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## **INTRODUCTION**

GlaxoSmithKline (GSK) is one of the world's leading research-based pharmaceutical and healthcare companies. GSK's global mission is to improve the quality of human life by enabling people to do more, feel better and live longer. Our business and behaviour are guided by the GSK Values of Transparency, Respect, Integrity, and Patient Focus. Conducting our business in accordance with the GSK Values and in full compliance with the law helps GSK achieve its mission. Our Values of Transparency, Respect, Integrity and Patient Focus form the foundation for building a high-performance culture. They affirm our commitment to ethical behaviour and commercial practices as we work to establish trust with customers and the public. We know that ethical standards are not static and that to ensure we are truly an ethical company we need to live our Values and make the right decision all of the time.

GSK is committed to establishing and maintaining an effective compliance program in accordance with the "Compliance Program Guidance for Pharmaceutical Manufacturers," published by the Office of Inspector General, US Department of Health and Human Services (the "HHS-OIG Guidance"). Our Compliance Program is one of the key components of our commitment to the highest standards of corporate conduct.

The purpose of our Compliance Program is to prevent and detect violations of law or company policy. As the HHS-OIG Guidance recognizes, however, 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 HHS-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; we regularly review and enhance our Compliance Program to meet our evolving compliance needs.

## **Overview of Compliance Program**

### **I. Leadership and Structure**

#### **Compliance Officer**

We have selected Neil Falkingham as our Compliance Officer, to serve as the focal point for compliance activities. We are committed to ensuring that Neil Falkingham, as Compliance Officer, has the ability to effectuate change within the organization as necessary and to exercise independent judgment. Neil Falkingham is charged with the responsibility of developing, operating and monitoring the Compliance Program. His contact information follows:

Phone: **9194859923**

E-mail: [Neil.E.Falkingham@gsk.com](mailto:Neil.E.Falkingham@gsk.com)

Mail: 5.5A PO Box 13398 RTP, NC 27709, USA  
(This is a secure post office box)

Assisting the Corporate Compliance Officer are Ethics & Compliance Officers that work with the GSK business units to identify and address compliance issues. Ethics & Compliance Officers are senior level leaders with direct access to the leadership teams of GSK functions. They are a source of expertise and a point of contact for anyone

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with a question on ethics or compliance with GSK policies. Ethics & 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.

Ethics & Compliance Officers are assigned to the following areas:

Chris Royal US Pharma Ethics & Compliance Officer <a href="mailto:Chris.M.Royal@gsk.com">Chris.M.Royal@gsk.com</a>	Mike Stubbins Research & Development Ethics & Compliance Officer <a href="mailto:Mike.2.Stubbins@gsk.com">Mike.2.Stubbins@gsk.com</a>
Yvonne Stewart Pharma Supply Chain Ethics & Compliance Officer <a href="mailto:Yvonne.M.Stewart@gsk.com">Yvonne.M.Stewart@gsk.com</a>	Dominique Giulini Consumer Healthcare Ethics & Compliance Officer <a href="mailto:Dominique.X.Giulini@gsk.com">Dominique.X.Giulini@gsk.com</a>

## Compliance Committees

GSK has established an Internal Control Framework to ensure that Principal 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 & Risk 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. Additionally, Business Units and Global Support Functions designated by the ROCC are accountable for setting up a Risk Management and Compliance Board (RMCB) to ensure appropriate risk management and implementation of internal controls for relevant Principal Risks within their scope of accountability. Business Unit and Global Support Function Heads report to the ROCC annually in regard to their oversight, including how their activities support applicable enterprise risk strategies.

## II. Written standards

### Code of Conduct

Ethical conduct is a priority for GSK and we are committed to performance with integrity. It is important that we conduct our business with honesty and integrity and in compliance with applicable legal and regulatory requirements.

GSK's Code of Conduct is our statement of ethical and compliance principles that guide our daily operations. The Code establishes that we expect management, employees, and agents of the company to act in accordance with law and applicable company policy. The Code brings together a number of company policy principles, and provides a working guide for how employees should apply GSK Values and Behaviours across all our business practices.

The Code of Conduct can be accessed using the following URL:  
<https://us.gsk.com/media/5194/english-code-of-conduct.pdf>

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## US Policies and Practices

Our US Policies and Practices 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
- Providing meals or educational items to a healthcare professional
- 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 of human safety information related to GSK products

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

## Research and Development Policies

The Research and Development (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 US Government. These Policies cover a range of activities including:

- 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 US Government
- Meals or educational items provided to a healthcare professional
- 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:

- Product samples intended for free distribution to patients for consumer use

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- Financial support for continued medical education
- Health educational scholarships
- Fair market value payments for legitimate professional services (e.g., consulting, advisory boards)
- Research sponsorship and related activities

This limit has been documented in GSK Policies and 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.

### III. Education and Training

We provide employees at all levels of the company with the support they need to make ethical choices through a variety of programs, many of which are designed to reinforce our Values. GSK provides training and education programs to make sure employees understand our codes and policies, comply with the law, and know what standards of behaviour 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. Recertification on significant policies (e.g. US Policies and Practices) is required on a regular basis for GSK employees in the US who work in Sales and Marketing and Payer Markets.

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

### IV. Internal Lines of Communication

#### Reporting Concerns

GSK encourages employees, complementary & contingency workers, vendors and any other groups we do business with to report concerns over possible misconduct, potential conflicts, or known breaches of our Code of Conduct, and other company policies and procedures. Ideally, concerns should be raised before problems develop.

People are encouraged to first seek help and to report concerns or suspected cases of misconduct through their line management, an Ethics & Compliance Officer, Legal or an HR representative.

#### Speak Up Integrity Line

For people who are unable or uncomfortable discussing a concern with these internal teams, they may also raise a concern by calling GSK's confidential, toll-free Speak Up Integrity Line or raising a web report. These reporting

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tools are globally supported, and reports can be raised anonymously if preferred. Employees in the US may call toll-free at 1-866-GSK-ETHICS (1-866-475-3844) at any time of day.

The Speak Up Integrity Line is promoted through the GSK Code of Conduct, on the GSK intranet and externally on gsk.com, as well as through training and communications. The Global Ethics & 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.

GSK encourages employees to report concerns without fear of reprisal. In line with our Value of Respect for People, the company endeavours to treat all questions or concerns about compliance in a confidential manner, even if the person reporting a question or concern identifies themselves.

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 against anyone who threatens or engages in retaliation or harassment of any person who has reported, or is considering reporting a concern in good faith.

The company will respond to and follow-up with reasonable concerns received on the Speak Up Integrity Line. The concern will be handled promptly, discreetly, and professionally. Depending on the findings of an inquiry, the company will take the action it deems appropriate in accordance with company policy.

## V. Auditing and Monitoring

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 Audit and Assurance group. We also monitor awareness of ethical issues and company policies through our Speak Up Integrity Line, 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.

## VI. Responding to Potential Violations and Corrective Action Procedures

GSK's Ethics & 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.