HealthManagement
Promoting Management and Leadership

Volume 9, Issue 3 /2007 - Safety

Reprocessing Medical Devices in Europe:Reform of the EU Medical Devices Directive

Author:

Dr. **Thomas Ulmer,**

Member of the European Parliament

Email: info@thomasulmer.eu

URL: www.thomasulmer.eu

In 2005 the European Commission introduced a proposal to amend the medical devices directive and thereby signalled its intention to boost competitiveness in the European medical devices sector. The purpose of the proposed changes was to simplify and clarify the existing legal framework. The amendments included provisions to enhance patient safety and establish a single legal framework to foster competitiveness.

The European Parliament voted to endorse the Commission's revised legislation without significant reservations, marking a further important achievement for the German Presidency. The proposals were then adopted by EU Health Ministers in late May. Achieving consensus on the first reading of legislation is highly unusual in Brussels and it was not expected in this case due to the significant differences in the positions of the various protagonists.

Reconciling Competing Interests

The proposals sought to update three directives, which collectively set down the basic requirements for securing market approval of medical devices. Product classification, i.e. risk assessment, risk management and risk-benefit analysis, are addressed first. However, a procedure for risk-based conformity assessment to be carried out by independent agencies (so-called notified bodies) is also envisaged. The three relevant directives are the medical devices Directive 93/42/EEC, the active implantable medical devices Directive 90/385/EEC and Directive 98/8/EC on biocides.

The term "medical device" encompasses a wide range of products. Around 400,000 different medical devices, ranging from simple syringes and spectacles to diagnostic and imaging equipment to highly sophisticated implantable devices, are currently available on the market.

With a workforce of approximately 350,000 employed in around 7,000 companies, the medical device industry has recorded significant growth in recent years. The challenge facing legislators is to strike a balance between the legitimate interests of patients and the competitiveness of industry. This will require providing additional safeguards to enhance patient protection while, at the same time, securing jobs in the sector.

Subsidiary Principle Applies to Reprocessing

The reprocessing of medical devices emerged as the most controversial issue because it is here that the interests of patients, hospitals, industry and the various actors in the healthcare sector collide. The rules on reprocessing vary among Member States. For example, reprocessing is banned in Spain and the United Kingdom, although the practice continues illegally. In Germany, on the other hand, legislation on reprocessing is unambiguous and is based on guidelines drawn up by the Robert Koch Institute. The Scandinavian countries intend to introduce similar rules.

The following cases, both of which are theoretically possible, give an insight into the legal complexities surrounding reprocessing:

1. In countries where a strict reprocessing ban applies, it is still possible to reprocess single use products legally, provided the reprocessor is willing to assume the third party liabilities of a manufacturer and, in so doing, operate as a manufacturer on the market.

2. It is also possible for a reprocessor to act on behalf of a hospital. As the reprocessor does not operate on the market, the hospital must assume full legal liability for the reprocessed products.

The understandable reluctance of manufacturers, hospitals and other users of medical devices to assume such a substantial risk led to calls for the introduction of European legislation to regulate reprocessing, using the German legislation as a template. This proposal was put by the Committee on the Environment, Public Health and Food Safety but failed to secure majority support in a plenary sitting of Parliament. The

introduction of such a legislative framework would implicitly answer the following questions: “Should the reprocessing of medical devices be permitted? Are the risks not too high?”

A report by a German academic was unambiguous. Professor Haindl from Hanover stated that it is simply not possible to safely reprocess many of the single-use medical devices currently being reprocessed. This raises a fundamental ethical consideration and poses the question: Can the reprocessing of medical devices be ethically justified?

At this point, it should be noted that the EU is not, and never has been, the appropriate authority for addressing ethical questions. For example, an accommodation has been found to address differences between Member States on funding research on human embryos. In light of the fact that the EU may not circumvent national views on questions of life, the only option available to it was to leave the crucial decision on reprocessing to Member States. In other words, the subsidiarity principle applies. In the event that a Member State chooses to allow reprocessing, EU-wide standards will apply and these will be set out in a forthcoming directive.

The Commission will carry out further studies to determine whether additional measures would ensure a high level of protection for patients. Within three years of the revised directive entering into force, the Commission must present Parliament and the Council with a report on the reprocessing of medical devices. This document may form the basis for additional regulations in this area.

Dangerous Chemicals: An Issue for Debate

Debate also focused on the so-called CMRs, dangerous substances used in the manufacture of medical devices. While it is essential that the use of such chemicals in medical devices must cease in the medium term, unfortunately this will not be possible in the short term because an outright ban would jeopardise production of certain products which are indispensable to the protection of human health. Parliament, therefore, approved a compromise proposal under which:

• Manufacturers should avoid or minimise the use of dangerous substances in the production of medical devices.

• Devices containing dangerous chemicals must be labelled accordingly.

• Where such a device is used in the treatment of children or pregnant women, the manufacturer must set out reasons for using the substances in question.

• All CMRs must be phased out within five years of the directive entering into force.

Less Bureaucracy

The adoption of the directive has helped cut EU bureaucracy. Contrary to the wishes of the Commission, an agreement was reached to streamline the work of EUDAMED (the European database of medical devices). It will no longer be necessary to register all custom-made devices on the database because, as MEPs noted, it is pointless to record such information if each device is unique.

Parliament also rejected a Commission proposal to require all medical devices to be labelled with a GMDN (‘Global Medical Device Nomenclature’) code. Rejection of the recommendation will save the industry hundreds of thousands of euro. Until now, companies have been forced to pay high charges to a valorisation agency to secure the rights for each individual code, resulting in many products not being placed on the market. Unlike the case of medicines, the GMDN code has no role in the registration procedure for medical devices and cannot, therefore, be compared to a pharmaceutical registration number.

Conclusion

On balance, all the relevant stakeholders are satisfied that the new rules create much greater clarity and legal certainty in the medical devices market. In particular, clear demarcation between the three directives - which rules apply to which products - will eliminate confusion. This will deliver time and cost savings to industry, and incentivise companies to prioritise innovation and job creation.

By significantly strengthening the rights of patients, the new measures will improve safety and

transparency and create long-term confidence in European medical devices. They also offer additional benefits to manufacturers who choose Europe as a location for doing business.

I believe our collective endeavours on this issue have contributed towards achieving the Lisbon goals, under which the European Union will strive to ensure Europe becomes the most successful, knowledge-based economic region in the world.

Published on : Sat, 26 May 2007