



SUNOVION PHARMACEUTICALS INC.

CORPORATE POLICY

WORKING TITLE: Direct to Consumer Advertising		POLICY NO. 3.08	
Supersedes:	Approval: Corporate Policy Review Committee (CPRC)	Date Issued: December 16, 2011	Page: 1 of 4

Section 1. SCOPE AND PURPOSE

This Policy reflects Sunovion's commitment to ensure that Direct to Consumer advertising complies with Food and Drug Administration regulations. Beyond meeting our legal obligations, as a member of PhRMA, we have voluntarily adopted the PhRMA Guiding Principles: Direct to Consumer Advertisements About Prescription Medicines. This Policy applies to all Sunovion Marketing Employees and their agents who are involved in the review, approval and production of Sunovion Direct to Consumer (DTC) Television and Print Advertising.

Section 2. DEFINITIONS

1. Direct to Consumer Television Advertisement is a portion of television air time on broadcast or cable television that is bought by a company for the purpose of presenting information about one or more of the company's medicines. A DTC television advertisement does not include sponsorship of activities.
2. Direct to Consumer Print Advertisement is space that is bought by a company in newspaper or magazine publications targeted to patients or consumers, or a direct mail communication paid for and disseminated by a company to patients or consumers, for the purpose of presenting information about one or more of the company's medicines. A DTC print advertisement does not include sponsorship of activities.
3. Direct to Consumer Digital Advertisement: An advertising unit (awareness, direct response) that is bought by a company through a digital ad network, digital content provider or website and targeted to patients or consumers for the purpose of presenting information about one or more of the company's products. A DTC digital advertisement does not include sponsorship of activities.

Section 3. GENERAL

All Sunovion DTC Advertising should be accurate, not misleading, make claims only when supported by substantial evidence, reflect a fair balance between risks and benefits and be consistent with FDA-approved labeling. Sunovion's Promotional Materials Review Committee (PMRC) must review all Sunovion DTC advertising for its compliance with this Policy.

Additionally, DTC advertising should:

1. Be designed to responsibly educate the Consumer about the medicine and the condition for which it may be prescribed;
2. Foster responsible communications between Patients and Healthcare Professionals to help Patients achieve better health and a more complete appreciation of both the health benefits and the known risks of the medicine being advertised;
3. Clearly indicate that the medicine is a prescription drug to distinguish such advertising from advertising for non-prescription products;
4. Include information about the availability of other options such as diet and lifestyle changes where appropriate for the advertised condition;
5. In DTC television advertising, clearly state the health condition(s) for which the medicine is approved and the major risks associated with the medicine being advertised, if the advertising identifies the product by name;
6. Be designed to achieve a balanced presentation of both the benefits and the risks associated with the prescription medicine. Specifically, risks and safety information, including the substance of relevant boxed warnings, should be presented with reasonably comparable prominence to the benefit information, in a clear, conspicuous and neutral manner, and without distraction from the content;
7. Include FDA's toll-free MedWatch telephone number and website for reporting potential adverse events in DTC Print Advertisements and DTC Digital Advertisements. DTC Television Advertisements should direct patients to a Print Advertisement containing FDA's toll-free MedWatch telephone number and website, and/or should provide the company's toll-free telephone number;
8. Acknowledge in the advertisement that actors are being used, if the advertisement features actors in the roles of Healthcare Professionals. Likewise, if actual Healthcare Professionals appear in such advertisements, the advertisement should include an acknowledgement if the Healthcare Professional is compensated for the appearance;
9. Accurately reflect the opinions, findings, beliefs or experience of any celebrity endorser. Sunovion should maintain verification of the basis of any actual or implied endorsements made by the celebrity endorser, including whether the endorser is or has been a user of the product if applicable;
10. Respect the seriousness of the health conditions and the medicine being advertised;
11. Be targeted to avoid audiences that are not age appropriate for the medicines involved. In particular, DTC Television and Print Advertisements containing content that may be inappropriate for children should be placed in programs or publications that are reasonably expected to draw an audience of approximately 90 percent adults (18 years or older); and
12. Include information about help for the uninsured and underinsured where appropriate.

SECTION 4. DTC ADVERTISING DEVELOPMENT AND LAUNCH

1. During the development of new DTC Television Advertising campaigns, Sunovion should seek and consider feedback from appropriate audiences, such as Healthcare Professionals and Patients, to gauge the educational impact for Patients and Consumers.
2. In order to foster responsible communication between Patients and Healthcare Professionals, Sunovion should spend an appropriate amount of time to educate Healthcare Professionals about a new medicine or a new therapeutic indication and to alert them to the upcoming advertising campaign before commencing the first DTC advertising campaign. In determining what constitutes an appropriate time, Sunovion should take into account the relative importance of informing patients of the availability of a new medicine, the complexity of the risk-benefit profile of that new medicine and Healthcare Professionals' knowledge of the condition being treated. Sunovion will continue to educate Healthcare Professionals as additional important information about a new medicine is obtained from all reliable sources.
3. Sunovion will submit all new DTC television advertisements to the FDA before releasing the advertisements for broadcast.
4. Sunovion should continue to responsibly alter or discontinue a DTC advertising campaign should new and reliable information indicate a serious previously unknown safety risk.

SECTION 5. GENERAL MATTERS

5.1 Amendment

Management reserves the right to amend this policy as appropriate at any time without prior notice, pursuant to Sunovion Corporate Policy 1.0, "**Corporate Policy Review Committee.**"

5.2 Failure to Comply

EMPLOYEES WHO VIOLATE ANY SUNOVION POLICIES AND PROCEDURES MAY 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 the Sunovion Compliance Hotline as set forth below. Reports of violations or suspected violations of alleged misconduct or wrongful behavior are maintained as confidential as practicable under the circumstances, and as necessary to conduct a full and fair investigation.

Reporting Hotline Options:

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

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

5.4 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.