Sharing regulatory intelligence: Are newsletters here to stay or is social media the future?

In 2009, the RING launched a project to look at newsletters and alternative ways of sharing RI. The purpose of the project was to identify the approaches used in the RING member companies with respect to newsletters, and whether novel approaches (including use of social media) were being considered as a way to enhance the gathering and delivery of regulatory intelligence.

The first step was to collect data on existing newsletters from among RING member companies. A short questionnaire was developed to gather data about different aspects of newsletters including the format, frequency, primary customers and information sources. Data were provided by twelve RING members and the data set provided information on 21 newsletters in total.

Ten of the RING member companies created at least one newsletter. The frequency of distribution of the newsletters ranged from weekly to twice-yearly. Around 70% of the newsletters were produced at least monthly and ran into several pages in length. Approximately half of the newsletters were noted to cover multiple regions or be global in nature as opposed to covering single regions. As you would expect, the primary customers were predominantly regulatory affairs staff in the region(s) covered by the newsletter; secondary customers included clinical development, pharmacovigilance and government affairs groups.

The questionnaire also asked respondents to list the primary sources of publicly and non-publicly available information used to populate the newsletter. Unsurprisingly, the key health authority websites featured highly. Other frequently mentioned websites were the European pharma industry association EFPIA’s Extranet (a site for EFPIA working group members), publications (eg, RA Pharma, Regulatory Rapporteur, Scrip) and the commercially available regulatory information database IDRAC. Some of the less frequently mentioned sites included those of the Official Journal (OJ) of the European Union, WHO and European Forum of Good Clinical Practice (EFGCP).

Non-publicly available information was noted to be included in around half of the newsletters. This was most commonly described as being reports written by attendees at conferences and workshops and notes from staff participating in trade association groups and forums. Two thirds of the newsletters also contained ‘value added features’, such as impact assessments or summaries of key information, which are prepared by both RI and non-RI staff.

It is also worth noting that feedback on the newsletter usefulness had been gathered for around half of the data set. This information was being used by the editors of the newsletters to modify and improve the content and format to better serve internal customers.

However, newsletters may have a limited audience if they are disseminated via email, and the controlled authoring and editing...
Networking sites allow individuals to tap into the combined wisdom of other regulatory professionals – questions and answers can be exchanged in real time rather than waiting for the outcome of a formal consultation process.

Social media – a new approach
Organisations and institutions of all sizes are embracing social media - their power, impact and value becoming more apparent in the last few years. Social media have enabled real-time reporting of political demonstrations and provided platforms for viral marketing campaigns that reach global audiences in a matter of seconds.

Put simply, social media enable social interaction and information exchange on the internet. They are, according to Kaplan and Haenlein, “internet applications that build on the ideological and technological foundations of Web 2.0.”

Whereas Web 1.0 was about accessing static, prescribed content, Web 2.0 is about creating dynamic, user-generated content, the importance of which is determined by the “crowd”.

According to Kaplan and Haenlein, there are six different types of social media:

- Collaborative projects, eg, Wikipedia (collaborative authoring)
- Blogs and microblogs, eg, Twitter
- Content communities, eg, Delicious (social bookmarking)
- Social networking sites, eg, FaceBook
- Virtual game worlds
- Virtual communities, eg, YouTube (video-sharing community).

How are social media utilised by RI specialists today?

Blogs: These are fast becoming the medium of choice for amateurs and experts alike to share their opinions on a particular subject matter. Short for ‘weblog’, blogs are, in essence, on-line diaries; collectively, they are known as the ‘blogosphere’. The blog is an excellent vehicle for RI specialists and other professionals in regulatory affairs to share their insights and experiences on the changing regulatory environment. There are a number of regulatory-orientated blogs on the web: Eye on FDA and the FDA law blog are a couple of good examples – both authored by experts.

Frequently, blogs are accompanied by discussion boards and commenting facilities. These allow readers to add their experiences and to challenge the thoughts from others in order to create a rich stream of intelligence that can be easily shared with others. In that regard, the blog offers an easy way to extract tacit regulatory knowledge (unpublished know-how) from the minds of colleagues where it might otherwise stay, reducing the need for lengthy face-to-face interviews. Blogs might also provide a useful vehicle for gathering comments on draft regulatory authority guidelines or feedback on health authority initiatives.

Microblogs: These allow users to post short statements (usually 140 characters) for others to view and comment on. Twitter is probably the most well-known microblog site – a site that allows users to follow a multitude of microbloggers, although there are others, such as Tumblr and Plurk, with similar functionality.

Twitter has a number of pharma/regulatory affairs-orientated microblogs that individuals can follow (eg, Tim Felgate, EFPIA, PharmaFocus and Pharma IQ). These microblogs provide a continuous stream of pharma and regulatory news and provide an alternative way to be alerted to the presence of newly released regulatory authority documents.

One potential application of microblogs for the RI specialist is to use them as a tool to provide real-time reporting of presentations being delivered at conferences – presentations that might contain useful intelligence (eg, release dates of important new guidelines or eagerly anticipated regulator initiatives). Due to their one-to-many dissemination feature, microblogs allow any number of internal stakeholders to follow the posts of their RI colleagues and comment as necessary. In that regard, microblogs make a useful alternative to lengthy email chains that can only be viewed by a limited number of people at any one time.

Wikis: Most people have heard of Wikipedia – the web-based encyclopaedia to which anyone can contribute. The ‘wiki’ (the Hawaiian word for quick) offers a collaborative space for multiple authors to create online documents that can be viewed and edited by any number of stakeholders. There are several applications of wikis for RI specialists, for example to create briefing documents on specific regulatory topics or for an encyclopaedia of regulatory terms. These documents can be accessible to everyone within an organisation (ie, displayed on an RI intranet site) and can be useful quick references for senior management, new starters or non-regulatory affairs professionals to facilitate their understanding of key regulatory issues.

Social/professional networking: Social networking platforms such as FaceBook, MySpace and Bebo are seen as the sole preserve of tech-savvy teenagers. For professionals who do not see these tools as serious applications but want to connect with one another, there are the more ‘grown-up’ professional networking sites such as LinkedIn and Ryze. LinkedIn also has a number of special interest groups specific to regulatory affairs that individuals can join (by application) – for example, TOPRA and ‘Reg-Info’. These interest groups are being used to exchange intelligence and advice on regulatory matters. In that respect, LinkedIn offers a faster alternative to trade associations when it comes to garnering industry experience on a particular regulatory issue or tapping into the combined wisdom of other regulatory professionals.

Questions and answers can be exchanged in real time rather than waiting for the outcome of a formal consultation process.

If data are mined appropriately (ie, within the terms of the user agreements and privacy policies), these professional networking sites could also facilitate key opinion leader (KOL) mapping exercises and professional profiling requests.
For RI specialists whose company establishes their own internal networking platform, one application could be to use it to identify internal subject matter experts when seeking comments coordinators for draft regulatory authority document reviews.

**RSS, news aggregators and tagging:** RSS (Really Simple Syndication) and news aggregators enable RI specialists to automate the gathering of online content from a multitude of regulatory websites (assuming they are RSS-enabled) and view them in one place.

The US FDA and EMA websites are now RSS-enabled, as are some national competent authority sites. The intelligence-gathering net can be cast much wider and use of aggregation tools can release the time used by RI specialists in manually checking each and every website for updates – time that can be better spent on providing analysis and perspective. The downside is that no ‘human filter’ is applied to the information gathered, and thus the news feed could be full of ‘irrelevant noise’.

Tagging and ‘tag clouds’ are replacing traditional folder structures in electronic document repositories, expediting storage and retrieval and thereby facilitating access to key regulatory intelligence material. For example, meeting minutes from a conference can be uploaded and tagged (tags are single words that capture the subject matter of the document, like the keywords above) and then retrieved quickly by clicking on those same tags in the tag cloud (rather than having to search through multiple layers of folders). As tags get re-used, so they alter in size (and sometimes colour) allowing the reader to quickly see which topics are the most popular or frequently cited.

**Is social media the future of regulatory intelligence?**

The RING’s opinion is that social media will have a role; however, the extent of that role is not yet clear. At least two of the following things must happen: firstly, the strengths and opportunities of social media (in a regulatory setting) must outweigh the weaknesses and the threats, particularly as benchmarked against traditional approaches such as the newsletter; secondly, the RI function must be prepared to proactively demonstrate the value of social media to internal customers and industry peers via a well-planned and carefully implemented engagement strategy, and to persevere with this strategy if there is resistance the first time around. The success of each of those elements will determine the extent to which social media will play a role in the future delivery of regulatory intelligence, ie, more success equals a greater role. The second RING member survey revealed relatively low uptake of social media in both the RI functions and the RING member organisations in general, so there is still much work to be done.

**Strengths and opportunities**

Social media have the potential to expedite or improve the gathering, dissemination and storing of regulatory intelligence. RSS and news aggregators automate the gathering process and allow more sources to be tracked at the same time. Social media remove barriers to participation, effectively allowing online conferences to take place with a much wider degree of audience participation. They also enable the sharing of tacit knowledge, something that knowledge management strategies frequently fail to accomplish. In short, social media improve operational efficiency and provide new sources of intelligence.

**Weaknesses and threats**

The second RING member survey revealed that technology platforms incorporating social media are not being taken up, predominately due to budget constraints and the limitations of the technology. However, there is also a cultural element that drives resistance to social media, despite the advantages mentioned above.

Regulatory affairs professionals are busy people. Commenting on an RI colleague’s blog post or following a real-time report via a microblog takes up precious time. The attitude is that these activities divert attention away from ‘business-critical’ activities. The appropriateness of social media in the regulatory setting is also questioned. There is the fear that an off-the-cuff remark typical of a social media exchange will be circulated quickly and read by many, with retaliation following swiftly if reputations are damaged. Unfortunately, some of the most useful regulatory intelligence – perhaps that concerning specific individuals – cannot be written down, as it may have legal ramifications. These concerns and threats are legitimate but they can be avoided with careful use. A ‘Best Practice Guide’ or policy, with specific examples, can help colleagues use social media responsibly in the workplace and avoid some of the threats mentioned above. These policies are usually applied at the organisation level and are not specific to regulatory.

**How can the RI function demonstrate the value of social media to its organisation?**

In a recent report, the management consultants McKinsey & Co noted: “The most intensive users of Web 2.0 [and by implication social media] are enjoying the biggest growth in market share. Many executives also see a positive impact on information sharing within their organisations.” Clearly, industry is recognising the value of social media and RI specialists should build on that momentum.

There are a number of strategies and tactics that could be used to demonstrate the value of social media to colleagues and industry peers. As with most strategies, a successful outcome will turn on a few critical success factors (CSFs) and efforts should be focused on achieving these.

In short, a successful outcome will see any cultural resistance to social media fall with a concomitant rise in user uptake and participation. The former is difficult to measure (base-lining can be done through peer-to-peer surveys); however, the latter can be measured and makes for a useful success metric. Some strategies and tactics include:

- Develop and implement an effective communications strategy to promote the use and added value of social media within a regulatory context. Seminars or ‘road show’ type events might be the best vehicle to do this.
- Highlight examples where social media yielded vital intelligence (not likely to be captured by other means) that influenced strategic decision-making (CSF).
- Allay colleagues’ fears over appropriateness or retaliation by demonstrating how potential threats can be avoided. Develop good practice guidelines to facilitate this threat management.
- Dispel colleagues’ notions of ‘time-wasting’ by demonstrating how participation is quick and easy and can encourage others to contribute with positive results.
- Get senior management buy-in. If the CEO or the head of regulatory affairs blogs or ‘tweets’ or is shown to be supportive and actively engaged in your social media strategy, so others lower down the organisation will likely participate. An organisation-wide (and funded) social media initiative is also more likely to be implemented, on which the RI specialist can ‘piggy-back’.

Focus – Regulatory intelligence

In continuing the momentum of any successful social media strategy, the RI function must demonstrate that it is deriving new insights that can be leveraged for strategic advantage.

- Emphasise the return-on-investment (ROI) of social media. Many applications are free but the additional intelligence and operating efficiencies could provide a competitive advantage and reduce opportunity costs at the same time (CSF).
- Ensure any initiative is aligned with your organisation’s policy on using social media.
- Pilot a number of social media initiatives within the regulatory department based on the suggested uses above. Incorporate social media into formal business processes; for example, using blogs or discussion boards to gather comments on draft regulatory authority guidelines.
- Create a number of super-users that can champion the virtues of social media.
- Partner with your organisation’s business or IT groups to leverage their expertise and align with any similar social media initiatives they might be implementing.
- Create awareness on which tools are available already and might be used without major additional investments in technology.
- Partner with your organisation’s training group to develop on-demand web-based training that will educate colleagues on how to use the social media tools, to help overcome any ‘technophobia’ they might have.

In continuing the momentum of any successful social media strategy, the RI function must demonstrate that it is managing the noise that some social media bring and is deriving new insights that can be leveraged for strategic advantage. One or two bad experiences (eg, delivering wrong intelligence or accidentally sharing proprietary information with a competitor) will undo everything.

Conclusions

Newsletters are a key deliverable for the RI function and there is perhaps an expectation among RI and other regulatory affairs professionals that they should stay. However, social media have risen in prominence and clearly have a purpose in a professional setting. RI specialists are starting to use social media more and more in their daily work. Social media cannot replace the minds of experienced regulatory professionals when it comes to providing insight and perspective on the changing regulatory environment; however, they have the potential to enhance the current methods used to gather, manage and deliver regulatory intelligence to internal stakeholders.

Social media will have a role to play in the future of regulatory intelligence. The extent of that role will depend on how successful the RI function is in demonstrating the strengths and opportunities of social media versus their weaknesses and threats (as compared with more traditional methods). It will also depend on resources and expertise within the RI function – RI specialists must become more knowledgeable themselves and keep up with the latest advances.

This means frequent outreach and partnering with IT professionals in the same organisation.

The expectations, preferences and needs of internal stakeholders will also determine the future of social media. If internal surveys favour newsletters even after repeated attempts to demonstrate the value of social media, then any further efforts to promote social media may be actively resisted. Of course, one compromise is that newsletters and social media unite to form an intelligence ‘mash-up’ in one space. Some content will be controlled; other content will stream in via embedded social media tools. Indeed, some technology vendors already offer so-called integrated solutions that allow this to happen. A mixture of the old and the new may be the answer and will see both the newsletter and social media play a role in the future of regulatory intelligence.

About EU RING*

The Regulatory Intelligence Networking Group (RING) is an industry forum whose creation in 2006 was prompted by the emergence of a new profession of regulatory intelligence specialists in the pharmaceutical and biopharmaceutical sectors. RING comprises representatives from some of the largest companies in the industry and aims to centralise non-confidential regulatory information. Its objective is to increase the efficiency and recognition of regulatory intelligence by sharing processes, practices and experience in non-product specific and non-confidential areas.

The RING comprises the following individuals: Ulrika Assargaard, Head Regulatory Intelligence at Hoffmann La Roche; Elisabeth Fournier-Zebari, Director Regulatory Intelligence, EU & other regions at Sanofi-Aventis; Carolyn Hynes, Director Global Regulatory Policy & Intelligence at Janssen R&D; Angelika Joos, Head Regulatory Policy Europe & RoW at MSD; Marianne Köhne, Head Regulatory Intelligence Office at Boehringer Ingelheim; Christine Mayer-Nicolai, Director, Head Global Regulatory Intelligence & European Regulatory Policy at Merck Serono; Helene Orme, Senior Manager Regulatory Policy and Intelligence at Abbott; Elaine Whiting, Associate Director Regulatory Policy, Intelligence and Labelling at AstraZeneca; Merete Schmiegelow, Regulatory Director, Regulatory Policies and Intelligence at Novo Nordisk; Helene Thybo, Regulatory Professional Regulatory Intelligence at Leo Pharma; Iain Todd, Manager Safety and Regulatory Intelligence at Pfizer; Carol Walker, Manager, Regulatory Intelligence and SOPs at Gilead; Birgit Wolf, Regulatory Intelligence Manager EU at Bayer Pharma AG; Alexa Hunter, Head Regulatory Intelligence at Merz Pharmaceuticals.

References

3 Ibid.