



SUNOVION PHARMACEUTICALS INC.

CORPORATE POLICY

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| WORKING TITLE: Business Courtesies Policy | | POLICY NO: 3.05 | |
| Supersedes: | Approval Signature: Corporate Policy Review Committee (CPRC) | Date Issued: August 5, 2010 Amended: August 23, 2012 | Page: 1 of 6 |

SECTION 1. PURPOSE:

- 1.1 This Policy is intended to define the parameters pursuant to which Sunovion Inc. and its subsidiaries ("Sunovion" or the "Company") may provide a meal or medically relevant item to a Healthcare Professional and to ensure compliance with applicable laws and regulations, and industry guidance related to such interactions with Healthcare Professionals.
- 1.2 This Policy sets forth the process, requirements, limitations, and examples for meals and medically relevant items associated with any Healthcare Professional interactions as well any giveaways provided directly to consumers.
- 1.3 This Policy is intended to be consistent with the PhRMA Code on Interactions with Healthcare Professionals (July 1, 2002, rev. July 10, 2008); the Anti-Kickback Statute (42 U.S.C § 1320a-76(b)); the Department of Health and Human Services ("DHHS") Office of the Inspector General ("OIG") Compliance Program Guidance for Pharmaceutical Manufacturers (68 Fed. Reg. 23731, May 5, 2003); DHHS regulations; the federal Food, Drug, and Cosmetic Act; and Food and Drug Administration ("FDA") regulations; relevant FDA guidance; Sunovion policies and guidelines; and other statutes and regulations as applicable.

SECTION 2. DEFINITIONS:

- 2.1 "Business Courtesies" means Meals and Medically Relevant Items provided to a Healthcare Professional.
- 2.2 "Consumer" means any person that has consumed or may consume a Sunovion product.
- 2.3 "Employee" means any person employed by the Company on a full-time, part-time, temporary or contract basis.
- 2.4 "Entertainment" means social or recreational activities, including, but not limited to, social invitations, concerts, shows, sporting events, golf, boating, hunting or fishing trips.

- 2.5 "Field Sales Representatives" means Employees who are engaged in field sales during which they detail Healthcare Professionals. The definition does not include those Employees who interact with Healthcare Professionals employed by a managed care organization or other Employees who may interact with Healthcare Professionals but are not field based.
- 2.6 "Giveaway" means any tangible or intangible article, thing or item of value that is related to a disease or condition for which Sunovion products are indicated and any materials that will accompany such Giveaways. For example, Giveaways may include, but are not limited to, hypoallergenic pillow cases, peak flow meter, disease state-related books or journals, dust cloth/pollen mitt, tissues, inhaler stand, calendar, etc. The term "Giveaway" shall not include coupons or vouchers for Company products.
- 2.7 "Healthcare Professional or HCP" refers to: (a) physicians, physician assistants, nurses, nurse practitioners, pharmacists, medical assistants, and other medical professionals involved in patient care, (b) scientists or others who, because of their professional reputations may have an influence on clinical opinions, even though they would not be prescribing pharmaceutical products, and (c) others who can influence the purchase and/or prescribing of Sunovion products, including group purchasing organizations, pharmacy benefit managers, managed care organizations, and other entities who arrange for the provision of healthcare services, such as, home healthcare agencies.
- 2.8 "Meals" refers to food, snacks and/or beverages.
- 2.9 "Medically Relevant Item" means an item of value designed primarily for the education of patients or HCPs if the item is not of substantial value (\$100 or less) and does not have value to an HCP outside of his or her professional responsibilities.
- 2.10 "PMRC" refers to the Promotional Materials Review Committee which consists of a member from the Marketing, Medical Affairs, Regulatory and Legal Affairs Departments.
- 2.11 "Policy" refers to this policy.
- 2.12 "Sponsor" is responsible for developing and submitting materials for review by PMRC

SECTION 3. APPLICABILITY AND RESPONSIBILITIES:

- 3.1 This Policy applies to all Employees, as well as others acting on behalf of Sunovion.
- 3.2 All Employees shall follow this Policy. Any Employee who violates this Policy and any manager who knowingly permits or directs a subordinate to do so, will be disciplined accordingly, up to and including termination of employment.

- 3.3 Any persons acting on behalf of Sunovion, including consultants, speakers, agents, or third party vendors shall be obligated to follow this Policy, as appropriate, in contractual arrangements or otherwise. All such persons acting on behalf of Sunovion under this Policy shall participate in periodic training on these requirements.
- 3.4 The primary responsibility for implementation and oversight of this Policy is with the Compliance Department.
- 3.5 Managers and supervisors shall be responsible, through direct operations and through the direction of their subordinates, for ensuring that all Business Courtesies and Giveaways meet the requirements of this Policy.
- 3.6 The Chief Compliance and Ethics Officer ("Chief Compliance Officer") or her/his designate shall be responsible for developing, operating, monitoring and auditing compliance with this Policy and shall assist management and Employees by providing information and advice on the implementation and continued adherence to the Policy. In addition, the Chief Compliance Officer or her/his designate shall be responsible for the tracking and reporting of Business Courtesies and Giveaways in accordance with applicable laws and Company policies.
- 3.7 Management, working with the Chief Compliance Officer, is responsible for ensuring that relevant Employees are trained on the Policy. Management is also responsible for ensuring that Employees understand that they are encouraged to ask questions about the Policy, discuss compliance issues, and report possible noncompliance to management, the Legal Affairs Department and/or the Chief Compliance Officer.
- 3.8 Any person (whether an Employee or person acting on behalf of Sunovion) who knows of and/or suspects a violation of this Policy shall immediately discuss the matter with her/his supervisor (in the case of an Employee) or vendor coordinator (if a consultant or agent). If such a discussion is impracticable or if a person should prefer, she/he may also report the matter to the Chief Compliance Officer, a member of the Legal Affairs Department or Human Resources Department, or through the Sunovion Compliance Hotline (via telephone at 866-886-1348 or via the internet at www.ethicspoint.com). However, any person must raise her/his suspicions or knowledge of a violation as contained in this Section.

SECTION 4. GENERAL:

- 4.1 Sunovion may, in accordance with this Policy and other Company Policies, provide certain Business Courtesies to HCPs in connection with an informational presentation, discussion, or other appropriate interaction.
- 4.2 Sunovion may, in accordance with this Policy and other Company Policies, provide certain Giveaways to Consumers on an occasional basis.
- 4.3 Business Courtesies and Giveaways shall not be conditioned upon any explicit or implicit agreement or understanding to use, purchase, order, recommend; nor arrange for the use, purchase, order, recommendation, prescribing or dispensing of any Sunovion product.

- 4.4 Except as provided in this Policy, the Code of Conduct and Ethics, and the Conflicts of Interest Policy, no gifts of any value should be given to an HCP.

MEALS, ENTERTAINMENT AND VENUE

- 4.5 In connection with approved promotional activities, including informational presentations and discussions with HCPs, Field Sales Representatives and/or their immediate managers may provide modest, occasional meals to HCPs if such meals: (1) are modest as judged by local standards, not to exceed \$25 per person; (2) are limited to in-office or in-hospital settings; (3) are not part of any Entertainment; and (4) the meal is provided in connection with approved promotional activities, including informational presentations and discussions. Except as otherwise permitted pursuant to this Policy, Field Sales Representatives and/or their Immediate Managers are prohibited from providing meals to an HCP outside of the in-office or in-hospital setting. No Entertainment may be provided to Healthcare Professionals.
- 4.6 Speaker programs or other organized promotional programs may include modest meals offered to attendees and should occur in a venue conducive to informational communication. Field Sales Representatives and/or their immediate managers may attend these events.
- 4.7 Company Employees, other than Field Sales Representatives or their immediate managers, may also provide meals to HCPs participating in training events such as Speaker Bureau Training, or other organized events such as Advisory Boards, and may also provide meals to HCPs in connection with interactive discussions, not to exceed \$250 per person per day (all inclusive), subject to and in accordance with this Policy and the Healthcare Professional Consultant Policy. Field Sales Representatives and/or their immediate managers may not attend such events.
- 4.8 This policy permits an allowance for a modest meal of up to \$125 per person depending on the type of meal (ie., breakfast, lunch or dinner) and local standards. In no event shall any meal for an HCP exceed \$125 per person per meal. In addition, the provision of alcohol at dinner programs shall be reasonable and pre-selected where possible. Alcohol is not allowed at breakfast, lunch or any other daytime function.
- 4.9 Venue chosen for any interaction with an HCP should be conducive to giving an informational presentation or interaction in accordance with this Policy.

MEDICALLY RELEVANT ITEMS FOR HEALTHCARE PROFESSIONALS

- 4.10 Medically Relevant Items may be distributed to HCPs in accordance with this Policy and other applicable Sunovion policies and guidelines. Such items shall be treated as third party communications in accordance with the External Communications Policy and must be reviewed and approved by the PMRC.
- 4.11 Any Medically Relevant Item provided to an HCP must not be of a substantial value (\$100 or less), must not have value to the HCP outside of his/her professional responsibilities, and must not be offered on more than an occasional basis.
- 4.12 Payments in cash or cash equivalents (such as gift cards) should not be offered

to healthcare professionals either directly or indirectly, except as compensation for bona fide services in accordance with the Healthcare Professional Consultant Policy.

Non-educational items (such as pens, note pads, or other reminder items) shall not be offered to HCPs even if accompanied by patient or physician educational materials.

GIVEAWAYS AND COUPONS/VOUCHERS FOR CONSUMERS

- 4.13 Giveaways may be distributed directly to Consumers in accordance with this Policy and other applicable Sunovion policies and guidelines. Such items shall be treated as third party communications in accordance with the External Communications Policy and must be reviewed and approved by the PMRC.
- 4.14 Giveaways should be provided on an occasional basis only. Such items must not exceed a value of up to \$20 per item per Consumer and should not exceed a total value of up to \$50 per Consumer per year.
- 4.15 Items may also be given out on an occasional basis to a Consumer as part of a sweepstakes or contest with a value not to exceed \$500. These items must be reasonably related to the disease state for which the Product is approved or provide disease state education.
- 4.16 Coupons or vouchers for Company products may be made available to Consumers subject to review and approval by the PMRC and compliance with other applicable Company policies.
- 4.17 The Sponsor of the Giveaway and/or coupon and voucher must maintain and track, as necessary, information regarding the coupon/voucher and type of Giveaway provided to the Consumer. Such data must be kept in accordance with the Company's Privacy Policies and Procedures.

SECTION 5. OTHER MATTERS:

5.1 Amendment

Management reserves the right to amend this policy as appropriate at any time without prior notice, pursuant to Sunovion Corporate Policy 1.0, "**Corporate Policy Review Committee**".

5.2 Aggregate Spend and State Reporting

The definition of a healthcare professional for purposes of aggregate spend and state or federal reporting requirements shall be as specified in the applicable law. If no specific definition is provided, the Company shall use the definition set forth under the Physician Payment Sunshine Act of 2009.

5.3 Failure to Comply

EMPLOYEES WHO VIOLATE ANY SUNOVION POLICIES AND PROCEDURES WILL BE SUBJECT TO DISCIPLINARY ACTION, UP TO AND INCLUDING TERMINATION OF EMPLOYMENT.

5.4 Reporting Concerns

Reports concerning wrongful behavior, violations or suspected violations of this or any other policy, the Code of Conduct and Ethics, law or regulation may be submitted on a confidential basis or may be submitted anonymously through Sunovion's Compliance Hotline as set forth below. Reports of violations or suspected violations of alleged misconduct or wrongful behavior will be maintained as confidential as practicable under the circumstances, and as necessary to conduct a full and fair investigation.

Reporting Hotline Options:

- (a) Toll free telephone number. 866-886-1348
- (b) Via the internet at: www.ethicspoint.com

5.5 Audit (as needed)

Each department; shall perform periodic reviews of the implementation of this Policy, under the oversight and guidance of the Chief Compliance and Ethics Officer.

5.6 Cross-References to other Corporate Policies (as needed)

Code of Conduct and Ethics
Anti-Corruption Policy
External Communication Policy
Travel and Entertainment Policy
Conflicts of Interest Policy
Healthcare Professional Consultant Policy

Promotional Materials Review & Disposition Process

PhRMA Code on Interactions with Healthcare Professionals (July 1, 2002, as revised January 2004 and 2008)