



SUNOVION PHARMACEUTICALS INC.
CORPORATE POLICY

WORKING TITLE: Educational Grants Policy		POLICY NO: 1.02	
Supersedes:	Approval: Corporate Policy Review Committee (CPRC)	Date Issued: March 18, 2008 Date Amended: August 3, 2011	Page: 1 of 7

Section 1. PURPOSE

- 1.1 This Policy is intended to define the parameters pursuant to which Sunovion Pharmaceuticals Inc., ("Sunovion" or the "Company") may provide educational grants and/or related funding ("Grants") to support (i) educational programs or activities designed to provide valuable scientific, clinical and/or policy information to the scientific and health care community, and to ensure compliance with all relevant laws and regulations and industry guidance related to the provision of such educational grants; (ii) patient education, or (iii) local community health programs designed to create awareness of disease states and/or treatment options.
- 1.2 This Policy is intended to be consistent with the federal Food, Drug, and Cosmetic Act and Food and Drug Administration ("FDA") regulations; relevant FDA guidance (including Guidance for Industry on Industry-Supported Scientific and Educational Activities (Nov. 1997)); the PhRMA Code on Interactions with Healthcare Professionals (July 1, 2002, rev. July 10, 2008); 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) (and related anti-kickback statutes and regulations); the Accreditation Council for Continuing Medical Education ("ACCME") Standards for Commercial Support and related requirements; any revisions to the foregoing, and other statutes and regulations as applicable.

Section 2. DEFINITIONS

- 2.1 "Charitable Organization" is an organization that is recognized by the Internal Revenue Service as exempt from taxation under Section 501(c) (3) of the Internal Revenue Code; not controlled or founded by an individual healthcare provider, private physician practice group or physician clinic; and not on the OIG List of Excluded Individuals and Entities, the U.S. General Services Administration Excluded Parties List System, or the U.S. Food and Drug Administration Debarment List.

- 2.2 "Grants Review Committee" is the committee that oversees the Sunovion Grants process and is responsible for making determinations regarding the approval/denial of Grants.
- 2.3 "Grants Coordinator" is responsible for the administration of the Grants review process under this policy.
- 2.4 "Grant Request" means a request received through the Sunovion online Grants Submission System (or through some other means approved by the Grants Review Committee) seeking funding for a particular educational program or event and which shall contain, at a minimum, the following information:
- Title of the program
 - General topic(s) to be covered
 - Proposed date and location
 - Intended audience
 - Anticipated number of attendees
 - Whether the program is accredited
 - Needs assessment
 - Copies of the proposed agenda/conference brochure, if available
- 2.5 "Grant Requestor" means an entity that submits a Grant Request for consideration by the Grants Review Committee. Examples of appropriate Grant Requestors include:
- Health Care Professional Organizations
 - Hospitals, Health Systems or Academic Medical Centers
 - Accredited Educational Providers
 - Patient Advocacy Groups
 - Disease Related Organizations
 - Medical Education Companies
 - Charitable Organizations
- 2.6 "Grant Funding" means the monetary support provided to the Grant Requestor in response to a Grant Request as approved by the Grants Review Committee.
- 2.7 "Letter of Agreement" or "LOA" means the legal agreement that is entered into between Sunovion and the Grant Requestor(s) prior to the provision of Grant Funding, which sets forth the responsibilities of the parties regarding Grant-related activities.
- 2.8 "Policy" refers to this Educational Grants Policy.
- 2.9 "Program" means any educational program, event, initiative or other activity for healthcare providers, patients, caregivers or the local community.
- 2.10 "Promotional Programs" are those programs that are either (1) organized or conducted by Sunovion itself, or (2) organized and conducted by a third party with funding from Sunovion, whose content is controlled by Sunovion.

Section 3. APPLICABILITY

- 3.1 This policy applies to Sunovion Pharmaceuticals Inc. and its affiliates, where applicable. All employees responsible for the review and/or determinations regarding Grants governed by this Policy shall participate in periodic training on these requirements.

3.2 This Policy applies to all funding provided by the Company for scientific and educational programs and related activities of third party professional organizations, institutions, and Charitable Organizations, such as:

- Funding to Support Independent Educational/ Scientific Meetings
- Grants to Institutions to Fund Patient Education Programs/ Events
- Grants to Institutions to Fund Visiting Professorships and Research-oriented education
- Grants to Support Travel for Fellows and Residents-in-Training to Attend Major National/ Regional Conferences

This Policy does not apply to such matters as Promotional Programs, support of professional organizations, exhibits or related opportunities, or grant funding for research, including investigator-initiated research, or to political or charitable contributions that are not intended to support programs or activities covered under this Policy.

3.3 Any persons acting on behalf of Sunovion, including consultants, agents, and/or 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.

Section 4. RESPONSIBILITIES

4.1 The primary responsibility for implementation and oversight of this Policy is with the Medical Affairs Department.

4.2 The Medical Affairs Department shall be responsible, through direct operations and through the direction of other departments, for the oversight, organization and functioning of the Grants review process, including operation of the Grants Review Committee, administering and updating the online Grants Submission System, and authoring and maintaining procedures to effectuate the process for the review and approval of Grants.

4.3 The Grants Review Committee, in consultation with Legal Affairs, shall be responsible for evaluating and making determinations regarding all Grant Requests received by the Company. Members of the Committee shall be responsible for maintaining the integrity of the Grants review process and compliance with all laws, regulations and all guidelines and policies related to Grants.

4.3.1 The Grants Review Committee shall include representatives from the following functions, who shall be appointed by the respective EVP/SVP of that function, and shall serve as the voting member of the Grants Review Committee: Clinical Research Medical Affairs (CRMA), and Regulatory Affairs. A representative from Legal Affairs shall provide counsel to the voting members with respect to each Grant Request. Sales and Marketing personnel may not participate in the Grants review process and may not make representations or assurances that a Grant Request will be approved.

- 4.3.2 The Clinical Research Medical Affairs representative shall serve as the chair of the Grants Review Committee and shall be the one responsible for the oversight of the Grants review process.
- 4.3.3 The Grants Coordinator shall be responsible for receiving and processing all Grant Requests, notifying Grant Requestors when their requests have been approved or denied, or when more information is required, and maintaining a tracking system to monitor Grant Requests and payment history.
- 4.3.4 It is the responsibility of each member of the Grants Review Committee to adhere to the requirements of this Policy and other applicable Company policies, and to review, and approve or deny each Grant Request based on the requirements set forth in this Policy and other relevant considerations.
- 4.3.5 The Grants Review Committee may approve Grant Funding for Grant Requests that are consistent with the Company's overall strategic goals and that are within the Company's budget parameters, provided, however, that Grant Funding, which exceeds individually or in the aggregate in any calendar year, Five Hundred Thousand Dollars (\$500,000.00) shall also require approval of the Chief Executive Officer.
- 4.3.6 A unanimous vote of the Grants Review Committee in consultation with Legal Affairs shall be required for Grant Funding to be approved.

Section 5. GENERAL POLICY

- 5.1 Sunovion may provide Grant Funding to support bona fide educational, scientific and related programs, which are designed to provide valuable scientific, clinical, policy or other relevant information to the scientific and/or healthcare community, patients and caregivers, or the local community.
- 5.2 Programs may be conducted by professional organizations, institutions, charitable organizations, or continuing education providers, and may be accredited or non-accredited.
- 5.3 The content of these Programs must be non-promotional and cannot be controlled or influenced by Sunovion.
- 5.4 Grant Funding may be limited to those programs that involve topics of interest to Sunovion, provided that the educational provider shall maintain control over the content of the Program, faculty selection, venue, Program audience, and disposition and distribution of Grant Funding.
- 5.5 The amount of the Grant Request must be appropriate for the scope of the Program.
- 5.6 Grants shall not be conditioned, in whole or in part, on any explicit or implied requirement or understanding to purchase, use, order, recommend, prescribe, or provide formulary status for any Sunovion product.

Section 6. SPECIFIC GUIDELINES/ CRITERIA FOR GRANTS

- 6.1 Grant Requests must describe the intended use of the Grant funds, confirming that the funds will be used for education or other stated initiatives.
- 6.2 Except as otherwise permitted by the Grants Review Committee, all Grant Requests must be submitted through the Sunovion online Grants Submission System.
- 6.3 Grant Funding shall not be provided to an individual physician or private physician practice for any reason.
- 6.4 Grant Funding shall not be provided to any entity that provides marketing, advertising, public relations, market research or other promotional services ("Commercial Activities") to Sunovion. If an entity has an affiliated company that provides Commercial Activities, such entity may be eligible Grant Funding provided it has appropriate controls and safeguards in place to ensure that any Program (i) remains independent, objective, balanced and scientifically rigorous, (ii) is not intended to promote a Sunovion product directly or indirectly, and (iii) is not in any way biased due to the affiliated company's relationship with Sunovion.
- 6.5 Grant Funding shall not be provided to any entity for such entity to promote its own services.
- 6.6 Sunovion shall not provide Grant Funding or support Programs with the intent to promote an unapproved product or an unapproved use of its Products.
- 6.7 Grant Funding shall not be provided to fund or sponsor Promotional Programs, promotional seminars or other promotional activity.
- 6.8 Grant Funding shall not be provided to pay for normal institutional overhead or for capital expenditures.
- 6.9 Grant Funding shall not be provided for Programs that have already occurred.
- 6.10 Sunovion shall not direct, control or attempt to direct or control, the Program in any way, including, **but not limited to**, Program planning, Program content, faculty, audience, agenda, educational methods or materials, or the planning or selection of the venue, or refreshments for the Program.
- 6.11 Except as otherwise approved by the Grants Review Committee, no Company employee should be a speaker at a Sunovion sponsored Program. If approved by the Grants Review Committee, the appropriate disclosures (approved in advance by the Grants Review Committee) must be made by the Sunovion employee to the Program Sponsor and the Program audience.
- 6.12 With written direction from a Program sponsor and subject to approval by the Grants Review Committee, Sunovion may assist in the distribution of invitations or Business Reply Cards for a Program.

- 6.13 Grant Funding may be provided to a medical institution to defray reasonable travel costs and expenses of its medical students, residents or fellows to attend a major educational/scientific meeting of a national, regional or specialty health care professional organization. Such attendees must be selected by the medical institution and not by Sunovion.
- 6.14 The terms of any approved Grant shall be contained in a Letter of Agreement (LOA). Each LOA shall provide Sunovion with the right to audit the Program in order to ensure adherence to the terms of the LOA.

Section 7. GENERAL

7.1 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.**"

7.2 Failure to Comply

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

7.3 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 the Sunovion Compliance Hotline as set forth below. Reports of violations or suspected violations of alleged misconduct or wrongful behavior are 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

Sunovion does not tolerate any form of retaliation or adverse action against any employee who submits a report of misconduct. In addition to these protections, an employee may also avail themselves of the remedies afforded under federal and state law, including the federal "False Claims Act," 31 U.S.C. Sections 3729-3733, the Commonwealth of Massachusetts Whistleblower Protection Act, M.G.L 149, Chapter 185 and the New Jersey Conscientious Employee Protection Act, N.J. Stat. Ann. Section 34:19, Sections 1 to 8.

7.4 Audit

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

7.5 Related Corporate Policies

Code of Conduct and Ethics

Conflicts of Interest Policy

Corporate Giving Policy

Support of Third Party Organizations Policy

Investigator-Initiated Studies Policy

External Communications Policy