

Toe the line

Involve regulatory experts from the outset to avoid inadvertently overstepping the boundaries in social media strategy

Pharmaceutical companies recognise the powerful opportunity to engage with healthcare consumers and healthcare professionals who are increasingly using the internet, including social media, to find health information. However, though they are eager to explore this potential, they are also understandably cautious, given the highly regulated nature of the industry.

Key regulatory agencies, like the US Food and Drug Administration (FDA) or the European Medicines Agency (EMA), have yet to produce official guidance to address specifically social media communications by drugmakers, but understanding the existing, relevant regulations and the regulatory implications of a social media campaign are critical to launching successful social media efforts. Drugmakers' regulatory departments and/or external regulatory consultants should play a central role in social media planning from the earliest stages. Expert counsel is critical for avoiding regulatory pitfalls and handling questions related to drug risk information, adverse event reporting, consumer-generated discussion of off-label uses and other areas of risk if and when they arise.

Ultimately, online communications and interaction between consumers and healthcare providers about health topics are likely to have an impact on patient health. Keeping the vast knowledge of pharmaceutical manufacturers out of online conversations, while others are free to voice their opinions, unverified claims and advice of varying quality, seems contrary to the goal of safeguarding and promoting public health.

The European Federation of Pharmaceutical Industries and Associations (EFPIA) states in its position paper on the European Commission's proposal to establish a legal framework for drugmakers to provide information directly to consumers: 'Pharmaceutical manufacturers are in a unique position to provide high quality, comprehensive and reliable information on the medicines they themselves have researched and the diseases they tackle.' Regulatory professionals are best suited

to ensure companies' engagement in social media is compliant and keeps public health as the primary objective.

In most organisations, the team tasked with overseeing the design and execution of a social media campaign should be multidisciplinary, representing, where appropriate, marketing, corporate communications, regulatory, medical affairs, legal and other relevant internal stakeholders, advises Glenn Byrd, director of regulatory affairs at Medimmune in the US. That team should set ground rules for the design and conduct of the campaign. "The line of communication needs to start really early," says Byrd. "Good communication and early communication is key."

MIXED APPROACHES

Different companies certainly take different approaches to social media, with some more conservative than others. The longstanding prohibition of direct-to-consumer advertising and promotions in Europe may predispose companies based there to be particularly conservative when it comes to social media.

"I think in pharma companies, it would depend if they are European or American subsidiaries in Europe," says Dr Salma Michor, CEO of Michor Consulting in Austria. "American companies in Europe would probably take a more American approach."

According to a Pew Internet and American Life Project report, 61 per cent of US adults surveyed go online in search of health information and of that group, 60 per cent engage in some form of social media activity. However, Americans are not the only ones participating in social media. A March 2010 survey, 'Social Media and Healthcare', by EPG Health Media, covering healthcare consumers in France, Germany, Italy, Spain and the UK, found that 44 per cent engage in health-related discussions via online social networks at least occasionally. At the time of writing, there are a minimum of 130 online patient communities devoted to specific medical conditions or topics, 97 of which are not supported by any company or brand, according to the *Dose*

of *Digital* Pharma and Healthcare Social Media Wiki. Clearly, consumers and patients around the world are seeking out information and engagement with others around health topics.

Drugmakers, too, have been drawn to social media. According to Cegedim Dendrite's '2010 Insights: A White Paper On Current Trends And Challenges Of The Pharmaceutical Industry' survey of more than 200 pharmaceutical company executives, 97 per cent of pharma companies are using social media in some form, although to different degrees. Most are still investing less than 5 per cent of their marketing budgets in social media.

Pharmaceutical companies' commitment to social media seems likely to increase as the benefits for companies, patients and healthcare providers become increasingly apparent. Social media channels can help drugmakers increase consumer engagement with their products and give the company a voice in conversations about relevant health topics, whether it is providing information about a specific product, education about a medical condition, or just a way to listen to, and learn about, patients' concerns. Some companies are even beginning to use social media as a way to recruit participants for clinical trials.

"One of the best uses of social media is not controversial: to build awareness of a disease state," says Ilyssa Levins, president of the Center for Communication Compliance in the US. Still, "regulatory caution makes good sense," she adds.

Byrd agrees, pointing out the need to understand how communications will be perceived by regulators. "It's critical for regulatory professionals to be involved when a company wants to participate in social media because it's easy to cross the line even if it's not intentional. Subtle changes can have a big impact from a regulatory standpoint," he says. The FDA has, in some cases, been critical of 'unbranded' websites because of elements such as colour schemes that were seen as too close to those of sponsor companies' products, even if the products were not identified.

While social media certainly presents a new set of challenges for pharma companies, it is still part of the marketing mix and in that respect, falls squarely within one of the core responsibilities of regulatory professionals. "Ensuring regulatory compliance for drugmakers' advertising and promotions efforts, which today includes social media, is already one of the critical areas of knowledge, competency and scope of practice for the regulatory professional," says Dr Sherry Keramidas, executive director of the Regulatory Affairs Professionals Society (RAPS) in the US. "The overarching responsibility to ensure balanced, accurate information hasn't changed."

The FDA held a closely watched two-day public meeting on social media in autumn 2009, but no official guidance has been forthcoming yet. The FDA has promised to release something on the topic by the end of 2010, while European regulators have not addressed the issue beyond existing regulations governing Internet communication in general.

"The social media environment is developing at a fast rate. Regulators, on the other hand, move somewhat more

slowly," says Tim Felgate, CEO of Applied Regulatory Consulting in the UK.

Given the global nature of social networks and the absence of specific guidance from EMA, the FDA's rules, when they come, could be viewed as the default guidance for global pharma companies choosing to engage in social media. It is unclear how EMA would address social media efforts that can be accessed by, but are not aimed primarily at, Europeans. Regulatory professionals around the world will keep track of this as it evolves.

APPROPRIATE ACCESS

Some of drugmakers' biggest concerns about entering the social media arena centre on the challenge of providing appropriate access to risk information, addressing adverse event reports and handling user discussions of off-label drug uses, according to the November 2009 *Regulatory Focus* article, 'Laying the groundwork for pharmaceutical companies' engagement in social media'. While communication technology is evolving fast, the core issues are not new and regulatory expertise is essential to address them. A company prepared in advance to respond to consumer-gener-

ated conversations will be better able to react quickly with appropriate, timely information.

"Social media is a dramatic step out of our comfort zone as regulatory professionals," says Byrd. "It's an interactive discussion, whereas regulatory professionals are used to being able to manage the message." However, he goes on to point out that just as with internal communications, in social media, it is important to set expectations and to "let people know the boundaries of what will and will not be permitted".

"The best promotional campaigns are created when you know what the regs are and know how to stay within them," offers Levins.

With the right approach and regulatory knowledge, pharmaceutical companies can engage in social media for the benefit of patients and healthcare providers as well as themselves. Regulatory professionals have the knowledge and the critical thinking skills to help make that a reality.

The Author

Zachary Brousseau is senior manager, communications, at the Regulatory Affairs Professionals Society (RAPS).



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