

New Climate

Sarah Houlton

Europe's new advertising controls and efforts to institute anti-fraud measures are looking more and more like those in the United States.

At a time when pharma's reputation is taking more knocks than ever, European regulatory bodies are taking note of their US brethren, tightening regulations and codes of practice to ensure that European Union (EU) companies do not indulge in inappropriate sales and marketing pushes. Whether it's giving expensive freebies to doctors, taking them on lavish trips for "educational" purposes, or even promoting their prescription-only products to the general public, unacceptable practices only damage the already precarious reputation of the pharmaceutical industry.

Probably the largest-ever government investigation into the influence of pharma's promotional efforts was carried out in the United Kingdom last year. One of the key claims made by the members of parliament on the Health Select Committee was that pharma "over promotes" its products, saying that intensive marketing encourages "inappropriate prescribing." This was countered by the Association of the British Pharmaceutical Industry (ABPI), which said most doctors receive a mere handful of visits from drug reps each month, and that the clinical and product information they receive is valued. However, the association accepted other findings—such as a need to publish pharma's ties to patient groups, and financial benefits received by doctors.

The complexity of the regulatory situation in the EU—with

both national and EU-wide bodies having a say—is mirrored by the way pharmaceutical sales and marketing are regulated and monitored. The disciplines remain largely self-regulated, with European trade associations and regulatory bodies in the individual member states having their own codes governing what pharma companies can do.

Still, the European Federation of Pharmaceutical Industries and Associations (EFPIA) offers leadership with its last updated code in November 2004, which covers the promotion of prescription products to healthcare profession. In addition to oral and written promotional activities, such as adverts in journals and by direct mail, the code also covers the activity of medical sales reps, the Internet and videos, as well as samples, gifts, and hospitality. It doesn't include nonpromotional medical and scientific information or any activities concerning the general public, though some of the national associations address these issues in their own codes.

Although the revised code was introduced over a year and a half ago, it has taken time for all the member associations to implement it within their own rules. So far, no companies have been sanctioned for breaching the EFPIA code, according to a spokesman, and the first meeting to discuss such matters was held at the end of May. "The first breach will probably be at the national level," the spokesman said, adding that EFPIA is more likely to impose sanctions if the breach occurs across more than one country.

ABPI Code

The ABPI's code is now one of the strictest codes in Europe. It came into effect at the beginning of January 2006, and all member companies must abide by it. In addition, about 60 nonmember companies have voluntarily agreed to adhere to its rules.

ABPI's code is managed by the Prescription Medicines Code of Practice Authority (PMCPA), which ABPI set up in 1993 to keep the implementation of the code at arm's length from the association itself. This allows members of the industry, the medical profession, or even the public to report breaches. PMCPA's director, Heather Simmonds, says that just over 100 complaints are received each year. Approximately three-quarters of these are likely to result in action.

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Sanctions

Severe sanctions are rare, but have been used in extreme cases. Most recently, Abbott was suspended from ABPI membership for at least six months, after PMCPA found that the company's employees had taken healthcare professionals to a greyhound racing track, senior hospital consultants to Wimbledon, and entertained one healthcare professional in a strip club. ABPI describes the case as one of the most serious breaches of the code thus far.

Although Abbott undertook a major investigation of events, reviewed its procedures, and disciplined the individuals who were directly involved, PMCPA decided that the only suitable punishment was suspension of its ABPI membership. They thought that merely issuing a public reprimand would not adequately reflect the seriousness of the breaches. This was the first time a company had been suspended from ABPI since 1996.

A serious breach by GlaxoSmithKline (GSK) that ended up in legal action happened in Italy a couple of years ago. GSK's reps were able to monitor doctors' prescribing habits closely, and offer inducements to those they felt were most likely to increase prescribing of the company's drugs. The Italian Guardia di Finanza claimed the company had spent 228 million on bribes, ranging from computers and holidays to cash. According to the complaint, GSK offered a number of cancer specialists a pro rata cash benefit, depending on the number of patients they treated with Hycamtin (topotecan), an expensive antineoplastic medicine. The investigation led to nearly 5,000 people being charged. Many of these were doctors, and more than 250 were GSK employees. The company was also charged with fiscal fraud and corporate crime.

In response, the government implemented a five percent tax on promotional activities. Half of this is destined to end up in an orphan drug fund, and the remainder will pay for a drug-information center. Farmindustria, the Italian association for pharma companies, estimates that this fund will reach as much as 200 million euros.

DTC advertising

Much of what is included in the EFPIA and various national codes will look reasonably familiar to those in the United States. But when it comes to DTC advertising of prescription medicines, things are very different—the practice is prohibited in the EU. The EU came close to agreeing to a pilot scheme

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for DTC advertising in 2002. However, the proposal to lift the ban on information for drugs to treat asthma, diabetes, and HIV/AIDS, was rejected by European Parliament.

Although DTC advertising of prescription meds is banned, companies are allowed to run disease awareness campaigns, which have become particularly common in the United Kingdom. Rather than a company promoting its drugs directly, it runs campaigns about the diseases those products are designed to treat. An example from Pfizer featured Pelé, the Brazilian soccer star, talking about erectile dysfunction, but with no mention of Viagra (even though at that point it was the only tablet-based therapeutic option).

While pharma companies say they don't want the EU to allow DTC, they do want to provide factual information about their medicines to patients. "Companies ought to be permitted to provide nonpromotional information to patients to provide them with details about their condition and the medicines to treat it, so that better choices can be made with greater patient involvement," says ABPI's director general Richard Barker.

Transparent links

The links between the industry and patient advocacy groups are facing

increasing scrutiny. In the United Kingdom, for example, the new ABPI Code of Practice requires that pharma companies make clear on their Web sites or in their annual reports to which groups they provide funding.

While the money pharma provides often keeps such organizations afloat, there is a growing concern about the

potential for drug companies to exert undue influence over the groups. As the companies invariably give money to support groups for the conditions their drugs treat, there is a good deal of suspicion about the motives behind the payments. Companies are now required to be transparent in their support, and the patient group must remain independent, regardless of how much money they receive.

However, a recent report from research and publishing organization Patient View shows that patient groups are not upholding their end of the obligation to be transparent. The research shows that just 11 percent of the 530 largest patient groups in the United Kingdom have made public statements that they receive money from the pharma industry. Only 10 nonprofit groups gave a transparent statement on their Web sites or in their annual reports of how much income came from industry. Fifty-eight groups made mention of the fact that some of their money comes from pharma.

In that way, companies' next challenge is not only to implement and embody these codes, but to introduce them in their interactions with all stakeholders—and ensure the end result is a more transparent approach to marketing and patient support activities. ★