Schering-Plough Corporation Compliance Program

1. Introduction

As evidenced by its substantial and continuing efforts, Schering-Plough Corporation is committed to establishing and maintaining an effective compliance program. Our Compliance Program is referred to as the “Leading with Integrity” Compliance Program (“Compliance Program”) and is one of the key components that helps the company achieve its vision to “earn trust everyday.” This program is organized around the seven elements of the Office of Inspector General, U.S. Department of Health and Human Services’ “Compliance Program Guidance for Pharmaceutical Manufacturers” (the “HHS-OIG Guidance”) and follows the Pharmaceutical Research and Manufacturers of America Code on Interactions with Healthcare Professionals (“PhRMA Code”). The Compliance Program is reinforced by the Company’s “Leader Behaviors,” which are behavioral expectations that help Schering-Plough operationalize its vision, mission, and values. The Leader Behaviors describe excellence in action and what behavior at work should look like for each Schering-Plough colleague. The behaviors include shared accountability and transparency, cross-functional teamwork and collaboration, listening and learning, benchmark and continuously improve, coaching and developing others, and business integrity.

Our Compliance Program is designed to meet the unique needs of our company, which includes ensuring that we meet our obligations under our Corporate Integrity Agreement (“CIA”) with the OIG. It seeks to prevent and detect violations of law or company policies and to ensure that each member of our workforce employs the Leader Behaviors so these behaviors become a part of our everyday performance at Schering-Plough. Each Schering-Plough colleague is expected to follow the Leader Behaviors and comply with our Standards of Global Business Practices (“Global Standards”) as well as other corporate policies, which support the Global Standards. However, because there is never any guarantee that improper employee conduct will be eliminated entirely, when Schering-Plough becomes aware of any event that may be a violation of a law or company policy, we follow established policies and procedures to investigate, take disciplinary action, and implement corrective measures, if necessary, to prevent future occurrences.

The Global Compliance and Business Practices group oversees the Compliance Program. The Compliance Program is dynamic, and is subject to regular review and enhancements by Global Compliance and Business Practices in order to meet the changing legal and regulatory requirements that impact Schering-Plough’s business practices. The oversight activities of these groups are supported by a commitment from the Executive Management Team to “Leading with Integrity.”

2. Overview of Schering-Plough’s Compliance Program
A. Leadership and Structure

The Global Compliance & Business Practices department is the center point for all Schering-Plough compliance activities. The Chief Compliance Officer and Senior Vice President, Global Compliance and Business Practices, reports to the Chief Executive Officer and has independent authority to review ongoing compliance activities and to effectuate change within the organization as needed. The Global Compliance and Business Practices department has over 100 employees, including full-time compliance officers located in key business units around the world. Schering-Plough is committed to supporting the efforts of the department and the global team of compliance professionals, who are charged with developing, operating and monitoring the Compliance Program.

The Executive Management Team oversees all compliance activities and is chaired by the Chief Executive Officer of the Company, and staffed with Senior Executives from multiple business units who review compliance initiatives and ongoing programs on a regular basis. In addition to the oversight provided by the Executive Management Team, the Senior Vice President, Global Compliance and Business Practices, reports regularly to the Business Practices Oversight Committee of the Board of Directors.

B. Written Standards

- A key element underpinning our Compliance Program is the Global Standards, which sets forth the ethical compliance principles that each colleague needs to follow in order do his/her job in full compliance with the law. Colleagues know that when they do the right thing, they will receive full support of management and their colleagues.

- In addition to the Global Standards, Schering-Plough’s Compliance Program consists of corporate policies, divisional standard operating procedures, and other standards and guidances that apply to its manufacturing, quality, research and development, and sales and marketing activities.

- The Compliance Program includes a specific focus on our U.S. Sales and Marketing Activities. With respect to the Company’s U.S. commercial operations division responsible for the manufacture, sale and marketing of Schering-Plough’s prescription products, Schering-Plough has adopted a program to ensure that all interactions with Healthcare Providers focus on informational, scientific and educational exchanges. (the “U.S. Compliance Program”) Among others, we have policies and procedures in three key areas to conform with industry standards, the OIG guidance, and applicable laws, including policies and procedures relating to: (1) data integrity pertaining to government
reimbursement practices; (2) kickbacks and other illegal remuneration; and (3) compliance with laws regulating drug samples.

- For purposes of the California Drug Marketing Practices Statute, our U.S. Compliance Program includes an annual spending limit of no more than $2000 per healthcare professional for (i) in-office meals that should not exceed $25 per person, (ii) out-of-office meals permissible under the PhRMA Code provided in conjunction with an educational or informational discussion (e.g. speaker programs) which must be modest by local standards and which may generally not exceed $125 per person, and (iii) any educational items given to a healthcare professional which must be valued at $100 or less and do not have value to a customer outside of his or her practice / business. The $2,000 is set as an upper limit, not a spending goal. In rare circumstances, an exception may be made to this limit however this is only permissible if full written disclosure and approval is obtained from either a Regional Director or Business Unit Vice President. (This limit is also subject to certain laws governing interactions with government employees.) Certain items or activities of limited value are not included in the internal spending limit including: (i) nominal educational items valued at less than $15 and (ii) patient items (i.e. peak flow meters, starter kits, etc.)

C. Education and Training

One critical element of any effective compliance program is education and training so colleagues know the dos and don’ts of how we expect them to conduct business. Accordingly, Schering-Plough has established comprehensive communication and training programs to ensure that colleagues know where to go to access policies and procedures and receive appropriate training on these policies and procedures. Colleagues are trained on an annual and ongoing basis and the training is reviewed and updated accordingly. Schering-Plough has established four separate training and education sessions for U.S. sales and marketing employees and supporting corporate functions, as described more fully below. Additional training is provided depending on an individual employee’s job function. At all times, employees have access to the comprehensive training modules, and the policies and procedures that are part of the Compliance Program.

- Standards of Global Business Practices. This on-line general training module reviews the Global Standards, reinforces the new corporate vision of “Leading with Integrity”, and focuses on underlying themes, including Leader Behaviors, earning trust and business integrity.
• **Promotional and Product Services Training.** This on-line training module reviews the Company’s rules and regulations applicable to our promotional practices and applicable laws and guidances, including the Anti-Kickback Statute, Fraud and Abuse guidelines, the PhRMA Code and the OIG Guidance for Pharmaceutical Manufacturers.

• **Managed Care Training.** This on-line training module reviews the Company’s rules and regulations applicable to our relationships with our Managed Care Customers.

• **Pricing Training.** This on-line training module describes the Company’s rules and regulations and federal laws relating to pricing, including the False Claims Act, Medicare, Medicaid and Section 340B; and explains the methodology employed by the Schering-Plough U.S. Pricing Team to calculate Best Price, AMP and ASP. The course further reviews the Company’s pricing guides; methods for calculating Chargebacks and Rebates; the legislative price reporting calculations required for each government program; and how actions of individual SP employees can impact government price reporting.

D. Internal Lines of Communication

As part of Schering-Plough’s Compliance Program, we have numerous forms of communication that focus on ensuring that employees are up-to-date on important information and initiatives. Employees are kept informed of policy changes and new training or compliance initiatives through internal communications, bulletins posted on the company intranet, or communications from Senior Management which are cascaded through the organization via email or voice mail.

The Company’s anonymous disclosure program, known as the Integrity Action Line, facilitates communications within the organization regarding compliance with Company policies and procedures and federal and state laws and regulations. The Integrity Action Line is a toll-free hotline, which allows any individual to anonymously disclose compliance issues. It is staffed 24 hours a day, 365 days a year and has multi-lingual capabilities. As part of the disclosure program, Schering-Plough has implemented policies which prohibit retaliation against an employee for prompt, good faith and truthful reports of violations of laws or corporate policy by other employees.

E. Auditing and Monitoring

To bolster the Company’s Compliance Program we have established an audit program that includes activities to monitor, audit and evaluate compliance with the company’s policies and procedures and federal and state laws and regulations. The nature of our activities as well as the extent and frequency of
our compliance monitoring and auditing is dependent upon factors, including changing regulatory requirements, changes in business practices, and other considerations. The audit program is reviewed annually to ensure that it is focused on the significant business activities and risks.

F. Responding to Potential Violations

The Company has established policies on discipline that set out the consequences that may be imposed upon employees who violate the law or company policy, up to and including termination. Although each situation is considered on a case-by-case basis, we consistently undertake appropriate disciplinary action to address inappropriate conduct and deter future violations.

To further enhance our Compliance Program employees and relevant vendors are screened against three federal exclusion lists; the HHS/OIG list of Excluded Individuals/Entities, the General Services Administration List of Parties Excluded from Federal Programs and the FDA Debarment list to ensure they are not ineligible from participating in federal healthcare programs.

G. Corrective Action Procedures

The Company is committed to preventing and detecting violations of law and internal policies and procedures and taking appropriate corrective actions as necessary. Schering-Plough is committed to compliance, and our Global Standards and policies obligate employees to comply with all applicable laws, and to report potential improper conduct. Nonetheless, the OIG has recognized that an effective compliance program may not entirely eliminate improper conduct by individuals. In order to address the possibility of improper conduct, our program is designed to ensure that we respond promptly to potential violations of law or company policy, take appropriate disciplinary action, assess whether the violation is in part due to gaps in our policies, practices or internal controls, and take action to prevent future violations.

Schering-Plough is committed to “Leading with Integrity” in its compliance efforts, and in furtherance of this commitment we are continually striving to assess and improve our Compliance Program. We communicate the principles of compliance to Schering-Plough employees at all levels in order to operationalize our vision, mission, and values and to earn trust every day.

For additional information, please contact Schering-Plough at 800-428-5375.