

GlaxoSmithKline Compliance Program – U.S. Operations

Summary

SmithKline Beecham Corporation, d/b/a GlaxoSmithKline (the “Company” or “GSK”) is committed to conducting its business with honesty and integrity, and with high standards for ethical behavior and compliance with applicable laws and regulations. GlaxoSmithKline has established a Corporate Ethics & Compliance department to support this important commitment by providing oversight and guidance to ensure an effective compliance program and to foster an ethical culture.

Section 119402 of the California Health & Safety Code requires a pharmaceutical company to adopt a Comprehensive Compliance Program that is in accordance with the U.S. Department of Health and Human Services, Office of Inspector General’s (“OIG”) “Compliance Program Guidance for Pharmaceutical Manufacturers” (“OIG Compliance Guidance”), and that includes policies for complying with the Pharmaceutical Research and Manufacturers of America “Code on Interactions with Healthcare Professionals” (“PhRMA Code”). Further, the law requires that the Program include an annual limit for certain items and activities given to healthcare professionals covered by this California law. Neither the OIG Compliance Guidance, nor the PhRMA Code is a compliance program in and of itself. Rather, these two documents set forth voluntary guidelines to be considered when developing a new compliance program or updating an existing one.

The stated purpose of the OIG Compliance Guidance is to “assist companies that develop, manufacture, market, and sell pharmaceutical drugs or biological products (pharmaceutical manufacturers) in developing and implementing internal controls and procedures that promote adherence to applicable statutes, regulations, and requirements of the federal healthcare programs and in evaluating and, as necessary, refining existing compliance programs.” The OIG Compliance Guidance is useful in that it provides the OIG’s views on the fundamental elements of pharmaceutical manufacturer compliance programs, as well as the principles that each pharmaceutical manufacturer should consider when creating and implementing an effective compliance program. The OIG Compliance Guidance recommends that each pharmaceutical manufacturer “adapt the objectives and principles underlying the measures outlined in this guidance to its own particular circumstances.”

The PhRMA Code addresses interactions with respect to the marketing of products and provides guidance on ensuring ethical relationships with healthcare professionals. The purpose of the PhRMA Code is to reinforce the intention that our interactions with healthcare professionals are to benefit patients and to enhance the practice of medicine.

GlaxoSmithKline has established a Comprehensive Compliance Program as required under Section 119402 of the California Health & Safety Code. This Program includes an annual limit on items provided to healthcare professionals covered under the Code. Our Comprehensive Compliance Program and Annual Declaration are publicly available on our website, <http://www.gsk.com>. These documents may also be obtained by calling 1-888-825-5249.

Table of Contents

Summary	1
Introduction.....	3
Leadership and Structure	4
Corporate Compliance Officer.....	5
Internal Control Framework	6
Written Standards of Conduct and Policies and Procedures.....	6
Standards of Ethical Conduct.....	6
Corporate Policies.....	6
GSK U.S. Pharmaceutical Policies	7
Research and Development (R&D) Policies.....	7
Annual Spend Limit for California Healthcare Professionals	8
Policy on Individuals or Entities Excluded from Federal Healthcare Programs	8
Training and Education.....	9
Internal Lines of Communication	9
Reporting Concerns	9
Integrity Helpline	10
Monitoring and Auditing	11
Addressing Misconduct and Developing Corrective Action	11

GlaxoSmithKline Compliance Program – U.S. Operations

Introduction

SmithKline Beecham Corporation, d/b/a GlaxoSmithKline (the “Company” or “GSK”) is a research-based pharmaceutical company with a powerful combination of skills and resources that provides a platform for delivering strong growth in today's rapidly changing healthcare environment. GSK's mission is to improve the quality of human life by enabling people to do more, feel better and live longer. While GSK is a global company, this document focuses on GSK's policies applicable to U.S. activities.

Through the diligent efforts of thousands of employees, past and present, GSK has built a reputation for conducting its business with integrity, in accordance with high standards of ethical behavior, and in compliance with the laws and regulations that govern our business. This reputation is among our most valuable assets and ultimately depends upon the individual actions of each of our employees all over the world.

We are proud that GSK was an early supporter of the PhRMA Code on Interactions with Healthcare Professionals. The PhRMA Code, adopted July 1, 2002, enhanced and re-issued January 2009, is based on the principle that a healthcare professional's care of patients should be based, and should be perceived as being based, solely on each patient's medical needs and the healthcare professional's medical knowledge and experience. The Code provides guidance relating to marketing of a member's product to healthcare professionals on such topics as informational presentations, consultants, financial support for educational conferences, scholarships and grants, and gifts. While the PhRMA Code is a voluntary Code, GSK has included within its compliance program, policies that support the PhRMA Code.

GSK has also studied the guidance issued by the U.S. Department of Health and Human Services OIG in April 2003 titled "Compliance Program Guidance for Pharmaceutical Manufacturers." The OIG Compliance Guidance is not a compliance program in and of itself. As stated in the document, “it is a set of voluntary guidelines that pharmaceutical manufacturers should consider when developing and implementing a compliance program or reviewing an existing one.” Compliance measures should be tailored to fit the unique environment of the company. The OIG recommends that each pharmaceutical manufacturer should adopt the objectives and principles underlying the Compliance Guidance to its own particular circumstance.

The OIG Compliance Guidance outlines the basic elements that the OIG considers fundamental to establishing an effective compliance program. These elements include:

- Designation of a Compliance Officer (CO) and compliance committee
- Implementation of written policies and procedures
- Conducting education and training programs for affected employees
- Developing lines of communication between the CO and all employees through hotlines or other means
- Conducting internal monitoring and auditing

- Enforcing standards through disciplinary guidelines
- Responding promptly to detected problems and undertaking corrective action

GSK has assessed its Corporate Compliance Program in relation to the OIG Compliance Guidance, and believes that its program is in accordance with the Compliance Guidance taking into account the flexibility provided by the OIG Guidance to adapt the guidelines to the particular circumstances applicable to GSK.

We have developed our own internal standards and systems that provide guidance to GSK representatives who interact with healthcare professionals (e.g. sales and marketing representatives, Research & Development (R&D) personnel). In addition, we provide training to these employees to ensure their familiarity and to facilitate their compliance with guidelines, regulations, and legal requirements.

GSK is aware that having compliance policies and providing training on these policies is not enough. Auditing and monitoring are required to best ensure we detect and correct behaviors inconsistent with our high ethical standards. GSK has monitoring and auditing processes in place designed to help detect and investigate suspected breaches of our policies and we take appropriate disciplinary action, including dismissal, where appropriate.

The purpose of our Compliance Program is to prevent and detect violations of law or company policy. As the OIG Guidance recognizes, the implementation of such a program cannot guarantee that improper employee conduct will be entirely eliminated. Nonetheless, it is GSK's expectation that employees will comply with our Code of Conduct and the policies established in support of such a Code. In the event that GSK becomes aware of violations of law or company policy, we will investigate the matter and, where appropriate, take disciplinary action and implement corrective measures to prevent future violations.

GSK has described below the fundamental elements of our Corporate Compliance Program. As OIG calls for in its Guidance, we have tailored our Compliance Program to fit the unique environment of our company. Moreover, our Compliance Program is dynamic; the Program is reviewed and enhanced as needed to meet existing compliance requirements.

Leadership and Structure

GSK's Corporate Ethics & Compliance program was established by the Board of Directors to support GSK's commitment to high standards of ethical conduct. The program is under the direction of the Corporate Compliance Officer, who reports to the Chief Executive Officer. Through the program, the Corporate Ethics & Compliance staff provides oversight and guidance to ensure compliance with applicable laws, regulations, and Company policies, and to foster a positive, ethical work environment for employees.

Corporate Compliance Officer

Simon M. Bicknell is Senior Vice President, Company Secretary of GlaxoSmithKline PLC and Corporate Compliance Officer. His contact information follows:

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 (This is a secure, off-site post office box.)

Assisting the Corporate Compliance Officer are Compliance Officers that work with the GSK business units to identify compliance issues and how to address them. Compliance officers are senior level managers with direct access to the leadership teams of GSK functions. They are a source of expertise and a point of contact for anyone with a question on ethics or compliance with GSK policies. Compliance officers are also responsible for defining the training needs of their section of the organization and communicating the latest news, policies and legislation affecting GSK.

Compliance Officers are assigned to the following areas:

Michael L. Shaw Compliance Officer, North America Michael.L.Shaw@gsk.com 1-215-751-7337	Seth B. Whitelaw Compliance Officer, Global R&D Seth.B.Whitelaw@gsk.com 1-610-787-4944
Keith A. Lamb Compliance Officer, GMS, Manufacturing Keith.A.Lamb@gsk.com 1-215-751-4568	James Dawson Compliance Officer, Consumer Health James.M.Dawson@gsk.com 1-412-200-3438
Gerard Geneen Compliance Officer, Pharma Europe Gerard.R.Geneen@gsk.com 44 20 8047 2365	Dave O'Shaughnessy Compliance Officer Asia Pacific, Japan & Emerging Markets Dave.O'Shaughnessy@gsk.com 44-20-8047-6179
Dirk Tant Risk Mgmt & Compliance Officer GSK Biologicals Dirk.I.Tant@gsk.com 32-10-85-6443	Joseph E. Henry Director, Corporate Compliance Joseph.E.Henry@gsk.com 1-215-751-3781

Internal Control Framework

While line management has responsibility for implementing effective internal controls for risk management and legal compliance, GSK has also established an Internal Control Framework to ensure that Significant Risks are reviewed and monitored and that specific issues and incidents (e.g. a compliance failure) are followed up and corrected. The GSK Board of Directors has established the Risk Oversight & Compliance Council (ROCC) to assist the Board Audit Committee in its review of risks and the system of internal controls necessary to address such risks. The ROCC is chaired by the Corporate Compliance Officer and includes at least three members of the Corporate Executive Team appointed by the CEO.

In addition, all business units and corporate functions have established high-level Risk Management and Compliance Boards (RMCBs) to oversee and ensure implementation of internal controls for risk management and legal compliance, and to provide regular reports to the ROCC on the performance of such controls, together with specific issues that arise.

Written Standards of Conduct and Policies and Procedures

Standards of Ethical Conduct

It is important to GSK's success that we conduct our business with honesty and integrity and in compliance with applicable legal and regulatory requirements. GSK has established a Code of Conduct policy that sets out the fundamental standards to be followed by employees in their everyday actions on behalf of the company and seeks to promote honest and ethical conduct.

Our Employee Guide to Business sets forth our fundamental legal and ethical principles for conducting GSK business and serves as a guide for employees and others who act for us. It summarizes GSK's corporate ethics and compliance policies, including our Code of Conduct, and identifies resources to assist employees in seeking guidance. This guide is communicated both within and outside the company. The documents can be accessed using the following URL: (<http://www.gsk.com/about/corp-gov-ethics.htm>).

Corporate Policies

Guidance on the GSK's standards is provided through related corporate policies and supporting procedures and guidelines. There are corporate policies governing a range of

activities including marketing activities, risk management and compliance, internal reporting, conflicts of interests, diversity, environmental, health and safety, adverse event reporting and many other areas. Each business sector has policies that include additional requirements and guidance.

GSK U.S. Pharmaceutical Policies

Our U.S. Pharmaceuticals Policies provide requirements and restrictions on activities by our sales, marketing and managed markets employees to ensure these activities meet legal requirements and high ethical standards. These Policies cover a range of activities including:

- Information that may be used by GSK personnel to promote GSK products
- Meals or gift items intended to benefit patients or related to a healthcare professional's practice
- Selection and retention of healthcare professionals for consultation
- Contacts between GSK sales representatives and consumers
- Conduct of GSK-sponsored speaker programs to educate health-care professionals
- Sponsoring independent medical education or providing charitable contributions
- Role of sales and marketing personnel at national or regional medical conventions
- Distribution of drug samples to healthcare professionals
- Reporting adverse events relating to GSK products.

These Policies, which are separate from and in addition to GSK Corporate Policies, apply to all employees in GSK U.S. Pharmaceuticals operations as well as other GSK employees when they are involved in the marketing or sale of pharmaceutical products in the U.S.

Research and Development (R&D) Policies

The R&D process is highly regulated, wherever GSK operates. As scientific advances raise new issues, we work closely with the regulators, policy makers, and stakeholders to develop new or refined standards. We have our own internal standards and systems to ensure that we comply with or exceed guidelines, regulations and legal requirements.

Policies apply to interactions of GSK R&D employees with healthcare professionals or with the U.S. Government. These Policies cover a range of activities including:

- Guidelines for requesting and receiving external consultancy in R&D over a defined monetary limit
- Standards for compensating, reimbursing, and providing financial benefits to healthcare practitioners, or their affiliated institutions or organizations, conducting GSK-sponsored or GSK-supported clinical studies

- Standards for determining the need for external experts and for selecting, using, compensating, and interacting with external experts within GSK R&D
- Framework and requirements for managing GSK's procurement, maintenance, and administration of research funding from agencies of the U.S. Government.
- Meals or gift items related to a healthcare professional's practice
- Sponsoring independent medical education or providing charitable contributions

Annual Spend Limit for California Healthcare Professionals

GSK has adopted a number of policies and processes designed to help ensure that its promotional practices are in accordance with the OIG Guidance and consistent with the PhRMA Code guidelines. GSK has also set an overall annual spend limit for the company when dealing with medical or healthcare professionals covered in Section 119402 of the California Health & Safety Code. GSK has established the annual company limit on promotional or other items provided to California medical or healthcare professionals of \$1,000. This annual limit is subject to revision.

In addition, consistent with the California statute, the following items have been excluded from the annual limit:

- Value of samples distributed
- Support for Independent Medical Education programs
- Research sponsorships
- Payments to healthcare professionals for services such as Advisory Boards, Speaker Training and Speaker Events
- Meals provided at Advisory Boards and Speaker Training

This limit has been communicated to GSK management teams and employees. Each GSK business unit and each employee is expected to manage their spends to comply with the annual limit. GSK has also established corporate monitoring processes for this limit. However, the company's systems to support this requirement are limited and we are unable to monitor all promotional or other items provided to a California healthcare professional including: individual items with a unit value of \$10 or less; approved gifts that may be provided to a California healthcare professional at a medical or other convention; or items that may be provided to a small number of medical professionals such as non-prescribing formulary committee members or medical students who currently lack a GSK customer identification number.

Policy on Individuals or Entities Excluded from Federal Healthcare Programs

In business areas that work with federal healthcare programs, we require applicants to disclose whether they are currently excluded, debarred, suspended, or otherwise ineligible to participate in the Federal healthcare programs or in Federal procurement or non-procurement programs; or have been convicted of a criminal offense that falls within the ambit of 42 U.S.C. §1320a-7(a), but have not yet been excluded, debarred, suspended, or otherwise declared ineligible. In addition, we screen GSK personnel who are responsible for marketing or selling products or involved in government pricing or contract obligations against the General Services Administration's List of parties Excluded from Federal Programs and the HHS/OIG List of Excluded Individuals/Entities.

Any identified ineligible persons are precluded from employment at GSK.

Training and Education

GSK provides training and education programs to make sure employees understand our codes and policies, comply with the law, and know what standards of behavior are required. Our global induction course includes training on our Code of Conduct. This ensures new employees understand the importance of ethical conduct from day one, know how to deal with potential dilemmas, and know where to seek help. We provide additional training for employees who will be working in areas such as sales and marketing, R&D, and product manufacturing. In addition, we provide training and workshops to keep employees up-to-date with changes and to reinforce key elements in GSK policies. Training on significant policies (e.g. U.S. Pharmaceutical Policies) is required on a regular basis for GSK employees in the U.S. who work in Sales and Marketing and Managed Markets.

Commitment to our Code of Conduct is reinforced by an annual management certification program. Certification documentation is managed electronically and is followed up to ensure completion.

Internal Lines of Communication

Reporting Concerns

Employees are encouraged to seek help and to report concerns or suspected cases of misconduct. They can do this through their line management, a compliance officer, through our Integrity Helpline, or through the Corporate Ethics & Compliance Officer's off-site post office box. The Integrity Helpline and post office box are promoted through

the Employee Guide to Business Conduct, on the GSK intranet, and through training and communications. The Corporate Ethics and Compliance department is promoted as a source of information and advice, as well as a mechanism for reporting concerns. Internal data suggests employees understand this and see it as a useful source of advice and guidance.

Integrity Helpline

All GSK employees are responsible for promptly reporting to the Company actual or potential violations of the Code of Conduct, corporate policy, or legal requirements. While in most cases concerns that an employee may have can be resolved with their direct supervisor, the company recognizes that there may be instances where an employee may prefer to use another channel. That is the purpose of the GSK Integrity Helpline. The Integrity Helpline is a confidential, toll-free number available to all GSK employees if they have questions or concerns on the Code of Conduct, company policy, or legal compliance. Employees in the U.S. and Canada may call toll-free at 1-866-GSK-ETHICS (1-866-475-3844) during normal business hours (Eastern Time).

Concerns may also be reported to Human Resources, Legal, or Corporate Security. There also are other company channels available for specialized questions or reports including: Corporate Communications (media issues); Environment, Health & Safety (chemical spills, workplace safety); Occupational Health (medical issues, indoor air quality); Clinical Safety and Pharmacovigilance (adverse event reporting); Quality Assurance (Good Manufacturing Practices regulations); Regulatory Affairs (New Drug Applications, FDA filings); and Worldwide Regulatory Compliance (Good Laboratory Practices and Good Clinical Practices regulations).

Callers to the Integrity Helpline will be provided anonymity if desired. Calls to the Integrity Helpline are not recorded and the company has taken steps to prevent caller identification through the phone system technology. The company is not provided information about the originating phone number or location, and features such as "caller ID" have been disabled.

The company recognizes that employees may be discouraged from reporting concerns if they believe that retaliation, retribution, or harassment may result. GSK will take disciplinary action up to and including termination for managers, supervisors or employees who engage in retaliation, retribution, or harassment of an employee who reports a compliance concern in good faith.

The company will respond to and follow-up reasonable inquiries received on the Integrity Helpline. Depending on the findings of the inquiry, the company will take the action it deems appropriate in accordance with company policy.

Monitoring and Auditing

Monitoring for compliance is first conducted by managers, and supplemented by independent monitoring in certain areas. Issues identified in monitoring may be escalated for investigation and incorporated in training and education programs. Audits are also conducted on a regular basis by our corporate audit group. We also monitor awareness of ethical issues and company policies through our Integrity Helpline, reporting channels, and surveys. As part of our commitment to continuous improvement, we benchmark our compliance program against other major companies, our industry peers, and government and regulatory standards.

Addressing Misconduct and Developing Corrective Action

GSK's Corporate Ethics and Compliance department ensures that allegations and suspected cases of misconduct brought to the compliance department's attention are investigated. We are committed to taking firm steps to correct misconduct including administering discipline, up to and including dismissal, where necessary. We also take corrective measures, such as retraining, increased monitoring, and warnings.