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EU MEDICAL DEVICE REGULATION & LANGUAGES

Q&A on the regulation, continued compliance and the impacts on content translations.

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WHAT ARE THE MAIN CHANGES TO THE MEDICAL DEVICE REGULATION (EU MDR)?

From the EU Commission website.

Note: Information in brackets [] is added by the authors of this Q&A document.

The new regulations contain a series of extremely important improvements to modernise the current system. Among them are:

- stricter ex-ante control for high-risk devices via a new pre-market scrutiny mechanism with the involvement of a pool of experts at EU level
- reinforcement of the criteria for designation and processes for oversight of notified bodies
- inclusion of certain aesthetic [cosmetic] devices that present the same characteristics and risk profile as analogous medical devices under the scope of the regulations
- a new risk classification system for in vitro diagnostic medical devices in line with international guidance
- improved transparency through a comprehensive EU database on medical devices and a device traceability system based on unique device identification
- introduction of an 'implant card' for patients containing information about implanted medical devices
- reinforcement of the rules on clinical evidence, including an EU-wide coordinated procedure for authorising multi-centre clinical investigations
- strengthening of post-market surveillance requirements for manufacturers
- improved coordination mechanisms between EU countries in the fields of vigilance and market surveillance

All actors involved with medical devices, from their manufacture to their use, will have to comply with the new Regulations by May 2021 (May 2022 for in vitro diagnostic medical devices). It is important that all actors are fully aware of the changes and start preparing for the implementation of the new Regulations as soon as possible.

HOW WILL I KNOW IF MY PRODUCTS WHICH ARE CURRENTLY MARKETED IN VARIOUS EUROPEAN UNION STATES, WILL CONTINUE TO BE COMPLIANT WITH THE IMPLEMENTATION OF THE NEW MDR IN 2020?

Compared to the process under AIMDD/MDD, there is no significant change for determining compliance to EU MDR.

All medical devices currently placed on the market under the AIMDD and the MDD must undergo an evaluation for compliance to the EU MDR before they can be placed on the EU market under EU MDR. Devices eligible for self-certification will need a new internal review performed and documented. All other devices will need to be submitted for review and approval by a Notified Body.

Devices currently placed on the market under AIMDD or MDD (“Legacy Products”) can continue to be distributed in the EU under a transition period that ends in May 2024, assuming their relevant AIMDD/MDD certificates do not expire before this date. No new certificates under AIMDD or MDD can be granted after the EU MDR is fully in force in May 2021.

If it becomes necessary to make a design, manufacturing or labeling change to Legacy Products before the end of the transition period, the change along with the entire device must be reviewed under EU MDR and the necessary certificates issued before that revised device could be place on the market.

WHAT DOCUMENTATION IS NECESSARY TO DEMONSTRATE CONFORMITY OF A DEVICE TO AN APPROVED AUTHORITY?

Similar to the MDD, conformity assessment procedures under the EU MDR vary by device class. All devices formerly subject to the AIMDD are now classified under the EU MDR (typically meeting the Class III definition).

Conformity assessment procedures under the EU MDR are set out in Article 52:

> ***"Prior to placing a device on the market, manufacturers shall undertake an assessment of the conformity of that device, in accordance with the applicable conformity assessment procedures set out in Annexes IX to XI."***

Whether this assessment also requires pre-market review by a Notified Body depends on the class of the device (Article 52).

For Class III devices and Class IIb devices that administer/remove a medicinal substance:

- Whether a device is also subject to a "clinical evaluation consultation" depends on the device class and other specific criteria in Article 54.
- Whether a device is also subject to "scrutiny" is dependent upon a Competent Authority's decision under Article 55, paragraph 2, or the MDCG and/or Commissions decision under Article 55, paragraph 3.

ARE PAPER IFU'S STILL NEEDED FOR NEAR PATIENT IVD'S?

Requirements for paper or electronic IFUs (eIFUs) are controlled by the existing EU Regulation (207/2012). This requires replacement with EU MDR and will be superseded by an "implementing act."

At this time, industry groups are advocating for the expansion of the scope of eIFUs to include all instructions for use for professional users, regardless of whether the device can only be used by professional users (meaning patient IFUs for devices used by both would still be in paper). The MDCG is also considering expanding the scope to specifically include stand-alone Software as a Medical Device (SaMD), although it was already possible to embed the IFU within stand-alone SaMD. The MDCG is further considering expansion to other types of devices such as contact lenses.

Labeling for near-patient IVDs, is set out in Chapter 3, Paragraph 20.1 of the EU IVDR:

> "(d) Instructions for use shall be provided together with devices. However, in duly justified and exceptional cases instructions for use shall not be required or may be abbreviated if the device can be used safely and as intended by the manufacturer without any such instructions for use.
> (e) Where multiple devices, with the exception of devices intended for self-testing or near-patient testing, are supplied to a single user and/or location, a single copy of the instructions for use may be provided if so agreed by the purchaser who in any case may request further copies to be provided free of charge.
> (f) When the device is intended for professional use only, instructions for use may be provided to the user in non-paper format (e.g. electronic), except when the device is intended for near-patient testing."

This indicates that eIFUs are not permitted for near-patient IVDs unless the implementing act to replace 207/2012 or another implementing act is published allowing this.

HOW DO THE REGULATIONS DIFFER FOR DEVICES THAT ARE INTENDED FOR USE BY PATIENT'S VS MEDICAL PROFESSIONALS?

The EU MDR does not distinguish between lay use and professional use with regard to requirements for device design, manufacturing, risk and safety. The principal difference is in the information provided to the user. Any information required under the EU MDR that is provided to a lay user must be written specifically for the lay user, taking into account the appropriate reading level and other factors appropriate for the intended user. Identification of the user and the appropriate human factors applicable should be part of the usability evaluation and product and labeling validation.

DO THESE DOCUMENTS NEED TO BE TRANSLATED INTO EVERY OFFICIAL UNION LANGUAGE?

Technical files do not need to be translated into the EU-27 official languages. Each manufacturer should work with their Notified Body to agree upon the languages necessary for the Technical File review.

Final product labeling also does not need to be fully translated to submit a complete Technical File. However, the Notified Body will expect to see procedures regarding how translations of labeling are managed and implemented, especially with regard to ensuring products are not distributed to a particular country without the necessary translated labeling being provided, either in the sales pack or on the internet as applicable.

WHAT ADDITIONAL CONTENT MUST BE TRANSLATED AS A RESULT OF THE MDR CHANGES?

There are no additional translation requirements under the EU MDR. In the EU MDR, the requirement is specifically:

> *"Manufacturers shall ensure that the device is accompanied by the information set out in Section 23 of Annex I in an official Union language(s) determined by the Member State in which the device is made available to the user or patient."* (Article 10, paragraph 11)

While this is not strictly speaking a new requirement comparing the EU MDR to the AIMDD/MDD, it is anticipated that there may be additional scrutiny by the Notified Bodies to ensure Economic Operators responsible for placing a product on a market are providing the required local languages. However, the languages required and any exemptions for professional use, have not been modified by the EU MDR and remain the sole responsibility of each Member State.

Note: In this case, Economic Operators could be the manufacturer, the authorized representative, or the distributor.

IS IT MANDATORY TO TRANSLATE SOFTWARE APPLICATIONS USED IN HOSPITALS BY PHYSICIAN'S AND TECHNICIANS IF THE USERS ARE PRESUMED TO BE FLUENT IN ENGLISH?

Each Member State has specific rules regarding official local language requirements and whether there are any exemptions for other languages based on criteria such as professional use (note: in some markets English may not be the, or the only, alternative for professional use). Manufacturers cannot presume technical users are fluent in any language other than the local language.

Manufacturers should apply their risk management system to determine the usability of any medical device including its instructions for use. All aspects of the use of the product should be considered including, but not limited to: technical skill and qualifications of the intended user; required training before use of the product; providing instructions in a local language for the use of software in another language; the risks related to the use and misuse of the software.

Manufacturers may also request derogations from a Member State's Ministry of Health to use a language other than that normally required. Such a request should be predicated upon usability information indicating another language is suitable for the intended user. A derogation may or may not be granted.

WHAT ADDITIONAL LANGUAGES MUST BE TRANSLATED AND HOW DOES THAT CHANGE GIVEN TYPE OF CONTENT (I.E. IFU, LABELING/ PACKAGING, ETC.)?

All labeling (IFU/DFU, sterile/sales pack labels, device markings) must be provided in the local languages specified by the Member States unless the information is provided in symbols.

Practically speaking, this means that if a Member State allows any other language besides the official language, the manufacturer could pick between any allowed (e.g. if English, German, or Swedish is allowed in place of the official Member State language). Likewise, if no exemptions are allowed, then the official language is required. This also means that if there is more than one official language for a Member State, and no exemptions are provided, then the labeling must be provided in all official languages (e.g. official languages in Belgium are Dutch, French, and German).

Symbols are typically useful on labeling such as package labels or device markings. Symbols are an extremely useful way to deal with the limited amount of space on these items. Using symbols eliminates both the need for text and the need to translate text. *

Device markings specifically should be analyzed for how they can be best marked considering their size and material composition, the service life of the device, and its use conditions (e.g. sterilized/cleaned between use; implantable devices, etc.).
When symbols are used, preference is given to symbols from harmonized standards or international standards. Manufacturers should consult ISO 15223-1, IEC 60417, and ISO 7000 to identify symbols appropriate for use with medical devices. All international standards symbols (with few limited exceptions) can be accessed by the public for free at: https://www.iso.org/obp/ui/#home. In order to access native versions of the files for use in their labeling, Manufacturers need to subscribe to the particular standards that contain them.

Under the EU MDR (and the previous directive), other symbols not in standards can be used if both explained in the IFU and validated for usability during design controls. *

*Note: Other geographies, such as the US, limit the use of symbols without accompanying text to those from international standards. If a symbol not from a standard is used, those geographies will still require accompanying text in the required local language, which may require translation depending on the market(s).

HOW IS MDR IMPACTING THE SSCP CLINICAL DELIVERABLE AND WHAT IS THE SUBSEQUENT IMPACT ON TRANSLATION?

The Summary of Safety and Clinical Performance (SSCP) is required for implantable devices (regardless of class) and Class III devices. (Article 32).

The EU MDR does not require that this document be translated. However, it does require that it is ***"...written in a way that is clear to the intended user and, if relevant, to the patient...."*** It is possible that guidance documents may be forthcoming from industry associations or the MDCG/Commission regarding the conditions under which the SSCP or a patient facing portion of it should be translated and into which languages.

Further implementing acts related to the SSCP may also be anticipated as mentioned in Article 32, paragraph 3.

ARE THERE ANY RESTRICTIONS TO WHAT TYPE OF SYMBOLS WE CAN USE?

See above for translations (#10). Preference is given to symbols from harmonized standards or international standards. Other symbols can be used if both explained in the IFU and validated for usability during design controls.

ABOUT ARGOS MULTILINGUAL

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