OVERVIEW OF OBLIGATIONS OF MANUFACTURERS AND IMPORTERS IN THE PROPOSED MEDICAL DEVICE REGULATION

On 26 September 2012 the Commission adopted a proposal for a Regulation of the European Parliament and of the Council on medical devices ("MDR"). On 25 September 2013 the Environment, Public Health and Food Safety Committee of the European Parliament adopted the next step in the legislative process and voted on the compromise and consolidated amendments. On 22 October 2013 the European Parliament adopted in plenary session the majority of the amendments of the Environment, Public Health and Food Safety Committee. The European Parliament will now start negotiations with the Council on this proposal. When the European Parliament and the Council have come to an agreement, this agreement will first be voted by the Environment, Public Health and Food Safety Committee, before the full Parliament gives its approval. Please note that the obligations as set out below are still in the process of adoption and hence are subject to change.

The Commission preferred to revise the current medical device directives by means of a regulation. The consequence of choosing a different legal instrument is that obligations become directly effective. This means that obligations contained in the MDR do not need to be implemented by national legislation, but are directly applicable to manufacturers and other persons falling within the personal scope of the MDR.

Below a general overview of the new MDR, as it is amended by the European Parliament, is given. **Part I** sets out the definitions of the most central concepts of the MDR. **Part II** contains obligations all manufacturers need to comply with under the MDR. The regulatory burden for manufacturers of custom-made devices is however lower and in some instances manufacturers of custom-made devices will not have to comply with a particular obligation. The general rules as well as the exceptions and particular obligations applicable to manufacturers of custom-made devices are set out.

Furthermore we understand that FEPPD is interested in the new rules in the MDR applicable to importers. Therefore, **Part III** sets out the obligations importers need to fulfil under the MDR.

I. GENERAL DEFINITIONS

The MDR defines in article 2 its most important concepts. The relevant concepts for this overview are set out below:

A **"manufacturer"** is the natural or legal person who manufactures or fully refurbishes a device or has a device designed, manufactured or fully refurbished, and markets that device under his name or trademark.

Fully refurbishing is the complete rebuilding of a device already placed on the market or put into service, or the making of a new device from used devices, in order to bring it in conformity with this Regulation, combined with the assignment of a new lifetime to the refurbished device (article 2 (19) MDR).

An **"importer"** is a natural or legal person established within the Union who places a device from a third country on the Union market (article 2 (21) MDR).

A **"medical device"** is any instrument, apparatus, appliance, software, implant, reagent, material or other article, intended by the manufacturer to be used, alone or in combination, for human beings for one or more of the specific medical purposes of:

- diagnosis, prevention, monitoring, treatment or alleviation or disease,
- diagnosis, monitoring, treatment, alleviation of or compensation for an injury or disability,
- investigation, replacement or modification of the anatomy or of a physiological process or state,
- control or support of conception,
- disinfection or sterilisation of any of the above-mentioned products,

and which does not achieve its principal intended action by pharmacological, immunological or metabolic means, in or on the human body, but which may be assisted in its function by such means (article 2 (1) MDR).

A **"custom-made device"** is any device specifically made in accordance with a written prescription of a doctor of medicine, a dental practitioner or any other person authorised by national law by virtue of this person's professional qualifications who gives, under his responsibility, specific design characteristics, and is intended for the sole use of a particular patient.

However, mass-produced devices which need to be adapted to meet the specific requirements of a doctor of medicine, a dental practitioner or any other professional user and devices which are mass-produced by means of industrial manufacturing processes in accordance with the written

prescriptions of doctors of medicine, dental practitioners or any other authorised person must not be considered to be custom-made devices (article 2 (3) MDR).

II. REGULATORY FRAMEWORK APPLICABLE TO MANUFACTURERS IN THE CURRENT AMENDED PROPOSAL OF THE REGULATION ON MEDICAL DEVICES

A. OBLIGATIONS APPLICABLE TO MANUFACTURERS

1. Compliance with the regulation

a. General obligation

The manufacturer is responsible for ensuring that devices have been designed and manufactured in accordance with the requirements of the MDR when placing devices on the market or putting them into service (article 8 (1) MDR).

For a medical device to be in compliance with the MDR, general safety and performance requirements as set out in Annex I of the MDR must be met (article 4 (2) MDR).

Furthermore, manufacturers must undertake an assessment of the conformity of the device. Different procedures for conducting conformity assessments apply according to the classification of the device. Devices are divided into classes I, IIa, IIb and III, taking into account their intended purpose and inherent risks (article 41; article 42; Annexes VII to XI MDR).

b. Particular obligation for manufacturers of custom-made devices

The conformity assessment procedure for manufacturers of custom-made devices is described in Annex XI of the MDR. Manufacturers of custom-made devices must draw up a statement before placing the device on the market. The custom-made device shall be accompanied by such a statement, which shall be made available to a specified patient or user, identified by name, an acronym or a numerical code (article 19 (2) MDR).

The statement must contain the following information:

- the name and address of the manufacturer and of any additional manufacturing sites;
- if applicable, the name and address of the authorised representative;
- data allowing identification of the device in question;
- a statement that the device is intended for exclusive use by a particular patient or user, identified by name, an acronym or a numerical code;
- the name of the doctor of medicine, dental practitioner or any other person authorised by national law by virtue of this person's professional qualifications who made out the prescription and, where applicable, the name of the health institution concerned;

- the specific characteristics of the product as indicated by the prescription;
- a statement that the device in question conforms to the general safety and performance requirements (Annex I) and, where applicable, indicating which general safety and performance requirements have not been fully met, together with the grounds therefor;
- where applicable, an indication that the device contains or incorporates a medicinal substance, including a human blood or plasma derivative, or tissues or cells of human origin or of animal origin as referred to in Commission Regulation (EU) No 722/2012.

The manufacturer of a custom-made device may be required by its Member State to submit to the competent authority a list of such devices which have been made available in its territory (article 19 (2) MDR).

2. Technical documentation

A manufacturer needs to draw up technical documentation that allows assessment of the conformity of the device with the requirements of the MDR (article 8 (2) MDR). The technical documentation must contain information about the description and specification of the device; the labels, packaging, instructions for use and language variants of the device; the design and manufacturing of the device; general safety and performance requirements; a summary of the risk/benefit analysis and risk management and product verification and validation (Annex II MDR).

When the technical documentation is voluminous or held in different locations, the manufacturer needs to provide summary technical documentation and grant access to the full technical documentation upon request by a competent authority. Manufacturers need to keep the technical information available to the competent authorities for a period of at least five years after the device has been placed on the market (article 8 (4) MDR). A device has been placed on the market when it was made available for the first time on the Union market (article 2 (17) MDR).

Manufacturers need to update their technical documentation with vigilance information, *i.e.* information on incidents received from healthcare professionals, patients and users, serious incidents, field safety corrective actions, periodic summary reports, trend reports, and field safety notices (article 65 MDR).

3. Harmonized standards

Manufacturers must ensure that medical devices have been designed and manufactured in accordance with the requirements of the MDR (article 8 (1) MDR). Article 6 (1) MDR contains the presumption that medical devices which are in conformity with the relevant harmonized standards, or parts thereof, the references of which have been published in the Official Journal of the European Union, are in conformity with the requirements of the MDR. Manufacturers who

manufacture medical devices in conformity with the harmonised standards that cover the requirements of the MDR can thus rely on the presumption contained in article 6 (1) MDR.

4. Information obligations

Manufacturers must accompany the device with the information needed to identify the device and its manufacturer, and communicate safety and performance related information to the user, professional or lay person[1], or other person, as appropriate (Section 19 of Annex I MDR). The information needs to be supplied in an official Union language which can be easily understood by the intended user or patient. The language(s) of the information to be supplied by the manufacturer may be determined by the law of the Member State where the device is made available[2] to the user or patient (article 8 (7) MDR).

5. Liability insurance

A manufacturer will have to take a liability insurance that covers damages to patients or users that can be directly attributed to a manufacturing defect of the same medical device (article 8 (10a) MDR).

6. Implant card

Manufacturers of implantable devices must provide an implant card with the device to the healthcare professional. The healthcare professional is responsible for making the implant card available to the particular patient who has been implanted with the device. The implant card contains information about:

- the identification of the device, including UDI;
- warnings, precautions or measures to be taken by the patient or a healthcare professional with regard to reciprocal interference with reasonably foreseeable external influences or environmental conditions;
- description of potential adverse effects;
- expected lifetime and necessary follow-up;
- principal characteristics of the device, including the materials used (article 16 MDR).

In the current proposal, manufacturers of dental implants do not fall under this obligation and are exempted from providing an implant card with the device to the healthcare professional (article 16 (1) MDR).

[1] 'lay person' is defined in the MDR as an individual who does not have formal education in a relevant field of healthcare or medical discipline (article 2 (26) MDR).
[2] 'making available on the market' is defined in the MDR as any supply of a device, other than an investigational device, for distribution, consumption or use on the Union market, whether in return for payment or free of charge (article 2 (16) MDR).

7. Clinical evaluation and clinical investigation

Manufacturers need to conduct clinical evaluation in order to demonstrate the conformity of medical devices with the general safety and performance requirements set out in Annex I (article 4(3) MDR). A clinical evaluation is the assessment and analysis of clinical data pertaining to a device in order to verify the safety and performance of the device when used as intended by the manufacturer (article 2 (32) MDR). The MDR sets out the principles and procedures to be followed by the manufacturers when conducting clinical evaluations (article 49 and Part A of Annex XIII MDR).

Unless it is duly justified for manufacturers of devices falling within class III and implantable devices to rely on existing clinical data, they need to perform clinical investigations in order to demonstrate the conformity of medical devices with the general safety and performance requirements. A clinical investigation is a systematic investigation in one or more human subjects, undertaken to assess the safety or performance of a device (article 2 (33) MDR). The MDR sets out principles and procedures that need to be complied with when performing clinical investigations (articles 50-60 MDR).

8. Corrective action

Manufacturers who consider or have reason to believe that a device which they have placed on the market is not in conformity with the MDR must immediately take the necessary corrective action to bring that product into conformity, withdraw it or recall it, as appropriate (article 8 (8) MDR). Corrective action is action to eliminate the cause of a potential or real non-conformity or other undesirable situation (article 2 (45) MDR).

Manufacturers must inform without delay the users of the device in question of the corrective action taken by means of a field safety notice and must enter this notice in the electronic system on vigilance (*see infra*, reporting obligations) (article 63 (5) MDR). The field safety notice is the communication of the manufacturer in relation to the field safety corrective action (article 2 (47) MDR).

9. Reporting obligations

a. General obligation

(i) Incidents and field safety corrective action

Manufacturers have the obligation to report any incidents and field safety corrective action within 15 days after they have become aware of the event (article 61 MDR) (*see supra*, corrective action).

An incident is any malfunction or deterioration in the characteristics or performance of a device made available on the market, any inadequacy in the information supplied by the manufacturer and any unexpected undesirable side-effect (article 2 (43) MDR). The manufacturer needs to indicate in its report the date and place of the incident, whether it is serious and provide information on the patient or user and healthcare professional involved in the incident in case this information is available.

A field safety corrective action is a corrective action taken by the manufacturer for technical or medical reasons to prevent or reduce the risk of a serious incident in relation to a device made available on the market (article 2 (46) MDR).

Manufacturers need to report to the electronic system of vigilance (article 61 MDR). The electronic system on vigilance is a system that will be set up and managed by the Commission in order to collate and process vigilance information (article 62 MDR).

(ii) Trend reporting

Manufacturers of medical devices classified in class IIb and III need to report to the electronic system of vigilance statistically significant increases in the frequency or severity

- of all incidents
- or of expected undesirable side-effects that have a significant impact on the risk-benefit analysis and which have led or may lead to unacceptable risks to the health or safety of patients, users or other persons when weighted against the intended benefits (article 64 MDR).

(iii) Safety and clinical performance

Manufacturers of class III medical devices and implantable devices need to draw up a report on the safety and clinical performance of the device based on the information collected during the clinical investigation (*see infra*, clinical evaluation and clinical investigation).

b. Exceptions applicable to manufacturers of custom-made devices

Manufacturers of custom-made devices need not to report incidents and field safety corrective action to the electronic system of vigilance but to the competent authority of the member state in which the device has been made available (article 61 and 62 MDR).

Manufacturers of custom-made devices are also exempted from drawing up a report on the safety and clinical performance of a device (article 26 MDR).

10. Cooperation with competent authorities

The MDR imposes cooperation obligations on the manufacturers. In response to a reasoned request from a competent authority, the manufacturer needs to provide the competent authority with all the information and documentation necessary to demonstrate the conformity of the device, in an official Union language which can be easily understood by that authority. Manufacturers need furthermore to cooperate with the authority, at its request, on any corrective action taken to eliminate the risks posed by devices which they have placed on the market or put into service (article 8 (9) MDR).

When manufacturers update their technical documentation with vigilance documentation (*see infra*, technical documentation), manufacturers also need to make this vigilance documentation available to their notified bodies, which shall assess the impact of the vigilance data on the conformity assessment and the certificate issued (article 65 MDR). Notified bodies are conformity assessment bodies designated in accordance with the MDR (article 2 (30) MDR).

11. Qualified person

a. General obligation

Manufacturers need to have within their organization at least one qualified person who possesses expert knowledge in the field of medical devices.

The expert knowledge must be demonstrated by:

a) a diploma, certificate or other evidence of formal qualification awarded on completion of a university degree or of an equivalent course of study, in law, in natural sciences, medicine, pharmacy, engineering or another relevant discipline,
or
b) three years of professional experience in regulatory affairs or in quality management systems relating to medical devices (article 13 MDR).

b. Exception for manufacturers of custom-made devices

Manufacturers of custom-made devices may demonstrate the required expert knowledge by at least two years of professional experience within the relevant field of manufacture (article 13 (1) MDR).
Manufacturers of custom-made devices who are micro-enterprises as defined by Commission Recommendation 2003/361/EC54[3] are exempted from this obligation (article 13 (1) MDR).

[3] Recommendation 2003/361/EC54 determines the staff headcount and financial ceilings of a micro-enterprise as an enterprise which employs fewer than 10 persons and whose annual turnover and/or annual balance sheet total does not exceed EUR 2 million.

12. EU declaration of conformity and CE marking of conformity

a. General obligation

Manufacturers need to draw up an EU declaration of conformity and affix the CE marking of conformity, when compliance of a device with the applicable requirements has been demonstrated following the applicable conformity assessment procedure (Article 8 (3) MDR; Article 17 juncto 18 MDR; article 19 MDR).

b. Exception for manufacturers of custom-made devices

Manufacturers of custom-made devices are exempted from the obligation to draw up an EU declaration of conformity and affix the CE marking of conformity (article 8 (3) MDR; article 18 MDR).

13. Quality management system

a. General obligation

Manufacturers need to institute and keep up to date a quality management system proportionate to the risk class and the type of device. A quality management system is a system that addresses the responsibility of the management; resource management, including selection and control of suppliers and subcontractors; product realisation; processes for monitoring and measurement of output, data analysis and product improvement (article 8 (5) MDR).

b. Exception applicable to manufacturers of custom-made devices

Manufacturers of custom-made devices do not need to institute a quality management system (article 8 (5) MDR).

14. Post-market surveillance plan

a. General obligation

A post-market surveillance plan is a systematic procedure to collect and review experience gained from the devices placed on the market or put into service.

The post-market surveillance plan sets out the process for collecting, recording and investigating complaints and reports from healthcare professionals, patients or users on suspected incidents related to a device, keeping a register of non-conforming products and product recalls or withdrawals, and if deemed appropriate due to the nature of the device, sample testing of marketed devices (article 8 (6) MDR). Part of the post-market surveillance plan is a plan for post-market clinical follow-up (Part B of Annex XIII MDR).

b. Exception applicable to manufacturers of custom-made devices

Manufacturers of custom-made devices are exempted from the obligation to keep up to date a 'post-market surveillance plan' (article 8(6) MDR), but do need to review and document experience gained in the post-production phase, including having a post-market clinical follow-up (Annex XI MDR).

15. Identification within the supply chain

a. General obligation

Manufacturers need to identify:
(a) any economic operator to whom they have supplied a device;
(b) any economic operator who has supplied them with a device;
(c) any health institution or healthcare professional to whom they have supplied a device (article 23 MDR).

b. Exception applicable to manufacturers of custom-made devices

Manufacturers of custom-made devices are exempted from the obligation to identify the relevant persons within the supply chain (article 23 MDR).

16. Unique Device Identification system (UDI)

a. General obligation

A Unique Device Identification system ("UDI system") is a system that allows identification and traceability of devices (article 24 (1) MDR). A Unique Device Identification ("UDI) is a series of numeric or alphanumeric characters that is created through internationally accepted device identification and coding standards and that allows unambiguous identification of specific devices on the market (article 2 (12) MDR).

The Commission is empowered to determine the devices, categories or groups of devices whose identification shall be based on the UDI system (article 24 (7) MDR).

Before placing it on the market, manufacturers must assign to a device a UDI, if that device belongs to the devices, categories or groups of devices determined by the Commission (article 24 (3) MDR).

b. Exception applicable to manufacturers of custom-made devices

Custom-made devices do not fall under the obligation to be part of the UDI system (article 24 (1) MDR).

17. Electronic system on registration of devices and economic operators

a. General obligation

Manufacturers need to submit information that is necessary and proportionate to describe and identify the device and to identify the manufacturers and, where applicable, the authorised representative and the importer to an electronic system, *i.e.* "the Electronic System on Registration of Devices and Economic Operators" (article 25 (2) MDR).

Where manufacturers have their devices designed and manufactured by another legal or natural person, the identity of that person must be part of the information to be submitted to this electronic system (article 8 (10) MDR).

b. Exception applicable to manufacturers of custom-made devices

Manufacturers of custom-made devices are exempted from the obligation to submit the necessary information to the electronic system (Article 25 (2) MDR).

III. OBLIGATIONS APPLICABLE TO IMPORTERS

The legal framework described in this part applies to importers. An importer, as defined in the MDR, must be understood as a natural or legal persons established within the Union who places a device from a third country (*i.e.* non-EU country) on the Union market.

1. Obligation to ensure compliance with MDR

Importers of medical devices need to fulfill certain obligations under the MDR to ensure that only medical devices that are in conformity with the MDR are placed on the market. An importer who considers or has reason to believe that a device is not in conformity with the MDR, must not place the device on the market until the device has been brought into conformity (article 11 (2) MDR).

Before placing a device on the market, an importer needs to ensure that:

- the appropriate conformity assessment procedure has been carried out by the manufacturer;
- an authorized representative in accordance with article 9 MDR has been designated by the manufacturer;
- the EU declaration of conformity and the technical documentation has been drawn up by the manufacturer;

- where applicable, the device bears the required CE marking of conformity;
- the device is labeled in accordance with the MDR and accompanied by the required instructions for use and EU declaration of conformity;
- where applicable, a Unique Device Identification has been assigned by the manufacturer in accordance with Article 24 MDR (article 11 (2) MDR).

2. Information obligations

Importers need to indicate the following information on the device, on its packaging or in a document accompanying the device:

- their name, registered trade name or registered trade mark;
- the address of their registered place of business at which they can be contacted;
- their location.

Any additional label must not obscure any information on the label provided by the manufacturer (article 11 (3) MDR).

3. Reporting obligations and corrective action

An importer must inform the manufacturer and his authorized representative of:

- devices he placed on the market and he considers or has reasons to believe are not in conformity with the MDR;
- devices that present a risk;
- complaints or reports from healthcare professionals, patients or users about suspected incidents related to a device he placed on the market (article 11 (2), (7) and (8) MDR);
- its monitoring activities (article 11 (6) and (7) MDR).

Where the device is not in conformity with the MDR, the importer needs to take corrective action to bring the device into conformity, withdraw or recall it (article 11 (7) MDR).

An importer must inform the competent authorities of the Member States in which the importer made the device available of the non-compliance and of any corrective action taken for a device presenting a risk. Where a notified body issued a certificate for the device in question, the importer also needs to inform the notified body (article 11 (7) MDR).

4. Registration obligation

The Commission will have to set up an electronic system to collate and process information that is necessary and proportionate to describe and identify the device and to identify the manufacturer and, where applicable, the authorised representative and the importer.

Importers have to submit the abovementioned information to the electronic system (Article 11 (4) MDR).

5. General safety and performance requirements

Importers must ensure, that the general safety and performance requirements of Annex I of the MDR, are not jeopardized, by the storage and transport conditions, while a device is under their responsibility (article 11 (5) MDR).

6. Monitoring

When deemed appropriate with regard to the risks presented by a device and in order to protect the health and safety of patients and users, the importer must carry out monitoring measures. The importer must carry out sample testing of marketed products, investigate complaints and keep a register of complaints, of non-conforming products and of product recalls and withdrawals (article 11 (6) MDR).

7. Cooperation obligation

The cooperation obligation of the importer consists on the one hand in keeping documents at the disposal of the market surveillance authorities and on the other hand in providing documents at the request of a market surveillance authority and/or competent national authority.

The importer needs to keep a copy of the EU declaration of conformity five years (and 15 years for implantable devices) at the disposal of the market surveillance authorities (article 11 (9) MDR).

The importer needs to ensure that for a period of 5 years after placing the device on the market, the following documents can be made available at the request of the market surveillance authority:

- Technical documentation
- A copy of the relevant certificate issued pursuant to article 45 MDR.

The obligation to keep documents and to provide these to the market surveillance authorities can be delegated to authorized representatives (article 11 (9) MDR).

The importer needs to provide a competent national authority with all the information and documentation necessary to demonstrate the conformity of a product. When the authorized representative for the device in question provides the required information, this obligation shall be considered as fulfilled (article 11 (10) MDR).

Importers must furthermore cooperate with a competent national authority, at its request, on any action taken to eliminate the risks posed by products which they have placed on the market (article 11 (10) MDR).

8. Cases in which obligations of manufacturers apply to importers

In the following instances the importer will assume the obligations incumbent on the manufacturers, namely when the importer:

1. makes available on the market a device under his name, registered trade name or registered trade mark;
2. changes the intended purpose of a device already placed on the market or put into service;
3. modifies a device already placed on the market or put into service in such a way that compliance with the applicable requirements may be affected[4].

This obligation does not include a person, who cannot be considered as a manufacturer according to the MDR, assembling or adapting a device already on the market to its intended purposes for an individual patient.

For devices placed on the market in sterile condition, it shall be presumed that the original condition of the device is adversely affected if the package that shall ensure the sterile condition is opened, damaged or otherwise negatively affected by the repackaging.

An importer who carries out any of the activities mentioned in the first two points above must comply with specific information obligations, reporting obligations and have a quality management system in place (article 14 MDR).

IV. CONCLUSION

This memorandum provides an overview of the obligations applicable to manufacturers in the MDR. Based on the MDR, dental prosthesis and dental crowns can fall under the definition of custom-made devices. It is for that reason that the exceptions applicable to manufacturers of custom-made devices were highlighted.

We understand that it is important for FEPPD to also have an overview of the legal obligations applicable to importers of medical devices into the EU. Therefore the legal framework applicable to persons placing a device from a third country on the Union market has been set out. This legal framework aims at transferring the obligations of the manufacturers to the importers in order to guarantee that imported medical devices need to comply with the same requirements as medical devices produced within the European Union.

[4] Modifying a device already placed on the market as described in point 3 does not include providing, including translating the necessary information relating to a device already placed on the market. Nor does it include changes to the outer packaging of a device already placed on the market, including a change of pack size, if the repackaging is necessary in order to market the product in the relevant Member State and if it is carried out in such conditions that the original condition of the device cannot be affected by it.

Note furthermore that the current medical device directives will be revised by means of a regulation. Consequently, the obligations contained in the MDR become directly applicable and do not require to be transposed into national legislation.

We hope the above overview of the regulatory framework for manufacturers and importers provides clear guidance on the proposed legislative changes that the new regulations will introduce. This guidance aims to be a helpful tool on the basis of which we are happy to receive any input. The input will enable us to identify and represent the interests of dental technicians in relation to the medical device regulations.