Working Paper on the Clarification of Article 14 b of Directive 93/42/EEC (MDD)

19 March 2004

Current text of Article 14b MDD

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).

Current text of Recital (4):

Whereas the harmonized provisions must be distinguished from the measures adopted by the Member States to manage the funding of public health and sickness insurance schemes relating directly or indirectly to such devices, whereas, therefore, the provisions do not affect the ability of the Member States to implement the abovementioned measures provided Community law is complied with.

The Report on the Functioning of the Medical Device Directive pointed to the need to clarify the way and conditions under which Member States can apply Article 14 b MDD. While reference is made here to Article 14 b of Directive 93/42/EEC, the same applies in principle to Article 13 of Directive 98/79/EC.

1) Clarification of the Scope of Article 14 b MDD

The MDD determines the conditions under which medical devices can be placed on the market and put into service. . It does not harmonize other aspects in relation to medical devices, such as their distribution, in-use requirements or reimbursement. Any Member State legislation on these aspects does, therefore, not fall in the scope of the MDD. The current wording of Article 14 b is ambiguous in that it appears to also refer to such measures and should, therefore, be clarified. This ambiguity relates to the title, the use of the term "availability" and the reference to Article 36.

In order to clarify the scope it is proposed to change the title of Article 14 b, to delete the term "availability" and the reference to Article 36 EC Treaty (now Article 30 EC Treaty), to elaborate Recital (4) and to add a new recital.

Such clarification would not have as a consequence that Member States have less possibilities to intervene on the market than currently is the case.

- ✓ Member States maintain the possibility to take action in non-harmonized areas, subject to 28 to 30 EC Treaty.

See in this regard the Commission Decision of 25 January 2002 on the national provisions concerning HIV testing kits notified under Article 95 (4) of the EC Treaty by the United Kingdom as regards Directive 97/79/EC on *in vitro* diagnostic medical devices (2002/65/EC)[1]). The Commission considered in this Decision that measure relating to the restrictions to the distribution of HIV testing kits did not require notification as it fell outside the scope of the Directive

✓ It does neither prevent Member States from taking, under specific conditions, precautionary measures.

According to the case law of the European Court of Justice a Member State may, in accordance with the precautionary principle, take protective measures without having to wait until the existence and gravity of those risks are fully demonstrated (see to that effect Case C-157/96 National Farmers' Union and Others [1998] ECR I-2211, paragraph 63). Any precautionary measure at Member State level must comply with the requirements as outlined in the Communication from the Commission on the precautionary principle (COM(2000)1) and as set out in the case law of the European Court of Justice. Application of the precautionary principle cannot lead to arbitrary measures to be adopted by Member States or the Commission.

2) Type of measures that can be taken by the Member States and relation with the Safeguard Clause

The description of the type of measures Member States can take under Article 14 b should be better specified with respect to the safeguard clause in Article 8 MDD. Under both provisions Member States can withdraw devices from the market, or prohibit or restrict their being placed on the market or put into service, can thus take product related measures. However, these measures are different as regards the basis for action and the consequences.

Under Article 8, Member States can take restrictive measures against products that are **non-compliant** with the Directive's provisions. The provisions and requirements of the regulatory framework are not questioned in these cases, but the compliance of a given product with these requirements is questioned. Therefore, the follow-up procedure does not provide for uniform Community measures (under the Comitology framework), but for an evaluation of the justification of the measure by the Commission and the information of all other Member States, thereby allowing them to take similar market surveillance measures. As the regulatory framework is not challenged, no clarifications or amendments to the regulatory framework are required in these cases.

Measures under Article 8 can be taken when the product "compromises" health or safety or "may compromise" health and safety. It is sufficient to establish that there is non-compliance and that non-compliance creates a risk or potential risk. In case non-compliance does not create a (potential) risk, the non-compliance should be solved through the "light touch" mechanism foreseen under Article 18 MDD together with article 8§3.

Under Article 14 b, Member States are given the possibility to take measures in case the device creates a **risk or a potential risk**, even if non-compliance with the current regulatory

[1] OJ L 25, 29.1.2002, p. 47

framework cannot be established. This is underlined by the fact that, contrary to Article 8, Article 14 b contains no reference to non-compliance.

Article 14 b seems essentially to provide a possibility to react on shortcomings of the regulatory framework detected by Member States. Such shortcomings might be the result of new, emerging technologies or new scientific findings in relation to risks for public health that require clarification of the provisions of the Directive.

> An example of its use is Commission Directive 2003/32/EC:
>
> *"(6) In order to improve the level of safety and health protection, it is necessary to further reinforce the protective measures against the overall risk of transmitting animal spongiform encephalopathies via medical devices.*
>
> *(11) Annex I to Directive 93/42/EEC sets out the essential requirements that medical devices must meet pursuant to that Directive. Points 8.1 and 8.2 of that Annex set out specific requirements intended to eliminate or reduce as far as possible the risk of infection for the patient, user and third parties due to tissues of animal origin and specifies that the solutions adopted by the manufacturer in the design and construction of the devices must conform to safety principles taking into account the generally acknowledged state of the art.*
> *(12) With regard to medical devices manufactured utilising tissues of animal origin it is necessary to adopt more detailed specifications in relation to the requirements of point 8.2 of Annex I to Directive 93/42/EEC and to specify certain aspects relating to the risk analysis and risk management in the framework of the conformity assessment procedures referred to in Article 11 of that Directive.*
> *(13) Some of the terms used in Directive 93/42/EEC should be further clarified in order to ensure a uniform implementation of this Directive.*

As a result, Article 14 b foresees for a different follow-up from that under Article 8. It is the Commission who assesses whether the measure is justified or not. In case it considers the measure justified, , the Commission proposes the adoption of Community-wide measures following agreement by Member States through the regulatory Committee procedure.

The term measure (proposed by the Commission) in Article 14 b must be understood in its broad sense. Depending on the case, it may be a directive (in case the measure is justified and should be made obligatory at Community level), a Commission Communication, or a voluntary measure (e.g. Guidance). Essential is that the measure was agreed through the regulatory Committee procedure.

> In case the Commission considers the measure not justified, it will reject the measure by a decision addressed to the Member States that adopted the national measure
>
> In case of clarifications and elaboration on existing provisions of the Directive, provisions will be adopted through the regulatory Committee procedure. In case the follow-up requires substantial changes to the Directive, probably a full-fledged amendment of the Directive following the co-decision procedure should be proposed.

National measures (and Commission follow-up) under Article 14 b can also be based on the precautionary principle. As mentioned above, any precautionary measure, be it at Member State or Commission level, must comply with the requirements outlined in the Commission

Communication on the precautionary principle and as set out in the case law of the European Court of Justice and cannot lead to arbitrary measures to be adopted by Member States.

Proposal

It is proposed to better specify the scope of article 14b and the description of the Member State measures under Article 14 b compared to the description of the measures under Article 8.

At the same occasion, it should be specified that in case the Commission considers national measures as unjustified, the Commission informs all Member States.

Proposed text of Article 14b

Health Protection 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, such products should be withdrawn from the market, or their placing on the market and putting into service should be prohibited or restricted, it may take any necessary and justified measures.

It shall then inform the Commission and all other Member States giving the reasons for its decision. The Commission shall, whenever possible, consult the interested parties and the Member States. Where the national measures are justified, the Commission shall adopt the necessary Community measures in accordance with the procedure referred to in Article 7(2). In case the national measures are unjustified, the Commission shall inform all Member States.

Proposed text of Recital (4)

Whereas the harmonized provisions must be distinguished from the measures adopted by the Member States to manage the funding of public health and sickness insurance schemes relating directly or indirectly to such devices, and to determine conditions for availability n of such devices; whereas, therefore, these provisions do not affect the ability of the Member States to implement the abovementioned measures provided Community law is complied with.

Proposed additional Recital (5):

Whereas, when a Member State considers that, as regards a given product or group of products, it is necessary, in order to protect health and safety and/or ensure compliance with the imperatives of public health, to withdrawn it from the market, or its placing on the market and putting into service should be prohibited or restricted, it may take any necessary and justified measures, whereas, in such cases, the Commission, whenever possible, consults the interested parties and the Member States and, if the national measures are justified, adopts the necessary Community measures in accordance with the procedure referred to in Article 7 (2).