SPECIAL REPORT

VOL. IV, ISSUE 3/MARCH 2, 2005

Rx COMPLIANCE REPORT

EXCLUSIVELY DEVOTED TO PHARMACEUTICAL SALES AND MARKETING COMPLIANCE

Scrutiny of pharma sales and marketing practices mounts worldwide

European regulatory trends pose serious challenge to U.S. companies, says expert

The pharmaceutical industry, already under siege by state and federal prosecutors for its sales and marketing practices in the United States, is now coming under significantly increased scrutiny worldwide. In some respects, the trend in Europe mirrors the trend in the U.S. where increased enforcement in recent years has come from a variety of state and federal agencies rather than the traditional agency, namely the Food and Drug Administration. Similar to the situation in the U.S., it is not the underlying statutes that have changed, it is their interpretation and enforcement. "The basic European Union-level legislative framework governing pharmaceutical marketing practices and manufacturers' relationships with physicians and other healthcare professionals has changed little for 13 years," says **Linda Horton,** a 30-year veteran of the FDA. "The rules were recodified in EU's 2001 Community code on medicinal products for human use and were tightened, slightly, in the April 2004 pharmaceutical review legislation." Nevertheless, Horton, now a partner with Hogan & Hartson in Brussels, Belgium, reports "a significant increase" in the level and intensity of enforcement activity involving various pharmaceutical marketing practices in "a wide range" of European countries. ▶ *Cont. on page 2*

Exclusive

State AGs cite "exploding" pharma caseload

Prosecutors from five states at ACI's drug pricing conference in New York yesterday said actions against pharma companies continue to rise dramatically. Assistant Attorney General **Patrick O'Connell** says Texas probably has "in excess of 100 open files," including many *qui tam* suits. Another Assistant AG reported roughly one new case filed against pharma each week.

That does not mean federal prosecutors plan to melt into the background. Assistant U.S. Attorney **Virginia Gibson** says the $2.1 billion recovered from pharma to date "is going to pale by comparison once the Medicare drug benefit goes into effect." Quality of care issues and antikickback laws will be "the two prisms" prosecutors will use to examine transactions under the new benefit, she says.

The next regular issue of *Rx Compliance Report* will cover the event in detail.

Drug manufacturers face increased enforcement of Foreign Corrupt Practices Act

A number of investigations of U.S. drug companies are underway in Europe and the Middle East concerning violation of the Foreign Corrupt Practices Act (FCPA), which prohibits any U.S. individual (including U.S. companies and their branches or affiliates) from offering or giving anything of value to foreign government officials. "This is not just a theoretical risk," warns **Joseph Tompkins,** a partner with Sidley Austin Brown & Wood in Washington, DC. "There are real investigations taking place right now. There are real cases that have been brought, and there are real people who will pay a price.". ▶ *Cont. on page 5*

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Scrutiny of pharma sales and marketing practices mounts worldwide

Horton says this has been accompanied by more stringent industry codes and a large number of governmental investigations. "Notably, enforcement is not being initiated only—or even principally—by traditional drug regulatory authorities," she reports. "Rather, from the north to the south of Europe, the challenges are being brought by prosecutors, tax police, competition authorities, and anti-corruption officials." Targeted activities include pharmaceutical companies' sales representatives' practices, the sponsorship of social activities in connection with medical congresses, and various company financial arrangements with medical experts.

Horton also reports that industry code bodies such as the European Federation of Pharmaceutical Industry Associations have recently tightened their rules, while national-level associations are handling increasing numbers of trade complaints.

Establishing global corporate practices

According to Horton, U.S. compliance and enforcement activities involving marketing practices have had a spillover effect on many companies' international operations. She says many global medical product companies are seeking to establish global corporate compliance policies for several reasons:

- First, drug companies have to decide what standards will govern operations of international affiliates when they put in place compliance programs to satisfy U.S. Attorneys and the Inspector General of the U.S. Department of Health and Human Services.

- Second, the precise source of a governmental enforcement action, or the country in which an issue might arise, can be difficult to predict. "The case may come from a prosecutor's office or government body with which the company has had little or no prior involvement," Horton explains. "Or it may be a competitor's complaint in one or more trade groups."

- As a result, Horton says, companies need to have solid, defensible compliance programs so that when an enforcement action or trade complaint occurs, the company has already put in place a robust compliance program including internal controls over marketing practices. "In some jurisidictions, diligent efforts to comply can result in dismissal of a case or mitigate a penalty," she adds.

- Third, she says, a company cannot easily put in place global strategies for the core business of developing and selling medicines (i.e., global Standard Operating Procedures governing operations) when local marketing practices are being determined solely at the local level.

- Fourth, efforts among chief executive officers to boost company image, emphasize the company's role in new product development, and maintain a high level of corporate integrity can be undermined as effectively by employees' improper activities abroad as in the U.S. CEOs find it difficult to understand, and even more difficult to explain, why a rule applies to dealings with doctors in one country but not in others, says Horton. "Word spreads fast in this information age if a company is in trouble abroad," she warns. Such bad news lowers stock value and may stimulate lawsuits or investigations by prosecutors and politicians elsewhere, warns Horton, noting the plethora of *qui tam* cases in the U.S.

- Fifth, in many countries, prescribers and purchasers of medicines are foreign government officials. The U.S. Foreign Corrupt Practices Act has long required companies to have rules on foreign affiliates' activities aimed at generating foreign governments' purchases, she notes (see related story, p. 1).

- Sixth, meanwhile, foreign governments are trying to manage spending on social security programs, including outlays for medicines. "Companies' marketing practices are a prime target for actions under criminal codes and anti-corruption, regulatory, or competition laws," says Horton.

- Seventh, U.S. officials interpret general U.S. statutes like Sarbanes Oxley (SOX) and the securities laws to include certain activities abroad. "Lax controls on drug sales representatives' travel and expenses might be viewed as a SOX issue," says Horton, "and the Securities and Exchange

Commission believes that companies must disclose material information about certain enforcement actions by foreign governments."

- Finally, drug companies are trying to better manage the big spending associated with current marketing practices, says Horton. "In the news last week were reports that several large companies contemplate possible reductions in large sales forces," she notes.

■ **Linda Horton,** Partner, Hogan & Hartson, Brussels, Belgium, LRHorton@hhlaw.com, Tel: [+[32 2] 505 0931/202-637-5795

Pharmaceutical marketing practices: European authorities tighten controls

By Linda Horton

Turning to national activities, and starting in northern Europe, the pharmaceutical industry in the UK has been through a tough year. As if the issues with antidepressant drug study data, flu vaccine, and COX-2 inhibitors were not enough, the UK Parliament's Select Health Committee held a much-publicized inquiry into the influence of the pharmaceutical industry on prescribing practice, patient groups, and regulators.

The inquiry closed earlier this month and a committee report will issue later this year. The evidence sessions held by the Health Committee since last July provided a forum for strident criticism of pharmaceutical companies. Singled out for particular criticism were the spending on marketing rather than R & D; what is viewed as selective publication of clinical trial data, particularly suppression of negative results; drug company representatives' "ghost-writing" of articles published with an expert shown as author; and company sponsorship of physicians to attend lavish conferences in exotic locations. Even a seemingly benign activity--support of disease awareness campaigns and sponsorship of patient organizations--came under attack, characterized by some Members of Parliament as "disease mongering." The UK Medicines and Healthcare products Regulatory Agency (MHRA) was accused of excessive closeness to industry, a pro-approval bias, and undue secrecy.

Although it is too soon to tell what legislative or other recommendations might emerge from the Health Committee's report, already the industry is tackling the issues raised. At the parliamentary inquiry, the Association of the British Pharmaceutical Industry (ABPI) defended the role of its Prescription Medicines Code of Practice Authority (PMCPA) in enforcing a code that elaborates on the requirements of EU and UK law. Certainly, of all the drug industry trade associations around the world, none has issued as much guidance on marketing practices as the ABPI, and no code enforcement body has handled as many adjudications as has the PMCPA.

Many rulings go against the company whose marketing practices were under attack. Still, further tightening is on the horizon in the UK.The ABPI is preparing to revise its Code of Practice rules regarding controls on the promotion of prescription medicines. Also, member companies have stepped up training and compliance activities, voluntarily refraining from certain marketing programs for products under safety reviews and posting clinical trial data.

Enforcement is on the rise in Sweden, with several prosecutions announced earlier this month.

The PMCPA caseload is on the rise, and counterpart bodies in other countries are likewise seeing an increase in trade complaints. An example of a successful challenge involved a competitor's offering of an ophthalmic lamp (valued at £175) or an educational grant (£250) to any clinician who started 20 patients on a ophthalmic drug product. This was seen as an inducement to prescribe the drug.

Concerning government action to enforce marketing rules, the MHRA possesses strong authority but has not, in the past, brought many cases, preferring to rely on the ABPI and its PMCPA. The last known case by the MHRA's predecessor, the Medicines Control Agency (MCA), was in 1988. Some observers believe that this may change given recent criticism against the backdrop of current concerns about drug safety and official secrecy.

Sweden imposes restrictions

Enforcement is on the rise in Sweden, with several prosecutions announced earlier this month. New agreements have been reached between the Swedish Association of the Pharmaceutical Industry and the organizations representing local goverenments, doctors, and the national drug purchasing authority on forms of cooperation between pharmaceutical companies and public-sector medical professionals.

Drug companies' ability to offer lavish marketing events and conferences to professionals has been severely limited. Restrictions include a cap on the level of reimbursment of travel expenses and costs for accommodation and food (50%); a requirement for invitations to scientific conferences to be sent to hospital management only, who then decide which healthcare professionals may attend; a ban on offering social activities (e.g. golf, theatre) in connection with conferences; and a ban on sponsorship of events organized by healthcare professionals themselves, such as hospital staff-parties.

Italian trade group initiates certification

Two developments in Italy are cases brought by tax authorities and new industry code requirements. Last May the Italian police force responsible for investigating economic crimes completed a two-year investigation into the drug industry's marketing practices. More recently, a number of cases have been in the news. In November 2004, a small U.S. company and its CEO became the subjects of a criminal investigation in Milan. The company is alleged to have paid a physician and hospital administrator in exchange for hospital contracts. In a second case, the Public Prosecutor for Verona is conducting an investigation involving 4,000 doctors and 300 officials of a global company. The allegation is that the company's sales representatives sought to influence doctors' prescribing preferences by offers of cash, cameras, computer equipment and holidays. In a third case in Florence, a major company is charged with illegal payments to doctors.

After these and other cases, the pharmaceutical trade association Farmindustria decided to require each member company to hire a 3rd-party body to audit and, each year, to certify the company's compliance with laws and the industry code on marketing practices. Drug companies are scrambling to meet the April 2005 deadline for the first certification.

Croatia

Transitional economies present special challenges to companies. In November 2004, a major pharmaceutical company announced an internal probe of its sales operations in Croatia, a country that will launch accession negotiations with the EU in a few years.

Pan-European initiatives

As noted earlier, the EFPIA (European Federation of Pharmaceutical Industries and Associations) has revised its Code of Conduct. The new Code bans choice of exotic venues for industry-sponsored conferences for healthcare professionals, tightens rules to ensure the predominance of scientific aspects of meetings, and draws a distinction between marketing practices and scientific informaiton activities of pharmaceutical companies. EFPIA comprises 29 national pharmaceutical industry associations and 43 leading pharmaceutical companies involved in the research, development and manufacturing in Europe of medicinal products for human use.

Two other governmental EU-level developments relating to marketing practices should be mentioned. One, the Draft Penalties Regulation, would allow the European Commission to penalize companies that violate rules related to European Medicines Agency (EMEA) product authorizations.

Also, the EU will launch, in October 2005, a new institution called the European Healthcare Fraud and Corruption Office (EHFCO). It will help EU Member States to coordinate enforcement activities rather than act as an enforcement body in its own right. The groundwork for the EHFCO has been put in place by bodies responsible for countering healthcare fraud and corruption in their country or region.

Among the practices which the EHFCO wishes to combat is the grant of material incentives by pharmaceutical companies to doctors practicing in public healthcare and to hospital staff responsible for procurement if they purchase from a particular supplier seeking to encourage purchase or prescribing of certain drugs.

In sum, the regulatory landscape in Europe is very challenging at present. ■

■ **Linda Horton,** Partner, Hogan & Hartson, lrhorton@hhlaw.com

▶ *Cont. from page 1*

Drug manufacturers face increased enforcement of Foreign Corrupt Practices Act

Tompkins says drug manufacturers should pay close attention to at least two trends. First is the continued vigorous enforcement of the FCPA by the Securities and Exchange Commission (SEC) and the U.S. Department of Justice (DOJ). He says both agencies have increased the size of their staff in this area over the last five years and he expects that trend to continue.

The second trend he points to flows from the Organization for Economic Cooperation and Development (OECD) Anti-bribery Convention, which he says "globalizes" the U.S. anti-bribery law. Over thirty countries are now party to that agreement. Now, he says, foreign governments may target U.S. companies under new FCPA-type laws. To the extent that companies have international operations or affiliates, subsidiaries or even sales representatives or agents outside the U.S., the FCPA must be on their list of things to be concerned about, says Tompkins.

A "surge" in investigations

In the pharmaceutical arena, there appears to be a surge in investigations taking place, reports Tompkins. One of the reasons for this, he explains, is that in many places such as Europe, South America, and the Far East, many of the hospitals and health care facilities are owned by the government and the doctors and other health care workers are considered government employees. As a result, some of the ongoing investigations, as well as some of the cases already settled, involve pharmaceutical companies giving something of value to a doctor or hospital for patient referrals or to get their drugs on the list of approved drugs for government reimbursement.

That restriction is very broadly defined in the FPCA, says Tompkins. "It does not only cover a government official," he says. "It also covers candidates for political office and parties." The law was recently amended to cover employees and officers from international organizations such as the World Bank, he adds.

Uneven enforcement cited

According to Tompkins, the FCPA has been unevenly enforced since it was enacted by Congress in 1977. After being largely dormant during the 1980s, he says, enforcement of the FCPA has been much more vigorous during the past decade. The Criminal Division of the U.S. Department of Justice now has a specialized unit of attorneys that oversee enforcement of the FCPA and the Enforcement Division of the SEC also has a group of attorneys and auditors engaged in FCPA investigations and compliance.

"This is not just a theoretical risk," says defense counsel Joseph Tompkins. "There are real investigations taking place right now. There are real cases that have been brought, and there are real people who will pay a price."

The FCPA contains two types of provisions. One is an anti-bribery provision prohibiting specified parties from offering or making a promise or payment to a "foreign official" for the purpose of acquiring business, obtaining an improper advantage, or influencing an official act. The other is accounting provisions requiring companies that issue securities under U.S. federal securities laws to maintain certain records, accounts and accounting controls.

According to Tompkins, the original purpose of the FCPA was to prohibit "issuers" under U.S. securities laws, along with U.S. citizens, resident aliens, and businesses organized under U.S. law, from making payments to foreign public officials in order to acquire or maintain foreign government business.

Since its enactment, however, the FCPA has been substantially revised twice, once in 1988 and once in 1998. "The 1988 amendment was intended to clarify and somewhat narrow the conduct subject to criminal sanctions," he says. "The 1998 amendment, in contrast, came into force on November 10, 1998, as part of the Anti-Bribery Act which significantly broadened application of the FCPA."

OECD "globalizes" the FCPA

A second critical trend Tompkins points to is the "globalization" of U.S. law by the OECD, which, in 1998, agreed to enact legislation similar to the FCPA. He says there were many complaints from U.S. companies competing with companies from other countries that were not bound by the same rules. As a result, the U.S. pushed the OECD nations to enact similar legislation. Five countries outside the OECD have since passed similar legislation.

The Convention was adopted and signed on December 17, 1997, by 33 countries, including the United States. All countries adopting the Convention committed to enact and enforce anti-foreign bribery laws, imposing criminal penalties for corrupt payments comparable to those otherwise applicable to bribery within the respective country's jurisdiction.

The OECD establishes standards in defining the offense of bribery of foreign officials, which is similar to the FCPA, says Tompkins. It requires parties to take all necessary measures to establish bribery of foreign officials as a criminal offense and adopt effective criminal penalties for bribery of foreign officials.

According to Tompkins, all ratifying countries have passed some form of implementing legislation. "The question is, what are these countries doing to enforce the law," he says, "and I think the answer is that it is kind of a mixed bag." Some countries are not enforcing it very much at all, he says, while others including Norway, Poland, and several other European countries, are consistently enforcing it.

Tompkins says the other significant part of the OECD agreement is that government agencies in these countries have agreed to cooperate with U.S. government agencies to investigate FCPA matters and trade information. "That has helped the SEC and the Department of Justice get information from other countries," he says.

SEC v. Schering-Plough

One of the most significant developments in this area came last year when Schering-Plough settled allegations for $500,000. Notably, the company's employees did not give anything of value to a government official. Rather, they gave a charitable donation to a foundation that had nothing to do with a pharmaceutical company. However, they did so at the request of a regional health official. The SEC took the position that qualified as an FCPA violation because they were allegedly trying to curry favor.

Specifically, a Polish branch office of Schering-Plough subsidiary, Schering-Plough Poland (SPP), paid approximately $74,000 to a Polish charitable foundation between 1999 and 2002. The founder of the foundation was the director of one of sixteen regional health authorities in Poland. While the foundation had nothing to do with health care, SPP's contributions were solicited by the director of the regional health authority.

The case was settled in June 2004. In addition to the $500,000 civil penalty for violating books and records provisions of FCPA, the settlement included a cease and desist order and the company was required to retain an Independent Consultant, approved by the SEC, to review and evaluate internal controls and record-keeping. The Independent Consultant's recommendations must be adopted by the company unless it can show them to be unduly burdensome, impractical or costly, and the company can propose an adequate alternative. ■

The Foreign Corrupt Practices Act: Enforcement and Penalties

I. Anti-bribery Penalties: Companies

Criminal penalties
- Up to $2 million criminal fine per violation

Civil penalties
- Up to $10K civil fine per violation

Collateral consequences
- Harm to public relations and reputation
- Inability to partake in U.S. government procurement or receive export licenses
- Unlawful FCPA payments are not tax deductible as business expense, but are taxable items

II. Anti-bribery Penalties: Individuals

Criminal penalties
- Up to $100K criminal fine per violation
- Up to 5 years' imprisonment per violation

Civil penalties
- Up to $10K civil fine per violation
- SEC may seek additional fines up to $100K based on expected profit

Collateral consequences
- Fines are NOT reimbursable by the company

Source: Sidley Austin Brown & Wood

The Foreign Corrupt Practices Act

Pharmaceutical companies are facing continued vigorous enforcement of the Foreign Corrupt Practices Act. In addition, they may be targeted by foreign governments under new FCPA-type laws. Here is a framework for looking at these laws developed by Joseph Tomkins and Paul Gerlach of Sidley Austin Brown & Wood:

Anti-bribery Rules Elements of FCPA Violation

- A "covered" person
- Must offer or give something of "value"
- To a "foreign official"
- To "obtain or retain business"
- With "corrupt" intent

Who is a "Covered" Person?

- Any foreign office, and any officer, director, employee, or agent, including foreign employees and agents
  - Issuers of registered securities in the U.S.
  - All U.S. citizens, residents, companies, and foreign branches of U.S. companies, and foreign branches of U.S. companies
  - Officers, directors, employees, and agents
  - Foreign companies or persons who commit acts in furtherance of corrupt payments while in the U.S.

What is "Value"?

- Offers to confer or conferring ANY benefit to recipient
  - Cash, reimbursements, extravagant hosted travel, non-monetary gifts, etc. to officials
  - Scholarships, contributions in name of official, etc.
  - Benefit to private person or entity at behest of official
- Applies to conduct "in furtherance of" corrupt payment, not just payment itself
  - Includes devising plan, processing check, etc.
- Need not be fully consummated or successful to create liability

Who is a "Foreign Official"?

- Foreign officials at all levels very broadly defined
  - Includes international organizations, political candidates and parties, government owned or controlled commercial enterprises, heads of government entities, etc.
- Private persons acting in official capacity
  - Includes ceremonial advisors, consultants, etc.

Is the Payment to "Obtain or Retain Business"?

- Payment made to obtain or retain business by:
  - Influencing any official act or decision
  - Inducing official to do or omit to do acts in violation of official duties
  - Securing any improper advantage
  - Inducing official to influence acts of government
- Need not relate to specific business opportunity
  - Business need not be with foreign government
- Bribes to reduce foreign duties/taxes can violate FCPA, but government must prove "business nexus"

Is There a "Corrupt" Intent?

- Benefit conferred or offered to induce foreign official to abuse or misuse his/her position or authority through action or inaction
- Quid pro quo generally assumed
  - Gift/payment made with reasonable expectations of some official favor in return
  - Quid pro quo need not be executed
  - Official need not be able to deliver "quo" herself
- Government need not establish defendant knew his/her conduct violated FCPA

Indirect Offers/Payments Prohibited

- Payments or offers/promises to pay any person while knowing all or portion of value will be given, directly or indirectly, to any foreign official are prohibited
- "Knowing" means:
  - Actual awareness
  - A firm belief as to the existence of such circumstance or that such circumstance will occur
  - A high probability of the existence of circumstance unless the person "actually believes that such circumstance does not exist"
  - No "willful blindness" - i.e., conscious disregard or deliberate ignorance of known circumstances that should alert one to FCPA violations is not permitted

Exceptions and Affirmative Defenses

- Exception:
  - "Routine" governmental action (i.e., "grease payments")
- Affirmative defenses
  - Payments authorized by written foreign law
  - Bona fide business expenditures

Exception: "Routine" Governmental Action

- Anti-bribery rules do not apply to payments to secure "routine" governmental action
- Examples:
  - Obtain permits, licenses, visas
  - Secure police protection, timely official inspections
  - Provide phone, mail, power, water service, loading/unloading cargo, protecting perishable products
  - "Actions of a similar nature"
- Ministerial acts, not discretionary actions
- Perform official function faster, not make a different substantive decision

Affirmative Defense: Written Foreign Law

- Lawful under WRITTEN law of host country
- Informal business customs or practices NOT covered
- Examples:
  - Lawful political contributions, modest gifts, training of officials
- Limited utility
- Significant downside risks

Affirmative Defense: Bona Fide Expenditures

- Reasonable business expenditures
  - Directly related to legitimate promotional or contract activities
  - Reasonable under the circumstances
  - Bona fide and made in good faith
- Examples:
  - Reimbursement for travel, meals, entertainment
  - Product samples

Source: Sidley Austin Brown & Wood

Key requirements for an FCPA compliance program

I. Components of an effective FCPA compliance program

Clearly stated FCPA policy and procedure
Description of the FCPA
Company policy prohibiting violations
Procedure to be followed before engaging in any foreign joint venture or foreign representative agreement

- Periodic FCPA training sessions
- Periodic certification of FCPA awareness and compliance
- Periodic internal audit review of contracts with and payments to foreign agents

II. Investigating and documenting agreements with foreign agents

Investigating potential foreign consultants/agents
Consultant questionnaire
Consultant's reputation, business history, past and present clients
Use local counsel, U.S. Embassy, State and Commerce Departments

Preparation of consultant agreement
Representations and warranties (re: compliance with FCPA, other U.S. laws)
Compliance with foreign country's laws and regulations
Periodic certification of compliance with FCPA
Consent to review consultant's books and records, if needed

III. Investigating and documenting agreements with foreign agents

Documentation of compliance efforts
Investigation and agreement
Review and approval process followed
Audit/internal payment controls

Source: Sidley Austin Brown & Wood

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.

"Recipe" for Regulatory Scrutiny

Increasing Public Healthcare Expenditure
+
Robust Regulatory Framework
+
Motivated Regulators
+
Media Scrutiny
+
Increasingly Unfavorable Public Opinion
=
Potential for Increased Healthcare Fraud Prosecutions

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 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.

In the 1990s, the focus of EU pharmaceutical regulation was to develop a unified process of drug authorization and to establish GCMPs.

Today, the target appears to be shifting, with more emphasis being put on marketing and sales ethics.

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

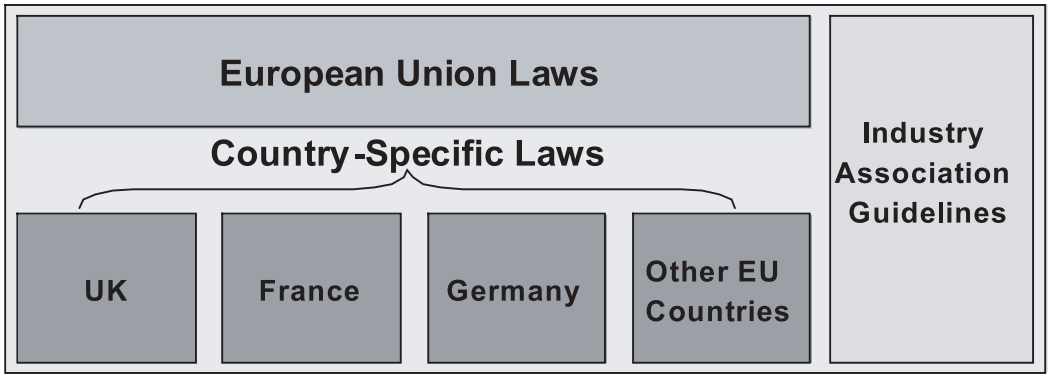
At a high level, EU law consists of four main types of legislation — regulations, directives, recommendations, and decisions. Regulations and directives are the most relevant to our discussion because they are applicable to all member states and their enforcement is mandatory.

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/EC[2] and 2004/726/EC[3], 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 (EMEA) 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 EMEA is binding in all member nations, making it a powerful player in European healthcare regulation.

In addition to EMEA'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, EMEA 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 stages[4], 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 Medicines[6] 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 GDP[8]. 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:

EMEA – 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/eur-lex/pri/en/oj/dat/2001/l_311/l_31120011128en00670128.pdf
3 http://europa.eu.int/eur-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 (EMEA)
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)

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Matthew Hay, Editor & Publisher
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107 S. West Street, P.M. 320, Alexandria, VA 22314
Phone: 703/960-0034 Fax: 703/960-0079
RxCompliance@aol.com
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Rx Compliance Report is published 24 times a year. Subscription price is $599 per year.