

MEMORANDUM

To: Whom it May Concern

From: Marc H. Miller, Division President

Re: Medical Device Content & Communications Under MDR/IVDR: Initial Findings

Introduction

The EU's new regulations governing medical devices, the Medical Device Regulations (MDR) and *In Vitro* Diagnostics Regulations (IVDR), contain a number of provisions that will directly affect medical device content, e.g. labeling, marketing, regulatory, clinical, training, etc. Based on expert opinion from noted regulatory resource, [Qserve](#), the MDR/IVDR are expected to increase both the volume and velocity of device-related content, while also increasing the amount of regulatory scrutiny applied. The expected result will be an industry-wide drive to deliver expanded throughput, flexibility, quality and control via content centralization and automation, combined with UDI-enabled digital technology and with an emphasis on risk management.

The following initial findings are taken from an in-process white paper, *The Future of Medical Device Content & Communication Under MDR/IVDR* (in conjunction with Qserve) for consideration by TransPerfect MDS existing and prospective clients.

Initial Finding: More device-related content will be subject to translation, and translation quality will be under increased scrutiny.

Under prior regulation (MDD), content language requirements were vaguely assigned to the National Implementing Legislations (Member States). Now, the MDR itself contains 25 explicit references to language requirements, including labeling and product information.

[Art. 10(11)] *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...clearly comprehensible to the intended user or patient.*

Note: new requirement for “clear comprehensibility” – raising the quality threshold for translated content.

Software

From a regulatory perspective, software UI is considered product labeling. Therefore, it is reasonable to assume all doubt regarding translation of UI has been removed through the labeling language requirements of Article 10. The new language requirements for software are expected to directly impact manufacturers' software translation/localization policies and procedures. This is especially true as the industry has demonstrated an uneven record of translating and controlling UI content. Additionally, more software will be classified as a medical device, and at a higher risk level (e.g. per MDR rule 11, many types of software will be classed IIb or III) – leading to increased scrutiny of newly translated UI.

Software translation/localization services that combine [technical analysis and consulting, medical device specialization, and validated tools](#) are best positioned to assist in an environment of increased regulatory scrutiny. Multilingual testing services – including test plans, case writing, and custom documentation – can be a valuable resource to provide evidence of conformity with MDR/IVDR requirements in EU markets.

Technical Files

[Art. 10(14)] *Manufacturers shall, upon request by a competent authority, provide it with all the information and documentation necessary to demonstrate the conformity of the device, in an official Union language determined by the Member State concerned.*

This new requirement has prompted discussion of “rapid response translations” of technical documentation to satisfy Competent Authority (CA) language requirements. However, due to the number of EU languages, volume of content contained in a typical technical file, and the turnaround/quality constraints of professional translation services, supplemental strategies are also under consideration:

- Provide initial documentation in English
- In consultation with CA, determine specific portions of technical file to provide in-language
- Submit plan to CA of anticipated timing for translated “regulatory file” (overview of the device, its intended use and mechanism of action as well as its classification, manufacturing and formal statements, with summaries of performance testing, biocompatibility, sterilization, packaging, shelf life, IFU/labeling and clinical evaluation, etc.)

Alternatively, some practitioners suggest a set of “core” documents to be available at all times in the official language(s) of the Member States where products are sold (e.g. label, IFU, product description, mechanism/mode of action or principle of operation, claims).

Finally, technology solutions are under consideration for automated translation of certain technical file content – see *Artificial Intelligence (AI)*, below.

Patient Implant Cards

Article 18 of the MDR requires that for implantable devices (except for those specifically exempted) a significant amount of information is to be provided to the patient in the form of an implant card. Some of this information can be provided,

...by any means that allow rapid access to that information and shall be stated in the language(s) determined by the concerned Member State. The information shall be written in a way that is readily understood by a lay person and shall be updated where appropriate. Updates of the information shall be made available to the patient via the website mentioned in point (a) of the first subparagraph.

This new requirement is a stark reminder of both increased volume and velocity of device-specific information required under the MDR/IVDR. It also points to delivery of the content through advanced electronic means, such as UDI-enabled digital distribution (see below).

Additional Safety Information

For implantable and class III devices, Article 32 of the new Regulation requires that a summary of safety and clinical performance (SSCP) be created. This information will be public, via the new Eudamed database, and “shall be written in a way that is clear to the intended user and, if relevant, to the patient”, in a further example of product-specific information to be provided in-language and with a high threshold of quality. Other post-market documents and content, such as the Periodic Safety Update Report (PSUR), will need to be created and controlled and may be subject to translation.

Initial Finding: Certain content types will be reclassified into more restrictive categories, resulting in greater regulatory scrutiny.

Software

Certain software may be reclassified as a medical device and at a higher risk level. New labeling language requirements mandate the translation/localization, and a higher quality threshold, of device UI.

Marketing Material

Article 20(5) of the MDR mandates that the CE Mark be included in promotional material which mentions that the device fulfills CE Marking requirements. (Note, this is in contrast to the current interpretation by several Notified Bodies under the MDD, where the CE Mark should NOT be included in the promotional material). This change illustrates the “regulatory drift” toward considering promotional material more as product labeling (see also the definition of “Information Materials” in MEDDEV 2.7.1 rev 4 which includes labeling, IFU and promotional materials). As such, promotional materials are subject to certain controls, such as Regulatory Affairs review and approval.

Additionally, Article 7 of the MDR makes plain that the practice of reviewing promotional material (including websites and social media feeds) for safety or performance claims made by the manufacturer, and comparing those to the data available in the technical documentation, will continue. Therefore, it is reasonable to expect that Regulatory oversight will become more common and extensive in order to ensure marketing content (and related translations) are complete, comprehensible, and correct versus technical data.

Initial Finding: Increased content volumes and control requirements under the MDR/IVDR will accelerate the adoption of content management, process automation, and UDI-enabled technologies.

As noted above, the requirements of the MDR/IVDR are expected to significantly increase the volume of content that manufacturers must create, control, translate, and distribute. It will also impose similar UDI requirements as currently exist in the US (although with some important differences). These developments will, in turn, lead device makers to accelerate the adoption of [technologies for content automation and UDI-enabled distribution](#).

Content Automation Technologies

Over the past decade, larger device manufacturers have implemented XML-based component content management systems (CCMS) in order to control content creation and automate content publication. While the direct cost of these systems has declined, the implementation and maintenance effort remains substantial – resulting in lower rates of adoption. However, due to increasing content volumes (including translation) and the regulatory requirement for improved content control, it is expected that adoption rates for these systems will rise in response to a fundamentally changed cost/benefit calculation.

Likewise, it is expected that modular, configurable translation management systems (TMS) such as [GlobalLink Project Director](#) will enjoy increased adoption as device makers look to centralize control of suppliers and assets, while enabling configurable, automated processes across various divisions and users. This strategy has already produced [lower cost, improved quality, and greater visibility in the pharmaceutical industry](#) and, due to increasing content requirements of the MDR/IVDR, the device industry is expected to follow suit.

e-Clinical Trial Technology

A primary focus of the MDR/IVDR is increased quantity and quality of clinical data for analysis and device approval. Also, rules that govern device approval via “substantial equivalence” have become much more restrictive. Together, these two changes will give rise to larger volumes of clinical content to be managed, controlled and shared.

In the pharma industry, with its large-scale clinical trial requirements, this issue has already been addressed with advanced [e-clinical trials technology](#), including e-feasibility, e-TMF, document and training management. Therefore, adoption rates of e-clinical trials technology across the device industry are also expected to rise.

UDI-Enabled Content Distribution

Although there are a number of key similarities, the EU version of UDI is essentially more burdensome than FDA's. Ironically, burdensome MDR/IVDR requirements make UDI-enabled technologies, such as the [EnCompass System](#), even more essential for manufacturers. By associating a product UDI with a unique web page via a scanning app, manufacturers can create a direct-to-user digital distribution channel for e.g., Patient Implant Cards, educational videos, IFUs, product catalogues, and links to online product ordering. UDI-enabled technology can also help satisfy MDR/IVDR supply chain requirements and has valuable master data management applications.

Initial Finding: Unanticipated content needs will emerge from unintended regulatory consequences.

Unintended Regulatory Consequences

Due to the large number of changed requirements – some of which have yet to be completely defined – it is expected that the MDR/IVDR will produce a number of unintended consequences. The implementation and use of UDI is an obvious example. By introducing a UDI requirement for product identification throughout the supply chain, regulators are driving manufacturers to UDI-enabled technologies. Some of these systems can be leveraged for supply chain control AND distribution of product information, such as patient implant cards. Here we see a positive unintended consequence: [validated, direct-to-user digital publishing based on UDI-enabled technology](#) as a result of MDR/IVDR requirements.

Increased Training Requirements

The extent and volume of regulatory changes due to MDR/IVDR is expected to drive an increase in training requirements in key areas such as Sales, Clinical, and Corporate Compliance. In order to automate record-keeping and ensure training compliance, many manufacturers have implemented computer-based learning management systems (LMS). It is expected that [translated/localized e-learning courses](#) will be extensively utilized to demonstrate conformity with new regulatory requirements.

Increased Translation Speed and Throughput

The need for rapid translation or real-time multilingual communication is expected to grow more common as a result of MDR/IVDR requirements. Technology-enabled services are key to meeting this need.

Artificial Intelligence (AI) – Potential translation requirements for large volumes of technical file content may be supported by developments in the field of artificial intelligence (AI). By developing specialized AI engines, certain portions of the technical file (e.g. test reports) can be automatically translated for more rapid regulatory response.

[Remote, Over-the-Phone, or Video Interpreting](#) – Additional complaint reporting requirements of the MDR/IVDR may require additional capabilities for real-time, multilingual communication. For instance, Article 84 of the MDR states,

If, in the course of the post-market surveillance, a need for preventive or corrective action or both is identified, the manufacturer shall implement the appropriate measures and inform the competent authorities concerned and, where applicable, the notified body. Where a serious incident is identified or a field safety corrective action is implemented, it shall be reported in accordance with Article 87.

In other words, all corrective actions initiated due to PMS data (and subsequent analysis) must be reported to the CA and NB...which is much more than "CAPA". Device makers take many corrective/preventive actions

which do not go through a formal CAPA procedure (e.g. design changes through ECO) and, in the absence of conversation or clarification, this change has the potential to inundate the CAs (and NBs) with information.

In general, communications from the field, among international departments, and between manufacturers and their EU clients, suppliers, and regulators are often facilitated when they are in-language. Technology-enabled interpreting services can fill this need, created by MDR/IVDR requirements, for increased, real-time communications between manufacturers and their critical EU counterparts.

Conclusion

The Global Life Sciences Practice Group at Ernest & Young estimates the total cost of industry compliance with key labeling and clinical data requirements of the MDR/IVDR at up to \$20 billion. A significant portion of this cost lies with increased content volumes and velocity brought on by changing regulatory requirements. Content centralization and process automation strategies, combined with UDI-enabled distribution technologies and effective process risk management are expected to play a significant role in addressing these emerging needs.

-end-