

# Tentative steps

## A plain legal guidance framework will empower the move to online opportunities

**In 2009, pharma first dipped its toe into the uncertain waters of social media. With luck, in 2010 some guidance will emerge from regulators on how they think pharma should approach the opportunities and challenges of the digital space.**

What is already clear is that consumers look to the internet frequently as a source of health information: the *Pew Internet & American Life Project* found that 61 per cent of US adults look online to find health information. The internet may not be the only source used by these individuals, as the same survey found that 86 per cent of US adults asked a healthcare professional, suggesting that people tend to double-check what they find out online with their doctor.

Consumers' hunger for online health information has been noted by the European Commission, and is a clear driver for its proposals relating to the provision of high quality health information to patients. The goal of providing accurate, up-to-date information to patients in Europe is a laudable one, and important, given the volume of inaccurate and misleading information available online.

So what opportunities are there for pharma companies in the digital space?

There is certainly no shortage of potential information channels available online: Twitter, YouTube, Facebook and blogs, to name a few. While this dizzying array of channels presents most industry sectors with an opportunity to make a mark by taking an innovative approach, the pharma industry has to consider its approach in the context of its legal and

regulatory responsibilities.

Social media channels are, by their very nature, dynamic. They offer the opportunity for real-time interaction and inherent in their nature is a lower degree of control for the hosts.

### CONCERNS

From a legal and regulatory perspective, there are many potential concerns for pharma companies to consider:

- Defamation; if a company hosts a website that includes user-generated content (UGC), that content may be defamatory, potentially exposing the company to liability.
- Copyright infringement; if any UGC on a company's website infringes a third party's copyright or other intellectual property right, the company could again find itself liable.
- Private and confidential information; UGC that is private or confidential information may also give rise to liability for the website owner.
- Outside licence references; UGC has the potential to include references to a company's medicinal products that fall outside the scope of the product's licence. This may be complicated further by differences in licence scope in different jurisdictions.
- Adverse event reports; UGC may, sometimes unwittingly, include details of an adverse event relating to one of the company's medicinal products, triggering regulatory reporting obligations.
- Promotional statements; UGC may include promotional statements about the company's products, potentially exposing the company to liability for

breaches of statutory and regulatory obligations.

The challenge for pharma companies is to find a way to exploit the great potential of, and demand for, social media opportunities, while minimising the risk of incurring liability in relation to their legal and regulatory obligations. Pharma companies will feel more comfortable instinctively if they police the content on the sites for which they are responsible. Not only will such policing require considerable resource, but it will also impact the dynamic, interactive nature of social media channels. So how have pharma companies approached social media opportunities to date?

### RELUCTANT PROGRESS

For some time, they were understandably reluctant to venture into social media channels in the absence of guidance from regulators. However, despite this, 2009 saw several débuts on Twitter, Facebook and YouTube, and a handful of corporate blogs was launched.

Importantly, in 2009 the US Food and Drug Administration (FDA) started to engage meaningfully with the challenges of the internet and social media, holding a public hearing in November. The presentations from the hearing are available online, on the FDA site, and provide interesting reading. It was made clear that industry cannot be expected to monitor every website on which it is featured. However, as noted above, both regulators and industry must provide creative solutions to ease the tension between the need to monitor content on a pharma company-sponsored site or

## In Brief

### EC Variations Regulation updated

A revision of the European Commission's (EC) Variations Regulation (Commission Regulation (EC) no 1234/2008) has been made, with effect from January 1, 2010.

All changes that occur following a product's placing on the EU market are considered in legal terms as 'variations'. These can be changes to the production process, product packaging or the address

of the manufacturer.

The aim of the revision was to simplify the legislative framework governing 'variations', thereby better regulating pharmaceuticals.

Prior to the revision, the EC states, a majority of products fell outside the scope of Community rules and were subject to divergent national provisions. This lack of harmonisation had negative consequences in terms of the administrative burden, both for industry and national regulatory authorities, and the overall functioning of the internal market.

### TOPRA regulatory intelligence network

The Organisation for Professionals in Regulatory Affairs (TOPRA) has launched a special interest network (SPIN) to drive regulatory intelligence.

The aim of this group will be to explore and share ideas and methods used for regulatory intelligence, and is formed from TOPRA members. It was established on February 23.

As the framework for the regulation of medicines grows ever more complex, it is becoming increasingly hard to pre-

dict how regulatory agencies will view applications.

In addition, more and more information is becoming available, a trend that will continue with the drive for greater transparency. Consequently, TOPRA believes it is important to know how to find this information, filter it and analyse it in ways that can increase understanding of the expectations of the regulatory agencies at both the national and international levels.

TOPRA members wanting further information on this SPIN should email: [spin@topra.org](mailto:spin@topra.org).

social media channel, and the potentially adverse impact of such monitoring on the dynamic nature of the site or channel.

Although some of the discussion at the hearing related to questions that apply to a direct-to-consumer environment, there is no doubt that any FDA guidance resulting from the hearing will influence the steps taken by other policy makers globally.

### RISK MANAGEMENT

In the absence of any clear guidance from regulators, pharma companies should apply some basic risk management strategies in order to try to minimise their exposure to risk when establishing a presence using social media channels. Not all strategies can be implemented for all channels. For example, a company cannot exert the same degree of control on third party sites, such as Twitter, as it can on its own blog.

- State your target audience; make it clear which jurisdiction(s) the social media channel is aimed at, reducing the risk of hitting legal and regulatory problems in other jurisdictions.
- Be clear with your policies; terms of use, privacy and comments policies are essential for a blog or any other channel that may attract substantial UGC. They should fulfil a range of functions, including: prohibiting defamatory, private or infringing content; setting out acceptable use guidelines; granting a licence to the company to use or remove content at its discretion; providing an effective reporting mechanism for offensive content; outlining how adverse events relating to the company's products should properly be reported; defining, in general terms, the range of comments that would be regarded as publishable; establishing procedures for dealing with complaints and taking down UGC; detailing appropriate disclaimers.
- Product discussion; the site's policies should set out whether or not the site is an appropriate forum for discussing the company's products. In all likelihood, the site should not be used for that purpose, although company fora for healthcare professionals may develop in due course that include such discussions (and would bring with them a range of other considerations and monitoring obligations).

### SIDEWIKI POSTING

The speed with which the internet and social media channels are evolving - and will continue to evolve - means that there will always be new challenges to address. For example, Google's new Sidewiki feature, that allows anyone to leave comment alongside a particular website page, is one of the latest developments with which pharma companies are grappling.

And it does not stop there. What about company- or product-related information posted by a pharma company's employees on their Facebook pages? Consider whether you need another company policy to deal with this.

There can be no doubt that the internet and the growing range of social media channels provide the pharma industry with great opportunities, particularly in the European Union context of the Commission's information to patients initiative. Patients have a right to reliable and up-to-date information on medicines, and the pharma industry should be at least partly responsible for enabling this. Although the industry is just beginning to use these new channels, there is a pressing need for guidance from regulators. Given the substantial challenges presented by the new channels, guidance from regulators should be formulated in close collaboration with the industry itself.

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