



# Go-to-market strategy development & case studies for suppliers

2023

# Objectives of the module

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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



## R&D

Prioritizing opportunities in novel vaccine development

## Manufacturing

Ability to go from small scale batches to large scale production of doses to deliver against demand

## 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

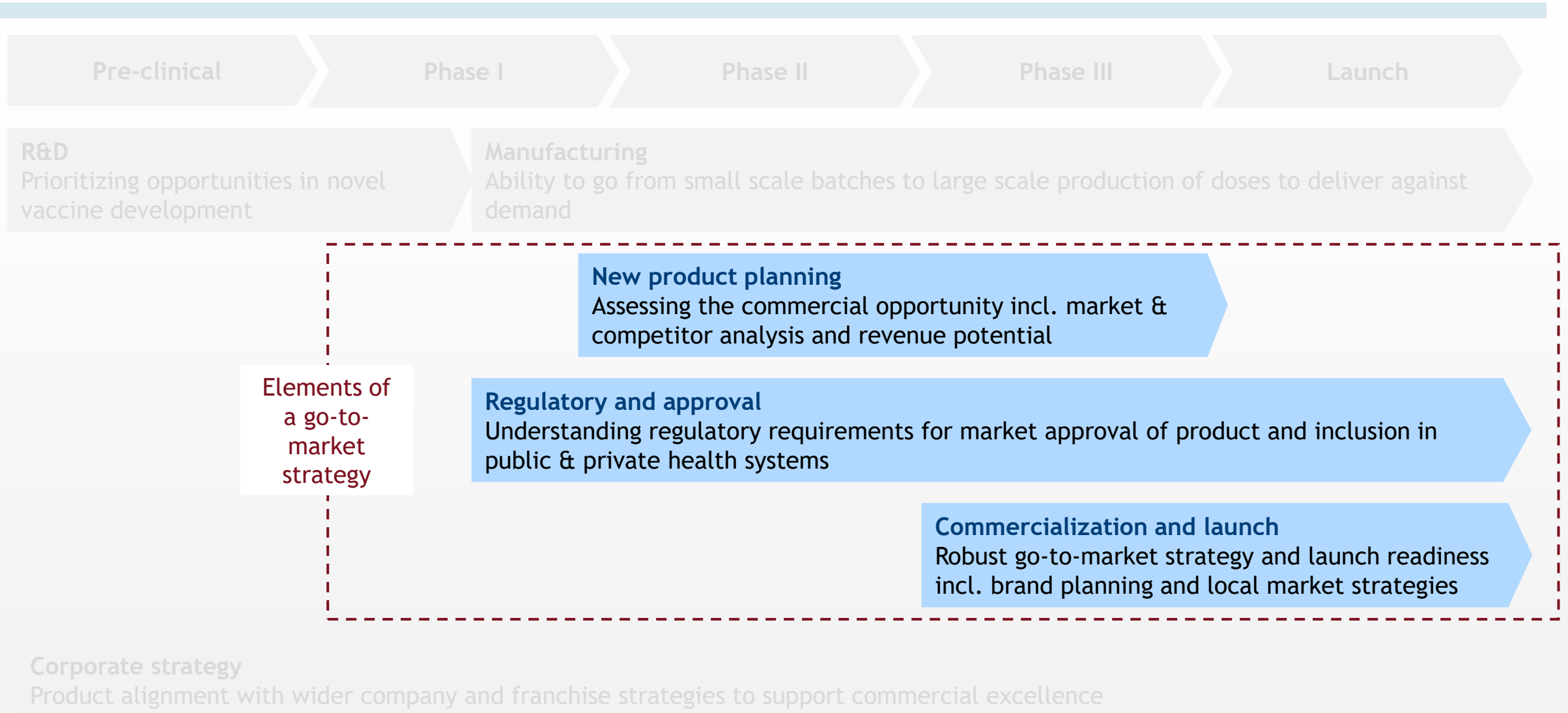
## Commercialization and launch

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

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



# 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?



# Understanding appropriate regulatory requirements for market approval of the product early on can ensure timely market access



## REGULATORY APPROVAL



### KEY CONSIDERATIONS

What needs to be considered?



### SOLUTIONS

What key analyses and activities can be done?



### SUCCESS FACTORS

What are the key success factors?

- Understanding each market's registration and regulatory requirements

- Mapping of country-specific registration and regulatory needs in the target markets, and estimating complexity and timelines

- Early understanding of registration requirements and building them into product development and new product planning

- 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

- 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

- Early engagement with partners and local agents for registration submission and life cycle management

- Identifying key regulatory agencies that you need to engage with, aligned with your market prioritization strategy, to inform your clinical strategy

- Identifying existing relationships/prior experience with regulatory stakeholders
- Understanding the role of local advocacy in product choice, if this exists

- 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)



## COMMERCIALIZATION AND LAUNCH



### KEY CONSIDERATIONS

What needs to be considered?



### SOLUTIONS

What key analyses and activities can be done?



### SUCCESS FACTORS

What are the key success factors?

- **Developing a robust brand strategy** specific to each earlier identified market

- Brand strategy bringing together analysis from new product planning and regulatory alongside previous market entry examples and available market-specific data sources

- **Comprehensive brand plan** that includes strong value propositions across key markets and stakeholders

- **Stakeholder engagement**

- Stakeholder mapping of relevant KOLs which are crucial for successful product adoption across each of the target markets
- Engagement strategies using specific value propositions identified in earlier processes

- **Access to KOLs that influence decision-making** and leveraging specific value propositions

- **Cross-functional team with appropriate capabilities**

- 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.

- **Integrated cross-functional team** with the right skills and decision-making capabilities

# 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?



### SOLUTIONS

What key analyses and activities can be done?



### SUCCESS FACTORS

What are the key success factors?

- Understanding the relevant tender processes, where appropriate

- Mapping out tender and reimbursement requirements and timelines for each of the key markets e.g., UNICEF, PAHO, self-procuring countries

- Early engagement on tendering pathways

- Supply chain planning

- 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

- 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





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