

Launching a New Product in the Biomedical Industry

By Cristina Paulon

A new product rollout is always a hot topic for companies, especially if the product in question is designated to remain the key corporate focus for the next few years. This absorbs high levels of attention at all internal and external levels, engaging everyone from the strategy execution team to the product launch squad and beyond.

In the medical devices industry, the success of a new product launch can often determine the positioning of the company over the coming years and, although all the components of the strategy contribute to this success, any one individual can also have the power to cause its failure. One example of this is aggressive pricing. It may disrupt the competition but at the same time, it can easily destroy the perceived value of the product, eroding margins once and for all. A seemingly perfect strategy and implementation is not enough to conquer the market if not backed up by optimum inventory schedules and supply forecasts. Incorrect prioritization of resources can lead to product shortages, subsequent client frustration and delays, which give competitors a window to react with their own new products.

So, even if your company is confident that they have the top technology, or the most efficient next generation solution to treat the given pathology, there are manifold challenges waiting to trip

you up and marginalize or eliminate your success. Product launch failures can be extremely expensive and need to be avoided at all cost. This article summarizes some of the main challenges faced by our key medical devices clients during product rollout programs implemented over recent years and illustrates how Tefen supported them.

Typical issues commonly identified in new product launches

Having a great product is essential and a good starting point, but it is not enough to ensure it succeeds on the market. The following five issues cover most of the common concerns that stand in the way of new product success:

- The **competitive landscape** and the consequent **positioning of the new product**, especially when it is not the first to market (strong existing competition) or represents a significant “shift” in relation to the previous standard of care;
- The **recent changes** in decision making processes for **product purchasing within health care** facilities making the buying situation “more fragmented, shifting towards the economic buyers”;

- The **reimbursement and clinical evidence collection** requirements, which increasingly impact significantly on the launch and typically lead to long and costly activities with an uncertain outcome;
- The **macro-economic landscape** in which the product is being launched and possible internal **financial difficulties** determining potentially high “budget constraints” and subsequent prioritization;
- Last, but not least, the difficulty that companies sometimes encounter during **implementation of the designed launch plan**: a really good plan is worth nothing if not executed well from end to end.

Because the launch of a new product is a long, complicated process and often involves most, if not all, organizational functions within the given company, it is important to have an overall framework to follow. This should ensure that all aspects are addressed at the right moment, with the best tools and approaches available. For this reason, after several years of supporting our clients in their new product introductions, the Tefen Life Science Practice Team has developed a product launch method which covers all the key phases and offers a solution-oriented and pragmatic approach to overcome the most common issues.

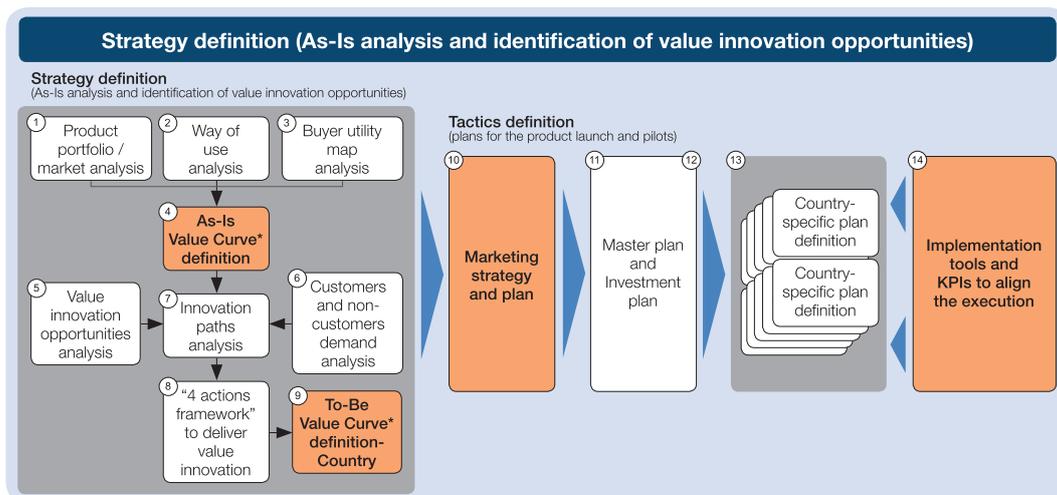
The Tefen Product Launch Method

The very first step of every launch is to define the launch goals. Our experience shows that these vary greatly. Some aim to redefine the rules of the game in a given therapy while others are a company’s reaction to the competition or campaigns to defend market shares.

In the initial phase, the main task is to assess the AS-IS situation, irrespective of whether this relates to the product portfolio and market analysis, the product itself or the customer side. This helps us understand the market and avoid underestimating the unknown elements that a new product often brings to the business. The following factors should be included in this analysis:

These launch goals must be clear in the minds of all responsible for the design and implementation of the launch, right up to the end of the journey, which could easily last for up to 2 years (from high level global strategy to country specific commercial launch).

1. **The market characteristics** (relevant when the new product is shifting the company’s scope of action), **competitors’** pricing and marketing strategies, the main **sales channels** and **NHS purchasing processes**, for the specific product category and, more in general, the dynamics of the market and **stakeholders** involved;

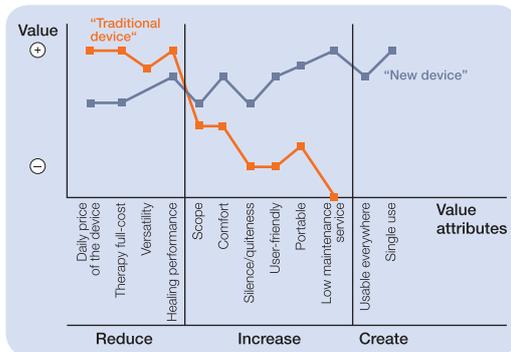


2. **The potential use**, (e.g. a new device might be applicable in different types of procedures, such as orthopedics, plastic, burns,...), with deeper analysis for those areas that the company is not familiar with, the **therapy delivery system**, the **users** and the peculiarities associated with all of the above (a more complicated device might require the surgeon to implant/use the product and equipment will need the involvement of the supply/logistics manager);

3. A clear understanding of **who will have to deal with the new product**, from the moment in which the sales representative sells it to the end of its use in therapy. This allows you to map its **use for all those involved** and how it can influence their perception of value.

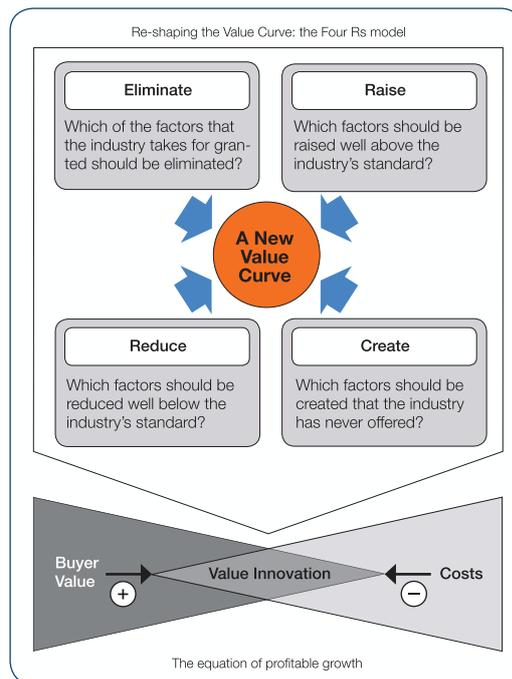
A Blue Ocean Approach to Positioning and Pricing

Once the market and technological background have been assessed, it is time to design the new value identity of the product in relation to price, the healing process, speed of action or the therapy delivery system.



One of the best ways to analyze and represent the proposed value of a product and to clarify whether it is a breakthrough innovation is through the Blue Ocean Strategy Methodology™ (BOS). The BOS value curves are an effective and clear way to show the key competitive advantages that the company should focus on in its communication and marketing strategy, and should bear in mind when defining the value chain.

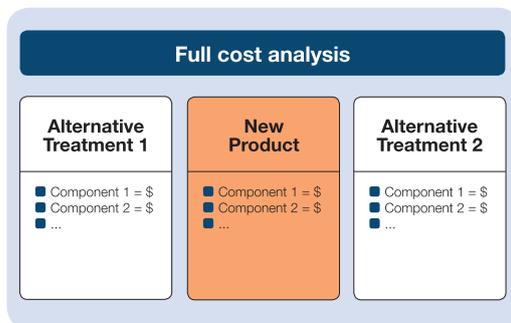
After product assessment and creation of new value through the four actions framework, the value curves show where the product is positioned within the existing market and competitive environment, where the benefits lie and which selected aspects it was appropriate to give up.



In the past, we applied this approach to help a major medical devices company position their absolutely innovative (at that time) stent, the Drug Eluting Stent for cardiologic procedures, which increased value for customers and patients by:

- Increasing first intervention success rate;
- Increasing the unitary product price;
- Creating a new component to the product (the drug), with a completely new platform;
- Reducing, for this reason, the overall costs of treatment for the health care system due to fewer re-stenosis incidents.

As we can see above, the pricing strategy for the new product is often a critical part of the strategy definition process and one for which the BOSTM again offers an evidence-based analytical solution.



The value based pricing approach analyzes the value perceived by the final customer (both HC professionals and patients) and compares it to an “equivalent costing model”, mapping the alternative cost of treatment with other therapies for the specific indications and justifying the premium price with the superior benefits provided by the product. This approach designs the product price and its position to reflect the benefit promised to the client by the product. The idea is to match the price with the value perceived and communicated to customers and patients.

Understanding the new stake holders

When drafting a way-to-market strategy, it is vital to understand who your key stake holders and clients are. However, companies with no strong knowledge of their specialties or with reduced capability to tap into the knowledge gleaned by a large and structured field force might find this step challenging. As one of our clients, Marketing VP at a large medical devices company revealed, “One problem we had to solve was how to maximize the reach-out to different clients, some of whom we did not even know, with the least risky and investment-free solutions. It was a challenge! But prioritization was key to finding the solution”.

Individual stakeholder profiles must be studied to find out how to communicate the product features to each stakeholder group in the most appropriate and coherent way (e.g. affordability might not be a relevant message to surgeons, while nurses would much more likely care about patients’ comfort). The stakeholders also include payers or supply managers, making it important

to build specific support tools for the sales force or for other field functions of the organization (product specialists, as an example).

You also need to identify the areas in which further knowledge is required so that different levels of the organization can communicate with customer groups or where training should be provided to reflect the importance of certain stakeholders.

For example, in the recent launch of a wound management product, research showed that specialized injury nurses are generally the people who decide how to deal with a wound after surgery or surgical consultation, while the surgeon is the decision maker when it comes to treating surgical incisions.

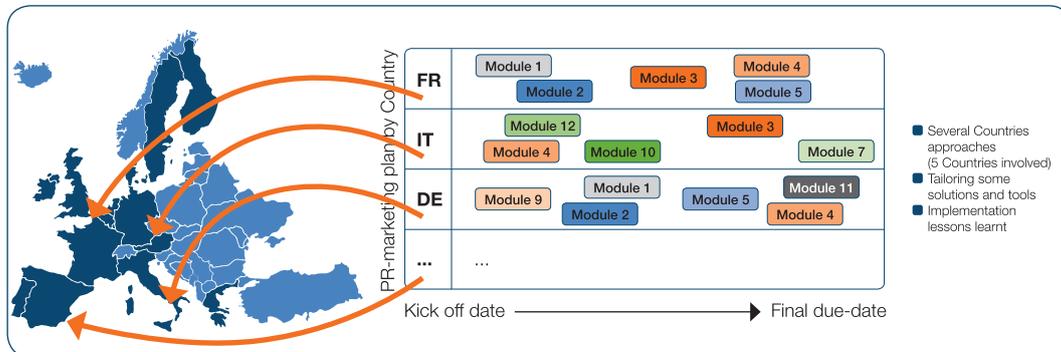
After having understood and mapped the client categories, the key customers must be identified within each group, based on their consumption/ personal profile (segmentation per customer needs). Targeting guidelines which reflected this segmentation should then be provided to the sales force, giving individually detailed goals which enable them to perform in alignment with your strategy.

From the global master plan to the Country specific implementation plans

After completing the above analyses, it is time to collect the data to build a coherent global master plan (or regional, e.g. European, North American), making sure that all strategy components are aligned with one another and with the overall goals of the launch. The global marketing strategy should detail:

- Accounts segmentation guidelines (based on clear drivers)
- Accounts targeting guidelines (rules for prioritization)
- Value proposition (by stakeholder), messaging and guidelines for communication
- Value delivery system
- Pricing guidelines

INDUSTRY



The global master plan illustrates how to translate the strategy into action, detailing actions, timelines, milestones, roles and responsibilities. This plan defines the timing for all the actions at global level (production of materials, selection of vendors, clinical studies) and the guidelines at local level.

Together with the master plan, an investment plan should also be prepared, explaining the budget linked with every single activity. Associating each element to a specific cost will help motivate the budget requests and will make it easier to prioritize investments based on their impact on revenue and therefore on the launch.

The Country marketing teams are then called upon to further detail the project plan by adding related information for action implementation.

Significant customization is mainly required in the following areas:

- **Reimbursement and market access activities:** all Countries work in a different way and require different levels of evidence in order to grant reimbursement to medical devices;
- **KOLs advocacy:** local relationships and network will be key to drive early advocacy and adoption;
- **Sales structure** (direct vs. indirect, web based vs. face-to-face) and **business model** (role of distributors and logistical aspects);
- Potential marketing and communication strategy plus materials;
- Pricing, (attention must be paid to problems such as parallel trading).

Lessons learned

Tefen has supported several clients in all of the phases described above, from the global design of the strategy (including pricing, positioning, market potential analyses plus marketing and health economics tools) to the implementation at Country level (leading large teams of professionals for all the work streams, from marketing to sales, reimbursement to market access, in designing and implementing the launch project). Our past experience has taught us a number of lessons.

Since each process of the workflow impacts on other steps, we focus in particular on **anticipating and coordinating the moment at which all functions involved in the launch plan communicate with one another** about goals, time-lines and strategic decisions.

For this reason, the following functions must be periodically aligned and realigned to the achievements and key strategic decisions, both at corporate level and in the given countries:

- Marketing (communication, PR, marketing materials, segmentation and targeting)
- Sales and sales training
- Clinical Affairs (evidence, training, KOL/Centers of Excellence advocacy)
- Reimbursement and pricing strategy
- Logistics and distribution

It is important that the pricing strategy is consistent with the reimbursement plan and with the regulatory constraints, while the prelaunch

marketing strategy must be well aligned with the clinical trials path in order to get the information and results needed to facilitate the product introduction.

It is also fundamental to get the commitment of the purchasing process stakeholders right from the start. **This is possible by formulating a global market access strategy which includes all the named aspects (pricing, value propositions, messages, reimbursement plan, regulatory issues, clinical trials)** and is consistently implemented.

Good communication is a prerequisite to ensure that the drafted plan gives the expected and desired outcome.

However, it is not just the task force in charge of implementation that determines the success of a launch strategy, but also the design team's ability to put in place **mechanisms that help us understand whether the strategy is implementable** and the willingness of the whole organization to buy the plan of action.

A common mistake that organizations often make is to build a marketing only strategy without involving the sales force. Although the sales guidelines may be well defined, they may not be aligned with the overall strategy or may not be possible to translate into action.

Marketing is often the key strategic “brain” of large medical device companies, while sales units have a deeper and valuable knowledge of customer needs and attitudes. Both these components are key to the design of a successful strategy.

One approach is to create joint teams of sales and marketing professionals, both involved in the commercialization of the new product, to discuss selected key aspects of the strategy. According to one of our clients, “you can have the best strategy on paper, but if your sales force does not buy it in completely, they will not be able to drive sales, and each part could end up blaming the other for the launch failure”. These sessions may be difficult to run but the results have always been extremely rewarding.

This type of controlled involvement helps to motivate the sales force and make them feel more enthusiastic about the launch, especially in the very early phases after launch.

In conclusion, we can say that the success of a product launch process is only partially influenced by the product itself, even if it is a breakthrough technology. This is even more true in such a highly complex market as life sciences, where social, economic and human factors count just as much as the intrinsic value of the product.



Cristina Paulon, Senior Consultant, Tefen Italy