



## **PHARMACEUTICALS INC.**

### **CORPORATE POLICY**

<b>WORKING TITLE:</b> <b>HealthCare Professional Consultant Policy</b>		<b>POLICY NO: 3.04</b>	
<b>Supersedes:</b>	<b>Approval Signature:</b> <b>Corporate Policy Review</b> <b>Committee (CPRC)</b>	<b>Date Issued: 2/24/09</b> <b>Amended: August 23, 2012</b>	<b>Page:1 of 10</b>

#### **SECTION 1. PURPOSE:**

- 1.1 This Policy is intended to set forth the parameters pursuant to which Sunovion Inc. and its United States subsidiaries, ("Sunovion" or the "Company") may engage a Healthcare Professional Consultant ("HCPC") to provide services to Sunovion and to ensure compliance with applicable laws and regulations and industry guidance related to such relationships.
- 1.2 This Policy defines the process, roles and responsibilities for all stages of an HCPC engagement including the preparation, submission, review and, if appropriate, approval of a Business Needs/Fair Market Value Assessment Form; the appropriate selection and contracting of a qualified, external HCPQ and the process for the execution of an approved HCPC engagement.
- 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, as well as laws of similar effect in other countries.

#### **SECTION 2. DEFINITIONS:**

- 2.1 "Advisory Board" refers to a meeting utilized to acquire needed information from a selected panel of qualified HCPCs on scientific, medical or business issues, product development and research programs, or in therapeutic areas of interest to Sunovion.

- 2.2 "Business Needs/Fair Market Value Assessment Form" is a form used to capture the business or scientific need for a proposed HCPC engagement; this form is submitted for review and approval prior to implementation of services.
- 2.3 Chief Compliance Officer means the Chief Compliance and Ethics Officer.
- 2.4 "Consultant Services Agreement" is a written agreement between Sunovion and a qualified, external HCPC regarding the provision of consulting services to Sunovion consistent with the Contract Review and Signing Authority Policy No. 3.03.
- 2.5 "Employee" means any person employed by the Company on a full-time, part-time, temporary or a contract basis.
- 2.6 "Fair Market Value" means remuneration consistent with the amounts paid for such services performed by similarly qualified persons in arms-length transactions, based upon industry standards and evaluations, and is not determined in any manner that takes into account the volume or value of any referrals or business.
- 2.7 "Healthcare Professional" 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 "Legitimate Business Need" is an identified and bona fide, pre-determined business and/or scientific purpose for which consulting services are required.
- 2.9 "Meals" refers to food, snacks and/or beverages.
- 2.10 "Policy" refers to this policy.

### **SECTION 3. APPLICABILITY AND RESPONSIBILITIES:**

- 3.1 This Policy applies to any and all relationships between Sunovion and HCPCs in the United States or abroad, where there is an exchange of payment for services, including, but not limited to:
- Research and Development Services (i.e., investigators)
  - Marketing Services
  - Advisory Boards
  - Presentations
  - Training
  - Other services

This Policy does not apply to non-Healthcare Professional consultants. Contracts with non-Healthcare Professional consultants are governed by the Contract Review and Signing Authority Policy No. 3.03.

- 3.2 All Employees of Sunovion 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 vendors shall be obligated to follow this Policy, as appropriate, in contractual arrangements or otherwise.
- 3.4 Managers and supervisors shall be responsible, through direct operations and through the direction of their subordinates, for ensuring that all requests for contracts with HCPCs meet the requirement of this Policy and other applicable Company policies, including but not limited to the Contract Review and Signing Authority Policy No. 3.03.
- 3.5 The Chief Compliance Officer or her/his designee 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.
- 3.6 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 their management, Legal Affairs and/or the Chief Compliance Officer.
- 3.7 The Compliance Department is primarily responsible for the tracking and reporting of any item of value provided to each HCPC in accordance with applicable state and federal reporting requirements and in accordance with applicable policies.
- 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, a member of the Human Resources Department, or through the Sunovion Compliance Hotline (via telephone at 866-886-1348 or via the internet at <http://www.ethicspoint.com>).

#### **SECTION 4. GENERAL:**

- 4.1 Anytime an HCPC is engaged to provide services to Sunovion, the relationship with the HCPC must be reflected in a contract approved pursuant to all applicable Company policies, including but not limited to the Contract Review and Signing Authority Policy No. 3.03.
- 4.2 Selection of HCPCs.
- 4.3 Sunovion may only engage an HCPC to fulfill a Legitimate Business Need. A Legitimate Business Need must be clearly identified and documented (using the attached Business Needs/Fair Market Assessment Form) in advance of entering into any agreement with an HCPC. The number of HCPCs retained for any engagement should not be greater than the number reasonably necessary to achieve the identified purpose.

- 4.4 Prior to initiating any agreement with an HCPC, a Business Need/ Fair Market Value Assessment Form (attached as Exhibit A to this Policy) must be completed, and a Curriculum Vitae ("CV") shall be provided by the HCPC.
- 4.5 The HCPC must be capable of providing the services at the time of contracting.
- 4.6 All HCPCs must be selected based on criteria directly related to the identified Legitimate Business Need. Persons selecting HCPCs must have the expertise to evaluate whether an HCPC meets the identified criteria, which should include the HCPCs experience, expertise, and special knowledge, or skills (as set forth in the HCPCs CV) that are necessary to fulfill the Legitimate Business Need. Such selection criteria may include, but are not limited to the following: (a) expertise in appropriate field or subject matter or demonstrated ability to provide required services; (b) educational or professional experience necessary to perform the requested services; (c) professional license in good standing, if applicable; (d) disease, therapeutic or business area knowledge; and (e) familiarity with applicable Sunovion product(s) and competitive products, where applicable.
- 4.7 Selection of any HCPC shall not be conditioned upon any explicit or implicit agreement or understanding to use, purchase, order, recommend or arrange for the use, purchase, order, recommendation, prescribing or dispensing of any Sunovion product. HCPC arrangements cannot be used as inducements or rewards for an HCPC to prescribe a particular medicine or course of treatment.
- 4.8 Any analysis, including a return on investment analysis, must not include an assessment of any change in a HCPCs prescribing or purchasing habits with respect to any Sunovion product in connection with her/his services as an HCPC for Sunovion.
- 4.9 All HCPC agreements must be reviewed and approved in accordance with this Policy and the Contract Review and Signing Authority Policy No. 3.03 prior to submission for execution.
- 4.10 Any meeting involving HCPCs must be held in a venue that is appropriate and conducive to the services being provided and be conducted in accordance with applicable policies.
- 4.11 Reimbursement and Compensation of HCPG.
- 4.11.1 Costs for travel, lodging and meals related to the provision of services by an HCPC ("HCPC Expenses") should be reimbursed in accordance with applicable policies regarding expense reimbursement. Reasonable HCPC expenses must be modest, appropriate and directly related to the main purpose for which the HCPC is being engaged. No other expenses of an HCPC may be provided except as approved by an Executive Vice President in consultation with the Legal Affairs Department.
- 4.11.2 Sunovion will not pay or reimburse the expense for any spouse, child or other family member or guest to travel to the location of any HCPC meeting or event.
- 4.11.3 Any meals provided to an HCPC as part of an Advisory Board, speaker training event or other program or activity should be consistent with the Sunovion Business Courtesies Policy and shall not exceed a total of two hundred and fifty dollars (\$250) per day depending on local standards. Exceptions may be made on a case by case basis by a Senior Vice President in consultation with the Legal Affairs Department.
- 4.11.4 All payments to HCPCs for services provided must be made in accordance with an HCPC agreement and this Policy. Compensation to HCPCs for services must be reasonable, set in advance, and must not exceed Fair Market Value. (See approved schedules provided by the Compliance Department in consultation with the Legal Affairs Department.)
- 4.11.5 No compensation, travel, lodging or other expenses can be paid for non-faculty, non-HCPCs at company meetings, including attendees who participate in interactive sessions,

except as provided by a fully-executed separate written services agreement prepared in accordance with the Contract Review and Signing Authority Policy.

4.11.6 A cap on annual compensation for any HCPC serving as a promotional speaker shall be established and shall be published to the Company.

4.11.7 Sunovion shall disclose payments made to HCPCs as required by law.

4.12 Services Provided by HCPC.

4.12.1 Services provided by HCPCs must be appropriately utilized and such use must be documented in writing.

4.12.2 Token consulting or advisory arrangements cannot be used to justify compensating an HCPC for his/her time or travel, lodging or any other out-of-pocket expenses.

4.13 Any HCPC who is a member of a committee that sets formularies or develops clinical guidelines shall disclose to such committee the existence and general nature of his or her relationship with Sunovion. Such HCPC shall continue to disclose to any such committee his/her relationship with Sunovion for two years beyond the termination of the HCPCs relationship with Sunovion.

4.14 Advisory Boards

4.14.1 Advisory Boards may not be used for the purpose of marketing and/or promoting Sunovion products to advisory board members.

4.14.2 All Advisory Boards must be reviewed and approved in writing, in advance by the Executive Vice President ("EVP") or their designee (VP or above) of the applicable department, who shall be provided in advance of such review with a completed Business Needs/Fair Market Value Assessment Form, meeting agenda and details regarding meeting specifics, including, but not limited to: date, time, location, number of HCPCs, HCPC compensation, duration of meeting, specific products and topics to be addressed, and a documented plan for use of insights and feedback obtained from HCPCs.

4.14.3 All presentation materials utilized at an Advisory Board must be submitted to and reviewed by Sunovion Legal Affairs and Research & Development, as applicable, in a reasonable timeframe prior to the meeting.

4.14.4 The number of Employees versus HCPCs attending an Advisory Board must be reasonable and shall be assessed on a case by case basis in accordance with the overall purpose of the meeting.

4.14.5 Payment to an HCPC for participation in an Advisory Board is subject to the HCPCs full attendance and active participation in discussions and/or activities directed towards satisfying the overall purpose of the Advisory Board.

4.14.6 Following an Advisory Board meeting, a report summarizing the meeting and the results consistent with the Legitimate Business Need shall be completed and maintained, and provided to the applicable Executive Vice President, or her/his designee (VP or above).

4.15 Speaker Training and Promotional Programs

4.15.1 HCPCs maybe retained to participate in Sunovion-sponsored speaker programs to help educate and inform other health professionals about the benefits, risks and appropriate uses of Sunovion products.

4.15.2 In addition to satisfying all other requirements of this Policy, any HCPC engaged as a speaker must complete a speaker training program that consists of product training, compliance training, and training on speaker program rules, prior to being utilized as a speaker.

4.15.3 Compensation for services and reimbursement of expenses to HCPCs as speakers is conditioned upon compliance with this Policy and all applicable speaker requirements by such speakers.

#### 4.16 Investigators

4.16.1 HCPCs (and/or their institutions) may be retained as clinical investigators to conduct work and provide services associated with clinical trials/studies sponsored by Sunovion.

4.16.2 Contracts with clinical investigators must not create any conflicts of interest that could jeopardize the health or welfare of human subjects participating in a clinical trial or that could impact, directly or indirectly, the design, analysis or results of the trial.

4.16.3 In addition to satisfying all other requirements of this Policy, the following additional requirements shall apply to investigators and their institutions involved in Sunovion-sponsored clinical trials:

- (i) Payment to investigators and their institutions must be linked to their performing specific and necessary services (e.g., medical procedures, collection of data).
- (ii) Notice of the financial relationship between Sunovion and the investigator/institution should be disclosed to study subjects in the informed consent.
- (iii) Compensation to HCPCs as investigators (or their institutions) is subject to the following:
  - a. Compensation must be reasonable relative to compensation for similar clinical studies sponsored by the pharmaceutical/ biotechnology industry in the country where the research is conducted.
  - b. Compensation shall not be tied to the outcome of clinical studies and shall not include Sunovion stock or stock options for work on individual studies.
  - c. No payment shall be made to HCPCs outside a clinical study for referring subjects to investigators for entry into any clinical study.
  - d. Compensation shall not include special incentives or rewards, except those prospectively identified in the Clinical Study Agreement and approved by the IRB/IEC

### **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 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 and federal reporting requirements shall be as specified in the applicable law. If no specific definition is provided, the Company shall use the definition provided under the Physician Payment Sunshine Act of 2009.

### 5.3 Failure to Comply

**EMPLOYEES WHO VIOLATE ANY 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 '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](http://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 Reference:

Code of Conduct and Ethics  
Speakers Bureau Program Requirements  
Grants Policy  
Contract Review and Signing Authority Policy  
External Communications Policy  
Business Courtesies Policy  
Travel and Entertainment Policy

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

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)

FDA Guidance for Industry on Industry-Supported Scientific and Educational Activities (Nov. 1997)

Exhibit A

**Business Needs/Fair Market Value Assessment Form**

This form is to be used whenever Sunovion, or any of its subsidiaries or affiliates ("Sunovion") is entering into an agreement for the provision of services with a party that is in a position to purchase or prescribe (or influence the purchase or prescribing of) Sunovion products. The purpose of this form is to document the business need for the service(s) and to ensure that the fees paid by Sunovion constitutes fair market value for the service(s). Fill in all sections where applicable.

<b>Full Legal Name of Outside Party:</b>	
<b>Title of Program:</b>	
<b>Product:</b>	
<b>Date and Duration of Program:</b>	
<b>Requestor/Primary Contact:</b>	
<b>Date Submitted:</b>	
<b>Reviewed By:</b> <i>(Applicable EVP or their designee VP or above)</i>	
<b>Reviewed By:</b> <i>(Legal)</i>	

<b>Program Purpose/Business Need/ Objective:</b>  Check one and provide further description:  <input type="checkbox"/> Training Services <input type="checkbox"/> Data/Reporting Services <input type="checkbox"/> Financial Services <input type="checkbox"/> Administrative Services <input type="checkbox"/> Inventory Management Services <input type="checkbox"/> Promotional Services <input type="checkbox"/> Other (Please specify):	<u>Objective:</u>  <u>Description:</u>
<b>Program Discussion Topics (attach agenda):</b>	



<b>Sunovion</b> personnel/representatives attending (including their roles): <b>Consultant</b> Selection Methodology and Qualifications:  <b>[Curriculum Vitae is required]</b>	
<b>Number of Consultants Participating:</b>	
<b>Recommended Fees based on Fair Market Value for Faculty and/or Attendees:</b>	<u>Recommended Fees:</u> (based on FMV tier)  <u>Fair Market Value Determined by</u> (check all that apply): <input type="checkbox"/> Personal knowledge of other substantially similar agreements or transactions entered into by Sunovion or other organizations. <input type="checkbox"/> Fee is standard for the industry for the specific type of service(s) provided. <input type="checkbox"/> An evaluation performed by a reputable, knowledgeable third party source familiar with the value of the service(s) in question. <u>Specify third party source:</u>  <input checked="" type="checkbox"/> Other (please specify): <u>See attached objective criteria</u>
<b>Venue (consistent with Sunovion policies):</b>	
<b>Projected Program Outcomes, if applicable:</b>	
<b>Mechanism of Dissemination for Output (how information will be collected and disseminated post Program*):</b>	

**\*A final copy to be provided to Legal**

**Attach Agenda**

**I hereby certify that the information provided on this form is true and correct; the purchase of the services outlined above satisfies an important and legitimate business need; the aggregate services contracted for do not exceed those which are reasonably necessary to accomplish a commercially reasonable business need; and the fee is consistent with the fair market value for such services and has been negotiated independent of, and is unrelated to, any other business arrangement with this entity**

Signature of Requestor: \_\_\_\_\_  
Print Name:  
Title:  
Date:

Signature of EVP/  
or their designee  
(VP or above) \_\_\_\_\_  
Print Name:  
Title:  
Date: