

Reducing Medical Device Packaging Waste and Improving Information Provision Through E-labelling

E-labelling offers patients and healthcare professionals the convenience of always having up-to-date information on their products, such as the latest safety updates. It also provides regulators with greater oversight and assurance that manufacturers are providing accurate and timely information. Dr. Jutta M. Hohenhörst, from Schlafender Hase, explores the benefits of e-labelling for the medical device sector and provides some practical tips for getting ahead with processes, procedures and solutions that deliver efficiencies and add value for patients.

In the consumer world, it's now common practice to access product information online. For detailed instructions or information about 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 has some way to go to match these 'e-labelling'

experiences, regulators are making moves to change this through new directives and guidance.

E-labelling Benefits

E-labelling makes externally-facing product information more dynamic and immediately accessible online or through an app. That could be as a downloadable document, as shorter-form searchable text, or in alternative formats such as audio- or video-based instructions. The idea is to make important information easier for users (patients, caregivers or healthcare providers) to access and digest – while also ensuring that the guidance is as up to date as possible.

Paper inserts (instructions for use – IFUs; or patient information leaflets – PILs) present a number of practical challenges that can be readily solved in the digital age. These include the risk of costly printed instructions being misplaced or damaged; poor accessibility due to very small print because the leaflets have to try to cover all bases; safety information being superseded; potential regulatory Requirements: Section 508 (<https://www.section508.gov/create/pdfs/>) and European Accessibility Act.¹

Regulatory Change Focused on Safety

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.

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 understates the scale of change that will be involved. Appreciating this, EMA is phasing in e-labelling by target user group in Europe. 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.

As medical device manufacturers prepare for a digital-first future, it is vital to ensure that content is correct, controlled and compliant at source, that content is transformed accurately across print and online formats. A pragmatic approach to this is likely to involve the application of intelligent proofreading software, which can identify any anomalies swiftly and reliably.

Developing an Effective E-labelling Strategy

There are five key 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.
- 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 (e.g. Asian and Australia) for examples of emerging best practice and target benefits.
- 4. Create a High-level Project Plan**
Produce a high-level project plan, in-

cluding key champions and stakeholders. This should include a cross-functional team to mirror the scope of e-labelling impact on a manufacturer. Build training and knowledge transfer into the resource planning.

- 5. Build & Present an ROI/Business Case**
Build the business case, highlighting the benefits of the e-labelling initiative to patient safety and the business, including wider environmental sustainability gains, making sure to address the four strategic priorities of any manufacturer: financial, patient, operational, and growth.

It is important to define the scope, objectives and key performance results and monitor these on an ongoing basis. Finally, communicate and celebrate all wins, to sustain momentum.

By getting ahead now, companies 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.

REFERENCES

1. <https://ec.europa.eu/social/main.jsp?catId=1202#:~:text=The%20European%20accessibility%20act%20is,EU%20leading%20to%20costs%20reduction>



Dr. Jutta Hohenhörst

Dr. Jutta Hohenhörst, Regional Sales Director at Schlafender Hase, has over 22 years' experience in the pharmaceutical business. She has experience in different departments from Supply Chain Management to Strategic Marketing in F. Hoffmann-La Roche HQ, AstraZeneca and Fresenius HQ. While working for IQVIA during 2005 and 2012 she broadened her knowledge through strategic consulting projects in the pharma, medical device and hospital sector.

Email: jutta.hohenhoerst@sh-p.de

ADCA Pure

Pharma, Cosmetic, Fine Chemical & Food

HIGH PURITY. HIGH DEMANDS.

High purity equipment for clean steam

Safety valves



Steam traps



Pressure regulators



Control valves



Pipeline ancillaries



Special equipment

