



Continuing Education



Industry Basics: R&D and marketing

Learning Objectives

Identify the main phases of the clinical trial process.

Describe the role of pharmacoeconomic studies in drug development and marketing.

Explain the different phases of the marketing life cycle.

Identify commonly used product promotion strategies.

Describe the major pharmaceutical distribution channels.

This second article in a three-part series provides an overview of pharmaceutical research and development and the marketing process. Topics include the clinical trial process, pharmacoeconomic studies, the marketing life cycle, product promotion strategies and major pharmaceutical distribution channels.

Thomas S. Foster, PharmD, Professor of Pharmacy and Anesthesiology, Colleges of Pharmacy and Medicine, University of Kentucky Medical Center, Lexington, KY; and Glenn Rosenthal, MA, MBA, EdD, Chair, Department of Pharmaceutical and Healthcare Business, University of the Sciences in Philadelphia, Philadelphia, PA, served as consultants for this article for the Certified Medical Representatives Institute, Inc.

Researchers use several methods to identify potential new drugs. The resulting experimental drugs must be analyzed thoroughly to determine their physical, chemical, biological and pharmaceutical properties. They are then tested extensively in animals to determine their toxicity. After completing required animal toxicity and chemical tests, a pharmaceutical company submits an Investigational New Drug (IND) Application to the FDA, along with the product information. Unless the FDA raises objections, clinical trials can begin in 30 days.

The clinical trial process involves human subjects and consists of several major phases:

- **Phase I** marks the initial introduction of the drug into normal human volunteers. These clinical trials help developers establish safe dosage ranges for the experimental drugs. They administer the drug to a relatively small number of subjects—from 20 to 80 healthy people—and then observe, measure and record how they react to, absorb, metabolize and ex-

crete the product. Phase I studies are generally considered to be safe.

- **Phase II** trials test an experimental drug's effectiveness in treating the condition for which it is intended. Typically, from 100 to 200 people suffering from the target disease receive the drug and are monitored for improvement. The FDA requires most drugs to undergo at least two controlled double-blind experiments. These carefully managed studies test the experimental compound against an identical-looking and identical-tasting placebo. Physicians, nurses and patients are unaware of which patients are getting which treatment. Final test results are analyzed statistically to determine if the experimental drug produces significant effects.
- **Phase III** trials, which may take two or more years, simulate how a compound will be employed in general medical practice. Physicians in clinics and hospitals administer the drug under controlled circumstances to large numbers of people, sometimes thousands, to prove

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 will appear in the March 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.

© 2009 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 PI-2.

its efficacy and identify any infrequent but possibly serious effects that have not yet shown up.

- **Phase IV** or postmarketing clinical trials occur after approval, although they are increasingly planned for early in the development process. They include continued tracking of drug safety and efficacy, research on expanding product use to new populations or to treat other conditions and pharmacoeconomic studies of the costs and outcomes of pharmacotherapy.

Upon completion of successful clinical trials, a pharmaceutical company submits a New Drug Application (NDA) to the FDA, requesting legal permission to market the new drug product. FDA physicians, pharmacologists, chemists and other professionals then study the NDA information to determine if the drug should be approved for marketing, deciding if the drug's therapeutic benefits outweigh its inherent risks.

Pharmacoeconomic studies

Studies employing pharmacoeconomics, the description and analysis of the costs and outcomes of pharmacotherapy, have become essential tools in drug development and marketing. Because of rising healthcare costs, purchasers of pharmaceutical products, including hospitals and managed care organizations, must carefully analyze their expenditures in both clinical and economic terms. These healthcare institutions have set up pharmacy and therapeutics (P&T) committees to review the efficacy, safety and costs of new products and select appropriate drugs for their organizations' formularies.

In addition, managed care organizations implement various strategies to control pharmaceutical costs, including tiered formularies, which require different levels of patient copays for a product depending on the tier into which it is placed. Group purchasing contracts, listing in the formulary and tier or copay level are all influenced by data on a product's pharmacoeconomic performance.

Pharmacoeconomic studies consider the value of the drug treatment regarding:

- Direct and indirect medical costs, such as the cost of physician visits, emergency room visits, hospitalizations that occur if the disease or condition is not adequately treated and a patient's loss of wages and/or expenses in seeking care
- Costs that are avoided or decreased, like lower rate of hospitalization
- Humanistic costs, such as increased quality of life or delayed admission to long-term care
- Total costs of drug therapy versus other forms of treatment, such as surgery (e.g., whether a drug treatment can produce better outcomes than expensive alternative methods of treatment such as surgery).

Thus, the traditional methods for valuing phar-

maceutical products on the basis of efficacy, safety and acquisition cost are being expanded with the addition of approaches based on determining the effectiveness and efficiency of reaching desired outcomes.

Pharmacoeconomic studies can help answer questions such as:

- Does the drug improve patients' health to a significant degree compared to less expensive alternatives?
- Does the drug offer patients enhanced quality of life in comparison to alternatives?
- Does a more expensive drug offer greater benefits (e.g., improved efficacy, fewer adverse events or a more convenient dosing regimen) that will reduce overall costs for a healthcare organization in comparison to an alternative product that has a lower price?

Because of rising healthcare costs, purchasers of pharmaceutical products must carefully analyze their expenditures in both clinical and economic terms

The pharmaceutical company that provides favorable pharmacoeconomic data to the P&T committee and other key decision makers will have a competitive advantage in the drug selection process. In order to have pharmacoeconomic data during negotiations with customers, even before the drug is ready to go on the market, many companies are incorporating pharmacoeconomic analysis into their clinical development plans (the planned schedule of studies) as soon as they have a clear picture of a product's performance.

Marketing life cycle

Different marketing conditions exist at each phase in a product's life cycle, so sales strategies must change accordingly (see figure on page 26).

During the *introduction phase*, the pharmaceutical company presents a new product to physicians and pharmacists for the first time. Products may be considered "innovative," improvements on existing therapies or brand extensions (e.g., new doses or formulations). The company must usually launch a comprehensive marketing campaign to stimulate primary product demand. Pharmacies and hospitals must be stocked before the new product is actually promoted. Product price is generally high during the introductory phase, reflecting the lack of direct competition and the uncertain sales future.

The *growth phase* begins when physicians and pharmacists show confidence in the value of the

product. Competition increases as modifications of the original product or competing products appear. The pharmaceutical company's advertisements focus on the advantages of its brand over competitors' brands, rather than on the general benefits of the product class. Increased sales and the efficiencies of established production methods make possible economies of scale, which contribute to profit. However, competition is usually intense, which means sustained marketing costs and pressure to maintain a competitive price. Price increases during this period may reflect only the effect of inflation.

During the *maturity and saturation phase*, growth in sales will come not from new prescribers but from a growth in population, or a change in

but it may also result from changes in medical thinking (e.g., guidelines recommending against the use of cough/cold medications in infants and children). Gross sales decline, but net profits may stabilize or even increase for a time when marketing costs are eliminated. Overall, though, profits are slim in this phase.

Product promotion strategies

Pharmaceutical marketers plan promotional programs based on the characteristics of individual products and the competition they face. The most commonly used strategies include the following:

Field selling. Highly trained healthcare sales representatives call on physicians, pharmacists, nurses, wholesalers, hospital personnel such as

The major responsibility of healthcare sales representatives is to provide "fair balance" in their product presentations.

medical thinking or disease incidence. Competition is intense as the product competes with similar products and generics for large-volume buyers. Some firms choose to increase their price when the product's patent expires to maintain overall revenue in the face of generics competition. Other firms compete directly with generics competition by lowering their prices aggressively. Total sales increase, but at a slower rate. Generally, companies rely less on sales representatives and more on direct mail and journal advertising at this stage.

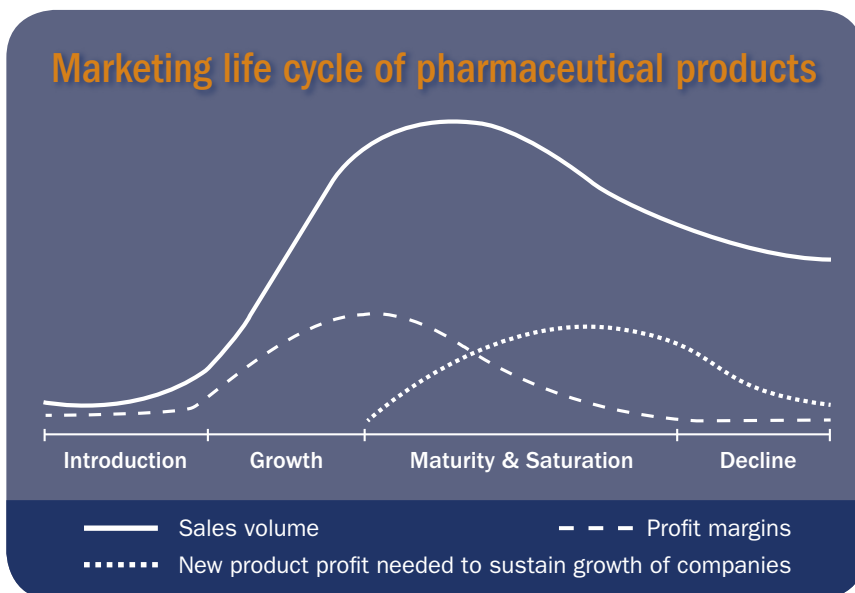
The *decline phase* is usually triggered by the introduction of new, more effective therapeutic agents,

administrators and others to discuss their needs, provide detailed scientific information, demonstrate product benefits and answer questions. They also provide data-based literature searches, set up exhibits and provide value-added services, such as patient educational brochures. Their major responsibility is to provide "fair balance" in their product presentations; that is, both positive and negative aspects of the product must be presented. Typical sales calls often last less than 10 minutes.

Space or journal advertising. Pharmaceutical companies advertise prescription drugs in medical journals and other healthcare publications to stimulate interest or keep existing products in the minds of physicians and other professionals. Usually, the advertisements include extensive summaries of product information from required FDA labeling and package insert materials.

DTC advertising. Pharmaceutical companies are now able to advertise their products directly to consumers. The primary purpose of direct-to-consumer (DTC) advertising is to increase the public's awareness of brand-name pharmaceuticals and new treatments available for certain disease states.

Sampling. When the law permits, pharmaceutical companies may distribute drug product samples to physicians, allowing them the



opportunity to gain experience using the drugs prior to formal prescription authorization.

Direct mailing. Pharmaceutical companies use direct mailings to aim promotional efforts at specific individuals rather than diverse groups. Typically, direct mail pieces are more obviously promotional than other types of marketing materials and carry more elaborate information (such as charts and graphs) than other written forms of advertising.

Support of continuing education. Pharmaceutical companies support many diverse educational programs for health professionals. Through this support, they gain opportunities to talk with physicians, introduce and promote products and develop exposure within medical organizations and various fields of therapy.

Electronic media. Marketing opportunities are available to pharmaceutical companies through the explosion in electronic communications and on-line information networks. Communication tools include e-mail, Web sites, desktop video-conferencing, CD-ROM formats, telemedicine and virtual reality.

Drug distribution

There are several common methods used by drug manufacturers to distribute their products.

Wholesalers. Wholesalers purchase pharmaceutical products from manufacturers and resell them to other businesses, mainly community pharmacies and hospitals. Manufacturers' use of wholesalers varies; some sell almost exclusively through wholesalers, many sell both directly to consumer outlets (e.g., pharmacies or hospitals) and through wholesalers, and others use wholesalers only as storage depots for additional inventory. Overall, though, wholesalers are the largest conduit for drug distribution.

Group purchasing organizations. Multi-hospital alliances, community pharmacies and state pharmaceutical associations are now forming buying groups that negotiate contracts with pharmaceutical manufacturers and specify prime vendors (wholesalers) to purchase, warehouse and distribute products to participating pharmacies at contract prices. The purchasing power of these groups produces aggressive price negotiations with vendors.

Direct selling. Many manufacturers do some direct distribution to retailers, hospitals and government agencies, which allows them to remain sensitive to customer needs and retain some control over product promotion and delivery. Direct hospital sales increase the familiarity of healthcare professionals with company products, which in turn might generate more demand for the products.

Drug repackaging companies. Drug repackagers buy brand-name and generic drugs in bulk quan-

Article Summary

- The clinical trial process consists of Phase I, Phase II, Phase III and Phase IV trials.
- Pharmacoeconomic studies have become essential tools in drug development and marketing.
- Different marketing conditions exist at each phase in a product's life cycle, so sales strategies must change accordingly.
- A wide variety of promotional strategies are available for marketing a pharmaceutical product.
- Drug distribution occurs through several major channels.

ties, repackage them in smaller units and sell them under their own label to private practice physicians, HMOs, ambulatory care centers, hospital emergency rooms and other healthcare providers who dispense directly to patients.

According to a 2007 report, most pharmaceutical products in the United States are sold or dispensed through drug retailers (e.g., community pharmacies). In 2006, retail distribution accounted for about 70% of U.S. prescription drug sales (in dollars).

Drug retailers include:

- Drug stores or community pharmacies, which may be either independent or chains. Community pharmacies provide both prescription and nonprescription medicines. They may also carry items such as cosmetics and toiletries. Chain pharmacies have the largest share of business in the community pharmacy sector and fill the largest portion of prescriptions—about 47%.
- Mass merchandisers (also referred to as discount stores) and supermarkets. In general, mass merchandisers carry a broader spectrum of goods than community pharmacies, but have incorporated pharmacies into their operations—sometimes as a way of drawing shoppers into their stores.
- Mail-order pharmacies. Mail-order pharmacies offer their products—both prescription and nonprescription medicines—through the mail, usually at discounted rates.

Specialty pharmacies have evolved in response to increased use of high-priced biotechnology products. These products target chronic and rare conditions, often affecting less than 3% of the population. These pharmacies offer manufacturers the ability to control distribution of products that may have special storage needs or carry a greater risk of adverse effects.

The final article in this series will focus on new directions for the pharmaceutical industry.