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The International Comparative Legal Guide to: Pharmaceutical Advertising 2011

A practical cross-border insight
into pharmaceutical advertising

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■ Preface by Tom Spencer, Counsel, GlaxoSmithKline Plc.

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Social Media and Pharma in the UK: a Review of the Pitfalls and the Latest Guidance

Taylor Wessing LLP

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Social media channels are the latest and most dynamic and interactive marketing tools available to business, but in the UK most pharmaceutical companies have watched from the sidelines, reluctant to enter the fray for fear of falling foul of the complex regulatory regime under which their sector operates. Recent guidance from the UK regulator – ahead of the FDA’s long-promised guidelines – has fuelled the sector’s appetite to engage through social media channels. But while the UK guidance is to be welcomed, pharmaceutical companies should ensure they are fully aware of all the potential risks that social media channels present, and should put in place comprehensive compliance policies and training programmes to ensure that they are properly equipped for the challenges of social media.

What is “Social Media” and Why Should you Care?

The rise of “social media” over the past few years has been meteoric. YouTube, Twitter and Facebook are household names in the world of social media. Facebook grew at such a rate that it had one million users within nine months of its creation and now has more than 500 million active users. All these users cannot only communicate with each other but are also increasingly seen as a target audience by large companies. A huge number of businesses already have Facebook pages and the last few months has seen an exponential growth in these companies using Facebook to attract a wider audience, often using the site to host online competitions or auctions. Twitter and YouTube have also enjoyed phenomenal growth since their establishment five years ago. Social media channels have changed dramatically the way people access, share and generate information, and represent a large and dynamic marketing opportunity for business. Pharmaceutical companies are no exception in having an appetite to use these channels as part of their business.

Blogs and online communities are also growing, allowing experiences to be recounted and shared worldwide. It is easy to see that these resources have the potential to provide access to millions of users and to be a very powerful tool for business.

All of these sites allow users to interact in near real time with others worldwide, and it is this aspect which gives them such potential as a marketing and information gathering and sharing tool. It is this – the interactive and real time nature of social media – which also poses the most risk to pharmaceutical companies engaging in the space.

Facebook, Twitter, YouTube and blogs are popular mainly because they provide a platform for everyone to upload content, often referred to as User Generated Content or “UGC”. UGC and its dynamic nature is also what makes these social media sites such a

powerful tool for the wide dissemination of information and for inviting discussion. From a pharmaceutical company’s perspective, however, it is UGC that poses the greatest risk.

Until recently, there was no express guidance in the UK for pharmaceutical companies wishing to use social media in relation to their business. Although the recent guidance on the use of digital communications by pharmaceutical companies in the UK is not definitive, it has been welcomed by the industry, and has shone some light on the path for pharmaceutical companies wishing to enter the social media fray.

What are the Potential Risks of Social Media?

General risks

Any company engaging in social media channels has a number of legal risks to consider. On top of the “standard” risks faced by any company entering the social media sphere, pharmaceutical companies also need to be mindful of the complex regulatory regime under which they operate.

At a basic level, website hosts are legally liable, as the publishers of the material, for all content which appears on any site they host. There are three main general risk factors which will affect all companies that operate social media channels:

Copyright infringement: UGC on a company website may infringe a third party’s copyright or other intellectual property rights. The host may find itself liable for that infringement even though a third party created the infringing content. Furthermore, the host may attract adverse publicity as a result.

Defamation: Companies will be at risk where they host a website which includes UGC that is defamatory. Again, the risk of adverse publicity as a result should not be ignored.

Private and confidential information: A contributor to a social media channel hosted by the company may reveal private and/or confidential information, either about the host itself or about the third party. This can be damaging not only to industry relations but may also give rise to legal liability for the host company.

The European Directive on electronic commerce (2000/31/EC) provides a relevant defence for website hosts: a host is not liable for information on the relevant site provided that the host company has no knowledge of the illegal or infringing material. In addition, the host must be able to show that it has in place an effective procedure for removing infringing or illegal content as soon as it is notified of such content. The Directive has been implemented into the laws of each EU Member State, but its interpretation differs throughout Europe.

Under English law, there is an argument that an online publisher that enables the public to post unmoderated content on the publisher's website is able, in relation to the UGC, to rely on this defence. Indeed, many companies are choosing to do so.

This argument is due to be tested later on this year however, when the European Court of Justice is expected to rule on the question of whether a host of a social networking site must monitor UGC for infringing material or else itself be liable for this content. To rule that the host is liable unless it can show that it monitors UGC would mean that website owners would be liable for UGC over which they had no control or knowledge. Currently, therefore, it would seem to make sense for a host company **not** to monitor UGC on its website.

In a bid to combat these risks, many social media channels, such as blogs, will pass all material through a moderator before it is posted. Although this detracts from the interactive and 'real time' nature of the blog, it does also mean that the host is able to vet material to ensure it is not illegal and does not infringe the rights of another, before it is posted on the site. Any company that hosts a site where UGC is permitted and/or encouraged will therefore need first to make a decision about what level of risk it is comfortable with.

However, the extra level of regulation in the pharmaceutical sector makes life less straightforward for a pharmaceutical company hosting a website.

The "Pharma Risks"

Many of the risks for pharma companies engaging in social media channels in the UK are the same as those in the US, such as the risk of statements being made which are outside of licence references. However, the EU prohibition on the advertising of prescription-only medicines to consumers adds a further level of risk compared to the US position.

The main piece of legislation governing the advertising of medicines in the EU is Directive 2001/83, also known as the "Community Code". It is here, in Article 88(1), that you find the prohibition in Europe on the advertising of prescription-only medicines to the public, or "DTC".

In early 2008, the European Commission launched a public consultation on their proposals to introduce legislation aimed at ensuring that all patients throughout Europe would have access via the internet to good quality, up-to-date and non-promotional information on prescription-only medicines. One of the drivers for the proposals was the apparent difference in the amounts and quality of information on medicines available in different European countries. Some saw these proposals as an opening of the door to the removal of the DTC prohibition in Europe, although this was not borne out in the Commission's response to the consultation.

Although these proposals remain under discussion three years later, the fact that they were put forward in the first place highlights the growing importance of the internet as an information resource, as well as the legislators' recognition of this.

The continuing prohibition on DTC in Europe only adds to the risks that pharmaceutical companies will bear over and above those borne by companies in other industries. In the UK, a pharmaceutical company will be deemed to be responsible for the contents – including UGC – of any website it sponsors, advertises on or instigates. Taken one step further, a company may even be found to be responsible for the content of a site for which a link is provided from the company's website (where the linked site contains information on one of the company's products, for example). Given how easily UGC could contain promotional statements about one of the pharma company's products – thereby

putting the pharma company in breach of the prohibition on advertising such products to the public – it is understandable that companies have been reluctant to enter the social media fray.

Where a pharmaceutical company is responsible for the contents of a website, there are some pharma-specific risks that it must consider in addition to the general risks outlined above:

1. **Promotional statements** – a pharmaceutical company may find itself liable for breaches of its statutory and regulatory obligations where UGC on a relevant site includes promotional statements about one of the company's products. For example, such a statement may amount to promotion of a prescription-only medicine to the public, contrary to UK law.
2. **Outside licence references** – UGC on a site may include a reference to one of the company's products that is outside the scope of its licensed indications, thereby exposing the company to potential liability. This issue can be made even more complex where it is not clear which countries a site is aimed at, and there are variations in the scope of the licensed indications between jurisdictions.
3. **Statements of adverse events** – UGC may include details of an adverse event relating to a company's product, even if it is not represented in this way. Any statement of this sort has the potential to trigger regulatory reporting obligations for the company.

The Latest UK Guidance

The Prescription Medicines Code of Practice Authority ("PMCPA") administers the ABPI's Code of Practice for the Pharmaceutical Industry (the "Code"). The Code is the self-regulatory code that applies to the promotion of prescription-only medicines to healthcare professionals in the UK, as well as to the provision of information about such medicines to members of the public. It goes further than the position under UK law.

On 1 April 2011 (no April fool, we're told) the PMCPA issued informal guidance on the use of digital communications by the pharmaceutical industry (the "PMCPA Guidance"). In doing so, they beat the FDA, who had initially promised guidance on the use of social media by pharmaceutical companies by the end of 2010, although this has yet to materialise.

The PMCPA Guidance does what the PMCPA has said pharmaceutical companies should have been doing ever since they started asking for guidance on social media in the sector: it applies the Code to social media. The guidance applies the Code of Practice to a number of social media channels, and in doing so the PMCPA has produced a helpful Q&A document. Whether this guidance will be sufficient to overcome the industry's concerns with entering into social media channels more meaningfully is, however, yet to be seen.

Let the Code be your starting point..

The PMCPA has decided not to amend the Code to make express provision for social media channels and their use by pharmaceutical companies. The PMCPA Guidance simply highlights those provisions of the Code that are most relevant to the use of social media channels in the sector.

For example, the clause in the Code (clause 22) that deals with relations with the public and the media is examined in detail. The PMCPA Guidance reminds pharmaceutical companies of what reference information about prescription-only medicines can be

made available to the public (such as SmPCs and Patient Information Leaflets), as well as the important principle that statements must not be made for the purposes of encouraging members of the public to ask their doctor for a specific medicine.

The PMCPA Guidance also makes the point that the Code applies regardless of the method of communication being used. For example, whenever a medicinal product is being promoted to a healthcare professional, certain prescribing and other information must also be provided, whether the promotion is carried out verbally or electronically.

Communicating with healthcare professionals using social media

Healthcare professionals are increasingly keen to use social media channels, as demonstrated by the uptake of Sermo in the US which boasts 1 million comments from healthcare professionals (<http://www.sermo.com>). Social media channels certainly represent an attractive alternative medium through which pharmaceutical companies can communicate with healthcare professionals.

The PMCPA Guidance states that pharmaceutical companies would need to ensure that the audience for any tweets promoting medicines would need to be healthcare professionals only. This means that pharmaceutical companies would have to set their Twitter accounts to “closed profile” and pre-approve anyone who wanted to follow them. This in turn means a resource consuming verification exercise, and it is unclear what standard of verification would be necessary. How would you know if @super_doc28 is really a healthcare professional? And where will the prescribing information be placed?

Running a discussion forum or blog? Pre-moderation required

Not surprisingly, the PMCPA Guidance confirms that pharmaceutical companies wishing to run a discussion forum, or host one on a third party website, need to pre-moderate the content to ensure it complies with the Code. So if a pharmaceutical company wants to keep the experience as interactive as possible, this will mean real time pre-moderation of content – which will sound to many like anathema to social media.

The Guidance confirms that a website sponsored by a pharmaceutical company that allows user comments will also need to be monitored by the pharmaceutical company for adverse event reports, although no specific frequency for monitoring is given.

Search engine optimisation and metadata

Metadata is the information about a webpage that is used by search engines in producing relevance rankings for specific search terms. The PMCPA Guidance states that: “*Generally speaking it would not be unreasonable for a company to try to ensure that its sites are ranked high on lists when the search is for that company or one of its medicines.*”

However, this is an area where real care must be taken, and adequate compliance training must be provided to those in the IT function (whether in-house or external) who are responsible for putting in place metadata. The Guidance is clear that all metadata should reflect the content of the relevant site, and not be promotional. In particular, “*use of metadata to link a specific medicine to a disease awareness site is likely to be unacceptable*”. Disease awareness is an area where pharmaceutical companies in

the UK seem more inclined to use social media, and so this guidance on metadata is important.

Wikipedia

There is an interesting question in the PMCPA Guidance on whether pharmaceutical companies can amend Wikipedia entries that contain incorrect information about them or their products. The PMCPA Guidance sensibly cautions against the possible dangers of selective correction of information, which could give rise to allegations of imbalanced or improper editing.

The Guidance also touches on pharmaceutical company employees commenting on non-company websites or blogs, and recommends that pharma companies have clear policies in place to govern the use of such sites. Pharmaceutical companies need to ensure not only that they have robust, Code compliant policies in place, but also that their employees and contractors are properly trained in relation to those policies.

Social Media Risks to Pharmaceutical Companies in their Capacity as Employers

As employers, pharmaceutical companies also need to be aware of potential risks to the business arising from their employees’ use of social media, or indeed their own use of social media to keep tabs on employees.

One risk to employers is that they will be held vicariously liable for discrimination, harassment or bullying which employees engage in amongst themselves, using social networks as a forum for their bullying behaviour. Where statements are made during the course of employment, the employer will generally be vicariously liable for the content of these statements. Unfortunately for employers, comments made online need not be made during the working day or even using office equipment, for an employer to be potentially liable for the comments.

The Code refers expressly to the fact that pharmaceutical companies are liable for the activities of their sales representatives “*within the scope of employment...even if contrary to instructions they have been given*”. Even where a pharmaceutical company employee is blogging or otherwise generating UGC in his or her personal capacity outside of the office, it is likely that the company could find itself liable under the Code where, for example, the UGC promotes a company product to the public.

Companies also need to be sure that employees are mindful of the information they give about the company and the light in which they portray the company. These are particular risks in the pharmaceutical industry, where confidentiality in relation to company products is particularly important.

To mitigate these risks, it may be tempting to enforce a blanket ban on the use of all social media sites at work, although this will not entirely remove the risks and is likely to be unpopular with employees. It will also not prevent employees from using such sites outside work and is likely to increase resentment amongst staff.

The best way of minimising the risks to pharmaceutical company employers is to review existing computer use policies and either update these to make specific reference to social media or introduce a specific social media policy which clearly lays out what is acceptable use of social media and what is prohibited. It is useful to refer in such a policy to specific social media channels and to lay out likely sanctions in case of a breach of the policy. These sanctions should be in line with, and referred to in, the company disciplinary and grievance policy. All staff should receive training

on the policy which gives examples of prohibited conduct but also uses that are acceptable.

Where Next for Pharma and Social Media?

Social media channels undoubtedly represent a substantial opportunity for the pharmaceutical industry. In the US alone, over 60 million people use web-based sources to research drugs, discuss them and find support groups, chatrooms and message boards (http://www.ahdionline.org/ca/ahdi-wa/news/articles/The_State_of_eHealth.pdf, page 3). The European Commission has also accepted that the way in which many consumers access health information has changed, and more and more are looking online for help, support and information about their medical conditions and the drugs they are being prescribed.

Social media channels offer real opportunities for pharmaceutical companies to engage with patients in a meaningful way, and the European Commission seems to have recognised this and be keen to utilise this potential. Possible benefits of social media may include assisting in clinical trial recruitment, and greater reporting of adverse events, leading ultimately to a better understanding of a medicine's side effect profile. Social media may also enable pharma companies to have a positive impact on their relationships with patient organisations: a recent survey found that the majority of patients' organisations consider pharma companies not to be "trustworthy". By utilising a communication channel which allows users to have a say (albeit that this say will have to be strictly monitored), companies may well be able to increase public faith in them.

While the Guidance from the PMCPA in the UK is helpful, it remains to be seen whether it gives UK pharmaceutical companies sufficient confidence to expand their social media activities.

Some pharmaceutical companies have already taken the plunge – using YouTube for disease awareness campaigns, for example – and it may be that the Guidance from the PMCPA encourages such companies to take their social media campaigns further. But the instantaneous nature of many social media channels will continue to present legal and regulatory compliance challenges.

For example, using social media channels as a quick method of disseminating corporate information sounds like a low risk activity for a pharmaceutical company. Certainly, some "corporate" type information, such as the date of the next AGM, can be shared through social media channels without posing a risk. However, pharmaceutical companies will need to ensure that all employees or agents with the ability to provide information on behalf of the company through a social media channel are trained on the Code and other relevant standard operating procedures. The eagerness to disseminate corporate news quickly and through the right channels needs to be considered in the context of a thorough understanding of the compliance requirements. Pharmaceutical company employees and agents also need to understand the ramifications of disseminating information that may breach relevant laws, including the fact that once the information is out there, there's no getting it back...

Managing the Risks

Pharmaceutical companies considering taking the plunge into social media in the UK should study the PMCPA's Guidance carefully, as well as relevant provisions of the Code.

In addition, they should consider a number of sensible risk management strategies before establishing a presence in social media channels:

- **Transparency** – this is a key principle that not only assists in managing risk, but should also enhance the response from the public to a pharmaceutical company's interaction in a social media channel as well as improving the public trust in the company. It is essential to set out clearly the company's involvement in the relevant site (e.g. as a sponsor). Pharmaceutical companies should ensure that the intended audience of the site or relevant page(s) is stated, both in terms of the type of individual (patient versus healthcare professional, for example) and any jurisdictional limitations. Finally, disclaimers should be included setting out what is, and what is not, the purpose of the site.
- **Clear policies** – these should include terms of use, privacy and comments policies for any site that will attract UGC. Policies should cover a range of issues, including: prohibiting defamatory or infringing content; clarifying what is regarded as acceptable use; giving the company the right to use or remove UGC as it sees fit; establishing how offensive content can be reported; detailing a mechanism for how adverse events relating to any of the company's products can properly be reported; establishing procedures for dealing with complaints and taking down UGC.
- **Company product discussion** – companies should set out whether the site can be used as a forum for discussing any of the company's products (as opposed, for example, to a particular disease). It is likely that the company will not want the site to be used for such discussions, because of the risks such discussions bring and the level of potential monitoring required.
- **Links** – it should be made clear to a user when they are leaving a page for which the pharma company is responsible, to visit a third party site.

Not all of these strategies can be used for all channels: some channels are operated through a third party website, where a pharmaceutical company's level of actual control is more limited. All four strategies are most appropriate for a pharma company blog, for example, where the company can set out the rules of engagement and control UGC if it chooses to. It will be important to ensure that use policies are tailored to the specific channel used and pharma companies should analyse channels they are proposing to use to ensure that they are the best forum for the information to be shared.

How Should Pharma's Use of Social Media be Regulated?

In the UK, the PMCPA has given a clear indication of how it considers pharmaceutical companies' use of social media should be regulated: apply the Code as you would for any other medium, and take into account the recent Guidance.

Although the FDA has yet to produce guidance in this area, it is expected that something will be forthcoming from them during 2011. Other European regulators may also publish guidance in this area.

As a matter of the general policy approach in this area, there are a couple of options for regulators to consider:

- **Accept "control" and its consequences:** a pharmaceutical company could simply be forced to accept control and put in place a comprehensive system to monitor and moderate content on social media channels that it sponsors or is otherwise associated with. In addition to placing a substantial resource burden on pharmaceutical companies, there is a substantial risk that excessive monitoring and draconian policies are likely to destroy meaningful use of the relevant social media channels and dampen the appetite for their use.

- **Facilitate but do not control:** this may not be a distinction that regulators are willing to accept, but could be a possible compromise position. A distinction would be made between website content that is clearly originated by a pharmaceutical company, and UGC in a forum that is merely “facilitated” by the company. For example, a company website may contain accurate, up-to-date and comprehensive information on its products (such as copies of the PILs and SmPCs), and other non-promotional disease awareness information for consumers. Such a resource could then link to a UGC-filled discussion forum on a relevant disease on the same site: consumers reading UGC in the forum could easily access the latest product information to help answer questions they may have from the forum discussion. This may be a compromise too far at this stage for the regulators, but it is an approach at least worth consideration.

There has also been some discussion about whether pharmaceutical companies should be entitled to respond to allegations or inaccuracies made in UGC in patient or healthcare professional fora. The Guidance from the PMCPA does refer to correcting inaccuracies on Wikipedia, and it is reasonable to assume that the PMCPA would take this into account when considering a similar scenario in relation to patient or healthcare professional fora. In this case, the pharmaceutical company would not be “editing” as such, but would need to exercise care to ensure that any response is balanced, accurate and non-promotional in nature. Clearly there are other considerations here: for example, would the company want to be drawn into a discussion in one of these fora?

Regulators also need to give careful consideration to those situations where a pharmaceutical company is simply not able to exert absolute control over content that is posted on “its” site (such as a site that a regulator would ordinarily regard as the

pharmaceutical company’s responsibility by virtue of its sponsorship of the site). For example, a pharma company may not always be able to have a third party comment removed from its page on a third party site simply because the comment amounts to a promotional statement about one of the company’s products.

Conclusions

This is, undoubtedly, a very challenging area to regulate. The speed of evolution of social media channels and the internet mean that any regulation must be flexible and frequently reviewed. The internet has changed the way in which consumers and healthcare professionals access health information, and the pharmaceutical industry must be able to use, and interact in, this space to ensure that consumers and healthcare professionals can access accurate and up-to-date medical information.

The PMCPA’s Guidance in the UK is to be welcomed, and praised. The PMCPA has gone where the FDA has yet to go, and has done so in a manner consistent with the approach it has long advocated for the use of social media by pharmaceutical companies: apply the Code. The FDA guidelines will be interesting reading if and when they arrive, but in the meantime it seems likely that pharmaceutical companies in the UK will start to explore in more detail the opportunities that social media presents. This in turn is likely to mean that, before long, the PMCPA will be asked to rule on the application of the Code to social media, creating precedent that will add to the Guidance and generate a little more certainty for pharmaceutical companies wishing to engage more fully in the world of social media.

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