Guest Editorial: Certain dental and consumer organisations in Europe voice concerns over proposals contained in new Medical Devices Regulation

Abstract

Since 13 October 2015, consultations have been taking place between the European Council, the European Commission and the European Parliament on the revision of the Medical Devices Directive. A number of European dental and consumer organisations have publicly aired their concerns over the proposal for a new Medical Devices Regulation published by the European Council, believing that the safety of patients has not been made the top priority. These organisations feel that some of the proposed requirements should be strengthened by adding more details and, in some cases, making them mandatory. Topics of primary importance are device labelling, devices releasing nanomaterials or hazardous substances, use of implants with the least associated risk, market approval criteria for dental amalgam, and better monitoring of market authorisation.

Since 13 October 2015, consultations have been taking place between the European Council, the European Commission and the European Parliament on the revision of the Medical Devices Directive. A number of European dental and consumer organisations* have publicly aired their concerns over the proposal for a new Medical Devices Regulation published by the European Council[1], believing that the safety of patients has not been made the top priority. These organisations feel that the proposed requirements described below, in particular, should be strengthened by adding more details and, in some cases, making them mandatory.

Device labelling

Annex I, point 19.3 (ob) states that:

> 'The instructions for use shall contain the following particulars:
> ...
> Information that allows the user to be informed and to brief the patient of any warnings, precautions, contra-indications, measures to be taken and limitations of use regarding the device. This information shall cover, where appropriate:
> ...
> *in the case of implantable devices the overall qualitative and quantitative information on the materials and substances to which patients can be exposed*'.

Dental fillings and dentures are included in the definition of an implantable device. Currently, for responsible dentists, it is almost impossible to protect patients adequately from associated health risks since manufacturers are not sufficiently required to publish the composition and the release rates of the materials used in dental devices. Even the European Commission's Scientific Committee on Emerging and Newly Identified Health Risks (SCENIHR) noted in their report about the health risks of amalgam and alternative filling materials[2] that dental restorative materials 'are defined as medical devices according to the Council Directive 93/42/EEC concerning medical devices and belong to

class IIa. Consequently, the certification process does not include examination of the design dossier and, therefore, the chemical specification does not have to be revealed to the third party. Although manufacturers are obliged to assess biocompatibility and the risk from unintended side effects, accessible information on the toxicity of the constituents of the materials as well as relevant exposure data is lacking. Therefore, the SCENIHR notes that it is not possible to provide a scientifically sound statement on the safety of these materials'.

The transparency of the composition of implantable devices is essential for the safety of patients, especially if those implants contain substances that are released into the body. The named organisations have called for a detailed indication from manufacturers about the corrosion, acid degradation, abrasion and overall release rates of medical products, as well as detailed and unambiguous information about their composition, including disinfectants (e.g. triclosan), phthalates, and other highly allergenic and toxic substances (down to 0.1%, specified in alloys as atomic percentage). Information is also needed on possible interactions with other dental filling materials (e.g. oral galvanism). Therefore, provision 19.3 (ob) in Annex I requires the addition of more specific details.

Devices releasing nanomaterials or hazardous substances

Annex VII, point 6.7, Rule 19, states:

> 'All devices incorporating or consisting of nanomaterial are in class III unless the nanomaterial is encapsulated or bound in such a manner that it cannot be released into the patient's or user's body when the device is used within its intended purpose'.

The dental and consumer organisations agree with the Class III classification of medical devices containing nanomaterials that could be released into the body, especially as the hazardous effects of nanomaterials in the body have not yet been explored adequately. Under this classification rule, manufacturers will be obliged to fulfil higher safety requirements and present clinical studies before a marketing authorisation can be granted. However, the organisations have called for this rule to be expanded to cover hazardous substances as well.

The approval conditions of medical devices are further regulated in Annex I, point 7.4, as follows:

> 'The devices shall be designed and manufactured in such a way as to reduce as far as possible the risks posed by substances or particles, including wear debris, degradation products, processing residues, that may be released from the device. Special attention shall be given to substances which are carcinogenic, mutagenic or toxic to reproduction, in accordance with Part 3 of Annex VI to Regulation (EC) No 1272/2008'.

The dental and consumer organisations have described this proposed wording as ambiguous because it affords manufacturers too much flexibility regarding the composition of their medical devices and the possibility of constituent materials releasing dangerous substances to the patient. They have called for stricter, more legally binding

wording, which prohibits the use of substances that are carcinogenic, mutagenic or toxic to reproduction, especially if they are able to be released into the body.

In addition, they have called for a revision of Annex VI to Regulation (EC) No 1272/2008[3] (*as referred to above*) because, for example, this Regulation does not include the official European Chemicals Agency classification of the hazardous substance mercury[4] as a material that is toxic to reproduction (i.e. Category 1B; May damage fertility or the unborn child, H360). It is known that mercury from dental amalgam is the main source of direct mercury exposure for consumers and that it can lead to adverse health effects[5]. Therefore, mercury should urgently be ascribed to the group of substances in this Regulation that are carcinogenic, mutagenic or toxic to reproduction so that, at the very least, the use of mercury in medical devices would be given 'special attention' according to this Regulation.

Doctors should use implants with the least risk

Recital 39a of the Council's position states that:

> 'The summary of safety and clinical performance should include in particular the place of the device in the context of diagnostic or therapeutic options taking into account the clinical evaluation of the device when compared to the other diagnostic or therapeutic alternates and the specific conditions under which this device and its alternatives may be considered'.

The dental and consumer organisations agree that the risk-benefit ratio of high-risk medical devices should be compared to the risk-benefit ratio of other medical procedures and/or types of products, especially for implants. Furthermore, they have called for a regulation to oblige doctors to use alternative implants that pose less risk to the patient in terms of preventive health protection. This is important as patients may be potentially sensitive to certain materials in medical devices and the number of atopic people has doubled in the last 20 years[6]. Such a requirement has also been mooted in a position paper issued by the German Ministry of Health[7]. Having said all this, the pre-condition to the implementation of this commitment would be a detailed knowledge of the composition and release rates of medical devices (*see above*).

Inadequate approval criteria for dental amalgam

In the proposed Regulation, detailed approval criteria for medical devices are not specified. Instead, there is a reliance on harmonised standards. Although the corrosion rate of metallic materials in dentistry is restricted by a threshold of 200$\mu g/cm^2$/7 days according to ISO 22674:2016, this standard does not cover amalgams, brazing alloys and materials for orthodontics. Also, the European harmonised version of this standard (EN ISO) has not yet been published by the European Commission. The requirements and test methods for dental amalgam are covered by ISO 24234:2015; however, with respect to the corrosion rate, the standard says 'Inclusion of a requirement for corrosion resistance was considered. However, it was agreed that the data available were insufficient to set a corrosion requirement in this edition of this International Standard'. It is therefore possible that the corrosion rate of mercury-containing dental amalgam could exceed the threshold for metallic materials specified in ISO 22674:2016. The

dental and consumer organisations believe it is unacceptable for this situation to occur and have called for adequate market approval criteria to be set.

Better monitoring of market authorisation

In order to ensure the safety of medical devices, the named European organisations have also called for a centralised European approval of Class III implantable medical devices and medical devices of medium to high risk (Class IIb). [This view is not shared by most other medical device industry representatives in Europe, who feel it will create an unnecessary level of bureaucracy without any proven safety benefits.] Currently, the market access of high-risk medical devices is approved by a Notified Body not by a public authority. Also clinical trials are not submitted to a public authority before market access.

References

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