OPINION OF ADVOCATE GENERAL RUIZ-JARABO COLOMER
delivered on 14 December 1995 *

1. In this case, the Commission alleges that the Republic of Italy has failed to bring national law into line with Council Directive 85/432/EEC of 16 September 1985 concerning the coordination of provisions laid down by law, regulation or administrative action in respect of certain activities in the field of pharmacy [1] ('the Directive').

2. The Commission seeks a declaration by the Court of Justice that 'by postponing from 1 October 1987 to 1 November 1990 the time-limit laid down in Article 5 of Council Directive 85/432/EEC (...) and by retaining until the latter date curricula for training in pharmacy which are incompatible with that directive, the Italian Republic has failed to fulfil its obligations under Directive 85/432 and particularly under Articles 1, 2 and 5 thereof'.

3. The aim of the Directive is to ensure that holders of a diploma, certificate or other university or equivalent qualification which meets the conditions laid down in Article 2 are entitled at least in all the Member States to access to certain activities in the field of pharmacy. These include the manufacture and testing of medicinal products, the preservation and distribution of medicinal products at the wholesale stage, their supply in pharmacies open to the public, the preparation, testing, storage and dispensing of medicinal products in hospitals and other similar activities.

4. To that end, the Directive requires the Member States to subordinate the award of diplomas, certificates and other formal qualifications in pharmacy to certain training conditions covering a period of at least five years and comprising:

'...

— at least four years of full-time theoretical and practical training [2] in a university, in a higher education institution of a level recognized as having equivalent status, or under the supervision of a university,

* Original language: Spanish.

1 — OJ 1985 L 253, p. 34.

2 — The course of training must comprise the following subjects: Plant and animal biology, Physics, General and inorganic chemistry, Organic chemistry, Analytical chemistry, Pharmaceutical chemistry, including analysis of medicinal products, General and applied biochemistry (medical), Anatomy and physiology; medical terminology, Microbiology, Pharmacology and pharmacotherapy, Pharmaceutical technology, Toxicology, Pharmacognosy, Legislation and, where appropriate, professional ethics.

— at least six months of in-service training in a pharmacy open to the public or in a hospital under the supervision of the pharmaceutical department of that hospital.

...'

5. Article 5 of the Directive imposed the following obligations on the Member States:

'1. Member States shall take the measures necessary to comply with this Directive before 1 October 1987. 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.'

Facts

6. The Italian legislation intended to bring national law into line with the Directive is the Presidential Decree of 31 October 1988 amending university training programmes leading to degrees in pharmacy and in pharmaceutical chemistry and technology. The decree was not published in the *Gazzetta Ufficiale della Repubblica Italiana* until 12 May 1989. [3]

7. Article 2 of the abovementioned Presidential Decree laid down 1 November 1990 as the deadline for the relevant universities to adopt the new curricula of the degree courses in question and allowed students who had enrolled between 1 November 1987 and 1 November 1990 to obtain their degrees without having followed the new curricula which complied with Community legislation.

8. Since it considered that the temporary measures allowed by the Presidential Decree did not fulfil the obligations which the Directive imposed upon the Italian Republic, the Commission sent the Italian Republic a letter of formal notice on 28 November 1991, pointing out that the Decree was incompatible with the Directive.

9. Since the Italian authorities did not reply to that letter, the Commission issued a reasoned opinion on 23 December 1992.

3 — The Italian Government sent the obligatory notification to the Commission by way of Official Communication No 3061 of 13 April 1990.

10. The Italian Government sent a letter to the Commission on 27 April 1993 stating that the delay in transposing the Directive was due to 'unavoidable requirements linked to the particular structure of Italian university education'. In order to resolve the situation, it proposed as a 'transitional solution' that students who had commenced their pharmaceutical studies after 1 October 1987 and who had not opted for the new curriculum which was compatible with the Directive could obtain a Community qualification if their training programme did in fact fulfil the academic requirements laid down in the Directive (examinations in all the disciplines mentioned therein and completion of the six-month in-service training).

11. In order to consider the abovementioned reply with greater knowledge of the facts, the Commission asked the Italian Government on 3 August 1993 for detailed information on the number of students affected (that is, students who had not opted for the new curriculum), the differences between the old and the new academic programmes and the system which the universities would use to contact the interested parties. The Commission also wanted to know whether the students affected would be obliged to follow additional courses, whether a period would be set for the completion of their training and, finally, whether a specific diploma was to be awarded.

12. The Italian authorities did not reply to the request for additional information from the Commission. Finally the Commission brought this action for failure to fulfil obligations on 22 November 1994.

Delay in transposing the Directive

13. The Italian Government acknowledges that the incorporation of the Directive into national law was tardy, years after the expiry of the time-limit laid down in Article 5. Thus, on that ground alone there is a manifest failure of the Member State to transpose a directive into national law within the prescribed period.

14. The fact that Article 2 of the 1988 Presidential Decree postpones until November 1990 the requirement of adapting curricula which, paradoxically, should have been amended before October 1987 makes the delay in transposing the Directive into national law all the more obvious.

15. None the less, the Italian Government submits in its rejoinder that infringement proceedings cannot be based on a complaint that there has been a delay (in implementing the Directive) where the pre-litigation procedure has been initiated by the Commission after transposition has already taken place.

16. That is the case here, since the Commission sent a letter of formal notice to the Italian authorities on 28 November 1991, that is, over a year after the publication of the Presidential Decree and its official notification by the Italian Government to the Commission itself, pursuant to Article 5(2) of the Directive.

17. The Italian Government claims not to have discovered any legal precedent in which the Court took a decision on the substance in an action under Article 169 of the Treaty for implementing a directive out of time where the relevant pre-litigation procedure had been initiated after that directive had been implemented.

18. In the context of the present case, such arguments can only lead either to denying that the Commission has a legal interest (capacity) in bringing these proceedings or to a declaration that the subject-matter itself of the infringement proceedings never existed. It is certainly true that the Italian Government's argument could, in theory, be upheld, for, under the mechanism of Article 169 of the Treaty, neither letters of formal notice nor reasoned opinions would make much sense if they were drawn up after the alleged infringement had already been terminated by the State which committed the infringement before the Commission sent it those 'requests' to take action.

19. However, the infringement complained of in the present case is not only that the Directive was implemented out of time but that the resulting situation, which did not comply with the requirements of the Community legislation deemed to have been infringed, was perpetuated by means of the implementing Italian legislation.

20. In the circumstances, I believe that the application is not vitiated by any procedural defect which renders it inadmissible. As I will explain, the Commission is acting within the limits of its powers and does not need to establish a specific or relevant interest, nor is it subject to a time-limit for the action and, finally, it was more than justified in bringing the action.

21. The Court has consistently held that the Commission, in the exercise of the powers which it has under Article 169 of the Treaty, does not have to show the existence of a specific interest in bringing the action, since, in the general interest of the Community, its function is to ensure that the provisions of the Treaty are applied by the Member States. [4] Thus, there need only be a presumption of infringement by a Member State for the Commission to be able legitimately to use the procedure provided for in Article 169 of the Treaty.

4 — Case 167/73 *Commission* v *France* [1974] ECR 359, paragraph 15, and Case C-182/94 *Commission* v *Italy* [1995] ECR I-1465.

22. The Commission is also not bound by any time-limit for bringing the action since it is also settled case-law that the rules of Article 169 of the Treaty must be applied and the Commission is not obliged to act within a specified period. [5] The Commission is thus entitled to decide, in its discretion, on what date it may be appropriate to bring an action and it is not for the Court to review the exercise of that discretion.

23. Even where an infringement has been brought to an end, there may be reasonable justification for bringing an action under Article 169 of the Treaty. As the Court has consistently held, one of the possible objectives of such an action consists in establishing the basis for liability on the part of a Member State as a result of its failure to fulfil its obligations. [6] This aim alone would therefore suffice for the action.

24. As regards in particular the field of academic qualifications, a finding that a Member State has previously failed to fulfil its obligations can also have the effect of rendering lawful non-recognition by the other Member States of qualifications awarded during the period in which the Community legislation had not been duly applied.

25. On the basis of the foregoing considerations, the arguments of the Italian State concerning the pursuit of the action brought by the Commission can be rejected and the substance of the infringement considered.

Incorrect transposition of the Directive

26. The delay in transposing the Directive into Italian national law is coupled with a serious defect in the transposition of its content. This defect consists of two infringements, one temporal and the other substantive, which are none the less closely linked: first, the Italian Republic has not transposed the Directive into national law within the prescribed period; secondly, when it eventually transposed it out of time, it did so under conditions which allowed irregularities incompatible with Community law to persist, without providing the appropriate remedy.

27. Both parties agree that the curricula for training in pharmacy prior to the entry into force of the 1988 Presidential Decree did not fulfil in Italy the requirements laid down by the Directive. The defendant Government has not refuted the Commission's arguments in this respect. [7]

5 — Case C-96/89 *Commission* v *Netherlands* [1991] ECR I-2461 and Case C-422/92 *Commission* v *Germany* [1995] ECR I-1097.

6 — Case 103/84 *Commission* v *Italy* [1986] ECR 1759 and Case 240/86 *Commission* v *Greece* [1988] ECR 1835.

7 — According to the Commission, the duration of the pharmacy degree course was four years rather than five, the compulsory subjects did not correspond to those set down in the Directive and the six-month in-service training period was not obligatory.

28. It was therefore necessary for those curricula to be brought into line with Community law in order to facilitate the mutual recognition of the corresponding qualifications for the exercise of the pharmaceutical activities described above. [8]

29. The Presidential Decree of 31 October 1988, which implements the Directive, makes the late transposition more serious by postponing until 1990 the application of the new curricula. Thus between October 1987 and November 1990 it permitted pharmacy students to train and obtain the corresponding academic qualifications under a system of theoretical and practical training which did not comply with the requirements of the Directive.

30. Contrary to what the Italian Government has maintained during the proceedings, that measure — not to put the new curricula into full effect until 1990 — was not a 'natural and unavoidable consequence of late transposition'. There was nothing to prevent it from arranging for a transitional system for students who had followed the curriculum not compatible with the Directive so that their academic qualifications complied fully with the new system.

31. It was perfectly possible to require students enrolled in Italian universities from 1987 and who were still studying in 1988 and 1989 to complete a level of theoretical and practical training which complied with the minimum content imposed by the Directive, if necessary by means of supplementary training programmes. Such a requirement would not have had any retroactive effect because it would have affected present or future situations or mere expectations, rather than established legal situations.

32. In their letter, referred to above, [9] of 27 April 1993 — which was also late — in reply to the Commission's reasoned opinion, the Italian authorities suggested a possible 'transitional solution', albeit in vague terms, which immediately prompted the Commission to ask for further information. The lack of cooperation on the part of the Italian Government, which did not reply to the latter request for information, is manifest.

33. In summary, the Italian Government need not have aggravated the breach of time-limits (for implementing the Directive) by a further breach in respect of substance or content. It should merely have included in the implementing Presidential Decree solutions which not only allowed students who had enrolled after 1987 to opt for the new curriculum, which complies with Community law, but also required those who had not so opted to complete appropriate supplementary training. By not doing so, it manifestly committed the twofold infringement complained of by the Commission.

8 — See point 3 above.

9 — See point 10 above.

34. The circumstances of the present case are very similar to those of Case C-40/93. [10] In that case, the Court declared that by deferring under national legislation (also of 1988) [11] until 1984/1985 the final date with regard to diplomas in medicine and surgery, the Italian Republic had failed to fulfil its obligations under two directives [12] concerning the mutual recognition of evidence of the formal qualifications, and the coordination of provisions, in respect of dental practitioners.

35. In that judgment, the Court accepted the argument of the Commission that by allowing graduates in Italy who had not been trained in conformity with the criteria laid down in Article 1 of the coordination directive and who had also not commenced their university medical training before the date laid down by Article 19 of the directive on recognition of qualifications to practise as dentists, the Italian Republic had failed to fulfil its obligations under those provisions. The Law in question thus created a category of dental practitioners — whose members are authorized to practise only on national territory — which does not correspond to any of those envisaged by those directives.

36. By that judgment the Court rejected the possibility — identical to that pleaded for by Italy in the present case — for a Member State unilaterally to defer the period prescribed by a directive for bringing academic curricula into line with its mandatory requirements. It also declared contrary to Community law the conduct of a Member State whose legislation validated university courses (in that case, courses in medicine; in the present case, courses in pharmacy) completed after the time-limit set down in a directive but which do not fulfil its requirements.

37. On the basis of the foregoing considerations, I propose that the Court uphold this application. In my view, the Italian Government has failed to fulfil, in respect of both time and content, its obligation to bring national law into line with the Directive and the Court should make a declaration to that effect.

38. Since the Commission has been successful in its application, the Italian Republic should be ordered, pursuant to Article 69(2) of the Rules of Procedure, to pay the costs.

10 — Case C-40/93 *Commission* v *Italy* [1995] ECR I-1319.

11 — Italian Law No 471 of 31 October 1988.

12 — The case concerned specifically infringement of Article 19 of Council Directive 78/686/EEC of 25 July 1978 concerning the mutual recognition of diplomas, certificates and other evidence of the formal qualifications of practitioners of dentistry, including measures to facilitate the effective exercise of the right of establishment and freedom to provide services (OJ 1978 L 233, p. 1) and Article 1 of Council Directive 78/687/EEC of 25 July 1978 concerning the coordination of provisions laid down by law, regulation or administrative action in respect of the activities of dental practitioners (OJ 1978 L 233, p. 10).

Conclusion

39. I therefore propose that the Court should:

1. Uphold the application and declare that, by postponing from 1 October 1987 to 1 November 1990 the time-limit laid down in Article 5 of Council Directive 85/432/EEC of 16 September 1985 concerning the coordination of provisions laid down by law, regulation or administrative action in respect of certain activities in the field of pharmacy, and by retaining until the latter date curricula for training in pharmacy which are incompatible with that directive, the Italian Republic has failed to fulfil its obligations under Directive 85/432;

2. Order the Italian Republic to pay the costs.