EU medical device laws to undergo revision

BRUSSELS, Belgium: The European Commission has announced a revision of the legislation governing medical devices in the EU dating from the 1990s. According to the European consumer organisation BEUC, the plans will affect a wide range of products, including dental filling materials, X-ray machines and various implants.

To date, medical devices in the EU have not been subject to any premarket approval by a regulatory authority but to a conformity assessment that involves an independent third party known as a notified body. The 80 notified bodies are monitored by the 27 member states. Once certified, devices bear the CE marking.

Recently, the existing directives have seen harsh criticism owing to the worldwide breast implants scandal caused by French manufacturer Poly Implant Prothese. Earlier this year, it was found that the company had used industrial silicone instead of medical grade silicone for its breast implants, contrary to the approval issued by the notified body, according to the European Commission.

With the revision, the authorities aim to eradicate the flaws and gaps in the EU legislation, increase consumer protection, reduce risk and avoid costly recalls, said Monique Goyens, Director-General of BEUC.

The proposal includes stricter control of manufacturers and extends the definition of medical devices to include more products within the scope of the legislation. Moreover, it recommends closer monitoring of the notified bodies. A scrutiny panel is to be established for this purpose in order to assess medical devices according to certain risk-based criteria. Overall, the proposal is aimed at better product traceability.

“High-risk devices, such as implants, need much more thorough controls before being put on the market. Consumers must be given more and better information on medical devices while having the back-up of redress if things go wrong,” Goyens added.

Eucomed, a medical technology industry association that represents 22,500 European designers, manufacturers and suppliers of medical technology, however, has raised some concerns about the proposal. Although the organisation welcomes stricter control and monitoring, it believes that the measures would ultimately lead to a move towards a centralised premarket authorisation system, similar to the system found in the US, which would affect European small and medium-sized companies negatively, Eucomed stated. With a centralised premarket system, patients would have to wait three to five years longer on average for the release of a device, according to the association.

Before the new regulations can be introduced, the proposal has to be approved jointly by the European Parliament and the Council of the European Union, which represents the governments of the member states.

EU Commission in Brussels has issued a proposal to review the existing regulations of medical devices in Europe. (DTIPhoto courtesy of Jan Kranendonk)
Contact allergies owing to gloves: A growing problem in dentistry

Experts believe that nitrile gloves cause contact allergies.

Ben Adriaanse
HOUTEN, Netherlands: In recent years, researchers have noted a significant increase in contact allergies to rubber additives among health care professionals. Although the cause of this cannot be stated with certainty, experts believe that nitrile gloves are responsible.

In the 1980s, the use of medical gloves made of natural rubber latex was introduced into dentistry. Owing to an alarming number of allergic reactions caused by certain proteins contained in latex, synthetic alternatives like nitrile and vinyl gloves emerged shortly afterwards. While they, like other alternatives, score significantly lower in comfort and elasticity, nitrile gloves are most commonly used by dentists.

According to Michel Paping, director of Budev, a Dutch research and development company focused on natural rubber latex allergens, type IV allergic reactions, which are immediate reactions to allergens in a product, are very rare nowadays owing to improved quality standards and production processes. Type IV reactions, however, are delayed reactions to the chemicals used in the production process and are more common and can arise in response to nitrile or vinyl. "In fact, I think that synthetic rubber gloves cause more contact allergies than natural rubber latex," he told Dental Tribune Netherlands.

It is not the raw, unprocessed rubber that causes type IV allergic contact eczema but the excipients added during the manufacturing process, such as vulcanisation accelerators, plasticisers, fillers, antioxidants and colourants. Excipients are present in both natural and synthetic rubber gloves, said Prof. An Goossens, a contact allergy expert at KU Leuven's Department of Dermatology in Belgium.

In 2010, a soft nitrile glove was introduced that weighed only 2.5 to 3.5 g. The production lines were shortened and the vulcanisation was performed at lower temperatures to save costs and energy. However, concerns have been raised about the thinner gloves.

"Producing thinner gloves and thereby being able to fit more gloves in a shipment, saves costs for raw materials and transport. However, the production of such a thin product and vulcanisation at lower temperatures inevitably requires extra and new chemicals. In addition, it is unavoidable that thinner gloves will score worse in strength and permeability," said Paping after his company had tested various types of nitrile gloves.

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Alongside the growing number of contact allergies in recent years that are likely caused by added chemicals or antimicrobial agents, Paping and his team have observed an increase in allergic reactions in daily practice. "Recently, we have seen that the professional body is becoming alarmed. Despite this, I am concerned that the average dentist is not aware of this matter," he said.

"When health care professionals start working in practice, they use the same glove out of habit. When gloves are ordered, the responsible person most often looks for the cheapest product and thereby being able to fit more gloves in a shipment, saves costs for raw materials and transport. However, the production of such a thin product and vulcanisation at lower temperatures inevitably requires extra and new chemicals. In addition, it is unavoidable that thinner gloves will score worse in strength and permeability," said Paping after his company had tested various types of nitrile gloves.

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US study suggests dentists cause implant failure

LOMA LINDA, Calif., USA: The indications and versatility of dental implants have increased, and so have complications. Researchers from the Loma Linda University School of Dentistry in the US have suggested that, regardless of patient risk factors like bruxism, successful long-term outcomes significantly depend on the experience of the clinician performing the procedure.

By reviewing the records of edentulous patients who had received full-arch maxillary and/or mandibular supported fixed complete dentures over a period of ten years, the researchers found that 12 per cent of implants failed when clinicians had less than five years of experience in the field. Implants were also twice as likely to fail if the surgeon had performed less than 50 implantations in his career, they report.

Other contributors to implant failure were identified as being related to the patient rather than the implant. Almost every third patient with diabetes or a history of bruxism had experienced implant failure.

Other risk factors commonly associated with implant failure like the type of prosthesis used, smoking or implant location were found to have less impact on long-term success, according to the researchers. They stated that the absolute rate of success was found to be 90 per cent.

Overall, the records of 50 patients treated with 297 implants at the school were reviewed.