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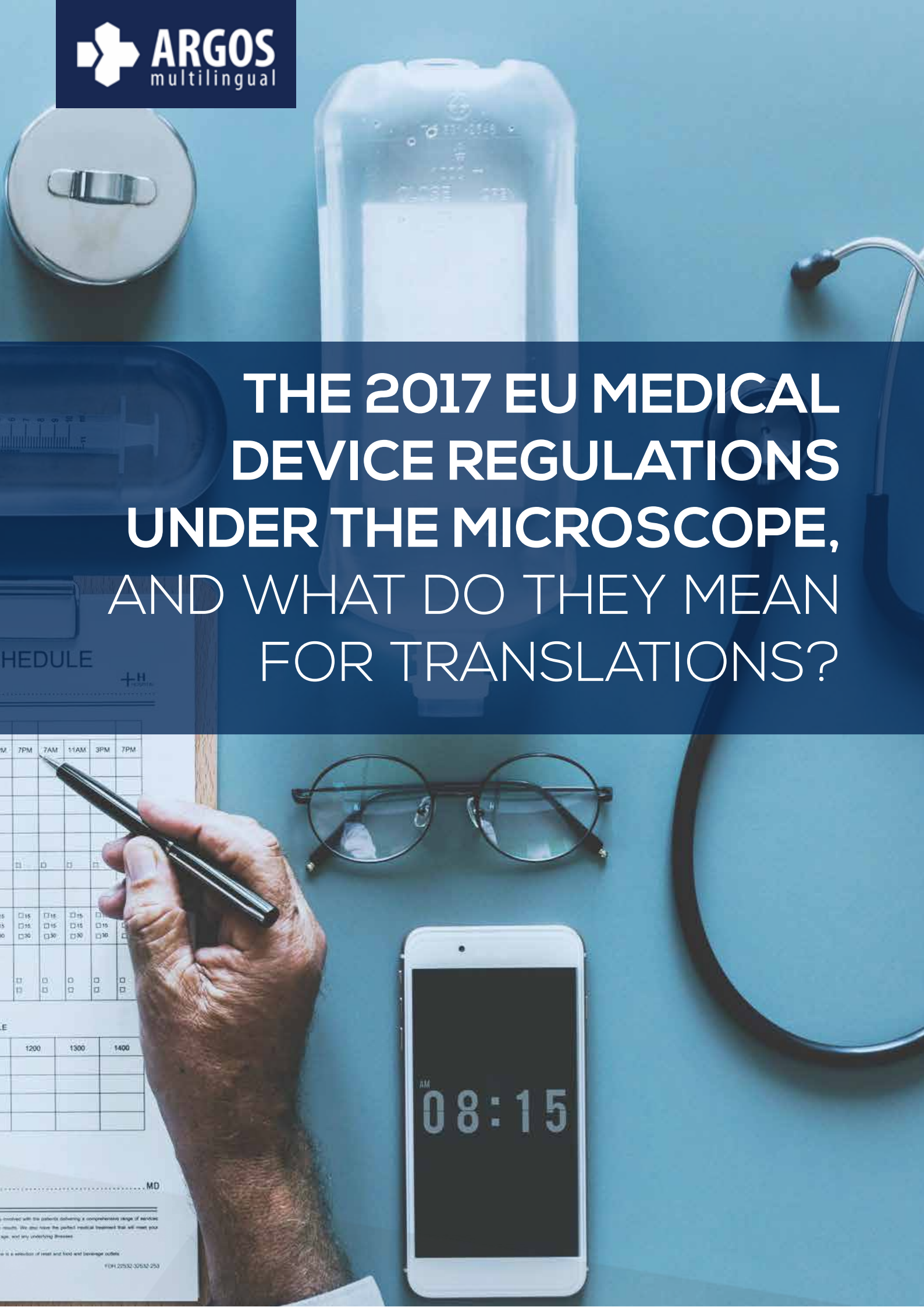
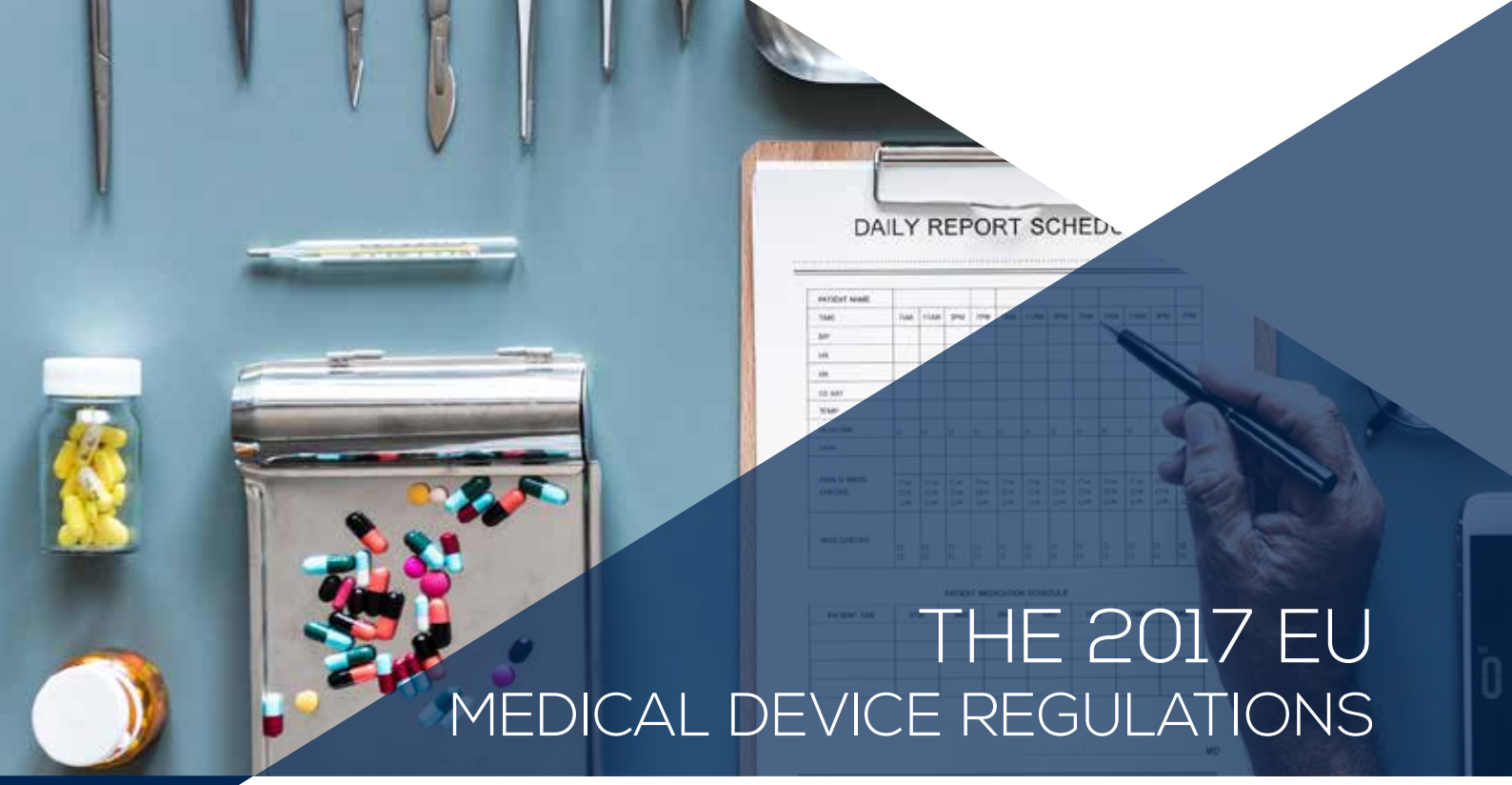
THE 2017 EU MEDICAL DEVICE REGULATIONS UNDER THE MICROSCOPE, AND WHAT DO THEY MEAN FOR TRANSLATIONS?



Argos Multilingual is a global language service provider experienced in dealing with localization needs during regulatory changes in our client's industries.

CONTENTS



THE 2017 EU MEDICAL DEVICE REGULATIONS

WHAT'S HAPPENED?

Two new European Regulations concerning medical devices and in vitro medical devices were adopted in May 2017. The new legislation impacts the whole medical device supply chain, meaning that in the medical device industry have begun to analyze their new responsibilities and create plans to address new areas of liability.

Directive 2001/83/EC, Regulation (EC) No 178/2002, and Regulation (EC) No 1223/2009 are amended, while Council Directives 90/385/EEC and 93/42/EEC are repealed by the Medical Devices Regulation (EU) 2017/745. The In Vitro Diagnostic Medical Devices Regulation (EU) 2017/746 repeals the Commission Decision 2010/227/EU and the earlier Directive 98/79/EC.

WHY THE CHANGES?

The existing regulatory framework has been in place since the 1990s. Since then, it has been amended on an ad hoc basis in order to handle changes. Recently, it has come under pressure to **modernize and better address risk management** in order to help ensure the ongoing safety of medical devices sold in the European Union. As a result, the European Commission presented two legislative proposals in September 2012, which were followed by five years of consultation and negotiation that concluded with a new set of regulations affecting manufacturers, distributors, notified bodies, importers, the supply chain, and member states.

BIG REGULATION...

The new regulations are wide-ranging, with the full English version (including annexes) running more than 180,000 words - nearly as long as *Jane Eyre* or *Great Expectations*. Unlike these treasures of English literature, the regulations are probably best tackled in the cold light of day with a steaming cup of coffee, a pen, and a notepad at your side. Fortunately, the regulation is also freely available in 23 other EU languages, which should comfort anyone whose native tongue is not English.

TIME TO ACT!

Because of the breadth of the new regulations, a three-year window has been provided to meet the requirements. If you haven't begun yet, the time to start planning is now. There is a lot to do if your business is to meet the implementation deadline of May 26, 2021* for medical devices and May 26, 2022 for in vitro diagnostic devices.

WHAT HAPPENS WHEN?

May 26, 2017:	MDR 2017/745 and IVDR 2017/746 came into effect.
November 26, 2017:	Notified Bodies could apply for designation under MDR and IVDR.
May 26, 2021*:	MDR deadline.
May 26, 2022:	IVDR deadline.
May 26, 2022:	The medical device databank, EUDAMED, will launch.
May 26, 2024:	Existing AIMD, MDD, and IVDD certificates may no longer be used to sell devices in the European market.
May 26, 2025:	Devices sold using existing AIMD, MDD, and IVDD certificates can no longer be put into service in Europe.

*originally the deadline for EU MDR was May 26, 2020, however due to the COVID-19 crisis the European Commission adopted a proposal to delay the date of application by a year.

THE NEW REGULATIONS IN A NUTSHELL

EUDAMED

One of the key developments related to the new regime is the creation of EUDAMED, a database for all Medical Devices sold to European markets. EUDAMED will be made available in all official European Union languages, and it aims to enable fast, transparent identification and tracking of every medical device in the European Union through the registration of unique device identifiers (UDIs).

UDIS

For those manufacturers who do business in the United States, the proposed process for UDIs should feel quite familiar – the new MDR and IVDR UDI implementation has been made with the benefit of hindsight and lessons learned from the FDA's UDI implementation. For those unfamiliar with the FDA's system, UDIs and EUDAMED are systems which allow for easier traceability and recall than is currently possible. The systems also enable centralized reporting and access to essential product information.

HOW TO MAKE UDIs HAPPEN

Manufacturers will need to integrate technology in order to maintain updated UDI-related information such as post-market clinical investigation data and performance studies. Manufacturers also need to include a UDI on every product label, meaning that their label designs need to be altered to reflect the new requirements. This can require considerable planning, as label space is already in short supply.

GOOD NEWS FOR MANUFACTURERS?

One of the benefits of the new system is that once a manufacturer's products have been assigned a UDI and the relevant information has been supplied to EUDAMED, device registration is done at the EU single-market level, making multiple national registrations a thing of the past.

MEDICAL DEVICE CLASSIFICATIONS

As we mentioned earlier, the new MDR and IVDR shine a spotlight on every aspect of regulation from the perspective of risk management. Medical Device and IVD classification has not escaped this scrutiny, and there are now an increased number of devices which notified bodies need to check prior to entry into the European Market.
Manufacturers are now required to perform thorough conformity assessments, the purpose of which is to determine whether their devices meet requirements for relevant classifications prior to submission to notified bodies.

LISTS ARE REPLACED BY RULES

While the previous system was a list-based one, the new regulation defines a series of rules that consider devices' risk to patients, their function, and their intended use. For medical devices, this results in four categories:

- Non-invasive
- Invasive
- Active
- Innovative devices that include other substances

The IVD classifications are completely overhauled with the new regulation, based on seven rules which are themselves based on the global harmonization task force (GHTF) rules. IVD products are then classified across four categories: A, B, C or D, where class A poses the least risk and class D the highest risk.

STANDARDIZATION: GOOD NEWS?

It's not all about red tape. Risk-based decision making built on the foundations established by the GHTF means that clinical trials currently taking place in multiple member states will now be replaced by a single coordinated assessment, resulting in potentially faster time-to-market. While it is undoubtedly good news that the rules are more in line with international classification practices, the impact will be substantial for IVD manufacturers. According to the ProClinical Life Sciences blog, 10 to 15% of IVDs currently require assessment by notified bodies. ProClinical Life Sciences also estimates that this will increase to 85 to 90% of IVDs under the new legislation.

What's more, many products which were not previously covered by the existing regulatory framework are now included as "products without an intended medical purpose." Examples include some aesthetic products like facial dermal fillers or colored contact lenses, which are now listed in MDR Annex XVI and therefore face stricter control.

SELF-DECLARATION

According to Annex VIII of the MDR and Annex VII of the IVDR, a risk matrix determines whether conformity assessments can be carried out internally (for certain low-risk devices like tongue depressors, disposable gloves, or specific IVD reagents) or whether they need to be assessed by a notified body.

Once a manufacturer has a declaration of conformity for a product, they can finally use the CE mark.

CLASSIFICATION NEXT STEPS

These changes will affect the way that current and future devices are classified. This will impact many areas of business, including manufacturing, clinical evidence gathering, and conformity assessment.

Manufacturers are advised to consult with appropriate specialists in order to decipher the new classification system, analyze the parts of their portfolio which are affected, and update technical documents in readiness for conformity assessments. In practice, this may also lead to additional translation requirements. It is logical to assume that changes made to technical documentation and file dossiers will affect all target markets, so **speak to us about building a language strategy ahead of time** so that you can guarantee compliance throughout your chosen markets.

PREVENTIVE / PROACTIVE POST-MARKET SURVEILLANCE

The recurring theme of risk management in the IVDR and MDR also extends to continuous safety improvement throughout a product's life cycle. What this means in practice is that the onus will be on manufacturers to monitor and report on a series of ongoing surveillance and control areas in order to diagnose and predict issues, resulting in **continuous preventive and corrective action reporting**.

There are also additional new requirements relating to post-market studies. Periodic Safety Update reports (PSURs), which analyze post-market surveillance data, and Post-Market Clinical/Performance Follow-Ups (PMCFs/PMPFs), which ensure that there is ongoing revision of clinical/performance evaluations, are detailed in Section 1 of Chapter VII of both regulations.

QUALITY MANAGEMENT

The new regulations make manufacturers responsible for demonstrating an effective quality management system (QMS). Key to this is how they exhibit a risk-based approach to decision making. Chapter II, "Economic Operators" introduces a completely new approach to supply chain regulation. This needs to be evidenced in investigation, diagnosis, monitoring, control, prediction, and prevention activities, and is specifically required in the monitoring of risks for any tasks which a manufacturer delegates to its third-party suppliers.

SUPPLY CHAIN AND ISO 13485:2012

While the current ISO standard for Medical Devices, ISO 13485:2012, is not stipulated as compulsory at this time, it is the accepted industry standard. Because of this, ISO 13485 is currently perceived as the most compatible system, not least because the standard is explicit in its requirements for the **effective selection and control of tasks performed by third-party suppliers**. By ensuring that their supply chains are ISO 13485 certified, manufacturers lessen their exposure to risk. They can also begin to manage the requirements laid out in the new regulations. Of course, manufacturers are urged to discuss the finer details of compatibility of their own QMS implementation with their certification bodies.

Along with a small number of other LSPs, Argos Multilingual is already certified to the ISO 13485:2012 standard.

CONTROVERSIAL NEW RESPONSIBILITIES FOR OTHER STAKE-HOLDERS

Importers and distributors are also given specific new legal oversight responsibilities. Authorized representatives and importers now need to make checks to a host of additional areas. These include not only CE marks, labeling, and conformity assessments, but also post-market Surveillance and recalls. Most controversially, they are also required to **decide *whether* products comply with the regulations** before either importing or refusing to import a product.

In the case of authorized representatives who are a subsidiary of a manufacturer (not an unusual arrangement), there is significant potential for conflicts of interest, as it is their responsibility to issue warnings to manufacturers and even report them to the authorities for non-compliance, which may make existing arrangements awkward.

Distributors will be subject to much greater legal liability for the products that are in their care. They will need to meet many of the same obligations as importers and authorized representatives, but without an obligation to label and without exposure to additional risks.

NEXT STEPS TO MITIGATE RISK

The new obligations introduce stakeholders to a much higher level of risk. Because of this, importers, authorized representatives, and distributors need to carefully analyze their new roles and responsibilities as well as their exposure to new risks.

In practice, importers and distributors are taking legal advice in order to renegotiate existing contracts with manufacturers, while ensuring that they have suitably robust and informed teams and processes in place in order to deal with the new regime. This will often mean that **they need to charge more** for the services they provide.

Manufacturers would do well to scrutinize existing contractual relationships very carefully as there is significant responsibility overlap between the different roles, and manufacturers need to be very wary of hidden potential risks. Erik Vollebregt's entertaining and insightful "Medical Devices Legal" blog explains the situation this way:

> *It becomes more important than ever to organise your supply chain contractually in a way as to avoid surprise, e.g. because a distributor decides to issue a local recall for a not so profitable product, that will be visible for every authority in the EU via EUDAMED and may spin off into something of epic proportions."*

He goes on to conclude that manufacturers need to force information sharing across the supply chain in order to help with the division of responsibilities and **reduce the potential for any "epic spin offs."**

WHAT ABOUT TRANSLATIONS?

Given the all-encompassing nature of the MDR/IVDR regulations, it may seem strange that translation and language requirements are only referenced about 60 times. Manufacturers should not get lulled into a false sense of security, however, as **translation needs are likely to increase as a result of the legislation**. As discussed earlier in the eBook, new UDI requirements will impact labeling layouts, making it essential that new designs take localized text expansion into account. Also, any **reclassifications to your products may result in significant changes to your technical documentation**, which will need to be translated to the languages of your target markets. Additionally, applications for clinical investigation and analyses of serious incidents and corrective actions may also require translation.

WHO DECIDES WHICH LANGUAGES NEED TRANSLATION?

Competent authorities in each member state will confirm the correct languages you need to translate into for each market. They will also determine what device information (IFUs, labels, documentation demonstrating conformity) will need to be translated.

IS E-LABELING STILL AN OPTION?

The European E-Labeling Regulation (207/2012) for medical devices remains unaffected by the new regulations. Therefore (broadly speaking) MDs and IVDs intended for professional use can continue to be supplied in an electronic format. We recommend that you refer to our blog post and webcast, which detail the steps to take in order to make use of this option and begin reducing publishing costs.

ONE LESS THING TO THINK ABOUT?

As we have seen, the chapter on “Economic Operators” makes risk management in your supply chain one of your many high priorities. Being able to rely upon a properly certified language service provider (such as Argos Multilingual) can help you **focus on the many other priorities you have as an MD or IVD manufacturer.**

NEXT STEPS

As we have illustrated, the MDR and IVDR involve some big changes to how the medical device markets operate. This is not a regulation that maintains the status quo, instead affecting multiple parts of the supply chain with the eventual aim of increasing safety and reducing risk.

GET MOVING NOW!

As the Medical Devices Legal Blog puts it, "Start now if you haven't already. The gap is large. The impact is enormous. **Your EU market is at risk."** During the transition periods of three years (MDR) and five years (IVDR), you should expect additional legislation. While this might sound like the regulations have become a moving target, anticipated changes should actually help add clarity where there is currently ambiguity. One thing is clear - **it is the responsibility of all stakeholders to stay apprised of any changes as they happen.**

HOW TO START?

All stakeholders are urged to **build steering groups** to formulate a thorough plan of action for implementation if they haven't done so already. These groups should be diverse and should regularly share knowledge and interpret the legislation from all available angles in order to fully assess business impact.

Some areas of the business will be obvious inclusions to the steering group, such as compliance, quality, legal, and regulatory teams. Other stakeholders might not be so obvious at first glance, but **will provide a new perspective on the opportunities and risks** found in the new regulations. To begin with, consider including representatives from operations, IT, authoring, marketing, and labeling teams, plus some of your key suppliers like publishers and language service providers.

Your strategic steering group will need to perform exhaustive gap analyses that assess risk and opportunity, as well as portfolio assessments for reclassifications to both existing and planned products. ROI calculations, supply chain analyses, risk matrices, and budgeting will all need to take place if your transition is going to be a success.

ABOUT ARGOS MULTILINGUAL

Argos Multilingual is a global language solutions provider with experience in the life sciences, industrial manufacturing, and software/hardware industries. Our business is built on three core values - quality at source, a partnership approach, and technology agnostic solutions. We are committed to giving you freedom of choice while providing customized strategies to fit your business needs, and we are ISO 9001, ISO 17100, EN ISO 13485, and ISO 27001 certified. With production centers in Krakow, Poland and Colorado, USA, we provide value through dedicated customer service and subject matter expertise in your industry.

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