

Public Policy Position

Direct-to-Consumer Broadcast Advertising in the United States

Merck believes that Direct-to-Consumer (DTC) advertising can be an important and helpful way to inform patients about diseases that may be relevant to them and therapeutic options they may want to discuss with their physician. Credible data demonstrate that DTC can have a positive impact on patient health in terms of diagnosis, treatment and adherence to prescribed therapies. We recognize that DTC is one channel amongst many to help educate patients. Print materials, telephone, websites and other channels are also utilized to provide more in-depth information to patients. The ultimate decision to prescribe a product for any specific patient remains with the physician following discussion with their patient. Merck adheres to a set of forward-looking principles on DTC advertising, including the policies and practices outlined below.

Merck's policies and practices:

- Merck will adhere to the letter and spirit of FDA regulations and guidelines governing DTC promotion.
- All PhRMA guidelines will be met or exceeded.
- Merck has a long-standing policy to voluntarily submit new DTC advertising campaigns to FDA for pre-review. Merck waits until it receives a response from FDA prior to running the advertising campaign and modifies the advertising consistent with any written comments received from FDA.
- Merck carries out comprehensive programs to educate physicians and other prescribers about a new product before commencing product-specific DTC broadcast advertising. In 2008 Merck adopted a policy requiring a minimum six month time period following the approval of a new product before launching DTC broadcast advertising.
- Health Care Professionals will have access to DTC broadcast advertising for new products through websites and/or professional representatives prior to broadcasting the advertisements to consumers.
- DTC ads will contain important and relevant information for patients:
 - DTC broadcast ads with branded product information will have appropriate benefit and risk information included
 - DTC will be appropriately balanced consistent with FDA regulations, and appropriate "taste and tone" will be approved by Merck's medical and legal departments, ensuring the view of the medical community is considered
 - Effective as of January 2009, Patient Assistance Program (PAP) information will be included as part of all DTC ads (at a minimum, an 800 number will be provided)
 - Celebrities in branded DTC ads must have the condition and use the advertised product
 - Regarding the use of actors and health professionals in DTC advertisements Merck will identify instances in which an actor is portraying a physician. In addition, if our product advertisements include a physician, we will identify that the physician has been compensated for appearing in the advertisement. This is consistent with current American Medical Association guidelines.
 - Patient education materials will be available through additional channels (in addition to broadcast DTC)
- Merck will conduct consumer market research testing of new DTC ads prior to broadcasting them.

*Merck and Schering-Plough are now one company.
We are working to update our public policy position
statements to reflect our new global organization.*

- Approved June 2008