

# ViiV Healthcare Company Compliance Program – US Operations

## **INTRODUCTION**

ViiV Healthcare Company (VH or the "Company") is a global specialist HIV company dedicated to delivering advances in treatment and care for people living with HIV. Our business and behavior are guided by the VH Values of Patient Focus, Transparency, Respect, and Integrity and Expectations of Courage, Accountability, Development and Teamwork. Conducting our business in accordance with the VH Values and Expectations and in full compliance with the law helps VH achieve its mission. Our Values of Patient Focus, Transparency, Respect, and Integrity form the foundation for building a high-performance culture. They affirm our commitment to ethical behavior 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 to make the right decision all of the time.

VH is committed to establishing and maintaining an effective compliance program in accordance with "Compliance Program Guidance for Pharmaceutical Manufacturers," published by the Office of Inspector General, U.S. 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 VH'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 VH 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.

VH 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

# **Chief Compliance Officer**

The Chief Compliance Officer serves as the focal point for VH's compliance activities. We are committed to ensuring that the Chief Compliance Officer, has the ability to effectuate change within the organization as necessary and to exercise independent judgment. The Chief Compliance Officer is charged with the responsibility for developing, operating and monitoring the Compliance Program. The Chief Compliance officer, through the Global Head of Compliance, and the Compliance team, facilitates the operation of VH's Corporate Compliance program to ensure compliance with applicable laws, regulations, and Company policies, and to foster a positive, ethical work environment for employees.

VH's Corporate Compliance program operates under the direction of the Head of Global Compliance, Karen Allman, who facilitates the operation of an Internal Control Framework for oversight and guidance to ensure compliance with applicable laws, regulations, and Company policies, and to foster a positive, ethical work environment for employees.



# **Risk Management and Compliance Boards**

VH has established an Internal Control Framework to ensure that Enterprise Risks are reviewed and monitored and that specific issues and incidents (e.g., a compliance failure) are followed up and corrected. VH has established the Risk Management and Compliance Boards (RMCBs) to assist the Company in its review of risks and the system of internal controls necessary to address such risks. In the US, the North America Leadership Team RMCB is co-chaired by the SVP & Head of VH North America and the Director of North America Compliance. RMCBs have been established to oversee and ensure implementation of internal controls for risk management and legal compliance, and to provide regular reports to the VH Executive Team (VET) on the performance of such controls together with specific issues that arise.

#### II. Written standards

## **Code of Conduct**

Ethical conduct is a priority for VH 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.

VH adopted the Code of Conduct of its majority shareholder GlaxoSmithKline. The 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 of Conduct brings together a number of Company policy principles, and provides a working guide for how employees should apply values across all our business practices.

The Code of Conduct can be accessed using the following URL: <a href="https://www.gsk.com/media/4800/english-code-of-conduct.pdf">https://www.gsk.com/media/4800/english-code-of-conduct.pdf</a>

### **US Compliance Policies**

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

- Reporting adverse events relating to VH products
- Information that may be used by VH personnel to promote VH products
- Providing meals, educational items or reprints to a healthcare professional
- Provision of samples of VH products
- Selection and retention of healthcare professionals for consultation
- Contacts between VH sales representatives and consumers
- Conduct of VH-sponsored educational programs to educate healthcare professionals
- Sponsoring independent medical education or providing charitable contributions
- Role of sales and marketing personnel at national or regional medical conventions

These Policies, which are in addition to VH Corporate Policies, apply to all employees in VH US operations as well as other VH employees when they are involved in the marketing or selling of pharmaceutical products in the U.S.



# **Annual Spend Limit for California Healthcare Professionals**

VH 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. VH 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. VH 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:

- 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 VH US Policies and communicated to VH management teams and employees. The VH US local operating company and each employee is expected to manage their spends to comply with the annual limit. VH 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 and Expectations. VH 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 payer markets. In addition, we provide training and workshops to keep employees up-to-date with changes and to reinforce key elements in VH policies. Recertification on significant policies is required on a regular basis for VH employees in the U.S. 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**

VH 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, Compliance, 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 VH's confidential, toll-free Speak Up Integrity Line or raising a web report. These reporting tools are globally supported, and reports can be raised anonymously if preferred. Employees in the U.S. and Canada 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 Code of Conduct, on the VH intranet and externally on <u>viivhealthcare.com</u>, as well as through training and communications. The Legal & 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.

VH encourages employees to report concerns without fear of reprisal. In line with our Values, the Company endeavors 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. VH 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 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 with policies and laws is first conducted by managers, and supplemented by independent monitoring in certain areas. The Audit and Assurance group also conduct independent audits of our business activities on a regular basis.

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

VH's Legal & 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.