ORDER OF THE COURT OF FIRST INSTANCE (Second Chamber)
29 October 1993 *

In Case T-463/93,

GUNA Srl, a company governed by Italian law, established in Milan (Italy), represented by Giuseppe Calabi, Marco Frigessi di Rattalma and Lucio Rubini, of the Milan Bar, with an address for service in Luxembourg at the Chambers of Arendt & Medernach, 8-10 Rue Mathias Hardt,

applicant,

v

Council of the European Communities, represented by Jill Aussant and Giorgio Maganza, Legal Advisers, acting as Agents, with an address for service in Luxembourg at the office of Bruno Eynard, Manager of the Legal Directorate of the European Investment Bank, 100 Boulevard Konrad Adenauer,

defendant,

supported by

Commission of the European Communities, represented by Antonio Aresu, of its Legal Service, acting as Agent, with an address for service in Luxembourg at the office of Nicola Annecchino, also of its Legal Service, Wagner Centre, Kirchberg,

intervener,

APPLICATION for the annulment of Articles 7 and 9 of Council Directive 92/73/EEC of 22 September 1992 widening the scope of Directives 65/65/EEC and 75/319/EEC on the approximation of provisions laid down by law, regulation or

* Language of the case: Italian.

administrative action relating to medicinal products and laying down additional provisions on homeopathic medicinal products (OJ 1992 L 297, p. 8),

THE COURT OF FIRST INSTANCE
OF THE EUROPEAN COMMUNITIES (Second Chamber),

composed of: J. L. Cruz Vilaça, President, C. P. Briët, A. Kalogeropoulos, D. P. M. Barrington and J. Biancarelli, Judges,

Registrar: H. Jung,

makes the following

Order

1 On 22 September 1992, the Council adopted Directive 92/73/EEC widening the scope of Directives 65/65/EEC and 75/319/EEC on the approximation of provisions laid down by law, regulation or administrative action relating to medicinal products and laying down additional provisions on homeopathic medicinal products (OJ 1992 L 297, p. 8, hereinafter 'the directive at issue').

2 The directive at issue lays down different arrangements governing the authorization to market homeopathic medicinal products according to whether they are administered orally or externally, or in some other way. Those administered orally or externally are thus eligible for the simplified registration procedure referred to in Article 7 of the directive at issue, while those administered in some other way are subject, under Article 9 thereof, to an authorization procedure which includes,

in particular, the proof of therapeutic efficacy referred to in Article 28 of Council 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 1975 L 147, p. 13).

3 The applicant, which manufactures and imports into Italy homeopathic medicinal products, including injectable medicinal products, considered that the requirement laid down by Article 9 of the directive at issue effectively suspends and revokes the authorization granted to it by the Italian authorities, since it would not be possible, given that they are quite different in composition and function, to apply to homeopathic medicinal products the methods of analysis and tests used for conventional medicinal products. By application lodged at the Registry of the Court of Justice on 23 December 1992, it brought an action under Article 173, second paragraph, of the EEC Treaty, seeking the annulment of Articles 7 and 9 of the directive at issue.

4 By a document, lodged at the Registry of the Court of Justice on 5 March 1993, the Council raised an objection of inadmissibility under Article 91(1) of the Rules of Procedure of the Court of Justice and requested the Court to rule on that objection without going to the substance of the case.

5 By application lodged at the Registry of the Court of Justice on 6 April 1993, the Commission applied to intervene in support of the form of order sought by the Council. By applications lodged at the Registry of the Court of Justice, on 7 May and 12 May 1993 respectively, the European Council of Doctors for Plurality in Medicine and Biologische Heilmittel Heel GmbH applied to intervene in support of the form of order sought by the applicant.

6 By order of the President of the Court of Justice of 26 May 1993, the Commission was permitted to intervene in support of the form of order sought by the defendant.

7 By order of 27 September 1993, the Court of Justice referred the case to the Court of First Instance, pursuant to Article 4 of Council Decision 93/350/Euratom, ECSC, EEC of 8 June 1993, amending Decision 88/591/ECSC, EEC, Euratom establishing the Court of First Instance of the European Communities (OJ 1993 L 144, p. 21).

8 Under Article 114(3) of the Rules of Procedure of the Court of First Instance, the remainder of the proceedings concerning the objection of inadmissibility are to be oral unless the Court otherwise decides. The Court of First Instance (Second Chamber) considers that, in this case, it has sufficient information and it is not necessary to open the oral procedure.

Admissibility

Arguments of the parties

9 In its objection of inadmissibility, the Council contends, first, that directives cannot, on the basis of the actual wording of the second paragraph of Article 173 of the Treaty, which — in contrast to the first paragraph — refers only to decisions and regulations, form the subject of an application for annulment brought by an individual.

10 Secondly, the Council points out that the application is in any event inadmissible because the measure at issue is not of direct and individual concern to the applicant. According to the defendant, the directive cannot be the source of the direct damage cited by the applicant, since it is the authorities of the Member States which have to evaluate the results of the scientific procedures and tests applied. The Council points out that the applicant has carefully avoided any reference to Article 9(2) of the directive at issue, which leaves the Member States discretion as to the possibility of introducing or retaining specific rules for the pharmacological and toxicological tests and clinical trials of injectable homeopathic medicinal products, in accordance with the principles and characteristics of homeopathy as practised in the Member State in question. Moreover, even assuming it were concerned by the directive at issue, the applicant would, in the Council's view, be affected only in its capacity of manufacturer and importer of the medicinal products in question, in the same way as any other Community manufacturer and importer, and could not therefore be deemed to be individually concerned.

11 The applicant, however, claims that it would be contrary to the spirit of the Treaty and the Court's 'tradition of case-law' to take the view that individuals are in principle prohibited from challenging Community directives and, consequently, that it has the right to challenge the directive, pursuant to Article 173, second paragraph, of the Treaty, even though that provision makes no mention of such a possibility. In the view of the applicant, the directive at issue, and in particular Article 9 thereof, causes it direct damage, inasmuch as the Member State has no discretion over its implementation. It submits that since homeopathic medicinal products cannot be tested using the methods applied to 'conventional' medicinal products, the requirement of proof of therapeutic efficacy is excessively difficult. It considers that, in those circumstances, Article 9 of the directive at issue actually constitutes a decision of direct concern to it, since the Member State will have to suspend and revoke — without being able to decide for itself, make its own assessment or exercise discretion — the authorization to market injectable homeopathic medicinal products it had accorded the applicant.

12 The applicant further considers that the directive at issue is of individual concern to it because it requires the authorization accorded to the applicant to be compulsorily and automatically revoked. The individual damage, required for an application under the second paragraph of Article 173 of the Treaty to be admissible, must take into account the fact that the applicant has a right which it claims has been prejudiced, in accordance with the common principles of administrative law in the legal orders of the Member States. The applicant submits that rigid application of the concept of 'individual damage' would in fact make it impossible for individuals to challenge directives.

Findings of the Court

13 Under the second paragraph of Article 173 of the Treaty, any natural or legal person may, under the conditions referred to in the first paragraph of Article 173 institute proceedings 'against a decision addressed to that person or against a decision which, although in the form of a regulation or a decision addressed to another person, is of direct and individual concern to the former'.

14 In this case, and without it being necessary to consider all of the points raised between the parties concerning whether or not an individual may bring an action for the annulment of a directive, it should be noted that the provisions at issue of Directive 92/73/EEC are not of direct and individual concern to the applicant.

15 First of all the applicant itself considers itself directly concerned only by Article 9 of the directive at issue. It is only in so far as Article 7 of the directive is the rule from which Article 9 derogates that the applicant is seeking its annulment also.

16 Secondly, contrary to what is claimed by the applicant, in so far as Article 9(2) of the directive at issue provides that a 'Member State may introduce or retain in its territory specific rules for the pharmacological and toxicological tests and clinical trials of homeopathic medicinal products other than those referred to in Article 7(1) in accordance with the principles and characteristics of homeopathy as practised in that Member State', it allows the Member States to exercise discretion as to the tests to be applied to those homeopathic products unable to benefit from the simplified registration procedure referred to in Article 7 of the directive.

17 Thirdly, in any event, as is apparent from the Court's consistent case-law (see the judgment of the Court of Justice in Case 25/62 *Plaumann* v *Commission* [1963] ECR 197, and, in connection with an application against a directive, the order of the Court of Justice in Case 160/88 *Fedesa and Others* v *Council* [1988] ECR 6399, paragraph 14), for a person to be individually concerned by a measure, his legal position must be affected because of circumstances which distinguish him individually just as in the case of the person addressed. However, the directive at issue concerns the applicant only in its objective capacity of manufacturer and importer of homeopathic medicinal products, in the same way as any other economic operator in the same situation.

18 It follows that the application is manifestly inadmissible.

19 Under Article 111 of its Rules of Procedure, where an application is manifestly inadmissible, the Court of First Instance may, by reasoned order, and without taking any further steps in the proceedings, give a decision on the action. In those circumstances, there is no need to give a decision on the applications to intervene submitted by the European Council of Doctors for Plurality in Medicine and by Biologische Heilmittel Heel GmbH in support of the form of order sought by the applicant.

Costs

20 Under Article 87(2) of the Rules of Procedure of the Court of First Instance, the unsuccessful party is to be ordered to pay the costs if they have been applied for in the successful party's pleadings. Since the applicant has been unsuccessful, it must be ordered to pay the costs.

21 Under Article 87(4) of the Rules of Procedure of the Court of First Instance, the Member States and institutions which intervened in the proceedings are to bear their own costs. In those circumstances, the Commission should bear its own costs.

22 Under Article 87(6) of the Rules of Procedure of the Court of First Instance, where a case does not proceed to judgment, the costs are to be in the discretion of the Court of First Instance. The Court considers that, in view of the circumstances of the case, the applicants to intervene should bear their own costs.

On those grounds,

THE COURT OF FIRST INSTANCE (Second Chamber)

hereby orders:

1. **The application is dismissed as inadmissible.**

2. **There is no need to give a decision on the applications to intervene submitted by the European Council of Doctors for Plurality in Medicine and by Biologische Heilmittel Heel GmbH.**

3. **The applicant is ordered to bear its own costs, together with those incurred by the Council.**

4. **The Commission and the applicants to intervene are ordered to bear their own costs.**

Luxembourg, 29 October 1993.

H. Jung — Registrar

J. L. Cruz Vilaça — President