Where other products are concerned, however they may be classified in national law, it is for the national court to determine whether a monopoly of the right to market such products granted to pharmacists is necessary for the protection of public health or of consumers and whether those two aims cannot be achieved by measures less restrictive of intra-Community trade.

REPORT FOR THE HEARING
in Case C-60/89 *

I — Legal background and facts of the case

A — *Legal background*

(a) *The French legislation on the distribution of medicinal products*

Article L.511 of the Code de la Santé Publique (Public Health Code) defines medicinal products as 'any substance or combination of substances presented for treating or preventing disease in human beings or animals and any product which may be administered to humans or animals with a view to making a medical diagnosis or to restoring, correcting or modifying their physiological functions'. Medicinal products are to be distinguished, in particular, from cosmetic and bodily hygiene products, which are defined by Article L.658-1 of the same code as 'all substances or products other than medicinal products intended to be brought into contact with various parts of the human body or teeth or mucous membrane, with a view to cleaning them, protecting them, keeping them in good condition, changing their appearance, perfuming them or correcting their odours'.

Pursuant to Article L.511, cosmetic products are not to be regarded as medicinal products unless they contain certain substances. The same applies to dietetic products.

Trade in medicinal products is strictly regulated. Under Article L.601 of the Code de la Santé Publique, proprietary medicinal products, namely 'any ready-prepared medicinal product, presented in a particular packaging and under a special name', may be marketed only after a marketing authorization for them has been issued by the Ministre des Affaires Sociales (Minister for Social Affairs).

Pursuant to Article L.512 of the code, the marketing of medicinal products and proprietary medicinal products (as well as the sale of other products such as medicinal plants appearing in the pharmacopoeia) *may be undertaken only by pharmacists* who fulfil

* Language of the case: French.

the conditions laid down by Article L.514 and must take place in a *dispensary*, the number of which is limited by Articles L.570 to L.573. Pursuant to Article L.514, a person wishing to practise the profession of pharmacist must satisfy 'all requirements as to proper professional ethical standards' and also (a) hold a pharmacist's diploma, (b) be of French nationality or have the nationality of one of the Member States of the European Economic Community and (c) be a member of the Ordre des Pharmaciens.

Article L.570 et seq. of the Code de la Santé Publique *limit the number of dispensaries by reference to population.* The general rules are contained in Article L.571, which provides for a dispensary for every 3 000 inhabitants in cities of 30 000 or more inhabitants, one for every 2 500 inhabitants in cities with a population of between 5 000 and 30 000 inhabitants and one for every 2 000 inhabitants in municipalities with a population of fewer than 5 000 inhabitants.

Article L.572 lays down different requirements for the départements of Haut-Rhin, Bas-Rhin and Moselle, namely one dispensary for every 5 000 inhabitants. Special rules apply to the overseas départements.

Article L.596 of the Code de la Santé Publique provides that every establishment involved in the production, wholesale sale or distribution of medicinal and other products covered by the pharmacists' monopoly 'must be owned by a pharmacist or by a company in whose management or overall administration a pharmacist is involved'.

Encroachments on the pharmacists' monopoly are penalized under Article L.517 of the Code de la Santé Publique by a fine of FF 3 600 to 30 000 or imprisonment of six days to six months or both and infringements of Articles L.596 and L.601 of the code are penalized under Article L.518 by a fine of FF 360 to 15 000 or imprisonment of six days to three months or both.

(b) *The Community legislation on medicinal products and cosmetics*

1. Medicinal products and pharmacy

Council Directive 65/65/EEC of 26 January 1965 (Official Journal, English Special Edition 1965-1966, p. 20) defines a medicinal product as 'Any substance or combination of substances presented for treating or preventing disease in human beings or animals' or 'Any substance or combination of substances which may be administered to human beings or animals with a view to making a medical diagnosis or to restoring, correcting or modifying physiological functions in human beings or in animals'.

Proprietary medicinal products are defined as 'Any ready-prepared medicinal product placed on the market under a special name and in a special pack' (Article 1 of the directive).

The essential purpose of Directive 65/65 is to require an *authorization for the marketing* of proprietary medicinal products. Pursuant to Article 3, 'No proprietary medicinal product may be placed on the market in a

Member State unless an authorization has been issued by a competent authority of the Member State concerned'. The directive lays down, in particular, the conditions for granting and withdrawing such authorization for products to be placed on the market.

Directive 65/65 has been amended on several occasions, essentially in order to promote the free movement of pharmaceutical products. Thus, Council Directive 75/319/EEC of 20 May 1975 (Official Journal 1975 L 147, p. 13) established *inter alia* a system to facilitate the issue of marketing authorizations in several Member States, through a 'Committee for Proprietary Medicinal Products' provided for by Article 8. The system was reinforced and modified by Council Directive 83/570/EEC of 26 October 1983 (Official Journal 1983 L 332, p. 1) and by Council Directive 87/21/EEC of 22 December 1986 (Official Journal 1987 L 15, p. 36). Council Directive 87/22/EEC of 22 December 1986 (Official Journal 1987 L 15, p. 38) concerns high-technology medicinal products. Finally, Council Decision 75/320/EEC of 20 May 1975 (Official Journal 1975 L 147, p. 23) established a 'Pharmaceutical Committee' responsible for examining questions relating to the application of directives on proprietary medicinal products and giving its opinion to the Commission in connexion with the preparation of directives concerning proprietary medicinal products.

As regards *the pursuit of the profession of pharmacist*, Council Directive 85/432/EEC of 16 September 1985 (Official Journal 1985 L 253, p. 34 lays down the conditions for the issue of diplomas, certificates and other evidence of formal qualifications in pharmacy and facilitates access by the holders of such qualifications to a limited field of activities. Council Directive 85/433/EEC of 16 September 1985 (Official Journal L 253, p. 37) is concerned with the mutual recognition of diplomas and other evidence of formal qualifications in pharmacy.

2. Cosmetics

Council Directive 76/768/EEC of 27 July 1976 on the approximation of the laws of the Member States relating to cosmetic products (Official Journal 1976 L 262, p. 169) defines a cosmetic product as 'any substance or product intended for placing in contact with the various external parts of the human body (epidermis, hair system, nails, lips and external genital organs) or with the teeth and the mucous membranes of the oral cavity with a view exclusively or principally to cleaning them, perfuming them or protecting them in order to keep them in good condition, change their appearance or correct body odours'.

Article 2 of the same directive provides that cosmetic products put on the market within the Community 'must not be liable to cause damage to human health when they are applied under normal conditions of use', and pursuant to Article 7 the Member States may not restrict the marketing of cosmetic products which are in conformity with the directive.

As regards the distinction between medicinal products and cosmetic products, the fifth recital in the preamble to Directive 76/768 states that the delimitation between the scope of that directive and that of the directive applicable to medicinal products

'follows in particular from the detailed definition of cosmetic products, which refers both to their areas of application and to the purposes of their use . . . this directive is not applicable to the products that fall under the definition of cosmetic products but are exclusively intended to protect from disease'.

B — *The facts of the dispute and the questions submitted by the Cour d'Appel, Aix-en-Provence, France*

(a) *The facts of the case*

Criminal proceedings were instituted against Mr Samanni, the manager of a 'Casino'shop in Marseilles, following a complaint made by the Syndicat des Pharmaciens des Bouches-du-Rhône (Pharmacists' Association of the Bouches-du-Rhône), for selling in his self-service shop, in May 1986, eosin of a strength of 2% and modified alcohol of a strength of 70%, on the ground that those products must be regarded as medicinal products which in France are included within the pharmacists' monopoly.

Mr Monteil, the purchasing manager of the 'Casino'group, who had furnished supplies to Mr Sammani's shop, was prosecuted as an accessory.

On 14 June both defendants were fined FF 8 000 by the Tribunal Correctionnel (Criminal Court), Marseilles, and ordered to pay 1 franc damages to the Syndicat des Pharmaciens des Bouches-du-Rhône and FF 2 000 costs. They appealed to the Cour d'Appel, Aix-en-Provence.

Before that Court they claimed that neither eosin of a strength of 2% nor alcohol of a strength of 70% could be regarded as a medicinal product by virtue either of their presentation or of their function.

(b) By judgment of 7 November 1988, the Cour d'Appel, Aix-en-Provence, therefore sought a preliminary ruling from the Court of Justice as to 'whether eosin of a strength of 2% and modified alcohol of a strength of 70% are medicinal products the right to sell which is reserved to pharmacists, as defined by European Community law'.

The order for reference was received at the Court Registry on 1 March 1989.

Pursuant to Article 20 of the Protocol on the Statute of the Court of Justice of the EEC, written observations were submitted by the defendants in the main proceedings, represented by Fourgoux et Associés, Paris, by the Italian Government, represented by Pier Giorgio Ferri, Avvocato dello Stato, acting as Agent, and by the Commission of the European Communities, represented by Blanca Rodríguez Galindo, a member of the Commission's Legal Department, and Hervé Lehman, a French official seconded to the Legal Department of the Commission under the national civil service exchange scheme, acting as Agents.

Upon hearing the report of the Judge-Rapporteur and the views of the Advocate General, the Court decided to open the oral procedure without any preparatory inquiry.

By decision of 13 June 1990, the Court assigned the case to the Fifth Chamber.

II — Summary of the written observations submitted to the Court

A — *Observations of Mr Samanni and Mr Monteil*

Mr Sammani and Mr Monteil ('the defendants') observe first that the question submitted to the Court seeks to classify the products at issue by reference both to Directive 65/65 on the approximation of the laws of the Member States relating to proprietary medicinal products and to Directive 76/768 on cosmetic products.

It is therefore necessary to draw a dividing line between medicinal products and cosmetic products.

In the proceedings against them, eosin and modified alcohol of a strength of 70% are classified as medicinal products, so that they may be sold only by pharmacists and a marketing authorization is required for that purpose.

The defendants state that the medicinal products and cosmetics sectors have been the subject of far-reaching harmonization, as was acknowledged by the Court of Justice in its judgment in Joined Cases 87 and 88/85 *Legia* [1986] ECR 1707, with the result that recourse to Articles 30 and 36 of the EEC Treaty should progressively become unnecessary.

They also state that by virtue of the principle of proportionality, restrictions imposed on the free movement of goods under Article 36 of the EEC Treaty must be limited to what is necessary in order to achieve the legitimately pursued objective of protection of public health, and it is for the national authorities to prove that the measures adopted are lawful.

According to the defendants, Directive 76/768 on cosmetic products lays down the maximum level of protection of public health, and any additional measure is disproportionate and cannot therefore be justified on the basis of Article 36 of the EEC Treaty.

As regards more specifically the classification of the products at issue, Messrs Samanni and Monteil contend that they are disinfectants in common use and not medicinal products. Medical works list various antiseptics, bactericides or disinfectants which are nevertheless not classified as medicinal products. Furthermore, the products at issue are intended not to be taken internally but to be applied externally.

The French administrative authority responsible for competition, consumer affairs and the prevention of fraud itself considers that those products have no direct link with any pathological condition. In addition, the presentation of those products is such as to preclude any risk of confusion with medicinal products.

Both the products concerned are cosmetic products falling within the definition of such products given in Directive 76/768. They are designed above all to be brought into

contact with the skin or nails, mainly in order to clean, perfume or protect them and keep them in good condition. Neither product presents any danger to consumers, particularly since they are sold in 'Casino' shops with the instruction 'Do not swallow'.

In those circumstances, Messrs Samanni and Monteil propose that the Court state in reply to the question referred to it that the products at issue fall within the definition of cosmetic products and not that of medicinal products and that accordingly no Member State may restrict the marketing of cosmetic products which fulfil the requirements of Directive 76/768.

B — The *Commission* states first that the definition of medicinal products in Directive 65/65 relates either to the presentation of the product or to its functions. However, the purpose of the directive, and of its definition of medicinal products, is not to determine a category of products included in the pharmacists' monopoly but to specify products which, in the interest of protecting public health, are subject to a system of prior marketing authorizations under the conditions laid down in the directive.

The second recital in the preamble to Directive 85/432 also states that the geographical distribution of dispensaries and the monopoly of the supply of medicinal products continue to be matters for the Member States.

Whilst it is true that, in view of the particular nature of medicinal products, a general rule exists in all the Member States by virtue of which such products may be sold to the public only through pharmacies, the approach adopted nevertheless differs considerably from one Member State to another — for example Germany, Ireland, the Netherlands and the United Kingdom allow certain medicinal products, known as 'over-the-counter' medicinal products, to be sold through outlets other than pharmacies.

Under those circumstances it is necessary, in the Community context, to examine the national rules on the distribution of medicinal products in the light of the rules on the free movement of goods where imported products are concerned.

In that regard, the Commission points out that the channelling of sales through a particular marketing network may have an impact on imports, which could be affected both by the reduction in total sales and by the increase in prices which might result.

The Commission observes, however, that such measures apply without distinction, ruling out any discrimination, and that the question therefore arises whether they are contrary to Article 30 of the EEC Treaty. If so, it would be necessary to determine whether they might be justified under Article 36, which the Commission considers to be the case in the absence of sufficient harmonization in that sector.

As far as the products at issue in this case are concerned, the Commission observes that eosin of a strength of 2% is regarded as an antiseptic and antibacterial agent and is used for the treatment of infectious skin conditions such as herpes, eczema, burns and ulcers. Alcohol is used in particular to prevent human skin infections. It seems clear to the Commission in those circumstances that neither eosin of a strength of 2% nor alcohol of a strength of 70% is used for any of the purposes covered by Directive 76/768 on cosmetic products. Accordingly, in so far as those products are presented as antiseptics or antibacterial agents for the treatment of disorders they should be regarded as medicinal products within the meaning of Directive 65/65.

The Commission therefore proposes that the Court should state in reply to the question submitted by the Cour d'Appel, Aix-en-Provence, that 'eosin of a strength of 2% and alcohol of a strength of 70% must, in so far as they are presented with a view to being applied to the human skin as antiseptic or antibacterial agents for the treatment of infections, be regarded as medicinal products within the meaning of Council Directive 65/65 on the approximation of the laws of the Member States relating to proprietary medicinal products' and that 'neither the applicable Community rules nor Articles 30 and 36 of the EEC Treaty prohibit a Member State from granting to pharmacists, on grounds of health protection, a monopoly of the sale of certain products regarded as medicinal products'.

C — The *Italian Government* states that it is necessary to take into account, in classifying the products at issue, all the factors set out in Directive 65/65 and that the specific application of the criteria laid down in the directive is a matter for the Member States, which enjoy a degree of discretion provided that no manifest error of appraisal is committed.

F. Grévisse
Judge-Rapporteur