



DOCUMENT TYPE:

DOCUMENT NO:

GCP-Overview of Elan Compliance Policies

TITLE:

Overview of Elan Compliance Policies and Key Principles

VERSION:

1

Signature History :

Action	Name	Date
Approver	Bell, Wanda	16-March-2011

Revision History :

Rev. #	Issue Date	Summary of Change
0	---	Review Overview Formatting
1	17-March-2011	Approved by CCSC 14March 2011

Overview of Elan Compliance Policies and Key Principles

PURPOSE

As a pharmaceutical manufacturer, Elan Corporation, plc (Elan) conducts a wide array of activities in the health care marketplace, including research, medical and other education. Each of these activities is subject to numerous legal and ethical standards, many of which are unique to the health care industry. Elan is committed to complying with all applicable laws and regulations, including international equivalents and/or any relevant and applicable international requirements, and adhering to the highest ethical standards in all of its activities.

Elan's Compliance Policies are designed to provide guidance to Elan employees on the legal and ethical standards relating to the most common activities as well as other financial arrangements with HCPs. Employees who are uncertain about how a Policy applies to a particular arrangement or who encounter a situation that does not seem to be covered by any Policy should discuss it with their manager, the Office of Compliance, or the Legal Department.

Elan is committed to conducting its business in a manner fully consistent with these requirements, and failure to comply with these standards can have serious consequences, both criminal and civil, for Elan as well as for individual employees. Therefore, Elan employees must be familiar with and adhere to applicable Company policies for the activities in which they engage. Appropriate disciplinary action, up to and including termination, may be taken against any employee whose conduct violates Elan's policies or applicable laws and regulations.

Any exception to any Elan Compliance Policy must be granted by Elan's Office of Compliance and Legal Department.

SCOPE

This policy applies to all employees of Elan Corporation, plc and its affiliates, as well as all contractors, consultants, temporary employees, and external agencies who act on behalf of the company or its affiliates.

DEFINITIONS

Healthcare Professional:

- (1) Any member of the medical, dental, nursing, or pharmacy professions who is licensed to provide health care and/or to prescribe, dispense, or administer prescription drugs,
- (2) any entity whose primary function is to provide health care and/or is involved in prescribing, dispensing, or administering prescription drugs (e.g. hospital, nursing home, pharmacy),
- (3) any individual with an advanced scientific degree (e.g., Ph.D.) who performs services related to clinical research conducted for, or on behalf of Elan,
- (4) employees of managed care organizations, insurance companies, pharmacies or similar organizations, including anyone on a formulary committee or otherwise responsible for prescription drug coverage decisions, or
- (5) any employee, agent, or contractor of the individuals or entities listed in (1) through (4).

GOVERNING PRINCIPLES

1. Overview of Legal and Ethical Standards

Elan's commercial, scientific, medical, and educational arrangements with HCPs are subject to the requirements of a variety of legal and ethical rules. The Company is committed to conducting its affairs in compliance with these standards.

A. Anti-Kickback Law

The anti-kickback law is potentially an issue whenever Elan provides anything of value to HCPs or other persons who are in a position to influence the utilization of Company products or services. Under the anti-kickback law, it is illegal to offer, pay, solicit, or receive any remuneration to induce or in return for:

- Purchasing or ordering, or recommending or arranging for the purchase or order of, a reimbursable item or service; or
- Referring an individual for an item or service reimbursed under a federal health care program.

“Remuneration” is defined very broadly to include anything of value, including not only cash, but also free items or services or even the opportunity to earn money. “Federal health care programs” include Medicare, Medicaid, the Department of Veterans Affairs health care facility network, Tricare/CHAMPUS, the Indian Health Service, maternal and child health block grant programs, and other federally financed programs. The anti-

kickback statute also applies to private health plans acting as prescription drug plan (PDP) sponsors under Medicare Part D or that offer a prescription drug benefit as “Medicare Advantage” plan (MA-PD) sponsors. [In addition, the anti-kickback statute potentially applies to employers and unions that receive federal subsidies to offer a prescription drug plan under the Part D program.]

A violation of the statute can lead to severe penalties, including criminal and/or civil fines for the Company and individual employees, imprisonment of individuals, and possibly exclusion of Elan products from eligibility for reimbursement under Medicare and Medicaid. Many states have anti-kickback laws that apply to items and services reimbursed under Medicaid and other state programs, and several states have anti-kickback laws that apply to all items and services, even those not reimbursed under a government program.

Because the anti-kickback law is so broad, Congress enacted a number of exceptions and “safe harbors” that specify practices that will not violate the law. These exceptions are relatively narrow. However, the mere fact that a practice does not meet an exception or safe harbor does not necessarily mean that it is illegal. The Department of Health and Human Services Office of the Inspector General (OIG) has also issued additional guidance to the pharmaceutical industry on designing and implementing voluntary compliance programs. Despite these measures, there are many “gray areas” in the field of medical product and service promotion. Elan’s Policies seek to provide rules for various types of common promotional and educational activities to assure that they comply with anti-kickback laws. If a particular activity is not discussed in Elan’s Policies, the Office of Compliance should be consulted.

B. False Claims and Other Billing Standards

Numerous federal and state laws prohibit the submission of “false” or “fraudulent” claims or any other documents in support of a claim for payment by government programs, commercial insurers, and other health care plans. A document can be false if it omits information material to a decision relating to reimbursement. Violations of these laws can lead to fines, imprisonment, or exclusion from health care programs.

False claims and false statement laws have been applied to health care manufacturers where the manufacturer took action which allegedly “caused” its HCP to submit false claims. The Company needs to be particularly careful about reimbursement consulting relating to its products. Any materials disseminated by Elan to HCPs must be approved by the appropriate review committee, pursuant to Elan Compliance policies.

C. Food and Drug Administration Restrictions on Promotional Activities

The Food and Drug Administration (FDA) regulates the labeling and advertising of Elan products. Promotional materials must not be false or misleading, or lacking in fair

balance, and must not make unsubstantiated claims. In addition, with certain narrow exceptions, promotional materials may not discuss unapproved products, unapproved uses of approved products, or comparisons of competitor drugs without support of head-to-head controlled studies.

FDA periodically issues policies which also provide standards for analyzing other types of promotional activities. One such document is the FDA's Guidance on Industry-Supported Scientific and Educational Activities, which sets forth criteria for identifying continuing medical education (CME) and similar activities that will not be subject to FDA regulation as advertising or promotional labeling. Some of the factors that are relevant when evaluating educational programs under the Guidance are: the degree to which the manufacturer will direct or influence the content of the program or the selection of speakers; whether the program will disclose the manufacturer's sponsorship of the program and/or financial relationships with speakers; and whether the focus of the program is scientific or commercial.

FDA's restrictions on promotional activities apply not only to promotional materials distributed by Elan but also to Elan products that are commercially presented at promotional programs, such as meetings, seminars, congresses, or speaker programs. See Elan's Global Compliance Policies on Promotional Speaker Programs, Commercial Booths, Development and Approval of Promotional Materials, and External Funding: Charitable Contributions and Sponsorships.

D. Other Applicable State Laws

State professional licensing laws provide for license revocation or other disciplinary action to be taken against a practitioner who engages in unprofessional conduct. Many states define unprofessional conduct to include soliciting or receiving remuneration in return for referrals or for ordering or promoting products or conducting unnecessary medical procedures. These laws penalize licensed practitioners rather than manufacturers, but Elan's policy is not to engage in any activity that could cause its HCPs to violate their professional or ethical obligations.

Several states have also enacted laws that limit or require pharmaceutical manufacturers to report certain gifts and commercial expenditures and/or pricing information to state regulatory bodies. Other states require pharmaceutical manufacturers to have an active compliance program that is consistent with the PhRMA Code and the OIG guidance on interactions with health care professionals.

All commercial programs must receive appropriate approvals pursuant to Elan's Compliance policies prior to implementation.

E. Industry Standards

In addition to the federal and state requirements discussed above, a number of trade groups have issued standards governing pharmaceutical promotional and educational practices.

PhRMA Code: The Pharmaceutical Research and Manufacturers Association (PhRMA) has issued the “PhRMA Code on Interactions with Healthcare Professionals” (the “PhRMA Code” or “the Code”), with which the member companies of PhRMA have voluntarily undertaken to comply. In addition, several states require pharmaceutical companies to adopt a compliance program that is consistent with the PhRMA Code. Although Elan is not a member of PhRMA, Elan has committed to following the guidelines set forth in the PhRMA Code. The Code was most recently updated in July 2008, and the revised provisions took effect in January 2009. All Elan employees must be aware of the requirements set forth in the PhRMA Code, and the Code has been incorporated into Elan’s Policies.

The Code states that any interaction between the industry and health care professionals should focus on providing scientific and educational information and supporting scientific and medical research to maximize patient benefits. More specifically, the Code provides guidance in areas including entertainment, speaker training programs, grants, continuing education, consultants, and educational and health care practice-related items.

AMA Guidelines on Gifts to HCPs from Industry: In December of 1990, the American Medical Association (AMA) adopted its “Guidelines on Gifts to HCPs from Industry” (“AMA Guidelines”), which later were adopted for the most part by drug and medical equipment manufacturer trade associations.¹ The AMA Guidelines address many of the same areas of the PhRMA Code. In many of these areas, such as the guidelines on gifts to HCPs, the PhRMA Code is more restrictive than the AMA Guidelines. In such cases, Elan will follow the PhRMA Code.

Accreditation Counsel for Continuing Medical Education Standards for Commercial Support of Continuing Medical Education: The Accreditation Council for Continuing Medical Education (ACCME) has issued standards which are largely consistent with the FDA Guidance on Industry-Supported Scientific and Educational Activities. These standards were most recently updated in September of 2004, although the ACCME continues to supplement the Standards through an FAQ available on its website. Under the ACCME Standards, a CME program sponsor must retain responsibility for independence, resolution of personal conflicts of interest, appropriate use of commercial support, appropriate use of commercial promotion, presenting content and format without

¹ In 2000, the AMA clarified these Guidelines in the *AMA Addendum II: Council on Ethical and Judicial Affairs Clarification of Gifts to HCPs from Industry*.

commercial bias, and mandatory disclosure of information relevant to potential commercial bias (such as financial relationships with faculty). As part of these responsibilities, all agreements between a commercial supporter and a provider must be in writing.

2. Taste and Tone

Elan employees must conduct themselves with the highest level of integrity at all times.

Elan activities must demonstrate the highest ethical standards in their development and implementation.

Likewise, materials developed or disseminated by or on behalf of Elan must reflect a taste and tone consistent with Elan's overarching commitment to these standards.

3. General Rules for Analysis of Commercial, Scientific, Medical and Educational Arrangements

Because of the scope of commercial, scientific, medical, and educational activities conducted by Elan, some arrangements may not be specifically addressed by Elan's policies.

All such arrangements and activities must be approved by Elan's Office of Compliance and Legal Department prior to implementation. In the absence of such a policy, it may be useful to consider the following general standards when evaluating a particular program.

- **No "Magic Words."** All remuneration to HCPs must comply with the principles underlying these Policies, regardless of the form or description of the payment (e.g., payments based on fair market value for bona fide services). Thus, simply calling a payment a "grant," "consulting arrangement," "promotional allowance," "honorarium," or any other term is not sufficient justification for the payment.
- **Direct and Indirect Compensation.** Elan's policies apply to compensation that is provided directly to a HCP by Elan as well as to compensation provided indirectly or through a third party. For example, if Elan hires a third-party vendor to run a promotional program, Elan's policies will apply to all activities and payments by the third-party.
- **No Exception for "Pilot" Programs.** The fact that an inappropriate arrangement is isolated or limited in scope is not a sufficient justification for the relationship.

- **Type of Organization.** As a practical matter, the type of HCP involved will influence the analysis of a particular arrangement. The more that the HCP has the ability to influence the use of Elan products, the more review the relationship should receive. For example, contributions to charitable foundations often raise only limited concerns, whereas physician arrangements warrant particularly careful review.
- **Fair Market Value.** Whenever an arrangement involves payment for items or services, the amount of payment must be consistent with the fair market value of the items or services provided.
- **Nature of Activity.** Funding for activities which provide tangible benefits to Elan (other than increased product sales) are less likely to raise concerns than funding for activities which simply support HCPs' programs.
- **Contingency on Product Recommendations.** Except for price-related concessions such as discounts, concessions generally may not be contingent on the HCP's agreement to purchase or recommend the use of Elan products.
- **Impact on Costs and Quality of Care.** If an arrangement will increase costs or adversely affect the quality of care, it will raise greater regulatory concerns. For example, managed care organizations generally have little incentive to increase costs since they receive capitated payment rates, and therefore clinically appropriate arrangements with them may warrant less scrutiny with respect to costs.
- **Amount of Funding.** The greater the value provided to a HCP, the greater the degree of care that must be taken when considering the arrangement.
- **“Carve-outs.”** Some commercial restrictions apply only to patients covered under federal health care programs such as Medicare, Medicaid, Public Health Service grants, or the like. To the extent that an arrangement does not involve compensation relating to patients whose care is paid for under federal health care programs or will not otherwise influence the care provided to such patients, the arrangement may raise fewer concerns.
- **State specific requirements.** Even when no federal health care programs are implicated, some states impose commercial restrictions of their own which must be followed (e.g., state all-payor statutes or state gift limit or reporting statutes).
- **Unfair Competition.** Arrangements which provide unfair competitive advantages or which otherwise foreclose competition raise increased concerns.

- **Documentation and Recordkeeping.** Elan employees must maintain documentation of remuneration provided to HCPs which is sufficient to establish that the arrangement meets Company Policies.

4. Reporting Violations

Every Elan employee is obligated to report any suspected violation of Elan's Policies to his or her direct manager, the Office of Compliance, or the Legal Department. Managers must report any suspected violation of the law or Elan's Policies to the Office of Compliance or the Legal Department. Alternatively, employees may report violations anonymously in the following ways:

- **Call:** (in the U.S.) 1-866-OUR-ELAN (1-866-687-3526). You can use this same number outside the U.S. by first calling your local AT&T Direct Access Number.
- **Email:** Use the employee feedback system located on Elan's Intranet under Corporate Compliance. The system is designed to allow you to send comments anonymously. Mails are never traced and confidentiality is always respected.
- **Mail:** "The Network", (Attention: Elan Inc.), 333 Research Court, Norcross, GA, 30092 USA

Employees reporting suspected violations will not be required to give their names. All communications regarding any suspected violation of Elan's policies will be handled in confidence to the extent possible. No employee who in good faith reports suspected wrongdoing will be subject to retaliation or discipline for having reported suspected wrongdoing, even if the information incriminates other management, managers or employees, or even if the report ultimately is established to be erroneous. Such retaliation by a manager or any other employee will be grounds for termination. Failure to report wrongdoing of which an employee has knowledge may, in itself, be a basis for disciplinary action, up to and including termination of employment.

More information can be found in the Elan Policy on Discipline.

Finally, if employees become aware of practices of competitors which conflict with Elan's standards and place the Company at a significant competitive disadvantage, they should bring them to the attention of the Office of Compliance or the Legal Department. Competitors' practices, however, cannot justify a deviation from Elan's Policies. While Elan personnel are strongly encouraged to bring questionable competitor practices to the attention of the Office of Compliance or the Legal Department for review, they must conform at all times to the Company's ethical standards. Among other things, Elan personnel must not attempt to obtain trade secret information from our competitors.



Title:
Document No:
Version:

Overview of Elan Compliance Policies and Key Principles
GCP-Overview of Elan Compliance Policies
1

Elan policies can be found on the Office of Compliance tab of the Elan intranet:

http://synapse/Departments/office_of_compliance/PoliciesandProcedures/default.asp