Think XEVMPD – but Bigger: Understanding the Evolution towards IDMP

Guest Post By: Damien Daulon, Product Life Group 6/20/2106

Past experience has left many companies reluctant to address Identification of Medicinal Products (IDMP) until the final version of implementation guidance has been published.

When the Extended EudraVigilance Medicinal Product Dictionary (XEVMPD) standard was mandated to start in July 2012, companies rushed into preparing. But in the months leading up to implementation, there was so much uncertainty. Updated texts were issued, then the European Medicines Agency issued the Q&A explaining how to use the model. The number of tasks to perform in such a short period turned the XEVMPD experience into a nightmare for companies. Companies don't want a repeat of that experience with IDMP.

This is understandable, but it's not practical given the work that needs to be done to be ready for IDMP.

One of the problems is that companies have never really been informed about what the XEVMPD – or IDMP – is about. What is the purpose, process, parties involved, tools involved, and the information involved? The primary goal of XEVMPD was to have a centralised inventory of the medicines registered in Europe in order to improve data analysis and signal management and facilitate the management of pharmacovigilance cases – or adverse events. XEVMPD was also designed to facilitate regulatory actions and legal obligations such as PSUR submissions and referral procedures, but also to collect pharmacovigilance fees.

Having a greater understanding of XEVMPD will also help companies prepare for IDMP because – at least for iteration 1 – it can be seen as an evolution of XEVMPD, but with wider scope. Having gained an understanding, conducting an IDMP pilot project with one or two products to test the IDMP model with real cases also starts to make more sense. While a number of required fields already exist with XEVMPD there are new fields, some of which involve data that aren't readily available in current regulatory databases or referentials.

This is particularly true for data held in manufacturing databases, such as details about product packaging and product dispensing – for example, the precise dimensions of a syringe or container, the references for specific colour codes or barcodes.

Simplifying the Journey

Once companies see what has to be done to get these new data elements, the need for a way to simplify the passage of data from one part of the organisation to another becomes patently clear – in other words, regulatory information management and master data management. Without a RIM approach tied to MDM finding this information will be enormously time consuming and a drain on resources.

The good news about IDMP as it now stands is that it is an evolution from XEVMPD and therefore it is possible to fit the relevant data from XEVMPD to the IDMP model. The changes brought about with the introduction of iterations has meant the transition from XEVMPD to IDMP can be made smoother, while still requiring an enormous commitment from companies.

To start with at least, IDMP won't deviate substantially from XEVMPD in terms of submission process and the type of information required. In the long run, however, IDMP is expected to evolve further and collect data as it relates to the origin of products in order to understand the source of adverse event cases.

Again, understanding why this will matter will help companies to put IDMP into broader perspective. The fact is that having a central database that describes where the product comes from, including active ingredient(s) and excipients, will make it possible to cross check the information and link adverse event cases to the original manufacturer and process. From there, regulators can target the manufacturer and have them assess their steps to determine what is causing the issue and how to prevent it from occurring again. Having more information will also help to track products and stem the tide of counterfeiting.

While that capability is still several years away, knowing the end goal and the potential of IDMP gives it meaning and helps companies to understand what they are working towards.

Where are you in your IDMP journey and how well do you understand the purpose of the standards?