

Guest commentary

Crafting a Global Healthcare Compliance Strategy: The European Union Compliance Landscape

By Noah Shannon and Judith Braun-Davis

Ask an executive from a major pharmaceutical company about the PhRMA Code, FDA, or Office of Inspector General for Health and Human Services and you will receive a lengthy and well-informed response, says **Noah Shannon** of Polaris Management Partners. That is because most major pharmaceutical firms have spent the past five years aggressively responding to healthcare law issues in their largest market, the United States. Ask those same individuals about the EFPIA Code, EMEA, or European Healthcare Fraud and Corruption Office, he adds, and you will probably be met with a significantly less informed response. In short, Shannon says, few U.S.-based pharmaceutical industry executives, including compliance professionals, are familiar with regulations and organizations governing their marketing and sales activities in the European Union.

What follows is a primer on European Union healthcare law that addresses the legal frameworks impacting pharmaceutical companies' international sales and marketing activities along with recommendations on how companies can best craft an effective global compliance approach.

The Challenge

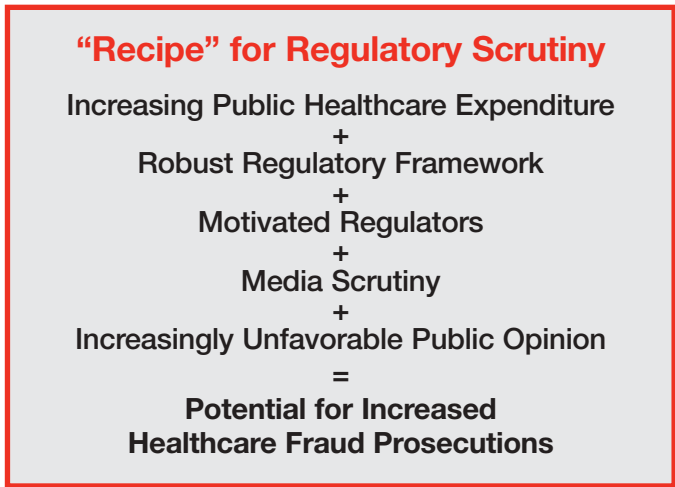
With prosecutions few and far between, European healthcare law regulation was previously not a central focus for pharmaceutical companies. However, as evidenced by recent Italian and German anti-kickback investigations of a top-five pharma company, and the UK's upcoming prosecution of six other companies for price-fixing and fraud, this appears to be changing. Overseas regulators are increasingly pursuing healthcare fraud prosecutions targeted at the pharmaceutical industry, presenting a new challenge for global pharmaceutical companies: how to craft a rational approach to healthcare law compliance that meets obligations coming from three directions – U.S. law, non-U.S. national law, and international treaties and agreements?

Europe Defined

After the United States, Europe is the world's second largest pharmaceutical market, with nearly \$150 billion in annual spending. For the purposes of this article, "Europe" will refer to nations that belong to the European Union (EU). While this does not encompass the entirety of the European population, it does account for approximately 90 percent of European pharmaceutical spending, with Germany, France, and the United Kingdom as the three largest individual markets.¹ Further, the nations of the EU are the most advanced in terms of healthcare regulation, providing a leading indicator of what course other European nations are likely to take.

A Recipe For Prosecution

Before diving into the specifics of European law, a few words should be said about the increase in European healthcare fraud prosecutions and the accompanying shift in public perception of the industry. As in the United States, increasing regulatory scrutiny of the pharmaceutical industry is not an isolated activity in which prosecutors just decide to pursue cases against companies. Rather, there appears to be a "recipe" of critical factors, which create an environment ripe for increased regulatory scrutiny.



These factors include: 1) increasing public healthcare expenditure, which provides governments an incentive to recoup funds paid to healthcare providers, 2) a robust regulatory framework providing laws and precedents to support

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prosecution, 3) motivated regulators with incentives to pursue major cases, 4) media scrutiny of the industry including headlines intended to highlight malfeasance, and 5) increasingly unfavorable public opinion of the industry, often resulting from media coverage.

These five factors are closely interrelated, feeding off of one

another and creating a fertile environment for prosecution. While Europe is increasingly exhibiting all of these characteristics, this article will focus on two key areas: regulatory frameworks and the role of regulatory bodies.

European Law

While the interplay of European regulators is very different from that of their counterparts in the United States, the U.S. system provides an instructive analogy. U.S. healthcare regulation is primarily

driven by federal and state laws. In many cases, states have their own versions of federal laws, such as anti-kickback and False Claims statutes. Offending entities may be prosecuted under either or both sets of laws. The European system can be viewed similarly with EU Regulations and individual country-specific laws taking the place of U.S federal and state laws, respectively. In addition to government regulation, companies operating in Europe often voluntarily submit to guidelines set by industry associations, much like PhRMA and ACCME in the United States.

This article will discuss EU laws and regulatory bodies as well as pan-European industry association guidelines. We will touch on specific national laws, regulators, and associations as necessary to describe their relationships with EU-wide activities, but will not go into detail on each nation’s regulatory landscape.

European Union Laws

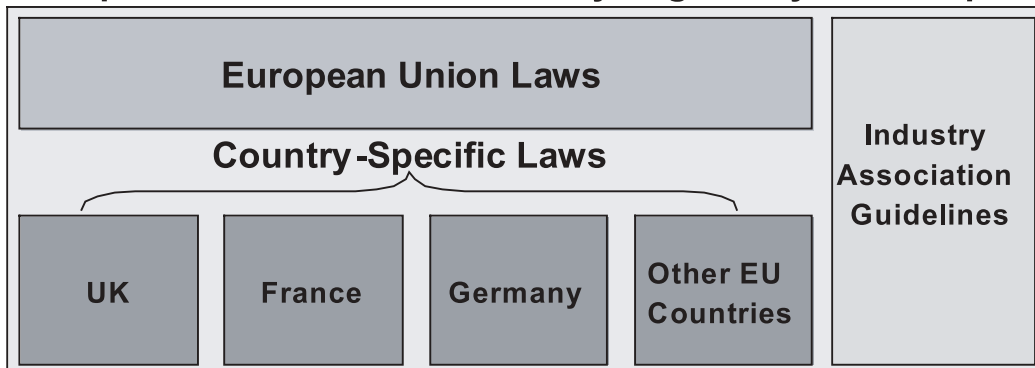
At a high level, EU law consists of four main types of legislation — regulations, directives, recommendations, and decisions. Regulations and directives are the most relevant to our discussion because they are applicable to all member states and their enforcement is mandatory.

Relevant EU Regulations and Directives

In the 1990s, the focus of EU pharmaceutical regulation was to develop a unified process of drug authorization and to establish good clinical and manufacturing practices. Sales and marketing of drugs was primarily regulated by the Council Directive 92/28/EEC on Advertising of Medicinal Products for Human Use but was otherwise not a key regulatory focus.

During the past four years the target appears to be shifting, with more emphasis being put on marketing and sales ethics. Two Directives, 2001/83/EC² and 2004/726/EC³, were put in place to meet this challenge; the Directives include terms on creating a more ethical sales and marketing environment by building

European Pharmaceutical Industry Regulatory Landscape



upon existing legislation. The combination of these Directives ultimately echoes many provisions of the OIG, PhRMA Code, and ACCME Standards. For example, the 2004 Directive states, “hospitality at sales promotion events shall always be strictly limited to their main purpose and must not be extended to persons other than health-care professionals.”

In addition to the above directives, which address aspects of pharmaceutical sales and marketing, the EU developed legislation that mimics two key provisions of U.S. law relevant to the pharmaceutical industry, the False Claims Act and the Anti-Kickback Statute. With the passage of the European Union Conventions on Civil and Criminal Corruption, the EU adopted a common definition of corruption, offering specific guidelines of what constitutes a bribe as well protections for witnesses to fraudulent activities that resemble U.S. whistleblower provisions.

EU Regulatory Bodies

The EU enforces healthcare regulations and guidelines through a set of regulatory bodies, each focusing on different aspects of policy development and enforcement. Its regulatory framework is multi-layered, where EU regulatory bodies create legislation that is enforced by EU as well as member state enforcement agencies.

Again, the United States can be used as an analogy. In the U.S., regulatory functions such as drug approval and healthcare fraud investigation are pursued by different bodies. Further, voluntary trade organizations focus on providing guidelines in areas relevant to their members.

Drug Approval

Established in 1995, the European Medicines Evaluation Agency (EMA) is the EU’s equivalent to the U.S. Food and Drug Administration (FDA). Its primary charter is the evaluation, approval, and review of pharmaceutical and biotechnology products for marketing within the EU. Approval or withdrawal of any compound decided by the EMA is binding in all member nations, making it a powerful player in European healthcare regulation.

In addition to EMA’s centralized drug review process, it also supports a decentralized review process in which it collaborates with EU member state counterparts to support pan-European approval for drugs submitted at the national level. National counterparts include the United Kingdom’s

Medicines & Healthcare products Regulatory Agency (MHRA), Germany’s Federal Institute for Drugs and Medical Devices (BfARM), and similar national agencies across the EU.

Beyond drug approval and withdrawal, EMA pursues other healthcare law-related functions including publishing guidance documents and position papers on such topics as marketing practices, pharmacovigilance, and other critical areas.

Fraud Investigations

Two organizations are active in addressing pan-European healthcare fraud issues: the European Anti-Fraud Office (OLAF) and the European Healthcare Fraud and Corruption Office (EHFCO). Since 1989, OLAF has been the EU’s primary mechanism for fighting fraud. OLAF’s charter is similar to that of the Office of Inspector General (OIG) within each U.S. government agency. Both organizations focus on preventing and responding to fraud committed against government bodies within their respective purviews.

The EHFCO, still in its formative stages⁴, was created specifically to address

healthcare related fraud. It can be seen as a European analog to the Office Inspector General of Health and Human Services within the United States. As with the OIG, EHFCO includes in its charter the “Prevention, detection, investigation, and sanctions”⁵ related to healthcare fraud. Further, the EHFCO will

coordinate with fraud prevention offices in member nations, such as the United Kingdom’s Serious Fraud Office (SFO) and National Health Service Counter Fraud and Security Management (CFSMS) Investigators, to share best practices and provide procedural support to combat corrupt practices.

The combination of rising costs, increased media scrutiny and negative shifts in public opinion suggests that increasing regulatory scrutiny and related fines may soon follow.

Trade Organization Guidelines

As in the United States, European healthcare regulation is impacted by non-governmental guidelines, such as those developed by trade organizations. In the United States, three organizations play a major role in driving healthcare policy: 1) the Pharmaceutical Research and Manufacturers of America (PhRMA), the pharmaceutical industry trade organization, 2) the American Medical Association (AMA), the nation's largest physician's association, and 3) the Accreditation Council for Continuing Medical Education (ACCME), which maintains standards for providers of continuing medical education (CME). Europe has its own version of each organization with charters closely mimicking their U.S. counterparts.

Pharmaceutical Manufacturers Trade Organization

Founded in 1978, the European Federation of Pharmaceutical Industries and Associations (EFPIA) can be seen as a Europe-wide version of PhRMA, joining together national pharmaceutical industry advocacy groups to represent their common interests across the European continent. EFPIA brings together 29 European national pharmaceutical industry associations and counts as members 43 pharmaceutical firms operating in Europe, including many major U.S. firms. In addition to supporting industry interests involving intellectual property, trade, and other key commercial issues, EFPIA takes positions on several issues relevant to healthcare law, including a recent position on the disclosure of clinical trial data.

Like PhRMA, EFPIA has also developed voluntary guidelines for the promotional activities conducted by its members. The "EFPIA Code" or European Code of Practice for Promotion of Medicines⁶ covers much of the same ground as the PhRMA code, including rules on conducting promotional and information activities as well as guidelines on gifts and hospitality.

Physician Association

As in the United States, every European nation has a voluntary association representing the interests of physicians. In 1963, these national associations joined together to form a pan-European confederation representing their collective interests across the continent. The organization they formed is called the European Association of Senior Hospital Physicians

(AEMH). As might be expected, the AEMH plays a role similar to that of the American Medical Association (AMA), improving medical training and working conditions for its members as well as raising standards for patient medical care.

Also like the AMA, AEMH commissions working groups to develop positions on all issues relevant to its members, including healthcare law compliance. Its charter states, "In order to fulfill its purpose, the AEMH implements all appropriate and legal measures."⁷ As scrutiny of the pharmaceutical industry's interactions with physicians increases, it is likely that the AEMH will take more concrete action to maintain the positive perception of its members, as the AMA has with its guidance on "Gifts to Physicians from Industry."

Continuing Medical Education Association

Established in 1999, Europe's accrediting body for continuing medical education (CME) is the aptly named EACCME or European Accreditation Council for CME. As with its U.S. counterpart, the ACCME, the organization is primarily concerned with maintaining standards that ensure the quality and effectiveness of continuing medical education. In doing so, the EACCME developed accreditation guidelines for all members, which require accuracy, objectivity, and avoidance of conflicts of interest. Of particular interest to pharmaceutical manufacturers, the EACCME spells out guidelines for commercial funding of CME. These guidelines include provisions nearly identical to those laid out in the ACCME's Standards for Commercial Support, such as, "The provider must assure that the educational program approved for international CME credit is not influenced or biased by commercial organizations" and "Educational grants should always be made with no strings attached and should always be acknowledged in the printed program."

What's Next?

If we return to our "recipe" for regulatory scrutiny, it is clear that the EU has two necessary ingredients that may lead to an increase in healthcare industry fraud prosecutions: a framework of laws governing healthcare and a comprehensive set of regulators that develop and enforce policies. Meanwhile, Europe is facing increasing public healthcare expenditure, with spending rising significantly relative to GDP⁸. This environment of rising costs, combined with media scrutiny and negative shifts in

public opinion, best illustrated by the recent buzz in the UK over release of clinical trial data, suggests that increasing regulatory scrutiny and related fines may soon follow.

In future articles, we will offer similar primers on the healthcare law landscapes of additional international markets important to major pharmaceutical firms. We will also outline compliance strategies intended to support a global view of compliance, incorporating policies and business practices to reduce compliance risk across all relevant markets. ■

For more information visit:

EMA – www.emea.eu.int

OLAF –

europa.eu.int/comm/anti_fraud/index_en.html

EFPIA – www.efpia.org

AEMH – www.aemh.org

EACCME – www.eaccme.be

1 IMS 2003

2 http://europa.eu.int/lex/pri/en/oj/dat/2001/L_311/L_31120011128en00670128.pdf

3 http://europa.eu.int/lex/pri/en/oj/dat/2004/L_136/L_13620040430en00340057.pdf

4 EHFCO is expected to be fully operation by October 2005, according to planning documents developed by the European Healthcare Fraud and Corruption Conference

5 European Healthcare Fraud & Corruption Conference 2004

6 http://www.efpia.org/6_publ/codecon/Promomedicin_.PDF

7 www.AEMH.org

8 Regulating Pharmaceuticals in Europe, Mossialos 2004

Summary of EU Regulatory Bodies

Regulation Type	US Governing Body	European Union Equivalent
Drug Approval	Food and Drug Administration (FDA)	European Medicines Evaluation Agency (EMA)
Healthcare Fraud Investigation	Office of Inspector General (OIG) of Health and Human Services	European Anti-Fraud Office (OLAF) European Healthcare Fraud and Corruption Office (EHFCO)
Pharmaceutical Trade Association	Pharmaceutical Research and Manufacturers of America (PhRMA)	European Federation of Pharmaceutical Industries and Associations (EFPIA)
Physician Association	American Medical Association (AMA)	European Association of Senior Hospital Physicians (AEMH)
CME Standards Board	Accreditation Council for Continuing Medical Education (ACCME)	European Accreditation Council for CME (EACCME)

For more information about Polaris Management Partners, visit www.polarismanagement.com.

Part D Contracting and Fraud and Abuse Issues

Thursday, March 3, 2005; 1:00 p.m. – 2:30 p.m. Eastern Time

Speakers:

Bill Sarraille, partner in the firm's Health Care group who has counseled leading pharmaceutical manufacturers and others on the strategic and legal implications of the Part D benefit

Anna Spencer, senior associate in the firm's Health Care group

The teleconference will last approximately 90 minutes, and speakers will welcome questions. You will receive a dial-in number upon registering. RSVP ASAP to rsvp@sidley.com or by telephone at 202/736-8565.