PhRMA Guiding Principles
Direct to Consumer Advertisements About Prescription Medicines

PhRMA

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Preamble

Given the progress that continues to be made in society's battle against disease, patients are seeking more information about medical problems and potential treatments so they can better understand their health care options and communicate effectively with their physicians. An important benefit of direct to consumer (DTC) advertising is that it fosters an informed conversation about health, disease and treatments between patients and their health care practitioners.

A strong empirical record demonstrates that DTC communications about prescription medicines serve 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.

The Pharmaceutical Research and Manufacturers of America (PhRMA), represents America's leading pharmaceutical research and biotechnology companies. As the companies responsible for developing new and innovative medicines, PhRMA members want patients and consumers to talk to their physicians about the medicines that may help them and to fully understand the known risks regarding these medicines. We know that DTC communications, particularly DTC television advertising, can be a powerful tool for reaching and educating millions of people, and we are committed to ensuring that our DTC communications provide accurate, accessible and useful health information to patients and consumers. DTC advertising of such important and powerful products as prescription drugs should be responsibly designed to achieve these goals and to encourage the appropriate use of these products.

First and foremost, we have a responsibility to ensure that our DTC communications comply with the regulations of the Food and Drug Administration (FDA). In general, the FDA requires all DTC information:

- To be accurate and not misleading;
- To make claims only when supported by substantial evidence;
- To reflect balance between risks and benefits; and
- To be consistent with the FDA-approved labeling.

Innovative biopharmaceutical companies take their responsibilities to comply with FDA requirements seriously. Companies devote substantial time and effort, and often ask for input from FDA, to ensure that DTC communications are accurate, fairly balanced and meet all applicable legal requirements. PhRMA member companies will engage in a dialogue with FDA to maximize opportunities for FDA review of DTC advertising prior to release, consistent with these Principles and the Agency's priorities and resources.

Beyond meeting their legal obligations, companies strive to deliver messages that fundamentally serve to educate patients and consumers and encourage them to seek guidance from their health care professionals.

To express the commitment of PhRMA members to deliver DTC communications that serve as valuable contributors to public health, PhRMA has established the following revised voluntary *Guiding Principles*. This version of PhRMA's *Guiding Principles* will become effective March 2, 2009.

Guiding Principles

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.

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.

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.

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.

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.

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 and to alert them to the upcoming advertising campaign 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.

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.

8. Companies should submit all new DTC television advertisements to the FDA before releasing these advertisements for broadcast.

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.

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.

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.

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.

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.

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 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. 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.

15. All DTC advertising should respect the seriousness of the health conditions and the medicine being advertised.

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).

17. Companies are encouraged to promote health and disease awareness as part of their DTC advertising.

18. Companies should include information in all DTC advertising, where appropriate, about help for the uninsured and underinsured.

Accountability for the Guiding Principles

Companies commit to establishing internal processes to ensure compliance with these *Guiding Principles*. Companies also commit to distributing these guidelines internally and to their advertising agencies.

Each company's intentions with regard to these *Guiding Principles* will be made public.

Companies that announce their intention to abide by these revised *Guiding Principles* and that complete an annual certification that they have policies and procedures in place to foster compliance with these Principles will be considered signatory companies to these Principles and identified by PhRMA on a public web site. The annual certification must be signed by the company's Chief Executive Officer and Chief Compliance Officer. The web site will identify the companies that commit to abide by these *Guiding Principles*, and, at the appropriate time, publish the status of annual certification for each of these companies.

PhRMA's office of accountability is responsible for receiving comments from the general public and from health care professionals regarding DTC advertising conducted by any signatory company to these Principles.

The PhRMA office of accountability provides to the signatory company at issue any comment that is reasonably related to compliance with the Principles.

The PhRMA office of accountability issues periodic reports to the public regarding the nature of the comments and the signatory companies' responses, and provides a copy of each report to the FDA.

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Questions and Answers

Q: *What is meant by a "direct to consumer television advertisement" in the context of these Principles?*

A: A 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.

Q: *What is meant by "direct to consumer print advertisement" in the context of these Principles?*

A: A 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.

Q: *How long must a company wait under Principle 6 before advertising a new medicine after the medicine is approved by FDA?*

A: Principle 6 demonstrates the companies' commitment to devote sufficient resources and time to health care professional education before launching a direct to consumer advertising campaign. Principle 6 ensures that health care professionals will have a reasonable opportunity to learn about new medications before their patients ask questions about them so they will have accurate, up-to-date information to use in responding to patients' inquiries and guiding patients to the most appropriate treatment option. Establishing a single uniform waiting period for all companies and all medicines could have the unintended consequence of denying patients important information about new medicines, even after health care professionals have been well educated. In setting the appropriate periods of time, companies may consider adjusting the periods to take into account such factors as the level of health care professional awareness of the new medicine or indication.

Q: *What considerations should a company take into account in designing a program to educate health care professionals before commencing the first DTC advertising campaign?*

A: Each company will decide for itself how best to implement an effective educational program, taking into account such factors as health care professionals' knowledge of the condition being treated, the severity and/or prevalence of the condition, the novelty of the new treatment, and the complexity of the medicine's risk-benefit profile and directions for use. Companies should make reasonable efforts to reach out to relevant health care professionals who would be interested in learning about the new medicine or indication.

Q: *Does Principle 8 require companies to do more than what is already required under current FDA regulations?*

A: Yes. Current law provides that companies must submit their DTC television advertisements to FDA upon first use for FDA's review at its discretion. Under Principle 8, while not intending to place additional burdens on FDA, companies commit to submitting new DTC television advertisements to FDA earlier than currently required and a reasonable time in advance of first use to give FDA the opportunity to comment, consistent with its priorities and resources. Companies also commit to inform FDA when they submit an advertisement of the earliest date the advertisement is scheduled to air.

Q: *Should companies notify FDA if they are specifically requesting feedback on a particular advertisement submitted under Principle 8?*

A: In order to permit FDA to allocate its resources effectively, companies should notify FDA if they are specifically requesting feedback on a submitted DTC advertisement. Companies also should indicate whether the requested FDA review is time-sensitive to help FDA prioritize its review activities. As a general matter, we understand that FDA expects companies to submit the following information with the submitted DTC advertisement: (1) a statement indicating whether the company is submitting the advertisement for prior Agency review and feedback, or for the Agency's information; (2) if feedback is requested, a statement identifying whether the company is requesting FDA review on a priority basis; (3) a brief description of the reasons for any request for priority review (e.g., identifying the basis for the submission and the nature of any change the company deems significant); and (4) the earliest date the company plans to finalize the advertisement. Companies typically should reserve a priority review request for those submissions that are most time-sensitive, keeping in mind that FDA may choose to review only one iteration of a particular new DTC advertisement on a priority basis.

Q: *PhRMA states that, under Principle 8, companies should submit new DTC television advertisements to the FDA a reasonable time before releasing the advertisement for broadcast to give FDA the opportunity to comment,*

consistent with its priorities and resources. What constitutes "a reasonable time" in this context?

A: The precise time frame for submission of a particular DTC advertisement will vary depending on the advertisement in question and purpose of the submission. If a company is specifically requesting feedback from FDA, either by priority review or standard review, it should submit the DTC advertisement far enough in advance to permit the Agency to perform the requested review. Although the timing of FDA's review of DTC advertisements will be dictated by the Agency's priorities and resources, a company seeking priority review will maximize its opportunity to receive comments from the Agency if the company allows 30 calendar days for FDA review and comment. A company seeking non-priority review for a particular advertisement should try to allow more than 30 calendar days for FDA review, while less lead time could be appropriate if a company is submitting a particular advertisement for the Agency's information.

Q: *Does Principle 8 require companies to submit a new DTC television advertisement to FDA in advance, even if the advertisement reflects only minor changes to a previously submitted advertisement?*

A: No. Under Principle 8, companies should submit only new television advertisements or advertisements that have been changed in a way that the companies believe is significant. For instance, where a company changes an existing advertisement—possibly by changing a telephone number listed on the screen or by replacing an actor—to use for a different targeted audience, but does not substantially change the advertisement's script or theme, then the company is not required under Principle 8 to submit the changed advertisement to FDA. However, where a company changes an advertisement so that the benefit and/or risk information is presented in a different way, the company likely has made a significant change, and the advertisement should be submitted to FDA. Other circumstances that typically would trigger submission of DTC television advertisements under Principle 8 include: (1) introduction of a new or never-before-advertised product; (2) new indications for existing products; (3) significant new risk information; (4) new comparative claims or patient outcome claims; or (5) new patient populations.

Q: *Does Principle 8 necessarily require a company to submit the final version of a new DTC television advertisement to FDA prior to releasing the advertisement for broadcast?*

A: No. The details of what will be submitted may be addressed in dialogue between companies and FDA.

Q: *Would additional dialogue between companies and the FDA be helpful as Principle 8 is implemented?*

A: Yes. Additional dialogue should occur to maximize opportunities for FDA review of DTC television advertising prior to release, consistent with this principle and the Agency's priorities and resources.

Q. *Does Principle 9 require companies to mention in DTC television advertisements that the FDA's MedWatch number can be found in print advertisements or web sites?*

A. Principle 9 states that companies should direct viewers of DTC television advertisements to a print advertisement containing FDA's toll-free MedWatch telephone number and web site, and/or should provide the company's toll-free telephone number. Pursuant to statute, the FDA is currently conducting a study, in consultation with its Risk Communication Advisory Committee, to determine if inclusion of FDA's MedWatch information in DTC television advertisements would detract from the presentation of risk information. The FDA has stated that it will provide guidance on this issue after completing its research. Companies abiding by PhRMA's *Guiding Principles* will follow FDA's guidance.

Q. *Under Principles 3 and 12, does a company have to mention another medication that may also be appropriate for treating the advertised condition?*

A. No. These Principles are intended to encourage companies to include in their advertisements information about therapeutic options and appropriate steps patients could take (which may or may not include other medicines), in consultation with health care professionals, to treat their disease or condition. This is consistent with the pharmaceutical industry's goal of helping patients achieve better overall health.

Q. *Does Principle 10 require that all actors portraying health care professionals in DTC television and print advertisements need to be disclosed in the advertisements?*

A. Actors who have a central role playing health care professionals in a DTC television or print advertising campaign should be identified in the advertisements as actors. Actors who are shown as health care professionals in the background in a DTC advertisement need not be disclosed.

Q. *Is there only one right way to present risk information in advertisements?*

A. No. An advertisement will comply with Principle 14 if it presents information about the medicine's risks in a way that patients are reasonably likely to take in and understand this information. For television advertisements, the visual and audio presentation of risk information should be similar in terms of prominence and clarity to the visual and audio presentation of other information about the medicine. Of course, even the most informative advertisements can't provide information on all possible risks that may relate to each individual patient. Therefore, the conversation between a patient and a health care professional is critical to the patient's understanding of whether a medicine is right for that individual patient. DTC advertisements should motivate patients to ask their health care professionals for more information about a medicine's risks and

benefits. These objectives can be achieved in a variety of ways, and each company will exercise its judgment consistent with FDA requirements.

Q. *Principle 14 refers to the inclusion of relevant boxed warnings in DTC television and print advertisements. Must DTC advertisements replicate boxed (or "black box") warnings in their entirety?*

A. No. The FDA requires all DTC advertisements to present a brief summary relating to side effects, contraindications, and effectiveness, which would be expected to include the substance of relevant boxed warnings. However, the language in these warnings is often complex and technical, as they typically are geared toward health care professionals. In order to ensure important risk information is communicated in a manner that is readily understood, boxed warnings may be translated into language more appropriate to consumers. Companies should work with the FDA in developing such consumer appropriate translation of relevant boxed warnings.

Q. *Who will define how risk information can be presented with reasonably comparable prominence to benefit information and "in a clear, conspicuous and neutral manner," as stated in Principle 14?*

A. As this language is based on current laws and regulations enforced by the FDA, it is ultimately up to the FDA to provide guidance on these standards. Companies will follow FDA's guidance and will work with the FDA to implement these standards appropriately.

Q. *What happens if a comment from the public about a company's DTC advertisement conflicts with recommendations or comments the company has received from FDA regarding the advertisement?*

A. The FDA has the authority to determine whether a particular advertisement is consistent with FDA regulations. If FDA chooses to give recommendations or comments on a particular DTC advertisement and the company follows those recommendations or comments, the company will be able to respond to any complaint regarding that aspect of the DTC advertisement that it complies with the PhRMA Principles by virtue of the fact that it followed FDA's recommendations.

Q. *Does Principle 15 suggest that all advertisements should be somber in tone and should not employ lightness, humor or entertainment?*

A. No. Principle 15 recognizes that health conditions and medical treatments are serious issues for patients. While humor or entertainment may not be appropriate in conveying all messages, they may be effective tools for attracting public attention to a particular disease or treatment, reducing any stigma associated with the condition, communicating educational messages about health conditions, and motivating patients to discuss those conditions openly with their health care providers.

Q. *What criteria should be applied to determine whether a company has complied with Principle 16 and targeted its advertising to avoid audiences that are not age appropriate for the messages in the advertisements?*

A. Advertisements containing content that may be inappropriate for children should be targeted to programs or publications that are reasonably expected to draw an audience of approximately 90 percent adults (18 years or older). In determining where to place their advertisements, companies may also consider whether the medicine being advertised addresses a public health concern. Companies will be individually responsible for examining reliable, up-to-date audience composition data, to the extent that information is available, to determine whether a particular program or publication is reasonably likely to attract an audience that is age appropriate for a particular advertisement. In addition, a medicine's lack of a pediatric indication does not mean that the content of an advertisement for that medicine is inappropriate for children.

Q. *How should companies evaluate whether particular advertisements have "content that may be inappropriate for children" under Principle 16?*

A. In making this evaluation, companies should focus on whether the content—including text (visual or audio), images and themes—in the advertisement, taken as a whole, is sexually explicit in nature such that it is not suitable for children.

PhRMA

New Medicines. New Hope.®

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