



COVIDIEN

Covidien: Positive Results for Life

Covidien FCPA Compliance Program Overview

▪ Policies & Procedures:

- Covidien Guide to Business Conduct (Annual Certification Process for all Employees)
- Covidien FCPA & Anti-Bribery Policy
- International Comprehensive Compliance Program (CCP)
- One-Page Laminated Summary of the CCP
- FAQs
- Hypothetical Examples for Field Sales Force
- FCPA Tool Kit
- Distributor Management Program
- HCP Spend Tracking (In Process)

▪ Training:

- Live Training for Covidien Employees (Annual Sales Meetings/New Hire Orientation/Other Meetings)
- On-Line Training – All new hires with computers receive FCPA on-line training module within first 3 months. New customized module to be launched this December.
- Live training for third-party distributors
- Internal auditor training
- APAC Ethics Circles

▪ Controls & Testing:

- Internal Audit (Forensic Audit for Investigations)
- SOx
- Pre-Approval Forms (CPA Form)
- Accounting system for spotting red flags

One-Page Laminated Summary

Covidien's International Anti-Bribery & Compliance Program Summary



Introduction: Covidien has an International Compliance Program related to what you can and cannot provide to healthcare professionals (HCP) outside of the U.S. in the form of gifts, business courtesies, meals, travel, grants, discounts and consulting arrangements. The documents that reflect Covidien's Program include: (1) Covidien's International (Non-U.S.) Comprehensive Compliance Program Regarding Interactions with Healthcare Professionals; (2) Covidien Global FCPA and Anti-Bribery Policy; (3) Covidien FCPA & Anti-Bribery FAQs and Hypothetical Examples; and (4) live and web-based training materials. This document is simply a short summary reference of this Program. Please consult these documents, or a Legal Department Representative, for a complete explanation of the Program. Thank you for your support.

Gifts to Individual Medical or Healthcare Professionals: Gift giving to healthcare professionals is generally prohibited, except for: modest gifts (i.e., USD50/€35 and under) given in good faith and without the intent to obtain or keep specific business or to obtain some improper advantage. This exception includes gifts of modest value that benefit patients, have an educational purpose, can be used in the healthcare professional's practice or that reflect local holidays, traditions or customs, or for significant life events (e.g., birth of child; death of family member). (See your county controller or Legal Department representative for spending limits related to medical textbooks and anatomical models, which may exceed the USD50/€35 gift limit.)

Covidien-Sponsored Product Training and Education Meetings for Customers: Covidien supports training and education to facilitate the safe and effective use of its products (when necessary).

Educational Grants and Charitable Donations: Grants and charitable donations are permitted only if the grant or donation is intended for a charitable or other philanthropic purpose and/or to support bona fide educational or research programs. Such funding must not take into account the volume or value of purchases made by, or anticipated from, the grant recipient. Please consult the Covidien Delegation of Authority for approvals.

Discounts: Certain pricing and discounting practices are permitted so long as they conform to the requirements of applicable local law. When in doubt, please contact your Legal Department Representative.

Consulting and Personal Services Arrangements: Covidien may compensate individuals, including physicians or other customers or potential customers, for bona fide consulting and personal services, where the services have value to Covidien and the fees are based on the services actually provided. All such arrangements must be in writing.

Interactions with Third-Party Distributors and Agents: Covidien relies on its third-party business partners in order

ACTIVITY	PERMITTED	NOT PERMITTED
Gifts	<ul style="list-style-type: none"> OK to give healthcare professional (HCP) modest gifts (i.e., USD50 and under) given in good faith and without the intent to obtain or keep specific business or to obtain some improper advantage. Gifts should either: (1) have an educational purpose (e.g., text book); (2) benefit the patient (e.g., anatomical model); (3) be used in the HCP's practice; or (4) reflect local holidays, traditions or customs, or for significant life events (e.g., birth of child; death of family member). Minimal value branded promotional items. <p>(Note regarding all expense limits: Business units may impose more restrictive limits based on local law, custom, cost of living and business practices. Under exceptional circumstances, business units may also obtain an increase in these limits, but only through the Chief Compliance Counsel's prior written authorization. Where exceptions are referenced in this document, exceptions must be obtained from the Chief Compliance Counsel or an attorney in the Legal Department delegated by the Chief Compliance Counsel.)</p>	<ul style="list-style-type: none"> Frequent gift giving. Tickets to sporting events or the theater (unless an exception has been obtained). Golf outings where Covidien pays for the HCP or Government Official (unless an exception has been obtained). Gifts given to any HCP or government official in order to obtain or keep business or to obtain some improper advantage. Gifts given as a "thank you" for the purchase of Covidien products. Gifts of cash or cash equivalents, such as gift certificates (unless an exception has been obtained). Gift giving contrary to the regulations of the country where the HCP is licensed to practice.
Business Courtesies	<ul style="list-style-type: none"> Meals or other modest hospitality in conjunction with a meeting when the meeting is directly related to performing a contract or the promotion, demonstration or explanation of Covidien products. The meeting should occur close to the healthcare professional's (or Government Official's) place of business. Meals or other hospitality in conjunction with a professional society meeting, trade show, or similar event that are modest in amount according to local standards. Travel and lodging expenses are not permitted unless for a legitimate business need (e.g., plant tour or demonstration of non-portable equipment). These per person expense limits (exclusive of tip & tax) apply unless your business unit imposes lower limits: Dinner USD125/€95; Other meals/drinks/snacks USD50/€35 (Note: the total daily limit for all meals/drinks/snacks and dinner is USD175/€130. The more expensive meal may be lunch. Remember that such expenses should be infrequent.) <p>See Note above regarding expense limits.</p>	<ul style="list-style-type: none"> Travel and lodging expenses unless there is a legitimate business need (e.g., plant tour or demonstration of non-portable equipment). Entertainment or recreational activities such as theater or sporting events (unless an exception has been obtained). Any business courtesy to any HCP or government official in order to obtain or keep business or to obtain some improper advantage. Any business courtesy to the spouse or guest of a HCP, or any other person, that does not have a bona fide interest in the subject of the meeting or event. Business courtesies that are contrary to the regulations of the country where the HCP is licensed to practice.
Medical Conferences or Congresses	<ul style="list-style-type: none"> Payment of reasonable educational grants or reasonable expenses on behalf of: (1) third-party conference/congress meeting organizers; (2) training institutions; or (3) healthcare professionals (including healthcare professionals in training), for the registration, travel and lodging of attendees to nationally and regionally-recognized meetings dedicated primarily to promoting objective scientific and educational activities and discourse. 	<ul style="list-style-type: none"> Any financial support for the spouse or guest of a HCP that does not have a bona fide interest in the subject of the meeting or event. Any educational grant or other financial support that is contrary to the regulations of the country where the HCP is licensed to practice. Educational grants given to any HCP or government official in order to obtain or keep business or to obtain some improper advantage.

The Compliance Training Challenges in Emea

- Ongoing Training Sessions of all Covidien Emea Sales Forces
- Legal Visibility and Compliance Message at all levels of the organization
- Ensure to have tailored made Training Program to your audience with a view to build compliance culture rather than imposing Compliance to the Business

Covidien & Third-Party Relationships Requirements

Covidien requires that all International Distributors, Sales Representatives, Consultants and Resellers that Covidien retains must:

- ✓ Be qualified to represent, sell or promote Covidien products and services;
- ✓ Be honest and ethical in their business dealings;
- ✓ Be transparent in providing information to Covidien in connection with the sale of products and/or performance of services for Covidien;
- ✓ Comply with all applicable laws, including the laws of the countries in which products will be sold and/or services will be provided; and
- ✓ Receive only reasonable compensation that is consistent and commensurate with the services provided to Covidien.

Covidien's Commitment to Compliance

Establishing compliance with the FCPA and Ethical behavior

- **Due Diligence**
- **Contractual Safeguards**
- **Training of Third-Party Distributors**

Each Covidien global business unit has developed its own operating procedures for the retention, operation and termination of third-party distributors and agents.

Standard Operating Procedures – Due Diligence

Conduct Due Diligence on all prospective third-party relationships or upon a “renewal” of an existing agreement

- Know the ownership and business background of third-party agent, representative or distributor. Confirm with reliable independent sources.
- Solicit questionnaires to obtain necessary information, (e.g., capabilities; office locations; affiliations with government officials or their family members; references).
- Check the agent’s, distributor’s or representative’s background:
 - country desk officers at State and Commerce
 - commercial attaché at U.S. embassy
 - published press reports

Does agent have a reputation for integrity & ethical behavior?

Standard Operating Procedures – Contractual Safeguards

Adopt Adequate Contractual Safeguards

- **Should include representations and warranties**
 - Is not a foreign official or affiliated or related to a foreign official
 - Understands and will abide by FCPA, OECD and local law
 - Has not previously engaged in questionable conduct and will not in the future

- **Should also include procedural safeguards**
 - Mandatory provisions such as: reasonable access to agent's books; transparency; annual compliance certifications; payment restrictions (check/wire only - no third-party payees or countries); termination rights

 - Suggested provisions such as: notification of change of ownership; no assignments of rights or transferability

Standard Operating Procedures - Training

Develop and Implement Training programs for Third-Party Relationships

- Fully dedicated Emea Distributor manager to assist in the SOP and training
- All Third-Party Relationships **MUST** be provided with training upon entering into an agreement with Covidien
- Training Certificate are issued

Ethics Circles

Key features:

- Employees allocated into small Ethics Circle groups
- Frequent Short Meetings (Bi-monthly, 1 hour each)
- Integrity Champion (mid-level manager) to facilitate each group's meeting
- Senior Leaders to co-facilitate at least one group's meeting (preferably different groups from previous meeting) anywhere in Asia
- Employees can attend another group's meeting anywhere in Asia if cannot attend allocated group's meeting
- Prescribed agenda for every meeting
- Information Sheet (questions/comments/feedback) to be returned to Legal after each meeting

Ethics Circles

Typical Agenda:

5 Minutes	Welcome and Introduction
30 Minutes	Review quiz from previous meeting – group discussion. Powerpoint presentation on selected aspects of Covidien’s ethics/compliance policies and quiz.
20 Minutes	General discussions and brainstorm quiz to submit for use in the next Ethics Circle Meeting; or Role play (e.g. group breaks into 2 teams: doctor who made improper requests and salesperson who has to deal with the doctor)
5 Minutes	Take attendance Set date for next meeting Complete and return Information Sheet (comments and ideas for future meetings)

Ethics Circles

Sample Quiz and Response to questions on the Quiz

*You became aware of a Covidien distributor entertaining doctors at a massage parlor.
You should:*

- a) Tell the distributor you need to go along to supervise the event.*
- b) Not worry as the distributor is not subject to our company policy.*
- c) Require the distributor to stop such entertainment of doctors as it is against our company policies.***
- d) Get the name of the massage parlor for your own future meetings with doctors.*

Reasoning for the answer/Response to questions received:

Covidien's distributors are subject to our FCPA/Anti-bribery policies which prohibit hospitality at inappropriate places including places with adult entertainment or where the setting is not conducive to the exchange of scientific, educational or business information.

Their distribution agreements with Covidien require them to comply with Covidien's compliance and ethical conduct policies and to attend Covidien FCPA/Anti-bribery training.

Feedback from Employees on Ethics Circles

The eight questions for this time are very specific, which explain the managing methods and the principles clearly. This kind of training is very necessary.

Everyone was enthusiastic during the discussion. The questions were very relevant to our daily work experiences. Through the discussion everyone could understand Covidien's rules on ethical behaviour. We also discussed examples of violating Covidien's policies. All agreed to be strict in carrying out their work and to use Covidien's values as a guide in completing their work.

Everyone was very positive in the discussions, and also agreed this discussion was useful. ... My colleagues deeply understood the ethics, and gave an example in the discussion, it was agreed we should work strictly to adhere to the ethics and the company's values in our everyday work.