



Continuing Education



Marketing: Approaches and regulations

Learning Objectives

Describe ways to increase the effectiveness of sales presentations.

Describe several options for advertising pharmaceutical products.

Explain how sampling, continuing education programs and promotional items are used to market pharmaceutical products.

Describe how pharmaceutical marketing is regulated in the United States.

Describe how pharmaceutical marketing is regulated internationally.

This second article in a three-part series discusses strategic marketing approaches, including sales presentations, journal advertising, direct-to-consumer advertising, direct mail, sampling, continuing education programs and promotional items. U.S. and international regulations governing pharmaceutical marketing are also discussed.

Thirwall W. Bonham, Ph.D., associate dean for administration and research, Pamplin College of Business, Virginia Polytechnic Institute and State University, Blacksburg, VA; and Glenn Rosenthal, M.A., M.B.A., Ed.D., program director and assistant professor, pharmaceutical marketing and management program, University of the Sciences, Philadelphia, served as consultants for this article for the Certified Medical Representatives Institute Inc.

Marketing goals for pharmaceutical products can be achieved through a variety of strategic options, including sales presentations, advertising and other approaches.

Sales presentations

Formerly referred to as “detailing,” sales presentations involve making personal calls for sales purposes. Often used following the introduction of a drug, these presentations offer the opportunity to speak to prescribers directly and respond to their questions. Accordingly, they are a potent method for influencing prescriber habits and increasing new product sales. They are also useful for brand building.

As the responsibility for patient care shifts from individual practitioners to teams of healthcare providers, group sales presentations are becoming an attractive and cost-effective option. Increasingly, sales efforts are being directed toward nurses, technicians and others with decision-making influence.

In general, sales force representatives have always had difficulty securing interviews with busy physicians. Once they do get some time with a physician, they may only have minutes or even sec-

onds to communicate their message. Thus, it is vital to support detailing personnel with innovative, high-quality sales tools to help them make their points quickly and effectively.

In order to build better relationships with physicians and improve sales effectiveness, some pharmaceutical companies are now segmenting physicians. This means that a company analyzes data on physicians’ prescribing habits, looking at the current stage of their careers, to target those most likely to prescribe more of a given drug over time, no matter how much they currently prescribe. One company that used this lifetime-value analysis approach replaced a quarter of the physicians it had previously thought were of greatest value (most of whom were in midcareer) with young physicians, including residents and new practitioners, who, though not currently high-volume prescribers, were expected to prescribe more over time.

Improving relations with physicians also includes providing better and more tailored information about products and the diseases they treat. To do so, companies need to ascertain physicians’ attitudes about issues such as alternative therapies, preferences for certain classes of drugs, experimenting with new or different drugs, and insurance restrictions. Com-

RECEIVE CREDIT AND RECOGNITION

Continuing Education in Pharmaceutical Representative aims to provide reps with information to help them meet the needs of the people they serve and to contribute to reps’ personal and professional development. Every third issue includes a self-assessment quiz covering the previous three Continuing Education articles. The quiz for this article appears in the September issue. Reps who correctly complete the quiz and return it to the CMR Institute with a nominal handling fee will receive a completion recognition form showing that they have successfully completed the three-part educational series and earned .25 CEU (2.5 contact hours). The CMR Institute also will send a letter of recognition to reps’ managers upon completion of a quarterly series. A Certificate of Achievement will be awarded to any representative who successfully completes four quizzes or has obtained 1.0 CEU.

Note: The Continuing Education quizzes are not part of CMR Institute’s certification program and do not count as credits toward the CMR® designation.

About the CMR Institute:

The Certified Medical Representatives Institute is an independent non-profit educational organization established in 1966 to provide a source of professional development and certification for pharmaceutical representatives. The institute provides an up-to-date, approved continuing education curriculum designed to expand and enhance internal company training and development in a cost-effective manner. The curriculum concentrates on providing a general knowledge base and avoids such areas as selling skills and specific product education.

© 2005 The Certified Medical Representatives Institute Inc., Roanoke, VA 24014. All rights reserved. No part of this article may be reproduced by any method or in any form without written permission from the CMR Institute. Reprints of this article are available from the CMR Institute. Request Continuing Education article DM-2.

panies can then use the most effective approaches to reach higher-value prescribers and further personalize and strengthen relationships with them.

In addition, healthcare representatives must identify how doctors want to receive product information. Preferences include once-monthly detailing visits, learning about products at dinner meetings, e-detailing, teleconferences, e-mail updates, direct mail and call-in centers.

Advertising

Journal advertising. This is a mainstay of pharmaceutical product communication strategy. This category includes familiar journals such as *The Lancet* and *The Journal of the American Medical Association*, as well as other periodicals, such as free magazines distributed by practitioner associations. When companies decide where to place an advertisement, the type of drug and the audience to be targeted are deciding factors.

A challenge with advertising in journals and other medical publications is that the exact circulation and readership numbers of these publications may not be available. Also, the relationship between claimed readership and advertising results cannot be exactly determined. However, if a magazine has remained financially viable, it probably has a large enough subscription base to make ad placement potentially worthwhile.

Direct-to-consumer (DTC) advertising. Pharmaceutical marketers have found that newspapers and magazines provide a particularly good forum for direct-to-consumer advertising. These media provide sufficient space to include the disclosure information federal regulations require whenever a brand-name product is advertised in conjunction with an indication. An additional advantage is that potential customers may hold onto print ads for future reference or pass them along to other potential customers.

Traditionally, the high cost of advertising time on television meant that an advertisement long enough to convey disclosure information would be prohibitively expensive. However, in 1997, U.S. Food and Drug Administration policy eliminated the need for disclosure, paving the way for increased DTC advertising through this medium.

Direct mail. This method can be quite effective for promoting pharmaceutical products. Typically, direct mail pieces carry more elaborate information (such as charts and graphs) than other written forms of advertising. The goal of a direct mail piece is to deliver selling messages through creative, interesting techniques. To engage and involve readers, it may be helpful to incorporate some kind of incentive and include a response card.

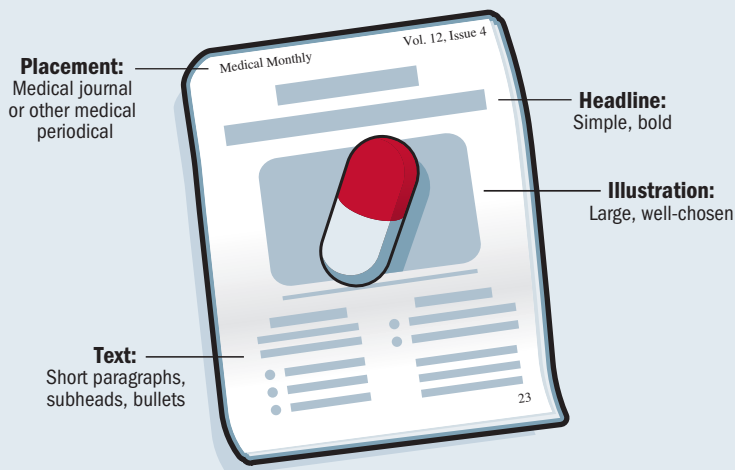
Other strategies

Sampling. Pharmaceutical marketers value sampling because it allows physicians to develop firsthand experience

Figure 1

Journal advertising

Advertising in journals such as *The Lancet* or other professional periodicals is a mainstay of pharmaceutical product communication strategy.



with a drug in their own patient population. A free sample can introduce patients and physicians to the product or reinforce an impression of a brand they have already heard about. Once patients have started therapy on a particular drug and are having a good experience (no adverse effects, etc.), they are unlikely to switch to another branded product or a generic version. Thus, sampling is particularly important for drugs used to treat chronic conditions, which may be taken for long periods of time.

Because samples are expensive, some pharmaceutical companies have experimented with vouchers or coupons that can be redeemed for trial portions of drugs at local pharmacies. Vouchers are advantageous because they:

- Are cheaper to produce than samples.
- Cut regulatory paperwork for pharmaceutical companies and physicians.
- Provide trackable data showing which samples result in prescriptions.

However, the long-established practice of leaving actual product samples remains the dominant form of sampling.

The Prescription Drug Marketing Act (PDMA), enacted in 1988, bans the sale, purchase or trade of prescription drug samples and coupons. With penalties ranging from \$250,000 to \$1 million and imprisonment of up to 10 years, pharmaceutical companies and their healthcare representatives must be fully cognizant of the PDMA regulations concerning sample accountability.

Continuing education. These programs are a good way to reinforce brand and product recognition among physicians and pharmacists. By organizing or supporting continuing education programs, pharmaceutical companies also gain an opportunity to solicit feedback.

Types of continuing education programs include seminars, symposia/conventions, dinner meetings, continuing medical education courses, and telephone and video conferences. To avoid any appearance of inappropriate influence, many companies present programs that place more emphasis on the therapeutic category of a drug and less emphasis on the specific product they want to promote.

Promotional items. These serve as brand and product reminders. From the marketer's perspective, these items should be inexpensive and flexible. In addition, the less "promotional" their appearance, the better. It is important to consider whether the items are earning an appropriate return on investment. Giveaway items must also comply with regulatory stipulations

promulgated by the FDA, the European Economic Community and the Washington-based Pharmaceutical Research and Manufacturers of America's Code on Interactions with Healthcare Professionals.

U.S. regulations

Within the FDA's Center for Drug Evaluation and Research, the Division of Drug Marketing, Advertising, and Communications (DDMAC) regulates advertising, labeling and promotional activities. The DDMAC has established clear guidelines for how prescription drugs can be advertised in the United States. These strict guidelines state that advertisements cannot be false or misleading or omit material facts. The FDA considers any activity or document that promotes a drug product and that is sponsored by the manufacturer to be advertising. It also mandates that there must be a fair balance between information about the drug's effectiveness and risk.

The FDA plans to review its policy allowing direct-to-consumer television advertising for drugs. The reevaluation was prompted by complaints from physicians and consumer groups that this practice contributes to increased drug costs to pay for advertising and to cover the costs of prescription drugs demanded by patients.

The DDMAC is increasing its surveillance of pharmaceutical marketing communication. Companies have noted that certain types of claims appear to be of particular concern to the FDA, including:

- Promotion of unapproved or off-label uses for a product.
- Claims of superiority or uniqueness relative to another drug without significant clinical trial data.
- Pharmacoeconomic claims.
- Quality-of-life claims.

Manufacturers who are repeatedly found to be in violation of FDA advertising guidelines can be asked to submit advertising and promotional material to the FDA prior to public release. If the pharmaceutical company cited does not comply with FDA mandates, the FDA can take a range of criminal and civil actions.

Besides providing advertising guidelines, the federal government has warned pharmaceutical companies that they are not allowed to offer financial incentives to physicians, pharmacists or other healthcare professionals for prescribing or recommending certain drugs or switching patients from one medication to another.

International regulations

The World Health Organization adopted ethical guidelines for pharmaceutical advertising and promotion in 1988. This group urged member countries to take account of these guidelines in developing their own national regulations for medicinal advertisements and promotions. It also appealed to pharmaceutical companies to adopt these guidelines.

Article Summary

- **Sales presentations offer the opportunity to speak to prescribers directly and respond to their questions.**
 - Group sales presentations are becoming an attractive and cost-effective option.
 - Techniques for improving sales effectiveness include segmenting physicians, determining their attitudes about certain issues and identifying how they want to receive product information.
- **Advertising strategies include journal advertising, direct-to-consumer advertising and direct mail.**
- **Other marketing approaches include sampling, continuing education programs and promotional items.**
- **Within the FDA's Center for Drug Evaluation and Research, the Division of Drug Marketing, Advertising, and Communications regulates advertising, labeling and promotional activities.**
 - The FDA considers any activity or document that promotes a drug product and that is sponsored by the manufacturer to be advertising.
 - The DDMAC is increasing its surveillance of pharmaceutical marketing communication.
- **The World Health Organization, the Council of the European Communities and the International Federation of Pharmaceutical Manufacturers Association have all adopted guidelines for pharmaceutical advertising and promotion.**

The Council of the European Communities established a council directive in 1992 covering all aspects of pharmaceutical marketing. Specifically, the directive:

- Prohibits direct-to-consumer advertising of prescription drugs.
- Stipulates that advertising to healthcare providers qualified to prescribe medications must contain essential information compatible with the summary of product characteristics (similar to the U.S. package insert).
- Specifies that sales representatives must have sufficient training and knowledge to provide accurate medical information about their products.
- Requires sales representatives to provide a summary of product characteristics and details about price at each physician visit.
- Provides guidelines to companies on gifts to healthcare providers, hospitality at medical meetings and use of samples.

Under the European Economic Community directive, member states are responsible for ensuring adequate means for monitoring the advertising and promotion of prescription drugs. The directive also requires member states to make provisions for ordering the cessation of inappropriate advertising, including instituting legal proceedings against the offending company.

The International Federation of Pharmaceutical Manufacturers Association (IFPMA) is an association of 50 national pharmaceutical associations worldwide. In 1981, the IFPMA established a Code of Pharmaceutical Marketing Practices, which states that promotional material for pharmaceutical products should be accurate, fair and objective. The code further states that advertising should not only conform to legal requirements but should also be of high ethical standards and in good taste.

The IFPMA enforces its guidelines primarily through the use of negative publicity. Advertisements and promotions that do not comply with IFPMA standards are publicized widely. In addition, complaints are referred to the member association in the country where the company's headquarters are located.

The next article in the series will focus on evolving marketing strategies.