IDMP at a Crossroads

In 2020, will growing urgency around veterinary regulations disrupt progress on human medicinal product standards, and will anyone at last speak up for patients? Frits Stulp of Iperion Life Sciences Consultancy calls for focus and mutual support during what will be a critical year for the regulatory network's improved patient safety initiatives.

Providing annual reviews on IDMP progress has proved painful in recent years because momentum has not always been where it should be, due to shifting timescales and fluctuating focus and alignment among the various stakeholders. But 2019 has seen some decent progress, particularly at a substance level, as well as a crystallisation of ideas about what needs to happen next.

Common Substance Definitions: A Proof of Concept

One of the important developments in 2019 has been the demonstration of the impact shared definitions of substances can have internationally, via a proof-of-concept project led by the Dutch regulator (Medicines Evaluation Board) on behalf of the European regulatory network. This considered the benefits of data continuity in a substances context, from a scientific point of view. Specifically, it explored how agreed descriptions/coding for complex molecules would help in cross-border medicines management – for instance in scenarios where a patient loses their medication on holiday, or needs a new prescription, and a healthcare provider needs to check the active ingredients, and identify any contraindications or allergy implications.

The proof-of-concept study is currently demonstrating that describing molecules in a consistent, agreed way, with common mapping, would provide significant support for data and process interoperability. Instead of individual professionals having to sift through dossiers to confirm the constituent ingredients of equivalent products, they could simply exchange the agreed identifier – much as people use their social security number to identify themselves as individuals to different government organisations. Here, the primary benefit is reduced risk of wrong medicines being issued (though the efficiency gains for all stakeholders, and the accelerated speed of decision-making, are clear sub-benefits).

This is just one of up to 20 use cases making up the business case for IDMP – that is, for having a common method of identifying medicines. Interestingly, in the US, a project has been underway for some time looking at incorporating *images* of drugs into a central medicines database, with potential benefits for elderly or vulnerable patients or their carers, who have reference to only limited information, such as the known colours of pills. The aim of that particular project is to capture images of every tablet on the market, so that medication can be identified visually – as a further dimension to the common descriptions being captured.

The Rise of the Veterinary Regulatory Agenda

IDMP developments in relation to substances are not yet being matched by developments around product-level descriptions. And there have been some concerns that momentum might once again be lost here, at least in relation to human medicines, as measures to address veterinary medicine data come into central focus. Standardising veterinary medicines information was always part of the EU/EMA plan, and a team is now championing the cause with January 2022 now designated as a hard deadline for compliance with standardised identifiers.

Some in the human medicines industry fear that advances with product-level data will now take a back seat, causing new delays to progress with IDMP implementation. Yet there is no reason why the two streams of work should not happen in parallel. Indeed, they could both feed off and help drive the other, as there will be considerable commonality between most of the process requirements – and one of the big points of IDMP is to foster greater efficiency/replication of proven success.

Veterinary implementations of data standards will put pressure on affected industry stakeholders to establish target operating models for product and substance data, which is something all medicines companies now need to do anyway. So if veterinary work streams move along at a slightly faster pace now, this could even help accelerate or boost the business case for broader/human medicines data transformation efforts. Certainly there is no need for working parties with interests in human and veterinary medicines to plan their projects sequentially. Parallel planning makes much more sense, especially if the respective work parties can learn from each other and accelerate overall progress.

The target go-live date for human medicines/IDMP compliance is 2023, and it is in everyone's interests that we keep to this deadline. So if we can harmonise the process, rather than create two sets of definitions, vocabularies and so on, so much the better for everyone concerned. With a concerted effort, I believe we can all hit our deadlines, and in 2020 it would be immensely encouraging to see all industry stakeholders – regulator, industry and technology vendors – come together to drive progress against SPOR data standards1, whichever angle they are coming from.

Patient Representation: Championing Electronic Product Information

In the context of human medicines, something else we very much need to see in 2020 is greater and more prominent representation of the patient voice in discussions and developments. It is ironic that, despite the public being the ultimate intended beneficiaries of IDMP medicinal data standards, this important stakeholder group currently has no seat at the table.

It has long been accepted that few patients bother to open up and read the lengthy advice leaflets included with drugs, with their microscopic print and overly-thorough detail with a strong legal leaning. To address this, in due course patients will increasingly have access to more fit-for-purpose 'instructions for use' (IFU) content, and potentially broader product information, through a choice of media and distribution channels.

Audio instructions, video explanations and pictograms, delivered via websites or mobile platforms, are among the planned options. So, wherever patients are, and whatever their ability to comprehend the information, they will have a more accessible means of learning about the products on offer to them, how to get the best from them and when and how NOT to take them. Again, it cannot be overstated that the interpretation of the source information across different media is heavily dependent on having common data standards, reducing the risk of meaning or accuracy being lost in translation.

But currently the rollout of these initiatives feels too far off, and it doesn't help that there is no one specifically campaigning on patients' behalf for these innovations to happen sooner; for a deadline for at least a first iteration of a new IFU format. As medicines become increasingly complex in their make-up, and as treatments become more personalised, the role of user-friendly content will only become more important, too.

Again, standardised approaches to data are central to progress here, not least because companies need a way to govern and trace all of the information they are putting out into the market. A common set of definitions will allow both the pharmaceutical industry and the regulator to have an agreed understanding of the product, in whatever communication may follow.

Cooperation & Mutual Support is the Answer in 2020

My hope for 2020 is that it will be a year of decisive action. Stakeholders from across the life sciences industry should look at the encouraging progress and development of use cases for substance data, and accept veterinary medicine data developments as additional blocks they can build on for human medicines data developments under IDMP.

In the meantime, all stakeholders need to work together to prioritise and drive the patient agenda. This involves demanding more work towards common definitions and process flow, so that a standardised European approach to electronic patient information can take shape – and a deadline for compliance can be set. People pay their taxes for this kind of thing: it's time the industry delivered.

REFERENCES

1. Substance, product, organisation and referential (SPOR) master data, European Medicines Agency

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