# The Public's Growing Appetite for Product Data

Whatever international regulators' demands might be, society's expectations will ultimately dictate the need to prepare comprehensive, up-to-date product data that patients, clinicians and pharmacists can scrutinise on demand, says Frits Stulp of Iperion Life Sciences Consultancy.

As momentum builds anew towards ISO IDMP compliance, life sciences companies could be forgiven for a lacklustre response, after a series of delays to its rollout. Most organisations have already jumped through so many regulatory hoops, bolstered teams and implemented IT systems and new processes, to meet each new set of guidelines and mandates that come along, seeing this as a condition of staying in the market and a necessary expense. They knew IDMP would be realised eventually, so the final preparations that lay ahead were always inevitable, but that doesn't mean firms are embracing the latest implementation advice with enthusiasm.

Yet there is another far more important factor at play here, and that is the public's growing appetite for access to medicinal product data: not just the wider healthcare market, but consumers themselves. In the detail of specific regulatory mandates, it is easy to lose sight of why new measures are being introduced, but bringing the industry back to the original drivers for IDMP and other information-based regulations can help to reframe compliance initiatives with a more positive and strategically significant emphasis. After all, life sciences firms have hard-won reputations to protect – and being responsible for good patient outcomes, and upholding patients' best interests, are high on their list of corporate pledges.

This being the case, it is worth keeping patients, clinicians, pharmacists and the wider public front of mind when evaluating priorities and best next steps towards IDMP and other emerging international quality and safety standards.


**Beyond Formats: Defining an Operating Model for Product Transparency**

Looking specifically at IDMP, which is now moving closer to becoming a reality, life sciences firms should now be looking to embrace evolving regulatory standards, to define a practical target operating model for managing their product data. The aim of this is to ensure that what is submitted to regulators is an accurate reflection of the current truth.

While much of the advice around ISO IDMP preparations concerns how different categories of data must be categorised and formatted – the nitty-gritty of how to keep within the specific database parameters – the bigger picture surrounds how firms can get that data into the hands of those who need it – and quickly. This doesn't just include the European Medicines Agency (EMA) and other international regulatory bodies, which before long will insist on accurate and complete data filings alongside traditional dossiers. It also includes the patients of medical products, and those prescribing or selling them.

**Patient-centricity**

Companies can become so caught up in their regulatory obligations that they lose sight of why compliance exists and is so important. Once product records are brought under control, and consolidated in a robust, credible and definitive living record (a single, up-to-date version of the product truth), there are plenty of other keen consumers of that information besides the industry watchdogs.

Certainly, in the digital age, it should not be taking months or years for the latest safety advice to filter through to patients, simply because patient information leaflets haven't been updated. In future, we can expect to see QR codes (matrix barcodes, which when scanned open a relevant web page) being used as standard on medical products, as a means to providing links to the latest, revised instructions for use online. That is, access to complete, up-to-the-minute advice will be much more immediate and convenient than it is today.

All of which comes back to the need for companies to have an accurate master data source, along with visibility of where this data is re-used and a way of managing interoperability between the central master and wherever information has been reproduced. Even keeping submitted regulatory dossiers and electronic data equivalents in sync will require appropriate controls, because information may continue to be updated after original documentation has been put together.

**A Call to Action**

It is undoubtedly unfortunate that the timelines around IDMP have been subject to delays over recent years, slowing down preparation of a definitive data truth about products that clinicians, pharmacies, patients and other stakeholders could benefit from today. But this should not be allowed to stymie all progress. For just a few hundred euros, any company today can buy the ISO IDMP specifications from their local standards organisation and begin working toward a target operating model for wider data exchange.


It is worth remembering that 60 countries participated actively in proposing and setting these new ISO standards, and 160 countries have pledged to recognise and enforce them. That's a strong endorsement to justify preparing and managing electronic product data in support of wider public access. Committing to this is an important step toward the democratisation of healthcare and medicine data, something respected industry players talked about a lot during the spring/early summer conference season.

If society's growing expectations are not enough of a driver for change (and they should be), consider this. A technological giant like Amazon may yet disrupt the life sciences industry, using as its leverage its superior grasp on information management to create new value around medicinal products for consumers. It is not beyond the bounds of credibility to imagine that if Amazon wanted to buy the intellectual property for a drug compound, along with the other operational elements to running a pharmaceutical business, it could establish a healthcare organisation with relative ease.

In the life sciences industry, product information is vastly underestimated as a business asset, and if firms don't want to leave themselves exposed to huge risk by failing to gain control of this, they must act now.


## Frits Stulp

Frits Stulp is the managing director of Iperion Life Sciences Consultancy. With over 20 years of experience in the life sciences industry, he has worked on multiple regulatory compliance projects, becoming an IDMP SME programme manager and adviser to several high-profile pharmaceutical companies, regulatory authorities and software suppliers. He is currently the project manager for the EU Substance Registration System (MEB/EMA); is an active member of the EMA ISO IDMP Task Force for Substances and Products; and is the IRISS Forum IDMP topic lead. He holds an MSc in pharmacochemistry from the Free University of Amsterdam. Frits recently spoke at AMPLEXOR's 21st annual BE THE EXPERT industry forum in Provence, France, on how life sciences organisations can best prepare to deliver standardised data versions of their regulatory dossiers, which will ultimately form a public record of their product information – including the latest safety data.

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