ARTICLE

Devices without a medical purpose: how do they fit into the MDR?

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ABSTRACT

In this article we explore a newly introduced product category described in Annex XVI of the Regulation (EU) 2017/745 on medical devices (MDR): "Devices without an intended medical purpose".

Products like decorative contact lenses, substances for dermal filling and equipment for liposuction would fall into this category. The definition of a medical device does not include products without an intended medical purpose. Still, the aforementioned device groups are similar in function and risk profile to medical devices. The overall aim was thus to introduce regulatory mechanisms that correspond to these similarities.

We list the basic MDR requirements, including clinical evaluation and post-market surveillance, which manufacturers of Annex XVI products will have to comply with in order to place their products on the EU market.

Finally, we discuss some important timelines for manufacturers and propose a few useful regulatory strategies.

Non-medical devices

A new category has been introduced in the Medical Device Regulation (MDR, 2017/745) – "Devices without an intended medical purpose". For the sake of convenience, we will name these products "non-medical devices".

The MDR (Annex XVI) lists six categories of devices with non-medical use:

1. Contact lenses or other items intended to be introduced into or onto the eye,[1] for example, non-prescription decorative contact lenses.
2. Products intended to be totally or partially introduced into the human body through surgically invasive means for the purpose of modifying the anatomy or fixation of body parts with the exception of tattooing products and piercings. Examples (see also Figure 1) include horn implants, eyeball implants, genital beading, breast implants.
3. Substances, combinations of substances, or items intended to be used for facial or other dermal or mucous membrane filling by subcutaneous, submucous or intradermal injection or other introduction, excluding those for tattooing. Examples include dermal fillers (either Botox or hyaluronic acid).
4. Equipment intended to be used to reduce, remove or destroy adipose tissue, such as equipment for liposuction, lipolysis or lipoplasty. An example is body sculpting equipment.
5. High intensity electromagnetic radiation (eg, infrared, visible light and ultra-violet) emitting equipment intended for use on the human body, including coherent and non-coherent sources, monochromatic and broad spectrum, such as lasers and intense pulsed light equipment, for skin resurfacing, tattoo or hair removal or other skin treatment. Examples include intense pulsed light (IPL) machines for body hair removal or skin rejuvenation.
6. Equipment intended for brain stimulation that apply electrical currents or magnetic or electromagnetic fields that penetrate the cranium to modify neuronal activity in the brain, for example, transcranial (non-surgically invasive) stimulation.

The new MDR Annex XVI category includes products with aesthetic or another non-medical uses that are similar in function and risk profile to devices intended for a medical purpose.

Take, as an example, non-corrective contact lenses (commonly known as plano lenses) or decorative lenses which are not considered to be medical devices under the Medical Device Directive (MDD) as they have no corrective function.[2] These products would qualify for the Annex XVI category since they have no medical purpose.

On the other hand, some non-corrective contact lenses, coloured or not, do have a medical purpose. They may serve, for example, to treat congenital or traumatic conditions and are also used in clinical practice or a post-surgical setting as a medical prosthesis. These and other contact lenses with specific medical claims are recognised as medical devices with medical purpose under the MDD and MDR and will not, therefore, fall into the non-medical device category in Annex XVI. Likewise, all breast implants are regulated under the MDD.

Please note that non-medical devices may be intended both for a lay person (an individual who does not have formal education in a relevant field of healthcare or medical discipline) and/or prescription use.

The rationale of the legislation behind the newly introduced Annex XVI group is clear. These products share comparable risks with medical devices and, therefore, it makes sense that they also have at least a risk management system in place to ensure product safety.

In the past, many non-medical devices have had safety problems. For example, there have been numerous cases where coloured contact lenses caused cuts, scratches, corneal abrasions, corneal ulcers and serious bacterial infections such as keratitis, leading to the need for eye surgery or even to a loss of vision.

How to place non-medical devices on the market

Manufacturers of Annex XVI products sold in Europe will have to comply with the requirements laid out in the MDR for general medical devices.

There are number of steps to take in order to comply with the MDR requirements:

- Specify the intended purpose of your device
- Identify the product classification
- Establish a risk management system and ensure your device complies with common specifications (CSs)
- Conduct a clinical evaluation[3] for your device
- Ensure your device complies with other relevant MDR requirements
- Pass a conformity assessment carried out by a notified body, if so required
- Draw up a declaration of conformity and affix a CE marking on the device
- Comply with the obligations relating to the unique device identifier (UDI) system
- Appoint a person responsible for regulatory compliance (PRRC)
- Submit key information about the manufacturer, authorised representative and importer to the electronic database (EUDAMED)
- Place your product on the market anywhere in the EU
- Meet the post-market surveillance (PMS)[4] and vigilance requirements.

For a complete list of manufacturers' obligations, refer to Article 10 of the MDR. The obligations of importers and distributers are described in Articles 13 and 14, respectively.

Defining the product's intended use

In general, it is recommended to define the intended use of any medical product early in its development and this is also true for products without an intended medical purpose.

The MDD defines intended purpose as: "The use for which the device is intended according to the data supplied by the manufacturer on the labelling, in the instructions and/or in promotional materials."

It is important to note that the MDR definition goes beyond that of the MDD to include sales materials and clinical evaluation: "Use for which a device is intended according to the data supplied by the manufacturer on the label, in the instructions for use or in promotional or sales materials or statements and as specified by the manufacturer in the clinical evaluation."

Defining and phrasing the intended purpose of a device is of the utmost importance and must be formulated in a precise, unambiguous and consistent way throughout the product's documentation.

The definition of a product's intended purpose has many far-reaching consequences of which, to name a few:

- It could affect whether the product is classified as a medical device or not
- Slight wording differences may sometimes impact on product classification that determines the conformity assessment route for the device
- It will be an integral part of all technical documentation, including labelling, promotional and clinical documentation
- Clinical evidence shall be appropriate in view of the characteristics of the device and its intended purpose.

The manufacturers of borderline and aesthetic products may sometimes fine-tune the intended use of their products to position these within the desired regulatory framework.

Common specifications

Devices without an intended medical purpose will need to demonstrate compliance with CSs which will address, at the very least, the application of risk management and, where necessary, clinical evaluation regarding safety.

Originally, the European Commission (EC) promised to adopt the necessary CS for each of the six product categories by 26 May 2020 (the original date of application – DoA). These were supposed to be applied six months from the date of their entry into force or from the DoA, whichever was the latest. That did not happen.

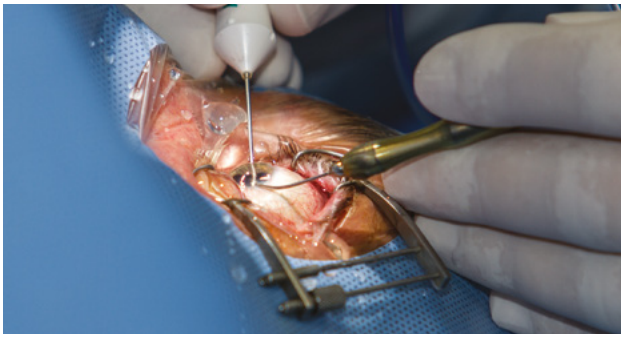
On 3 June the EC updated the MDR and IVDR implementing measures rolling plan,[5] according to which, CS for products without a medical purpose should be adopted during Q4 2020.

At the moment, the Commission has only published a draft version of CS for another group of products – reprocessing single-use medical devices.[6] This comprehensive document presents in detail the requirements for the reprocessing of single-use devices which, among others, relate to risk management, the preliminary assessment of the suitability of a single-use device for reprocessing and the validation of procedures.

FIGURE 1

Examples of products introduced into the human body through surgically invasive means

Breast implants



Eyeball implants

Devices with a medical and a non-medical intended purpose

Devices with both a medical and a non-medical intended purpose will need to "fulfil cumulatively the requirements applicable to devices with an intended medical purpose and those applicable to devices without an intended medical purpose."

Therefore, product functions related to the medical use of the device will need to show compliance with the relevant harmonised standards. Likewise, the functions related to the non-medical use of the device will need to show compliance with the CS for that product category.

In general, medical devices which are compliant with the relevant harmonised standards (or their relevant parts) are presumed to conform to the requirements of the Regulation covered by those standards or parts thereof.

At the time of writing, no MDR standards have yet been harmonised, although the majority of existing and new standards are expected to be adopted by May 2024. So, one simple question presents itself – which standards should manufacturers use as a reference and benchmark for safety and performance until the harmonised standards become available?

A possible model for standard use has recently been suggested by MedTech Europe[7] and includes:

- The state-of-the-art versions of standards which are harmonised under the current Directives
- Other published standards identified as candidates for harmonisation under the respective Regulation; or
- Appropriate international and European consensus standards (International Organization for Standardization/International Electrotechnical Commission or European Standards), given that harmonised standards mostly originate from these.

With regard to devices included in Annex XVI, these will need to meet the expectations defined by the CS, taking into account the state of the art and, in particular, existing harmonised standards for analogous devices with a medical purpose, based on similar technology.

The same would apply to the functions related to the non-medical use of a dual device. This means that the manufacturer of a non-medical device will also need to evaluate and take into consideration any existing harmonised standards for analogous devices with a medical purpose, based on similar technology (NB: reference to any used CS or harmonised standard should also be included in the post-marketing clinical follow-up [PMCF] plan.). Our opinion is that all non-medical devices will need to meet horizontal harmonised standards, such as ISO 14971 and others.

In some cases, it may be possible to "split" a dual product into two products; with and without a medical purpose, and place them on the market separately.

It is clear that a heavy workload lies ahead for manufacturers and they should move quickly to meet the new DoA 26 May 2020 deadline.

The transition to Annex XVI MDR compliance will certainly be smoother for devices that are already CE certified. However, the manufacturers of these products will still need to make additional efforts to meet higher and/or new MDR standards for clinical evaluation, PMS, product traceability and other areas.

Compliance with MDR requirements will be far more challenging for aesthetic product manufacturers who have no experience of medical device regulations.

The key element for success, from our experience, is to gain the full support of top management as this process requires team work, significant time and may also be costly.

Clinical evaluation

Clinical evaluation is required for all devices regulated under MDR including Annex XVI products.

During the clinical evaluation process, a manufacturer should plan and continuously generate, collect and analyse the clinical data for the device in order to verify its safety and performance, including clinical benefits.

For the devices without an intended medical purpose, clinical benefit will be understood as a demonstration of device performance.

Clinical evaluation for non-medical devices will be based on relevant data concerning safety, including data from PMS, PMCF and, where applicable, specific clinical investigation.

For non-medical devices, clinical investigations shall be performed unless "reliance on existing clinical data from an analogous medical device is duly justified". This means that clinical investigations may be required for the majority of Annex XVI products.

The Medical Device Coordination Group (MDCG) guidance on clinical evaluation equivalence[8] explains that an "analogous device" should be understood as a "medical device which is similar in terms of functioning and risks profile and has a medical purpose".

In order to justify such use of clinical data from an analogous device, the manufacturer should apply the principles for demonstration of equivalence. There shall be no significant difference in the safety and performance between the product and the presumed analogous medical device.

PMS and PMCF

PMS is a collection of processes and activities used to monitor the performance of a medical device. These activities are planned to generate information regarding use of the device to identify device design and/or usage problems and accurately characterise the real-world device behaviour and clinical outcomes. PMS should be performed according to a device-specific PMS plan, which should contain the PMCF plan.

A PMCF plan is aimed to proactively collect and evaluate clinical data of a CE marked medical device placed on the market or put into service within its intended purpose.

There are a number of things that are common in both PMS and PMCF activities so it is important to distinguish between them. PMS includes various surveillance activities for the product on the market including reporting on sales, incidents, recalls, product complaints, user feedback and complaints, feedback received on conferences or exhibitions or fairs.

On the other hand, PMCF is mostly focused on the clinical feedback from the market, and not just any feedback. PMCF gathers clinical experience through product performance metrics analysis; interviewing healthcare professionals; writing product case studies; performing observational studies in hospitals; gathering feedback from patients via surveys; and the review of literature. Of course, one of the PMCF methods would be to plan to conduct the PMCF study, if necessary.

Importance advice for manufacturers would be to include a PMCF plan in their product-specific PMS plan, although the MDR offers the possibility for providing justification as to why a PMCF may not be applicable. Among others, PMCF activities may include a manufacturer device registry, PMCF studies, planned real-world evidence (RWE) analyses, surveys and others.

The findings of the PMCF should be analysed by the manufacturer and its results will be documented in the PMCF evaluation report, which will be part of the clinical evaluation report (CER) and the technical documentation. The conclusions of the PMCF evaluation report will be taken into account to update the clinical evaluation, risk management documentation, PMS plan and the summary of safety and clinical performance (SSCP), if applicable.

We encourage manufacturers to use the PMCF plan[9] and PMCF report[10] templates that have recently been published by the MDCG.

Timelines, timelines, timelines

The long-expected MDR date of application has recently been postponed for a year – from 26 May 2020 to 26 May 2021.[11]

Do not be misled to think now there is time to relax.

As for other medical devices, the qualification of the products covered by Annex XVI that are currently pursuant to Directive 93/42/EEC (MDD) will remain valid until the DoA – 26 May 2021. Therefore, manufacturers must have their MDD certificates issued or renewed before 26 May 2021 in order to use soft transition and place their products on the market until 26 May 2024, at the latest. However, contact with notified bodies should be made as soon as possible to check their availability to work on new MDD certificates or their renewals as many of them will already busy with ongoing MDR projects.

Bear in mind that any significant product change on the product can only be made only before 26 May 2021 (Article 120[3]).[12]

Although the DoA has been delayed for a year, the deadline for when

the new MDR certificates need to be available remains the same, by 26 May 2024. From this perspective, the MDR delay is not a true delay, as companies now have less time to translate their MDD into MDR certificates and the capabilities of notified bodies are not expected to grow. Due to this and other reasons, it is advisable not to plan MDR certification towards the end of the transition period.

There is another even more important issue to take into consideration. Once the MDR application certification procedure with the notify body has been initiated, most of the technical documentation (TD) needs to be ready for evaluation within six months. Failure to meet this deadline, withdrawal of application or refusal of TD for any reason will result in the certification process being discontinued and this will be recorded in the EUDAMED database.

TD for evaluation should include at the very least, information as per MDR Annex II, sec. 1 and sec. 3(c), including a clinical evaluation plan. Other documents and information could also be requested by the notified body.

Finally, if the product under Annex XVI is currently not regulated as a medical device, it will need to achieve compliance with all MDR requirements by 26 May 2021 in order to be marketed in the EU. This includes some heavy-duty documents, including PMS and PMCF plans. As previously mentioned, companies will be given six months from the publication of CS to meet the specific product requirements. ■

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