

Merck's Alignment with PhRMA DTC Principles

(Updated January 30, 2009)

Effective January 1, 2006, the Pharmaceutical Research Manufacturer's Association (PhRMA) implemented the "PhRMA Guiding Principles – Direct to Consumer Advertisements About Prescription Medicine." These are voluntary guidelines intended to reflect the commitment of PhRMA member companies to ensure that, in addition to meeting all applicable legal requirements, Direct to Consumer (DTC) communications contribute to public health by fostering an informed conversation about health, disease and treatments between patients and their healthcare practitioners.

PhRMA has revised the Guiding Principles, **effective March 2, 2009**. Merck has committed to comply with these voluntary PhRMA principles, which reflect many of the practices already established at Merck with regard to development and placement of DTC advertising. The purpose of this document is to provide direction on how Merck intends to ensure that its DTC communications are in compliance. Below is each PhRMA Principle, followed by Merck's comment as it relates to the Principle.

Merck's Comments Regarding PhRMA DTC Guiding Principles

- **PhRMA Guiding Principle #1** – *These Principles are premised on the recognition that DTC advertising of prescription medicines can benefit the public health by increasing awareness about diseases, educating patients about treatment options, motivating patients to contact their physicians and engage in a dialogue about health concerns, 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.*

Merck's approach to DTC advertising is rooted in providing understandable, relevant, and responsible information about diseases, conditions, and treatment options to consumers to enable an informative dialogue with his or her health care professional that can lead to diagnosis and appropriate treatment.

- **PhRMA Guiding Principle #2** – *In accordance with FDA regulations, all DTC information should be accurate and not misleading, should make claims only when supported by substantial evidence, should reflect balance between risks and benefits, and should be consistent with FDA approved labeling. Accordingly, companies should continue to base promotional claims on FDA approved labeling and not promote medicines for off-label uses, including in DTC advertisements.*

According to FDA regulations, any prescription drug promotion must be compliant in this respect. In order to ensure that DTC communications created by Merck meet applicable laws and regulations and comply with PhRMA's DTC Principles, we will continue to review all DTC communications in Medical/Legal boards*. We will also continue our long-standing practice of submitting new DTC content to the FDA (DDMAC or APLB) for advisory comments prior to issuance.

*Merck's medical/legal boards are comprised of physicians and lawyers that review promotional materials prior to use for the purposes of ensuring scientific and medical accuracy, and compliance with Merck's policies and FDA regulations.

- **PhRMA Guiding Principle #3** – *DTC television and print advertising which is designed to market a prescription drug should also be designed to responsibly educate the consumer about that medicine and, where appropriate, the condition for which it may be prescribed. During the development of new DTC television advertising campaigns, companies should seek and consider feedback from appropriate audiences, such as health care professionals and patients, to gauge the educational impact for patients and consumers.*

Merck will continue to develop DTC messages that inform consumers about our products and incorporate messages about disease conditions, where appropriate, in DTC television and print advertising. In the development of new DTC TV advertising campaigns, Merck will continue to conduct market research with appropriate customers to assess the educational impact for patients and consumers and apply findings where appropriate.

- **PhRMA Guiding Principle #4** – *DTC television and print advertising of prescription drugs should clearly indicate that the medicine is a prescription drug to distinguish such advertising from other advertising for non-prescription products.*

Consistent with FDA regulatory requirements, it has been a long-standing practice at Merck that every DTC product claim advertisement for a Merck prescription drug includes this disclosure.

- **PhRMA Guiding Principle #5** – *DTC television and print advertising should foster responsible communications between patients and health care professionals 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.*

Merck will continue to create DTC messages designed to foster responsible communications between patients and health care professionals. Merck strives to develop DTC messages in consumer-friendly language so that patients are better prepared to engage in a responsible discussion with their health care professional. Merck continues to develop FDA-approved consumer-friendly Patient Product Information (PPI) that also meets the brief summary requirement or to utilize a brief summary written in consumer-friendly language.

- **PhRMA Guiding Principle #6** – *In order to foster responsible communication between patients and health care professionals, companies should spend an appropriate amount of time to educate health professionals about a new medicine or a new therapeutic indication before commencing the first DTC advertising campaign. In determining what constitutes an appropriate time, companies 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 health care professionals' knowledge of the condition being treated. Companies are encouraged to consider individually setting specific periods of time, with or without exceptions, to educate health care professionals before launching a branded DTC television or print advertising campaign. Companies should continue to educate health care professionals as additional valid information about a new medicine is obtained from all reliable sources.*

Merck's current policy requires a minimum six month time period following the approval of a new product before launching DTC broadcast advertising about the new product.

- **PhRMA Guiding Principle #7** – *Working with the FDA, companies should continue to responsibly alter or discontinue a DTC advertising campaign should new and reliable information indicate a serious previously unknown safety risk.*

Merck is committed to working with the FDA to responsibly alter or discontinue a DTC advertising campaign should new and reliable information indicate a serious previously unknown risk.

- **PhRMA Guiding Principle #8** – *Companies should submit all new DTC television advertisements to the FDA before releasing these advertisements for broadcast.*
Merck will continue its longstanding practice of submitting new DTC television advertising to FDA prior to airing.
- **PhRMA Guiding Principle #9** – *DTC print advertisements for prescription medicines should include FDA's toll-free MedWatch telephone number and website for reporting potential adverse events. DTC television advertisements for prescription medicines 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.*
In DTC print advertisements, Merck will require the inclusion of FDA's toll-free MedWatch telephone number and website. In DTC television advertisements, Merck will continue to include an 800 number that consumers can call to obtain further information, including the FDA-approved patient labeling and physician prescribing information for the advertised medicine or vaccine, as well as a reference to DTC print advertisements and product websites containing FDA's toll-free MedWatch telephone number and website.
- **PhRMA Guiding Principle #10** – *Companies that choose to feature actors in the roles of health care professionals in a DTC television or print advertisement that identifies a particular product should acknowledge in the advertisement that actors are being used. Likewise, if actual health care professionals appear in such advertisements, the advertisement should include an acknowledgement if the health care professional is compensated for the appearance.*
Should Merck choose to feature actors in the role of health care professionals in DTC television or print product claim advertisements, we will acknowledge that an actor is being used. Should Merck choose to feature actual health care professionals in DTC television or print product claim advertisements, we will include a statement that acknowledges if the health care professional has been compensated for this appearance.
- **PhRMA Guiding Principle #11** – *Where a DTC television or print advertisement features a celebrity endorser, the endorsements should accurately reflect the opinions, findings, beliefs or experience of the endorser. Companies should maintain verification of the basis of any actual or implied endorsements made by the celebrity endorser in the DTC advertisement, including whether the endorser is or has been a user of the product if applicable.*
Should Merck feature a celebrity endorser in a DTC television or print advertisement, we will insure the celebrity's endorsement accurately reflects his or her opinions, findings, beliefs or experiences. The celebrity must have the condition for which the drug is advertised and he/she must be taking the advertised product. For vaccines, the celebrity must have been administered the vaccine or must be the parent or spouse of someone who was administered the vaccine. We will maintain verification of the basis of any actual or implied endorsement, including verification that the endorser has been a user of the advertised product or has been administered the advertised vaccine.

- **PhRMA Guiding Principle #12** – *DTC television and print advertising should include information about the availability of other options such as diet and lifestyle changes where appropriate for the advertised condition.*

Merck will continue our current practice of providing information about other options such as diet and lifestyle changes where appropriate for the advertised condition.

- **PhRMA Guiding Principle #13** – *DTC television advertising that identifies a product by name should clearly state the health conditions for which the medicine is approved and the major risks associated with the medicine being advertised.*

Consistent with this principle, Merck will not create television “reminder” advertisements.

- **PhRMA Guiding Principle #14** – *DTC television and print advertising should be designed to achieve a balanced presentation of both the benefits and the risks associated with the advertised 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. In addition, DTC television advertisements should support responsible patient education by directing patients to health care professionals as well as to print advertisements and/or websites where additional benefit and risk information is available.*

Merck strives to create DTC communication that responsibly educates consumers in consumer-friendly language. Merck considers the content, language, and format to help ensure a reasonably comparably balanced presentation of benefits and risks in a clear style that promotes comprehension and does not distract from the content. Merck does not use broadcast DTC advertising for any of our medicines that have a boxed warning. If we were to consider doing so, Merck would add appropriate information relating to the boxed warning, consistent with FDA regulations and guidance, to any broadcast DTC advertisement. In addition, Merck strives to develop Patient Product Information (PPI) in consumer-friendly language for promoted products and includes it in branded DTC materials. The PPI also serves as the brief summary in DTC print ads. Merck believes that clear, balanced, consumer-friendly presentations support comprehension and the patient/physician interaction.

- **PhRMA Guiding Principle #15** – *All DTC advertising should respect the seriousness of the health conditions and the medicine being advertised.*

Merck strives to achieve this goal in all branded DTC communications. Our approach will not trivialize a condition or the advertised Merck product.

- **PhRMA Guiding Principle #16** – *In terms of content and placement, DTC television and print advertisements should be targeted to avoid audiences that are not age appropriate for the messages 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).*

It has consistently been Merck’s practice, through analysis of markets and programming, to carefully review the appropriateness of our DTC broadcast and print advertisement placement. Media placement is assessed during the course of a campaign.

- **PhRMA Guiding Principle #17** – *Companies are encouraged to promote health and disease awareness as part of their DTC advertising.*

Merck creates a wide variety of health and disease awareness communications directed to the consumer. These include patient brochures and internet websites, including *Merck Source*, as well as health care professional-directed communications that incorporate disease, condition, and product information.

- **PhRMA Guiding Principle #18** – *Companies are encouraged to include information in all DTC advertising, where feasible, about help for the uninsured and underinsured.*

Merck will incorporate patient access messages in all DTC advertising, including television, print and internet. These messages will include a telephone number and a website that consumers can use to obtain more information.

For additional information on the PhRMA Guiding Principles click on the following link:
<http://www.phrma.org/dtc>