



Approximate study time: 1 hour



Level: Introductory/Intermediate



Audience: Sales and marketing, regulatory affairs, and legal personnel



Category: Sales and marketing



Region: USA



CPD Points: 1



Module outline

Direct-to-consumer (DTC) advertising

- The big picture
- Information generally expected in DTC ads
- Modified requirements for communications in print media
- Omit some prescription information
- Use consumer-friendly language
- Presenting quantitative efficacy and risk information
- Broadcast advertisements
- Major statement
- Adequate provision
- Pre-dissemination review of television advertisements
- PhRMA Guiding Principles

Online promotion

- Static versus interactive communications
- Responsibility for interactive promotional media
- Requirements for submission of interactive promotional media
- Responding to unsolicited requests for off-label information
- Media with character space limitations
- Correcting independent third-party misinformation
- Assessment

Advertisements and promotional labeling of prescription drugs in the USA must comply with statutory and regulatory requirements.

Advertising and promotion are also subject to guidance from the Food and Drug Administration (FDA) and from industry and professional codes of practice. By identifying the requirements and summarizing the extensive guidance that applies, this course and its companions will help you to advertise and promote your products without incurring legal or regulatory sanctions.

Unlike the great majority of other countries, the advertising of prescription drugs directly to consumers is permitted in the USA. Spending by drug companies on direct-to-consumer (DTC) advertising of prescription drugs has increased more than four-fold over two decades, with a dramatic increase in the number of TV ads. In addition, the Internet and social media platforms have increasingly enabled companies to engage more actively with the public.

In addition to those that apply to all advertising and promotion of prescription drugs, specific regulatory requirements and industry and regulatory guidances apply to DTC advertising and promotion, including online promotion, and we discuss these in this course.



Who will benefit from this module?

Sales and marketing personnel need to understand the legal and regulatory requirements that must be met when advertising and promoting prescription drugs in the USA. In addition, this module will be of benefit to regulatory affairs and legal personnel involved with aspects of marketing.



Learning objectives

- List types of information generally expected to be included in consumer-directed communications
- Specify modified regulatory requirements for DTC communications in print media
- Access FDA guidance on presenting quantitative efficacy and risk information in DTC communications
- Summarize statutory requirements and FDA guidance on presentation of the major statement in broadcast advertisements, and outline the response of an industry advocacy group
- Specify ways of making adequate provision, in broadcast ads, for access to product labeling
- Comply with statutory requirements and FDA recommendations on pre-dissemination submission of broadcast ads to the agency for review, and outline FDA enforcement actions for non-compliance
- Access guiding principles, from the Pharmaceutical Research and Manufacturers of America, on DTC advertising
- Identify sponsors' responsibilities for interactive promotional media
- Submit interactive promotional media to the FDA in compliance with the agency's draft guidance
- Respond, in compliance with FDA draft guidance, to unsolicited requests for off-label information
- Comply with FDA draft guidance on how sponsors should deal with promotional communications in online media that impose limits on the number of text characters that can be used
- Correct online misinformation by independent third parties, in compliance with FDA draft guidance

