Electronic Product Information: Are Companies Ready?

Regional health authorities across the world are developing an increased appetite for electronic product information, which could be a much more efficient and patient-friendly way of conveying the latest manufacturing details and safety recommendations. But how ready are life sciences firms to deliver regulated product information in this way, and what could it mean to companies themselves?

Amplexor's Agnes Cwienczek assesses the broader potential business case, and suggests how companies might determine their readiness for delivering reliable electronic product information – and begin to scope the work ahead.

Continued reliance on paper-based instruction leaflets to inform patients and healthcare professionals when and how to use medicinal products or medical devices, and to advise them about required safety considerations, makes increasingly less sense in the digital world.

Although they may remain an important option for mature generations or populations without ready access to the internet, paper leaflets are far from the most effective or efficient means of disseminating critical information. The documents may be mislaid, for instance. The small print may be very hard to read, and there may be several pages to plough through because of the detail that companies are required to cover – not to mention the multiple languages that may need to be included.

All of this is likely to be off-putting to the patient. There is a risk that the leaflets may not be read, or that it may be difficult to distil key information relevant to a patient's particular circumstances. Too often the content is not user-friendly, nor well pitched for the target reader.

More critically, paper-based product information/instructions-for-use can soon become out-of-date, either because new safety signals have been identified since the current batch of products went into distribution, or because key medicines have been sitting in a patient's medicine cabinet for months or even years. Obtaining updated safety guidance out with products can take quite a bit of time, depending on companies' cycle times and how much stock is already out in markets.

At the same time, an over-reliance on non-structured product information – which is typically the case when preparing paper patient leaflets – can make it difficult for companies to accurately assess the likely impact of any changes to content, to ensure compliant documentation while keeping pace with market demands.

'Digital First' Makes Practical Sense

For all of the reasons cited above, health/regulatory agencies across the world are showing increasing interest in introducing standardised requirements for electronic product information (ePI) – including the package leaflet for patients and the summary of product characteristics (SmPC) for healthcare professionals. Issuing product information electronically, and managing the contents in a structured way, will promote more confident decision-making among healthcare professionals, for instance, making it easier for them to search for the latest safety advice. In addition, patients will be able to more readily find the information that matters to them – correct dosage information for their needs, any contra-indications or adverse reactions to look out for, and so on.

The idea is to make all of the latest details and advice about a product readily accessible online / via a mobile phone – via a web link, or by scanning a barcode/QR code on a product label, with the ability to display the information as required by a specific context. For human pharmaceuticals and medicinal products, providing structured electronic product information is already mandatory in the US, while countries/regions including Canada, the EU and Asia are piloting or looking at programmes too, defining guiding principles and polling the market for feedback.

For life sciences manufacturers and distributors, a gradual shift towards digital product information delivery would be a positive development for a whole host of reasons. An obvious benefit is speed-to-market with the latest safety advice, boosting the patient experience and overall outcomes, not to mention public trust. Another substantial advantage is cost efficiency. As long as organisations have streamlined and reliable means of managing and approving changes to content, being able to publish this online/digitally will in due course relieve the pressure on paper-based information publishing – and all of the logistics involved, not to mention the potential for label/leaflet waste each time information or viable messages changes. And of course, shorter change management, review and publishing cycles contribute to accelerated regulatory processes, resulting in improved speed-to-market with products, and strengthened continuity of supply.

Even if paper leaflets persist for some time, the ability to publish updates or additional details online/digitally and easily provide access when and as required paves the way to scale back some of the busy text that is currently included in paper-based product information and IFUs. That might be different language versions, legal small print, or tailored advice for specific patient categories.

Making it Happen: Enabling Labelling Transformation

With so much to gain as product information goes digital, it follows that life sciences companies should embrace the potential at their earliest opportunity. But how ready are they? How conducive are their information/content management processes to deploying accurate, structured information and updating it at frequent intervals, as needs dictate – and across global markets?

The answer, unfortunately, is that most life sciences companies are not ready for this at all – certainly not pharmaceutical companies. Their capabilities for managing regulated content in a structured manner are so constrained that many companies – especially those with low volumes of changes over time – outsource their labelling management requirements if those go beyond paper. It seems easier to send data and get structured print-ready files back two to three times a year, than to contemplate transforming their regulatory content management backbones to better support process innovation.

This, in turn, is potentially limiting their operational progress in all sorts of ways. For starters, teams have limited sight of which markets are still supplying products with outdated product information and IFUs. That's before they can even envisage distributing this content in new and more dynamic ways.

Delivering electronic/digital product information is actually a robust use case for structured content management, where companies can confidently assemble the latest, correct information (which has been approved for use), for the current purpose. If companies had a facilitating content management backbone extending from one end of the organisation to the other globally, and were able to work with approved core data assets which had been captured in a structured way to enable easy re-use, they would have the potential to transform the way they manage labelling – and publish changes online.

A Three-pronged Attack

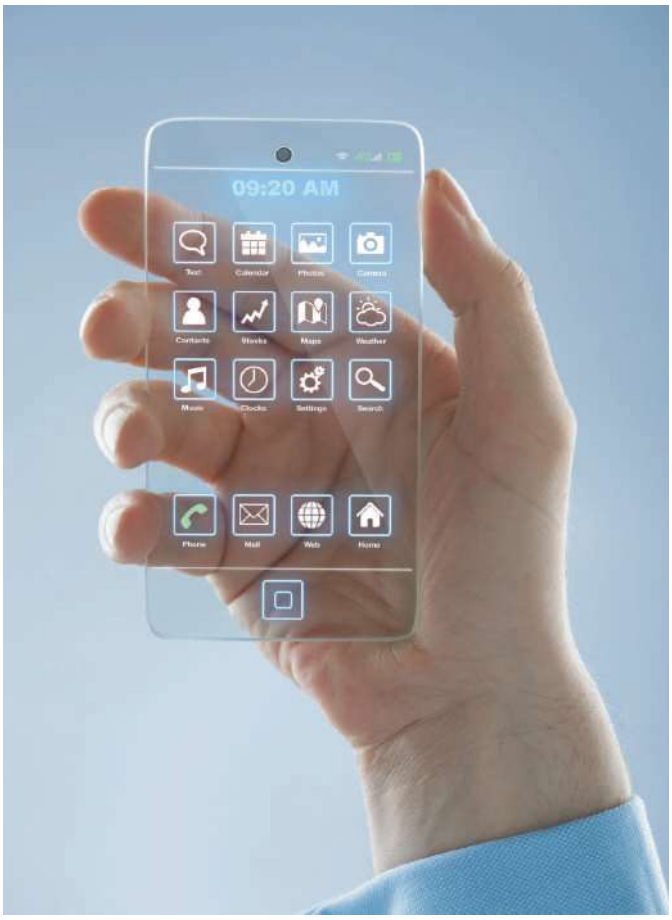
So how might life sciences companies move forward, so that they can start capitalising on new efficiencies and lay the groundwork for electronic product information delivery?

Successful transformation of label content lifecycle management will rely on improvements to content, technology, and processes – in concert. That is, any investment in technology to support digital transformation must be matched by measures to assess, connect, clean up and restructure current data sources; and new thinking about how information and content processes could be managed in future to drive innovative, more effective and efficient labelling strategies.

Certainly, at a regional level companies should start to unify as much of their information and content preparation as possible, in accordance with regional or local regulatory requirements. Using the controlled vocabularies set out by electronic submission standards (currently xEVMPD in the EU, to be succeeded by the more detailed ISO IDMP-based requirements; and Structured Product Labelling (SPL) in the US; regulatory agencies and health authorities (HAs) provide or have begun to provide recommended schema), they can start to impose improved consistency in a way regulated product information is constructed. This will help them create solid content components or building blocks for all labelling.

Establishing a definitive repository for correct, current, approved content assets is essential as well – along with details of current product registration and marketing status and submission activities globally, including information about which labels are in circulation where. So, an end-to-end regulatory information management (RIM) platform will play an important part, forming the backbone across which all active and historic content, along with associated status information, can be viewed and managed.

With a vision for positive change in place, companies can begin thinking through the details. Considerations may include: How well aligned is our labelling content within the regulatory boundaries? How easy is it to conduct an impact assessment and introduce changes? How well do we manage oversight and control? How well connected is the end-to-end process across the organisation? Do we understand who owns which content? Do we have the technology and mindset in place to deal with structured content? To what extent are we utilising vocabularies and master data in our content? Will we need a conversion tool to analyse, compare and transform existing labelling information? How can we transition to structured content, and how will we stay aligned with evolving IDMP data parameters? Also, if we run a pilot, how will this work?



Crucially, life sciences companies must look for the added value they can deliver from all of this, for their own operations and for their market partners and for patients. Returning to the business case for electronic product information, new value is likely to include greater information accuracy; easier content creation and validation; accelerated regulatory processes; rapid safety updates; and the phasing out of frequent print updates and the potential for wastage each time information changes.

Waiting for regulators to mandate change to (structured) electronic product information delivery will be to leave all of this too late. The path to digitisation may be a gradual one, but there is no doubt that global markets are converging towards the same goal. That's because agencies understand that continuing with current labelling practices and product information delivery is unsustainable from every angle – something companies already know deep down too.

Agnes Cwienczek

Agnes Cwienczek is Head of Product Management and Consulting at Amplexor with a remit that includes the provision of business process and data management expertise in the areas of regulatory information management, document management, and submission management. Prior to joining Amplexor, Agnes worked at Merck in its Global Regulatory and Quality Assurance department. She received her Master's degree in information management from the University of Koblenz-Landau.

Email: agnes.cwienczek@amplexor.com