SUNOVION

Guidelines for Interactions with Healthcare Professionals

COMPLIANCE & ETHICS
Lighting the way from integrity to success

Last Updated March 2014

Table of Contents

Introduction

Our Mission

Sunovion is dedicated to discovering, developing and commercializing innovative pharmaceutical products and services that improve health and quality of life. We understand our responsibility to ensure that decisions are guided first and foremost by what is in the best interests of patients. We are committed to the welfare of the patients we serve, the growth and empowerment of our employees and the success of our Company.

Purpose of the Guidelines

These Guidelines for Interactions with Healthcare Professionals (Guidelines) are designed to assist you in performing your job in an ethical and compliant manner. There are many laws, regulations and industry standards that apply to our interactions with Healthcare Professionals. It is important that you understand and comply with the spirit and letter of these requirements because your compliance will enable Sunovion to fulfill its mission to the patients we serve and is critical to the success of the Company.

For purposes of these Guidelines, a "Healthcare Professional" is any individual or organization in a position to purchase or prescribe a Sunovion product or recommend or influence the decision to purchase or prescribe a Sunovion product. Healthcare Professionals include, but are not limited to, physicians, psychiatrists, sleep specialists, pharmacists, respiratory therapists, polysomnographic technologists, nurse practitioners, physician's assistants, discharge planners, pharmacy and therapeutic committee members, managed care organizations, hospitals, pharmacy benefit management organizations, physician practices, and any executives of these organizations or institutions who are in a position to recommend the use of or influence the prescribing decisions with respect to a Sunovion product.

Sunovion is committed to the highest ethical standards and to compliance with all applicable laws and regulations. These Guidelines are applicable to all employees and agents of Sunovion. Failure to adhere to these Guidelines could have serious repercussions for Sunovion and any employees or agents involved in the non-conforming conduct. These repercussions could include significant fines for Sunovion, the loss of Medicare and/or Medicaid coverage for Sunovion products, termination of contractual relationships with customers and partners, and criminal

prosecution for the individuals engaged in the improper conduct. **In addition, Sunovion employees and agents who do not adhere to these Guidelines will be subject to disciplinary action, up to and including termination of employment or services.**

If you become aware of a violation of these Guidelines, it is **your responsibility to promptly report** the matter by **contacting the Compliance Department directly or anonymously through Sunovion's Compliance Hotline (via telephone at 866-886-1348 or at www.sunovion.ethicspoint.com)**. Sunovion will not discipline, discriminate or retaliate against any employee who reports a concern or complaint in good faith, or who cooperates in any investigation or inquiry regarding such conduct, whether or not such information is ultimately determined to be a violation of the Guidelines. Moreover, Sunovion will not tolerate any adverse action or retaliation taken against any employee or agent by a supervisor or other employee on account of any complaint or concern raised.

If you have any questions about interpreting or applying these Guidelines, you should discuss the matter with your supervisor or a member of the Compliance Department. Thank you for your continued support and commitment to upholding the highest ethical standards in all you do as an employee of Sunovion and a member of the communities where we conduct business.

Overview of Laws, Regulations and Industry Guidance

This section provides a brief overview of the laws, regulations and industry guidance that apply to our activities as a pharmaceutical company. This section does not provide an exhaustive description of every law that applies to Sunovion. Rather, the laws described in this section are those that are of most significance to our Company as we interact with Healthcare Professionals.

ACCME Standards

The Accreditation Council for Continuing Medical Education (ACCME) is responsible for overseeing the continuing medical education (CME) process. The ACCME standards provide specific criteria to ensure that commercial supporters and accredited providers are acting appropriately with regard to CME activities and that CME activities are free from commercial influence and bias.

Pharmaceutical companies, including Sunovion, are committed to supporting CME for Healthcare Professionals. Although pharmaceutical companies provide

significant financial support to CME activities, generally in the form of educational grants, they are prohibited from having influence over the CME event because CME activities should be free from commercial influence and bias.

An accredited CME provider oversees all aspects of the CME activity, including establishing objectives, choosing faculty and designing and evaluating the program. Commercial supporters are not allowed to control the planning, content or execution of CME activities.

Adverse Event Reporting

The Food and Drug Administration (FDA) requires pharmaceutical companies to establish and maintain records and make reports of all adverse drug experiences associated with the use of their drug products. Please see the Adverse Events section of these Guidelines for more information.

Anti-Kickback Statute

The purpose of the Anti-Kickback Statute is to ensure that money, or anything else of value, does not interfere with Healthcare Professionals' independent clinical and formulary decisions. The Federal Anti-Kickback statute makes it a criminal offense to knowingly and willfully offer, solicit, pay or receive any remuneration in cash or in kind, to induce or in exchange for, the purchasing, ordering or recommending of any good or service reimbursable by any Federal healthcare program, such as Medicaid or Medicare. "*Remuneration*" is broadly defined under the Anti-Kickback Statute to include almost anything of value, if the purpose of providing that value is to influence the judgment of Healthcare Professionals. In addition to pharmaceutical company employees, Healthcare Professionals are also subject to penalties for violating this law. The penalties for violation of the Anti-Kickback Statute include imprisonment, fines and exclusion from participation in government programs.

The Anti-Kickback Statute is very broad and is applied to a wide range of activities. It is not a law that prevents the pharmaceutical industry from promoting its products; however, the law places certain parameters around *how* and *why* we provide certain things of value (such as meals or gifts) to Healthcare Professionals. The Federal government has stated that compliance with the PhRMA Code on Interactions with Healthcare Professionals substantially reduces the risk of fraud and abuse and helps to demonstrate a good faith effort to comply with the applicable federal healthcare program requirements including the Anti-Kickback Statute.

False Claims Act

The purpose of the False Claims Act is to ensure that inappropriate practices are not leading to increased government expenditures on prescription drugs or patient harm from inappropriate prescribing. The False Claims Act imposes civil liability against a person or entity who knowingly or with reckless disregard, presents a false claim for payment, or uses a false record or statement to get a claim paid or approved or causes a third party to either of the above. Penalties for violation of the False Claims Act include steep fines for each false claim.

Although the False Claims Act is applicable to a variety of activities, it is most often applied to the pharmaceutical industry in government price reporting and off-label promotion cases. In government price reporting cases, the False Claims Act is applied when a pharmaceutical company submits (or causes to submit) false, fraudulent or misleading information to the government as part of the government price reporting process, such as the submission of Best Price, or if a company fails to return an overpayment from the government. In off-label promotion cases, the government essentially says that when a pharmaceutical company *promotes* its products for off-label uses, it is causing a third party (generally a physician) to present a false claim for payment. It would be a false claim because the government is reimbursing the cost of an off-label prescription that it would otherwise not have chosen to pay. Using approved promotional materials and promoting in accordance with a product's approved labeling helps ensure compliance with the False Claims Act.

Food and Drug Administration Laws

Federal Food, Drug & Cosmetic Act

The FDA plays a very important role in the pharmaceutical industry and regulates a wide variety of industry activities. The Federal Food, Drug and Cosmetic Act (FDCA) provides the FDA with broad authority to regulate drug approvals and drug advertising and promotion. The spirit and letter of all FDA laws, regulations and guidance documents relate to ensuring patient safety.

The purpose of the FDCA, and the regulations enacted pursuant to this law, is to ensure that information about prescription drugs provided to Healthcare Professionals and patients is adequate, balanced and truthful. Therefore, the FDA has the authority to regulate the labeling, advertising and promotion of pharmaceutical products. Labeling includes all information on a drug's package or label, prescribing information contained in the package insert and any other written, printed or graphic material provided about a drug.

Violations of the FDCA occur when the FDA considers a company's product to be misbranded because its labeling is false or misleading or fails to contain adequate directions for a product's intended use (off-label promotion).

Compliance with the FDCA can be accomplished by ensuring that all Company promotion is truthful, accurate, not misleading and within a product's approved label.

Prescription Drug Marketing Act of 1987

The Prescription Drug Marketing Act of 1987 (PDMA) is a law that prohibits the sale, purchase or trade of drug samples. It is illegal for anyone, including a Healthcare Professional, to sell, purchase or trade or offer to sell, purchase or trade any drug sample or seek reimbursement. The purpose of the PDMA is to ensure that drug samples are used appropriately to benefit patients. The PDMA requires pharmaceutical companies to maintain detailed records regarding the distribution of drug samples and to report to the FDA when samples are lost or stolen or when unaccounted for quantities exceed a certain threshold. Failure to comply with the PDMA may result in significant fines and criminal prosecution.

OIG Compliance Program Guidance

In April 2003, the United States Department of Health and Human Services Office of Inspector General released its Compliance Program Guidance for Pharmaceutical Manufacturers ("OIG Guidance"). The purpose of the OIG Guidance is to assist pharmaceutical companies in developing and implementing a compliance program—internal controls and procedures that promote adherence to applicable laws and requirements of Federal healthcare programs.

The OIG Guidance identifies several high risk areas for pharmaceutical companies including: (1) integrity of data used by state and federal governments to establish payment amounts; (2) kickbacks and other illegal remuneration; and (3) compliance with laws regulating drug samples.

In order to mitigate these risks, consideration should be given to the following factors when entering into any business arrangement or interactions with Healthcare Professionals:

- Does the arrangement skew clinical decision-making?
- Does the arrangement have the potential to increase costs to Federal Health Care Programs?
- Does the arrangement have the potential to be a disguised discount?
- Would the arrangement result in inappropriate over/under-utilization of a Company product?
- Does it raise patient safety or quality of care concerns?
- If information is provided, is it complete, accurate and not misleading?

PhRMA Code on Interactions with Healthcare Professionals

In July 2002, the Pharmaceutical Research and Manufacturers of America (PhRMA), a trade organization, released its Code on Interactions with Healthcare Professionals ("PhRMA Code"). In July 2008, PhRMA released a revised version of the PhRMA Code. The purpose of the PhRMA Code is to reinforce that pharmaceutical company interactions with Healthcare Professionals are to benefit Patients and enhance the practice of medicine. The PhRMA Code is based on the principle that a Healthcare Professional's care of Patients should be based, and should be perceived as being based, solely on each Patient's medical needs and the Healthcare Professional's medical knowledge and experience. Effective marketing of medicines ensures that Patients have access to the products that they need and that the products are used correctly for maximum Patient benefit. The PhRMA Code provides examples of proper and improper practices regarding pharmaceutical companies' interactions with Healthcare Professionals. The majority of the pharmaceutical industry, including Sunovion, has adopted and embraced the PhRMA Code.

Privacy Laws

Many state, Federal and international privacy laws apply to pharmaceutical companies. Although these laws govern various activities, they are all based on common privacy principles that aim to protect individuals' personal information. The spirit of all privacy laws is that people should know when companies are using their personal information, why the personal information is being used and how the personal information is protected.

The most important privacy law that affects the healthcare industry is the Health Insurance Portability and Accountability Act of 1996 (HIPAA). The HIPAA "Privacy Rule," as it is commonly called, aims to protect the privacy of individually identifiable health information of Patients and research subjects. The HIPAA Privacy Rule directly applies to healthcare providers, health plans and healthcare clearinghouses and indirectly affects pharmaceutical company operations. Please see the Information Protection section of these Guidelines for more information.

Sunshine Act

Sunovion, under The Patient Protection and Affordability Care Act (Sunshine Act), is required to report all payments and transfers of value given to physicians and certain designated Teaching Hospitals. Reports are submitted to the Centers for Medicare & Medicaid Services (CMS) on an annual basis. All of the spend information contained in the reports will be available on a public, searchable website. Physicians have the right to review their reports and dispute reports that are false or inaccurate.

As Field Sales Personnel, it is important that you accurately record any item of value provided to HCPs, such as food at Lunch & Learns, Speaker Program dinners and reprints. Please refer to the specific guidelines outlined in your training for more information.

Promotion and Sales Calls

Promotional Messages and Discussions

One of Sunovion Field Sales Personnel's primary responsibilities is to provide Healthcare Professionals with accurate information about Sunovion products. When interacting with Healthcare Professionals, Field Sales Personnel must follow these principles:

a. **Message Statements:** All product discussions must be consistent with PMRC-approved materials.

b. **Prescribing Information:** All messaging must be consistent with the current, approved Prescribing Information (PI). All product message statements must be truthful, not misleading and within the approved PI. A full copy of the PI must be left for each Sunovion product presented.

c. **Off-label Discussions:** Off-label discussions and promotion are prohibited. If a Healthcare Professional mentions an off-label use or dosage, you may not address or discuss the off-label use or dosage with that Healthcare Professional. You must tell the Healthcare Professional that the product is not indicated for that use or dosage and then inform him/her of the approved indication and provide a copy of the full PI. If a Healthcare Professional wants further information on an off-label use or dosage, you may offer to assist the Healthcare Professional by submitting a Medical Information Request Form (MIRF). Please see the Medical Information section of these Guidelines for more information.

d. **Provision of Risk Information:** The risks associated with our products must never be minimized during our discussions with or in the materials provided to Healthcare Professionals. For a prescriber to properly assess whether a Sunovion therapy is appropriate for a given patient, he/she must have a full understanding of not only the product's potential benefits but also its possible side effects. Accurate safety information should always balance discussions of our products' benefits.

e. **Discussion of Competitive Products:** Discussions involving the mention of competing product(s), including PI-to-PI comparisons, cannot occur unless included in PMRC-approved materials.

Promotional Materials

The Promotional Materials Review Committee (PMRC) must approve any and all promotional materials. Homemade materials in any form (commonly referred to as "Homemade Bread "or " Homebrew Pieces") are never allowed.

All materials used to support Sunovion product messaging must be approved through the PMRC process—this includes publicly available articles or materials provided by Sunovion employees or its contractors. Promotional materials may only include claims about the product that are consistent with the product's labeling.

Once approved, promotional materials cannot be altered in any way. The materials must be used in the format, style and for the use approved by the PMRC. Therefore, laminating, cutting, hi-lighting, underlining, disassembling, mixing/matching or otherwise marking or changing the nature, use purpose or presentation of the materials is not permitted.

Sales Force Training and Informational Materials

All materials to be used for any type of sales force training or to be provided to the sales force for informational purposes must first be submitted to and approved by Sunovion's Sales Training and Development Department and the Product Brand Team to ensure consistency with the overall sales training plan and brand strategy. Upon Sales Training and Development's and the Brand's review and approval, the materials will be submitted to PMRC for PMRC review and approval. Field personnel may only use PMRC-approved materials. This includes, but is not limited to, material utilized for the following reasons:

- Internal educational purposes;
- Informational/background purposes; or
- Disease-state or product messaging.

Gifts/Medically Relevant Items

It is appropriate for Sunovion, where permitted by law, to provide Medically Relevant Items to Healthcare Professionals. A Medically Relevant Item is an item of value designed primarily for the education of patients or Healthcare Professionals if the item is not of substantial value ($100 or less) and does not have value to the Healthcare Professional outside of his or her professional responsibilities. For example, an anatomical model for use in an examination room is intended for the education of the patients and is therefore appropriate, whereas a DVD or CD player may have independent value to a Healthcare Professional outside of his or her professional responsibilities, even if it could also be used to provide education to patients, and therefore is not appropriate. Medically Relevant Items must relate to a disease or condition for which Sunovion products are indicated.

Medically Relevant Items are treated as third party communications in accordance with the External Communications Policy and must be reviewed and approved by PMRC. Medically Relevant Items should not be offered on more than an occasional basis (*i.e., no more than four (4) times per year)*. All approved Medically Relevant Items provided to Healthcare Professionals must be documented properly so that Sunovion can comply with transparency law requirements.

It is appropriate to provide product samples for patient use in accordance with the Prescription Drug Marketing Act.

Under no circumstances may a gift be offered or provided with the intent of, directly or indirectly, influencing or encouraging the recipient to purchase, prescribe, refer, sell, arrange for the purchase or sale, or recommend formulary placement of any Sunovion product.

Approved Medically Relevant Items may be provided as part of a product detail but may never be tied to the promotional detail itself or be made contingent on a commitment from the Healthcare Professional to prescribe the Sunovion product.

Prohibited Gifts

- Providing items for Healthcare Professionals' use that do not advance disease or treatment education—even if they are practice-related items of minimal value (such as pens, note pads, mugs and similar "reminder" items with company or product logos)—may foster misperceptions that company interactions with Healthcare Professionals are not based on informing them about medical and scientific issues. Such non-educational items are prohibited under the PhRMA Code and must not be offered to customers or members of their staff, even if patient or physician education materials accompany them.

- Items intended for the personal benefit of Healthcare Professionals (such as floral arrangements, artwork, music CDs or tickets to a sporting event) likewise must not be offered.

- Payments in cash or cash equivalents (such as gift certificates) must not be offered to Healthcare Professionals either directly or indirectly, except as compensation for bona fide services in accordance with the Sunovion Health Professional Consultant Policy.

- No gifts may be provided to Federal, state or local government employees.

- The provision of samples for a Healthcare Professional's personal or family use is prohibited.

Cash or equivalent payments of any kind create a potential appearance of impropriety or conflict of interest.

A Sunovion Employee may not purchase a gift in a manner inconsistent with these Guidelines, with her/his own funds, even if the employee does not intend to seek reimbursement from Sunovion.

Managers are responsible for monitoring the activities and performance of their employees and ensuring that they understand and comply with these Guidelines.

Giveaways and Coupons/Vouchers for Consumers

A Giveaway is any tangible or intangible article or item of value that is related to a disease or condition for which Sunovion products are indicated. For example, Giveaways may include hypoallergenic pillowcases, peak flow meters, disease state-related books or journals, dust cloths/pollen mitts, tissues, inhaler stands, calendars, etc. While PMRC-approved Coupons or Vouchers for Company products may be provided to Healthcare Professionals for distribution to patients, PMRC-approved Giveaways may only be distributed directly to Consumers.

Meals

Informational presentations and discussions by Sunovion Field Sales Personnel and others speaking on behalf of Sunovion provide Healthcare Professionals with

valuable scientific and clinical information about medicines that may lead to improved patient care.

In connection with approved promotional activities, including informational presentations and clinical or product-related discussions with Healthcare Professionals, Field Sales Personnel and/or their immediate managers may provide modest, occasional meals to Healthcare Professionals if such meals:

- Are modest as judged by local standards, not to exceed $25 per person;
- Are limited to in-office or in-institutional settings (where permitted by institutional policies/guidelines);
- Do not involve any form of entertainment;
- The meal is provided in connection with approved promotional activities, including informational presentations and discussions;
- Are permitted by state law; and
- Are documented properly so that Sunovion can comply with transparency law requirements.

Speaker programs or other organized promotional programs may include a modest meal of up to $125/person for attendees and must occur in a venue conducive to informational communication. In addition, if alcohol is provided with dinner programs, the amount must be reasonable and pre-ordered or selected where possible. Field Sales Personnel and/or their immediate managers may attend these events.

Company employees, other than Field Sales Personnel or their immediate managers, may also provide meals to Healthcare Professionals participating in Company events such as Speakers Bureau Training or Advisory Boards, and may also provide meals to Healthcare Professionals in connection with interactive discussions, not to exceed $125 per person (including tax and tip) or a total of $250 per person per day (all inclusive). Field Sales Personnel and/or their immediate managers may **not** attend such events. Other employees in the Sales organization should check with the Compliance Department prior to attending a Speaker Bureau Training or Advisory Board meeting.

The venue chosen for any interaction with a Healthcare Professional should be conducive to giving an informational presentation or interaction. Resorts, casinos and other high profile restaurant venues may attract unwanted media attention and should be avoided – when in doubt, check with the Compliance Department.

Prohibited Meals and Entertainment

- Inclusion of a Healthcare Professional's spouse or other inappropriate guest in a meal accompanying an informational presentation made by or on behalf of Sunovion is prohibited.

- Offering "take-out" meals or meals to be eaten without a Sunovion representative being present (such as "dine & dash" programs) is prohibited.

- Recreation and entertainment events are prohibited for all Healthcare Professionals other than full-time Sunovion employees, even if the HCP pays for himself/herself. This prohibition also applies to Company consultants and contractors who are Healthcare Professionals..

- No meals may be provided in cash or cash equivalents (*e.g.,* gift certificates for restaurant meals).

A Sunovion employee may not provide meals and entertainment inconsistent with these Guidelines with his/her own funds, even if the employee does not intend to seek reimbursement from Sunovion.

Promotional Speakers Bureau Programs and Speaker Training Meetings

Sunovion has a strong history of partnering with Healthcare Professionals to advance medical education. Our Promotional Speakers Bureau Programs are designed to provide Healthcare Professionals with the information they need to make informed treatment decisions regarding our products, the disease states our products treat and support the patients who are prescribed our products as part of their treatment regimen. Company decisions regarding the selection or retention of Healthcare Professionals as Speakers are made based on defined criteria such as general medical expertise and reputation, knowledge and experience regarding a particular therapeutic area and communication skills. Speaking arrangements are neither inducements nor rewards for prescribing Sunovion products.

Sunovion has established a Speakers Bureau Program that facilitates peer-to-peer presentation of approved scientific information by paid members of the Speakers Bureau faculty to Healthcare Professionals attending the program. The following criteria are applicable to, and must be satisfied for, each Sunovion Speakers Bureau event:

- The event must be scheduled and conducted through the Sunovion-approved Speakers Bureau vendor;
- Only individuals who are members of the Speakers Bureau faculty and who have entered into an agreement approved by the Sunovion Legal Affairs Department are permitted to present at Speakers Bureau events. All Speakers Bureau faculty members must receive formal training on the presentation, the supporting data, and legal, compliance and regulatory

requirements concerning Speakers Bureau presentations before giving a presentation pursuant to this program;

- The faculty member may only use Sunovion-approved materials;
- No fee or other compensation may be made to Speakers Bureau event attendees;
- Speakers Bureau materials must be presented in their entirety. Truncated, altered or abbreviated Speakers Bureau Programs are not permitted;
- Speaker selection must not be based on the prescribing habits of the Healthcare Professional;
- Meals will be provided in an appropriate venue and only up to $125 per attendee; and
- Sunovion Field Sales Personnel attend the Speakers Bureau Program to facilitate, not present or promote product information or ask questions during the presentation.
- Off-label questions must be answered by speakers according to the instructions provided at speaker training

All Sunovion Speakers Bureau Programs are considered promotional and are reviewed and approved under the same standards as product advertising and other promotional materials the Company distributes.

Sunovion provides its Speakers with various approved printed and electronic materials to facilitate their presentations. Speakers are not permitted to distribute copies of the presentation materials or any other additional content to attendees, nor are they allowed to leave behind any other materials including case studies, publications or information about their practices. They are also not allowed to use the materials in any other manner other than for such speaker presentations.

For more detailed information on conducting speaker programs please reference the Speaker Program Work Instructions document which is available on The Beacon.

Call Notes and Other Field Documentation Related to Call Notes

While a call note is a very important business tool, it is important to remember that as with other documentation, such as e-mails and text messages, clarity and accuracy are essential. Unfortunately, when we're in a hurry, not as thoughtful as we should be or using personal shorthand, how we describe and document what may be a perfectly appropriate interaction or activity may be misconstrued or misperceived. Remember, it may be days or weeks before you go back and review your call notes, so clarity, thoughtfulness and accuracy will be key in helping you remember your most recent detail as well as laying the groundwork for your next

interaction with that Healthcare Professional. Finally, call notes are for business purposes to support business objectives; therefore, it is imperative that you act professionally when documenting your observations. Call notes are not to capture personal feelings, opinions or descriptions about the Healthcare Professionals upon whom you call. They should not be emotionally based, nor should you speculate or make assumptions about your customers or their future behavior. Call notes must only be documented in the Sunovion call note system. Handwritten call notes and call notes captured outside of the Sunovion call note system are prohibited.

As an additional consideration, any documentation you create in furthering the Company's business objectives should be approached with the same amount of care as for call notes as described above. This is especially true for e-mails that you may exchange with your manager or fellow Field Sales Personnel, as e-mails are typically treated more casually than other business documents.

Pricing Information

Field Sales Personnel's promotional activities are not focused or based on the health care finance and reimbursement issues surrounding them. Similarly, Sunovion Field Sales Personnel do not market or compare competitor pricing. We recognize, however, that you may be asked such questions. You may only discuss **PMRC-approved** pricing information, including Managed Care formulary information, with Healthcare Professionals. You may provide co-pay information to Healthcare Professionals so long as it is accurate and has been approved and provided to you by the Sunovion Organized Customer Group. As with other PMRC-approved materials, they should not be altered, copied, modified or changed in any way and should only be used as directed by the PMRC.

Specific pharmacy prices of Sunovion or competitor products should not be given to customers. No discussions should take place regarding "the spread" (*i.e.,* the difference between the amount charged by a pharmaceutical company and the amount reimbursed by Medicare).

Field Sales Personnel cannot assist Healthcare Professionals with filling out or submitting any insurance related paperwork. This includes, but is not limited to Prescription Assistance Program (PAP) applications and Prior Authorization forms.

Interactions with Patients

Field Sales Personnel should limit their discussions about Sunovion products and disease states to the Healthcare Professionals upon whom they are calling.

Field Sales Personnel may attend local patient education events if approved by their local management team. However, they may ***never*** participate in product or disease state discussions directly with patients. Any questions regarding Sunovion products, their use (*e.g.,* "how do I use the Xopenex HFA® metered dose inhaler?"), or disease state must be directed to their Healthcare Professional.

Notes to Healthcare Professionals

Notes to Healthcare Professionals should not contain any of Sunovion's product names nor should they be promotional in any way (no product names, no product claims). Notes should be brief and for a specific purpose such as logistics. You may attach the note to promotional pieces approved by Sunovion's PMRC for leave behind purposes (*e.g.,* "Dr. Smith, I'm so sorry I missed you. I would like to meet with you for a few minutes to discuss this information. I'll arrange my schedule to accommodate your availability.") These guidelines apply regardless of the form of the note (e.g. written, electronic, etc.)

Notes created and distributed by Field Sales Personnel that do not meet the parameters set forth above would be considered "homemade," unapproved pieces.

Samples

Sunovion may provide free sample product of FDA-approved products to prescribing Healthcare Professionals for the clinical benefit of their patients. Sample product is made available to prescribing Healthcare Professionals or to Healthcare Professionals otherwise authorized to receive sample product of prescription drugs under applicable state law for the approved indication of the Sunovion product. These sample products allow the patient and Healthcare Professional to become familiar with the clinical profile of the product and how treatment can be managed for that particular patient. The distribution, maintenance and storage of sample products are overseen by the FDA, as set forth in the PDMA.

Field Sales Personnel must comply with the PDMA, including all documentation requirements. These requirements are set forth in the Sunovion Sample SOPs. The key components of these requirements are:

- Sample **only** approved licensed and validated practitioners;
- Always **witness** the Healthcare Professional's signature;
- **DO NOT leave** any samples of prescription drugs if the Healthcare Professional is unable or unwilling to sign;
- Misrepresentation/Falsification of sample documents is against Company policy and may lead to termination of employment. If falsification of sample documents is identified, Sunovion is required to notify the FDA, which could lead to criminal charges;
- Properly store samples in compliance with the specifications in the products' PI;
- **Account for all product.** Significant losses identified through Sunovion's sample reconciliation process are reported to the FDA;
- **DO NOT remove** Sunovion's or any other drug samples from Healthcare Professionals' offices;
- **DO NOT accept** samples back from a Healthcare Professional for any reason; and
- Ensure that you record the proper **strength, quantity and lot number** for each sample.

Services Provided by Healthcare Professionals

Sunovion often enters into service arrangements with Healthcare Professionals who may be compensated for such services. When Sunovion enters into a service agreement it must satisfy the requirements set forth by the Legal Affairs Department. Service agreements with Healthcare Professionals *(e.g., Advisory Board Agreements, Consulting Agreements, Speaker Agreements)* must meet a legitimate Sunovion business need. Service providers must be well qualified in terms of education and experience. Compensation may not exceed the fair market value of the services provided. Full payment to the service provider should not occur until the documented services have been provided to Sunovion.

Under no circumstances may a service agreement be offered or provided with the intent of directly or indirectly influencing or encouraging the recipient to purchase, prescribe, refer, sell, arrange for the purchase or sale, or recommend formulary placement of any Sunovion product. Service agreements may not be offered in connection with discussions, negotiations or decisions involving product pricing or purchasing, or formulary decisions.

No Sunovion employees may enter into service agreements with Healthcare Professionals unless a request for such a service agreement is first referred to the Legal Affairs Department for determination of appropriateness and processing.

When necessary, consultants must obtain permission from their institution or disclose to their institution prior to engaging with Sunovion to provide services.

While modest meals or receptions may be appropriate with Healthcare Professional service providers, recreational or entertainment events in conjunction with these meetings are prohibited.

Healthcare Professionals Who Are Members of Committees That Set Formularies or Develop Clinical Practice Guidelines

Healthcare Professionals who are members of committees that set formularies of covered medicines or develop clinical practice guidelines that may influence the prescribing of medicines often have significant experience in their fields. That experience can be of great benefit to Sunovion and ultimately to patients if these individuals choose to serve as speakers or consultants. To avoid even the appearance of impropriety, any Healthcare Professional who is a member of a committee that sets formularies or develops clinical guidelines and also serves as a speaker or consultant for Sunovion must disclose to the committee the existence and nature of his or her relationship with the Company. This disclosure requirement should extend for at least two years beyond the termination of any speaker or consultant arrangement.

Upon disclosure, Healthcare Professionals who serve as speakers or consultants for Sunovion should be required to follow the procedures set forth by the committee of which they are a member, which may include recusing themselves from decisions relating to the medicines for which they have provided speaking or consulting services.

Medical and Business Information

Medical Information

The Medical Information Department ("Medical Information") responds to unsolicited (non-prompted) medical inquiries received from Healthcare Professionals, Consumers or other Customers about Sunovion pre-clinical data, marketed products or the disease states that these products treat. In addition, Medical Information responds to Healthcare Professionals' unsolicited questions that are more clinically in-depth than the information provided in PMRC-approved materials used in Field Sales Personnel's discussions. Medical Information provides accurate, balanced, comprehensive and scientifically reviewed and supported information when responding to specific medical and Sunovion product questions.

The FDA generally allows pharmaceutical companies to respond, through appropriate channels, to **unsolicited** inquiries from Healthcare Professionals for off-label information, provided that it is part of an exchange of scientific information and does not contain any corporate claims of safety or effectiveness for the off-label use.

Any unsolicited request for medical information that you receive from Healthcare Professionals about off-label uses of Sunovion marketed products or investigational drugs must be referred to Sunovion's Medical Information Department. Provide the requesting Healthcare Professional with a MIRF form or the toll-free number for Medical Information: 1-800-739-0565. When you receive an unsolicited request for medical information, you should ensure that the MIRF form is fully completed to accurately capture the nature of the unsolicited request.

Adverse Events

Sunovion is committed to ensuring that it provides safe and effective products to the patients we serve. Part of our role as a manufacturer is to provide a system for the intake, processing, reporting and tracking of post-marketing adverse drug experiences for Sunovion marketed products.

Sunovion is responsible for the processing, management and investigation of reported Adverse Events.

Definition of Adverse Event

An Adverse Event ("AE") is any untoward medical occurrence in a patient or clinical trial subject administered a medicinal product and which does not necessarily have a causal relationship with this treatment. An AE can therefore be any unfavorable

and unintended sign (for example an abnormal laboratory finding), symptom or disease temporally associated with the use of a medicinal product, whether or not considered related to the medicinal product.

Employee Responsibilities

If you receive a potential Adverse Event report, it is your responsibility to notify the Pharmacovigilance and Risk Management Department (PVRM) within one (1) business day of becoming aware of the event. Life-threatening and fatal AEs must be reported to PVRM immediately. All potential AEs and other reportable safety information are to be reported to PVRM via e-mail to sunovionsafety@druginfo.com or alternatively by calling 877-737-7226 (Option #1—Report an AE). Employees who are unsure whether or not something reported to them meets the criteria of an AE should report the event and allow PVRM to investigate further. You are expected to respond to any inquiries from PVRM promptly, but no later than one (1) business day of the PVRM request.

The FDA and other international regulatory authorities have very specific reporting requirements relating to safety. You play a key role in ensuring Sunovion meets those regulatory requirements by responding to requests for additional information from PVRM within one business day.

Product Complaints

Sunovion is also committed to ensuring that the products we provide are of the highest quality and that we communicate the appropriate information on the proper use of our products.

Definition of Product Complaint

A Product Complaint (PC) is any written, electronic or oral communication that alleges deficiencies related to the identity, quality, durability, reliability, safety, effectiveness or performance of a product placed on a market or used in a clinical study. There are two types of complaints as follows:

Technical Product Complaints: This includes reports of product, labeling or packaging defects, or failure of the product to meet specifications or perform as expected. All technical product complaints are evaluated to ensure that any associated descriptions of potential Adverse Events are identified and reported.

Adverse Event Reports: All adverse event reports received are reviewed to determine if a technical defect is potentially associated with the event reported.

Employee Responsibilities

If you receive a potential product complaint, it is your responsibility to notify the Quality Compliance and Audit department (QCA) within one (1) business day of

receipt. All potential PCs should be reported to QCA via e-mail to productcomplaints@sunovion.com or alternatively by calling 866-468-1701. Employees who are unsure whether or not something reported to them meets the criteria of a PC should report the complaint and allow QCA to investigate further.

Information Protection

Confidential and Proprietary Information

It is important to keep in mind the various policies and procedures in place to protect Sunovion's confidential and proprietary information. This protection is vital in ensuring that Sunovion remains competitive as well as sensitive to the privacy of our vendors, customers and the patients we serve.

As employees of Sunovion, you have an obligation to safeguard and not disclose any confidential or proprietary information to non-employees. This includes information such as business forecasts and marketing and product plans and strategies. While sometimes this information may be marked as "For Internal Use Only" or "Not for Distribution," not all proprietary information, such as verbal discussions or draft documents, may be as clearly marked. When in doubt, treat all information as confidential and proprietary until you have had a chance to discuss with your manager or the Legal Affairs Department.

There are policies and procedures in place to assist us with protecting our Company's informational assets. Any confidential information or defamatory statements about the Company or its Employee should not be disclosed or posted by any Company Employees on social media networks and/or the internet.

You should also take great care that you don't unintentionally compromise the confidentiality of Sunovion information by discussing such information in informal, public forums such as airports or restaurants. Additionally, you should never participate in any benchmarking surveys, market research or similar activities when requested by third parties without seeking management approval. Often times, these surveys are competitive intelligence gathering activities. However, since there may be legitimate surveys in which the Company may, for business purposes, wish to engage, you should forward all requests to senior managers to review with the Legal Affairs Department.

Not only must we guard against disclosing Company proprietary information, but we also must guard against inappropriately obtaining confidential information belonging to others. If you receive confidential information about a competitor anonymously or accidentally (*e.g.,* pricing information provided to you by a customer), you should immediately send the information to the Legal Affairs Department for appropriate handling.

Press Inquiries

If you are contacted by anyone in the media or financial community, you should immediately turn those requests over to the Corporate Communications Department.

Special Issues regarding Respecting Patient Information

All Sunovion Employees must respect the privacy of all clinical or patient data. For example, Field Sales Representatives' job duties regularly put them in the position of potentially encountering personal health information of Patients of the Healthcare Professionals upon whom they call. Healthcare Professionals and other covered entities are subject to the provisions of the Federal HIPAA privacy and security regulations. Sunovion has developed a Position Statement setting forth Sunovion representatives' obligations in regarding to HIPAA and our customers to which HIPAA applies.

Sunovion Field Sales Personnel are **prohibited** from:

- Removing any patient protected health information from Customers' facilities;
- Making notes that record or reference any patient protected health information disclosed to them during their visit to Customers' facilities;
- Making handwritten or electronic copies of the patient protected health information; and
- Disclosing, either verbally or in writing, to any third party, including Sunovion Home Office personnel, any patient protected health information disclosed to them during a product detail or other interaction with a Customer.

The Position Statement is on The Source. We respect the privacy of our customers' patients' protected health information and take all steps necessary to protect the confidentiality of any protected health information disclosed during a product detail or other interaction. Therefore, Field Sales Personnel should not proactively seek out patient information or otherwise abuse, manipulate or use to your advantage access to patient information.

Prescriber Data

Sunovion uses non-patient identified prescriber data to facilitate the efficient flow of information to Healthcare Professionals. Such prescriber data, which does not identify individual patients, may serve many purposes, including enabling Sunovion to: (a) impart important safety and risk information to prescribers of a particular drug; (b) conduct research; (c) comply with FDA mandated risk management plans that require drug companies to identify and interact with physicians who prescribe certain drugs; (d) track adverse events of marketed prescription drugs; and (e) focus marketing activities on those Healthcare Professionals who would most likely benefit from information about a particular drug.

When Sunovion chooses to use non-patient identified prescriber data to facilitate communications with Healthcare Professionals, we must use this data responsibly. We should respect and abide by the wishes of any Healthcare Professional who asks that his or her prescriber data not be made available to Field Sales Personnel.

Records Management and Retention

Appropriate creation, maintenance/retention and destruction or deletion of Sunovion business records and information is critical to the Company's operations. Sunovion is committed to a compliant records and information management program which consists of a corporate retention policy and records retention schedule. Legal, business and regulatory requirements apply to the majority of our routine business records and information. Many departments within Sunovion have procedures that document the proper retention and disposal/destruction of records to help maintain, store and, when appropriate, destroy Company records in compliance with applicable regulatory, legal, employment, tax and business requirements.

When you know of a legal request for documents or are notified by Sunovion's Legal Affairs Department of a dispute involving information held by you, you cannot alter or destroy any information that you may have in your possession that may be related to the dispute or request—even if a document retention policy or procedure otherwise requires destruction.

It is important to note that when we talk about "information" or "records" it applies to any document, record and/or information regardless of format or media including but not limited to electronic, paper, microfilm and audio.

For further information regarding Sunovion's corporate records management policy and retention schedule, please contact Rimsupport@sunovion.com

Requests for Funding or Educational Support

Independence and Decision Making

No grants, scholarships, subsidies or support should be provided or offered to a Healthcare Professional in exchange for prescribing products or for a commitment to continue prescribing products. Nothing should be offered or provided in a manner or on conditions that would interfere with the independence of a Healthcare Professional's prescribing practices.

Investigator Initiated Studies (IIS)/Post-Market Research Support Requests

Healthcare Professionals may at times bring opportunities to support research, both scientific and market, to Sunovion's attention that may involve Sunovion marketed products. Sunovion may choose to fund such research projects, provided that the proposed project answers a question or addresses a topic that justifies further research in accordance with generally accepted research standards. To determine whether the proposed research project is related to a scientific or market topic, Sunovion has a structured review and approval process. Each project undergoes a rigorous internal review, must further a legitimate scientific or business goal of the Company, and must be for a specific research project (not to support a Healthcare Professional's general research program).

The following criteria are applicable to and must be satisfied for all research activities funded by Sunovion:

- All requests for research activity funding must be submitted sufficiently far in advance of initiation of the research for Sunovion to sufficiently evaluate the proposed project. Sunovion cannot fund research projects that have already been initiated or completed.
- There must be a written contract acceptable to the Sunovion Legal Affairs Department that specifies the nature of the research to be conducted.

Field Sales Personnel's Role and Responsibility

Field Sales Personnel are often the primary contact of the Company to Healthcare Professionals and may be the first Company contact to hear of such proposals. If a Healthcare Professional brings a proposed research opportunity to a Field Sales Personnel's attention, she/he should provide the Healthcare Professional with the Sunovion Home Office Grant Coordinator contact information or the Grant Website Address.

Grants for Educational Programs

Sunovion is committed to supporting quality scientific and educational programs (both accredited CME programs and non-accredited programs) and activities of third-party professional organizations and hospitals that are ***independently*** developed and conducted by qualified medical education providers. Sunovion supports these programs in order to improve the lives of patients with medical conditions our products may treat.

Sunovion will consider requests to support programs and activities designed to educate Healthcare Professionals and/or Patients in therapeutic areas of interest to Sunovion. Sunovion will also consider support for programs or activities related to other issues of interest to Sunovion and which benefit patient care and/or medical/science initiatives.

For these programs to be eligible for funding by Sunovion, we must ensure that Sunovion involvement in the program remains limited. One of the key ways we ensure that there is only appropriate interaction between Sunovion and requestors (CME and non-CME) is by creating a grant review and approval process that limits and distances Sunovion's involvement, particularly that of Sales and Marketing.

In addition, no one at Sunovion, including anyone in Sales, Area Medical Specialists, Medical Affairs or Marketing, can dictate the content of any continuing education presentation, who the faculty or presenters should be, who is allowed to attend, or where the venue for the program will take place. This is all the responsibility of the continuing education provider, whether a third-party professional society or a hospital. Any substantive involvement by Sunovion in any of these continuing education program activities has the potential of converting legitimate continuing education activities into impermissible promotional activities.

Financial assistance for scholarships or other educational funds to permit medical students, residents, fellows, and other Healthcare Professionals in training to attend carefully selected educational conferences may be offered so long as the selection of individuals who will receive the funds is made by the academic or training institution. "Carefully selected educational conferences" are generally defined as the major educational, scientific, or policymaking meetings of national, regional or specialty medical associations.

Funding for the following activities is **not permitted** under these Guidelines:

- Social events held in conjunction with Customer meetings;
- Programs that primarily address the business needs of Healthcare Professionals (*e.g.,* reimbursement billing seminars, office management programs);
- Customer meetings or activities that have no educational or scientific component of specific interest to Sunovion, such as office parties, holiday parties, barbecues or picnics; and
- Funding that offsets the cost for a particular Healthcare Professional to attend an educational program.

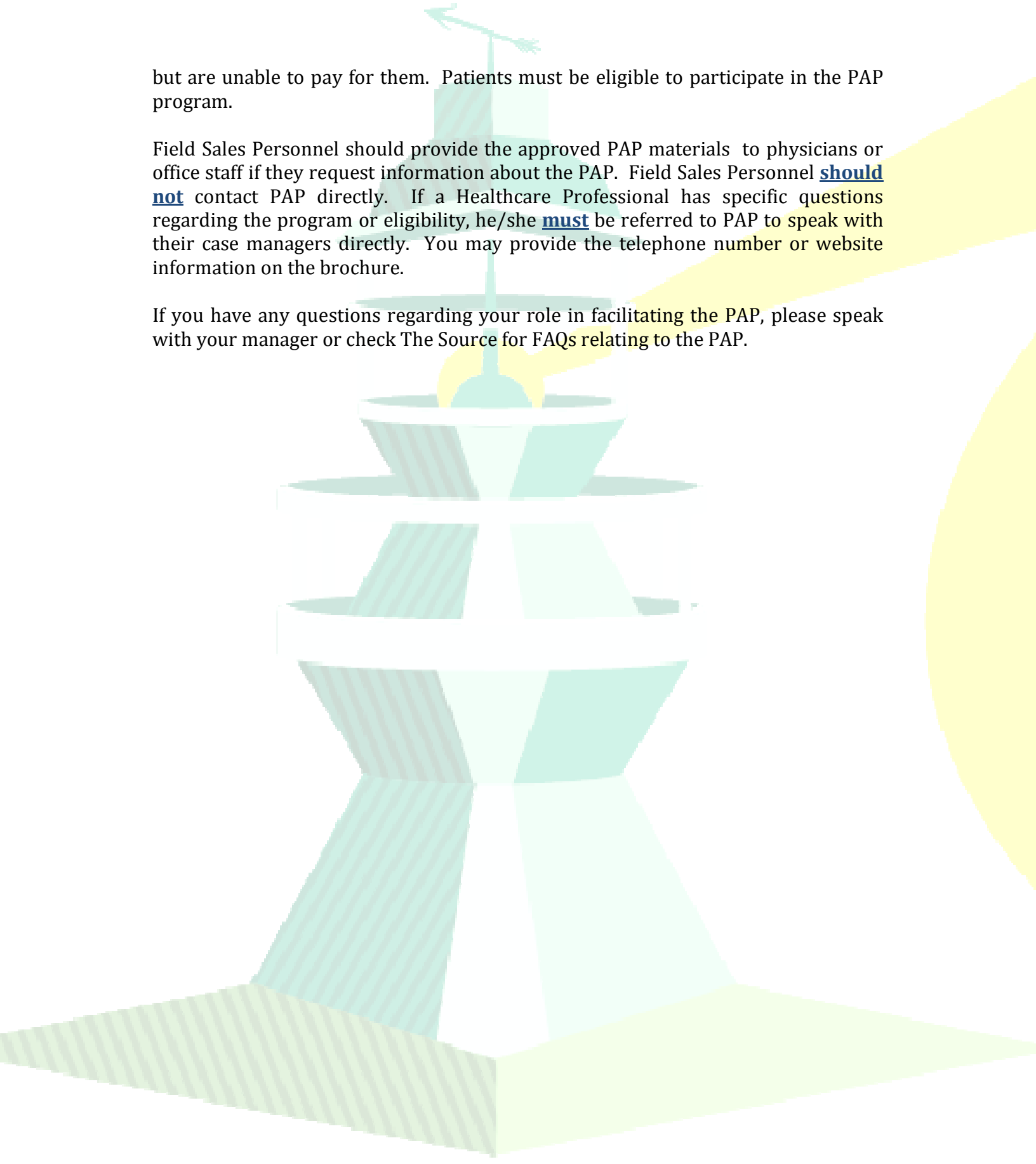
Prescription Assistance Program

Sunovion has developed a prescription assistance program (PAP) to help provide certain Sunovion products to eligible patients who are prescribed those products

but are unable to pay for them. Patients must be eligible to participate in the PAP program.

Field Sales Personnel should provide the approved PAP materials to physicians or office staff if they request information about the PAP. Field Sales Personnel **should not** contact PAP directly. If a Healthcare Professional has specific questions regarding the program or eligibility, he/she **must** be referred to PAP to speak with their case managers directly. You may provide the telephone number or website information on the brochure.

If you have any questions regarding your role in facilitating the PAP, please speak with your manager or check The Source for FAQs relating to the PAP.



Compliance Department Resources

The Sunovion Compliance Department is available to assist you with any questions that you have regarding these Guidelines or any other compliance matter.

Chief Compliance Officer:

Matthew D'Ambrosio, Sr. Vice President Compliance & Ethics
Matthew.Dambrosio@sunovion.com 508-787-4167

Compliance Policy, Investigations, and Training:

Averi Price, Sr. Director Compliance and Ethics
Averi.Price@sunovion.com 508-357-7580

Paul Ham, Associate Director Compliance and Ethics
Paul.Ham@sunovion.com 508-787-4199

General Mailbox:
CorporateCompliance@sunovion.com

Compliance Monitoring and Transparency (Aggregate Spend/Sunshine Act):

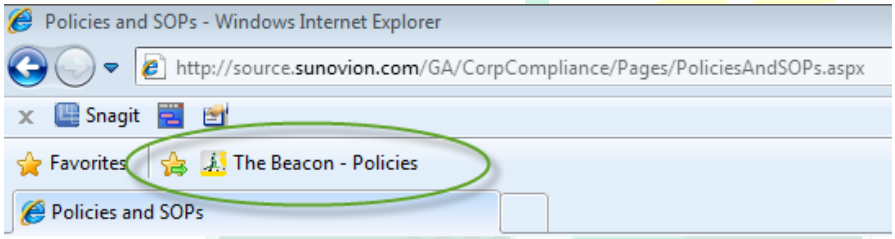
Joseph Wholley, Sr. Director Compliance Monitoring
Joseph.Wholley@sunovion.com 508-787-4287

General Mailbox:
Aggregate.Spend@sunovion.com

The Beacon:

Your direct connection to all Sunovion policies, procedures, and training materials.

**Available for download on your iPad through the Symantec App Store.*



**Also available through your Sunovion issued laptop via the desktop shortcut or favorites bar in Internet Explorer.*

The Compliance & Ethics Hotline:

By phone:
866-886-1348

By internet:
www.sunovion.ethicspoint.com

If you become aware of a violation of these Guidelines or Sunovion's Code of Conduct, it is **your responsibility to promptly report** the matter by **contacting the Compliance Department directly or anonymously through Sunovion's Compliance Hotline.** Sunovion will not discipline, discriminate or retaliate against any employee who reports a concern or complaint in good faith, or who cooperates in any investigation or inquiry regarding such conduct, whether or not such information is ultimately determined to be a violation. Moreover, Sunovion will not tolerate any adverse action or retaliation taken against any employee or agent by a supervisor or other employee on account of any complaint or concern raised.

All reports of conduct received through the Compliance Hotline or otherwise that may violate Sunovion's Code of Conduct and Ethics, Sunovion policy, procedure or guidance document will be kept confidential to the fullest extent practicable. The Compliance Department will look into the conduct in question and determine the appropriate follow-up, if any, with Legal Affairs, Human Resources and/or other Departments or affected business units.

###