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REPORT

on the health implications of Council Directive 93/42/EEC of 14 June 1993 concerning medical devices
(2001/2270(INI))

Committee on the Environment, Public Health and Consumer Policy

Rapporteur: Minerva Melpomeni Malliori

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PROCEDURAL PAGE

At the sitting of 17 January 2002 the President of Parliament announced that the Committee on the Environment, Public Health and Consumer Policy had been authorised to draw up an own-initiative report, pursuant to Rule 163 of the Rules of Procedure, on the health implications of Council Directive 93/42/EEC of 14 June 1993 concerning medical devices.

The Committee on the Environment, Public Health and Consumer Policy appointed Minerva Melpomeni Malliori rapporteur at its meeting of 22 January 2002.

The committee considered the draft report at its meeting of 19 March 2003 and 23 April 2003..

At the last meeting it adopted the motion for a resolution by 47 votes with 1 abstention.

The following were present for the vote: Caroline F. Jackson chairman;and Alexander de Roo., vice-chairman; Minerva Melpomeni Malliori, rapporteur; María del Pilar Ayuso González, Jean-Louis Bernié, Hans Blokland, David Robert Bowe, John Bowis, Martin Callanan, Dorette Corbey, Anne Ferreira, Christel Fiebiger (for Pernille Frahm), Marialiese Flemming, Karl-Heinz Florenz, Monica Frassoni (for Inger Schörling), Cristina García-Orcoyen Tormo, Laura González Álvarez, Robert Goodwill, Cristina Gutiérrez Cortines, Jutta D. Haug (for Torben Lund), Marie Anne Isler Béguin, Hedwig Keppelhoff-Wiechert (for Paolo Costa), Christa Klaß, Eija-Riitta Anneli Korhola, Bernd Lange, Peter Liese, Giorgio Lisi (for Avril Doyle), Caroline Lucas (for Hiltrud Breyer), Emilia Franziska Müller, Riitta Myller, Giuseppe Nisticò, Ria G.H.C. Oomen-Ruijten, Neil Parish (for Françoise Grossetête), Béatrice Patrie, Marit Paulsen, Fernando Pérez Royo (for Rosemarie Müller), Dagmar Roth-Behrendt, Guido Sacconi, Yvonne Sandberg-Fries, Karin Scheele, Horst Schnellhardt, Bart Staes (for Patricia McKenna), Catherine Stihler, Astrid Thors, Antonios Trakatellis, Elena Valenciano Martínez-Orozco, Kathleen Van Brempt, Peder Wachtmeister, Phillip Whitehead.

The report was tabled on 24 April 2003.

The deadline for tabling amendments will be indicated in the draft agenda for the relevant part-session.

MOTION FOR A RESOLUTION

European Parliament resolution on the health implications of Council Directive 93/42/EEC of 14 June 1993 concerning medical devices (2001/2270(INI))

The European Parliament,

– having regard to the Directive 93/42/EC[1] of the 14 June 1993 concerning medical devices,

– having regard to Article 152 of the EC Treaty,

– having regard to Rule 163 of its Rules of Procedure,

– having regard to the report of the Committee on the Environment, Public Health and Consumer Policy (A5-0125/2003),

A. Whereas the Medical Device Directive provides an appropriate legal framework with a view to safety aspects and technological evolution;

B. Having regard to the new perspectives on the safety of such products,

C. Whereas there is room for improvement in several areas;

1. Concludes that some medical devices need to be reclassified, and that Article 13 in the 93/42/EC Directive is a suitable instrument for this purpose;

2. Stresses that a distinction should be made between medical devices having a pharmacological effect, and the others, those with a pharmacological effect being subject to Directive 2001/83/CEE;

3. Stresses that Clinical Data needs to available and relevant for the medical device in question, in particular for Class IIA, IIB and III devices;

4. Calls on the Commission to explain in writing whether soft PVC medical devices comply with the essential requirements laid down in directive 93/42/EC or not;

5. Underlines that Post Market Surveillance, and the gathering of such information must be improved. The Post Market Surveillance must reflect the risks involved with the device and there must be a system in place for tracking high risk devices; stresses that better education is needed, and guidance need to be developed on the issue;

6. Stresses the need for correct informative labelling and leaflets containing instructions for use, which also describe any possible side-effects of these devices;

7. Urges the Member States to take the necessary measures to ensure that single use devices are not reused, as the reuse of medical devices intended for single-use only poses a risk for patients and hospital staff; calls upon action to encourage promotion of

[1] OJ L 169, 12.7.1993, p. 1 - 43

studies and research in this area.

8. Strongly suggests the implementation and follow-up of the findings and the results reached by the working group on Notifed Bodies (NBOG), established by the competent authorites in July 2000;

9. Instructs its President to forward this resolution to the Council and Commission.

EXPLANATORY STATEMENT

The legal framework for Medical Devices comprises three directives; the 1990 Directive on Active and Implantable Medical Devices, the 1993/42 Directive on Medical Devices, which is the main directive, and the 1998 Directive on In Vitro Diagnostics Medical Devices.

The 1993 Directive requests the Commission to submit a report to the Council and the European Parliament, no later than five years from date of implementation of the Directive. The Commission has not yet published its report, the Medical Experts Group has however produced a report on the functioning of Directive 93/42 (final report 05-06-2002 corr 1.)

The Directives on medical devices are based on the New Approach towards technical harmonisation, and aims to set the highest levels of safety to provide access to the Community market and to promote innovation. Although national law implementing the Directives is recent, and the medical Devices Directives provide in themselves an appropriate legal framework with a view to safety aspects and technological evolution, a review of the functioning of the regulatory framework is to be made in order to make improvements to the framework and its implementation where possible.

This follow up report and recommendations from the European Parliament is an important contribution to this review process of the Directive.

The New Approach

Under the New Approach, the Directives define the essential requirements that devices have to meet when they are put on the market or put into service. Products can only be put on the market or put into service, if they were subject to a risk assessment, a risk management process and a risk/benefit analysis. In order to allow technical progress to be taken into consideration in the design and manufacturing of medical devices, the directives do not specify technological solutions to be adopted by manufacturers.

According to the findings by the Medical Experts Group as well as conclusions drawn from discussions held with stakeholders and responsible authorities in the Member States, the most critical areas where improvements should be made concern issues such as; **reuse of devices, reclassification of devices, proper implementation of clinical data, improved post market surveillance procedures and designation and monitoring of Notified Bodies.**

Classification of devices

Medical devices are classified on the basis of a decision tree into 4 classes. The classes determine the conformity assessment procedures available for a particular device. The rules are built on the concept of a risk-based approach related to the duration of use, invasiveness and hazards associated with the medical device.

Class I - low risk. Assessment procedures can be carried out under the sole responsibility of the manufacturers.

Class IIA - medium risk. The intervention of a notified body is compulsory at the production

stage.

Class IIB - medium risk. These devices have a high-risk potential. Inspection by a Notified Body is required with regard to the design and manufacture of devices.

Explicit prior authorisation is required as for IIA and IIB devices with regards to conformity, in order for the devices to be placed on the market.

Class III - high risk. Class III devices are subject to the strictest evaluation, comprising clinical data and design review.

Reclassification of devices and incoherence in classification rules

There is currently a different classification used for single use surgical instruments and reusable non-sterile instruments. The first group requires conformity assessment by a Notified Body
(Class II) while the second group are classified as Class I devices, for which the conformity assessment procedure does not require intervention of a Notified Body. As the potential risk of reusable non-sterile surgical equipment seems higher than that of single use instruments, it has been suggested that the same classification should apply for both single use and reusable versions of products with the same intended purpose, i.e. both should fall under the requirement of a conformity assessment, involving a Notified Body.

The Medical Expert Group suggests some upgrades of medical devices. This concerns upgrades of devices from Class IIB to III, such as breast implants, stents and orthopaedic implants. The orthopaedic implants need to undergo stricter controls and a more explicit description of the construction and use of the device has to be provided.
It is considered that the risk associated with devices which are in direct contact with the central nervous system (for example use in brain surgery) do not diminish with duration of contact therefore all these devices should be in Class III. Currently surgically invasive devices for transient use (less than 60 minutes) belong to Class IIA, as a consequence this group should be upgraded to Class III. Article 13 in the Directive should be used for this purpose. Under this article Member States can propose to reclassify a device or a family of devices.

Reuse of devices

Some hospitals tend to consciously use some devices incorrectly. Devices that have been designed by the manufacturer for single use are often reused. The device is sterilised as is seen fit by the hospitals, which may not always be the right method in eliminating risks, ignoring the manufacturer's instructions. Infectious organisms may be introduced into the patient's blood stream, due to the difficulty of cleaning single-use devices. If cleaning is not achieved inactivation of all micro-organisms cannot be guaranteed, and thereby putting the health and lives of patients and hospital staff at risk.

The Medical Devices Directive 93/42/EEC has no reference to the actual use of a device and the reprocessing of single use medical devices is not regulated in the Directive. The Directive regulates the placing on the market of a brand new product and the service of the product, i.e.

the intended use of it. The manufacturer is responsible for guaranteeing its safety, and only the manufacturer can guarantee that a device is safe to reuse through suitable procedures and technical quality control on homogenous batches. Action should be taken to ensure that no single-use devices are re-utilised.

Information is crucial. The hospitals should ensure that the hospital staff, using medical devices be fully and accurately informed and instructed about the conditions of use. If they are not well informed, because they do not receive the packing slips containing the instructions for use, the responsibility of the hospital may be engaged.

In the event of re-use of single-use devices informed consent by the patient should be mandatory. The patient should be clearly told of all the relevant factors, including the fact that he/she is to be treated with a reused single device.

Training is another important aspect. Hospitals should establish and maintain controlling and correcting mechanisms, so as to ensure the implementation of the legal provisions. That requires training of the hospital staff at regular intervals.

Stakeholders call for Community action in the field of re-use of single devices and urge the Commission to encourage studies and research on the issue. Some Member States already have enforced measures against reuse of single devices in place. All other Member States should be encouraged to develop and enforce equivalent rules.

Clinical evaluation

Shortcomings have been highlighted on the implementation of the Directive's provisions on clinical data. Manufacturers do not always have clinical data available. The Medical Device Directive requires that confirmation of conformity with the requirements concerning the characteristics and performances under the normal conditions of use of the device and the evaluation of the undesirable side effects be based - **"as a general rule"** - on clinical data. This could be a linguistic problem, and is being interpreted in some Member States that clinical evaluation is not always needed. Clinical data must be available for medical devices, in particular Class IIA, IIB and III.

The current problem with clinical data is that it may not be relevant for the device in question, this concerns in particular similar devices that have different functions. This can in turn pose risks to the patients. Again stakeholders believe that the problems encountered concern mainly the interpretation of the Directive rather than shortcomings in the regulatory framework.

The main issue at stake is rather how to interpret the clinical data available.
A task force has been set up, Clinical Evaluation Task Force (CETF), comprising representatives from Member States, Notified Bodies and industry in order to develop guidelines on how to apply the provisions on clinical data. The issues under discussion are:

What is relevant?
When?
The parameters to be applied

How many tests need to be made?
Having the necessary skills to interpret the data.

Post market surveillance

The Directive asks for the provision of a systematic procedure to review experience gained in the post production phase. The manufacturer should have a systematic procedure in place to collect, review this information and take appropriate follow up action.
There is currently no system in place to systematically gather PMS information and there is particular deficiency in gathering information on long-term implants. Better guidance and education is thus needed. The Post Market Surveillance must reflect the risks involved with the device in question. There must also be a system for tracking devices within the present vigilance system, and the exchange of information between Member States must be improved. If a device or implant is expected to have a lifecycle of say ten years, and problems occur after five years, in such a case, it must be possible to track the device/implant.

This is closely connected with the question of **patient information.** This is not considered to be an issue to be dealt with in the Directive, but rather for best practice to be developed, complementing measures taken at national level, respecting the subsidiarity principle.

Notified Bodies

The Notified Bodies are entities (private or public) designated by the competent authorities of Member States to carry out tasks relating to conformity assessment of medical devices. The manufacturer is free to choose any Notified Body that has been designated for the required scope of products and conformity assessment.
There are currently around 60 Notified Bodies in the European Union. Concerns relate to the competence of some of these bodies, difference of interpretation between them and lack of transparency in the performance and control of their activities. There are too many Notified Bodies competing on the market and some of their mandates are considered too wide. It falls on the national authorities to control the situation, as it is the national authorities that designate the Notified Bodies. The competent authority should also withdraw a Notified Body its licence if it is not fulfilling the requirements. The industry also bears a responsibility not to use Notified Bodies, which do not possess the necessary competence.

A working group has been established by the competent authorities in July 2000, the Notified Body Operations Group (NBOG), to look into these issues and it is working on developing best practice, guidance and a handbook for the designating authorities. Specialisation seems to be the best solution and the possible development of a centre of excellence.

Conclusions

The following conclusions can be drawn:

1. The Medical Device Directive provides an appropriate legal framework with a view to safety aspects and technological evolution, however there is room for improvement in several

areas.

2. Some devices need to be reclassified. Article 13 in the Directive is a suitable instrument for this purpose, as Member States can propose to reclassify a single device or a family of devices through Article 7 of the Directive, the "regulatory committee".

3. Clinical Data provided needs to be available for medical devices, and in particular for Class IIA, IIB and III devices, and to be relevant for the device in question.

4. Post Market Surveillance, and the gathering of such information must be improved. The Post Market Surveillance must reflect the risks involved with the device and there must be a system in place for tracking high risk devices. Better education is needed and guidance needs to be developed on the issue.

5. The reuse of medical devices intended for single-use only poses a risk for patients and hospital staff. Action should be called upon to encourage the promotion of studies and research in this area. Members States should take the necessary measures to ensure that single use devices are not reused.

6. The findings and results by the working group on Notified Bodies (NBOG), established by the competent authorities in July 2000, should be followed up an implemented.