BACKGROUNDER ON MEDICAL DEVICES DIRECTIVE REVIEW

I. Introduction to the medical devices sector

Medical technology extends and improves life and alleviates pain, injury and handicap. Millions of patients in Europe depend on medical technology, at home, at the doctor's, at hospital and in nursing homes. Wheelchairs, orthopaedic shoes, artificial heart valves, contact lenses, insulin pens, hip prostheses, condoms, oxygen masks, scanners, pregnancy tests, surgical instruments, bandages, syringes, life-support machines, demineralised bone filling for bone defects: all these products and many more fall under the definition of **medical device**. The uniqueness of the medical devices sector resides in its enormous diversity and innovativeness. There are more than 10.000 different categories of products.

The user training and technical support provided by the manufacturer are often indispensable. Feedback from doctors, nurses and patients enables the industry to constantly perfect its technology. Products have an average lifecycle of only 18 months before an improved product becomes available. The European medical technology industry invests an average of more than 6% of sales in R&D and employs near to 400.000 highly skilled workers. Small and medium sized companies make up more than 80% of this sector. Eucomed represents the majority of designers, manufacturers and suppliers of medical devices in Europe (more on www.eucomed.org).

Medical technology is one of the two fundamental pillars of healthcare products, along with pharmaceuticals. Medical devices nevertheless represent not even 7% of total healthcare expenditure in Europe, a modest share if you consider the benefits for every member of society. They are different from medicinal products in very many ways, and this is reflected in the way they are regulated at EU level. For more information on the differences between medical devices and pharmaceuticals, **click here**.

Three **"New Approach" directives** harmonize the rules pertaining to the free circulation of medical devices in the EU. These are the Medical Devices Directive (93/42/EC); the Active Implantable Medical Devices Directive (90/385/EC); and the "in vitro" diagnostic medical devices Directive (98/79/EC). Products that fall within their scope must meet all applicable essential safety and administrative requirements and must be CE marked to show that they comply. Such products may then be freely sold throughout the European Economic Area (EEA) without being the subject of additional national legislation, except in the field of funding and reimbursement.

II. Directive 93/42/EEC Review: suggested clarifications and fine-tuning

Given the complexity and rapid evolution of this sector, a regular review of Directive 93/42/EEC has been provided for by the regulator. On 22 December 2005, the European Commission published its proposed amendments after extensive stakeholder consultation. The proposed modifications are only minor and are in general supported by Eucomed. The text is now with the European Parliament Environment in first reading.

A. CLARIFICATION OF THE SCOPE

1. Software – with the exception of standalone software for diagnostics, standalone software should not generally be considered as a medical device.

In the proposed text, software has been included in the definition of medical devices. A very large variety of medical devices nowadays operate with some form of software, which is an integral part of the medical device and is already covered by the original text of the Directive. "Standalone" software for diagnostics purposes should fall within the definition of a medical device. But standalone software, which could be used in the context of a medical treatment without "participating" in the treatment (data collection, transfer, etc) should not be covered.

This can be illustrated with the two following examples:

Pacemakers to support or fully take over the heart's own pacing are becoming increasingly sophisticated. A big step forward is the possibility of reprogramming these implanted electronic devices in accordance with the development of the patient's state of health. The inclusion of specific software in pacemakers allows for this reprogramming. The software is an integral part of the device. It cannot be used independently.

Special software can be used to monitor and analyze the patient's vascular activity and determine the changes required in the parameters of the pacemaker for example. This type of diagnostic software is standalone and can be considered as part of the treatment.

Computerized patient management is increasingly used for clinical data collection, interdisciplinary decisions and treatment schedules. The computer is essential for data storage, statistical analysis, and providing all needed information. It can also be used to provide tools for enhancing the conduct of the study. The software used in this context is clearly not a medical device.

2. The revised Directive should prevail over any overlapping Directives.

Some medical devices could fall within the scope of other EU legislation such as the Medicinal Products Directive (2001/83/EEC), the Cosmetic Products Directive (76/768/EEC), the Personal Protective Equipment Directive (89/686/EEC) or the Machinery Directive (98/37/EEC). Clear provisions are necessary to determine which legislation prevails, and thereby create the necessary legal certainty. Given the *Lex Specialis* principle, products that fall under the definition of medical devices should not be covered by any other legislation.

B. HYBRID PRODUCTS

The original provisions of the directive relating to hybrid products adequately addressed their specificity and only required updating.

Hybrid products are medical devices incorporating, as an integral part, a medicinal substance which is liable to act upon the body with action ancillary to that of the device. The current procedure to verify the quality, safety and usefulness of the medicinal substance has worked well so far. Only an update was required to reflect the recent revision of the medicinal products legislation (Directive 2001/83/EEC). However the Commission's proposal includes additional procedures, which will increase the

administrative burden on the industry with no added value for the patient and could result in non-harmonized rules across the EU.

"Drug-eluting" stents used in interventional cardiology are hybrid products. Thanks to a balloon catheter, this small metal tube-shaped device is placed in the occluded area of an artery, for example. The cardiologist can visualize the precise position of the stent as he is placing it. The procedure (angioplasty with a stent) is minimally invasive and lasts less than an hour. The patient can go home and resume a normal life almost immediately.

The medicinal substance coating of the stent helps to ensure the durability of the results by reducing the occurrence of restenosis (re-occlusion). Its action is ancillary to that of the stent.

Drug-eluting stents were made rapidly available to patients in the EU thanks to the existing regulatory framework established by Directive 93/42/EEC. This framework provides for consultation with the European Medicines Evaluation Agency to establish the quality and safety of the medicinal substance in analogy with the applicable requirements of the Medicinal Products Directive. This system has worked well so far.

The proposed changes introduce elements of uncertainty in the determination of responsibilities and applicable requirements.

C. TRANSPARENCY

The modalities for providing information to the general public and the user should be more realistic.

Eucomed generally supports the Commission's move to provide more information to the general public and the user about medical devices. The use of the Global Medical Devices Nomenclature codes should be considered as a part of this information, and not be required to appear on the product label as requested by a new provision in the proposed text. Indeed, the correct determination of the appropriate code is far from being simple and this could lead to different interpretations (there are over 18.000 terms and related definitions). Moreover, the GMDN is an evolving system and new codes are regularly added. If the GMDN code has to appear on the label, any variation will require the manufacturer to change the label, which represents a considerable cost with no benefit to the patient or user.

D. E-LABELLING

Eucomed would also welcome the possibility of providing information for the safe and correct use of medical devices through modern means of communication (electronic support). These include the Internet, CDRoms or integrated support systems such as a pacemaker programmer that displays instructions for use in the user's language on a built-in screen. New provisions in the text would be necessary for this. With 20 different EU languages (and soon more), the size and volume of the paper instructions for use are considerable. Explanatory video recordings or animations can contribute to the safe use of certain devices. Electronic support can also be more easily updated and disseminated. A Directive written in 2005 should clearly provide for the use of state-of-the-art means of communication.

E. DESIGN AND ERGONOMICS

The new provisions on ergonomic design are unnecessary, as the directive already addresses this important aspect via the risk analysis process.

The conduct of an appropriate internal risk analysis of the product design is mandatory. This risk analysis includes an evaluation of the ergonomics of the device, particularly in the case of non-professional use. The additional provisions proposed in the text could be confusing and subject to different interpretations at member state level.

F. CLASSIFICATION

The revised text includes provisions that could affect the classification of several wound care products without justification.

If reclassification of a medical device is thought to be necessary by the Member States, the *ad hoc* procedure should be utilized. In every case, decisions should be based on sound science and duly justified on the grounds of patient safety.