



SUNOVION PHARMACEUTICALS INC.

CORPORATE POLICY

WORKING TITLE: Social Media Policy		POLICY NO: 1.3-02	
Supersedes:	Approval: Corporate Policy Review Committee (CPRC)	Date Issued: May 1, 2014	Page: 1 of 9

SECTION 1. PURPOSE

- 1.1 Sunovion Pharmaceuticals Inc. (“Sunovion” or the “Company”) is committed to open, transparent and timely communications and has established this Policy to guide the use of Social Media on behalf of the Company’s objectives in a responsible manner.
- 1.2 The purpose of this Policy is to provide guidance to employees, vendors and third parties, acting on the Company’s behalf, on the creation of Company-sponsored Social Media sites, as well as for appropriately engaging in Company-sponsored Social Media.
- 1.3 This Policy also outlines the responsibilities of employees and particular departments in conducting Company-sponsored Social Media projects.

SECTION 2. DEFINITIONS

2.1 Social Media and User Generated Content

- 2.1.1 **Social Media** is a broad term used to describe a variety of digital platforms or channels that engage or encourage users to interact in real or near-real time. For the purposes of this Corporate Policy, Social Media includes web and mobile technologies that enable conversations and/or information sharing among organizations, communities and individuals. These technologies include websites, blogs, online commenting, microblogging, social networks, virtual worlds, apps, share features and wikis that allow users to post comments, rate (e.g., “like”) posts or vote on topics, as well as those platforms where such interactivity is available but disabled.

- 2.1.2 **User Generated Content** (“UGC”) means any data or media that is contributed by individual users of a website or Social Media platform, including but not limited to consumers, non-employees and agents acting on behalf of the Company.
- 2.2 **Company-Sponsored Social Media** are social media channels and sites created by Sunovion, using Sunovion content, typically on third-party social media platforms or services.
- All Sunovion Social Media channels and sites must be reported to the Social Media Advisory Board, which will maintain a list of active company sponsored Social Media projects.
- 2.3 **Confidential Information** refers to any valuable, proprietary information that is generally not known to the public and which has not otherwise been purposefully disclosed to the public, including any information that Sunovion has obtained through a contractual relationship with another company and has agreed not to disclose through a confidentiality agreement or the like. (See also as defined in Information Security Policy 7.02 and the Code of Conduct and Ethics.)
- 2.4 **Non-Compliant Activity** is any engagement, post or comment made by a Sunovion Employee or Agent acting on the Company’s behalf on a Sunovion sponsored and/or owned Social Media channel that falls outside of the scope of Company policies, procedures, guidelines, or applicable laws and regulations.
- 2.5 **Employee** (for the purposes of this Policy) means any person employed by the Company on a full-time, part-time, contract or temporary basis.
- 2.6 **Vendors** include contractors, consultants, vendors or third-party providers used to create or maintain a Social Media program on Sunovion’s behalf.
- 2.7 **Project Sponsor** means a Sunovion Employee who leads the development of the Social Media strategy and Protocol and ushers it through appropriate internal review. This person may or may not also be the Community Manager.
- 2.8 **Community Manager** means a designated Employee who is responsible for monitoring and managing a Social Media channel or site. Day-to-day functions may be assigned to an Employee or a Vendor.
- 2.9 **Social Media Advisory Board** (“SMAB”) provides direction to the Project Sponsor and the relevant Content Review Committee on any new use of Social Media, particularly for product promotional communication. The SMAB is comprised of members representing various functions involved in Social Media, including Legal Affairs, Pharmacovigilance (PVRM), Compliance and Ethics, Commercial, Corporate

Communications, Clinical Development and Medical Affairs (CDMA), Regulatory Affairs and Information Technology. The Chief Compliance and Ethics Officer shall designate the committee chair.

SECTION 3. APPLICABILITY AND RESPONSIBILITIES

3.1 Applicability

- 3.1.1 This Policy applies to the Company's use of any Company-sponsored Social Media activities, including but not limited to business communications, promotional and non-promotional initiatives, and in conjunction with research activities, including clinical trial recruitment, patient-centric observation, health economics outcomes research ("HEOR") and registries.
- 3.1.2 This Policy applies to all Employees, vendors and third parties acting on behalf of the Company and their engagement in or participation on Company-sponsored Social Media activities. (For example, an Employee engaging in Company-sponsored Social Media from home may fall under the Policy). It does not apply to the personal use of Social Media and does not seek to restrict protected rights, communications or other forms of speech.

3.2 Responsibilities

3.2.1 Corporate Communications

Corporate Communications is responsible for reviewing and approving all Social Media communications that convey the Sunovion corporate point of view (non-promotional), unrelated to Sunovion's products. Corporate Communications is responsible for the approval and development of any such Sunovion Social Media platform (e.g., creation of an official Sunovion Twitter account or YouTube channel) and for Community Management of General and Administration (G&A) departmental Social Media initiatives. Corporate Communications is also responsible for any corporate internal (e.g., intranet, Sunovion apps, blogs) Social Media activities. Corporate Communications must work in conjunction with Legal Affairs, Regulatory and other stakeholders when launching Social Media initiatives to ensure that regulatory and legal requirements are met.

3.2.2 Business Function

The Executive Leadership Team ("ELT") member presiding over each business function is responsible for designating a Project Sponsor within

their business function to be accountable for the approval, development and management of any Social Media initiatives (promotional or non-promotional) developed by their function.

3.2.3 Employees, Vendors and Third Parties

Employees, vendors and third parties acting on behalf of the Company are responsible for adhering to this Policy and other Company guidance around Social Media. Sunovion acknowledges Employees' personal rights to use Social Media, as well as other legally protected forms of speech. However, as with other forms of communication, good judgment, caution and adherence to the Code of Conduct and Ethics and other applicable policies should be maintained when utilizing Social Media channels.

3.2.3.1 When utilizing Social Media on behalf of the Company, Employees must remain vigilant about protecting the privacy of personally identifiable information or protected health information and our requirement to report adverse events.

3.2.3.2 Employees who engage in Social Media communications involving Sunovion or any of its products or who begin a dialogue about these topics online are responsible for monitoring these discussions in accordance with all applicable Company policies and requirements listed in §§ 4.4.2 and 4.4.3.

3.2.3.3 Employees are responsible for reporting inappropriate behavior/comments on Company-owned and/or sponsored Social Media properties and for ensuring that all such activities are in accordance with the Code of Conduct and Ethics and other Company policies, procedures, and guidelines, as well as applicable laws and regulations.

3.3 Social Media Advisory Board (“SMAB”)

The Social Media Advisory Board is responsible for developing direction for Project Sponsors and Content Review Committees regarding any potential Social Media program that involves a Social Media technology or activity new to Sunovion. For new uses of Social Media, the Social Media Advisory Board will review strategy, conceptual content and proposed protocols for allowing and monitoring UGC. Once a protocol for a particular channel is approved and written, it will be up to the Content Review Committees to ensure subsequent use of the same platform and adoption of the same protocol(s). The SMAB will need to review subsequent uses of the same platform if a Project Sponsor proposes

developing an initiative out of the scope of the protocol, or in the event the platform changes or updates the way information is shared; if this occurs a new protocol will be created and approved. For example, SMAB may dictate whether two-way communication may be allowed or not on a specific Social Media channel, per current regulatory and legal guidance. The Social Media SOP provides additional guidance on developing Social Media strategies and protocols.

3.3.1 SMAB will maintain a centralized database of active Company-Sponsored Social Media projects. The Content Review Committees, including the Promotional Materials Review Committee (“PMRC”), Medical Science Review Committee (“MSRC”) and Corporate Communications Review Committee (“CCRC”), will keep SMAB informed of newly approved Company-Sponsored Media sites on a monthly basis. PMRC will be responsible for submitting a list of promotional social media sites to the FDA on a monthly basis, in accordance with FDA’s January 2014 Guidance for Industry on Fulfilling Regulatory Requirements for Postmarketing Submissions of Interactive Promotional Media for Prescription Human and Animal Drugs and Biologics.

3.3.2 SMAB is responsible for regularly reviewing and updating this Policy as appropriate.

3.4 **Chief Compliance and Ethics Officer**

The Chief Compliance and Ethics Officer is responsible for designating the SMAB Chair and for enforcing this Policy.

3.5 **Project Sponsor**

Each Project must have a Project Sponsor who remains accountable for the Project during its life cycle and makes certain all relevant Sunovion policies are followed and applied. The Project Sponsor is responsible for developing and executing the Social Media strategy and protocol(s), and for ensuring appropriate SMAB and Content Review Committee approval as needed. The Project Sponsor must ensure the Social Media protocol(s) includes procedures for reporting adverse events, responding to any comments, posts or interactions that occur on the site, including the designation of a full-time Community Manager that is responsible for the day-to-day management of the site. The Project Manager should also establish a timeline for the activity, as well as allocate a plan of action for closing down the site. A Project Sponsor must always secure appropriate approvals of content from the relevant Content Review Committee, as applicable (e.g., PMRC, MSRC) and inform SMAB about its Social Media initiative.

3.6 Community Manager

The Project Sponsor will designate a Community Manager responsible for following all Sunovion procedures outlined in the Social Media protocol and related SOPs. Although day-to-day duties may be conducted by a vendor, contractor or third party provider, a Sunovion Company employee must remain responsible for each channel or site. A Community Manager should be knowledgeable about the content and operation of the Social Media platform and channel. It is up to the Community Manager to ensure that the Social Media initiatives for which they are responsible is in compliance with all applicable Company policies, procedures, guidelines, as well as laws, regulations and industry standards. They are also responsible for tracking and reporting to their Project Sponsor and/or functional leadership on the measurement and analysis of the effectiveness of the Social Media campaign. Responsibilities include monitoring the site and reporting any inappropriate, illegal or harmful content.

SECTION 4. GENERAL

4.1 Planning and Creating a Social Media Project

Sunovion may engage in Social Media, provided the program meets the requirements outlined in this and other related policies.

4.2 Responsibility for Content

The Project Sponsor and designated Community Manager are accountable for knowing when the Company is responsible for content, including User Generated Content.

4.2.1 Sunovion is responsible for communications on sites that are owned, controlled, created, influenced or operated by, or on behalf of, the Company.

4.2.2 Sunovion is responsible for the content generated by an Employee or agent who is acting on behalf of the Company, i.e., to promote its products and health information.

4.2.3 Sunovion is responsible for communication on a third-party site if the Company has control or influence on the third-party site. For example, if Sunovion collaborates or has editorial, preview or review privileges, then the Company may be responsible for the content.

4.2.4 Sunovion may not be responsible for non-Company UGC on its Social Media platforms that is truly independent of Sunovion and the user has no

affiliation with Sunovion. Nevertheless, Sunovion is responsible for reporting adverse events and product complaints (see § 5.6.3) and for directing unsolicited requests for information about products to an appropriate channel of communication (see § 5.6.5).

- 4.2.5 Sunovion may not be responsible for non-Company UGC that shares, alters or comments on Sunovion or its products on non-Company sites, pages or accounts. For example, Sunovion is responsible for Company-sponsored content on Twitter or Facebook and may allow sharing or reposting of the Company content, but is not responsible for modifications or comments made by a user who shares, reposts, or retweets the content.
- 4.3 To ensure the reputation of Sunovion and the public perception of its products (approved and in development) are protected, external communications using Social Media must be managed in a responsible and consistent manner. This includes complying with the Sunovion Code of Conduct and Ethics and all applicable Company policies and procedures, as well as applicable laws, regulations, industry standards and guidance, including the FDA's December 2011 *Guidance for Industry Responding to Unsolicited Requests for Off-Label Information About Prescription Drugs and Medical Devices*.
- 4.4 Any Sponsor developing Social Media campaigns or materials that fall under PMRC purview for promotional activities or disease state awareness must adhere to the Promotional Materials Review and Disposition Process SOP (SUN-REG-SOP-004).
- 4.5 Any Sponsor developing Social Media to advertise for clinical trial recruitment must adhere to the Review and Approval of Subject Recruitment Materials SOP (SUN-REG-SOP-007).
- 4.6 **Community Management**

Each Social Media program or activity must be monitored and managed by an Employee or agent of the Company who will serve as a Community Manager. The Functional Leader in charge of the campaign will designate the Community Manager and will coordinate a replacement, should the need arise due to employee vacancies or staffing changes.

- 4.6.1 Community Managers must actively and routinely monitor the Social Media channels for which they are responsible (including those controlled or operated by vendors on their behalf) in accordance with an SMAB or Content Review Committee approved monitoring plan, especially as it pertains to the Company, its activities, products and pipeline. This

includes, but is not limited to, documenting and reporting any comments that may be concerning or related to the safety, efficacy or unapproved use of a product, including adverse events and product complaints. Interactions must follow approved language or guidance from MSRC, PMRC, SMAB or other relevant committees and adhere to all directions outlined in this Policy.

- 4.6.2 Community Managers must have administrative rights to all Sunovion-owned and/or sponsored Social Media platforms, even if the platform is managed by an agency or vendor.
- 4.6.3 All Sunovion social communities must have Community Participation Rules posted (usually in the Terms of Use) on the site. These terms of use should outline the expectations of participation on the site. The Community Participation Rules should be approved as part of the channel approval process.

4.7 Adverse Events (“AE”) Reporting Protocol

Any employee or Company representative must report AEs or product complaints in accordance with the Reporting of Adverse Drug Experiences, Product Complaints and Other Safety Information by Sunovion Employees and Agents Policy 9.01.

4.8 Terms & Conditions for Social Media Platforms

Prior to launching a new Sunovion Social Media channel, the Project Sponsor proposing the new Social Media channel must ensure that the Terms and Conditions of that Social Media platform have been reviewed and approved by Legal Affairs.

Since social media platform Terms & Conditions are often updated, it is the Community Manager’s responsibility to monitor for changes to a live channel’s Terms & Conditions and have changes reviewed by Legal Affairs. In some cases, changes to a platform’s Terms & Conditions may result in new guidance from Legal Affairs or Compliance to manage content differently, administer the channel in a different way or terminate the use of the channel altogether.

- 4.9 Sunovion reserves the right at any time to terminate any Social Media initiatives and/or properties that are deemed non-compliant with this Policy or any Company SOPs or policies, or for business reasons.

SECTION 5. OTHER MATERIALS

5.1 Amendment

Management reserves the right to amend this policy as appropriate at any time without prior notice.

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.

5.4.1 Reporting Hotline Options:

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

5.4 Audit

The Compliance Department 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-References to Other Corporate Policies

- 5.5.1 Sunovion Code of Conduct and Ethics
- 5.5.2 External Communications Policy
- 5.5.3 Reporting of Adverse Drug Experiences, PCs and Other Safety Information by Sunovion Employees and Agents
- 5.5.4 Information Security Policy