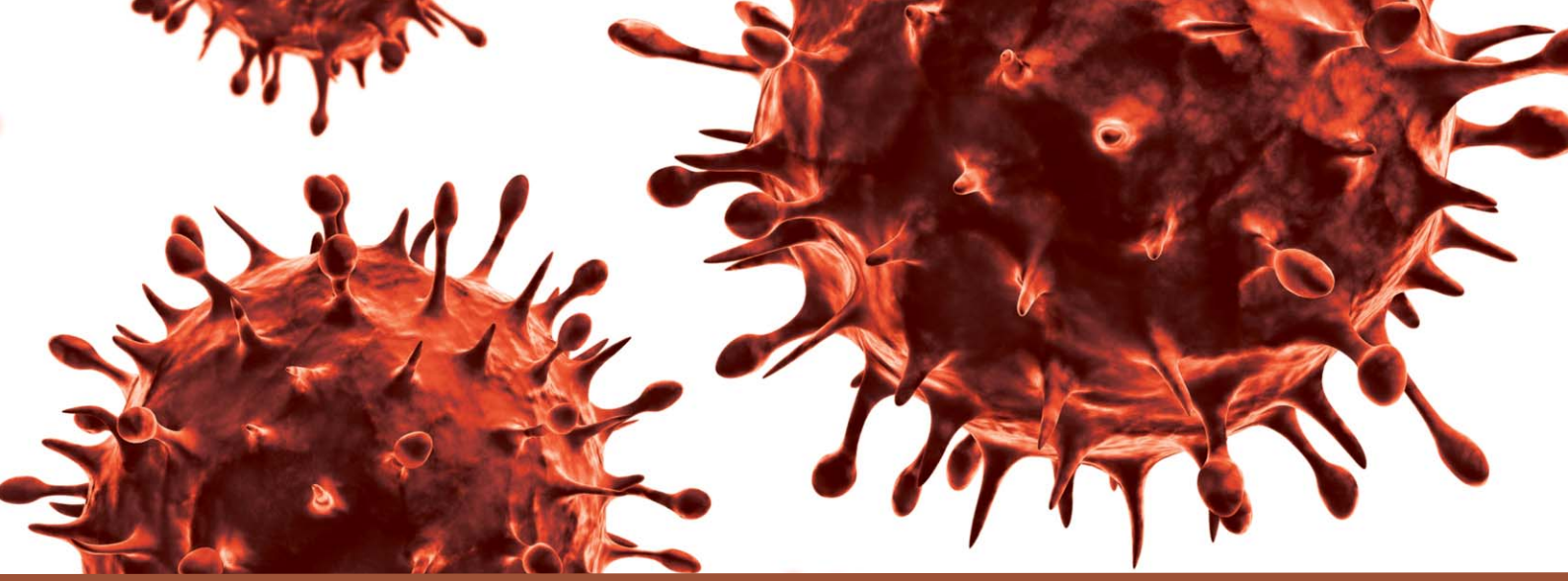


ICLG

The International Comparative Legal Guide to:

Pharmaceutical Advertising 2014

11th Edition

A practical cross-border insight into pharmaceutical advertising

Published by Global Legal Group, with contributions from:

A. Lopes Muniz Advogados Associados
Adams & Adams
Advokatfirmaet Grette DA
Arnold & Porter LLP
Arthur Cox
Biolato Longo Ridola & Mori
Boga & Associates
Clayton Utz
Clifford Chance
CMS Cameron McKenna
CMS, Russia
Debarliev, Dameski & Kelesoska Attorneys at Law
Edwards Wildman Palmer LLP
Faus & Moliner
Herbst Kinsky Rechtsanwälte GmbH
Hwang Mok Park P.C.
Jones Day
Jusmedico Advokatanpartsselskab
Life Sciences Legal Advocaten
Mannheimer Swartling Advokatbyrå
Mehmet Gün & Partners
Nishimura & Asahi
OLIVARES
PDG Avocats
Roschier, Attorneys Ltd.
Schellenberg Wittmer Ltd
Sołtysiński Kawecki & Szlęzak
Subramaniam & Associates (SNA)
Tilleke & Gibbins
Van Innis & Delarue
Vieira de Almeida & Associados

GLG
Global Legal Group

The International Comparative Legal Guide to: Pharmaceutical Advertising 2014

GLG
Global Legal Group

Contributing Editor
Ian Dodds-Smith,
Arnold & Porter (UK) LLP

Account Managers
Assel Ashirbayeva,
Edmond Atta, Beth Bassett,
Antony Dine, Dror Levy,
Maria Lopez, Florjan
Osmani, Paul Regan,
Gordon Sambrooks,
Oliver Smith, Rory Smith

Sales Support Manager
Toni Wyatt

Sub Editors
Nicholas Catlin
Amy Hirst

Editors
Beatriz Arroyo
Gemma Bridge

Senior Editor
Suzie Kidd

Group Consulting Editor
Alan Falach

Group Publisher
Richard Firth

Published by
Global Legal Group Ltd.
59 Tanner Street
London SE1 3PL, UK
Tel: +44 20 7367 0720
Fax: +44 20 7407 5255
Email: info@glgroup.co.uk
URL: www.glgroup.co.uk

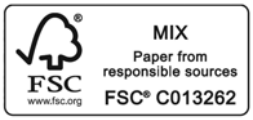
GLG Cover Design
F&F Studio Design

GLG Cover Image Source
iStockphoto

Printed by
Information Press Ltd
June 2014

ISBN 978-1-910083-03-1
ISSN 1743-3363

Strategic Partners



Preface:

General Chapter:

Country Question and Answer Chapters:

Further copies of this book and others in the series can be ordered from the publisher. Please call +44 20 7367 0720

Social Media and the Pharmaceutical Industry: Managing the Risks

Jackie Mulryne

Arnold & Porter (UK) LLP and Arnold & Porter LLP

Abraham Gitterman

Introduction

The rise in the use of social media in recent years has been commented on by many, and numerous media savvy companies across a range of industries have sought to take advantage of the high level of consumer engagement, seeking to speak directly to customers. However, pharmaceutical companies have so far been reluctant to use social media in the same way. The reason for this is clear; the large amount of regulation controlling advertising of medicinal products, and in particular direct-to-consumer advertising, means that pharmaceutical companies could potentially breach the rules with every post, by every user. This article discusses the recent guidance in the EU and US that seeks to guide companies through these difficulties, and offers some practical tips for pharmaceutical companies looking to increase their online interactions with patients.

The Use of Social Media by Pharmaceutical Companies

Social media is a broad term used to refer to a variety of internet-based tools for sharing and disseminating information. These can take many different forms, including internet forums, blogs, wikis and social networks, but all allow the publication and sharing of information in a social environment. The most well-known – Facebook, Twitter and YouTube – are known as the "Big Three", although in reality there are a wide variety of social media platforms that are used to share information between users. Indeed, most websites now have some social aspect to them, even if it is just a comments box.

In relation to healthcare, the European Commission's Digital Agenda for Europe reported that in 2012, 41% of people looked online for health information more than once a month, and a further 40% did so less than once a month. In terms of use by pharmaceutical companies specifically, the majority of companies appear to be engaging in "listening", whereby they gain knowledge and insight from social media and other websites by searching for posts which mention their company name or products.[1] However, while this monitors social media sites, it does not engage with them.

It is clear that a number of pharmaceutical companies have become more active in social media.[2] For example, Boehringer Ingelheim (BI) was recently the subject of a Twitter case study,[3] and was praised for using tweets and live chats, and noted to be the first pharmaceutical company to do so. BI also has a "social media centre" that gathers together its Facebook, Twitter, Pinterest and YouTube sites in one place. Companies have also developed disease-specific platforms. For example, Novartis has developed a specific Pinterest board (a pin-board-style photo-sharing website that allows users to create and manage theme-based image collections such as events, interests, and hobbies) to raise awareness of advanced breast cancer.[4] Similarly, Janssen has launched an initiative on Tumblr (a microblogging platform for sharing images, video, music and comments) to engage people living with HIV.[5]

This chapter focuses on the active use of social media, and not other forms of digital communications used by companies. The key distinction is the interaction and engagement with users, rather than simply broadcasting or monitoring information.

Risks of Using Social Media

One of the biggest concerns for companies utilising social media is the risk of being held responsible for user-generated content over which they have no control. This can cause problems for a company in any sector, which may have concerns such as liability for copyright infringement or defamation.

However, in the pharmaceutical context, there are additional concerns. Where a company sponsors, advertises on or instigates a website where prescription-only medicines are discussed, there is a high risk that regulators may deem the company to be responsible for all content on that website, whether or not it was generated by the company. Due to the strict rules on advertising, discussed elsewhere in this publication, such uncontrolled content can lead to breach of the regulations. For example, in the EU, there is a prohibition on the advertising of prescription-only medicines to the general public. Because of the very wide definition of advertising, there is a high risk of information disseminated via social media being categorised as promotional. In the UK, a recent Prescription Medicines Code of Practice Authority ("PMCPA") case considered photographs of a product of Abbott that were placed on the photographer's Facebook page.[6] As the company had consented to the use of the photographs on Facebook, it was held responsible for such use. Facebook is an open access website, and not limited to professional use; therefore, the photographs were found to be promotion of the product to the public by the company. Similar risks are likely to arise in relation to comments by the public about use of a product outside of its authorised indication for use. The company will also be required to monitor the site for any references to adverse events, which may trigger pharmacovigilance reporting requirements.

Companies have tried to limit their exposure by limiting how consumers can comment on their websites. For example, BI has disabled the ability to comment on certain videos on its YouTube site, and users do not have the ability to upload videos to the channel.[7] Facebook's advertising guidelines contain an express prohibition on promoting the sale of prescription-only medicinal products: "*Ads must not promote the sale of prescription pharmaceuticals. Ads for online pharmacies are prohibited except that ads for certified pharmacies may be permitted with prior approval from Facebook.*"[8] On a brief review of the pages of pharmaceutical companies, most also provide guidance along these lines. For example, Pfizer's Facebook wall is not disabled, so users are free to comment on posts made by the company. However, users cannot post their own items directly onto the wall, which has a disclaimer stating: "*While we do not endorse any users' comments other than our own, we still have to be mindful of the important regulations that govern our industry. If your post references a pharmaceutical brand from any company – positive or negative – we will need to remove it because, among other reasons, we can't guarantee that it will represent Fair Balance*".[9] GlaxoSmithKline's Facebook page applies a similar policy.[10]

However, because of the risks, other companies have chosen to remove their social media pages entirely. For example, Janssen closed its psoriasis Facebook page in 2012 as it considered that having to remove posts was stifling legitimate patient discussion.[11]

Current Guidance for Pharmaceutical Companies on the Use of Social Media

Given the risks involved, companies have looked to legislation and regulatory authorities for guidance on what is permissible. In the EU, the definition of "advertising" under Directive 2001/83/EC (the "Directive")[12] includes a wide range of activities that are designed to promote the prescription, supply, sale or consumption of medicinal products.[13] The Directive contains a prohibition on advertising prescription-only medicinal products to the general public, and controls the advertising of prescription-only medicines to healthcare professionals.[14] However, it does not deal with digital communications specifically.

The European Commission recognised the status of the internet as a front-line resource for health information, and included proposals on providing information to patients via the internet in the "pharmaceutical package" published in December 2008. However, this proposal was viewed as controversial by the authorities of many Member States, and has not progressed within the European institutions. In any event, it does not offer guidance on the use of social media.

In practice, companies rely on the guidance provided by the competent authorities and several codes of practice (and cases determined by regulators and industry bodies). On the whole, guidance and legislation have not kept up with the fast-moving digital world. For example, the European Federation of Pharmaceutical Industries and Associations' ("EFPIA") Code on the Promotion of Prescription-Only Medicines to, and Interactions with, Healthcare Professionals[15] contains an annex relating to websites, although this focuses on static websites published by pharmaceutical companies, rather than more active social media tools. Similarly, in Germany, despite an update of the *Heilmittelwerbegesetz* (Advertising of Medicinal Substances Act) in October 2012, social media was not specifically addressed. As a result, industry has to apply the provisions within the *Heilmittelwerbegesetz* to the use of social media, without the assistance of specific guidance in this area. This is unsatisfactory when a company is looking for specific guidance to determine the limits of what it can do.

EU National Guidance

In recent years, some of the national regulatory agencies in the EU have started to offer social media-specific guidance for pharmaceutical companies. We set out some examples below:

UK

In February 2014, the PMCPA published a new Guide on Digital Communications (the "Guide"). This serves as an update to the original version published in April 2011, and includes advice on how companies can make the best use of digital communication tools such as Twitter, Facebook, Pinterest and Wikipedia whilst complying with restrictions under the Association of British Pharmaceutical Industry ("ABPI") Code of Practice.[16]

The Guide makes it clear that companies should be able to use any method of communication to provide materials to any audience. However such communications must follow the requirements of the ABPI Code, in particular in relation to promotion of prescription-only medicines. The approach that companies should take with any promotional activity is to examine who their audience is and whether the materials are to be proactively distributed or reactively available in response to a request. In relation to social media, the Guide emphasises that it may be difficult to use social media to communicate solely with healthcare professionals, as it may not be possible to limit the audience so that members of the public are not able to access the materials.

For example, in relation to Twitter, the Guide states "*Given these restrictions and the character limit on twitter, it is highly unlikely that the use of this medium to promote prescription only medicines would meet the requirements of the Code.*"[17] The PMCPA has stood by this guidance in a recent decision relating to two tweets sent by an events company referring to meetings and mentioning the name of a prescription-only medicine and its indication. The PMCPA found that there had been a breach of the ABPI Code by the company, despite the low number of followers (55), the time of tweet (1:37am) and the fact a third party contractor had posted the tweets.[18] It is important that companies take this guidance seriously; in a case from 2011, the PMCPA found that the company was in breach of the ABPI Code for a tweet sent out by an employee, despite the tweet being sent in breach of the company's social media policy and from a personal Twitter account.[19] This means that companies could be found responsible for the activities of their employees (and in some cases contractors), regardless of internal training or the fact that employees may be acting in breach of company policies.

The Guide also addresses online discussion forums: companies are likely to be responsible for the content of such discussions (whether on their own website or through a third party provider), so it is important that they have full control over the content. Similar considerations apply to blogs, about which the PMCPA concludes "*Given that, by their very nature, blogs are for contributors to freely and spontaneously express their personal views on a subject, pharmaceutical companies should not sponsor such sites on the internet if they were intended, or could*

reasonably be expected, to discuss medicines and their uses as it would be impossible to guarantee their compliance with the Code."[20]

The Medicines and Healthcare products Regulatory Agency ("MHRA") has recently stated that it has seen an increase in the number of complaints about advertising on social media, and received its first Twitter complaints in 2013. Social media cases now account for more than 10% of the complaints received by the MHRA. This shows that companies are increasingly using social media in the UK, but also that the regulatory authorities are increasingly aware of the risks associated with such use.

France

The regulatory authority in France, the ANSM (*Agence nationale de sécurité du médicament et des produits de santé*), has provided guidance for industry via its updated Charter on Communications on the Internet.[21] This specifically addresses social media issues, and warns that by its nature, social media leads to content that is free and uncontrollable; this is likely to lead to breach of the legislation. For example, advertising to the general public, in the form of a "product" page, is not possible where the company cannot moderate the content and users' reviews. Similarly, the "like" function on Facebook can be interpreted as endorsements for the product, and is, therefore, considered to be contrary to the Charter.

Spain

The current edition of the Spanish pharmaceutical industry association (*Farmaindustria*) Code of Practice provides a section on the digital environment, which includes guidance on the use of social media.[22] The key principle underpinning this section is that companies must refrain from using digital methods that, by their nature, characteristics, technical limitations and conditions of use, do not allow companies to guarantee compliance with the requirements of the Code.

The Code advises companies to implement usage and style guidelines establishing rules of conduct in digital media, as well as a procedure for monitoring the content to which companies provide access, host, temporarily copy or link, together with the consequences of non-compliance. These rules should address the obligation to correct any irregularities promptly.

The Code reminds companies that promotion of medicinal products to healthcare professionals through the internet must be within a technical, scientific and professional context, and that measures must be taken to ensure that this promotion is disseminated exclusively to healthcare professionals.

US Guidance

The United States is one of the only jurisdictions in the world to allow pharmaceutical companies to directly promote prescription-only medicines to consumers. The US Food and Drug Administration ("FDA") regulates the labelling and advertising of prescription-only medicinal products directed to both consumers and healthcare professionals.[23] The FDA generally recognises two types of labelling: (1) FDA-required labelling (e.g. prescribing information and product information); and (2) promotional labelling.

Promotional labelling is any labelling, other than the FDA-required labelling, that is devised for promotion of the product.[24] Generally, FDA regulations require promotional materials, regardless of medium, to include certain safety information (e.g. warnings, precautions, side effects, contraindications, etc.) in a "fair and balanced" manner. The promotional materials must not be false or misleading and must reveal all material facts. Companies must submit promotional labelling and materials to the FDA at the time of their initial dissemination,[25] and the FDA also monitors television advertisements, magazines, websites, and social media platforms to ensure compliance with the regulations.

The use of social media, or "interactive promotional media", by pharmaceutical companies in the US, however, has caused a number of concerns, in particular about whether materials disseminated via social media contain all the necessary information. As in the EU, the use of such platforms is associated with regulatory uncertainty because the FDA has failed to issue regulations or guidance regarding this new form of promotion. The FDA has issued several Warning and Untitled Letters regarding interactive promotional media, most recently to Institut Biochimique SA in February 2014, citing the company's Facebook page for omitting risk information and material facts.[26]

To address these concerns, the FDA issued its "first" draft social media guidance in January 2014, entitled "Draft Guidance for Industry: Fulfilling Regulatory Requirements for Post-marketing Submissions of Interactive Promotional Media for Prescription Human and Animal Drugs and Biologics" (the "FDA Guidance"). The FDA Guidance outlines the considerations to be taken into account in determining whether communications using social media are subject to the FDA's post-marketing submission requirements. In addition, it makes practical recommendations on how companies can fulfil the requirement to submit post-marketing promotional materials to the FDA in order to deal with the volume of information that is continuously posted and shared through social media.

Under the draft FDA Guidance, companies are responsible for submitting post-marketing information to the FDA if they "*own, control, create, influence, or operate*" the interactive promotional media platform. In fact, the FDA emphasises that a company is responsible for promotion both on sites that it owns or controls, and third party sites, if the company exerts influence over a site in any way, even if the influence is limited in scope. This would include collaborating on, or having editorial, preview, or review privilege over, the content. The FDA also explains that companies are responsible for content generated by an employee or agent who is acting on behalf of the company to promote the company's product. However, the FDA acknowledges that companies are "*generally not responsible for [user generated content] (UGC) that is truly independent of the firm (i.e., is not produced by, or on behalf of, or prompted by the firm...*)".

The remainder of the FDA Guidance explains the frequency with which companies must submit promotional materials generated on these platforms to comply with the "initial dissemination" requirements.[27] For example, at the time of "initial display", companies should submit details of all sites for which they are responsible, including the passive product website, and any interactive component. For third party sites on which the company's participation is limited to interactive or real-time communications, the FDA asks that companies submit the home page, interactive page, and the company's first communication at the time of initial display.

While the FDA Guidance provides some limited insights into the FDA's general approach to the use of social media, many questions remain, and the FDA has already announced plans to publish three additional Guidance documents on interactive promotional media this year.[28]

Other Considerations and Risks

Pharmacovigilance

Patient safety is a key consideration for any new initiative in the pharmaceutical field, and the pharmacovigilance requirements apply equally to data that arises from digital platforms. Indeed, the recently updated Good Pharmacovigilance Practices ("GVP") guidelines in the EU state: "*Marketing authorisation holders may also consider utilising their websites to facilitate the collection of reports of suspected adverse reactions*".[29]

National authorities have also emphasised the importance of collecting and reporting safety information from digital media. In the UK, for example, the PMCPA Guide states that safety "*is very important. Companies are obliged to collect adverse events and report them if appropriate so any interaction must include plans for reviewing the site to meet pharmacovigilance requirements.*"[30] The ABPI has also published specific guidance in this area,[31] which outlines the obligations of marketing authorisation holders to monitor, collect and manage product safety (or quality) information generated through digital media. In particular, regardless of the nature of an adverse event, marketing authorisation holders who monitor digital media or communicate to, or receive feedback from, the public by way of digital media have an obligation to collect and follow up on all reports of adverse events. It is also important that the company captures when the information was posted, when the company became aware of it, and additional information, such as an identifiable patient, a product, an adverse event and an identifiable reporter (e.g. an email address).

In relation to non-company sponsored sites, the ABPI advises that while any adverse events should be reported appropriately, there is no obligation to monitor such sites for reports. It is, therefore, not necessary for companies to routinely trawl the internet beyond their own sites looking for individual spontaneous reports, although if a marketing authorisation holder becomes aware of a suspected adverse reaction, the information should be assessed to determine whether it qualifies for reporting.

Access to information and security protection

Companies are conscious of the need to restrict certain content on company websites to healthcare professionals or individuals in particular countries, and to provide specific information to patients. However, this distinction is particularly difficult when combined with social media, where the very ethos is not to restrict content or comments.

The EFPIA Code states that the information provided on company websites need not be encrypted or otherwise restricted.[32] Across the EU, however, different countries have approached security in different ways. In the UK, the need for access restrictions is not specifically advised in the ABPI Code. However, in France and Germany, the guidance is rather more restrictive, and requires that advertising aimed at healthcare professionals should have "real" restrictions so that consumers cannot access it, such as access codes provided after verification of appropriate medical qualifications.[33] Similarly, in Spain, the Code of Practice requires digital platforms and websites to require individuals who access the content to declare their status as healthcare professionals authorised to prescribe or dispense medicines. It is difficult to see how this can be done in relation to followers of a company's Twitter account.

Jurisdiction

Websites can be accessed from countries other than the country where the information is placed on the internet, and by people who are not its intended audience. Similarly, companies can add information to the internet in countries which have less stringent controls over promotion of medicinal products, and this information can be accessed by patients in other countries. There is, therefore, an issue as to which regulatory body can enforce which advertising rules in order to control the website, and the extent to which a regulator can actually enforce the rules in its country if the company is located outside the jurisdiction and does not accept its enforcement provisions.

This is a particular problem for social media, as it is difficult to limit access to websites such as Facebook to users from a specific country. Companies have therefore attempted to impose their own limitations on users. For example, Novartis launched a product website for Gilenya that integrates with social media channels like Twitter, Facebook and YouTube to contact patients in the US with multiple sclerosis. However, Novartis has configured its Facebook and YouTube channels so that users outside of the US are unable to access them, while its Twitter channel includes "USOnly" in its profile name and description, and as a hashtag on every tweet. The product website states "For US Residents Only", while non-US residents are directed to Novartis' global corporate site. However, it is not always clear if these methods are foolproof, particularly the use of hashtags, which rely on Twitter users recognising (and presumably ignoring) information relating to other jurisdictions.

In the UK, the PMCPA Guide includes specific information relating to the activities of overseas parent/affiliate companies, which is in line with the guidance in the ABPI Code.[34] It makes clear that a UK company is responsible under the ABPI Code for activities of parents and affiliates that are carried out in the UK, or with UK healthcare professionals abroad, and for information that specifically refers to the availability or use of a medicine in the UK. Similarly, the French Charter applies to any site hosted in France or addressed to the French public, or healthcare professionals working in France.

Managing the Risks

Given the risks associated with being liable for content over which a company has no control, and the lack of detailed guidance from regulatory agencies, a company must consider how it will use and respond to social media. It is useful to note the three categories of control identified by the ABPI, as set out below:

- Listening/No control: a company can establish a static website containing approved product information, allowing one-way communication only. It can steer clear of social media sites or engaging directly with patients, although it can monitor such sites. This is undoubtedly the lowest risk option, but is unlikely to meet the realities of business in the 21st century.
- Broadcasting/Reactive control: a company can be active on social media sites, but be clear that it is not engaging with patients (although the company may seek to correct inaccuracies made by users). This raises the company's online presence and participates in new social technologies while limiting some of the risks associated with direct interactions with users.
- Engaging/Active control: a company may seek to control every company-sponsored, and third party platform relating to company products, and scrutinise every comment or post before it is made public. While this

strategy produces a significant monitoring burden for companies, it will significantly reduce the risk of being found liable for user-generated content. However, such active control may also stifle free discussion and the full "social" aspect that is the aim of many social media sites. In addition, it seems unlikely that a company will be able to control every comment before it is posted, leaving it open to liability for "missed" posts.

In practice, many companies are choosing to take this route as patients demand access to more information about their products, and to talk to people who are going through similar experiences. The company then has to limit potential risks by having clear policies on user comments, and ensuring that these policies are followed.

Another option for companies is to use third party agents to manage their social media presence. The PMCPA Guide acknowledges that it may be possible for a pharmaceutical company to provide funding to a third party patient group to develop a social media site on a disease area. However, such arrangements must be strictly arm's length, and there must be no possibility that the company has any influence over the content of the site. The site should also carry a declaration that it has been sponsored by the company. This is likely to be complicated to set up and robust procedures should be put in place to ensure that there can be no breaches of the relevant advertising rules.

Whichever strategy is adopted, risks can be reduced by following these steps:

- Set out the nature of the company's involvement. If the site is a company site, this should be clear and the company's policies on how user-generated content will be dealt with should be stated (e.g. "this is a PharmaCo platform and its content is controlled by X and X means"). If the site is a third party site, it should be clearly stated that it has been set up in collaboration with the company, or if the company's involvement is limited to sponsorship (through an arm's length arrangement).
- Be clear on any jurisdiction or audience-specific criteria; enforce these distinctions and ensure they operate effectively.
- Be clear when something has been published by the company, or an employee, so there is no suggestion of disguised promotion.
- Avoid discussion of company products.
- Approve all company content before publishing.
- Consider appointing a dedicated social media moderator and contributor, and set out clear escalation and oversight procedures for that person.
- Implement a global policy on social media to ensure that affiliates in one country do not inadvertently infringe the regulatory requirements in another.
- Establish clear internal policies and procedures for reporting adverse events and dealing with complaints.
- Ensure employees, and in particular sales representatives, are aware of the risks associated with the use of social media and are thoroughly trained on company policies.

Acknowledgment

The authors would like to thank their colleagues Silvia Valverde and Katie Woodhouse for their assistance with this chapter.

Endnotes

1 Pharma Social Media Listening; Benchmarking Innovative Practices in the Healthcare Industry.

2 PMLive Pharma social media directory: http://www.pmlive.com/digital_handbook/social_media/pharma_social_media_directory.

3 Success stories Boehringer Ingelheim: https://business.twitter.com/success-stories/boehringer-ingelheim.

4 http://www.pinterest.com/countus.

5 http://positivelytogether.tumblr.com.

6 Case 2576/2/13 (completed April 2013): *GP v Abbott*. Advertisements for Hidrasec.

7 http://www.youtube.com/user/BoehringerUK.

8 https://www.facebook.com/ad_guidelines.php.

9 https://www.facebook.com/Pfizer/app_103822229704881.

10 https://www.facebook.com/GSK.

11 PMLive "Janssen to close groundbreaking psoriasis Facebook page", 21 March 2012.

12 Directive 2001/83/EC of 6 November 2001 on the Community Code relating to medicinal products for human use, as amended.

13 Directive, Article 86.

14 Directive, Article 88.

15 EFPIA Code on the Promotion of Prescription-Only Medicines and Interactions with Healthcare Professionals, June 2013.

16 ABPI Code of Practice for the Pharmaceutical Industry, 2014.

17 PMCPA Guidance on Digital Communications, February 2014, Question 1.

18 Case 2612/6/13 (completed August 2013): *Ex-employee v Gedeon Richter*.

19 Case 2455/11/11 (completed December 2011): *Anonymous v Allergan*. Botox tweet.

20 PMCPA Guidance on Digital Communications, February 2014, Question 10.

21 *Charte pour la communication et la promotion des produits de santé (médicaments et dispositifs médicaux) sur Internet et le e-media*, 20 June 2013.

22 Farmaindustria Code of Practice for the Pharmaceutical Industry, 2014.

23 U.S.C. §§ 352 (a), (n).

24 21 C.F.R. §§ 202.1(1)(2).

25 21 C.F.R. § 314.81(b)(3)(i).

26 See http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/EnforcementActivitiesbyFDA/WarningLettersandNoticeofViolationLetterstoPharmaceuticalCompanies/UCM388800.pdf.

27 21 C.F.R. § 314.81(b)(3)(i).

28 FDA, Guidance Agenda: New & Revised Draft Guidances CDER is Planning to Publish During Calendar Year 2014, 31 January 2014.

29 Guidelines on good pharmacovigilance practices (GVP), Module VI – Management and reporting of adverse reactions to medicinal products, 22 June 2012, EMA/873138/2011, section VI.B.1.1.4.

30 PMCPA Guidance on Digital Communications, February 2014, Question 6.

31 ABPI Guidance notes on the management of adverse events and product complaints from digital media, 8 April 2013.

32 EFPIA Code, Annex B, section 2(b)(iii).

33 See for example the DocCheck registration process in Germany.

34 ABPI Code, clause 25.2.

Jackie Mulryne

Arnold & Porter (UK) LLP
Tower 42, 25 Old Broad Street
London, EC2N 1HQ
United Kingdom

Tel: +44 20 7786 6123
Fax: +44 20 7786 6299
Email: Jacqueline.Mulryne@aporter.com
URL: www.arnoldporter.com

Ms. Mulryne is an associate in the firm's London office and a member of the healthcare group. Ms. Mulryne advises clients in the biotechnology, pharmaceutical, and medical device sectors, and has a broad practice providing regulatory compliance and public policy advice. She advises on UK and EU law, and has experience with a range of regulatory issues that arise throughout the product life cycle, including borderline classification, clinical research, authorisation, advertising and labelling, and pricing and reimbursement. She has assisted a number of life science and medical device companies in developing and implementing cross-border regulatory action and compliance programmes.

Ms. Mulryne advises on public and administrative law cases brought before the UK and European courts, including actions arising from the decisions of regulatory bodies, such as the Medicines and Healthcare products Regulatory Agency (MHRA), the European Medicines Agency (EMA) and the National Institute for Health and Care Excellence (NICE).

Ms. Mulryne trained at Arnold & Porter (UK) LLP, and also spent time in the firm's Brussels office. She gained a Natural Sciences degree from Christ's College, Cambridge University, and completed her Graduate Diploma in Law and Legal Practice Course at Nottingham Law School.

Abraham Gitterman

Arnold & Porter LLP
555 Twelfth Street, NW
Washington, D.C. 20004-1206
USA

Tel: +1 202 942 5000
Fax: +1 202 942 5999
Email: Abraham.Gitterman@aporter.com
URL: www.arnoldporter.com

Abraham Gitterman is an associate with Arnold & Porter LLP in Washington, D.C., where his practice focuses on FDA and health-care regulatory matters involving pharmaceuticals, medical devices, medical technology and software, and mobile apps. Mr. Gitterman is also involved with reviewing, auditing and developing corporate compliance programmes for various life science companies and healthcare entities to ensure compliance with the False Claims Act, the Anti-Kickback Statute, and the Federal Food, Drug, and Cosmetic Act. He is admitted only in Pennsylvania and New Jersey, and is practising law in the District of Columbia during the pendency of his application for admission to the D.C. Bar and under the supervision of lawyers of the firm who are members in good standing of the D.C. Bar.

ARNOLD & PORTER (UK) LLP

Arnold & Porter LLP is an international law firm with over 800 attorneys in six offices in the USA, together with offices in London and Brussels.

The EU lifesciences team, headed by Ian Dodds-Smith and based in London, has unrivalled experience in advising on every aspect of the regulation of medicines, devices, cosmetics, foods and borderline products. The team includes a number of lawyers with scientific qualifications, including three physicians. It is regularly ranked as the leading firm providing regulatory advice and specialist litigation services to the lifesciences sector.

The team of 15 lawyers specialising in this field in London is complemented by Arnold & Porter's highly regarded pharmaceutical and medical devices regulatory practice headed by Dan Kracov in Washington, D.C., with a team of 20 lawyers.

For further information, please contact Ian Dodds-Smith in the London office on +44 20 7786 6100, or Dan Kracov in Washington, D.C. on +1 202 942 5120.

Other titles in the ICLG series include:

- Alternative Investment Funds
- Aviation Law
- Business Crime
- Cartels & Leniency
- Class & Group Actions
- Competition Litigation
- Construction & Engineering Law
- Copyright
- Corporate Governance
- Corporate Immigration
- Corporate Recovery & Insolvency
- Corporate Tax
- Data Protection
- Employment & Labour Law
- Environment & Climate Change Law
- Franchise
- Insurance & Reinsurance
- International Arbitration
- Lending & Secured Finance
- Litigation & Dispute Resolution
- Merger Control
- Mergers & Acquisitions
- Mining Law
- Oil & Gas Regulation
- Patents
- Private Client
- Product Liability
- Project Finance
- Public Procurement
- Real Estate
- Securitisation
- Shipping Law
- Telecoms, Media & Internet
- Trade Marks

GLG
Global Legal Group

59 Tanner Street, London SE1 3PL, United Kingdom
Tel: +44 20 7367 0720 / Fax: +44 20 7407 5255
Email: sales@glgroup.co.uk

www.iclg.co.uk