OPINION OF ADVOCATE GENERAL VAN GERVEN
delivered on 28 April 1993 *

Mr President,
Members of the Court,

1. By the present action the Commission, acting in accordance with Article 141 of the Euratom Treaty, is seeking a declaration that the Italian Republic, by failing to adopt the laws, regulations and administrative provisions necessary to comply with Articles 1, 2(1) and (2), 3 and 5 of Council Directive 84/466/Euratom of 3 September 1984 laying down basic measures for the radiation protection of persons undergoing medical examination or treatment [1] (hereinafter 'the Directive'), has failed to fulfil its obligations under the Euratom Treaty.

2. Article 7 of the Directive provides that Member States are to transpose the Directive into national law before 1 January 1986. The Italian Republic concedes that formal transposition has not yet taken place, but claims that that is unnecessary, because the Directive adds nothing to the content of Circular No 62 of 2 August 1984, which had already been sent to all the competent Italian authorities and services.

3. As the Court has consistently held, mere administrative practices cannot be regarded as proper fulfilment of the obligation imposed on Member States to which directives are addressed. [2] Such practices can be changed as and when the authorities please and are not publicized widely enough. The expression 'administrative practices' also includes internal memoranda and circulars. [3]

It is also settled law that the transposition of a directive into domestic law does not necessarily require that its provisions be incorporated formally and verbatim in express, specific legislation; a general legal context may, depending on the content of the directive, be adequate for the purpose provided that it does indeed guarantee the full application of the directive in a sufficiently clear and precise manner so that, where the directive is intended to create rights for individuals, the persons concerned can ascertain the full extent of their rights and, where appropriate,

* Original language: Dutch.

1 — OJ 1984 L 265, p. 1.

2 — See Case 102/79 *Commission* v *Belgium* [1980] ECR 1473, paragraph 11, recently upheld in Case C-235/91 *Commission* v *Ireland* [1992] ECR I-5917, paragraph 10, and Case C-236/91 *Commission* v *Ireland* [1992] ECR I-5933, paragraph 6.

3 — See Case C-64/90 *Commission* v *France* [1991] ECR I-4335, where the Court held that circulars do not constitute adequate transposition of a directive. That judgment also concerned a directive the protection of public health.

rely on them before the national courts. [4] In order to secure the full implementation of directives in law and not only in fact, Member States must establish a clear legal framework in the area in question. [5]

4. In accordance with that line of decisions, Italian Circular No 62 cannot be regarded as constituting adequate transposition of the Directive into Italian law. It is apparent from the written and oral submissions of the parties that the circular was never officially published. It is also apparent that the circular could be altered as and when the Italian authorities considered it appropriate and that it contained only recommendations with no binding nature, while — as regards medical attendance (Articles 2 and 5) and control of the appliances used (Article 3) — the Directive requires the introduction of a certain number of specific and binding rules from which users of the medical services concerned can, if necessary, derive subjective rights.

Only a legislative measure which is binding on everyone can guarantee the Italian citizens whom the Directive is intended to protect the legal certainty and protection prescribed therein.

5. In sum, I propose that the Court should:

(1) declare that by failing to adopt the laws, regulations and administrative provisions necessary to implement Council Directive 84/466/Euratom of 3 September 1984 laying down basic measures for the radiation protection of persons undergoing medical examination or treatment, the Italian Republic has failed to fulfil its obligations under the Euratom Treaty;

(2) order the Italian Republic to pay the costs.

4 — See, for example, Case C-131/88 *Commission* v *Germany* [1991] ECR I-825, paragraph 6; Case C-59/89 *Commission* v *Germany* [1991] ECR I-2607, paragraph 18; and Case C-64/90, cited above, paragraph 1 of the summary.

5 — Case C-339/87 *Commission* v *Netherlands* [1990] ECR I-851, paragraph 25, recently upheld in Case C-64/90, cited above, paragraph 1 of the summary.