U.S. POLICY ON HEALTHCARE COMPLIANCE

Effective Date: October 1, 2015
Version: 5
Policy No.: VRX-US-CMP-001
Approved by: VP, Chief Compliance Officer and the Compliance Policy Committee

U.S. Policy on Healthcare Compliance

1. Purpose and Scope

As a pharmaceutical company, Valeant Pharmaceuticals International, Inc., including all its subsidiaries and divisions ("Valeant"), conducts a wide array of activities in the U.S. healthcare marketplace, including research, medical and other education, marketing, and sales. Each of these activities is subject to numerous legal and ethical standards, many of which are unique to the U.S. healthcare industry. Valeant is committed to complying with all applicable U.S. laws and regulations and adhering to the highest ethical standards in its marketing, promotional, educational, and research activities.

Valeant's U.S. Healthcare Compliance Policies are designed to provide guidance to Valeant employees, agents and contractors on the legal and ethical standards in the United States relating to the most common marketing and sales activities as well as other usual financial arrangements with Healthcare Professionals (as defined below). 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 supervisor or a member of the Compliance Department.

Valeant 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 Valeant as well as for individual employees. Therefore, Valeant employees whose job duties are affected by the Policies must be familiar with and adhere to them. Appropriate disciplinary action, up to, and including, termination, may be taken against any employee whose conduct violates Valeant's U.S. Healthcare Compliance Policies or applicable laws and regulations.

2. Definitions

a. Healthcare Professional

For the purpose of this Policy, Healthcare Professional ("HCP") includes licensed medical practitioners, medical staff members involved in providing patient care, including, but not limited to, physicians, nurses, nurse practitioners, physician assistants, medical assistants, office technicians, dentists, dental assistants, dental hygienists, medical residents, pharmacists, optometrists, and other individuals in the position to arrange for or recommend Valeant products.

b. Promotional Review Committee

All Promotional Materials must be reviewed and approved by a Valeant Promotional Review Committee ("PRC") prior to dissemination or use. Use of any Promotional Materials that have not been approved by PRC is strictly prohibited. The PRC will also approve field bulletins for certain materials, such as reprints of scientific articles that instruct sales representatives as to the proper use of the materials.

c. Promotional Materials

Promotional Materials are any materials used with HCPs, consumers, or other customers or used for internal training of sales representatives that directly or

indirectly promote, discuss, or refer to the safety, efficacy, use or attributes of a Valeant product or competitor product or a disease state or condition treated by a Valeant product, regardless of the material's origin, form or manner of use.

Promotional materials include, but are not limited to: sales aids, journal ads, reprints, sales training materials (including training materials associated with a particular promotional piece), direct mail pieces, professional or patient education videos or materials, promotional speaker slide decks, speaker program invitations, disease awareness materials, internet content (including Valeant product websites), television ads, commercial/convention exhibits, medically relevant items for the sales force to distribute to HCPs (e.g., textbooks), materials and tools used to train HCPs on the use of the device, biologic or cosmetic products, direct to patient materials to be provided through HCPs or at open houses/patient events, economic benefit materials and leave-behinds, product label to product label comparisons or other types of product comparisons to be used with customers, competitor pricing and advertising documents to be used with customers.

3. Vice President, Chief Compliance Officer and U.S. Compliance Officer

Valeant has appointed a Vice President, Chief Compliance Officer to oversee compliance activities in the United States. The Vice President, Chief Compliance Officer has appropriate authority to exercise independent judgment and has free and unencumbered access to the Chief Executive Officer and the Audit and Risk Committee of Valeant's Board of Directors.

In addition, Valeant has appointed a U.S. Compliance Officer to oversee compliance activities specific to U.S. healthcare requirements and who reports directly to the Chief Compliance Officer. Employees should feel free to contact the Vice President, Chief Compliance Officer directly at Seana.carson@valeant.com or the U.S. Compliance Officer directly at 908-927-1709 to discuss any compliance-related issues.

4. Overview of Legal and Ethical Standards

Valeant's promotional, educational, and clinical arrangements with customers are subject to the requirements of a variety of legal and ethical rules. Valeant is committed to conducting its affairs in compliance with these standards.

a. Anti-Kickback Statute

The federal *Anti-Kickback Statute* is potentially applicable whenever Valeant provides anything of value to customers or other persons who are in a position to influence the utilization of Valeant products or services. Under the Anti-Kickback Statute, it is illegal to offer, pay, solicit, or receive any remuneration to induce or in return for:

- Purchasing, ordering, recommending or arranging for the purchase of an item or service that is reimbursable by a federal healthcare program; or

- Referring an individual for an item or service reimbursed under a federal healthcare program.

"Remuneration" is defined very broadly to include anything of value, including not only cash, but also free items, services or even the opportunity to earn money. "Federal healthcare programs" include Medicare, Medicaid, the Department of Veterans Affairs healthcare 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.

A violation of the statute can lead to severe penalties, including criminal and/or civil fines for Valeant and individual employees, imprisonment of individuals, and possibly exclusion of Valeant products from eligibility for reimbursement under Medicare and Medicaid. Many states have different and possibly more restrictive 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 Statute is so broad, Congress has enacted a number of exceptions and "safe harbors" that specify practices that may 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. Valeant's Compliance 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 Valeant's policies, the Legal Department or the Compliance Department should be consulted.

b. <u>False Claims and Other Billing Standards</u>

Numerous federal and state laws including, but not limited, to the *Federal False Claims Act* 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 healthcare plans. A document can also 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 healthcare programs.

False claims and false statement laws have been applied to pharmaceutical manufacturers where the manufacturer took action which allegedly caused its customer to submit false claims. Valeant needs to be particularly careful about reimbursement relating to its products. Any materials disseminated to HCPs relating to reimbursement or coding must be approved by the PRC. Where information to support reimbursement is provided directly to carriers, their medical directors or their committees, all such information must first be reviewed by Legal, Regulatory and Medical Affairs.

c. Food and Drug Administration Restrictions on Promotion

The Food and Drug Administration ("FDA") regulates the labeling, marketing, sale, promotion and advertising of Valeant 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.

The 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 the FDA's regulations 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 marketing.

The FDA's restrictions on promotion apply not only to promotional materials distributed by Valeant, but also to information on Valeant products that is presented at non-independent promotional meetings, speaker events, and seminars conducted or funded by Valeant. Valeant's Policies on Promotion and Grants and Investigator-Initiated Studies seek to ensure that such programs either comply with the criteria for independence in the CME Guidance or comply with FDA's requirements for promotional activities.

d. 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 Valeant's policy is not to engage in any activity that could cause its customers to violate their professional or ethical obligations.

Several states have also enacted laws that limit or require pharmaceutical and device manufacturers to report certain gifts and marketing expenditures and/or pricing information to state regulatory bodies. Other states require pharmaceutical and medical device manufacturers to have an active compliance program that is consistent with the PhRMA Code, the AdvaMed Code and the OIG Guidance on Interactions with Healthcare Professionals.

Therefore, when new marketing and sales practices and programs are implemented, refer to the State Disclosure Law Reference Guide for related state-specific guidance.

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" ("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 Valeant is not a member of PhRMA, Valeant is 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 Valeant employees whose job duties are affected by these policies must be aware of the requirements set forth in the PhRMA Code, and the Code has been incorporated into Valeant's Policies. The complete PhRMA Code is attached to this policy as Appendix A.

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

AdvaMed Code: The Advanced Medical Technology Association ("AdvaMed") represents companies that develop, manufacture, produce and market medical products, technologies and related services and therapies used to diagnose, treat, monitor, manage and alleviate healthcare conditions and disabilities to enable patients to live longer and healthier lives. AdvaMed adopted the "Code of Ethics on Interactions with Health Care Professionals" ("AdvaMed Code") to ensure ethical interactions between companies and Healthcare Professionals. The complete AdvaMed Code is attached to this policy as Appendix B.

AMA Guidelines on Gifts to Physicians from Industry: In December of 1990, the American Medical Association ("AMA") adopted its "Guidelines on Gifts to Physicians 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 physicians, the PhRMA Code is more restrictive than the AMA Guidelines. In such cases, Valeant 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. The ACCME 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

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

responsibility for independence, resolution of personal conflicts of interest, appropriate use of commercial support, appropriate use of commercial promotion, presenting content and format without 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 HCP must be in writing.

5. General Rules for Analysis of Promotional, Educational, or Research Arrangements

Because of the scope of marketing, sales, educational, and research activities conducted by Valeant, some arrangements may not be specifically addressed by Valeant's policies. In the absence of such a policy, it may be useful to consider the following general standards when evaluating a particular program.

- **Payments.** All remuneration to customers 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.** Valeant's policies apply to compensation that is provided directly to a customer by Valeant as well as to compensation provided indirectly or through a third party. For example, if Valeant hires a third-party vendor to run a promotional program, Valeant's policies will apply to all activities and payments by the third-party.

- **No Exceptions.** The fact that an inappropriate arrangement is isolated or limited in scope is not a sufficient justification for the relationship.

- **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.

- **State specific requirements.** Even when no federal healthcare programs are implicated, some states impose marketing 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.** Valeant employees must maintain documentation of remuneration provided to customers which is sufficient to establish that the arrangement meets Valeant Policies.

6. Training

Valeant has an annual U.S. Healthcare Compliance training program that includes certification by appropriate employees. The training covers the relevant U.S. healthcare laws, industry codes, and Valeant's policies. Employees are also trained on the consequences of failing to comply with the requirements of Valeant's compliance

program, which includes appropriate disciplinary action, up to, and including, termination of employment.

7. Reporting Violations

Valeant employees are obligated to report any suspected violation of Valeant's policies to his or her supervisor, the Vice President, Chief Compliance Officer, the U.S. Compliance Officer or the Legal Department. Supervisors must in turn report any suspected violation of the U.S. healthcare laws or Valeant's policies to the Vice President, Chief Compliance Officer or the Executive Vice President, General Counsel.

Alternatively, employees may report violations using the Business Ethics Hotline, described in Valeant's Business Ethics Reporting Policy which is administered through My Safe Workplace, a third party who provides a confidential, anonymous means of submitting concerns. Employees can contact the Business Ethics Hotline available 24 hours a day, 7 days a week at 1-888-451-4510 or Email at www.valeant.ethicspoint.com.

Employees reporting suspected violations will not be required to give their names. All communications regarding any suspected violation of Valeant'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, supervisors or employees, or even if the report ultimately is established to be erroneous. Such retaliation by a manager, supervisor, or any other employee will be grounds for termination. If an employee who reports a violation is directly involved in a violation of the law or of Valeant's policies, the fact that he or she reported the violation will be given appropriate consideration in any resulting disciplinary action. Failure to report wrongdoing of which an employee has knowledge may, in itself, be basis for disciplinary action, up to, and including, termination of employment.

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

8. Auditing and Monitoring

Valeant self-assesses and periodically audits its employees to ensure compliance with its policies and procedures. All policies are periodically reviewed as well.

9. At-Will Employment

Unless otherwise expressly specified in writing, all employment with Valeant is on an at-will basis, as outlined in the current Valeant employee handbook. At-will employment means that all employment with Valeant is terminable with or without cause, and is terminable without prior notice. Nothing in Valeant's compliance policies shall be construed to convey any additional rights to any Valeant employee.

10. Review of Policy

The Chief Compliance Officer or his or her designee will periodically review this policy and update as necessary. Failure to comply with this policy may result in disciplinary procedures up to, and including, termination in accordance with Valeant's Policy on Compliance Investigations, Employee Discipline, and Corrective and Preventive Actions, as well as immediate termination of the arrangement.

11. Related Policies

Please see the following Valeant policies for more information:

- U.S. Policy on Product Promotions: Pharmaceuticals (VRX-US-CMP-002)
- U.S. Policy on Product Promotions: Devices, Cosmetics and OTC (VRX-US-CMP-017)
- U.S. Policy on Meals and Educational Items Provided to Healthcare Professionals (VRX-US-CMP-003)
- U.S. Policy on Market Research (VRX-US-CMP-004)
- U.S. Policy on Medical Science Liaisons (VRX-US-CMP-008)
- U.S. Policy on Professional Information Requests (VRX-US-CMP-009)
- U.S. Policy on Use of Off-Label Reprints (VRX-US-CMP-010)
- U.S. Policy on Fee-for-Service Arrangements with U.S. Healthcare Professionals and Related Institutions or Organizations (VRX-US-CMP-005)
- U.S. Policy on Grants and Investigator-Initiated Studies (VRX-US-CMP-011)
- U.S. Policy on Charitable Contributions and Donations (VRX-US-CMP-012)
- U.S. Policy on Clinical Trials (VRX-US-CMP-013)
- U.S. Policy on Public Disclosure of Research Data (VRX-US-CMP-014)
- U.S. Policy on Compliance Investigations, Employee Discipline, and Corrective and Preventive Actions (VRX-US-CMP-006)
- U.S. Policy on Compensation (VRX-US-CMP-007)
- U.S. Policy on Product Discounts, Rebates and Pricing (VRX-US-CMP-016)
- U.S. Policy on Speaker Programs (VRX-US-CMP-018)
- Standards of Business Conduct
- Business Ethics Reporting Policy

- State Disclosure Law Reference Guide

12. Questions

Questions about this Policy should be directed to the Vice President, Chief Compliance Officer or the U.S. Compliance Officer.