

5 Questions for the CEO Before Your Next Launch

By Kevin O'Neill, Integrated Product Launch, 2014

There are many challenges to successfully launching a pharmaceutical product in today's market. Clinical development, regulatory approval, competing products, health care reform, pricing pressures, and more hurdles at every turn. However, some of the biggest challenges come from within your organization. The pressures to launch and meet therapeutic and financial expectations are huge. These pressures can result in a noisy internal environment that is difficult to manage and maintain focus on the best path to market.

Today's pharmaceutical and biotechnology companies are staffed with experts in a wide range of disciplines needed to discover, develop, register and commercialize their products. Each one of these disciplines has a legitimate and powerful voice about the value and potential of the product they are guiding through the process. Companies also have to incorporate external advice from experts, patients, payers and other consultants. Senior managers at these companies stay informed through multiple layers of committees that may or may not be integrated with all key stakeholders. This high-intelligence and high energy environment presents some of the biggest challenges to a successful launch.

Most companies invest the majority of their resources in developing strategies and tactics to successfully manage the external challenges facing a product launch. The smart companies make sure that sufficient internal resources (e.g., structural, environmental, cultural and financial) are invested to ensure that their product is perfectly suited for a significant market need. Here are 5 key questions that can help a CEO determine if their launch effort is heading down the right track or off the rails.

1. **Do you have a detailed and integrated launch plan?** In today's pharmaceutical market there is no room for error. Commercial planning must be integrated early and in many critical stages of drug development. Effective planning will help avert costly delays, missed opportunities and ensure that products reach their full clinical and commercial potential.
2. **Do you have a dedicated and empowered launch team?** Is the team composed of each of the key stakeholders in the process? The team environment is critical and the team leader should have access to all the expertise needed to address challenges and move forward. Can the team make critical developmental decisions (clinical, regulatory, legal, commercial, etc.)? Obviously senior managers must endorse core decisions but the team must have the organizational support to channel their expertise into developing strategies for the best path to success.

3. **Do you have a clearly defined, decision making process?** Your process must ensure rapid decisions by informed experts? Decision making can be a great strength or a chronic weakness. Your process should be ingrained in the practices of the entire organization. Decision owners, key stake holders and the broader internal audiences need to be informed at appropriate times and final decisions must be respected.
4. **Do you have the discipline to not launch?** Few products have ideal profiles but when the target profile is not complete, it takes great strength of will to delay until the data are available to ensure competitiveness.
5. **Does your price reflect the value of your drug?** Are you ready to adjust and approve pricing that accurately reflects the final value of your product? Once the data is in, your product may be more or less than what you expected. Be prepared to make final adjustments when the picture comes into focus.

There are many more challenges that companies face but setting the internal focus is crucial for ensuring that the breakthrough product that you are developing truly is a – breakthrough. The key is to have systems and processes in place so that in the highly pressurized pre-launch environment your strategies will be focused and perfectly suited for an awaiting market.