OPINION OF ADVOCATE GENERAL SAGGIO

delivered on 25 June 1998 *

1. On 1 August 1997, the Commission of the European Communities brought an action under Article 169 of the EC Treaty for a declaration that, by failing to adopt the laws, regulations and administrative provisions necessary to comply with 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 administrative action relating to medicinal products and laying down additional provisions on homeopathic medicinal products (hereinafter 'the Directive'), [1] the Kingdom of Belgium has failed to fulfil its obligations under the EC Treaty and the Directive.

2. Under the first subparagraph of Article 10(1) of the Directive, Member States were to take the measures necessary to comply with the Directive by 31 December 1993 and forthwith to inform the Commission thereof.

3. Since it had not received any communication from the Belgian Government relating to the transposition of the Directive into Belgian law and had no information to show that the Kingdom of Belgium had fulfilled its obligation to comply with the provisions of the Directive, on 10 February 1994, under the procedure provided for by Article 169 of the Treaty, the Commission called upon that State to submit its observations within a period of two months.

4. By letter of 12 June 1995 from the Belgian permanent representation to the European Union, the Belgian authorities informed the Commission that measures to transpose the Directive were being prepared.

5. As it had received no further information on the adoption of such measures, the Commission, by letter of 4 March 1997, sent a reasoned opinion to the Kingdom of Belgium, in which it expressed the view that, by failing to adopt the laws, regulations and administrative provisions necessary to comply with the Directive, the Kingdom of Belgium had failed to fulfil its obligations under the Directive. The Commission also called on the Kingdom of Belgium, pursuant to the second paragraph of Article 169 of the Treaty, to take the measures necessary to comply with that reasoned opinion within two months of its notification.

* Original language: Italian.

1 — OJ 1992 L 297, p. 8.

6. On 29 April 1997 the Belgian authorities sent the Commission the draft Royal Decree which contained provisions implementing the Directive.

7. In its application the Commission points out that since, according to settled case-law, the Member States to whom a directive is addressed are obliged to bring their domestic legislation into line with the provisions of that directive within the period prescribed therein and may not plead provisions, practices or circumstances existing in their internal legal systems in order to justify a failure to comply with the obligations and time-limits laid down in Community directives, the defendant State has failed to fulfil its obligations under the Directive inasmuch as on expiry of the period prescribed by the Directive it had not adopted any measures to implement the provisions thereof.

8. In its defence the Kingdom of Belgium does not dispute that it had failed to adopt the domestic provisions necessary to implement the Directive. It merely points out that a draft Royal Decree concerning the registration of medicines and containing provisions implementing the Directive was sent to the Conseil d'État in May 1997 and was thus awaiting the opinion of that body.

9. In the light of the evidence put forward by the parties I consider that the application brought by the Commission is well founded. The Kingdom of Belgium has not implemented the provisions of the Directive within the period prescribed by Article 10 thereof.

Moreover, it must be borne in mind that, according to consistent case-law, the fact that the procedure for transposing the Directive was in progress, as argued by the defendant government, does not mean that the application is unfounded or devoid of purpose since 'the question whether a Member State has failed to fulfil its obligations must be determined by reference to the situation prevailing in the Member State at the end of the period laid down in the reasoned opinion, and subsequent changes cannot be taken into account'. [2]

10. In the light of the foregoing observations, I propose that the Court should:

(1) declare that, by failing to adopt the laws, regulations and administrative provisions necessary to comply with Council Directive 92/73/EEC of 22 September

2 — See, most recently, Joined Cases C-232/95 and C-233/95 *Commission* v *Greece* [1998] ECR I-3343.

1992 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 the Kingdom of Belgium has failed to fulfil its obligations under the Directive;

(2) order the Kingdom of Belgium to pay the costs.