OPINION OF MR ADVOCATE GENERAL DARMON
delivered on 4 February 1992 *

Mr President,
Members of the Court,

1. In the present application the Commission is seeking a declaration that the Hellenic Republic has failed to fulfil its Community obligations by requiring that cosmetic products may be marketed only if a declaration is made accompanied by information and supporting documents and if a file is kept containing particulars which are already printed on the packaging, containers or labels of the products or which are not justified for the purposes of prompt and appropriate medical treatment.

2. Council Directive 76/768/EEC of 27 July 1976 [1] (hereinafter referred to as 'the directive') harmonized the national legislative provisions on cosmetic products. Article 7(1) provides that 'Member States may not, for reasons related to the requirements laid down in this directive and the Annexes thereto, refuse, prohibit or restrict the marketing of any cosmetic products which comply with the requirements of this directive and the Annexes thereto.'

3. Article 6(1) provides that cosmetic products may be marketed only if their packaging, containers or labels bear certain information referred to therein 'in indelible, easily legible and visible lettering'.

4. Article 7(3) provides that 'a Member State may require, for the purposes of prompt and appropriate medical treatment in the event of difficulties, that adequate and sufficient information regarding substances contained in cosmetic products is made available to the competent authority, which shall ensure that this information is used only for the purposes of such treatment.'

5. In its judgment in *Firma Eau de Cologne & Parfümerie-Fabrik Glockengasse No 4711* v *Provide SRL* [2] the Court held that

'the directive has provided exhaustively for the harmonization of national rules on the packaging and labelling' [3]

and that the list of particulars required by Article 6(1) was also exhaustive. [4]

6. In support of its application for a declaration of failure to fulfil obligations the Commission claims that Greek law is incompatible with the directive in two respects.

* Original language: French.

1 — On the approximation of the laws of the Member States relating to cosmetic products (OJ 1976 L 262, p. 169).

2 — Judgment in Case 150/88 [1989] ECR 3891.

3 — Paragraph 28.

4 — See paragraph 17.

7. It refers, in the first place, to Article 2 of the Presidential Decree No 532 of 23 May 1981 provides that 'cosmetic products may be marketed only after the manufacturer, or in the case of imported products, the person responsible for marketing, has lodged a declaration with the National Drugs board together with the following information and supporting documents:

(a) the name of the product;

(b) its form;

(c) its composition in terms of ingredients and their quantities;

(d) the name and address of the laboratory or factory where it is made;

(e) the surname and first name and address of the person responsible for marketing;

(f) the physical and chemical constants and a description of the product;

(g) a specimen of the instructions for use;

(h) a specimen of the wording on the label or on each container,

8. The Commission considers that that provision is contrary to the directive. In my opinion the particulars required under (a), (c) and (f) could, if necessary, constitute the 'adequate and sufficient information regarding substances contained in cosmetic products' which the Member State may under Article 7(3) of the directive require to be made available to the competent authority 'for purposes of prompt and appropriate medical treatment in the event of difficulties'. However, in addition to the requirement of a declaration to the National Drugs Board, Article 2(2) of Presidential Decree No 532 provides that 'manufacturers or those responsible for the marketing of cosmetic products are required, for the purposes of prompt and appropriate medical treatment in the event of difficulties, to make available to the Anti-Poisons Centre sufficient directions and information relating to the ingredients of their products. The Anti-Poisons Centre shall ensure that such information is used solely for therapeutic purposes.' That provision seems to constitute exercise of the option given by Article 7(3) of the directive.

9. In my opinion, if a directive allows a Member State to require certain information to be communicated to the *competent authority* for the purposes of preventing any impairment of public health, it is not clear that national legislation which provides for such information to be communicated to *several bodies* is of such a nature that it should be declared incompatible with the Community legislation. The administrative organization of a Member State may justify two authorities, both empowered to inform the public quickly of what should be done in the event of difficulties caused by a cosmetic product, being given the information necessary for that purpose, and in particular information relating to the composition of the product. On the other hand, it cannot be excluded that a Member

State which multiplies the requirements of a declaration to various bodies, even for reasons to do with public health, may go beyond the derogation allowed by the directive from the principle of the free movement of goods.

10. I do not think, however, that the Court has to decide that delicate issue today. It is sufficient, in my opinion, to hold that of the information which must be forwarded to the National Drugs Board the particulars under (b), (d), (e), (g) and (h) are not necessary to enable speedy therapeutic action in the event of difficulties.

11. It is true that at the hearing the Greek Government mentioned a Presidential Decree, No 40/91 of 28 February 1991, which revoked Decree No 532. The Commission has not withdrawn its application. The Court has consistently held that if, subsequent to an application to the Court, the substance of the default ceases to exist, this does not affect the merits of the Commission's application.[5] Irrespective of the proceedings which it has initiated, the Commission must examine the new provision of national law in order to determine whether it correctly transposes the directive. It is apparent from the documents before the Court that the Greek Government proposed to remove certain of the information required in the declaration to be sent to the National Drugs Board. The delicate question which I previously raised may, perhaps, one day be submitted to the Court. As things stand, it does not, in my opinion, require to be settled by the Court today.

12. The second head of incompatibility requires less time for consideration. The Commission objects to Article 5 of the Presidential Decree No 532 which requires that every manufacturer or person responsible for marketing the cosmetic product must keep at the undertaking's seat in Greece a complete file for each manufactured or imported product, containing all particulars relating to the composition, in terms of ingredients and their quantities, the physical and chemical constants and the description of the product, to the formal record of the manufacture and inspection of each batch and the method adopted for such inspection, so that the manufacturer and importer may be in a position, in the event of inspection by sample, of demonstrating the properties of the product.

13. In a letter from its Permanent Representation dated 23 February 1987 the Greek Government informed the Commission that that requirement would be revoked.

14. There is nothing in the directive enabling Member States to lay down such a provision.

15. It seems that Decree No 40/91, cited by the Greek Government at the hearing, has brought Greek law into line with the directive on that point. Nevertheless, the Greek Government did not comply with the reasoned opinion within the prescribed period and the default, in that respect, is established.

5 — See, for example, the judgment in Case 69/77 Commission v Italy [1978] ECR 1749.

16. I therefore conclude that the Court should:

1. declare that the Hellenic Republic has failed to fulfil its obligations under Council Directive 76/768/EEC of 27 July 1976 on the approximation of the laws of the Member States relating to cosmetic products

   (a) by requiring that cosmetic products may be marketed only if a declaration containing information other than that which a Member State may require under Article 7(3) of the directive is lodged with the competent national authority,

   (b) by requiring that every manufacturer of and person responsible for marketing a cosmetic product must keep at the seat of his undertaking in Greece a file for each manufactured or imported product, containing all particulars relating to the composition, properties and the description of the product, to the formal record of the manufacture and inspection of each batch and to the method adopted for such inspection;

2. order the Hellenic Republic to pay the costs.