Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 on in vitro diagnostic medical devices

Article 21

Amendment of directives

[[X1]1 In Directive 98/37/EC, the second indent of Article 1(3), 'machinery for medical use, used in direct contact with patients' shall be replaced by the following:**]**

— medical devices,

.

2 Directive 93/42/EEC is hereby amended as follows:

a in Article 1(2):

— point (c) shall be replaced by the following:

(c) "*in vitro* diagnostic medical device" means any medical device which is a reagent, reagent product, calibrator, control material, kit, instrument, apparatus, equipment or system, whether used alone or in combination, intended by the manufacturer to be used *in vitro* for the examination of specimens, including blood and tissue donations,

derived from the human body, solely or principally for the purpose of providing information:

— concerning a physiological or pathological state, or

— concerning a congenital abnormality, or

— to determine the safety and compatibility with potential recipients, or

— to monitor therapeutic measures.

Specimen receptacles are considered to be *in vitro* diagnostic medical devices. "Specimen receptacles" are those devices, whether vacuum-type or not, specifically intended by their manufacturers for the primary containment and preservation of specimens derived from the human body for the purpose of *in vitro* diagnostic examination.

Products for general laboratory use are not *in vitro* diagnostic medical devices unless such products, in view of their characteristics, are specifically intended by their manufacturer to be used for *in vitro* diagnostic examination;

— point (i) shall be replaced by the following:

(i) "putting into service"	means the stage at which a device has been made available to the final user as being ready for use on the Community market for the first time for its intended purpose;

— the following point shall be added:

(j) "authorised representative"	means any natural or legal person established in the Community who, explicitly designated by the manufacturer, acts and may be addressed by authorities and bodies in the Community instead of the manufacturer with regard to the latter's obligations under this Directive;

b Article 2 shall be replaced by the following:

Article 2

Placing on the market and putting into service

Member States shall take all necessary steps to ensure that devices may be placed on the market and/or put into service only if they comply with the requirements laid down in this Directive when duly supplied andproperly installed, maintained and used in accordance with their intended purpose.

c the following paragraph shall be added to Article 14(1):

For all medical devices of classes IIb and III, Member States may request to be informed of all data allowing for identification of such devices together with the label and the instructions for use when such devices are put into service within their territory.

d the following Articles shall be inserted:

Article 14a

European databank

1 Regulatory data in accordance with this Directive shall be stored in a European database accessible to the competent authorities to enable them to carry out their tasks relating to this Directive on a well-informed basis.

The databank shall contain the following:

a data relating to registration of manufacturers and devices in accordance with Article 14;

b data relating to certificates issued, modified, supplemented, suspended, withdrawn or refused according to the procedures, as laid down in Annexes II to VII;

c data obtained in accordance with the vigilance procedure as defined in Article 10;

2 Data shall be forwarded in a standardised format.

3 The procedures implementing this Article shall be adopted in accordance with the procedure laid down in Article 7(2).

Article 14b

Particular health monitoring measures

Where a Member State considers, in relation to a given product or group of products, that, in order to ensure protection of health and safety and/or to ensure that public health requirements are observed pursuant to Article 36 of the Treaty, the availability of such products should be prohibited, restricted or subjected to particular requirements, it may take any necessary and justified transitional measures. It shall then inform the Commission and all the other Member States giving the reasons for its decision. The Commission shall, whenever possible, consult the interested parties and the Member States and, where the national measures are justified, adopt necessary Community measures in accordance with the procedure referred to in Article 7(2).

e the following paragraphs shall be added to Article 16:

5. The notified body shall inform the other notified bodies and the competent authority about all certificates suspended or withdrawn and, on request, about certificates issued or refused. It shall also make available, on request, all additional relevant information.

6 Where a notified body finds that pertinent requirements of this Directive have not been met or are no longer met by the manufacturer or where a certificate should not have been issued, it shall, taking account of the principle of proportionality, suspend or withdraw the certificate issued or place any restrictions on it unless compliance with such requirements is ensured by the implementation of appropriate corrective measures by the manufacturer. In the case of suspension or withdrawal of the certificate or of any restriction placed on it or in cases where an intervention of the competent authority may become necessary, the notified body shall inform its competent authority thereof. The Member State shall inform the other Member States and the Commission.

7 The notified body shall, on request, supply all relevant information and documents including budgetary documents, required to enable the Member State to verify compliance with Annex XI requirements.

f the following paragraph shall be added to Article 18:

Those provisions shall also apply where the CE marking has been affixed in accordance with the procedures in this Directive, but inappropriately, on products that are not covered by this Directive.

g in Article 22(4), the first subparagraph shall be replaced by the following:

4. Member States shall accept:

— devices which conform to the rules in force in their territory on 31 December 1994 being placed on the market during a period of five years following the adoption of this Directive, and

— the aforementioned devices being put into service until 30 June 2001 at the latest.

h Annex II, section 6.2, Annex III, section 7.1, Annex V, section 5.2 and Annex VI, section 5.2 shall be deleted;

i in Annex XI, section 3 the following sentence shall be inserted after the second sentence: ‘This presupposes the availability of sufficient scientific staff within the organisation who possess experience and knowledge sufficient to assess the medical

functionality and performance of devices for which it has been notified, having regard to the requirements of this Directive and, in particular, those set out in Annex I.'

Editorial Information

X1 Substituted by Corrigendum to Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 on in vitro diagnostic medical devices (Official Journal of the European Communities L 331 of 7 December 1998).