

Good Data Discipline: Responding to New XEVMPD Maintenance Guidelines

At the end of January 2014, formal guidelines were issued concerning the way updates must be made to European pharmacovigilance data. Miranda Pothiwala, director at Samarind, discusses the implications now that tight timeframes have been set for getting submitted product data in order.

As of two years ago, any life sciences company distributing products in Europe has been subject to a mandate to submit comprehensive product information and documentation to a central electronic database – the EudraVigilance Medicinal Product Dictionary (EVMPD) – in the interests of improving patient safety. To give the requiring authority, the European Medicines Agency (EMA), chance to absorb and organize all of this content, companies were asked not to submit updates to this initial information until formal guidelines had been issued on the process for ongoing data maintenance. At the end of January, that guidance was finally published, putting pharma organizations under new pressure to respond and get their submitted information up to date.

Achieving data maintenance compliance

The extended EudraVigilance Medicinal Product Dictionary (XEVMPD), as the latest incarnation of the central European database is known, aims to catalogue all human drug products marketed in EU countries. So what's new under the data maintenance guidelines?

Since the original submission deadline (July 2, 2012) there have been various timelines proposed for maintaining the data. There has been talk of a two-speed maintenance process – significant changes to be notified within 30 days and lesser ones within 12 months or as an annual report. The EMA's draft guidelines in December suggested that everything – not just new marketing authorizations (MAs) – should be notified within 15 days, which the industry was obviously not happy about. The final guidance achieves a middle ground: new MAs should still be notified within 15 days of approval, and all other changes should be submitted within 30 days.

Another challenge is that updates are required across ALL products - because new data fields have now been introduced. This means, in effect, that all companies must resubmit all their product information. Companies must now indicate the **size** of their operations, for example. They also need to provide information about the **legal basis** of the marketing authorization for each submission, and apply the right **medicinal product code**, to ensure correct categorization - e.g. herbal, pharmaceutical, etc. Finally, the authorized pharmaceutical form covering the **dosage** of products must be included, in addition to the existing 'as administered' dosage form.

Transition period

The Agency is proposing a transition phase, between June and December of this year, during which marketing authorization holders are expected to bring their product data up to date *and* improve the quality of the data they have already submitted. But, however prepared companies feel, this won't be easy. As organizations prepare to respond to the new requirements, they will need to take stock of where they are today and how far they still have to go before they are able to meet the latest XEVMPD requirements reliably and as painlessly as possible.

A conservative estimate based on Samarind's regular contact with pharma companies, suggests that 30-40% of affected organizations have yet to finish their original submissions, so do not yet even have a complete data set registered with the XEVMPD. Worse still, many firms had shelved XEVMPD initiatives whilst the new guidelines were being confirmed so have made little progress over the last 18 months. This has left companies with a lot of catching up to do.

Although much of the required content already exists in companies, this is widely dispersed and is often captured manually in spreadsheets. The European Medicines Agency provided a free online data entry tool, EVWEB, to make the process easier, but its parameters are basic and use of the tool has resulted in variable quality in the information that has been submitted. In other cases, any initial sense of urgency soon became diluted once the deadline had passed, and as organizations realized that there were no real consequences for non-compliance - in that no firm has so far been penalized for this.

But the EVMPD/XEVMPD initiative is a work in progress and now that standards have been issued concerning the way data must be

updated, the Agency is likely to come down more heavily on companies that do not get their data in order. At the very least this could lead to reputation damage if high-profile brands are exposed as being tardy in their submission activity - especially given that the whole point of pharmacovigilance is to improve consumer safety. Furthermore the Agency has made it clear that the XEVMPD data will be used in the calculation of pharmacovigilance fees – a fact that significantly heightens the importance of the data.

Reducing the burden

The only safe way to achieve compliance is to have reliable, fit-for-purpose processes and systems in place which are geared towards clean, easy and stable data capture, management and reporting. By investing in good data management systems, good data quality and consistency, and easy traceability of information, companies not only improve their ability to meet their EVMPD obligations; they also stand to benefit from all sorts of additional internal efficiencies.

Capturing holistic information in a single central place means there is a 'single place of truth': information only has to be entered once yet can be accessed readily by anyone who needs it (assuming they have the relevant authorizations) and repurposed in all sorts of different ways. Controls and rules can be added too - for example to prompt actions, such as updates at given times.

Whereas point solutions can help with simple submissions, a more sophisticated solution used internally to store, organize and manage data on an ongoing basis creates all sorts of opportunities for operational improvements. These might include accelerated workflow,

improvements to data quality and reporting, easier auditing and broader information compliance, and so on. For the purposes of management reporting, as well as the delivery of the many compliance reports that health authorities require, a fit-for-purpose data management solution would enable the necessary documentation to be produced at the touch of a button. By smoothing administrative processes, the right software could also help companies get new products to market in better quality and more quickly.

Improving data quality

One of the issues the European Medicines Agency has been grappling with has been the poor quality of data that companies have submitted to its central database to date. For a limited period, the Agency encouraged pharma companies to input their own categories into the controlled vocabularies used in the medicinal product dictionary. This has led to overlapping fields and duplication of content. As it has sought to clean up this data, the Agency has had to consolidate some of these codes; this is one of the reasons companies now need to resubmit a lot of content.

Going forward, companies will need to ensure that the data they submit is cleaner and more accurate. This means removing duplication and manual re-entry in internal data capture and management processes. Yet, as long as pharma companies continue to manage and update their product information manually, using spreadsheets, the scope for error will only grow.

With eCTD (electronic common technical document)-based electronic regulatory submissions, validation criteria and tools exist to provide assurance around data quality. It is

likely that similar aids and tools will be made available in due course to help ensure clean, compliant data for EVMPD.

Quality control

Patient safety – the ultimate goal of pharmacovigilance – relies on good data quality and reliability, so this is where initiatives must now be concentrated. Certainly, the last thing companies want is to be seen to fail to deliver against public health and safety improvement targets. This means making a concerted effort to streamline processes and eliminate repetitive practices.

Getting this right sooner rather than later will pay off, however. Over time the European Medicine Agency's requirements will become increasingly stringent. The next iteration of XEVMPD, ISO IDMP - which is expected to become mandatory in 2016 - will take pharmacovigilance reporting to the next level, introducing significantly more data requirements and additional controls over data quality among other measures. It is also expected to have broader geographical application – ie. beyond Europe.

All of this suggests that any investment made now in achieving compliance will be recouped several-fold in efficiency gains over the coming years.

About the author – Miranda Pothiawala

Miranda is director and head of software at Samarind RMS. Steeped in knowledge of regulatory submissions and data management in the pharmaceutical and medical device industries, Miranda is also an expert on EudraVigilance and compliance with the EMA's EVMPD medicinal product dictionary. Miranda is an active member of the IRISS IDMP industry group, which is collaborating on EVMPD's successor, and sits on a small sub-group focused on improving the quality of data companies submit to the EMA.

Miranda has a Bachelor of Arts in English and Mathematics from the University of Liverpool, where she was also awarded the Maths Prize. She has professional qualifications in Programming, Analysis and Systems Design as well as numerous other official business and IT credentials. She is a member of TOPRA and ISPE.

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