Is Europe Ready?

With less than two years to go until the implementation of the EU's Falsified Medicines Directive, firms along the entire pharma supply chain are running out of time to prepare. To be ready on time, industry stakeholders need to step up their game

Christoph Krähenbühl at 3C Excellis Europe

February saw an important milestone for all pharmaceutical manufacturers supplying the European market and their supply chain partners – the 9th marked the beginning of the two-year countdown until the EU's Falsified Medicines Directive (EU-FMD) compliance mandate comes into force across Europe. From that date, pharma companies will no longer be able to legally put products on the European market unless they comply with the three critical 'safety features' requirements. Every pack of medicines must be:

- Tamper-evidenced
- Carrying a 2D data matrix encoding a unique identifier (UI)
- The UI must have been uploaded into a Europe-wide system of repositories for systematic check-out at pharmacies

Achieving readiness to fulfil these conditions is a huge undertaking and the question being asked is: 'How realistic is the prospect that Europe will be ready in February 2019?' In order to answer this, let us consider the different areas of work in turn.

Stakeholder Obligations

The first major area covers the responsibility of all pharma manufacturers supplying Europe to routinely serialise their products, apply tamper-evidence and implement systems and processes to manage the serial numbers securely. Once the EU-FMD has come into force, every pack in the market must have a corresponding UI available for the duration of its shelf life in the relevant repositories for verification in the pharmacy.

Wholesalers are also required to establish technical capabilities to handle serialised products, as there are a number of cases in which they will need to scan UIs against the repositories for verification such as risk-based verification, exporting medicines from Europe and early dispense. The third stakeholder group that needs to implement new technology is pharmacists, who will be legally obliged to scan every medicine that is dispensed to the public.

European Repository Systems

The second major area of work involves setting up the Europe-wide infrastructure of repositories systems specified in the Directive, a task that is delegated to industry stakeholders. This is a significant amount of work that includes not just the design, build and implementation of interconnected systems to cover the whole of Europe from manufacturer to dispensary, but also the set-up of the supporting organisation structures and business processes at both European and national levels in each of the participating 32 countries.

Despite the monumental task, however, indications are that one can be cautiously optimistic about progress. Stakeholders from all parts of the industry – with their competing and often conflicting interests – have been actively collaborating since before the publication of the Directive in 2011. As of February 2017, at the time of writing, the European Medicines Verification Organisation (EMVO) has been in existence for two years and a growing number of countries – 15 at the time of writing – have also set up their National Medicines Verification Organisations (NMVOs) or are close to the point of achieving this major milestone (1).

Progress on the technical side follows this trajectory. The European Hub that the manufacturers will connect to in order to upload the UI data, the central piece of this infrastructure, was opened in 2014 and has been connected to the first national system, Germany's SecurPharm, since mid-2015. Other countries are also making progress towards the establishment of their national systems, helped by the 'blueprint' approach: a shortlist of three providers favoured and pre-checked by the EMVO in order to achieve consistency and interoperability as well as cost-efficiency.

So far, 10 countries have completed their vendor selection or are very close. While that number may seem low at this point, the blueprint method provides a strong foundation for a rapid rollout following the successful establishment of the organisational underpinning. This leaves us with reasonable hope that the organisational and systems infrastructure at the EMVO and NMVO levels will almost certainly be ready and operational across all of Europe by February 2019.

Pharma Manufacturers

Unfortunately, other areas of this large and complex project are not showing the same rate of progress and the state of readiness across the industry certainly raises cause for apprehension. For a start, the latest 'state of play' update published on the EMVO's website shows that, out of an estimated 2,500 manufacturers that will need to be

on-boarded, only 50 are currently connected or in the process.

Given that there are just over 100 weeks to go, this low number of active participants is a serious concern. It is an indication reflected by other anecdotal evidence that many firms are taking an overly optimistic view and delaying their implementation – especially smaller and mid-size companies. What is even more worrying is the fact that even the major businesses with well-established projects in place – driven partly by serialisation requirements in other markets – are still anxious whether they will be fully ready for the European deadline in February 2019.

It is beyond the scope of this article to speculate about why so many firms are risking their European business, but one argument sometimes made is that the lawmakers will move the compliance deadline when it becomes clear that industry will not be ready in time. This argument may be based not just on wishful thinking, but also on the experience in other markets where compliance dates were, indeed, subject to change.

However, there are no indications that this scenario will play out in Europe – the Directive and Delegated Regulation are very clear about the date. In fact, Article 50 is concise and to the point, stating: "This Regulation shall enter into force on the twentieth day following that of its publication in the Official Journal of the European Union. It shall apply from 9 February 2019." Neither the Q&A published on the European Commission's website, nor any public statements, give support to the assumption that a change of date is being considered.

Wholesalers and Pharmacists

Finally, there are those further along in the supply chain across Europe: around 10,000 wholesalers and approximately 150,000 pharmacists who all need to invest in establishing new technical capabilities and procedures to manage shipments of serialised products and support the routine scan of the UI on every single pack that is dispensed to a patient.

Wholesalers are likely to be ahead of the curve, given that other regulations like the 2013 Guideline on Good Distribution Practice of Medicinal Products for Human Use have raised the bar on process and system requirements that this group needs to comply with. This adds to the EU-FMD's demands that set out a number of scenarios in which they will need to scan UIs against the repositories for verification or even check-out (DR Article 22 ad 23). Many wholesalers and distributors are indeed reported to be making progress towards establishing procedures that will allow them to comply with their regulatory obligations, including the readiness to connect to the national systems as and when they come online.

On the other hand, the pharmacy sector is generally less advanced. Pharmacists have been exposed to serialisation and traceability expectations for less time than manufacturers and their position naturally lies further back along the adoption curve. However, they are now engaging with the other stakeholders in many European member states and getting increasingly involved and committed to progress at national level. A sign of this progress is the implementation of full-scale pilot schemes involving community pharmacies that are planned to take place in several countries later this year. In parallel, extensive engagement with the pharmacy systems' IT providers is under way to ensure that the 'last mile' of the technical end-to-end system provision is in place to meet the 2019 deadline.

Are We Ready?

The EU-FMD is an ambitious regulation and the practical challenges of execution across 32 countries with their diverse backgrounds, practices and requirements are daunting. But while it is true that there are still many details to be worked through, the basic stipulations are very clear and have been published for over half a decade now – the Directive was published in 2011. The roadmap for achieving EU-FMD readiness should be well known and, in some areas – notably the work area to establish the medicines verification infrastructure consisting of the European Hub and national systems – good progress has been made. It now remains for all other stakeholders to step up to the challenge and do their bit.

The anniversary of the publication of the Delegated Regulation is a good reminder that time flies, and everyone involved in the supply of pharmaceutical products to patients in Europe will need to focus on the ultimate goal to be achieved in just over 100 weeks: ensuring the provision of safe medicines to every European citizen.

Reference

1. Visit: www.emvo-medicines.eu

About the author

Christoph Krähenbühl, Senior Director at 3C Excellis Europe, is widely recognised as a thought leader in pharma serialisation. He has been involved in serialisation schemes since 2006 as Serialisation Project Manager and Product Security Manager at AstraZeneca. Christoph has also been supporting the European stakeholder response to the EU-FMD as an expert on the European Federation of Pharmaceutical Industries and Associations team and as a member of the EMVO management team.
Email: christophk@3cintegrity.com