

Policy Title:	Direct to Consumer Advertising
Policy Number:	LEG-CIA- POL-005.7

1. PURPOSE

Direct to consumer (DTC) advertising about prescription medicines (DTC Advertising) plays an integral role in benefiting the public health by raising consumer/patient awareness about diseases; educating consumers/patients about treatment options; motivating patients to contact their healthcare professional (HCP) about health concerns; fostering an informed conversation between patients and their HCPs about health concerns, treatments, and known risks associated with a medicine; increasing the likelihood that patients will receive appropriate care for conditions that are frequently under-diagnosed and under-treated; and encouraging compliance with prescription drug treatment regimens.

The purpose of this Policy is to memorialize Daiichi Sankyo Inc.'s (DSI) adoption and implementation of the PhRMA DTC Guiding Principles and to ensure that all DTC Advertising of a DSI prescription medicine complies with the PhRMA DTC Guiding Principles, Food and Drug Administration (FDA) regulations, and any other applicable laws, rules, and regulations.

2. SCOPE

This Policy applies to all DSI Employees and Contingent Workers who create, review, approve and/or disseminate DSI DTC Advertising. This includes DSI Employees and Contingent Workers within Daiichi Sankyo Pharma Development ("DSPD") Division, Daiichi Sankyo U.S. Business ("DSUSB") Division and the U.S. Corporate Division ("USCD"), including without limitation, global functions within those divisions.

3. COMPLYING WITH PHRMA DTC GUIDELINES AND PRINCIPLES

[DSI DTC Advertising that does not conform to this Policy is not permitted and will not be approved by DSI. No person, regardless of his or her position with, or relationship to, DSI has the authority to override any provision of this Policy or to grant permission to any other person to violate this Policy. Any questions pertaining to DSI DTC Advertising should be directed to the Legal Affairs Department. DSI will monitor compliance with the requirements of the PhRMA DTC Guiding Principles on an ongoing basis

- In accordance with FDA regulations, all DSI DTC Advertising must be accurate, truthful and not misleading; supported by appropriate evidence; reflect the balance between risks and benefits; and be consistent with FDA approved labeling. DSI will base all promotional claims on FDA approved labeling, including in DTC advertisements.

Policy Title:	Direct to Consumer Advertising
Policy Number:	LEG-CIA- POL-005.7

- All DSI DTC Advertising must be reviewed and approved by the DSI Product Material Review Team (PMRT), or its functional equivalent for co-promoted products.
- DSI DTC Television Advertising and DSI DTC Print Advertising (collectively, “DSI DTC Television and Print Advertising”) must be designed to responsibly educate the consumer about the prescription medication and, where appropriate, the condition for which it may be prescribed. During the development of new DSI DTC Television Advertising campaigns, DSI should seek and consider feedback from appropriate audiences, for example HCPs and patients, to gauge the educational impact for patients and consumers.
- DSI DTC Television and Print Advertising shall comply with all applicable federal laws, FDA regulations, and federal healthcare program requirements, including, but not limited to, those set forth at 21 U.S.C. § 352(n) and 21 C.F.R. § 202.1.
- DSI DTC Television and Print Advertising will clearly indicate that the medicine is a prescription drug, in order to distinguish such advertising from the advertising of non-prescription products.
- DSI DTC Television and Print Advertising will foster responsible communications between patients and HCPs to help patients achieve better health and a more complete appreciation of both the health benefits and the known risks associated with the medicine being advertised. DSI will also ensure that DSI DTC Television Advertising includes a major statement conveying all of the product’s most important risk information in consumer-friendly language and that DSI DTC Print Advertising contains a Brief Summary relating to side effects, contraindications and effectiveness written in consumer-friendly language.
- DSI will determine whether and when it is appropriate to engage in DTC Advertising. In order to foster responsible communication between patients and HCPs, DSI will spend an appropriate amount of time to educate HCPs about a new medicine or a new therapeutic indication and to alert them to the upcoming DS Advertising campaign before commencing the first DSI DTC Advertising campaign. In determining what constitutes an appropriate time, DSI will 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 HCPs’ knowledge of the condition being treated. DSI will consider setting specific periods of time, with or without exceptions, to educate HCPs before launching a DSI DTC Television or Print Advertising campaign. DSI will continue to educate

Policy Title:	Direct to Consumer Advertising
Policy Number:	LEG-CIA- POL-005.7

HCPs as additional valid information about a new medicine is obtained from all reliable sources.

- DSI will work with the FDA to responsibly alter or discontinue a DSI DTC Advertising campaign should new and reliable information indicate a serious previously unknown safety risk.
- DSI will submit all new DSI DTC Television Advertising to the FDA before releasing it for broadcast. In accordance with FDA regulations, DSI DTC Print Advertising will be submitted at the time of publication, unless FDA comment is requested by DSI.
- DSI DTC Print Advertising will include the FDA's toll-free MedWatch telephone number and website for reporting potential adverse events. DSI DTC Television Advertising will provide DSI's toll-free telephone number and/or direct patients to a related DSI DTC Print Advertising, containing the FDA's toll-free MedWatch telephone number and website.
- If DSI uses an actor to portray an HCP in DSI DTC Television or Print Advertising, DSI will acknowledge in the advertisement that an actor is being used. If an actual HCP appears, the advertisement will include a statement that acknowledges if the HCP has been compensated for his/her appearance.
- If a DSI DTC Television or Print Advertising features a celebrity endorser, DSI will ensure that the endorsement accurately reflects the opinions, findings, beliefs or experience of the celebrity endorser. DSI will maintain verification of the basis of any actual or implied endorsement(s) made by the celebrity endorser in the advertisement, including, if applicable, whether the endorser is, or has been, a user of the prescription medicine.
- Where appropriate, DSI DTC Television and Print Advertising will include information about the availability of other options, such as diet and lifestyle changes, for the advertised condition.
- DSI DTC Television Advertising will clearly state the health conditions for which the medicine is approved and the major risks associated with the medicine being advertised.
- DSI DTC Television and Print Advertising will be designed to achieve a balanced presentation of both the benefits and the risks associated with the advertised prescription medicine. Specifically, risks and safety information, including the

Policy Title:	Direct to Consumer Advertising
Policy Number:	LEG-CIA- POL-005.7

substance of relevant boxed warnings, will be presented with reasonably comparable prominence to the benefit information, in a clear, conspicuous and neutral manner, and without distraction from the content. In addition, DSI DTC Television Advertising will support responsible patient education by directing patients to HCPs and related DSI DTC Print Advertising and/or websites where additional benefit and risk information is available.

- All DSI DTC Advertising will respect the seriousness of the health condition(s) and the medicine being advertised.
- In terms of content and placement, DSI DTC Television and Print Advertising will be targeted to avoid audiences that are not age appropriate for the messages involved. In particular, DSI DTC Television and Print Advertising containing content that may be inappropriate for children will be placed in programs or publications that are reasonably expected to draw an audience of adults (18 years or older).
- DSI will consider promoting health and disease awareness as part of its DSI DTC Advertising.
- Where practical and appropriate, DSI will include information in DSI DTC Advertising, directing patients to Company resources that may help them with the cost of the advertised prescription medicines, via the *Open Care Program*, or equivalent program.
- All DSI DTC television advertising that identifies a prescription medicine by name will include direction as to where patients can find information about the cost of the medicine, such as a company-developed website, including the list price and average, estimated or typical patient out-of-pocket costs, or other context about the potential cost of the medicines.
- To the extent required by law, all DSI DTC television advertisements will include the Wholesale Acquisition Cost (WAC) for the advertised prescription medicine.
- All DSI use of Social Media or Social Media Activities relating to advertising shall be prepared and disseminated in accordance with DSI's established Social Media for Business Use Procedure (PA-CIA-AOP-001).

Policy Title:	Direct to Consumer Advertising
Policy Number:	LEG-CIA- POL-005.7

4. COMPLIANCE

Within the US:

Failure to follow this Policy may subject a Contingent Worker to disciplinary action, up to and including termination. Any Contingent Worker who becomes aware of an actual or potential violation of this or any policy must promptly report it to their Manager, and/or one of the following Daiichi Sankyo, Inc. departments: Compliance, Legal Affairs, Human Resources, or the Compliance Hotline at (877-48ALERT) or the Compliance Hotline website (dsi.alertline.com). The Company follows a policy of non-retaliation and no Contingent Worker will be subject to retaliatory action for reporting in good faith a suspected violation of this Policy.

Outside of the US:

Failure to follow this Policy may subject a Contingent Worker to disciplinary action, up to and including termination. Any Contingent Worker who becomes aware of an actual or potential violation of this or any policy must promptly report it to their Manager and/or the US Legal Affairs Department. The Company follows a policy of non-retaliation and no Contingent Worker will be subject to retaliatory action for reporting in good faith a suspected violation of this Policy.

5. POLICY REFERENCES, FORMS AND TEMPLATES

- *DSI US Standards of Business Conduct*
- *Creation and Approval of Advertising and Product Material – Product Material Review Process (PMRP) (LEG-CIA-AOP-013)*
- *Use of Advertising and Promotional Material (COM-CIA-POL-005)*
- *Social Media for Business Use Procedure (PA-CIA-AOP-001)*
- *DDMAC Guidance for Industry Consumer-Directed Broadcast Advertisements (Dated: 8/1999);*
- *DDMAC Draft Guidance for Industry Brief Summary: Disclosing Risk Information in Consumer-Directed Print Advertisements (Dated: 1/2004);*
- *PhRMA Guiding Principles Direct to Consumer Advertisements About Prescription Medicines (Revised: 10/2018; Effective: 4/15/2019);*
- *Guidance for Industry Product Name Placement, Size, and Prominence in Advertising and Promotional Labeling (Dated: 1/2012)*

Policy Title:	Direct to Consumer Advertising
Policy Number:	LEG-CIA- POL-005.7

- *OPDP Draft Guidance for Industry Direct-to-Consumer Television Advertisements – FDAAA DTC Television Ad Pre-Dissemination Review Program (Dated: 3/2012)*

Policy Title:	Direct to Consumer Advertising
Policy Number:	LEG-CIA- POL-005.7

6. ABBREVIATIONS AND DEFINITIONS

a. Abbreviations

Abbreviation	Term
CDER	Center for Drug Evaluation and Research
DDMAC	Division of Drug Marketing, Advertising and Communications. In 2011, the DDMAC was converted from a division to an office within CDER's Office of Medical Policy and became known as OPDP.
DSI	Daiichi Sankyo, Inc.
DSI DTC Television and Print Advertising	Collectively refers to DSI DTC Television Advertising and DS DTC Print Advertising
DSI DTC Television or Print Advertising	Collectively refers to DSI DTC Television Advertising or DS DTC Print Advertising
DTC	Direct to consumer
FDA	Food and Drug Administration
FDAAA	Food and Drug Administration Amendments Act of 2007
HCP	Healthcare Professional
OPDP	Office of Prescription Drug Promotion
PhRMA	Pharmaceutical Research and Manufacturers of America
PhRMA DTC Guiding Principles	PhRMA Guiding Principles on Direct to Consumer Advertising about Prescription Medicines (Last revised: 12/2008; Effective: 3/2/2009)
PMRT	Product Material Review Team
Policy	Policy on Direct to Consumer Advertising
P&T Committee	Pharmacy and Therapeutics Committee
WAC	Wholesale Acquisition Cost

b. Terms

Policy Title:	Direct to Consumer Advertising
Policy Number:	LEG-CIA- POL-005.7

Term	Definition
Brief Summary	A true statement of information including side effects, warnings, precautions, contraindications and any such information under such headings as cautions, special considerations, important notes, etc.
Contingent Worker	All individuals who provide services to DSI subject to a contingency. Typically, the contingency is a temporary need for services for a limited period of time, a select service, or a specific result/outcome. Contingent Workers include agency temporary workers, independent contractors, consultants, vendors, contract workers and fellows.
DSI DTC Print Advertising	DTC Advertising of a DSI prescription medicine, which appears in print.
DSI DTC Television Advertising	DTC Advertising of a DSI prescription medicine, which appears on television.
DSI DTC Television and Print Advertising	Collectively refers to: DSI DTC Television Advertising and DS DTC Print Advertising
DSI DTC Television or Print Advertising	Collectively refers to: DSI DTC Television Advertising or DS DTC Print Advertising
DTC Advertising	Any promotional effort by a pharmaceutical company to present prescription drug information to the general public through the lay media. Advertising may appear in various media, including, but not limited to, magazines, newspapers, non-medical journals, and direct-mail letters, as well as on the television, radio, videos, Internet websites and streaming services (such as Hulu and Netflix)
Employee	An individual hired directly by the Company and paid through the Company payroll as an employee for an ongoing, indefinite period to perform work for the Company on a weekly schedule.
Healthcare Professional	All medical professionals including, but not limited to, physicians, medical students, nurses, nurse practitioners, physician assistants, pharmacists and medical technicians. "HCP" also includes other employees or staff involved in purchasing or prescribing or prescribing decisions including, but not limited to, formulary and P&T committee members.
Open Care Program	Offers assistance to qualified individuals who demonstrate medical and financial need. The program provides free products to those who are prescribed DSI products and are under insured and uninsured, as well as unable to identify alternative payment sources.

Policy Title:	Direct to Consumer Advertising
Policy Number:	LEG-CIA- POL-005.7

Social Media (SM)	DSI defines SM as the application of mobile and web-based technologies to turn communication into interactive or multi-directional (e.g., two-way) dialogue. SM data consists of any user-generated content that is either a) propagated by a single user or b) the product of interaction between one or more users/contributors. SM data exists in various formats such written information, photos, videos, and audio files. SM exchange includes all forms of online publishing, digital media sharing and online discussions in Social Networks, Collaborative Forums, Social Communities and other bi-directional social interaction technologies, including but not limited to blogs, micro-blogs, wikis, user-generated video, location-based applications, and audio.
Social Media Activity	Any SM project proposed and/or conducted on behalf of DS. An SM Activity may be either: <ul style="list-style-type: none"> • Non-Product/Non-Disease State Company SM activities: company SM activities, which are not related to company products or the disease states that they treat, or • Product/-Disease State Company SM activities: Company SM activities, which are related to Company products or the disease states that they treat.
Wholesale Acquisition Cost	The list price from a manufacturer to a wholesaler or a direct purchaser without discounts
Term	Definition