

# Office of Accountability Report



## Report of First Survey of Signatory Companies

### Introduction

On July 19, 2005, PhRMA's Board of Directors unanimously approved *Guiding Principles on Direct to Consumer Advertisements About Prescription Medicines* to express the voluntary commitment of PhRMA members to enhance the educational and informative nature of their DTC communications in the interest of better serving the public health. These *Guiding Principles* help ensure that DTC advertising remains an important and powerful tool to educate patients while at the same time addressing many of the concerns publicly expressed about DTC advertising over the past few years.

Pursuant to the Principles, PhRMA established an Office of Accountability to receive comments about signatory companies' compliance with the *Guiding Principles* and to forward those comments to the appropriate member company for further consideration. Additionally, the *Guiding Principles* state that the Office of Accountability will issue periodic reports to the public regarding the nature of the comments and the signatory companies' responses, and will provide a copy of each report to the FDA. This is the first such report issued by the Office of Accountability.

### Methodology

PhRMA's Office of Accountability conducted a survey of all signatory companies in July 2006 asking them for the number and nature of comments they received (both through the Office as well as independently) between January 6, 2006, when the Principles took effect, and June 30, 2006. Unless otherwise indicated, all information provided in this report is based solely on signatory companies' survey responses.

### Implementation of the *Guiding Principles*

All of the responding signatory companies that currently conduct DTC advertising reported that they have instituted internal procedures to implement the *Guiding Principles*.

Examples of the types of internal procedures implemented by signatory companies include providing training on the *Guiding Principles*, establishing multidisciplinary teams of personnel (e.g., medical, legal, brand, regulatory) to review print and TV ads to ensure compliance with regulations as well as the *Guiding Principles*, modification of internal guidelines for advertising, and establishment of standard operating procedures to collect and respond to comments received about advertisements.

Most signatory companies reported that they have alerted advertising and media professionals with whom they work about the *Guiding Principles*. Generally this included activities such as supplying vendors with copies of the *Guiding Principles*, providing training on the *Principles* and ensuring that the *Principles* are considered in the development of new advertising materials.

## Survey Results

Signatory companies reported receiving a total of 284 comments during the first six months of 2006. Of those, 191 comments (67%) related to television advertisements, 89 (31%) related to print advertisements, and four (1%) related to other forms of advertising.

The majority of comments (250) received by signatory companies were submitted by patients or consumers. Twenty-six comments were submitted by health care professionals, one was submitted by a consumer advocacy group, and three came from other sources.

**Table 1: Source of Comments**

	Patients/ Consumers	Health Care Providers	Consumer Advocacy Groups	Other
Television	173	17	1	0
Print	77	9	0	3

## Comments Relating to the *Guiding Principles*

One hundred eighty-six comments related to the *Guiding Principles*. Of those, one hundred thirty-seven were about television ads, 45 about print ads, and four about other forms of advertising.

Responding signatory companies identified 36 comments received relating to Principle 1 -- 33 for television ads and three for print ads. Principle 1 states the premise under which the *Guiding Principles* were enacted including the value of DTC advertising to informing patients. In general, companies reported that the comments received were positive reactions to advertisements. Some people commented negatively about specific actors or actresses. People who submitted comments were generally thanked in writing by the relevant signatory company for their comments.

Survey responses indicated that ninety-two comments were received relating to Principle 2 -- 76 for television ads, 12 for print ads, and four for other forms of advertising. Principle 2 states that all advertising should be done "in accordance with FDA regulations" and should be "consistent with FDA approved labeling." Comments relating to Principle 2 included those referencing specific side effects experienced by the patient, claiming that the product worked or did not work as stated. Responses included written thank you letters, forwarding specific questions to medical specialists, and revision of an advertisement. In one case, the responding company noted that the advertisement at issue was no longer being used.

There were four comments reportedly received relating to Principle 3 -- one for television ads and three for print ads. Principle 3 encourages signatory companies to "responsibly educate the consumer about that medicine and, where appropriate, the condition for which it may be prescribed." Reported comments included inquiries as to whether the advertised medicine was also approved for an additional indication and suggestions for additional information to include in the advertisements. Signatory companies responded in writing to the commenters.

One comment was reported relating to Principle 4, in which the commenter asked the signatory company to contact their physician for a refill. Principle 4 calls on companies to clearly indicate that the medicine being advertised is a prescription drug. The signatory company responded that they do not call-in refill requests for their products.

Survey responses state that there were 11 comments received relating to Principle 5 -- five for television ads and six for print ads. Principle 5 calls on signatory companies to encourage responsible communications between patients and their health care providers about the risks and benefits for the medicines advertised. Comments included thanks to the signatory company for encouraging the patient to discuss side effects with their physician, statements of either approval or disapproval of the focus on health care providers in the advertisements, and complaint(s) that there was not enough time to answer all the questions that the advertisement

generated. Signatory companies responded in writing to commenters.

No comments were received relating to Principles 6, 7, and 8 according to survey responses. Principle 6 states that companies should spend an appropriate amount of time educating health care professionals about a new medicine prior to initiating a direct-to-consumer advertising campaign. Principle 7 calls on signatory companies to work with FDA to responsibly alter or discontinue a DTC advertising campaign should new information indicate a serious or previously unknown risk. Principle 8 states that signatories should submit television ads to FDA prior to their broadcast.

Two comments were reportedly received relating to Principle 9 – one each for both television and print ads. Principle 9 states that television and print ads should include information on other treatment options where appropriate for the advertised condition. One comment thanked the signatory company for including information about diet and lifestyle changes while the other asked about non-prescription options. Signatory companies sent letters of thanks.

**Table 2: Comments Relating to Principles**

	<u>Television</u>	<u>Print</u>	<u>Other</u>	<u>Total</u>
Principle 1	33	3	0	36
Principle 2	76	12	4	92
Principle 3	1	3	n/a	4
Principle 4	1	0	n/a	1
Principle 5	5	6	n/a	11
Principle 6	0	0	0	0
Principle 7	0	0	0	0
Principle 8	0	0	0	0
Principle 9	1	1	n/a	2
Principle 10	1	n/a	n/a	1
Principle 11	5	0	n/a	5
Principle 12	3	12	0	15
Principle 13	2	3	n/a	5
Principle 14	1	5	0	6
Principle 15	8	0	0	8
<b>Total</b>	<b>137</b>	<b>45</b>	<b>4</b>	<b>186</b>

There was one comment received relating to Principle 10, which calls for television advertisements to “clearly state the health conditions for which the medicine is approved and the major risks associated with the medicine being advertised.” The commenter stated that the advertisement at issue did not meet this standard. “The signatory company reported conducting an internal review, withdrawing the advertisement at issue, and modifying other messages to make it clear that they are sponsorships that do not fall within the Principles' definition of a DTC television advertisement.”

Survey responses indicated that there were five comments received relating to Principle 11 which states that “risks and safety information in DTC television advertising should be presented in clear, understandable language, without distraction from the content, and in a manner that supports the responsible dialogue

between patients and health care professionals.” Comments included expressions of appreciation for including information on risks, concern that the advertisement placed too much of an emphasis on risks, causing patients to become unnecessarily alarmed, and inquiry into specific side effects mentioned in the advertisement. Signatory companies responded by sending thank you letters to commenters and by forwarding calls to medical specialists to answer specific medical questions.

Fifteen comments were reportedly received relating to Principle 12 -- three for television advertisements and 12 for print advertisements. Principle 12 states that "all DTC advertising should respect the seriousness of the health conditions and the medicine being advertised." Most comments reflected the commenter's dislike of the creative aspects of advertisements. Signatory companies responded by thanking the commenters for their input and explaining the consumer testing process that surrounds development of new advertisements.

Survey responses indicated there were five comments received relating to Principle 13 -- two for television and three for print ads. Principle 13 states that the content and placement of ads "should be targeted to avoid audiences that are not age appropriate for the messages involved." The comments questioned the placement near television shows, other commercials, and journal selection and asked about the approval status of the medicines. Company responses included answering commenter's questions about whether the medicine in question was approved for use in children.

Six comments were reportedly received relating to Principle 14 -- one for television advertisements and five for print ads. Principle 14 encourages companies "to promote health and disease awareness as part of their DTC advertising." Consumers expressed their appreciation for educational materials they received from signatory companies based on their advertisements. The signatory companies thanked the consumers for their comments in writing.

According to the survey responses, there were eight comments received relating to Principle 15, which calls on companies to include information about help for the uninsured and underinsured where feasible. All of the comments referred to television advertisements and reflected consumers' requests for additional information about the assistance programs mentioned in the advertisements. Signatory companies responded by providing additional information and resources for those consumers.

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