Objectives of the module

This module gives an overview of important aspects for creating a strong go-to-market strategy. It includes key considerations, analyses and success factors to help vaccine manufacturers develop successful strategies for commercial excellence.

The module includes:

• An overview of several considerations, solutions and key success factors across new product planning, regulatory & approval and commercialization & launch
• Case study examples from previous product launches to highlight lessons learned
Vaccine development and commercialization is a complex process requiring significant investment and expertise to ensure commercial success for manufacturers.

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Targeted go-to-market strategies are critical in ensuring R&D investments translate into successful commercialization of a product.

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**New product planning**
- Assessing the commercial opportunity incl. market & competitor analysis and revenue potential

**Regulatory and approval**
- Understanding regulatory requirements for market approval of product and inclusion in public & private health systems

**Commercialization and launch**
- Robust go-to-market strategy and launch readiness incl. brand planning and local market strategies

**Corporate strategy**
- Product alignment with wider company and franchise strategies to support commercial excellence
During the new product planning process, a company must accurately define the opportunity and set the stage for marketing of the brand.

### NEW PRODUCT PLANNING

#### KEY CONSIDERATIONS

- What needs to be considered?

#### SOLUTIONS

- What key analyses and activities can be done?

#### SUCCESS FACTORS

- What are the key success factors?

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| **Using the right data to assess market trends, demand and segmentation** | • Target market definition, customer segmentation and key country mapping to inform launch market prioritisation  
• Demand forecasting to inform other functions incl. manufacturing and clinical strategy | • Accurately defining the target segments, key markets and demand forecasts |
| **Assess the competitive environment and define the value proposition** | • Competitive intelligence to inform strategy and product positioning  
• Patient journey and treatment leverage points  
• Market research for different stakeholders through activities incl. advisory boards, KOL interviews etc. | • Being clear on the product’s value proposition across stakeholders and evidence required to support it vs competitors |
| **Assess the broader landscape including the role of changing policy and relevant payers in the health system** | • Cost-benefit, budget impact analysis  
• Continued data generation strategy to address requirements for target markets  
• Landscape analysis of existing and future policy trends that could impact product launch | • Deep understanding of the broader environment and the shaping that would be required to ensure successful launch |
Understanding appropriate regulatory requirements for market approval of the product early on can ensure timely market access

**KEY CONSIDERATIONS**

- Understanding each market’s registration and regulatory requirements
- Identifying the key partners and local agents required for registering in countries where you don’t have a local presence and/or in absence of a dedicated internal regulatory team
- Identifying key regulatory agencies that you need to engage with, aligned with your market prioritization strategy, to inform your clinical strategy

**SOLUTIONS**

- Mapping of country-specific registration and regulatory needs in the target markets, and estimating complexity and timelines
- Due diligence including in-person meetings to assess potential partners’ and local agents’ success rates and actual on-ground resource
- Aligning on right incentive model to ensure partner is motivated to maximize your outcomes
- Identifying existing relationships/prior experience with regulatory stakeholders
- Understanding the role of local advocacy in product choice, if this exists

**SUCCESS FACTORS**

- Early understanding of registration requirements and building them into product development and new product planning
- Early engagement with partners and local agents for registration submission and life cycle management
- Key relationships with authorities involved in the decision-making process
Leveraging earlier product planning and knowing the regulatory environment can help develop robust GTM strategies which include brand plans and KOL engagement (1/2)

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<tr>
<td>• Developing a robust brand strategy specific to each earlier identified market</td>
<td>• Brand strategy bringing together analysis from new product planning and regulatory alongside previous market entry examples and available market-specific data sources</td>
<td>• Comprehensive brand plan that includes strong value propositions across key markets and stakeholders</td>
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<td>• Stakeholder engagement</td>
<td>• Stakeholder mapping of relevant KOLs which are crucial for successful product adoption across each of the target markets</td>
<td>• Access to KOLs that influence decision-making and leveraging specific value propositions</td>
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<td>• Cross-functional team with appropriate capabilities</td>
<td>• Assess internal GTM capabilities and structure a cross-functional team with accountability aligning with the different verticals of the brand strategy e.g., marketing, policy, market access etc.</td>
<td>• Integrated cross-functional team with the right skills and decision-making capabilities</td>
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Leveraging earlier product planning and knowing the regulatory environment can help develop robust GTM strategies which include brand plans and KOL engagement (2/2)

**COMMERCIALIZATION AND LAUNCH**

**KEY CONSIDERATIONS**
- What needs to be considered?
  - Understanding the relevant tender processes, where appropriate
  - Supply chain planning

**SOLUTIONS**
- What key analyses and activities can be done?
  - Mapping out tender and reimbursement requirements and timelines for each of the key markets e.g., UNICEF, PAHO, self-procuring countries
  - Earlier processes, such as good demand forecasting, and regular communication with procurers, can mitigate potential supply issues
  - Creating contingency plans and conducting scenario-based simulations

**SUCCESS FACTORS**
- What are the key success factors?
  - Early engagement on tendering pathways
  - Strong collaboration across partners including procurers, distributors, logistics partners etc.
Case Study: Rapidly changing policy environment can have a detrimental impact on commercial success of products

Context

• Cervical cancer is the fourth most common cancer among women globally, primarily in LMICs, and more than 95% of cases can be attributed to HPV infection
• Vaccines that protect against HPV infection can prevent over 70% of cervical cancer cases but many LMICs have yet to introduce the vaccine due to poor supply and high cost

Market landscape

• In 2014/15, two vaccines were available in the market (HPV2 and HPV4), both developed by MNCs with limited supply and unaffordable prices for LMICs
• With the need for another supplier to enter the LMIC market with a more affordable vaccine and sufficient supply, global health partners looked to DCVMs, including Innovax, to serve the global market with their HPV2 product

Launch story

With support from global health partners to address the need for sufficient and affordable supply of HPV vaccines, Innovax launched their HPV2 product globally including in LMICs.

With HPV2 being Innovax’s first WHO PQed product, it was integral to invest in the right capabilities to ensure a successful launch amongst well-known brands.

1. Global health partnerships
   • Worked with several partners to develop their go-to-market capabilities including understanding the market access and regulatory requirements for LMIC markets

2. Sufficient investment in expediting regulatory approval
   • Innovax’s parent company, YST, provided sufficient capital to support the launch of HPV2 including expediting the BLA and PQ to ensure LMIC market access

Despite support from global health partners, Innovax’s HPV2 product did not see any uptake in global markets driven by the changing HPV vaccine policy environment, but also due to the heavy MNC brand reputation and Innovax’s focus on the large domestic market in China

Several external and internal factors impacted Innovax’s success, serving as lessons for the future:

• Being aware of the changes in the policy landscape that could impact the success of your product when it is time to launch (e.g., WHO guidance, country product preferences etc.)
• Internal buy-in and alignment on market prioritization to ensure appropriate investment is made (e.g., balancing domestic market vs other markets)
• Investing in a brand strategy that aligns with stakeholders to help build reputation as a newcomer
Case Study: Stakeholder engagement requires identifying the right stakeholders who have the influencing power over product selection

Context

• Philippines has one of the highest prevalence of Hepatitis B virus (HBV) in the world
• Despite the high burden, HBV is not well understood, has a high stigma, is underreported and has far too few diagnoses and/or treatments

Market landscape

• Several branded HBV medicines existed within the market at high costs (up to $300/month), despite more affordable options being available including generics
• Dispensing doctors and pharmacies benefit off higher margin products and so are reluctant to prescribe lower priced options
• This created an imbalance between affordability of HBV treatments and prescribing preferences of healthcare professionals

Launch story

Gilead decided to relaunch its product “Viread”, a branded HBV medicine, at a no-profit pricing to set a ceiling on the market price for HBV treatment ($30/month)

A three-dimensional launch strategy was put in place with government advocacy as a primary focus knowing that building awareness organically through traditional marketing activities would have taken too long and required substantial budget

1. Government advocacy
   • US embassy engagement to raise the profile of the disease
   • MOH engagement and roundtable discussions with senators, congressmen and cabinet officials

2. Traditional MNC launch process
   • Launch events with KOL speakers and local doctors
   • Regional training programs & patient awareness campaigns with local governments and large corporations
   • National sales force

3. Regional pilot program
   • Demonstrating the level of burden and cost effectiveness of the HBV campaign to increase the advocacy for government support and local/corporate resources

MOH finally launched a national pilot program and ended up negotiating the purchase of a generic version of “Viread” at a lower cost from another supplier

The product relaunch was unsuccessful for Gilead due to loosely defined key success factors:

• Lack of clarity on the right stakeholders with vested interest in the program to support the product adoption
• Waning involvement throughout MOH’s decision-making process, either directly or indirectly via partners to funnel technical advice
Case Study: Targeted market access and KOL strategies with varied value propositions can ensure product adoption across several markets

Context

- Meningitis has a high burden of disease globally, but varies widely across markets due to serotypes differences
- With this variability, a vaccine covering multiple serotypes needed to position itself as a comprehensive solution to multiple markets with different serotype prevalence

Market landscape

- Most countries were using single serotype vaccines (Men C, MenB and/or MenA depending on prevalence) in their national immunization programmes (NIPs) as the manufacturer was coming to market with a multivalent vaccine (MenACWY)
- Countries had been using monovalent vaccines for several years and had seen a significant decline in the meningococcal disease from these serotypes - but other serotypes were starting to cause concern including W and Y

Launch story

Understanding the increase in other meningococcal serotypes causing disease in countries, the manufacturer worked to highlight the unmet need that their new MenACWY vaccine could address

Key activities focused on targeted market access activities accounting for country differences.

1. Market-specific strategies
   - Identified key launch markets with W and Y prevalence that would benefit from product
   - Conducted market-specific studies, including cost-effectiveness, due to country variability in serotype prevalence

2. Value proposition over SOC
   - Leveraged market-specific data to highlight value proposition of including W and Y vs only single serotype vaccines
   - Focused on broader impact of switching, including societal impact

3. Engaging a variety of KOLs
   - Developed a brand strategy that included engagement with parents (decision-makers of vaccination for children), patient advocacy groups and NITAGs using different value propositions to influence product choice

Six key countries moved from single serotype vaccines to Men ACWY for their NIPs with ongoing work to move several others

Key success factors for the commercial success of this vaccine included:

- Focusing on a narrow scope of key markets and specific populations for the initial launch
- Understanding the drivers for each of the KOLs (e.g., governments wanting to understand budget implications vs patient advocacy groups focused on societal impact) and developing relevant value propositions