The impact of regulatory intelligence in the wider pharmaceutical business and demonstrating its value

Abstract
This article discusses the impact of regulatory intelligence (RI) to the wider pharmaceutical business, looking at how RI strategy leads to a regulatory project strategy, which in turn feeds into a cross-functional or corporate strategy.

Introduction
Does RI lead to intelligent regulatory affairs? Yes, but we probably all recognise that; if implemented well it also leads to informed and timely strategic decisions for the wider business and portfolio. To be fully effective as RI leads we must demonstrate this value to senior management. Are we looking for support (eg, at director/board level), for a defined reporting line, for process ownership and accountability, or simply for recognition?

It is also important to define the limitations of RI. It will be difficult to convince management and colleagues if we are not sure of the role, and therefore the contribution, of RI. RI is not the same as business intelligence, which focuses on gathering comprehensive knowledge of factors affecting the business such as sales, production and operation metrics and is used to make better business decisions; nor is it competitive intelligence (CI) which focuses on the legal and ethical collection and analysis of information regarding capabilities, vulnerabilities and intentions of business competitors. CI provides valuable information which contributes to the initial target product profile (TPP) and is often regarded as a key business activity, although changing legislation can have a more immediate and dramatic impact on the business.

Competitor knowledge helps position the brand name and hence product; however, setting the international non-proprietary name (INN) requires multidisciplinary input and RA should ensure that the trade name and timings conform to regional guidelines (RI input).

A job description could be drafted to include the following key points:
- Understand and define ‘regulatory intelligence’
- Establish and work to clear processes, eg, SOPs, job description, reporting line
- Join relevant external RI networking groups
- Relate RI more to daily work/role through targeted training and portfolio strategy
- Work with other key ‘information-providing’ and ‘information-requiring’ departments to define needs, preferred styles and opportunities

Focus – Regulatory intelligence

Author
Davina Stevenson, Senior Regulatory Affairs Manager, Mundipharma Research Ltd, UK.

Keywords
Regulatory intelligence (RI); Processes; Strategy; Value chain; Competitive intelligence (CI); Knowledge management (KM); key intelligence topic (KIT).

Regulatory intelligence strategy
‘Regulatory intelligence’ (active analysis and interpretation) does not equate to ‘regulatory information’ (raw data). Regardless of the intelligence gathered by a company and the tailoring of RI provisions, the strategy will never evolve or be successful if this information isn’t interpreted, analysed, disseminated and integrated. RI is therefore the act of gathering, monitoring and analysing regulatory information from various internal and external sources before disseminating filtered data, supplemented by expert interpretation and comment to appropriate company personnel by various means.

All companies perform RI to some extent, with the RI scope varying due to geography, resources and company size. An increasing number of companies are establishing dedicated intelligence groups. It is often perceived that RI is an expensive provision and a burden which many small companies cannot afford; in reality there is a wide range of information sources, many of which are free, publicly available sources. In the modern technology age it is possible to subscribe to various regulatory portals. However, regardless of the sophisticated data-mining provisions, there must be human input to interpret findings and implement these accordingly. A balance should be achieved between the desired target audience, available resources and access to proprietary databases (eg, IDRAC or Tarius).

Regardless of the size of a company, a documented RI strategy is required to allow for more measurable actions and allocation of key tasks to ensure compliance, future awareness and adequate resourcing. This should serve as a living document, as priorities and the environment change, or indeed to fit with personal development plans. A more concise RI business plan to present to senior management can engage support and serve as a performance assessment measure. Customer satisfaction surveys may allow for improvements but will also promote internal awareness of the RI function.

Establishing an RI function is not solely dependent on resources and company size, but is heavily dependent on company culture and management support. It is important to define the expectations from senior management. Are we looking for resources, for support (eg, at director/board level), for a defined reporting line, for process ownership and accountability, or simply for recognition?
Capitalise on existing provisions, eg, e-learning software, intranet, free subscriptions. Highlight the input to the value chain to engage management support.

Larger RI functions may be able to capitalise on the impact of RI by tackling several areas, while smaller RI functions may need to focus on particular areas (see Table 1). It is necessary to clearly state which countries, information or topics will be monitored routinely and to determine if this fits with business needs. This requires identification of RI customers and may help to determine which research tools will be used (databases, websites, consultants), resource requirements and importantly, where resources can be shared.

It is also necessary to have a process for evaluating and communicating this information to the user, preferably connecting knowledge management (KM) and RI to daily work activities (eg, project closure meetings to gather knowledge through experience) and more informal learning efforts and opportunities. If tasks are to be divided then it is important to identify individuals with strong research skills and an interest in data monitoring and analysis. It may be beneficial to identify individuals for particular focal areas of RI which partner well with daily roles, eg, quality-RI, oncology-RI, labelling-RI, UK-RI. Via this ‘RI champion’ approach, the RI officers will already have established networks for information distribution, eg, cross-functional project teams, and be fully aware of business priorities.

Regulatory strategy
RI business value can be demonstrated through input to regulatory strategy, operations and development teams; periodic summaries of RI contributions to senior management; and attending or organising key operational and education meetings. Regulatory strategy can be considered as an end product of RI with high quality information vital for successful drug development. Regulatory analysis should consist of conventional approaches (regulatory opportunities), SWOT (strengths, weaknesses, opportunities, and threats), scenario planning, competitor analysis and more strategic approaches (iterative conversations, focus on risk analysis and mitigation, alignment with cross-functional departments) and postulates that RI can be iteratively applied to strategy by:

- Identifying regulatory opportunities
- Understanding the context of the product, disease area and external environment
- Viewing the regulatory competitive landscape
- Finding emerging signals and patterns
- Applying and communicating experience and findings.

RI can advance the product lifecycle (value chain3) in terms of procedural, technical, scientific and strategic input. Core roles include general information gathering and tracking legislation, followed by information dissemination. Procedural intelligence can include advising on marketing authorisation application format, content and copy requirements and subsequent RoW dossier preparation and compilation of internal working practice documents, templates and policies. Significant information on past precedence

Figure 1: RI business contribution – pharma drivers, RI actions and tasks

**Reduce production cost and R&D spend**
- ACTION: Provide information to assist with implementation of quality by design (QbD) in manufacturing arena; support clinical trials operations with suitable trial designs
- TASK: Gather information on QbD implementation by networking and preparing briefing document; data mine and summarise ClinTrial.gov for competitor trials.

**More and better new products**
- ACTION: Participate in due diligence activities to develop portfolio and expand into new therapeutic areas
- TASK: Analyse business opportunities in terms of regulatory requirements and document in a SWOT analysis, looking at competitor EPARs, therapeutic guidance, regional variations in regulations and emerging legislation.

**Market expansion**
- ACTION: Support regulatory preparation of RoW and/or CEE dossiers
- TASK: Gather advice from local contacts and prepare comparison to EU requirements/prior CTD MAAs.

**Strengthen market position**
- ACTION: Support regulatory development plan for generic and over-the-counter (OTC) lifecycle phases
- TASK: Tailored training course for commercial colleagues explaining the registration requirements for OTC switch.

Figure 2: Intelligence sources feeding into and from common information sources

- Competitor intelligence (market and products)
- Legal Intelligence (patents, tradenames and competitors)
- Pharmacological intelligence (portfolio planning and competitors)
- Regulatory intelligence (environment and products)
- Business intelligence (strategy and risk mitigation)

Information and knowledge management
Focus – Regulatory intelligence

and competitor products can be gained through RI, eg, European assessment reports (EPARs) and competitor labelling.

Corporate and portfolio strategy

Having the correct regulatory information and using it to design and implement good regulatory strategy can lead to reduced time to market (both via accelerated development and smoother registration assessment), reduced costs, increased compliance and ultimately optimisation of return on investment. RI can also be used to formulate corporate policy and to comment on formal documentation such as EMA concept papers or US FDA dockets either directly or via trade associations. Regardless, comments must be professional, constructive and scientifically sound, and preparation by a RI officer or working group can ensure consistency. Essentially, analysis of similar products and adjustment for the current regulatory climate influences strategy, which in turn drives policies.

The main pharma forces are deemed to be substitutes, supplies, competition, customers and new entrants – RI can, however, help to counter these forces at a business, portfolio or disease/therapeutic level. Figure 1 highlights the actions and tasks which RI can contribute to some of the main pharma drivers. It is important to note that the wider commercial effects cannot be felt without RI being fully embraced by regulatory professionals.

There are a number of established commercial and industrial intelligence types and the same principles and practices can be employed throughout the pharmaceutical lifespan to enhance the role of RI. Other sectors have long recognised that strategy is heavily influenced by information accessibility and quality. Essentially, intelligence differs from information, knowledge and understanding – it brings together interpreted, screened and evaluated elements and impacts on decision-making, policy-making and planning with either strategic or tactical importance.

Military intelligence favours combined judgement of several individuals to integrate diverse and voluminous information about complex situations. Intelligence reports can either intend to orient policymakers and feed into goal-setting and problem identification activities (orientation reports including factual background material; updated on specific current subjects; speculation on future conditions); or can provide more direct backup for specific decisions (estimates of strength; probability and timing of specific events). Building a knowledge base of common key intelligence topics (KITs) may help to reflect daily activities and engage senior management (see Table 2). Identification can be either responsive (but for actionable focused information rather than just basic information searching) or

<table>
<thead>
<tr>
<th>KIT category</th>
<th>RI/pharma examples</th>
<th>Required intelligence operations</th>
</tr>
</thead>
<tbody>
<tr>
<td>Strategic decisions and actions</td>
<td>Development of strategic development plans and regulatory requirements for new territories</td>
<td>Business and intelligence analysis supported by secondary source research with current human-source collection inputs</td>
</tr>
<tr>
<td>Early-warning topics</td>
<td>Competitor initiatives (eg, ClinicalTrials.gov, EPARs), technological surprises and health authority actions</td>
<td>Human-source collection and monitoring with analysis serving as detection mechanism</td>
</tr>
<tr>
<td>Descriptions of key players</td>
<td>Competitors, customers, suppliers, regulators and potential partners in the specific marketplace (eg, due diligence input).</td>
<td>Analytical profiles, sometimes tailored to the specific user questions or planned actions.</td>
</tr>
</tbody>
</table>
Regulatory intelligence requires processes to cope with data proliferation, evaluation of data (in terms of reliability and relevance) as well as the more difficult tasks of integration and synthesis

Regulatory intelligence requires processes to cope with data proliferation, evaluation of data (in terms of reliability and relevance) as well as the more difficult tasks of integration and synthesis

Summarising the impact of RI
RI should allow individuals to be fully empowered, informed and effective as regulatory professionals and core project representatives. However, this catalyst for further personal learning is also a tool and resource to shape and refine company strategy. Having the correct regulatory information and using it to design and implement good regulatory strategy can lead to reduced time to market, increased compliance, reduced costs of development (due to the acceleration of this process) and therefore optimisation of return on investment. The impact of RI is not directly attributed to the size of company, the product focus or the availability of electronic RI systems, but rather on the company culture and the enthusiasm of staff to contribute to and utilise the RI/KM process. Not only does RI lead to intelligent regulatory affairs but it also leads to intelligent strategic decisions for the wider business and portfolio, and hence a stronger organisational presence in an increasingly pressured modern pharma sector.

References
2 The Society of Competitive Intelligence Professionals (SCIP).
15 Rasmussen M. ‘Risk & Regulatory Intelligence (or should it be Wisdom?)’, Corporate Integrity, LLC. 2009; 8 April.