



EUROPEAN COMMISSION
ENTERPRISE DIRECTORATE-GENERAL

Single Market : regulatory environment, standardisation and New Approach
Pressure equipment, medical devices, metrology

Brussels,
G4/SH D(2004)

Note to the File

Question with regard to Directive 98/79/EC on *in vitro* diagnostic medical devices

Member State Competent Authorities raised the question whether or not IVDs manufactured and used within the same health institutions, but used in order to test samples from patients from other health institutions, are excluded from the scope of Directive 98/79/EC of the European Parliament and of the European Council of 27 October 1998 on *in vitro* medical devices.

The question relates in particular to Articles 1 (5) and 9 (13) of Directive 98/79/EC. Article 1 of the Directive contains definitions and defines the scope of the Directive. Its paragraph 5 reads:

“This Directive shall not apply to devices manufactured and used only within the same health institution and on the premises of their manufacture or used on premises in the immediate vicinity without having been transferred to another legal entity. This does not affect the right of Member State to subject such activities to appropriate protection requirements.”

The motivation of this provision is expressed in Recital 10, which reads:

“Whereas, having regard to the principle of subsidiarity, reagents which are produced within health-institution laboratories for use in that environment and are not subject to commercial transactions are not covered by this Directive;”

Article 1 (5) sets out the scope of the Directive, which means that once an *in vitro* medical device (IVD) fulfils the criteria laid down in this provision, no other provision of the Directive shall apply to it unless specified that it is a derogation to Article 1 (5). Accordingly, IVDs are excluded from the scope if they fulfil the following three criteria:

- the IVDs are manufactured on the premises of a health institution;
- the IVDs are used on these premises or in the immediate vicinity (which means: no transportation of the IVDs);
- the IVDs are not transferred to another legal entity.

According to these criteria, IVDs manufactured and used in one health institution are excluded from the scope of the IVD. Whether or not the IVDs are used on in-house or out-house patients is irrelevant.

Article 9 (13), cited by some Member States in favour of including such IVDs in the scope of the Directive, reads:

“The provisions of this Article shall apply accordingly to any natural or legal person who manufactures devices covered by this Directive and, without placing them on the market, puts them into service and uses them in the context of his professional activity.”

The motivation for this provision is to be found in Recital 11:

“Whereas, however, devices that are manufactured and intended to be used in a professional and commercial context for purposes of medical analysis without being marketed are subject to this Directive;”

According to its clear wording – and to its place in the text of the Directive – this provision applies to the IVDs covered by the Directive. It therefore does not limit or widen the scope of the Directive, which is defined in Article 1. The provision would apply in the case of a manufacturer of IVD’s which carries out the analysis, but without being a health institution.

In conclusion, according to the reading of the Commission’s services IVDs manufactured and used in one health institution are excluded from the scope of the Directive, irrespective of whether they are used for testing samples of patients of that institution or of another institution. Obviously, any final interpretation of the Directive is left to the European Court of Justice.

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