

# Manage information

**Intelligent use of data gathered for regulators can bring a competitive edge to marketing plans**

**Recording detailed product and licence lifecycle information purely to meet regulatory requirements misses a significant opportunity. Competitively, it should be seen as a company's chance to plan its marketing activities more strategically and steal a lead over its rivals.**

**T**racking the licensing and marketing status of a broad variety of drugs across multiple markets globally is a significant and growing challenge for pharmaceutical organisations. As it is, companies are overwhelmed by the mass of information and, with so many products and territories to monitor, it is not surprising that senior marketing personnel feel they are losing control.

Fortunately, this missed opportunity is being resolved by the general drive to improve and standardise regulatory information management. This means organisations are capturing more data than ever before and, importantly, the kind of information that could be exploited for commercial advantage if properly handled.

## **Bigger picture**

All too often, however, companies become so embroiled in the detail of regulatory information management (IM) requirements that they overlook the broader opportunity for improvement associated with having ready access to better information.

While regulatory compliance is clearly

readily, so as to achieve a single, meaningful version of the truth, which can inform insightful commercial decision-making.

Where the pharma industry is at an advantage is in its extensive use of enterprise applications. This gives companies a good starting point, in that they are already generating a lot of raw data. At the other end of the spectrum, the industry has been slow at adopting business intelligence solutions, meaning the plethora of data being collected is not fully exploited. The challenge is to integrate information more effectively so that more can be done with it. Process optimisation and behavioural changes across teams of users are also required, so that real benefits can be felt.

## **Marketing planning**

A comprehensive regulatory IM solution is likely to include registration planning and tracking, submission planning, publishing and tracking, registration management (including activities beyond initial licence approval) and high-level portfolio management.

Few pharmaceutical companies, however, are even close to achieving anything resembling holistic reporting.

An independent survey conducted by Gens & Associates found that some 70 per cent of life sciences firms persist in using manual tracking and spreadsheets to generate reports. Most companies use a combination of

tools to manage and track information, and these are applied in a disjointed way.

ISI's own focus groups have confirmed, too, that many life sciences companies struggle with even the most basic information, such as knowing which products are registered where.

In other cases, regulatory IM has been approached too discretely, driven by

specific questions around submissions, obligations to do with scheduled items such as annual reports or manufacturing changes, or marketing authorisation status. While each is important, regulatory and commercial advantages stem from having an information strategy capable of creating something bigger than the sum of the parts.

The risks of falling short on both a regulatory and commercial front are significant. Poorly harnessed product status information could result in a breach of licence terms, falling foul of changing country-specific regulations and ultimately compromising patient safety. Commercially, it could mean protracted, inefficient and costly administrative processes, delays in getting to market and a failure to maximise revenue opportunities.

In some cases, it is easier for organisations to start from scratch with a new IT system for managing all of this regulatory and related data, rather than trying to fill in the cracks in an existing, fragmented legacy set-up. This provides an opportunity to ensure that the resulting tracking systems are managed logically for the users, with information categorised in a way that feels familiar to them and with data that is clean and consistent.

## **Post approval**

Certainly, companies have been more progressive when it comes to regulatory requirements. Yet, where companies are beginning to get to grips with the information requirements of the fuller regulatory lifecycle, in many cases their vigilance does not yet extend to post-approval commitments, which also need to be tracked and managed.

This can add a further layer of complexity, since commitments may vary by market. On the manufacturing side, for example, companies can enhance the decision-making process by having actionable information on formulation and dosage, on manufacturing facilities and locations,

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important, there are other areas that life sciences firms could be addressing with the information they are now collating, such as commercial planning, including the targeting of new markets, mergers and acquisitions and the pursuit of new types of industry partnership.

To achieve this, companies need to find ways to release and share content more

and on when the product can be released to various regions.

Until now, most tracking tools in use among life sciences organisations have not incorporated planning. Nor have they facilitated the integration of various sources of data, limiting the potential impact of the information companies are monitoring. As the Gens survey showed, far too many companies are still relying on simple spreadsheets to manage their tracking and planning. However, as markets become increasingly global, the need to track and plan more strategically becomes paramount, going far beyond these simple solutions.

***“Many companies are preparing to make organisational and procedural changes to submission operations over the next two years, with significant investment being made by the 60 largest pharma firms”***

Encouragingly, there is a growing realisation of the need for change. Gens reports that many companies are preparing to make organisational and procedural changes to submission operations over the next two years, with significant investment being made by the 60 largest pharma firms globally in submission management and registration tracking projects. Among the top 30 companies, 88 per cent are now making substantial changes to their submission management activities, with the aim of benefiting from the ability to engage in more predictive planning.

Reasons cited include the need to support the electronic Common Technical Document (eCTD) submissions publishing standard, and the growing requirement to address emerging markets. Organisations now want an authoritative source of information concerning registrations and product files. Cost reduction, too, is a big driver; after all, efficient management of information reduces the need to take people away from the core functions to respond to a regulatory request. Another catalyst is the need for tools for data mining to ensure greater control of in-licensing and divestitures and to manage global capabilities more effectively and efficiently.

Crucially, the clear commercial advantages that new systems afford give the relevant departments greater leverage in securing a budget for their regulatory IM initiatives.

From a regulatory perspective, life sciences organisations have little choice but to sharpen their information recording and tracking capabilities, which means finding order where previously there was chaos.

The same applies if they want to expand their markets globally, maximise relationships with affiliates and minimise the disruptive impact of mergers and acquisitions, all of which are high priorities commercially.

As the pace of change in the industry continues to accelerate, a holistic regulatory IM strategy is what will separate the achievers from those left struggling to compete.

## The Author

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**Note:** We would like to make clear that the 'Regulatory intelligence' article published in the April 2011 issue was derived from information from Davina Stevenson's book based on her TOPRA MSc dissertation.

# Adverse event reports up

**The number of adverse drug events reported to the US Food and Drug Administration's (FDA) Adverse Event Reporting System (AERS) has more than doubled in recent years, according to new research in the Archives of Internal Medicine.**

AERS, the largest system of its kind in the world, was launched in 1969 and serves as a computerised database designed to support the FDA's post-marketing safety surveillance programme for all approved drugs and biologics. Currently, AERS receives about 500,000 adverse event reports each year, the research found. The reports, which come from healthcare professionals and consumers, can lead to FDA regulatory actions, including new labelling requirements and even withdrawal of products from the market.

Between 2000 and 2010, the number of reports submitted increased by more than 11 per cent every year, according to the new analysis, which was led by a researcher at the University of Maryland. In all, 2.2 million reports came in during the 10-year period, making up 55 per cent of the total number of reports in the whole 31-year-old database.

The researchers speculated that the increase in AERS may be due to the growing elderly population, who may be more likely to experience adverse events, or to the simple fact that more drugs are being prescribed. However, they noted that the increase may also be related to the modern media climate, in which news stories about adverse events for a particular drug tend to trigger a spate of additional reports.

The analysis comes straight after the related news of the US Supreme Court's unanimous ruling that investors may sue drug makers for securities fraud if they fail to disclose adverse event reports, even if the data is not statistically significant.

Justice Sonia Sotomayor wrote on behalf of the court that the ruling 'does not mean that pharmaceutical manufacturers must disclose all reports of adverse events' but that they must disclose those that plausibly indicate a reliable causal link, even one that is not backed up by statistically significant evidence.

The Supreme Court was reviewing a 2004 lawsuit brought against Matrixx for allegedly failing to disclose reports that its cold medicine Zicam destroyed patients' sense of smell.



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