

Pre-Commercial Marketing and Planning

Laying the Ground Work for Future Success

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Executive Summary

Because the stakes are high, the key to minimizing risk while maximizing future success is effective pre-commercial planning and marketing.

The pharmaceutical, biotech, and medical device industries are among the most challenging and exciting businesses marketers can work in. Marketers are challenged to work in a highly regulated and fiercely competitive environment where scientific understanding and technology are evolving rapidly. The drug-development process consumes resources at an alarming rate; to maximize this investment, every effort must be made to ensure the success of the products that may eventually make it to market. Because the stakes are high, the key to minimizing risk while maximizing future success is effective pre-commercial planning and marketing.

Traditionally, most companies only begin product marketing efforts when there is a reasonable amount of certainty that a product is likely to make it to market, usually at the end of Phase II clinical trials, which in many instances is too late to begin pre-commercial planning and marketing efforts. Marketers must weigh the risk of delaying these activities against the financial implications of initiating a commercial plan while the product's safety and efficacy profile are not completely known. In the fast-paced and ever-evolving market of pharmaceutical and biotech products, early planning and marketing efforts play a significant role in the future success of a product. The delayed initiation of these activities significantly decreases the benefits and options available to marketers.

Marketing activities for pre-commercial products differ significantly from in-line/in-market brand and product marketing tactics. Pre-commercial marketing requires the collaboration of multiple brand stakeholders, including clinical affairs, pre-clinical, regulatory affairs, legal, medical affairs, marketing, and sales. Additionally, everyone involved with the brand should have an understanding of the broad commercial issues that will or are likely to affect the product when it reaches the market. This paper will explore how to develop an Informed View of the Market, which is the starting point in effective pre-commercial planning and marketing. An Informed View will help marketers identify hurdles and challenges, as well as potential solutions at an early stage. Ultimately, an Informed View of the Market will enable and empower the product development process, guide and inform critical decision-making processes, and greatly enhance the future success of the product.

Successful pre-commercial marketing is based on a broad-view of all elements that encompass a product, including clinical trial design and endpoints, regulatory requirements, pricing, reimbursement standards and hurdles, as well as marketing elements.

Defining an Informed View of the Market

There have been many advances in understanding the human body, and in the science and technology that support product development. At the same time, there are many challenges in the clinical delivery of healthcare to patients.

Message Delivery Challenges

To maximize a product's success, it is critical to understand and address broad commercial issues early in the development life cycle. Early efforts begin with developing a communications plan to deliver consistent messages. Challenges effecting message delivery include:

- Numerous treatment options
 - Limited time to grasp and internalize safety, efficacy, and value of the product
- Limited physician time
- Payer pressure to ensure appropriate care is delivered while maintaining control over costs

Key Drivers in the Marketplace

An Informed View of the Market provides a broad understanding of the key drivers in a therapeutic area that will impact the future success of a product.

- Therapeutic area
 - Patient classification
 - Current treatment approaches
 - Treatment guidelines
 - Competitive products and patent status
 - Forecasts for the therapeutic area and product
- Key regulatory milestones and requirements
- Key opinion leaders
- Key professional associations
- Future treatment evolution
- Patient access and managed care acceptance and reimbursement
- Long-term value of a specific treatment

Pre-commercial marketing requires collaboration with multiple stakeholders to maximize the product's success in the marketplace.

Obtaining an Informed View of the Market

An Informed View of the Market has implications for all areas of product development, including pre-clinical and clinical development, pharmacology, regulatory affairs, legal, medical affairs, and sales and marketing. It is critical to gain commitment from, and ensure collaboration between, all teams responsible for a product's development from the beginning. Developing an Informed View will uncover recommendations and key insights into all of these key functional areas, and the value of this process is in integrating these learnings into the product's development and marketing plans.

Research the Market

The starting point is a thorough review of the therapeutic area, including assessing market research reports and published literature, reviewing treatment guidelines, identifying key opinion leaders, and determining influential professional associations.

It is also crucial to conduct a thorough examination of current treatment approaches and uncover unmet needs. These areas can provide insight into how the standard of care is likely to evolve in the future. It is also important to determine the availability and use of "me too" and generic products in the therapeutic area. Payers are much more likely to place hurdles for use of more expensive branded products if there are several generic or "me too" products available. Discussions with key stakeholders — physicians, patients, payers, nurses, and pharmacists — are an extremely effective and valuable means to confirm and enhance the understanding of a therapeutic area and the product.

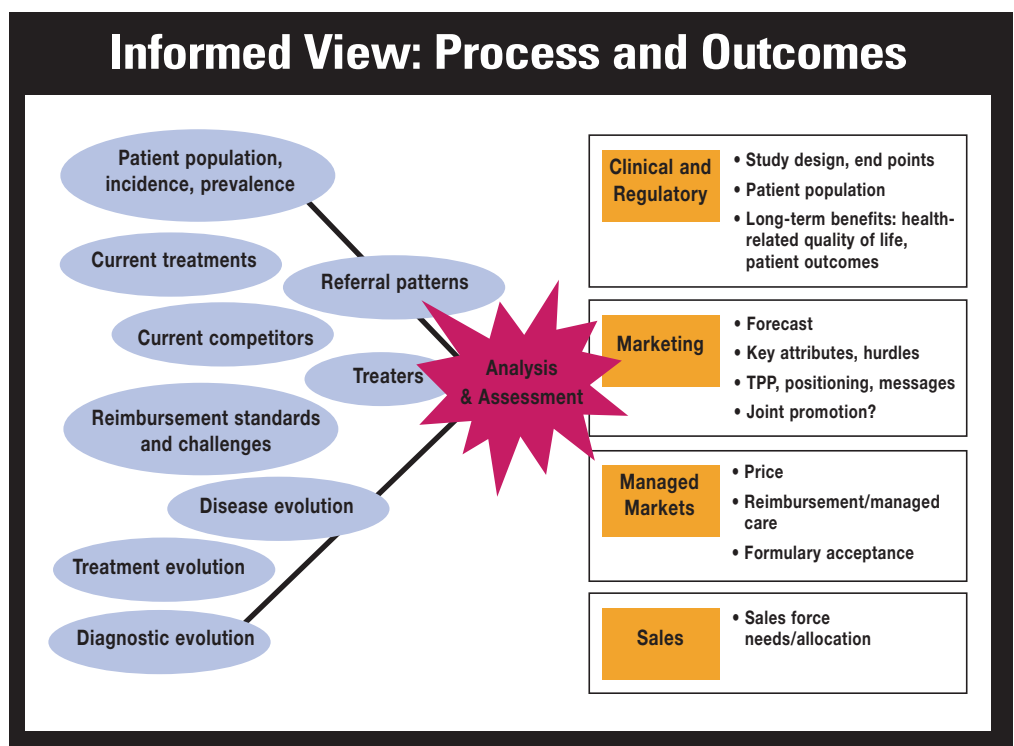
An understanding of current treatments and potential treatment evolution scenarios is not complete without considering patient access and reimbursement. Physicians, payers, and patients are demanding to know if a treatment "will work for a specific individual." Companies must clearly define how the treatment will fit into clinical practice and identify patient populations, whether for clinical trials or for treatment. Clear articulation of these areas will aid physicians in determining when to use the product. These data will also make it easier for payers to evaluate the product and determine reimbursement levels and requirements.

Analysis and Assessment

Once the information is gathered, it is critical to analyze and assess the data for new and recurring themes. New themes might suggest additional areas for research. Recurring themes could suggest key drivers or potential hurdles in the market. The end goal for the analysis and assessment is to incorporate key learnings into development and marketing plans.

Process and Outcomes

Developing an Informed View can be a large project and challenge for marketers to undertake on their own. The process should involve engaging internal team members from competitive intelligence, clinical affairs, regulatory affairs, medical affairs, and other key functional areas to assist in the research and analysis. Additionally, there are strategic marketing consultants who can support the product or brand team's research, analysis, and planning needs.



Developing an Informed View: Critical Activities

The process of developing an Informed View will highlight key drivers and potential hurdles/challenges for the product in a given therapeutic area, as well as provide guidance for development plans.

Taking Action

Successful pre-commercial marketing requires a broad view of all the elements that will impact a product's success. The process of developing an Informed View will highlight key drivers and potential hurdles/challenges for the product in a given therapeutic area, as well as provide guidance for development plans. By its very nature, pre-commercial marketing requires cross-team collaboration and buy in for it to be successful.

Tactical Steps

- Secure cross-team buy in and collaboration
 - Begin with the upper management team and work collaboratively to gain buy in and support of other departments and teams — clinical affairs, medical affairs, pre-clinical, regulatory affairs, legal, and sales/marketing
 - Form a pre-commercial team: Identify an individual to represent each of the departments and functions involved in the product's pre-commercial development
- Engage the pre-commercial team regularly
 - Establish on-going communications
 - Develop a secure Web portal, e-mail, and face-to-face meetings
- Areas to research
 - Develop an overview of the therapeutic area
 - Define patient populations and incidence and prevalence of disease
 - Identify physicians and other healthcare providers (HCPs) involved in care
 - Engage key opinion leaders
 - Partner with influential professional associations
 - Understand and profile the current standard of care and treatment options
 - Research therapeutic guidelines (if available)
 - Research available products — advantages and challenges/limitations
 - Uncover unmet needs

Developing an Informed View: Critical Activities (continued)

- Draft a treatment evolution scenario
 - Research products in development — mechanisms of action, advantages, and challenges
 - Speculate how treatments will evolve in the future, confirm assumptions with HCPs
- Review and understand regulatory requirements and guidances
 - Identify and understand hurdles approved products faced
 - Review pre-clinical and clinical development plan to ensure regulatory requirements are being met
 - Understand how the data will support future marketing programs
- Define the appropriate managed markets
 - Research prices for approved products
 - Understand current reimbursement practices and hurdles/challenges faced in securing reimbursement
 - Speculate future challenges, confirm assumptions with experts
- Analyze information
 - Review the information to understand dynamics, key drivers, potential hurdles/challenges
 - Identify areas where questions remain
- Discuss findings
 - Share findings with pre-commercial team
 - Explore remaining questions
- Integrate learnings
 - Include in strategic plans (ie, clinical development, regulatory, managed markets, marketing plan, etc.) and tactical programs

Benefits of an Informed View

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Physician Knowledge

Understanding which healthcare providers are involved in treating a particular condition can provide valuable insights into physician referral patterns, educational needs, and potential patient education materials. These insights can have a profound impact on business planning, such as the size of the sales force to support these areas, as well as pre-commercial strategic and tactical program priorities.

Current and Future Treatment Scenarios

Studying the current state of patient access and reimbursement can provide valuable insights into challenges existing products have encountered, as well as predict potential challenges for new products. The benefit of this early understanding is the time to plan and implement measures that will overcome future hurdles.

Predicting a future treatment evolution scenario provides valuable insight into where the product is likely to fit into clinical practice and identifies potential hurdles. Information gathered can be used to guide critical decisions around the most appropriate use of a product.

Long-Term Value

An area of increasing importance is in demonstrating long-term value of a product. Another area of growing import is demonstrating the possibility of changing the natural course of a disease. These data sets are quickly becoming equally as important as demonstrating safety and efficacy. Demonstrating a change in the natural course of disease can be the transition of a life-threatening condition to a chronic, but manageable condition or significantly decreasing the likelihood of surgery. The ideal is to include these data as secondary endpoints in the Phase III trials, which can provide marketers with critical differentiators pre- and post-launch. This information is highly valued by physicians, patients, and payers. It takes time to plan and implement these studies, and the sooner the planning begins the sooner the data will be available.

Benefits of an Informed View *(continued)*

Potential Benefits from a Comprehensive Pre-Commercial Marketing Plan

- Determining the trials and end points that could provide a competitive advantage at launch and post-launch
- Guiding the selection of the most appropriate use for the product
- Having time to prepare plans to properly address regulatory issues that may arise
- Developing proactive solutions to address future reimbursement challenges
- Identifying early indicators of important long-term data needs, such as patient outcomes or health-related quality of life parameters
- Identifying internal departments and teams that need to be involved in the pre-commercial phase
- Addressing manufacturing and distribution concerns/issues that may arise
- Conducting focus-group research on branding and positioning
- Identifying educational needs for healthcare providers and patients
- Developing plans that will accompany the product through launch (ie, publications, public relations, promotional medical education plan, etc.)
- Developing transition plans to a launch team

Pre-commercial marketing differs significantly from in-line/in-market product and brand marketing.

Conclusion

Ultimately, an Informed View of the Market will enable and empower the product development process, guide and inform critical decision-making processes, and greatly enhance the future success of the product.

A Plan for Success

- Successful pre-commercial planning and marketing is based on a broad-view of all elements that encompass a product, including clinical trial design and endpoints, regulatory requirements, pricing, reimbursement standards and hurdles, as well as marketing elements.
- Pre-commercial planning and marketing requires collaboration with multiple stakeholders in order to maximize the product's success in the marketplace.
- Marketers have to go beyond the traditional knowledge requirements for a therapeutic area and invest in understanding the broader commercial issues while little is known about a potential product and its eventual success.

The process of gaining an in-depth knowledge of the therapeutic area, product, and environment, coupled with analysis and assessment will guide the strategic plan and pull-through with tactical programs. This process is a large undertaking and takes time, but the benefits allow companies to maximize the success of the product once it is on the market. Two options exist for maximizing efficiency and completing the research and analysis in a timely manner: assign pre-commercial team members to conduct research in areas within their expertise and use a smaller working team to analyze and assess information or engage the services of a strategic marketing consultant.

A Strategic Marketing Consultant

- Provides a thorough understanding of the process, guides the team on next steps, and provides solutions to overcome hurdles.
- Supports research, analysis, and assessment, which allows the team to focus on other internal responsibilities.
- Identifies key drivers and hurdles and helps develop strategies and tactical programs.
- Communicates broad-based therapeutic and product development (ie, clinical, regulatory, marketing, etc.) knowledge.

About L3 Healthcare Marketing

L3 Healthcare Marketing is a strategic healthcare communications and marketing company specializing in market conditioning for novel products and technologies. Our ideas are grounded in market insight, vast pharmaceutical and biotech experience, and a pragmatic approach that delivers comprehensive and timely results. Leverage our market knowledge, business planning, and strategic development services to maximize your product's potential.

To access a Podcast on this topic featuring Laurie Lucas, Principal, L3 Healthcare Marketing, please visit <http://www.pharmavoices.com/podcasts>.

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