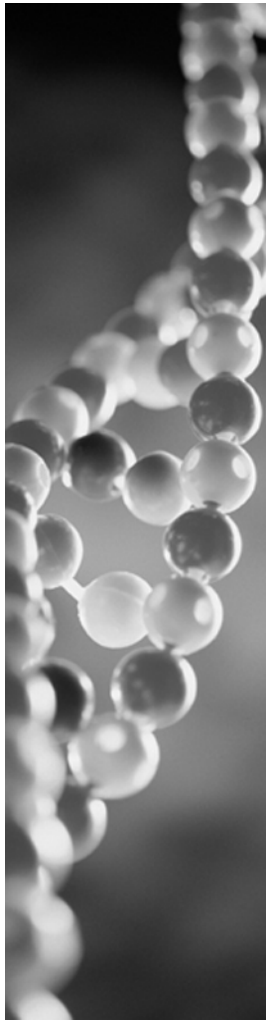
Trends in Europe: Coping with National Differences in Regulation of Marketing Practices and Relationships with Health Professionals



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The European regulatory framework

- The pharmaceutical industry in Europe is subject to a complex array of EU-level directives, national laws, and industry codes at the international, regional, and national levels.

- EU Directive 2001/83/EC on the Community code on medicinal products for human use (“Community Code”) sets forth the general regulatory framework governing the advertising and marketing of medicines in the EU.

More information for consumers?

- One current topic of debate in Europe is whether companies should be able to provide patients with factual and non-promotional information about medicinal products.
- The Community Code:
  - Calls upon the Commission to present a report to the European Parliament and the Council in 2007 on “current practice with regard to information provision – particularly on the Internet – and its risks and benefits for patients”
  - Provides that “the Commission shall, if appropriate, put forward proposals setting out an information strategy to ensure good quality, objective, reliable and non promotional information on medicinal products and other treatments and shall address the question of the information source's liability.” (Article 88a)

More information for consumers?

- On 19 April 2007 the European Commission published its draft report on current practice:
  - The common basic principle is that advertising to the public is prohibited for prescription-only medicines.
  - However, the rules and practices on what information can be available still vary significantly among Member States.
  - Certain Member States apply very restrictive rules with some seeing an expansive role for medicines regulatory agencies in the provision of various kinds of information.
  - Others allow for several types of non-promotional information to be made available, with some allowing certain information activities performed under partnerships of public and private organisations, including health professionals' associations, patients' organisations and the industry.
  - The result is unequal access of patients, and the public at large, to information on medicinal products.

More information for consumers?

- However, the European Commission does not intend to lift the ban of direct-to-consumer advertising of prescription medicines.

Regulatory landscape is changing

- The 2004 Community Code revision made very few changes in requirements in place since 1992.
- However, broader changes have been made in national laws, EFPIA and IPFMA codes, and national codes.
- European policymakers and the press have heightened attention to marketing practices (as well as safety).
- Enforcement actions by European authorities and code bodies have increased and sometimes cases are brought under laws that are not very familiar to company offiicials.
- Sensitive areas are off-label use, hospitality, and grants/contracts/sponsorships.
- U.S. enforcement activities can affect global operations.
- “Building a shield” with a compliance plan can help.

Regulatory oversight comes from multiple directions

- As EU Member States have implemented the relevant provisions of the Directive and added their own requirements, pharmaceutical companies have witnessed increased scrutiny of their marketing practices.

- The regulatory officials and prosecutors cracking down on marketing practices are not simply (or even principally) drug regulatory authorities but also local prosecutors, tax authorities, and anti-bribery authorities.

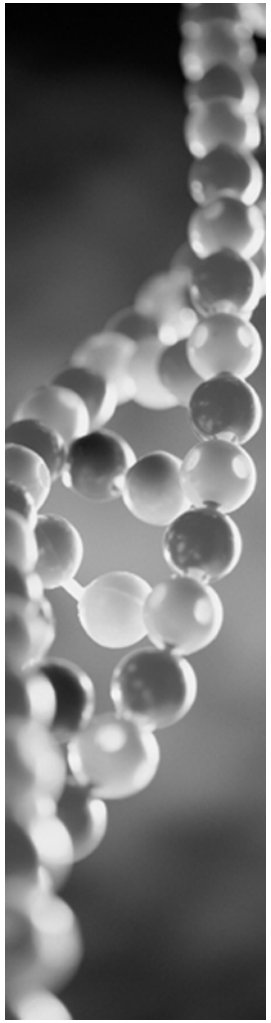
- This phenomenon is true around the world, including in Europe, U.S., and China.

Challenging areas: payments (for services or as inducements?), off-label use, and hospitality

- Sometimes payments to doctors are seen as bribery where doctors are government officials or as "commercial bribery" in countries with "anti-kickback" laws. Examples:
  - Schering SEC case involving charities in Poland
  - Micrus case involving alleged bribes of government-employed doctors in France and Turkey
  - Cases in Germany involving marketed drugs and in Italy re patient registries
- What if there are discussions of unauthorized products or unauthorized uses of approved products?
  - 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 program.
- Sponsorship of events can raise numerous legal or code issues.

Areas of challenge:

Partnering with and engaging healthcare professionals



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When and for what purposes may a drug company give a doctor money or other pecuniary benefits?

- It is understood that payments for inducing prescribing are strictly forbidden.
- But 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 this area change has been particularly rapid and companies are still getting into trouble with authorities and code bodies.
- Some countries' laws or codes or society rules require institutional approval of doctors' outside activities

Codes of Practice

- The International Federation of Pharmaceutical Manufacturers & Associations (IFPMA) Code of Pharmaceutical Marketing Practices 2006 Revision
- The European Federation of Pharmaceutical Industries and Associations (EFPIA) Code of Practice on the Promotion of Medicines 2004
- National Codes of Practice, e.g.,
  - Industry groups at EU member state level
  - Pharmaceutical Research and Manufacturers of America (PhRMA) Code on Interactions with Healthcare Professionals (not applicable outside the United States, but includes pertinent standards)

IFPMA Code – general principles

- Basis of Interaction
  - Member companies' relationships with healthcare professionals are intended to **benefit patients** and to enhance the practice of medicine
  - Interactions should be **focused on informing** healthcare professionals about products, providing scientific and educational information and supporting medical research and education
- Independence of Healthcare Professionals
  - **No financial benefit or benefit-in-kind for prescribing** (including grants, scholarships, subsidies, support, consulting contracts or educational or practice related items) may be provided or offered to a healthcare professional in exchange for prescribing, recommending, purchasing, supplying or administering products or for a commitment to continue to do so
  - **No**thing may be offered or provided in a manner or on conditions that would have an **inappropriate influence** on a healthcare professional's prescribing practices

IFPMA Code: **Transparency of Promotion**

- Promotion should not be disguised
- Clinical assessments, postmarketing surveillance and experience programmes and postauthorization studies must not be disguised promotion
- Such assessments, programmes and studies must be conducted with a primarily scientific or educational purpose
- Material relating to pharmaceutical products and their uses, whether promotional in nature or not, which is sponsored by a company should clearly indicate by whom it has been sponsored

IFPMA Code – company responsibility

- Company Procedures and Responsibilities
  - Companies should establish and maintain appropriate procedures to ensure full compliance with relevant codes and applicable law and to review and monitor all of their promotional activities and materials
  - A designated company employee, with sufficient knowledge and appropriate scientific or healthcare qualifications should be responsible for approving all promotional communications. Also, a senior company employee could be made responsible, provided that scientific advice is taken

IFPMA Code – consultants

- Compensation and reimbursement
  - It is appropriate for consultants who provide services to be offered:
    - reasonable compensation for those services; and
    - reimbursement for reasonable travel, lodging, and meal expenses incurred as part of providing those services
  - Compensation and reimbursement that would be inappropriate in other contexts can be acceptable for genuine consulting arrangements
  - Token consulting or advisory arrangements should not be used to justify compensating healthcare professionals

IFPMA Code – consultants

- Factors supporting the existence of a genuine consulting arrangement (not all factors may be relevant to any particular arrangement):
  - a written contract which specifies the nature of the services to be provided and the basis for payment of those services
  - a legitimate need for the services has been clearly identified in advance of requesting the services and entering into arrangements with the prospective consultants
  - the criteria for selecting consultants are directly related to the identified purpose and the persons responsible for selecting the consultants have the expertise necessary to evaluate whether the particular healthcare professionals meet those criteria

IFPMA Code - consultants

- Factors supporting the existence of a genuine consulting arrangement, continued:
  - the number of healthcare professionals retained is not greater than the number reasonably necessary to achieve the identified purpose
  - the retaining company maintains records concerning and makes appropriate use of the services provided by consultants
  - the hiring of the healthcare professional to provide the relevant service is not an inducement to prescribe a particular product

EFPIA Code of Practice on the Promotion of Medicines

- The EFPIA Code does not contain specific detailed provisions on engaging healthcare professionals as consultants
- However it:
  - Does contain relevant high-level principles:
    - e.g. no gift, pecuniary advantage or benefit in kind may be supplied, offered or promised to a healthcare professional as an inducement to prescribe, supply, sell or administer a medicinal product
  - Encourages compliance with the letter and spirit of the provisions of the IFPMA Code of Pharmaceutical Marketing Practices where applicable
  - Sets out only minimum standards which EFPIA member associations must apply. Accordingly, there are often more detailed provisions at national level

UK/ABPI: Relationships with health professionals

- It is now specifically stated that items must not be offered for the personal benefit of health professionals or administrative staff.
- It remains the case that items must be inexpensive - the limit is £6, excluding VAT - and relevant to the recipients' profession
- promotional aids are more likely to be acceptable under the new code if they benefit patient care
- more guidance is provided on the types of items that are both acceptable and unacceptable
- promotional competitions and quizzes are banned

UK/ABPI: Relationships with the public and patient groups

- More guidance on how companies may respond to patients' needs for reference information on medicines.
- Promotion of prescription-only medicines to the public remains strictly prohibited.
- New: While companies are permitted to work with patient advocacy groups, their involvement must be made clear, and rules on arrangements for meetings are the same as those for health professionals.
- Companies must make public a list of all patient organizations to which they provide financial support, and a written agreement must be in place with every organization spelling out exactly the terms of the relationship and funding of every significant activity or ongoing co-operation.

PhRMA Code on Interactions with Healthcare Professionals

- The Pharmaceutical Research and Manufacturers of America (PhRMA) represents research-based pharmaceutical and biotechnology companies
- In regard to consultancy agreements, the PhRMA Code is similar to the provisions of the IFPMA Code
- The PhRMA Code also specifies that the following factors, among others, support the existence of a bona fide consulting arrangement:
  - the venue and circumstances of any meeting with consultants are conducive to the consulting services
  - activities related to the services are the primary focus of the meeting, and
  - any social or entertainment events are clearly subordinate in terms of time and emphasis
- It is not appropriate to pay honoraria or travel or lodging expenses to non-faculty and non-consultant attendees at company-sponsored meetings including attendees who participate in interactive sessions

Consultants: Company procedures

- Standard Operating Procedure
- Purpose
  - Legitimate scientific need for information, services or advice that can be met by entering into a partnering or consulting arrangement with the individual
  - No intent to influence or encourage the recipient to purchase, prescribe, sell or arrange for the prescribing, purchasing, sale or placement of any of the company's products or to reward any past such behaviour
- Selection criteria
  - Set in advance based on expertise needed to achieve the identified purpose
  - May not be chosen based on potential future business or as a reward for past business.
- Accordingly, return on investment analyses and other tracking for business generation may not be conducted in connection with the use of any partner or consultant.

Consultants: Company procedures

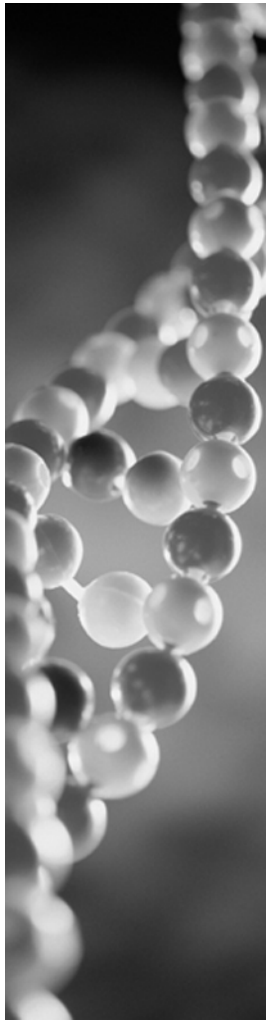
- Proposal
  - Subject to internal review
- Written contract
  - Sets out all services to be provided, the need for such services and how the services will be provided
  - Note the importance of transparency in this regard
    - for example, if the contract is being entered into to fulfil specific post-marketing obligations imposed by the authorities, such as a post-marketing obligation to continue to specifically monitor clinical trial patients, then state this explicitly in the contract. The contract should be clear on the face of it and readily understandable
  - Pay fair market value for the services performed and no more
    - for example it may not take into consideration the volume or value of business generated between the company and the consultant or others under his direction or control
  - Contract subject to approval by partner's or consultant's professional body or institutional employer

Consultants: Company procedures

- Research services
  - Written research protocol
  - Obtain all required consents and approvals
- Restrict information
  - Provide information to partner or consultant only to extent necessary for consultant to perform their consulting services.
  - Off-label use must not be encouraged
- Record keeping

Challenging areas:

Off-label use



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Ban on advertising unauthorized uses: Article 87, Community Code

1. Member States shall prohibit any advertising of a medicinal product in respect of which a marketing authorization has not been granted in accordance with Community law.
2. All parts of the advertising of a medicinal product must comply with the particulars listed in the summary of product characteristics.

Exceptions to ban on off-label use

EU

- Article 86(2). “Advertising” excludes:
- *correspondence, possibly accompanied by material of a non-promotional nature, needed to answer a* specific *question about a particular medicinal product*
- *factual, informative announcements and reference material relating, for example, to pack changes, adverse-reaction warnings as part of general drug precautions, trade catalogues and price lists, provided they include no product claims*
- *information relating to human health or diseases, provided that there is no reference, even indirect, to medicinal products*

U.S.

- Dissemination of off-label information pursuant to section 401 of the FDA Modernization Act (FDAMA);
- Non-promotional “scientific exchange” of information;
- Dissemination of off-label information under the holding of the *Washington Legal Foundation* (WLF) case;
- Responding to unsolicited requests from healthcare professionals;
- Sponsorship of independent Continuing Medical Education (CME).

What EFPIA Code Does Not Cover

- “The EFPIA Code is not intended to restrain or regulate the provision of non-promotional medical, scientific and factual information; nor is it intended to restrain or regulate activities directed towards the general public which relate solely to non-prescription only medicines.
- EFPIA, however, acknowledges that some member associations address these activities in their respective national codes, and encourages other member associations to do so, where appropriate.”

Examples of national code rules:

United Kingdom: ABPI Code

- "Representatives must not make claims … which are outside the terms of the marketing authorization for the medicine or are inconsistent with the summary of product characteristics. Indications for which the medicine does not have a marketing authorization must not be promoted."

Italy: Farmindustria Code

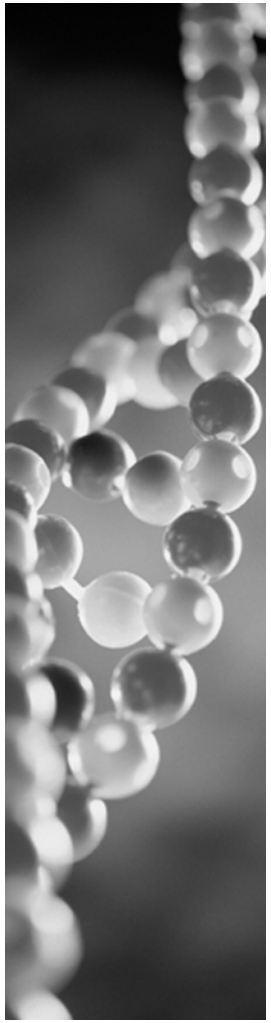
- "The information material prepared by the company on its products and used to provide information to physicians must be based on official documents issued by the Ministry of Health when the drug is registered or subsequently approved by the ministry on the basis of the relevant laws."

Consequently, best practice in EU:

- Sales reps should never volunteer information about off-label use.
- Sales reps should never solicit questions about off-label use.
- If sales reps receive unsolicited question (e.g. during visit, or during symposium), they should refer the questioner to medical affairs (“scientific service”).
- The scientific service response must be in writing and cannot include any promotional material.

Challenging areas:

Hospitality, Sponsorships to Conferences, Gifts



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Officials are looking for evidence of illegal inducements to prescribe or use products

- 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.
- 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. under many countries' regulatory laws or various criminal code provisions.

Article 86 Community Code: definition of “advertising”

- 1. For the purposes of this Title, **"advertising of medicinal products" shall include** any form of door-to-door information, canvassing activity or inducement designed to promote the prescription, supply, sale or consumption of medicinal products; it shall include in particular:
  - the advertising of medicinal products to the general public,
  - advertising of medicinal products to persons qualified to prescribe or supply them,
  - visits by medical sales representatives to persons qualified to prescribe medicinal products,
  - the supply of samples,
  - the provision of inducements to prescribe or supply medicinal products by the gift, offer or promise of any benefit or bonus, whether in money or in kind, except when their intrinsic value is minimal,
  - sponsorship of promotional meetings attended by persons qualified to prescribe or supply medicinal products,
  - **sponsorship of scientific congresses attended by persons qualified to prescribe or supply medicinal products and in particular payment of their travelling and accommodation expenses in connection therewith.**

Rules on hospitality cover both promotional and scientific meetings: Community Code

- 94.1 Where medicinal products are being promoted to persons qualified to prescribe or supply them, **no gifts, pecuniary advantages or benefits in kind** may be supplied, offered or promised to such persons **unless** they are **inexpensive and relevant** to the practice of medicine or pharmacy.
- **94.2 Hospitality at sales promotion events.**
- 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.
- **Article 95: Hospitality at scientific events**

  The provisions of Article 94(1) shall not prevent hospitality being offered, directly or indirectly, at events for purely professional and scientific purposes; such hospitality shall always be strictly limited to the main scientific objective of the event; it must not be extended to persons other than health-care professionals.

Article 9, EFPIA Code on Events and Hospitality

- All promotional, scientific or professional meetings, congresses, conferences, symposia, and other similar events (each, an “event”) organized or sponsored by a company must be held in an appropriate venue that is conducive to the main purpose of the event and may only offer hospitality when such hospitality is appropriate and otherwise complies with the provisions of any applicable code(s).

- No company may organize or sponsor an event that takes place outside its home country (an “international event”) unless:
  - most of the invitees are from outside of its home country *and,* given the countries of origin of most of the invitees, it makes greater logistical sense to hold the event in another country; or
  - given the location of the relevant resource or expertise that is the object or subject matter of the event, it makes greater logistical sense to hold the event in another country.

Article 9, EFPIA Code

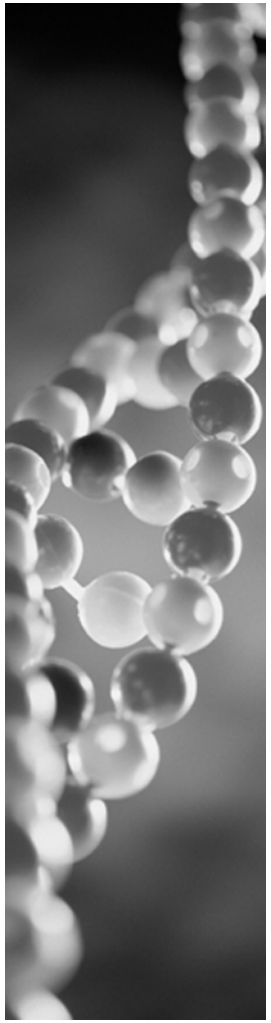
- Hospitality extended in connection with promotional, professional or scientific events shall be limited to travel, meals, accommodation and genuine registration fees.
- Hospitality may only be extended to persons who qualify as participants in their own right.
- All forms of hospitality offered to healthcare professionals shall be reasonable in level and strictly limited to the main purpose of the event. As a general rule, the hospitality provided must not exceed what healthcare professional recipients would normally be prepared to pay for themselves.
- Hospitality shall not include sponsoring or organizing entertainment (e.g., sporting or leisure) events. Companies should avoid using venues that are renowned for their entertainment facilities.
- Companies must comply with guidance concerning the meaning of the term “reasonable”, as used in this Article 9, as provided in, or in connection with, any applicable code(s).

US Physicians Attending Events in Europe: PhRMA Code and Health & Human Services Office of the Inspector General

- Companies may not pay physicians to attend a Congress
- Companies may not pay costs associated with attendance, including:
  - Airfare
  - Meals
  - Accommodations
  - Registration expenses
- *But, s*cholarships for healthcare professionals in training may be provided if recipient is selected by academic or training institution
- *Also,* companies may pay physicians who participate in legitimate advisory boards a fair market value consultant fee
  - Consultants may be reimbursed for reasonable expenditures (hotel, meals, airfare) as outlined in consulting contract

Consequences in Europe

Violations of Member State laws and industry codes in the marketing practices area



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Community Code framework

- The Community Code requires that Member States must ensure that there are adequate and effective methods to monitor the advertising of medicinal products
- Such methods, which may be based on a system of prior vetting, must in any event include legal provisions under which persons or organizations regarded under national law as having a legitimate interest in prohibiting any inconsistent advertisement may take legal action against such advertisement, or bring such advertisement before administrative authority competent either to decide on complaints or to initiate appropriate legal proceedings

Actions at national level

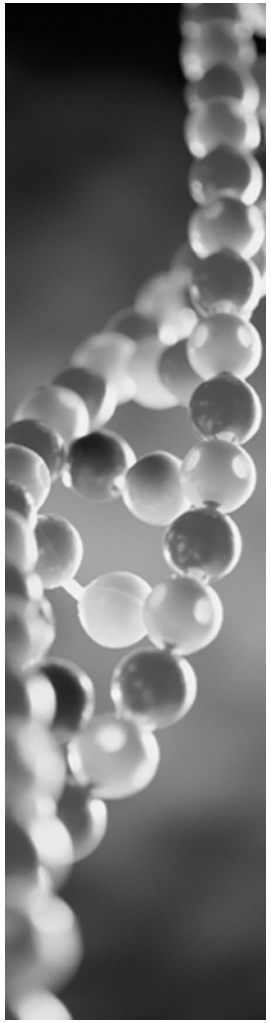
- Member States laws can be both criminal and civil
- National authorities of the EU Member States and industry associations will pursue companies for perceived non-compliance with the laws and codes of conduct established in this area.
- Examples of actions taken by national authorities include:
  - A criminal prosecution commenced by the Italian authorities against employees of a company and a number of healthcare professionals, alleging that healthcare professionals received gifts or financial rewards to induce them to prescribe products
  - 31 October 2006 decision by the UK Medicines and Healthcare Regulatory products Agency to uphold a complaint by an attendee of the Pharmacy Business magazines annual awards dinner that free samples of a prescription-only medicine were distributed to attendees at the dinner; (Immediate measures were taken to re-call the samples)

Actions at national level

- An example of action taken by an national industry association:
  - In 2006, an ABPI member company was publicly reprimanded for entertaining health professionals and their spouses at a meeting which was described as having no clear educational content in an unsuitable venue.
  - The result was suspension from membership of the ABPI for three months.
  - The Prescription Medicine Code of Practice Authority (PMCPA), which administers the Code, emphasised that it would subject companies in breach of the Code to admonishment through advertisements in the medical and pharmaceutical press
- Further details of Member States' national laws and Codes on marketing practices and cases are set out in the annex to this presentation

Response to the Challenges:

Marketing Practice Compliance Plan, Policies, and Procedures



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The 7 Elements of an Effective Compliance Plan (U.S. Health and Human Services Insp Gen)

Many companies are using this list as guidance:

1. Implement written policies and procedures;
2. Designate a compliance officer and compliance committee;
3. Conduct effective training and education;
4. Develop effective lines of communication;
5. Conduct internal monitoring and auditing;
6. Enforce standards through well-publicized disciplinary guidelines; and
7. Respond promptly to detected problems and undertake corrective action.

Building a Shield: *Standards and Policies*

- The foundation for any compliance plan is the issuance of standards and policies to guide business conduct.
- Since pharmaceutical manufacturers typically operate in multiple jurisdictions, there must be an undertaking to identify all applicable guidance for each jurisdiction (laws and codes).
- 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.

Building a shield:*Compliance plans that work; avoiding ones that are unrealistic and unachievable*

- How is a compliance plan best accomplished?
- Creation of a compliance plan is not primarily a drafting exercise to write down the policies and to publish them; identify “best practices” from a range of sources and put into the corporate compliance plan: not enough!
- This seemingly common sense and straightforward approach is, in fact, academic and idealistic.
- It can create organizational standards, without taking steps at the same time to change behavior and internal norms.
- 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 – bad conduct and also bad documents.

Building a shield: *Avoiding compliance plans that are unrealistic and unachievable*

- A better and more pragmatic approach is beginning with an assessment of the organization's current understanding and approach to regulatory compliance.
- A key step is the identification of those business activities that should be the subject of policies and procedures.
- Such an assessment can identify existing practices that already promote compliance as well as gaps to be filled.
- It will be necessary to identify any country-specific laws that need to be obeyed.
- The greater the enforcement risk, the greater the level of controls that should be considered.

Building a shield: coping with rapidly changing regulatory landscape and unfamiliar regulators

- Set risk-based priorities: company code needs to be strictest on:
  - the regulators' and codes authorities' areas of concern: off-label issues, hospitality, congresses, payments to doctors.
  - laws that forbid bribery, kickbacks, waste of public healthcare funds, or tax evasion.
  - areas where there is risk of accusation that a company's payments influenced the choice of products funded by a public healthcare system.
- U.S.-headquartered companies are developing global compliance plans due to offshore activities conducted abroad by affiliate companies.

Building a shield--*The compliance plan*

- In a compliance plan a company can structure its business activities to address regulatory risks and to reduce the possibility of unacceptable behavior by employees.
- A primarily reactive approach does not suffice.
- Policies and procedures are just pieces of paper (or computer bytes).
- Compliance issues pose business risks that must be actively managed like any other business challenge.
- What does this mean in practice?

Building a shield:
Assignment of compliance responsibility

- To have an effective compliance plan, employees in sales and marketing need to know that compliance is part of their jobs.
- There must be personnel charged with seeing that the compliance plan is being implemented and followed.
- Responsibility should be vested in a high level manager who has access to the highest levels within the organization.
- It is helpful if the compliance official is a lawyer or has access to sophisticated legal advice,
  - consistent across the business organization to the maximum possible extent but
  - 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, reminders, building compliance into performance

- 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.
- This training should be fully integrated into standard sales training and made a part of strategy meetings.
- Compliance materials and testing and evaluation tools should
- be readily accessible on-line.
- Every opportunity should be taken to remind employees of
- the organization’s ethical precepts and provide information they need to act according to those precepts.
- Compliance should be part of employee evaluation.

Building a shield: *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.
- Organizations also 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.
- Generally monitoring and auditing serves to assure there is not a gap between the plan and the reality.
- In some cases, however, auditing may identify instances of serious misconduct, and those situations must be addressed.

Building a shield: *Dealing with non-compliance*

- An effective plan can help ensure that any improper conduct is isolated and contrary to established written policy.
- The better the procedures to implement the policies, the more likely 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 organization in a much stronger position to address any questions from outside parties such as government bodies or trade code groups.
- The critical consideration is whether the organization responds to violations in a way that is consistent with its overall compliance objectives.
- One aspect of a response is the application of appropriate discipline commensurate with the violation.
- To have credibility, discipline must include everyone who participated in a material way, not just lower level employees.
- The organization needs to learn from its problems by taking steps to understand why the violation happened and identify changes in the procedures to avoid recurrences.
- Finally, the organization must determine whether the violation is of a type and scope to warrant some form of disclosure to regulators.

Conclusion

- Complex regulatory environment
- Increased enforcement
- Global effects of national laws and enforcement
- Industry efforts in the form of codes and individual company compliance efforts
- A compliance plan as a key part of the company's response
- Questions??

How to contact me: Linda Horton

- Counsels clients in the pharmaceuticals, medical devices, food, and animal health industries on regulatory requirements of the European Union, the U.S. Food and Drug Administration (FDA) and regulatory counterparts elsewhere.
- Recommended in various law firm rating publications.
- Focuses on regulatory pathways, EU, FDA and global, as well as clinical trials, authorizations, and marketing practices
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Annex For Reference:

National Laws and Codes on Marketing Practices and Relationships With Health Professionals

Belgium: *pharma.be* Code of Deontology and Mdeon Code of Ethics

- The new pharma.be Code of Deontology came into effect on 1 January 2006
- Sets out rules on advertising, promoting and marketing medicinal products for human consumption (based on EFPIA and IFPMA codes)
- Mdeon is a non-profit association set up by associations of doctors, pharmacist and pharmaceutical and medical devices manufacturers in Belgium.
- The Belgium Ministry of Health has delegated on Mdeon the responsibility to approve (granting the so-called “visas”) invitations made by pharmaceutical companies to HCPs to attend scientific meetings that involve and overnight stay.
- The procedure for the application and granting of visas is contained in Mdeon’s Code of Ethics which entered into force on November 2006.

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France: LEEM CME Code

- LEEM is the French association of pharmaceutical companies.
- In November 2006, LEEM and the French Ministry of Health agreed on a Code of Good Practices for the participation of the pharmaceutical industry in the Continued Medical Education (CME) of HCPs.

Germany: Drug Advertising

- *Section 7 Drug Advertising Act:*

- This section prohibits the grant of benefits relating to product-related advertising.

- Advertising activities which aim at promoting the company as a whole rather than any specific product do not fall under the scope of this provision.

Germany: Unfair Competition Law

- *Section 4 No. 11 Act against Unfair Competition:*

- **it is regarded as unfair competition to violate statutory provisions regulating the behavior in the market in the interest of market participants. Sections 17 to 35 of the *Doctors Professional Code* are regarded as provisions which regulate the behavior of doctors in the market.**

- If a pharmaceutical company causes a doctor to violate Section 33 para. 1 of the *Doctors´ Professional Code,* it violates the Unfair Competition Law.

Germany: Criminal Law

- Anticorruption provisions adopted by the German Parliament in 1997.
- *Section 331 Criminal Code: Acceptance of a benefit by a public official*
- **Applicable to employees in state owned or municipal hospitals or employees in private companies the shareholders of which are public entities.**
- **Section 331 para. 1 applies even if at the time the public official receives the benefit it is not yet determined which official act he will exercise in the future. The aim of obtaining the officials´ general benevolence towards the "donor" suffices for the criminal offence.**
- *Section 333 Criminal Code, Grant of a Benefit:*
- **The responsible person who causes a doctor to violate Section 331 Criminal Code commits an offence (Sec 333).**

Germany: *Doctors´ Professional Codes*

- Renewed by the State Medical Associations of the German Länder in 2003/2004: “Section 33 Doctors and Industry” as applicable in most German Länder
- Remuneration for services for manufacturers of pharmaceuticals must be appropriate to the service (Section 33 para. 1).
- Doctors may not receive gifts and benefits unless they are low of value (Section 33 para. 2).
- Acceptance of appropriate monetary benefits for the attendance of vocational training events does not violate professional laws. A benefit is inappropriate if it exceeds the costs of the doctor’s participation or training does not take center stage (Section 33 para. 3).

Germany: *Conduct Recommendations for the Cooperation between the Pharmaceutical Industry and Physicians*

- Published in 2003 by the Association of the German Drug Manufacturers (BAH), the German Association of the Pharmaceutical Industry (BPI) and the Association of Research-Based Pharmaceutical Companies (VFA)
- **- <u>Section 4.1:</u> Physicians may render services for companies only based on written agreements that clearly state both the nature of the service and the remuneration.**
- **- <u>Section 4.3:</u> Remuneration must be exclusively in cash and must be proportionate to the service rendered.**

Germany: *German Pharmaceutical Industry Association's Code of Conduct*

- Published by the German Association of the Pharmaceutical Industry (BPI) in 2000.

Section 17

- **Remuneration for services rendered by doctors to pharmaceutical companies must only be in cash, based on a written agreement (para. 1).**
- **Remuneration must not exceed an appropriate level and must be commensurate with the service rendered (para. 2).**

Italy : alleged improper payments

- 2004: 4,000 doctors and 273 drug company employees faced charges of alleged unlawful business practices. Allegedly involved offers of “cash, gifts and prizes to doctors and other healthcare professionals to encourage them to prescribe…
- 2006: company might be fined for alleged improper payments to doctors in connection with a screening programme for rare diseases, fees for publishing articles, and conducting clinical trials etc.
- There also were accusations of conducting screening for rare diseases without the patients’ knowledge.

The Netherlands: First action on misleading advertisement

- The Dutch Medicines Advertising standards Agency (CGR) took action against Dutch unit of a leading German company for the allegedly misleading advertising of a product after accepting complaints by the Dutch Medicines Evaluation Board (MEB).

- Case is notable because this is the first time that the MEB has lodged an advertising complaint.

Spain: Committee to examine marketing practices

As part of a national strategic plan, the Pharmacy Committee of the Spanish National Health System will look at:

- **The promotion and advertising of pharmaceuticals**
- **The accreditation of training and medical conferences**
- **New type of medical prescription form**

Sweden: Code of conduct for doctors and industry

- Starting 1 January 2005, an agreement between the Swedish Industry Association and the Swedish Medical Association is effective.

- Agreement is entitled "**Industry's provision of information and education to healthcare personnel**"

  - **Provides that the industry may pay only up to 50% of the cost of doctors' travel and accommodation at conferences;**
  - **Allows industry to cover conference fees;**
  - **Invitations must be sent to the doctor's employer who will decide whether the doctor can attend an event**

Switzerland

- Swissmedic, the Swiss Medicines Regulator, has issued guidelines allowing pharmaceutical companies to provide information about their products on the internet.
- The guidelines differentiate between information on prescription medicines addressed to HCPs which is allowed and direct-to-consumer advertising which is banned.
- The guidelines also require the use of a password system to restrict access by the general public to the HCP sections of the website.
- The guidelines came into force on January 1st 2007.

UK developments on marketing practices:

- House of Commons Select Health Committee report on influence of the pharmaceutical industry (2005)
- MHRA Blue guide:Advertising and promotion of medicines in the UK
- MHRA enforcement actions
- Joint memorandum of understanding between the ABPI, PMCPA and the MHRA, sets forth the arrangements for the regulation of the promotion of medicines for prescribing in the UK, available at www.mhra.gov.uk
- New Association of British Pharmaceutical Industry (ABPI) code effective 1 January 2006
- ABPI actions

UK: Enforcement of ABPI Code

- Last October a company was reprimanded for linking the provision of a “nurse audit service” to the use of the company’s product.
- A company was suspended for six months due to what were viewed as inappropriate hospitality activities.
- Other companies were declared to be in breach of the ABPI Code.
  - for linking the provision of medical and educational goods and services to the promotion of medicines in instructions to representatives relating to a nurse advisor program.
  - because a company’s public relations agency offered to pay journalists to attend a National Institute for Health and Clinical Excellence (NICE) appeal hearing.
  - erroneous reuse of an advertisement previously ruled in breach of the Code had erroneously been re-used.

Nearly half of doctors unaware of UK industry Code of Practice April 2006

- Nearly half of all doctors are unaware that the UK pharmaceutical industry operates a code of practice, a new survey has revealed.
- The survey showed just 52% of doctors were aware of the ABPI Code of Practice, with awareness being particularly low among hospital doctors, only 40% of whom knew of the code's existence.
- In total 400 doctors were surveyed, half of them hospital doctors, the other half GPs.
- Knowledge of the self-regulatory system was higher among GPs, with 65% of them saying they were aware of it.
- Results from the survey suggested that while awareness of the code was low among doctors, most of those who knew about it thought it worked well.Eighty per cent of doctors who were aware of the code believe it is either very or quite effective, against just 4% who said it was not effective at all.
- More than a third of those who knew about the survey (38%) did not believe it to be very effective - a sizeable group of doctors to win over.
- The survey also found that 57% of all those interviewed would like to know more about the code.
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