SUNOVION PHARMACEUTICALS INC.

CORPORATE POLICY

WORKING TITLE: Advisory Boards Policy		POLICY NO: 3.08	
Supersedes:	**Approval:** **Corporate Policy Review Committee (CPRC)**	**Date Issued:** **April 18, 2013**	**Page: 1 of 6**

SECTION 1. PURPOSE:

1.1 Advisory Boards provide a valuable source of information with respect to medical needs, patients and customer needs, marketplace dynamics, and the use of Sunovion products. The purpose of this Policy is to set forth requirements under which Sunovion Pharmaceuticals Inc. (the "Company" or "Sunovion") may conduct an Advisory Board where the Advisory Board Members of the Company will include Healthcare Professionals.

1.2 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; Food and Drug Administration ("FDA") regulations; relevant FDA guidance; Company policies and guidelines; and other statutes and regulations as applicable, as well as laws of similar effect in other countries.

SECTION 2. DEFINITIONS:

2.1 "**Advisory Board**" is defined as set forth in Corporate Policy No. 3.04, Healthcare Professional Consultant Policy, a summary of which is provided for convenience: "*refers to a meeting utilized to acquire needed information from a selected panel of qualified [Healthcare Professional Consultants] on scientific, medical or business issues, product development and research programs, or in therapeutic areas of interest to Sunovion.*"

2.1.1 Advisory Boards are distinguishable from Market Research where, in the later instance, the Company seeks feedback from individuals (blinded or unblinded to the Company and to the individuals) based upon the individual as representative of a particular type of group (e.g., physician specialty), to assist in understanding or extrapolating the general perspective of that group.

2.2 "**Business Needs/Fair Market Value Assessment Form**" or "FMV/BNF" is defined as set forth in Corporate Policy No. 3.04, Healthcare Professional Consultant Policy.

2.3 "**Healthcare Professional**" or "**HCP**" is defined as set forth in Corporate Policy No. 3.04, Healthcare Professional Consultant Policy, a summary of which is provided for convenience: "*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."

2.4 "**Initiator**" is defined as the Sunovion employee with ultimate responsibility for the planning and execution of the Advisory Board in accordance with this Policy. The Initiator must be a Sunovion employee at the Director level or above.

2.5 "**Legitimate Business Interest**" is defined as set forth in Corporate Policy No. 3.04, Healthcare Professional Consultant Policy.

SECTION 3. APPLICABILITY AND RESPONSIBILITIES:

3.1 This Policy and any related procedures apply to the planning and execution of all Company Advisory Boards. The Policy covers all employees of Sunovion, as well as vendors and other third parties conducting such meetings on Sunovion's behalf. If the Initiator of an Advisory Board retains a vendor to assist in planning and/or organizing an Advisory Board meeting, the Initiator must ensure that the vendor is aware of and compliant with this Policy.

3.2 Either the Vice President for the functional area, or the therapeutic area head, proposing the program must:

a) Approve the business need for an Advisory Board in advance of any project/program initiation; and
b) Subsequently assign a program Initiator or designate him or herself as the program Initiator.

3.2.1 For purposes of clarity, any and all Advisory Boards proposed by the field sales organization must be approved by the respective brand Vice President.

3.3 The Initiator, in all cases, must:

a) Develop the Advisory Board in conjunction with the Compliance and Ethics Department and Legal Affairs, and must obtain written approval from the Compliance and Ethics Department **prior to execution and before any commitments are made** (including any commitment with a potential vendor or venue);
b) Complete the FMV/BNF in accordance with Corporate Policy No. 3.04, Healthcare Professional Consultant Policy; and
c) Comply with the HCP contracting process consistent with Corporate Policy No. 3.03, Contract Review and Signing Authority, and Corporate Procedure No. 3.03A, Contract Review Standard Operating Procedure.

SECTION 4. SPECIFIC GUIDELINES:

4.1 **Legitimate Business Interest of Advisory Board**

4.1.1 The Company may conduct Advisory Boards to obtain input, opinions and advice from experts in a particular field where the Company lacks the required expertise or perspective that the respective experts can provide, consistent with the Company's Legitimate Business Interests.

4.1.2 An Advisory Board may be formed only when there is a legitimate need for feedback or advice on important clinical or business issues such as assisting the Company in developing protocols, strategies and tactics on research, development, marketing, therapeutic areas or other strategic business issues.

4.1.3 Advisory Boards may not be used as a mechanism to:

a) build relationships with Healthcare Professionals;
b) promote Sunovion products;
c) reward customers for purchasing, prescribing or recommending Sunovion products; or
d) as an inducement for purchasing, prescribing or recommending Company products.

4.2 **Advisory Board Planning**

4.2.1 Advisory Board Agreements

4.2.1.1 All Advisory Board members must enter into a written agreement with Sunovion which, consistent with Corporate Policy No. 3.03, Contract Review and Signing Authority, and Corporate Procedure No. 3.03A, Contract Review Standard Operating Procedure, shall be reviewed by Legal Affairs and signed prior to the planned Advisory Board.

4.2.1.2 Advisor agreements and the associated program, fees, meals, travel and venue must be consistent with the Sunovion Healthcare Professional Consultant Policy and the fair market values for those services.

4.2.2 Advisory Board Member and Venue Criteria

4.2.2.1 The members of the Advisory Board and the venue for the Advisory Board meeting must be selected consistent with the Company's applicable policies and applicable laws and regulations. For purposes of example only, some of the key elements of the Healthcare Professional Consultant Policy that apply to Advisory Boards include but are not limited to:

a) Meetings should be held at modest business-level venues within the continental United States and in an environment conducive to appropriately communicate and conduct the business purpose of the meeting. A reasonable and modest reception and meals in connection with the meeting are allowed but should not consume a disproportionate part of the meeting time and must be subordinate in terms of time and emphasis. No recreational or entertainment events may be provided in conjunction with an Advisory Board meeting.

b) Advisory Board members should be selected based upon the advisor's qualifications and expertise in the area for which advice is sought. Selection of the Advisory Board member should be done by persons with the requisite expertise necessary to evaluate the qualifications of the proposed Advisory Board member. Members cannot be selected based upon their use, recommendation or purchase of Sunovion products.

4.2.2.2 **Prohibited Individuals**: Federal and State government employees are prohibited from participating in Company Advisory Boards.

4.2.2.3 **Number of Advisory Board Members**: The number of Advisory Board Members should be kept to a minimum consistent with the goal of obtaining meaningful advice (typically 10-20 for national boards and 7-10 for regional boards).

4.3 **Physician Spend Reporting.** The Initiator must ensure that any and all Company expenditures (consulting fees, meals, travel expenses, etc.) on physicians related to an Advisory Board are accurately reported to the Company for state and federal transparency reporting.

4.4 **Meeting and Collection of Advice**. There are three stages for conducting an approved Advisory Board, each stage with specific requirements that must be met. The three stages are:

a) Pre-Meeting
b) Meeting
c) Post-Meeting

4.4.1 **Pre-Meeting**

4.4.1.1 During the planning process for the Advisory Board, the Initiator must be able to identify and document in writing a legitimate need for the advice sought (such as protocol development, product development strategies, marketing strategies, medical strategies and promotional messages or programs), that the Company lacks the in-house expertise for that advice and that it is not duplicative of advice or feedback previously obtained.

4.4.1.2 Any proposed Commercial employee attendees at a Clinical Advisory Board must be proposed in the planning phase of the Advisory Board and approved in advance by Legal Affairs and the Compliance and Ethics Department.

4.4.1.3 Consideration should also be given by the Initiator to:

a) The justification for the number of consultants reasonably required to undertake the research in question;

b) The slides, data, and other materials that will be used or presented at the meeting, including the list of questions or outline of the types of questions that will be asked at the Advisory Board to solicit appropriate feedback from the Advisory Board Members;

c) Establishing an effective mechanism to collect, review and consider advice obtained from the meeting. Feedback, analysis of feedback and key actions stemming from the input received (including decisions or rational to take no action) must be appropriately documented.

4.4.1.4 **Once these points have been considered, the Initiator must submit a formal proposal in accordance with the Sunovion Advisory Board Standard Operating Procedure**.

4.4.1.5 **Invitations**: Invitations to approved participants in the Advisory Board must be approved through the PMRC or MSRC process in accordance with the External Communications Policy. The invitation to the Advisory Board meeting should cite the PhRMA code and state that the invitation is for the Advisory Board member only.

4.4.1.6 **Guests** (Non-Advisory Board members): Sunovion will not pay for any guest expenses. If an Advisory Board member brings a guest, that member is responsible for the guest's expenses. No guest may attend any portion of the Advisory Board meeting, including meals and receptions.

4.4.1.7 **Combined Clinical and Commercial Meetings**: Advisory Boards will be designated as either Commercial or Clinical and led by the designated functional area. In addition, the budget and vendor(s) selected, if any, to coordinate the program should originate from the lead functional area. Any exception must be approved, in advance, through consultation with Legal Affairs and the Compliance and Ethics Department.

4.4.2 **The Meeting**

4.4.2.1 The meeting must be conducted as proposed and approved in advance by the Compliance and Ethics Department. Only materials that have been reviewed and

approved by the appropriate Company review committee for that specific Advisory Board may be presented to the Advisory Board Members.

4.4.2.2 **Sunovion attendees and their role in the meeting**

4.4.2.2.1 Attendance at Advisory Boards is limited to Company personnel with direct responsibility for the information being gathered, and their contracted third party that has responsibility for meeting logistics. The designated functional area (Commercial or Clinical) should lead the program. This includes leading and/or moderating each of the program sessions.

4.4.2.2.2 The presence of Clinical at a Commercial Advisory Board should be limited. Clinical representatives attending a Commercial Advisory Board may present a product and/or clinical overview, but only to the extent necessary to inform the subsequent commercial discussions.

4.4.2.2.3 The presence of the Commercial Organization at a Clinical Advisory Board also should be limited to those instances where there is a legitimate business reason for attending. It is never appropriate for a marketing presentation to be made at a Clinical Advisory Board, although a general Company overview/update may be appropriate.

4.4.2.2.4 **Under no circumstances are Therapeutic Specialists or Regional Business Managers permitted to attend an Advisory Board meeting.**

4.4.2.3 **Information presented to Advisory Boards by Sunovion**

4.4.2.3.1 The Advisory Board meeting, as reflected in the meeting agenda, must focus predominately on obtaining feedback, advice and/or recommendations from Advisory Board members.

4.4.2.3.2 Information presented must be limited to only that which is reasonably required by the Advisory Board members to assist them in providing informed feedback and advice to Sunovion. Off-label information may be presented only if needed to obtain the requested feedback on that specific data. If off-label information is presented, it must be identified as such to the Advisory Board members. Scientific data must be presented factually and objectively, with meaningful disclosure of limitations and in a non-promotional manner. Presenters must be limited to those individuals most qualified to present the information.

4.4.2.3.3 Initiator must establish a system prior to the Advisory Board meeting to ensure the capture of feedback at the meeting and a detailed plan as to how the information will be summarized, communicated, and used by the Company. **Video and/or audio recording is prohibited.**

4.4.3 **Post Meeting**

4.4.3.1 **<u>At the conclusion of any Advisory Board meeting, the Initiator must ensure that the following steps are taken with regard to the information obtained from the consultants</u>**:

a) Prepare a report that summarizes the results of the program that includes the feedback, analysis of feedback and key recommendations for further action.
   - Include in the report how Advisory Board members' feedback will be incorporated into any business or project plan.

- Include in the report, if applicable, the reason feedback from a consultants' meeting was not incorporated into the planned use of that information.

b) The final report should be distributed to relevant and appropriate Sunovion employees.

4.4.3.2 The Initiator shall maintain a final report along with all other relevant files, in accordance with Sunovion Records Management and Retention Policy.

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 Failure to Comply

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

5.3 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 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

5.4 Audit

Sunovion Internal Audit shall perform periodic reviews of the implementation of this Policy, under the oversight and guidance of the Chief Compliance and Ethics Officer.

5.5 Cross Referenced Documents

- Corporate Policy No. 1.3, External Communications Policy
- Corporate Policy No. 3.03, Contract Review and Signing Authority
- Corporate Procedure No. 3.03A, Contract Review Standard Operating Procedure
- Corporate Policy No. 3.04, Healthcare Professional Consultant Policy
- Corporate Policy No. 3.05, Business Courtesies Policy
- Sunovion Code of Conduct and Ethics
- Guidelines for Interactions with Healthcare Professionals
- Corporate Policy No. 1.15, Records Management and Retention Policy