



COMMISSION OF THE EUROPEAN COMMUNITIES

Brussels, 02.10.1998

COM(1998) 548 final

95/0013 (COD)

OPINION OF THE COMMISSION

pursuant to Article 189 b (2) (d) of the EC Treaty,
on the European Parliament's amendments
to the Council's common position regarding the

proposal for a
EUROPEAN PARLIAMENT AND COUNCIL DIRECTIVE
on in vitro diagnostic medical devices

AMENDING THE PROPOSAL OF THE COMMISSION

pursuant to Article 189 a (2) of the EC Treaty

1. BACKGROUND

a) Objective of the proposal

The proposal for a directive, based on Article 100a of the Treaty, is intended to harmonise national provisions applicable to the placing on the market of in vitro diagnostic medical devices. It lays down the requirements to be met by the products with regard to protecting the health and safety of patients, users and third parties; the conditions governing their placing on the market and aspects concerning checks on products already on the market. Article 21 also provides for a number of amendments to Directive 93/42/EEC on medical devices, to include devices manufactured using human tissues in the scope of Directive 93/42/EEC, and to bring Directive 93/42/EEC more closely into line with the Directive on in vitro diagnostic devices.

b) Date of the submission of the proposal to the Council (document COM(95)130 final – 95/0013 (COD)): 19 April 1995

c) Opinion of the Economic and Social Committee: 25 October 1995

d) Date of the European Parliament's opinion on first reading: 14 March 1996

e) Date of the adoption of the common position : 23 March 1996

f) Date of the presentation of an amended Commission proposal (document COM(96) 643 final): 20 December 1996

g) Commission communication to the European Parliament pursuant to Article 189b(2) (document SEC(1998) 555 final): 26 March 1998

h) Date of the European Parliament's decision on second reading: 18 June 1998

2. POSITION OF THE EUROPEAN PARLIAMENT

At its plenary session in June 1998, the European Parliament adopted 6 amendments to the Council common position. These are intended to:

- emphasise the need to notify the competent authorities of the placing on the market of new products, such as DNA micro-chips (amendment 1, Recital 29a)
- insist on the need for Community legislation on medical devices manufactured using human tissues or cells (amendment 2, Recital 33a);
- clarify that the option for Member States to demand supplementary information for certain medical devices is not a precondition for the placing on the market or putting into service of in vitro diagnostic medical devices (amendment 3, Article 10(2), second subparagraph);

- oblige manufacturers to translate the label and the instructions for use of the self-testing devices into one or more of the languages of the Member State where the in vitro diagnostic medical device reaches its final user (amendment 4, Annex I, (B)(8.1), fifth paragraph a);
- oblige manufacturers to submit the tests used for evaluating the risk of trisomy 21 (Down's Syndrome in the foetus) to certification by a third party (amendment 5, Annex II, List B, seventh indent a);
- emphasise, with regard to diagnosis, the primary importance of protecting the confidentiality of the information obtained and the principle of non-discrimination on the basis of the genetic characteristics of the person being examined (amendment 6, Article 1(4)).

3. OPINION OF THE COMMISSION

The Commission is able to accept the amendments:

- amendment 1 because the new recital relates to the notification procedure for "new products" provided for under Article 10(4), and gives an important example of the application of that Article;
- amendment 2 because the recital recalls the need, recognised by the Member States, for harmonised legislation on medical devices manufactured from substances of human origin. In addition to the essential part on in vitro diagnostic medical devices, the Commission proposal (COM(95) 130 final) provided for the inclusion of devices incorporating substances of human origin in the scope of Directive 93/42/EEC on medical devices. This part was separated from that relating to in vitro diagnostic devices and is still before the Council for a first reading;
- amendment 3 because it clarifies the interpretation that should be given to the procedure according to which Member States may request information regarding the labelling and the instructions for use of certain products. The addition is useful, as it prohibits supplementary national procedures other than those provided for in the Directive on the placing on the market of in vitro diagnostic medical devices.
- amendment 4 because it adds a useful clarification with regard to the extent of the labelling obligations for self-testing devices, in accordance with the principle already included in Article 4(4);
- amendment 5 because the extension of certification obligations by a third party to tests designed to assess the risk of trisomy 21 (Down's Syndrome) in the foetus is justified, as it is necessary to ensure a very high level of quality of devices as false positive results from the tests have serious consequences for the patient and the foetus;

- amendment 6 because it restates the rights set out in the European Convention for the Protection of Human Rights and Fundamental Freedoms with regard to the applications of biology and medicine referred to in Article 1(4).

For these reasons, and pursuant to Article 189a of the EC Treaty, the Commission has decided to amend its proposal to incorporate the 6 amendments adopted by the European Parliament.

Amended proposal for a
European Parliament and Council Directive
on in vitro diagnostic medical devices

(presented by the Commission pursuant to Article 189a(2) of the EC Treaty)

Common position of the
Council

Modified proposal

Recital 29a (new)

(29a) Whereas it is essential that manufacturers notify the competent authorities of the placing on the market of 'new products' with regard both to the technology used and the substances to be analysed or other parameters; this is true in particular of high-density DNA probe devices (known as micro-chips) used in genetic screening,

Recital 33a (new)

(33a) Whereas it is necessary to draw up as quickly as possible the legislation which is lacking on medical devices manufactured using substances of human origin;

Article 1(4)

For the purposes of this Directive, the removal, collection and use of tissues, cells and substances of human origin shall be governed, in relation to ethics, by the principles laid down in the Convention of the Council of Europe for the protection of human rights and dignity of the human being with regard to the application of biology and medicine and by any Member States' regulations on this matter.

For the purposes of this Directive, the removal, collection and use of tissues, cells and substances of human origin shall be governed, in relation to ethics, by the principles laid down in the Convention of the Council of Europe for the protection of human rights and dignity of the human being with regard to the application of biology and medicine and by any Member States' regulations on this matter. As regards diagnosis, protection of the confidentiality of data relating to private life and the principle of non-discrimination

on grounds of human inherited genetic characteristics shall be paramount.

Article 10(2), second
subparagraph (new)

These measures cannot constitute a precondition for the placing on the market and/or putting into service of devices which are in conformity with this Directive.

Annex 1, (B)(8.1),
5th subparagraph a
(new)

The decision whether to translate the instructions for use and the label into one or more languages of the European Union shall be left to the Member States, except that, for self-testing devices, the instructions for use and the label shall include a translation into the official language(s) of the Member State in which the device for self-testing reaches its final user.

Annex II, List B,
7th indent a (new)

Reagents and reagent products, including related calibrators, control materials and software, designed specifically for evaluating the risk of trisomy 21.

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DOCUMENTS

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