious misconduct which could affect the exercise of the activity concerned.

19. In its explanatory memorandum the Commission points out that the proposed measures concern solely the establishment of pharmacists and are not intended also to facilitate the provision of services. The reason given for this is that the services provided by pharmacists are of a quite different nature from those provided by the other liberal professions.

¹ See Article 13 of the directive on mutual recognition, COM(81) 4 final, p. 17

² See Article 14(3) of the directive on mutual recognition, COM(81) 4 final, p. 18

20. In order to ensure a comparably high level of pharmaceutical training in the Community, the Commission has proposed a Council decision setting up an Advisory Committee on Pharmaceutical Training.

V. Measures concerning freedom of movement in the health sector

21. It seems appropriate in this context to give a brief summary of the legal situation regarding the recognition of diplomas and the coordination of provisions laid down by law, regulation or administrative action in respect of other activities in the health sector.

22. In March 1969 - at the same time as it submitted the first proposals for directives on freedom of movement for pharmacists - the Commission submitted proposals to facilitate the effective exercise of the right of establishment and freedom to provide services for doctors and dentists¹, based on Articles 54, 57 and 63 of the EEC Treaty. After the European Parliament had delivered its opinion, proposing that the directives be extended to employed doctors and dentists², the Council adopted the directives on doctors on 16 June 1975³ and the directives on dentists on 25 July 1978⁴. The Council based these directives on Articles 49, 57, 66 and 235 of the EEC Treaty.

23. In 1969 and 1970 the Commission submitted further proposals to bring about freedom of movement for veterinary surgeons⁵, nurses⁶ and midwives⁷, on which the European Parliament delivered opinions⁸⁻¹⁰ and called once again for freedom of movement to be extended to employed persons.

¹
² OJ No. C 54, 28.4.1969, pp. 8-31

³ And included Article 48 as a further legal basis

⁴ Directives 75/362 and 75/363, OJ No. L 167, 30.6.1975, pp. 1 and 14

⁵ Directives 78/686 and 78/687, OJ No. L 233, 24.8.1978, pp. 1 and 10

⁶ OJ No. C 92, 20.7.1970, p. 18

⁷ OJ No. C 156, 8.12.1969, p. 13

⁸ OJ No. C 18, 12.2.1970, p. 1

⁹ Veterinary surgeons: OJ No. C 19, 28.2.1972, p. 10

¹⁰ Nurses: OJ No. C 65, 5.6.1970, p. 12

Midwives: OJ No. C 101, 4.8.1970, p. 26

Between 1977 and 1980¹⁻³ the Council adopted the directives, including Article 49 of the EEC Treaty as a further legal basis in respect of employed persons in accordance with the proposals of the European Parliament⁴.

24. The purpose of all these directives was to facilitate the effective exercise of the right of establishment and freedom to provide services. This results from Article 66 of the EEC Treaty, which is cited as a legal basis in every case. Each of the directives also covers employed persons and is based additionally on Article 49 of the EEC Treaty.

Initially the Council also included Article 235 of the EEC Treaty as a legal basis in respect of employed persons, but later - in the case of the directives on midwives - accepted the view of the Commission and the European Parliament that Article 49 of the EEC Treaty provided sufficient legal basis.

¹ Veterinary surgeons: OJ No. L 362, 23.12.1978, p. 1

² Nurses: OJ No. L 176, 15.7.1977, p. 1

³ Midwives: OJ No. L 33, 11.2.1980, p. 1

⁴ In the case of the directives on veterinary surgeons and nurses the Council additionally included Article 235 of the EEC Treaty as a legal basis

Part 2 Comments on the proposals

I. General

25. The Commission itself concedes that its 1981 proposals are more modest than those put forward in 1969 and 1972¹. Its justification for this restraint is that these proposals are better adapted to the present state of Community integration and that harmonization of the structure of the profession does not seem necessary.

26. The present proposals do indeed fall far short of the measures put forward in 1969 and 1972.

- The earlier proposals covered freedom to provide services as well as the right of establishment.
- The 1969 proposal for a directive on coordination in respect of the activities of self-employed pharmacists provided for pharmacists to have a monopoly of sales of medicinal products after a transitional period and regulated the question of the ownership of equipment and medicinal products.
- The supplementary 1972 proposal laid down rules governing the geographical distribution of dispensaries which meant that permission to operate was subject to restrictions.

27. The new proposals do, however, go further than the earlier proposals in one respect; according to Articles 3 and 17 respectively of the proposals for directives, and on the basis of Article 49 of the EEC Treaty, the right of establishment is to apply also to employed pharmacists. The Commission has here responded to the demands of the European Parliament², thus following the Council's example in the directives adopted in respect of the health sector³.

¹ COM(81) 4 final, Introduction, p. 3

² EP resolution, OJ No. C 101, 4.8.1970, p. 14 (paragraph 17) and Lautenschlager report, Doc. 80/1970, p. 41

³ Council Directive 75/362 concerning doctors, OJ No. L 167, 30.6.1975, p. 1

28. The Commission's restraint and the above-mentioned differences with regard to the earlier proposals do not in themselves merit an unfavourable opinion. If the present proposals nonetheless contain the necessary measures to assure freedom of movement for pharmacists, they are quite sufficient.

It must therefore be examined whether the Commission's proposals satisfy the requirements laid down in the Treaty as regards freedom of movement for these professions.

II. Right of establishment and freedom to provide services

29. The most striking difference by comparison with the earlier proposals is that these proposals are concerned solely with the right of establishment for pharmacists. Freedom to provide services is excluded on the grounds 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.¹ In the explanatory memorandum to the directive on mutual recognition² the Commission states that it considers such provisions inappropriate since it is difficult to judge at present whether they would serve a useful purpose.

30. These arguments are not convincing and conceal the true reasons for the Commission's inability at present to introduce freedom to provide services in respect of pharmaceutical activities.

The Commission is correct in saying that the pharmacist's freedom to provide services differs significantly from that of the other medical professions; the pharmacist is essentially engaged in selling a pharmaceutical product, whereas in the case of a doctor the service rendered is individual medical attention. The doctor, once his diploma has been recognized, can therefore establish himself in another Member State and immediately provide services such as treatment, prescribing medicines, consultation, etc.

¹ COM(81) 4 final, p. 8

² COM(81) 4 final, p. 10

31. Since the pharmacist's services involve the sale of medicinal products, provision of these services outside his country of establishment is dependent on whether the products concerned are authorized in the other country.

In its proposals the Commission does not make clear the exact nature of the obstacles preventing the introduction of freedom to provide services in respect of pharmacists.

What actually prevents the introduction of freedom to provide services is the fact that in the Community there is no mutual recognition of marketing authorizations for proprietary medicinal products. The Council has now adopted four directives on the approximation of provisions laid down by law, regulation or administrative action relating to proprietary medicinal products¹. The Commission has since submitted an amending proposal², which was approved by the European Parliament on 16 October 1981³ being a first step towards the free movement of proprietary medicinal products in the Community. Establishment of a unified market in medicinal products requires not only mutual recognition of marketing authorizations but also harmonization of the criteria and methods used in trials, abolition of all import controls and elimination of the problem of parallel imports.

The Commission should submit to the Council the proposals required in this area to ensure freedom to provide services by establishing a Community market in medicinal products.

¹ Directive 65/65 of 26.1.1965, OJ No. L 22, 9.2.1969, p. 369
Directive 75/318 of 20.5.1975, OJ No. L 147, 9.6.1975, p. 1
Directive 75/319 of 20.5.1975, OJ No. L 147, 9.6.1975, p. 13
Directive 78/25 of 12.12.1977, OJ No. L 11, 14.1.1978, p. 18

² COM(80) 789 final

³ EP resolution of 16.10.1981, OJ No. C 287, 9.11.1981, p. 120
on the basis of the von Wogau report (Doc. 1-246/81)

III. Renunciation of an integrated Community policy

32. Even if it is accepted that the Commission's work must be confined to facilitating the right of establishment because the lack of harmonization of the market in medicinal products prevents any facilitation at present of the freedom to provide services, the present proposals still seem to fall short of their intended objectives.

33. Firstly, the Commission's justification of these proposals seems contradictory. On the one hand, it states that harmonization is not an aim in itself and must be used only where necessary for the development of the common market. And yet the new restrictive policy is based not on what is necessary (what is required to bring about freedom of movement) but rather on what is politically possible at present. The proposals give the impression that instead of pointing the way, in accordance with the Commission's role as the 'driving force of the Community', they have been adapted to what is thought to be feasible.

This contradiction is made apparent on page 3 (Introduction) of the Commission's proposals. The Commission considers that its 1969 and 1972 proposals did not meet the restrictive criteria because they sought to create a uniform structure for the profession of pharmacist. To illustrate this, the Commission refers to the conditions governing the exercise of the profession which were then proposed (monopoly of sales, ownership of medicinal products, geographical distribution of dispensaries). Having said that this is not in line with its policy, the Commission then states on the same page of its explanatory memorandum that it does not exclude the possibility of further development and introduction of these same principles at a later stage. It is clear from this that the Commission has no precise idea of the form which freedom of movement for pharmacists will take.

34. As a further introductory remark it should be pointed out that the Commission's proposals do not meet the requirements of Article 57(3) of the EEC Treaty which states that:

'In the case of the medical and allied and pharmaceutical professions, the progressive abolition of restrictions shall be dependent upon coordination of the conditions for their exercise in the various Member States.'¹

In its proposals the Commission does not touch upon the areas of activity in the Member States, nor does it lay down the essential conditions for the exercise of the profession. It excludes the most important aspects governing the exercise of activities in the field of pharmacy, i.e.

- geographical distribution of dispensaries;
- monopoly of sales of medicinal products for pharmacists;
- ownership of medicinal products,

thereby allowing the divergent legal situations in the Member States to continue, and reserves for itself the possibility of regulating these aspects at Community level 'within the framework of an integrated Community health policy'.

It should now be examined whether regulation of these aspects at Community level is necessary and what effects the absence of any regulation will have on freedom of movement and the functioning of the common market.

1. Geographical distribution of dispensaries

35. The Commission originally excluded this aspect from its 1969 proposals also, but was subjected to pressure from the European Parliament² and submitted a proposal for a directive in 1972³. The European Parliament then opposed the principle of the geographical distribution of dispensaries and called on the Commission to withdraw its proposals. The reason given for the rejection of the proposals was that control of the geographical distribution of pharmacies would compromise freedom of movement within the Community.

¹ This point is also made by the Economic and Social Committee in its opinion of 2 July 1981, OJ No. C 230, 10.9.1981, p. 10

² EP resolution, OJ No. C 143, 3.12.1970, p. 23 (paragraph 6)

³ COM(72) 1375 final

Parliament hoped that approximation of national legislation could be brought about through liberalization, i.e. by removing national restrictions on distribution.

36. There are two obvious and diametrically opposed ways of solving the problem of the geographical distribution of dispensaries:

- (1) Introduction of provisions governing distribution in all the Member States on the basis of a uniform system

Aside from the constitutional problem which such restrictions on distribution would pose for the Federal Republic, given that in 1958 the Federal Constitutional Court declared unconstitutional such a restriction on the exercise of a profession¹, there are also economic arguments against privileged treatment of this sort. On the pretext of protecting public health, restrictions are placed on the freedom to exercise the profession of pharmacist and the pharmacist benefits from a guaranteed income which is contrary to the principles of free competition. The regulation of geographical distribution can at best prevent the excessive concentration of dispensaries in urban centres, it would not ensure that dispensaries are established in the poorly-served rural areas.

- (2) Liberalization of the establishment of dispensaries in all the Member States through simultaneous abolition of restrictions on distribution

At present five of the ten Member States of the Community do not have provisions governing geographical distribution (number of inhabitants per dispensary)². Only by guaranteeing the principle of unlimited freedom of establishment through Community law would it be possible to ensure that freedom to exercise the profession of pharmacist and freedom of movement are respected.

¹ Federal Constitutional Court, judgment of 11.6.1958, published in the Amtliche Sammlung, volume 7, p. 377

² These are: The Federal Republic of Germany, Greece, Ireland, the Netherlands and the United Kingdom; in the Netherlands, however, strict control is in fact exercised by the Pharmacists' Association; a legal measure equivalent to a restriction on distribution is being considered at present

37. The Commission's proposals once again seek to achieve a compromise by allowing the individual Member States to continue determining the question of establishment. In accordance with its restrictive policy it simply aims to ensure that nationals of other Member States receive equal treatment in complying with the various national conditions for the establishment of pharmacies.

This restrained approach (maintenance of national conditions governing the exercise of the profession and regulations governing distribution) does not, however, assure freedom of establishment, but instead increases the danger of imbalance and one-sided disadvantage.

38. The shortcomings of the solution proposed by the Commission can be seen from the following example:

- where one Community country allows freedom of establishment for pharmacies, without restriction as to number, while other Member States such as Belgium, France, Denmark and Luxembourg exercise strict control over the distribution of pharmacies, the present directive on the right of establishment will work to the disadvantage of the first country; pharmacists not permitted to practice in their own countries could establish themselves in that country without any restriction. This would lead to a marked increase in the number of dispensaries and intensify competition, whereas there would still be a privileged restraint on competition in the Member States with restrictions on geographical distribution.

39. Because of the differences in establishment opportunities, once the directives came into effect there would cease to be equality between German, British, Greek and Irish pharmacists and those from the other Community countries with restrictions on establishment, with the result that those in the first group would be put at a disadvantage. This situation of complete diversity is contrary to the basic rules of the common market as laid down in Articles 3(c) and (f) of the EEC Treaty. It is also at variance with the explanatory memorandum to the Commission's 1972 proposal which states that it is necessary to prevent a situation in which

'the achievement of freedom of establishment will cause an abnormal influx of applicants, particularly from countries which restrict the number of dispensaries, into the Member States where dispensaries may be freely set up',¹.

2. Protection for Member States through allowing restrictions on recognition of diplomas

40. The problem thus arises as to how the essence of the Commission's proposals for facilitating freedom of establishment can be preserved without opening the door to an uncontrolled influx of pharmacists into Member States with no geographical restrictions.

41. As part of a stage by stage approach, one could initially limit freedom of movement to employed pharmacists and make freedom of movement for self-employed practitioners conditional on the harmonization of the present differing establishment requirements in the Member States. A second, final stage in the harmonization process would be to introduce freedom for pharmacists to provide services, which in turn requires the existence of a common market in medical products.

However, such an approach, restricting freedom of movement to employed pharmacists, would no longer have any basis in Article 57 of the EEC Treaty, and would also do nothing for freedom of establishment for independent professions. It would furthermore rob the Commission's proposal of its content and shut markets completely to self-employed pharmacists.

42. An uncontrolled influx into Member States that allow unrestricted freedom of establishment could also be handled by less drastic changes to the Commission proposals:

Member States could be permitted, under a safeguard clause, not to apply the provisions for recognition of self-employed pharmacists where the establishment of a new pharmacy is involved. This restriction would enable Member States with no geographical distribution for dispensaries to limit the movement of pharmacists from other Member States to those taking over existing pharmacies, rather than establishing new pharmacies and hence causing an uncontrolled

¹COM(72) 1375 final, p. 2

increase in the total number of pharmacies.

43. The unequal treatment created by such a safeguard clause is only justifiable for a limited period. The Commission is therefore still asked to continue its efforts to secure harmonization of establishment requirements in the Member States in order to enable all pharmacists to establish themselves in any Member State under the same conditions. It should therefore not be left to the Member States alone to dispense with the safeguard clause at some later date. It is rather the task of the Commission to prepare further directives to harmonize establishment requirements and remove restrictions on the recognition of diplomas.

44. The safeguard clause only applies to restrictions on the recognition of diplomas. It has no bearing on the proposed directive coordinating legal and administrative provisions relating to activities in the field of pharmacy. The approximation of training for pharmacists concerns the future generation of pharmacists in all the Member States and has nothing to do with differing establishment criteria. To avoid giving the false impression that the coordination directive permits unrestricted access - as might appear from Article 1 of the proposal for a directive - a clarification should be inserted in the form of a proviso referring to the safeguard clause in Article 2 of the recognition directive.

3. Monopoly of sales and ownership of medicinal products

45. The monopoly of retail sales of medicinal products and the ownership of medicinal products, for which provision was made in the 1969 proposals¹, are not being proposed by the Commission at present. However, since reference is made to further development in these fields at a later stage within the framework of an integrated Community health policy, the question of the monopoly of sales should be discussed briefly here.

46. As was stated in the report of the Legal Affairs Committee² on the 1972 proposals, and particularly in the accompanying opinion of the Committee on Public Health and the Environment, the retention or introduction of a sales monopoly for pharmacists is of very doubtful value.

¹See points 5 and 6

²Doc. 102/74

47. In some Member States pharmaceuticals may be sold in outlets other than pharmacies (United Kingdom, Netherlands), and in all Member States pharmacists may sell products other than pharmaceuticals.

Monopoly of sales, as provided for in the Commission's 1969 proposal, is considered desirable for reasons of public health; the supply of medicinal products and advice by pharmacists alone is said to be an essential aspect of the protection of public health.

It should be recognized, on the other hand, that the nature of the pharmacist's profession has changed considerably in recent years; the preparation, manufacture and testing of medicinal products are now the responsibility of the pharmaceutical manufacturers and few medical preparations are made up by the pharmacist himself. In the case of industrially manufactured pharmaceuticals, the pharmacist's activity is almost entirely limited to the sale of the product. From the economic point of view, a sales monopoly seems to provide pharmacists with a level of protection which calls for re-examination. Together with restrictions on geographical distribution it largely excludes competition. In a market economy, however, free enterprise and freedom of establishment are the best means of assuring unrestricted competition and thereby providing the population with the best possible service. In this context a sales monopoly is acceptable only for special reasons of medical and consumer protection and accords with the special requirements concerning training and practice of the profession.

For these reasons the Commission should be urged now to consider all aspects of such a sales monopoly.

IV. Conclusions

48. After consideration of the directives proposed by the Commission, as compared with the proposals submitted in 1969 and 1972 and later withdrawn, and in the light of the differing legal situations in the Member States, it is to be concluded that
49. - The Commission's present proposals fall short of the directives submitted earlier;

50. - The lack of progress on the important and complex question of unifying the market in pharmaceuticals has prevented the Commission from submitting simultaneous proposals on freedom to provide services in respect of activities in the field of pharmacy, through which uniform legal provisions for all professions in the health sector would have been achieved;
51. - The Commission's decision not to regulate the geographical distribution of dispensaries and instead to allow the varying national provisions governing establishment to remain in effect would mean that those Member States which did not place any restrictions on the establishment of pharmacies would be placed at a disadvantage; this runs counter to the aim of freedom of establishment which is to assure equal conditions of access for all qualified persons seeking work in all the Member States;
52. - The Commission does not provide for any monopoly of sales of pharmaceuticals for pharmacists; this is, however, a matter which must be resolved;
53. - The Commission's proposals will not prevent an uncontrolled influx of pharmacists into Member States with no provisions for geographical distribution unless the Member States are permitted, under a safeguard clause, to limit the recognition of diplomas to pharmacists taking over existing pharmacies.
54. - The rules proposed by the Commission to coordinate training represent a welcome advance towards the creation of freedom of establishment and freedom to provide services in the field of pharmacy.

OPINION OF THE COMMITTEE ON BUDGETS

Letter from the chairman of the committee to Mrs Veil,
chairman of the Legal Affairs Committee

Brussels, 29.4.1983

Subject: Proposals for Council Directives and draft Council decision concerning
certain activities in the field of pharmacy (COM(81) 4 final)

Dear Madam Chairman,

I am pleased to inform you that the Committee on Budgets considered the above proposals for directives and draft Council decision at its meeting of 21 April 1983 in Brussels¹.

The committee adopted a favourable opinion unanimously, with one vote against.

However, it noted that the third proposal aims to create a new advisory committee, whereas Parliament has on several occasions called for a reorganization of the Commission's advisory bodies. The favourable opinion on these proposals is accordingly without prejudice to the results of the investigation of the Commission's advisory bodies currently being carried out by the Committee on Budgetary Control.

Yours sincerely,

Erwin LANGE

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Present: Mr LANGE, chairman; Mr NOTENBOOM, vice-chairman; Mrs BARBARELLA, vice-chairman; Mr ARNDT, Mr ADONNINO, Mr BATTERSBY, Mrs HOFF, Mr KELLETT-BOWMAN, Mr PFENNIG, Mr PRICE and Mr SCHÖN