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The International Comparative Legal Guide to:

# Pharmaceutical Advertising 2005

## A practical insight to cross-border Pharmaceutical Advertising work


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Chapter 5

# Building a Shield: Compliance Plans


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## Today's Difficult Enforcement Environment

Our prescription for pharmaceutical and medical device companies trying to cope with an increasingly difficult enforcement climate is a robust corporate compliance programme. As we discuss in this chapter, "building a shield" requires not only strong internal corporate policies, but also meaningful standard operating procedures, training, and monitoring. The objective is to reduce the risk of non-compliance. In many enforcement scenarios or industry code proceedings, a well-documented effort by a company to put in place strong compliance policies, SOPs, training, and monitoring may reduce the risk of serious penalties.

### Marketing pharmaceuticals and medical devices today

Today companies do much more than publish print advertisements in medical journals and send sales representatives to visit doctors, armed with large satchels full of product literature, samples, and medically oriented gifts, often with the company logo or the product name. These traditional activities continue as core features of companies' advertising and marketing programmes, complemented in the United States and New Zealand by direct-to-consumer advertising for certain types of products.

While print ads and detailing still are key tools for acquainting health professionals with drugs and devices, today it also is common for a manufacturer to be involved in a wide range of marketing activities, as well as scientific and educational relationships, with health care professionals.

Around the world, the pharmaceutical and medical device industries are subject to stringent laws affecting advertising and marketing of their products. What is allowed varies from one country to another, but many companies have engaged in such activities as company-sponsored marketing or educational events, educational programmes for medical students or fellows, continuing medical education, sponsorship of doctors' attendance at medical congresses (still common outside the United States), sponsorship of booths or other elements of medical congresses, satellite symposia, consultancies and expert boards, speaking engagements and speaker training, research grants, clinical trials, non-interventional studies, writing of journal articles, market research, provision of educational books, anatomical models, and other educational materials, donations of equipment, and charitable contributions.

### Problem areas: off-label use, payments, and hospitality

Sponsorship of events can raise numerous legal issues. What if there are discussions of unauthorised products or unauthorised uses of approved products? As discussed elsewhere in this book, laws vary, but whether off-label discussions are permitted often depends on whether an event is viewed as a promotional activity or as a scientific or educational programme.

For what purposes may a drug or medical device company give money or other pecuniary benefits to a doctor? While it is understood that payments for prescribing are strictly forbidden in many parts of the world, under what circumstances may doctors be hired as speakers, investigators, or consultants without such arrangements being viewed as improper inducement?

What kinds of hospitality may be funded by companies in connection with promotional events or with scientific or educational programmes? It is in this area where change has been particularly rapid, at least in North America and Europe, yet is one in which companies are still getting into trouble with authorities and code bodies. Increasingly regulations or industry codes forbid certain forms of entertainment altogether, such as tickets to sports events, or seek to ensure that medical content predominates over hospitality.

It appears that those company relationships with healthcare professionals that involve off-label use, payments to doctors, or subsidy of travel and entertainment are the ones most likely to attract attention from regulators, prosecutors, and code officials. Officials are looking for evidence of illegal inducements to prescribe or use products-forbidden under many countries' drug or medical device regulatory laws-or violations of various criminal code provisions.

In several countries, "dawn raids" have sent shockwaves through global and local companies doing business there. Among the laws recently cited in such investigations, and involving pharmaceutical or medical device companies' relations with healthcare professionals, are ones that forbid bribery, kickbacks, waste of public healthcare funds, or even tax evasion. Criminal or civil remedies might be invoked, particularly where there is concern that company payments influenced the choice of products funded by a public healthcare system. Where such factors are present, the doctors as well as the drug or medical device company may get into trouble.




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### What laws are being enforced

In many cases, the laws in question are ones that have been on the books for some time but, without question, are being enforced more now than in the past. Take, for example, the situation in European Union member states. The basic EU-level legislative framework governing pharmaceutical marketing practices and manufacturers' relationships with physicians and other healthcare professionals has changed little since 1992. The rules were recodified in the 2001 European Community code on medicinal products for human use. They were tightened, but only slightly, in the 2004 pharmaceutical review legislation. Overall, however, the legislative framework has been relatively stable and there is virtually no activity on this issue in the European Commission or European Medicines Agency.

What is different is increased enforcement in all parts of Europe, from Sweden and the UK in the North to Italy in the South, from Spain and France in the West to Poland and Turkey in the East. We have been tracking enforcement trends and at the end of this chapter give examples of the kinds of activities that have been targeted by government bodies in Europe.

### Role of industry codes

Also important in this field are industry codes and, here too, there is a trend toward more enforcement as well as a great deal of redrafting. Codes in France, Italy, Spain and the UK have been stringent for some time, reflecting the restrictive regulatory laws in those countries. Stricter codes have been put in place for Europe as a whole as well as Denmark, Hungary, Italy, Norway, Sweden, Switzerland, and the United States.

A revision of the European Federation of Pharmaceutical Industry Associations code will become effective January 1, 2006, and this revision will result in further changes in national-level codes by the relevant industry organisations. Hospitality in connection with marketing events will be severely limited, the rules against subsidising attendance at events by spouses at congresses are reiterated, and the continued applicability of country requirements and codes when doctors attend events outside their home countries is clarified. The EFPIA code has little coverage of scientific and educational activities, but many European country codes do regulate this topic to some degree. For example, association rules in both Sweden and Switzerland are requiring doctors to pay part of their expenses to medical conferences.

In Italy the trade association Farmindustria responded to a particularly challenging enforcement environment by adding a requirement that each member company employ a third-party body to assess compliance with the association's code.

### Crackdowns in the United Kingdom and the United States

In the United Kingdom a critical report by the House of Commons health committee, concerning the Influence of the Drug Industry, appears likely to generate an uptick in enforcement by the Medicines and Health product Regulatory Agency on advertising and marketing compliance, among other areas. At the same time, the Association of British Pharmaceutical Industry (ABPI) intends to maintain the high profile of its code enforcement body and is revamping and tightening its code of practice.

In the United States, the Neurontin settlement with Warner Lambert (Pfizer) is simply the most publicised example of the rising tide of U.S. enforcement actions. No discussion of corporate compliance plans would be complete without mention of this case, as the conditions of its settlement have been replicated in other companies' compliance programmes. Pharmaceutical and medical device companies cannot do business in the United States without being aware of the panoply of requirements, industry codes, and "guidance" governing their advertising, marketing and relationships with health professionals emanating not just from FDA and trade associations like PhRMA and AdvaMed, but also from the Office of the Inspector General, various U.S. Attorneys offices, and now the State of California. This regulatory Tower of Babel has led PhRMA to request that FDA be allowed to reassert its principal regulatory role in this arena.

### Special issues for U.S. companies

U.S. compliance and enforcement activities involving marketing practices have had a spillover effect on many companies' international operations. Also, for many years U.S. companies doing business abroad is the need to obey the Foreign Corrupt Practices Act in their employees' dealings with health care professionals who are public employees. Some practices that have been common industry practices may be construed as bribes by U.S. or foreign enforcement authorities.

Still to be determined is whether Sarbanes-Oxley, and similar corporate integrity laws in other countries, will have an impact on medical product marketing. For example, lax controls on drug sales representative's travel and expenses might be viewed as a Sarbanes-Oxley issue. Additionally, the Securities and Exchange Commission takes the position that companies must disclose material information about certain enforcement actions by foreign governments.

### Diversity of enforcement bodies

Concerning pharmaceutical advertising and marketing practices, what distinguishes this area of regulatory vulnerability from others is the marked uncertainty about the direction from which governmental "strikes" will occur. In many countries it is not simply, or even principally, traditional drug regulatory agency officials regulators that are coming after companies due to alleged marketing violations. Rather, a wide range of prosecutors with whom companies may have no established relationships are seizing documents and making public accusations.

### How long will this go on?

We see no end in sight to the wave of enforcement. In fact, the negative publicity connected with the recent drug safety debate has focused upon widespread industry practices involving both promotional efforts and various relations with health professionals. Regulators have gotten the message from politicians and the public that they are supposed to "get tough" on the drug industry.

Governments are trying to manage spending on social


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security programmes, including outlays for medicines, which means that companies' marketing practices are a prime target for actions under criminal codes and anti-corruption, regulatory, or competition laws.

These recent trends, coupled with the fact that public money is spent on pharmaceuticals and medical devices, mean that enforcement bodies will continue to crack down on company practices believed to increase inappropriate product use.

Where both the source of a possible attack and its timing are unclear, a company's best offense is a good defence: it needs to establish a compliance culture and "build a shield."

## Building a Shield

### The compliance plan

In the face of this dynamic and threatening enforcement climate, how can prudent business organisations protect themselves? There is no simple answer, but one necessary ingredient is the creation and implementation of a corporate compliance plan. Through such plans, organisations can structure their business activities to address regulatory risks and to reduce the possibility of unacceptable behaviour by employees.

Historically, to the extent corporations thought about compliance, most viewed it as a legal function directed at responding to discrete matters. The lawyers were not expected to prevent the problems, just deal with them after they surfaced. As the enforcement environment has become increasingly stringent, however, it has become apparent that a primarily reactive approach does not suffice. Instead, corporations need to understand that compliance issues pose business risks that must be actively managed like any other business challenge. What does this mean in practice?

### Standards and policies

The foundation for any compliance plan is the issuance of standards and policies to guide business conduct. Since pharmaceutical and device manufacturers typically operate in multiple jurisdictions, there must be an undertaking to identify all applicable guidance for each jurisdiction. Consideration should be given not only to legal requirements, but also to standards of conduct contained in industry codes such as the ABPI. That information then needs to be translated into policies, using language and examples that can be readily understood by the business people who have to follow them. Although there may be certain legal requirements that are unique to a particular jurisdiction, the policies should attempt to set forth broad standards of ethical conduct that should be considered generally acceptable. For example, many countries impose a limit on the monetary value of medically relevant gifts that may be given to health care providers, but those limits vary widely from country to country. Instead of developing separate policies for each country, a corporation might establish a modest standard that would need to be modified only for those countries with extremely low limits.

### Procedures

Policies alone do not offer sufficient protection. For each policy, detailed procedures should be developed that set forth the steps to be taken to ensure that there is compliance. Taking again the example of gifts, the procedures would explain the form of any gifts, the necessary approvals, and the documentation that must be completed. The latter aspect is crucial, because the documentation forms the basis for subsequent efforts to confirm compliance. The process of developing standards often identifies serious flaws in the underlying business practices that require correction, even apart from compliance considerations.

### Assignment of compliance responsibility

Policies and procedures are just pieces of paper (or computer bytes). To have an effective compliance plan, employees in sales and marketing need to know that compliance is part of their jobs, and there must be personnel charged with seeing that the compliance plan is being implemented and followed. The status of personnel assigned to that job speaks volumes about the corporation's priorities. Responsibility should be vested with a high level manager who has access to the highest levels within the organisation. Although the chief of compliance need not be a lawyer, access to sophisticated legal advice is absolutely necessary, and that advice needs to be consistent across the business organisation to the maximum possible extent, taking into account the requirement to comply with national variations that are even more stringent than the company's general norm.

### Training, access to policies and reminders

Likewise, policies and procedures have no value if employees do not know about them. Thus, part of the compliance mission is to educate and train employees about the policies and procedures. To ensure that compliance is not merely a footnote, this training should be fully integrated into standard sales training and made a part of strategy meetings. Compliance materials should be readily accessible on-line, as should testing and evaluation tools. Every opportunity should be taken to remind employees of the organisation's ethical precepts and to provide them with the information they need to act according to those precepts.

### Employee evaluation

Another way to assure compliance awareness and competency is to incorporate compliance considerations into the employee evaluation system. Supervisors, and the employees themselves, should be asked to comment on the employee's compliance record and the steps taken to attain the necessary awareness and competence. In this way, the organisation can send a strong message that compliance is an essential component of performance.

### Monitoring and auditing

No matter how good the training materials or the associated educational effort, experience teaches that some employees do not, or will not, act as expected. For this reason, it is not enough to issue policies and train people. Organisations also


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must take steps to assess the extent to which business conduct conforms to compliance standards. This is best accomplished through a system of monitoring and auditing.

**Monitoring** looks at broad patterns of activity, while auditing looks at particular transactions. For example, a monitoring system might measure the total amount of spending on certain programs or the totality of the financial relationship with particular institutions or health care providers. Such monitoring, by itself, would not necessarily show that there were any departures from policy, but it would enable the organisation to focus its resources on the areas most likely to raise issues.

**Auditing**, on the other hand, examines whether particular events or contracts, including the associated paperwork, complied with corporate policies and procedures. Indeed, the procedures should be designed with an eye toward identifying approvals and documentation that can be readily audited.

Typically, the auditing process engenders a certain amount of nervousness, and even resistance, among the employees whose transactions are being checked. To mitigate those reactions, it can be helpful to emphasise that the primary purpose of auditing is to ensure the effectiveness of the procedures and related training and that often issues can be addressed through adjustments to the procedures or further education. The possibility remains, however, that auditing may in fact identify instances of serious misconduct and those situations must be addressed.

### Dealing with non-compliance

As just noted, even with all of these efforts, the reality remains that no compliance programme can provide absolute protection against violations of policy, or even of law. What an effective plan can do is help ensure that any improper conduct is isolated and contrary to established written policy. Moreover, the better the procedures to implement the policies, the more likely it is that violations will involve instances of falsification or other forms of deceit by employees seeking to circumvent the policy. Typically, such a fact pattern puts an organisation in a much stronger position to address any questions from outside parties such as government bodies or trade code enforcement groups.

In any event, the critical consideration is whether the organisation responds to violations in a way that is consistent with its overall compliance objectives. Naturally, one aspect of a response is the application of appropriate discipline commensurate with the violation. For a plan to have credibility, it is essential that discipline include everyone who participated in a material way, not just lower level employees. It is important as well that the organisation learn from its problems by taking steps to understand why the violation happened and identify changes to the procedures that might avoid recurrences. Finally, the organisation must determine whether the violation is of a type and scope to warrant some form of disclosure to regulators.

### Compliance plans that work; avoiding ones that are unrealistic and unachievable

All of these considerations argue strongly for the development and implementation of a compliance plan. How is that best accomplished? There may be some inclination to view the creation of a compliance plan as primarily a drafting exercise: the task is simply to write down the expectations and policies and to publish them. "Best practices" can be identified from a range of sources an put into the corporate compliance plan.

The problem with this rather idealistic and academic approach is that it can create standards for the organisation, without taking steps at the same time to change behaviour. In the event of a problem, the gap between what the company says it does, and what its employees do in fact, can result in an enforcement nightmare - not only bad conduct, but also bad documents.

A better and more pragmatic approach is beginning with an assessment of the organisation's current understanding and approach to regulatory compliance. Such an assessment can identify existing practices that already promote compliance as well as gaps that need to be filled. For multinational corporations, it will be necessary to identify any country-specific laws (as well as overall EU directives) that need to be considered.

Another necessary step in an assessment is the identification of those business activities that should be the subject of policies and procedures. The greater the enforcement risk, the greater the level of controls that should be considered.

## Striking the Right Balance, Where Laws are Unharmonised

Finally, and critically, an organisation contemplating the establishment of a compliance plan that will operate in multiple jurisdictions must consider the advisability of developing standards of behavior that will be consistent, and lawful, across as many jurisdictions as is possible. Such an approach could not take full account of country by country variations that may arguably allow a wider range of behavior, but any losses in business flexibility would be compensated for by the ability to operate a more integrated compliance plan, with common expectations about acceptable conduct.

A company cannot easily put in place global strategies for its core business, developing and selling medicines and medical devices, if local marketing practices are being determined solely at local level. Furthermore, efforts by Chief Executive Officers (CEOs) to boost company image, emphasise the company's role in new product development, and maintain a high level of corporate integrity can be undermined when publicity erupts about improper activities by corporate employees whether in the company's home country or abroad.

After all, word spreads fast in this information age, if a company is in trouble. Bad news can lower stock value and can cause talented employees to seek work elsewhere. Worse, publicity about drug and medical device sales representative misconduct, even in another country, might stimulate prosecutorial investigations in the United States (U.S. qui tam cases, for example). It is, therefore, increasingly risky for global companies to leave entirely to local country managers, lawyers, and regulatory officials the task of achieving compliance with local laws.

At the same time, those in a company who are familiar with local requirements, as well as the local organisation's


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business managers, need to be engaged in building the compliance program at local level. It is critical to identify local customs, such as lavish gift-giving or hospitality, that create compliance challenges. What is particularly difficult is a situation where a practice viewed as suspect or even corrupt in highly developed markets (say, cash gifts from sales representatives at a doctor's family wedding or funeral) may be regarded as acceptable, or even expected, in a non-Western, developing, or transitional economy. In such cases, the practice needs to be carefully examined. When the company decides it must or should disallow observance of the local custom, it needs to take particular care to back up its decision with training. It also might need, for example, to arm sales representatives with polite explanations that can be provided to health professionals who request a favour that had in the past been permitted (and might still be provided by competitors). Also, because employees in markets who are forced to give up a previously accepted practice are at particular risk of "backsliding," the company needs to do more than train and explain. It also must implement an intensified level of monitoring and audits, to reinforce the adoption of the corporate ethical standard.

In some cases, the company might decide it can and should tolerate a local deviation that is fully lawful where practiced, even though it has been abandoned in wealthier markets. The issue of samples, donations, and supply of educational materials come to mind. In wealthier markets the practice of supplying samples is much less common than in years past, and strict U.S. and EU regulations have contributed to this trend. In less affluent countries, samples and starter packs may be expected, and drug companies could not easily abandon their distribution. Concerning charitable contributions and educational materials, it may be essential to insist that, in the United States, donations be made only to organisations possessing 501(c)(3) status under U.S. tax laws. A similar approach would be workable in the UK, which has an analogous mechanism for identifying charities whose donors enjoy special tax privileges. But to apply in a developing or transitional economy a requirement that only tax-exempt charities may receive corporate donations may be a limitation that unduly impedes corporate philanthropy to worthy charities providing healthcare services to those who are most needy. In such cases, the company can put in place alternative criteria to ensure the transparency of its donation as well as the legitimacy of a charity (e.g., that it is not a front for a doctor's private fund). Similar criteria can govern provision of medical books and other educational materials, e.g., that these be given only to institutions and not to individuals (as is required in some jurisdictions but anyway).

## Enforcement Trends That Make Compliance Plans a Dynamic Process

We have emphasised how your compliance plans need to be pragmatic instruments, with a large core of common elements but some room for local adjustments. In this section of the chapter, we offer illustrations that both demonstrate recent enforcement trends and have some predictive value for the future.

### Italy

Italy is a country that many people associate with loose business practices and cronyism. Despite this reputation (or perhaps because of this reputation and the country's effort to overcome it), Italy actually is one of the countries with the harshest enforcement environment for pharmaceutical companies.

What is happening in Italy could foreshadow what could happen in other countries who decide to upgrade their ethical practices, e.g., in preparation for EU accession.

In this regard, two developments in Italy are worthy of note: enforcement (e.g., use of tax laws as authority for audits of company spending) and a new industry code with several novel features.

In May 2004 the Italian police force responsible for investigating economic crimes completed a two-year investigation into the drug industry's marketing practices. Six months later, a small U.S. company and its CEO became the subject of a criminal investigation in Milan. The allegation is that the company paid a physician and the hospital administrator the sum of €13,500 in exchange for hospital contracts. In a second case, the Public Prosecutor for Verona has conducted 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 enforcement action, a major company is charged with illegal payments to doctors in Florence.

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

### Sweden

Of all the countries in Europe in which authorities have stepped up their enforcement activities concerning pharmaceutical marketing practices and relationships with healthcare professionals, Sweden stands out in terms of both increased enforcement and unusually stringent rules.

A chief prosecutor responsible for fraud cases recently launched an investigation of alleged corruption in the industry. At least two cases are being pursued. What is clear is that Swedish authorities hold strict views of pharmaceutical industry marketing practices. In April 2005 a major Swedish newspaper reported that a chief prosecutor who has been investigating corruption in the pharmaceutical industry has chosen several cases for enforcement action from among ones that already have received negative findings from the Swedish industry association's marketing practices committee. In one case, he was reportedly considering bringing a charge against a major company for sending approximately 30 doctors and nurses to a conference, paid for by the company, in Prague.

This harsher approach follows the adoption of new agreements, between the pharmaceutical industry and the organisations representing local governments, doctors, and the national drug purchasing authority, on the various forms of cooperation between pharmaceutical companies and public-sector medical professionals. January 1, 2005 marked the entry into force of one such agreement, between


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the Swedish Association of the Pharmaceutical Industry and the Swedish Federation of County Councils. It covers various types of cooperation between pharmaceutical companies and medical professionals in the public healthcare sector. Similar agreements have been signed between the same industry association and the Swedish Medical Association, as well as between the industry association and a government drug purchasing body known as Apoteket.

With these agreements, drug companies' ability to offer lavish marketing events and conferences to professionals has been severely limited. Restrictions include a cap on the level of reimbursement 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 will decide which healthcare professionals may attend; a ban on the offering of social activities (e.g. golf or theatre) in connection with conferences; and a ban on drug company sponsorship of events organised by healthcare professionals themselves, such as hospital staff parties.

The agreements stem from controversy that erupted in Sweden in 2002, and that continues, regarding pharmaceutical companies' payments to send doctors to conferences with minimal scientific content, at luxurious locations. The new agreements aim to ensure that activities involving the pharmaceutical industry and the healthcare sector are conducted in a responsible and relevant manner.

The new agreement with the Swedish Federation of County Councils extends to all employees within the public healthcare sector, in their contacts with pharmaceutical companies and with Swedish marketing companies within the pharmaceutical industry. It applies, as well, to subcontractors. The Swedish marketing companies have furthermore undertaken to ensure that the rules set out in the agreement are observed by their parent companies, and other subsidiaries of their parent companies, in their activities in, or targeted at, the Swedish market. Similarly, public healthcare, hospital and clinic management is expected to ensure that the terms of the agreement extend to private healthcare subcontractors through reference to the agreement in applicable sections of their contracts.

The agreement is legally binding on the parties, and it is supervised by the Swedish industry association's marketing practices committee, which can issue decisions and levy fines of up to about Euro 22,500 (SEK 250,000) when it deems them necessary. However, it should be noted that the Swedish county councils have considerable autonomy in healthcare and that every county must also agree separately with the terms of the agreement. While some county councils have not yet done so, others have decided the agreement with the council did not go far enough and have closed down their doctors' contacts and cooperation with the industry.

Although enforcement activities to date seem to be concentrated in the pharmaceutical sector rather than the medical device industry, it is advisable for companies in the latter industry to consider adopting practices for dealings with health care professionals that parallel those in place in the pharmaceutical industry, especially when the professionals are public employees. Some of the laws under which the Swedish authorities are investigating pharmaceutical companies, e.g., anti-bribery laws, are equally applicable to the medical device industry. Of particular note is the fact that these laws may apply to activities involving Swedish health care professionals that take place outside of Sweden. For example, a device maker who intends to pay for Swedish doctors to come to the U.S. for some type of event, perhaps involving instruction about the use of a particular device, needs to consider whether the arrangements may put the company and the doctors at risk.

The Swedish tougher stance on information and promotion activities could be seen as part of a new trend affecting the pharmaceutical industry's marketing practices in Europe. Denmark, Germany, and Norway have taken similar measures recently.

### The United Kingdom

In April 2005 the UK Parliament's Select Health Committee issued a report on the influence of the pharmaceutical industry. For the previous half-year it had underway a much-publicised inquiry into how the industry influences prescribing practice, patient groups, and regulators.

The parliamentary committee report was harshly critical of the industry as well as the UK Medicines and Healthcare products Regulatory Agency, which was accused of excessive closeness to industry, a pro-approval bias, undue secrecy, and lack of regulatory effectiveness. Singled out for particular criticism were a number of practices relevant to our current discussion: industry's 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 or contractors "ghost-writing" articles published in the name of a recognised expert; 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 organisations--came under attack, with some Members of Parliament calling this "disease mongering."

Already the industry is tackling the issues raised. At the parliamentary inquiry, the 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, have voluntarily refrained from certain marketing programmes for products under safety reviews, and are posting clinical trial data.

The UK parliamentary report is having an impact outside Great Britain. It reportedly is being read by officials in Scandanavian countries (which, as noted above, already have tight marketing codes) who wish to place additional restrictions on drug industry interactions with health care professionals.


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Increased client demand for EU legal services--particularly innovative companies in the pharmaceutical and medical device industries--led the firm to send her to Europe in 2004.

In Brussels Linda Horton leads a versatile team of 14 attorneys of multiple nationalities on pharmaceutical, medical device, and health law counseling. She works closely with the highly regarded food safety expert, EU regulatory affairs advisor Jacqueline Mailly, as well as attorneys in the firm's other 20 offices. Linda Horton's practice focuses on EU and U.S. regulatory strategies, advertising and marketing practices and company activities with health professionals, clinical trials, innovator rights and approval issues involving medicines, medical devices, and combinations. She also assists countries seeking to improve their legislative frameworks.

Linda Horton has taught international food, drug, and medical device law at the Georgetown University Law School (where she earned an LL.M. in international and comparative law in 1997) and FDA administrative law at George Washington University (where she received a J.D. in 1975). She was a charter member of the editorial board of the Food and Drug Law Journal and chaired the board in 1985-86. She served on the board of directors of the American National Standards Institute (ANSI) from 1994-99, and received an award for averting a U.S.-EU medical device standards dispute.

Since 2000 Linda has served on the board of the Regulatory Affairs Professional Society. She is admitted in the District of Columbia and Maryland.

## Building a Shield: Your Compliance Plan

In sum, taking into account the enforcement climate in many of your key markets, it is simply good business to put in place a robust compliance plan. Like effective laws, effective compliance plans are not merely words on paper, honoured officially but ignored on a day-to-day basis. Rather, a robust corporate compliance policy is developed through a comprehensive understanding of how you do business and builds upon the things you already are doing right. When the policy is girded by a system of structure of procedures, training, monitoring, and audits, you can more effectively manage and reduce the risk that the actions of a few employees might besmirch a corporate reputation and image achieved over decades of hard work and accomplishment.

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## HOGAN & HARTSON LLP

Hogan & Hartson has nine U.S. offices (Washington, D.C., New York, Baltimore, Northern Virginia, Miami, Boulder, Colorado Springs, Denver, Los Angeles), nine European offices (Berlin, Brussels, Budapest, London, Moscow, Munich, Paris, Prague, and Warsaw), and three Asian offices (Beijing, Shanghai, and Tokyo).

The firm was founded in 1904 and today is the largest and oldest law firm based in Washington, D.C. As the economy and clients' businesses globalised, so did Hogan & Hartson. The firm's over 1,000 lawyers work seamlessly across multiple practices and offices to provide clients with exceptional service and creative advice. Operating at the intersection of business and government, the firm's attorneys help clients structure and complete their projects and transactions; guide their businesses through the maze of government regulation; secure and defend their intellectual property; and vigorously represent their interests in all kinds of complex litigation and dispute resolution. The firm is consistently ranked among the top global law firms in industry surveys and major publications.

Hogan & Hartson's health practice, and its food, drug, medical device, and agriculture practice, together rank among the largest, most unique, dynamic and comprehensive in the world. Whether the project entails helping a start-up company obtain marketing approval from FDA for a life-saving therapy; representing a multinational corporation in a U.S. Department of Justice criminal investigation; counseling a company on FDA and EU requirements for clinical trials, advertising and marketing practices, or inspections; or taking clients to visit with the U.S. Congress or the European Parliament, the firm's attorneys and regulatory affairs specialists use their extensive, diverse experience to develop effective solutions to client needs. Wherever clients need help, Hogan & Hartson has a complete understanding not only of complex legal requirements, but also of the industries in which its clients function. The firm is noted for solid working relationships with the government agencies that regulate them, around the world and today has more FDA alumni than any other firm.


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