



GLOBAL LIFE SCIENCES: EU UPDATE

UK Medicines Self-Regulatory Bodies Have Started Issuing and Enforcing Advertising and Pharmacovigilance Guidelines in Social Media Context

The UK's medicines self-regulatory bodies, the Prescription Medicines Code of Practice Authority ("PMCPA") and Association of the British Pharmaceutical Industry ("ABPI"), have begun to issue and enforce guidelines on how EU and UK pharmaceutical advertising and pharmacovigilance laws apply to company-sponsored social media websites.

The PMCPA, which is responsible for enforcing the Code of Practice on the promotion of prescription-only medicines to healthcare professionals (the "Code"), took the first step by publishing its Guidelines on Digital Communications in April 2011. Amongst other issues, the PMCPA's Guidelines provide some clarification on key topics such as:

- What social media channels can be used to reach out to healthcare professionals;
- In what circumstances a company can sponsor a disease awareness social media website;
- Whether a company can correct a Wikipedia page;
- In what circumstances a company can sponsor a blog; and
- What constitutes a proper use of search engine optimisation.

In June 2011, the ABPI issued its Guidance Notes on the Management of Adverse Events and Product Complaints from Pharmaceutical Company Sponsored Websites. This document provides a degree of guidance and clarification on, *inter alia*:

- What constitutes a website under the "management or responsibility" of a marketing authorisation holder, to be screened for adverse events;
- How social media projects should be managed and documented;
- The frequency with which social media websites should be screened; and
- How to minimise data privacy risks arising from the collection of adverse events.

The PMCPA and ABPI documents provide welcome clarification in an area where the lack of official guidance has generated increasing frustration amongst pharmaceutical companies. However, these guidelines leave some issues open, such as:

- In what circumstances, if at all, Twitter can be used to communicate with healthcare professionals;
- Whether a company can ever be held responsible for the contents of a banner appearing as a result of user data mining;

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- How to manage risks that may arise from other social media channels than those listed in the guidelines, such as YouTube or Sidewiki; and
- Legal risks other than pharmaceutical regulatory related ones, e.g., those relating to defamation or intellectual property rights.

The PMCPA has started taking action against those pharmaceutical companies that do not comply with the Guidance Document on Digital Communications, as exemplified by a ruling by the PMCPA against a marketing authorisation holder published in August 2011.

In order to minimise compliance risks in this fast-evolving area, we recommend that companies take the following steps:

- Adopt and regularly update company guidelines on the use of social media to communicate with patients, the public, and healthcare professionals;
- Train staff and vendors, as appropriate, on pharmaceutical advertising and pharmacovigilance rules;
- Ensure that any proposed social media projects and related terms and conditions are approved by the legal department, in line with the EU and national legislation and available guidelines; and
- Ensure that any user-generated content on company-sponsored web pages is monitored, and any offending information or materials deleted, prior to being posted.

If you have any questions regarding this update, please contact the Sidley lawyer with whom you usually work.

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