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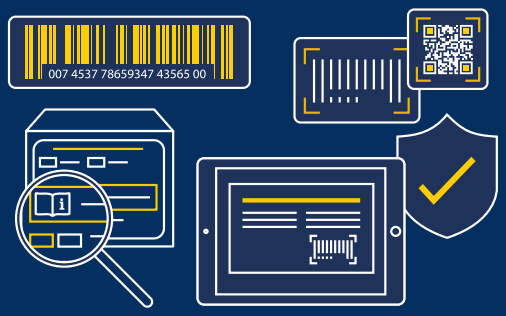
e-Labelling: The Road to Reduced Medical Device Packaging

Next steps for the sector as paper-based IFUs give way to digital alternatives



In so many aspects of everyday life, it has become second nature for customers to access product information online. For fuller instructions or additional insights into manufacturing practices, safety advice and so on, users can scan a QR code or go to a web address. This will take them to the latest details, in an easily digestible format - often including audio and video options now, for maximum accessibility.

Although the life sciences industry remains some way behind in this regard today, regulators are making clear moves to change this via new directives and guidance. The aim is to connect patients, physicians and other stakeholders across the healthcare ecosystem with a consistently up-to-date information source for product and safety information that isn't dependent on paper.

Asian markets and Australia are leading the way here, but steadily the trend towards e-labelling and digital patient information leaflets (e-PILs)/instructions for use (e-IFUs) is moving east and west, with European markets and North America now purposefully working towards and keenly promoting electronic alternatives to the folded physical inserts in tiny print that have traditionally accompanied medicinal and medical device products.

Gain over pain

The trend heralds all kinds of benefits. As paper-based information is de-emphasised, brands, manufacturers and distributors will no longer need to worry about inventory shelf life linked to whether current stock contains the latest safety information or manufacturing details. In due course, entire print runs will be eliminated and packaging simplified, reducing the volume and weight of shipped goods, with cost-efficiency and carbon emissions benefits. Healthcare professionals and patients meanwhile will no longer need to worry about PILs/IFUs going astray, or containing out-of-date advice. The latest information and recommendations will always be available on tap, online – and in a more dynamic and searchable form.

Change rarely happens without pain, however. In the short term, the shift to e-labelling will inevitably cause some disruption for manufacturers and supply chains as companies adapt systems, processes and skillsets, and adjust packaging specifications and operations. There are benefits to be gained here, too, however. Package inserts are a common bottleneck on production lines. As paper PILs/IFUs give way to digital equivalents, this step can be removed entirely with sizeable productivity and efficiency gains.

As e-labelling requirements move up the agenda and become a more tangible requirement, this eBook (the first of two) assesses the latest regulatory expectations and timelines applicable to the medical device industry. It then sets out the practical next steps manufacturers and suppliers can take now – both to prepare for compliance and to maximise the opportunities operationally and for customers. (A second e-book will extrapolate the guidance for pharma.)

Emerging requirements for medical device manufacturers & suppliers

Across many developed markets, the medical device industry is already subject to considerable regulatory change, geared to improving device traceability and patient safety. These measures have been driven by high-profile safety events, such as the PIP breast implant scandal in Europe; and by advances in technology which have seen a growth in both smart implanted and wearable devices, and in combination products (devices and pharmaceutical products that work in concert).

EMA's Medical Device Regulation and its in-vitro equivalent, IVDR, are among the updated sets of requirements designed to provide fit-for-purpose safety controls. (A table of current international resources and guidance links can be found in Appendix I; EU and UK-specific requirements are detailed in Appendices II and III.)

And specific guidance is being added all the time, around e-labelling. In December 2021, the European Commission adopted a new Implementing Regulation (EU) 2021/2226 for the use of e-IFUs for medical devices, with application from January 2022. The Regulation adapts the conditions and requirements for going 'paper free' for manufacturers of medical devices - including software covered by EMA MDR/IVDR.

The term 'e-labelling' potentially underplays the scale of change that will be involved as digital information delivery becomes the default for medical device product information and instructions for use. The changes have implications for production and the supply chain, continuing to point of delivery and beyond, all of which will need to be supported by an optimised IT infrastructure.

Expectations in the EU: scoping the changes

EU-MDR

Rather than mandate an overnight change, in Europe the EMA is phasing in e-labelling by target user group. For now, the provision to provide IFUs in an electronic format instead of paper form is limited to certain medical devices and accessories intended for use under specific conditions. These are devices used by 'professional users' (e.g. persons using the medical device in the course of their work) in the framework of a professional healthcare activity.

A next phase will see digital resources – via web sites and mobile apps – extended to patients. The idea is to get a robust digital platform in place before eventually doing away with paper-based IFU inserts altogether.

THE CURRENT SCOPE INCLUDES:

Implantable medical devices

Active implantable medical devices

Fixed medical devices and accessories

Designed to be installed, fixed, or otherwise secured at a specific location within a healthcare facility.

Medical devices equipped with an integrated system for displaying information

For use (IFU) software governed by the MDR.

Provisions for electronic information under MDR/IVDR

The wider and often overlooked impact of the EU Medical Device Regulation (MDR) is contained within Chapter III of the associated guidance, and refers to the general requirement of information supplied by the manufacturer.

MDR specifies that, if a manufacturer has a web site, information needed to identify the device, its manufacturer, and any safety and performance information relevant to the user, must be made available and kept up to date here. Given that safety and performance information is already captured within the IFU, it makes sense for medical device manufacturers to have an electronic version of their IFU accessible and controlled on localised company web sites.

Further key elements of the reinforced regulatory approach include the requirement to submit information to a central European Database on Medical Devices (EUDAMED), and to maintain stringent vigilance and conduct ongoing market surveillance. This applies to manufacturers and distributors of class III, class IIb and class IIa devices. (See Appendix II for further details.)

With patient safety and consistent information access in mind, movements are afoot to ensure that e-labelling is harmonised across the globe, in line with international minimum standards (see Appendix I). This should mean that investments made now will lay valuable foundations for eventual global delivery.

Transitioning to e-labelling

Given that patient safety is the ultimate goal, and that not everyone has access to or knows how to use electronic devices, devices intended for patient use must come with the guaranteed option to receive the most up-to-date, official printed product information – certainly in the near term. This co-existence of two versions of the content, at least for a period, underlines the extent of the transition manufacturers now face.

Yet taking advantage of the opportunity to complement paper-based advice with an online equivalent is a good strategy, enabling companies to align and hone their content management with a view to gradually phasing out the reliance on paper in due course, as device users become more comfortable with interacting with online or app-based resources. It offers manufacturers the opportunity to 'stage' an e-labelling transition, managing this strategic change programme to their own timeframe rather than one dictated by the regulatory authorities.

Any strategic initiative will have an impact across an entire manufacturing organisation and e-labelling is no different. By acting sooner rather than later, businesses can take early advantage of processes, procedures and solutions that provide a digital platform for the future, deliver efficiencies across today's labelling landscape, and add new value for patients.

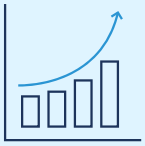
Just like the changes required, the potential benefits will span the whole business. On top of the positive impact on patient safety and adherence, the rollout of e-labelling will help promote:

Open access to new markets

New process efficiencies throughout the supply chain

Cost savings spanning resources, procurement, warehousing and transportation

Reduced environmental impact, increasing sustainability



A positive return to the bottom line and ultimately to shareholders

Many of the operational gains are based on the increased accuracy of content: of getting all aspects of labelling right first time. The more systematically device manufacturers manage their labelling, the better able they are to drive out waste and costs linked to relentless review and approval cycles and increase their speed to market, while mitigating the risk of rework and potential product recalls due to labelling errors.

These same philosophies and processes will also improve the content and data submitted to Health Authorities, expediting market approvals with the benefit of increased sales revenue.

The changes required to deliver these benefits will be felt widely, and require a joined-up approach to transformation to minimise the pain and maximise the numerous potential gains.

Impact on Regulatory Affairs

Control of accurate, structured content: moving away from document centricity

Traditional methods of document publishing no longer serve the interests of patients, healthcare providers, regulators or medical device manufacturers.

Boosted by the pandemic, the effort to modernise and digitise the way content is created, stored, managed, published and updated is enjoying accelerating momentum. The practice of copying, pasting and amending content from document to document is both time-consuming and prone to risk. To mitigate errors, medical device manufacturers are embracing structured content – the ability to rapidly generate assets for a range of different purposes from agreed, standardised master data with minimal manual intervention.

The benefits of following data standards are well known by now. To fulfil the different requirements for labelling content, standardisation can help ensure the successful integration of people, processes, systems to deliver compliant content both online and in printed form.

These principles also apply to manufacturers that have voluntarily begun to publish data to EUDAMED's available modules. These organisations are already experiencing the daily challenge of collating, cleansing and approving data while transforming content into a structured format for submission to the European database. The accuracy of this content is paramount, as it will form the foundation of accessible data within EUDAMED. Ultimately, this interoperable platform will serve as a collaborative registration system, disseminating information between global competent authorities and being made partially open to the public.

THE SIX MODULES OF EUDAMED

Actor and User Registration and Management	IDI/ Devices	Certificates and Notified Bodies	Clinical Investigation and Performance Studies	Vigilance and Post-market Surveillance	Market Surveillance
ALL	MF | PR | AR | IM	NB | EC	SP | CA	MF	CA | EC

AR = Authorized Representative, CA = Competent Authority, EC = European Commission, IM = Importer, MF = Manufacturer, NB = Notified Bodes, PR = System/Procedure Pack Producer, SP = Sponsor

Vigilance & Post-Market Surveillance

A big part of EUDAMED's value will be its ability to offer patients and healthcare practitioners access to the very latest safety advice about products. This in turn relies on that information being updated promptly and regularly, based on post-market surveillance and patient notifications. Regulations have been tightened to provide for this, placing new responsibility on medical device manufacturers to track and report real-world feedback about their products in a systematic, standardised way to the central European database.

The EUDAMED module for Vigilance & Post-Market Surveillance is targeted to go live in Q4-2024 - enabling manufacturers to report serious incidents and other reportable events, supporting the evaluation and coordination of such incidents and events by competent authorities.

In the meantime, device manufacturers must also have effective systems and procedures in place so that device users, having downloaded instructions for use from the web site, can be informed of any safety updates or corrective actions.

Impact on the Labelling Department

Inevitably, the Labelling department will shoulder the initial burden of any e-labelling initiative. Increased demands, at least in the short term, will include:

A heavier workload: managing e-labelling initiatives as well as the ongoing day-to-day labelling change programmes

A rise in the number of packaging and label formats: in the initial phases, e-labelling will increase both digital and printed formats

Multiplication of file types being created and controlled: artwork, audio and video, HTML & XML formats etc

A proliferation of distribution channels: depending on the market, there are likely to be numerous Health Authority platforms, print vendors and web sites requiring published content

Proof of compliance: due to increased regulation around content compliance and post-market surveillance

Increased workload

In the initial stages of any e-labelling programme, there will be a period where printed and online files will co-exist, doubling the graphic and artwork files required.

In some instances, a PDF version of the printed artwork will suffice as a static, legible, e-IFU posted online. For the larger multi-language IFUs, with complex pagination to insert into cartons, files must be transformed if they are too large and illegible for digital or online consumption on smart devices.

Looking to the future, static e-IFUs may not fulfil the aspirations of health authorities, healthcare providers or patients who expect intuitive, interactive and dynamic electronic content. Planning for the provision of accurate structured content will be the smarter way of creating a foundation for e-labelling.

Packaging and labels will need to be amended to include additional content. On-pack information will be required to notify healthcare providers and patients that an e-label exists. In other words, medical device manufacturers will need to clearly indicate on the label that the Instructions for Use are supplied in electronic form and how to access the e-IFU. This information will need to be provided on the packaging for each unit or, where appropriate, on the sales packaging.

In some cases, the integrity of carton or packaging may have been originally designed and transit-tested to include a folded paper insert. If this is the case, the pack specification and size of carton may need to be reformatted once the printed IFU is removed.

For fixed / installed medical devices, information must also be provided on the device itself. For software, the information will be provided where access to the software is granted.

All the above will increase the number of files in existence and which must be managed and handled through the labelling change process.

Multiplying file formats

Print and online files differ in numerous ways, from file format, resolution and size, to how colour is managed. As a result, printed IFU files will need to be converted or transformed to ensure they are fit for purpose in emerging digital/online use cases.

On top of this, MDR allows for audio and video files that have been approved by the Health Authority, to supplement e-IFUs - improving information accessibility and the opportunity for safe and effective use of a device. The Labelling department, and manufacturer, will be responsible for managing the creation, review, approval and distribution of all of these file formats, and for associating any audio and video files with the appropriate static content.

Some thought will need to be given to the current skillsets of the Labelling team, to ensure that they remain able to manage, articulate and brief graphic studios while controlling the lifecycle of additional files, as this will be imperative for an optimum and smooth transformation from paper to electronic formats.

Proliferation of distribution channels

As well as new file formats, teams will need to coordinate a growing range of distribution channels for their content. To date, Labelling departments have created and provided files for Health Authority (HA) approval, then issued these to manufacturing sites or contract manufacturers, and to print suppliers. In the future, electronic files will be required in HA databases and web sites, on localised company web sites and in due course to web application platforms. This will require enhanced control and governance of files to maintain consistency and accuracy across all channels, and so that updates can be managed in a controlled, coordinated and compliant manner.

Proof of compliance

Enhanced requirements around post-market surveillance and patient notifications will create a further burden for Labelling department, and the automation of audit logs and control of distribution ideally needs to be addressed during the formative stages of implementing an e-labelling programme.

Today all kinds of manual processes exist to meet localised e-labelling regulations across the globe. Yet, as digital channels become more important and the guidance evolves into regulation, manual processes will be too resource intensive and error prone to be sustainable. And any errors or inconsistencies between sources will be much more visible as information becomes more widely accessible and transparent, something the competent authorities will be watching out for.

Maintaining compliance also requires that companies will have effective systems and procedures in place to ensure that device users (those that have downloaded instructions for use from the web site) are kept informed of any updates or corrective actions.

The ability to handle the distribution of accurate files in various formats, to manage change processes optimally, and to demonstrate compliance at the click of a button, will be imperative in any effective e-labelling initiative.

Impact on the IT Infrastructure

Juggling all of this and keeping everything in sync will be impossible as long as manual processes and disjointed, function-specific systems are in place. Now, more than ever, teams will need centralised visibility and control from one end of the organisation to the other, and the assurance that the content they are working with is definitive, correct and consistent with everything else that's currently available, whatever the immediate purpose.

Achieving the optimum IT infrastructure to enable this will involve:

System integration

An effective e-labelling platform requires integration across a broader network of systems, platforms and cloud solutions, most obviously including:

- **Regulatory Information Management solutions/Content Management Systems (RIM/CMS);**
- **Artwork Management or Enterprise Labelling Solutions (AMS/ELS); and**
- **Quality Management Systems (QMS).**

But this is not the whole picture. Enterprise Resource Management (ERP) and Product Lifecycle Management (PLM) should also be considered within the context of e-labelling. That's because digital files and physical pack changes will affect the bill of materials, and any evolution of labelling content aligned to the development of the device across its lifecycle.

Integration will enable transparency and governance across the whole IT ecosystem. This will need to include the process of content creation and approval, transformation into digital formats, controlled distribution, and product and safety updates. Given how frequently requirements change, device manufacturers will need to ensure that the target platform is sufficiently flexible and futureproof too, thus creating a sustainable and compliant labelling/e-labelling foundation for the long term.

Within this integrated environment, any changes to regulations should trigger an impact analysis of all the printed and online collateral requiring amendment. The artwork or enterprise labelling solution should support this change programme, and approval of any impacted content distributing the updated files and data in a controlled manner.

Customer Relationship Management (CRM) functionality will also play an important role, in capturing patients' interactions with the e-IFU so that notifications of any changes can be issued to them. Fully time-stamped audit reports should capture these transactions and log them within the quality systems to show compliance.

Content management

At the heart of this integration is content, and specifically the agreed 'source of truth' from which all labelling will flow. Much has been written about end-to-end content management and the role of master data, but each company must determine how best to approach the subject, starting with the end goals in mind.

Structured Content Management allows medical device manufacturers to confidently manage all the individual elements that come together to create packaging and labelling components for a device, in a streamlined way. Without starting from scratch each time, and without incurring new risk of errors or inconsistency, they can build the various sections in an Instructions-for-Use document (text, tables, images, and other elements that make up the finished insert) from the latest approved content elements or fragments.

Moving from a document-centric, unstructured way of working to a managed content approach will futureproof existing printed and online labelling processes, allowing these to encompass dynamic e-labelling. Managing content as a series of approved fragments or elements will allow medical device manufacturers to achieve a dynamic interaction through links and associations across localised e-IFUs. The result will be an efficient and cost-effective way of updating online safety content, within the timeframes dictated by regulators, while also creating an audit trail to demonstrate compliance.

Controlled distribution of content

Beyond content management and approval, a robust distribution platform is required to manage the transfer of content, in whatever format and via all of the relevant channels.

Tight control and governance will be needed across all communication channels to ensure content is error-free, accurate and compliant with local regulations, and that it can be updated or recalled at any point.

Any solution or platform adopted for e-labelling will need to be scoped for long-term use, not least because there are specific requirements within MDR concerning the length of time e-IFUs files must be stored and kept accessible – ranging upwards from 10 years depending on the device.

The distribution platform must also account for enhanced post-market surveillance requirements for class III, class IIb and class IIa devices. Again, a fully time-stamped audit trail will be required for all safety notifications and updates, along with the reassurance that content is protected against unauthorised data access and tampering (to prevent counterfeiting, for instance).

Any personal data, meanwhile, must be subject to the highest standard of privacy and protection and comply with local data protection principles. Consent must be provided by the user for data to be collected and stored from electronic or digital services, such as information from product searches.

Website hosting

Keeping web content up to date is particularly important, given the assumption that online resources are easier to update than printed paper documents already circulated. (Meanwhile systematic updates to registered e-IFU users will take care of updates to healthcare professionals or patients who don't check back.)

Any Instructions for Use should be provided in a commonly used format that can be read with freely available software. Both the internet platform and address must be stable and directly accessible.

Version control of e-IFU files must be robust and automated where possible. That's because guidance states that **all previous versions of the e-IFU, along with dates of publication**, should also be available on the web site.

e-IFUs should be available in an official language of the Union determined by the Member State in which the device is made available.

Impact on production & the supply chain

The wider supply chain will also be affected by the shift to e-labelling. Initially, as paper and electronic IFUs co-exist, the number of components and production line changeovers will increase. The increase in packaging formats will also affect the procurement department.

Depending on the device, configuration of the supply chain and end user markets, manufacturers may end up having devices packed to go into healthcare settings, without leaflets, and into patient end user channels with printed inserts included.

All this will initially add to the complexity of the supply chain during the early stages of e-labelling but ultimately, as regulations evolve and demand the removal of printed IFUs, the wider patient safety, business and environmental benefits will be felt.

Why start now?

Any e-labelling initiative or programme will serve as a catalyst to drive continuous improvement. Ensuring the accuracy of content as it is transforms throughout the lifecycle, will reduce the risk of non-compliance, rework, and the ultimate sanction of product recalls. Strategic e-labelling initiatives also shine a light on the endless sustainability possibilities. Fewer printed materials, smaller pack sizes, a reduced transportation footprint and greater production efficiencies all play a part in improved Environmental, Sustainability and Governance (ESG) performance.

Although e-labelling is evolving at differing rates around the world, with patient-facing materials often the last phase, the explosion of e-commerce and mobile use shows how quickly and dramatically shifts in consumer behaviour can happen once new and convenient options are made available to them. So it makes good business sense to be ahead of this trend.

As medical device manufacturers prepare for a digital-first future, there are three fundamental steps that will provide the perfect springboard to this:

RIGHT FIRST TIME

Ensure content is correct, controlled and compliant at source

ERROR-FREE

Ensure content is transformed accurately across print and online platforms

CONTROLLED DISTRIBUTION

Ensure global transparency and governance across the distribution and lifecycle of content

These three essential capabilities afford manufacturers the ability to transform accurate content into any format, to be published in a physical or virtual form, as well as posted to competent authority databases.

Underpin all of this with an integrated infrastructure and simplified processes, with real-time controls, and manufacturers will be ready to fulfil any e-labelling requirements, avoiding the need for major 11th-hour resources and costs to meet impending deadlines.

Practical Next Steps

First, start with the end goals in mind and review all existing guidance, regulations and standards proposed by the Global Harmonization bodies to gain an understanding of today's regulatory landscape and tomorrow's potential.

Research industry sectors that have already adopted electronic labelling to understand their evolution and any pitfalls experienced.

Then, take proactive steps to create and execute a coordinated e-labelling strategy and plan:

1. Understand the regulatory landscapes & timeframes

Consider the current and future devices in scope and their target user groups.

EU-MDR requires a specific risk assessment to be undertaken by manufacturers to reduce potential risk as far as possible and access the appropriateness of the provision of Instructions for Use in electronic form.

2. Map the existing labelling process

Assess and map the existing labelling landscape, procedures and vendors to understand the company's readiness for electronic labelling. Create a gap analysis to feed into any business case.

3. Scope the e-labelling project

Scope the e-labelling project to align with any immediate needs, focusing on current and future target markets and the devices sold into those regions. Also consider developing foundations for the future, and start with that vision in mind: including patient interaction with online resources to boost the safe use of the device. Look to more established markets (eg Asian and Australia) for examples of emerging best practice and target benefits.

Target quick wins that can be championed and will provide evidence of early success.

4. Create a high-level project plan

Produce a high-level project plan, including key champions and stakeholder to be involved. This should include a cross-functional team to mirror the scope of e-labelling impact on a manufacturer. For some members of the e-labelling team, digital communication may be uncharted territory, so training and knowledge transfer must be built into the resource planning.

5. Build & present an ROI/business case

Build and present a return on investment (ROI) or business case, highlighting the benefits of the e-labelling initiative to patient safety and the business, including wider environmental sustainability gains. Review the Chairman's Statement to ensure alignment with any published strategic imperatives and ally e-labelling benefits to those ambitions, targets and goals. Ensure you encapsulate the four strategic priorities of any manufacturer: Financial; Patient; Operational; and Growth related.

> Once senior leadership has approved this strategic initiative, the real work begins. Devote time to defining the scope, objectives and key performance results. Remember, on an ongoing basis, to monitor and control the project progress against these criteria. Finally, be sure to communicate and celebrate all wins, as this digital journey will not be an easy undertaking though the paybacks will be extensive and enduring.

Appendix I

Region	Regulatory Authority	e-labelling guidelines	HA Link
Australia 	TGA	This guidance refers to requirements set out in clause 13A of Schedule 1 of the Therapeutic Goods (Medical Devices) Regulations 2002 (the MD Regulations). It provides an overview of different types of patient information material (patient information leaflets and patient implant cards)	Link
Canada 	Health Canada	Health Canada Guidance for the Labelling of Medical Devices. To assist manufacturers of non-in vitro diagnostic devices in complying with the labelling requirements under sections 21 - 23 of the Medical Devices Regulations	Link
Europe 	EMA	Regulation (EU) 2017/745 of the European Parliament and Council - 05 April 2017 on medical devices. Chapter III - Requirements regarding the information supplied with the Device states the 'Instructions for Use may be provided to the user in non-paper format (e.g. electronic)'	Link
India 	CDSCO	India has become the latest medical device market where regulators are accepting electronic indications for use (e-IFU)	Link
Japan 	PMDA	Digitization of package inserts, due to the revision of the Act on Securing Quality, Efficacy, and Safety of Products, including Pharmaceuticals and Medical Devices (Act No. 145 of 1960; the "PMD Act") was implemented on 01 August 2019	Link
Saudi 	SFDA	MDS – G5 Guidance on Requirements for Medical Device Listing and Marketing Authorization 23.1. General requirements regarding the information supplied by the manufacturer. Instructions for Use may be provided to the user in non-paper format (e.g. electronic)	Link
Singapore 	HSA	GN-23: Guidance on Labelling for Medical Devices HSA state, for devices not sold to the general public, Instructions for Use may be provided to the user either in paper or non-paper format	Link
Taiwan 	TFDA	The Medical Devices Act (MDA) May 2021 states, for specific medical devices announced by the central competent authority, the instructions set forth in the preceding paragraph may be replaced by electronic instructions. A pilot for replacing enclosed paper labelling with e-labelling is underway [2022]	Link
UK 	MHRA	Regulation 4J of the Medical Device Regulations 2002 [UK MDR 2002] allows manufacturers of certain types of medical devices and accessories to provide electronic Instructions for Use	Link
USA 	FDA	21 CFR Part 801 – General Labelling requirements for Medical Devices. In healthcare facilities, e-IFUs may be made available solely by electronic means [2004]	Link

With patient safety and consistent information access in mind, movements are afoot to ensure that e-labelling is harmonised across the globe, in line with international minimum standards. To this end, guidance developed for medical devices by the Global Harmonization Task Force (GHTF) takes up the initiatives from the International Medical Devices Regulators Forum (IMDRF), and seeks to promote global convergence of regulations. The aim is to ensure that equivalent, translated, compliant labelling content is available to healthcare providers and patients wherever they are in the world.

Appendix II

EU & UK medical device requirements relevant to labelling

EU | Medical Device Regulation & In-Vitro Medical Devices Regulations

There are over 500,000 types of medical devices and in vitro diagnostic products (IVDs) on the EU market that will be impacted by Medical Device Regulation (MDR) and the new harmonised regulatory framework (IVDR). Both sets of regulations are focused to ensure the safety and performance of devices on the European market.

These regulations will require further inspection of technical documentation, place rigorous requirements on clinical evaluation and increase traceability of devices throughout the supply chain. As a result, the EU legislation framework will become more robust, allowing greater protection of public health and safety.

EUDAMED | European Database on Medical Devices release dates

An IT system developed by the European Commission, EUDAMED is an integral part of the implementation of both Medical Devices Regulations (MDR & IVDR). The system will improve transparency and coordination of information regarding devices available on the EU market. It is a collaborative and interoperable platform, that functions as a registration system, a collaborative and dissemination system that will ultimately be partially open to the public.

EUDAMED is structured around 6 interconnected modules (see below) and a public web site:

1. **Actors Registration**
2. **UDI/Devices Registration**
3. **Notified Bodies & Certificates**
4. **Clinical Investigations & Performance Studies**
5. **Vigilance & Post-Market Surveillance**
6. **Market Surveillance**

By the end of 2023, EUDAMED Minimum Viable Product (MVP) for all six modules will be developed. This means the system implements, at a minimum, the Medical Devices Regulations required for competent authorities and all stakeholders to comply with their legal obligations.

The use of EUDAMED is not yet mandatory nor required. Some modules are available and can be used voluntarily. However, this use cannot be currently imposed. It will be Q4-2024, when a fully functional EUDAMED, with all 6 modules, is scheduled to go live. At this point, EUDAMED becomes mandatory regarding obligations and requirements related to **Actors, Vigilance, Clinical Investigation & Performance Studies, and Market Surveillance modules.**

The final input of data regarding **Device Identifiers (UDI), Notified Bodies and Certificates** become mandatory in Q2-2026.

EU| Unique Device Identifiers

The MDR regulations introduced an EU identification system for medical devices based on a Unique Device Identifier (UDI). This UDI system will facilitate easier traceability of medical devices, significantly enhancing the effectiveness of the post-market safety related activities for devices and allow for improved monitoring by competent authorities.

UKCA deadline extended to 01 January 2023

The UK Department for Business, Energy and Industrial Strategy (BEIS) announced in August 2021, the deadline for business to transition to UK Conformity Assessment marking (UKCA) would be extended to 1st January 2023.

The key changes to CE / UKCA marking rules are:

- **Goods first placed on the market in Great Britain from 1st January 2021 can either be CE or UKCA marked.**
- **The relevant Product Safety Regulations states that goods first placed on the market in Great Britain after 1st January 2023 must be UKCA marked.**
- **There are different requirements in Northern Ireland. The CE mark continues to be required in Northern Ireland, and there is currently no deadline to phase this out.**

Appendix III

Medical devices - key compliance dates/EU & UK

	2021	2022	2023	2024	2025	2026	2027
EU-MDR & IVDR	**26-May** MDR compliance deadline	**26-May** IVDR compliance deadline		**26-May** Ends grace period extended to devices certified under MDD			
EUDAMED			**Q4-2023** All six modules developed	**Q4-2024** The use of EUDAMED becomes mandatory*		**Q2-2026** All EUDAMED obligations become mandatory**	
UDI Placing UDI Carriers on device labels	**26-May** Implantable & Class III devices		**26-May** Class IIa & Class IIb devices		**26-May** Class I devices		
Direct marking on reusable devices			**26-May** Implantable & Class III devices		**26-May** Class IIa & Class IIb devices		**26-May** Class I devices
Placing UDI Carriers on IVDs device labels			**26-May** Class D IVDs		**26-May** Class C & Class B IVDs		**26-May** Class A IVDs
UKCA			**01-January** Medical Devices & IVDs***				

* Mandatory regarding obligations and requirements related to; **Actors, Vigilance, Clinical Investigation & Performance Studies and Market Surveillance** modules

** The use of EUDAMED becomes mandatory with regard to obligations and requirements for **UDI/Device and NB & Certificate** modules

*** Medical devices placed on the market in Great Britain (England, Wales & Scotland). Under the Northern Ireland Protocol, different rules apply in Northern Ireland to those in Great Britain.

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