



Overview of government decision processes for NVIs and product switches

2023

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Objectives

Introduction

Product Preferences

Product Selection

1. New vaccine introductions

2. Product switch

Objectives of the module

In select antigen markets, uptake of DCVM products is dependent on country product preference and selection processes.

This module aims to facilitate **improved understanding of country product preferences, processes and incentives to introduce/switch to help DCVMs capture demand in these markets.**

Suppliers can use this module to register products appropriately, conduct country-specific research to understand product selection processes, engage early with relevant stakeholders and emphasize the product attributes that will support introduction/switches.

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In select antigen markets, uptake of DCVM products is dependent on country product preference and selection processes



Gavi-supported countries can state their preferred products for PCV, Rota and HPV:

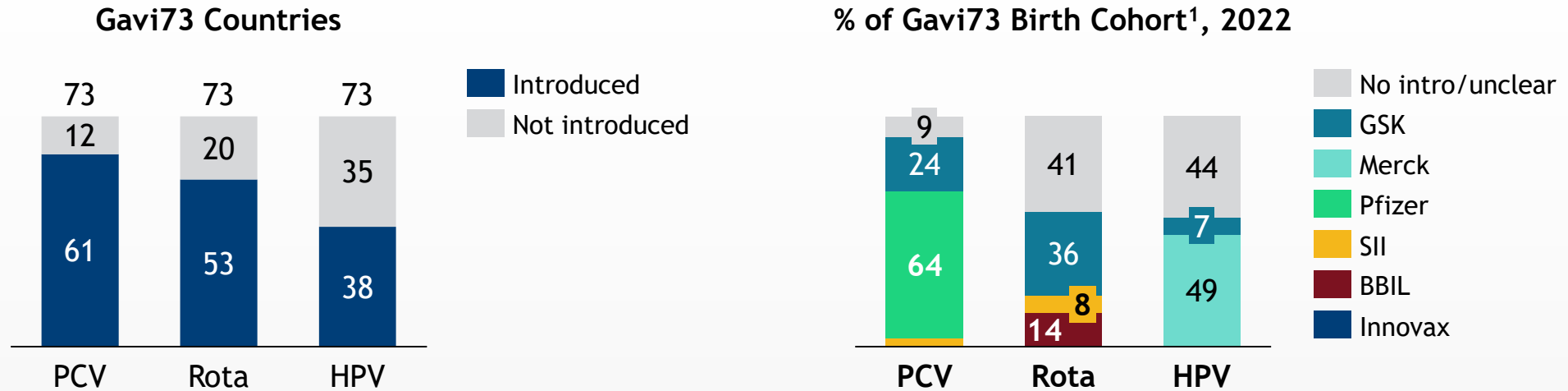
1. When [applying for Gavi support for introduction](#), and
2. Via [applications to switch products](#)¹

As Gavi supports additional vaccines, Gavi-supported countries may also be able to select preferred products for:

- Meningitis (given serotype coverage differences)
- Malaria (e.g., RTS,S vs. R21)
- RSV (maternal vs. mAb)

1. To date, Gavi73 countries have very limited experience with switching products in these markets

In these markets, MNCs are incumbents and hold majority of market share; opportunity for new suppliers will be driven by product switches



Implications:

- **PCV and Rota:** Uptake of new DCVM products depends on **countries deciding or being required to switch products** (e.g., due to shortages), since minimal demand is associated with countries yet to introduce
- **HPV:** Significant share of demand comes from countries yet to introduce; however, many countries have conducted HPV demos, which may influence their preferred product for full-scale introduction

Over the past 5 years, DCVMs have started to capture market share from MNCs in these markets and further opportunities can be captured with strong go-to-market strategies

DCVMs can capture demand in these markets by understanding country product preferences, processes and incentives to introduce/switch



What can suppliers do with the improved understanding facilitated by this document?

1. Develop products with profiles that meet country preferences, and prioritize market entry into countries more likely to prefer their product
2. Manufacture at capacities appropriate to match country demand for specific product profiles
3. Provide desired information to the right stakeholders at the right time to inform product adoption decisions

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Several product attributes drive country preferences, with importance depending on the market and the country



- 1 **Valency** tends to be more important where products have different serotype coverage and disease epidemiology varies geographically (e.g., PCV)
- 2 **Dose schedules (e.g., 2- vs. 3 dose schedule) and presentations (e.g., 5- vs. 10-dose vial, frozen vs liquid)** that help meet immunization targets of higher coverage, lower wastage and cost savings may be favoured
- 3 **Price** is an important driver of product choice in the Gavi market, and countries in later stages of transition tend to be more price sensitive as they bear a higher proportion of procurement costs

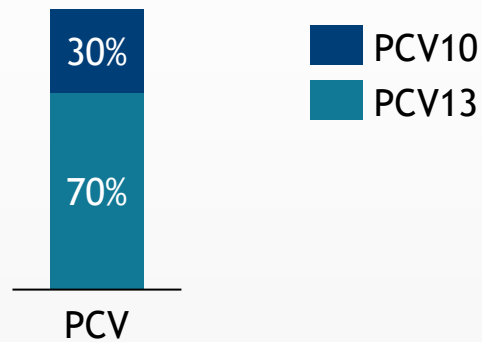
Countries may prioritize these factors differently depending on local immunization priorities and challenges (e.g., cold chain space is less likely to be important in a country that recently expanded its cold chain)¹

¹Note: some countries may not be using their preferred product due to shortages

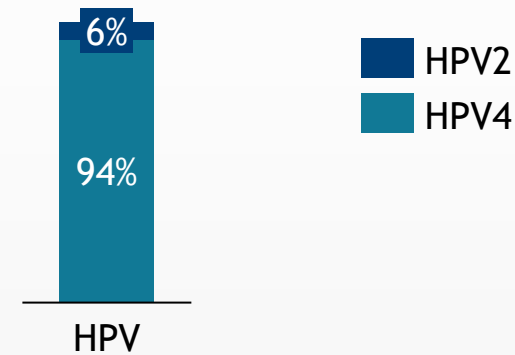
Despite the availability of low-cost products, high valency products have been preferred for PCV and HPV by Gavi countries



PCV - Market Share in Gavi Countries by Valency^{1,2}



HPV - Market Share in Gavi Countries by Valency^{1,2}



- Gavi countries tend to prefer HPV4, often citing higher valency as the driver
- Data suggests serotypes 16 and 18 covered in HPV2 prevent 70% of cervical cancer cases - types 6 and 11 which are covered in HPV4 protect against anogenital warts

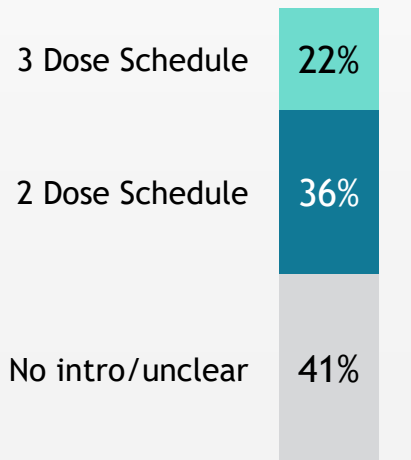
Dose schedules and presentations that support the achievement of immunization targets may be favoured by Gavi countries



Rota Example - Dose Schedule

- Majority of Gavi market that has introduced Rota still using a 2-dose schedule
- This is also driven by historic factors and order in which products have become prequalified

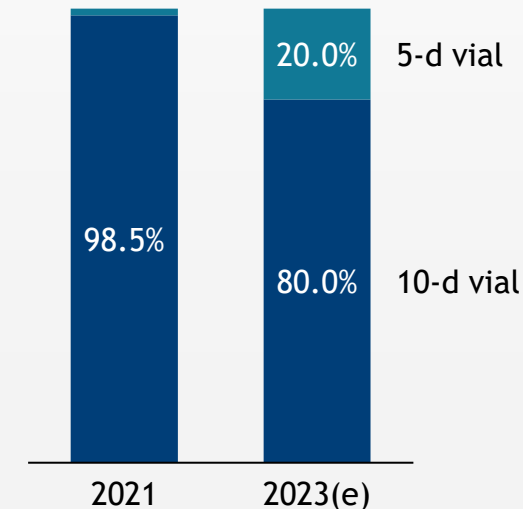
Gavi73 Birth Cohort Rota Split, 2022



MR Example - Presentation

- Study in Zambia showed a 5-percentage point improvement in coverage following a switch from 10-dose vials to 5-dose vial¹
- There is a push for greater MR 5-dose vial usage in RI, where it is most suited, to improve coverage

UNICEF MR presentation split²



¹Zambia Mixed-Method Study; ²UNICEF VIC 2021

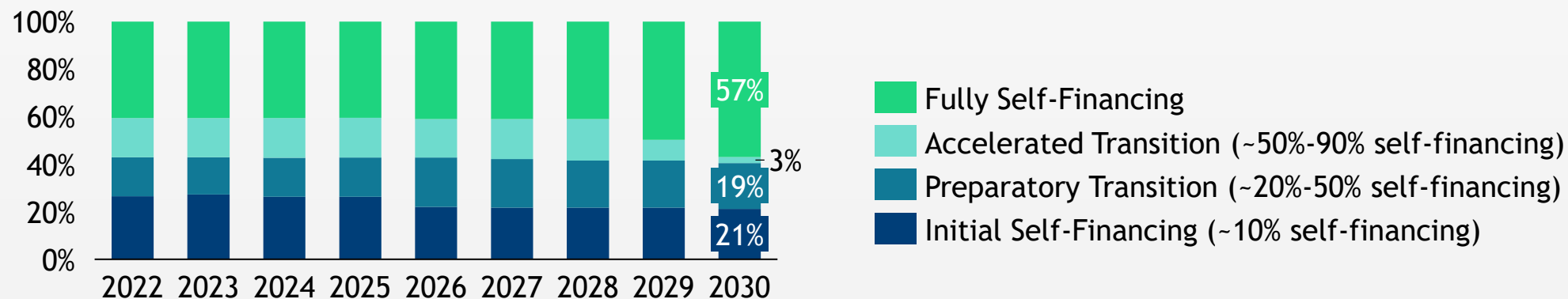
Countries in later transition stages appear more price sensitive and may be more likely to be driven by cost savings if other product elements are favourable



Countries in later stages of Gavi-transition:

- Face an increased incentive to lower procurement costs, to support sustainable transition; **visibility on pricing post-transition** is an important factor here
- May switch procurement channels, which could create a trigger to consider alternative products, if introduction has already occurred
- Will represent an increasing % of the Gavi birth cohort by 2030

% of Gavi Birth Cohort in Different Stages of Gavi Transition, 2022-2030



Non-product attributes also shape country choice, suggesting countries will not always select products that optimally meet their attribute preferences



Factor	Insights
Domestic manufacturing	<ul style="list-style-type: none"> In countries with domestic vaccine manufacturing capabilities, <ul style="list-style-type: none"> preference for local manufacturing often overrides other preferences (e.g., for lower price or other product attributes) opportunities for international suppliers tend to be greatest if via tech transfer to a local supplier
Openness to DCVMs	<ul style="list-style-type: none"> The extent to which countries have used DCVM products in the past¹ can shed light on openness to new DCVM products; openness to a specific manufacturer is expected to be higher if a country has used their products in the past Further, examining any trends in suppliers across a country's vaccine portfolio can shed light on any company preferences
Country readiness	<ul style="list-style-type: none"> Low DTP3 coverage and/or significant drop in DTP3 coverage can indicate likelihood that country will be prioritizing coverage gains before considering NVIs or switches
Other factors	<p>Country-specific research can help bring to light additional factors that influence product preference, e.g.:</p> <ul style="list-style-type: none"> Preferences for Halal-certified products by countries with large Muslim population Geopolitical pressure influencing product choices

Suppliers should research and consider how **individual country contexts affect eventual product choice**, particularly for high-volume countries where procurement is complex and local production is prominent

¹See MIC Opportunities Database

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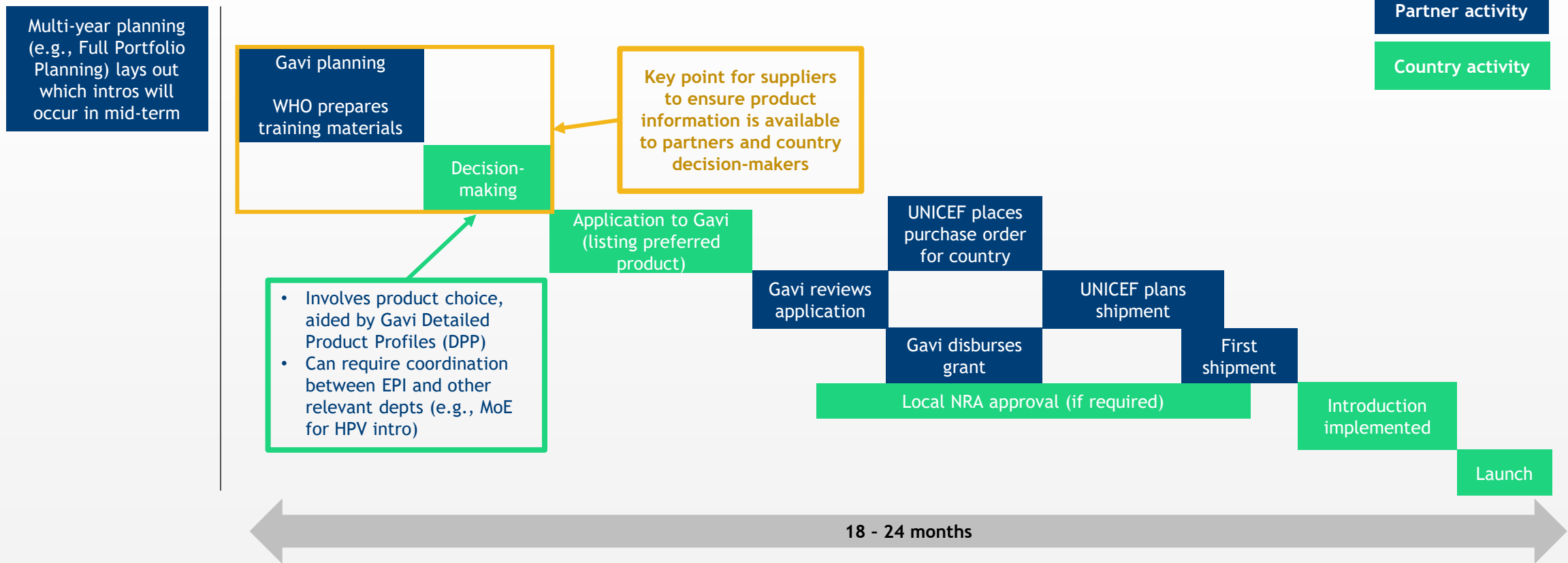
1. New vaccine introductions

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The new vaccine introduction (NVI) process can take 18-24 months, and countries' preferred products are usually stipulated upfront in their applications to Gavi



Product selection as part of the NVI process (timing varies per country):

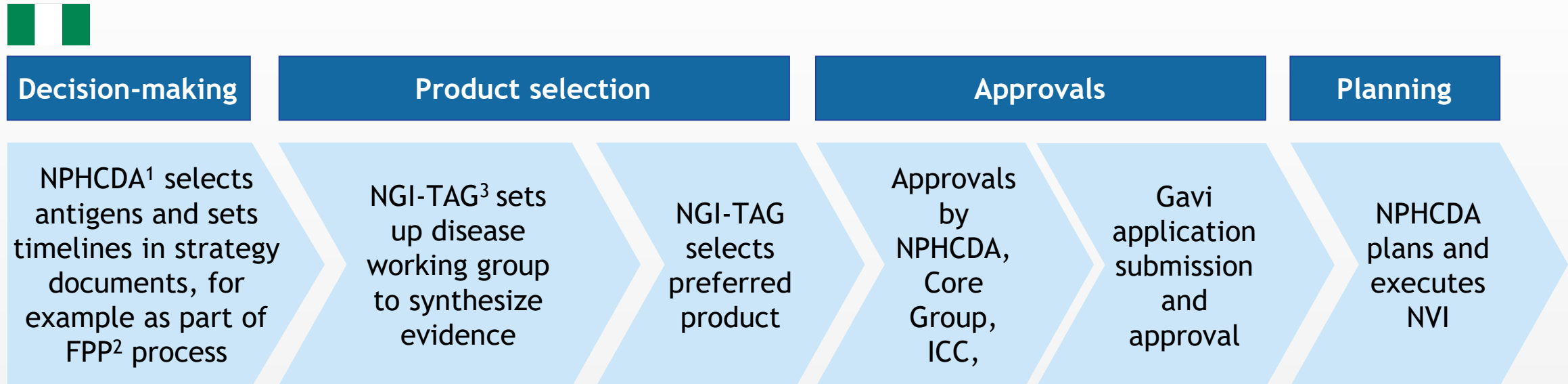


Suppliers should work with Gavi to ensure their products are listed on the Gavi DPP as soon as possible after WHO PQ application is submitted; this step is critical for country stakeholders to become aware of the production option

Example: Nigeria has a defined process to select products for introduction - some variation is expected from product to product



- Typically, as part of the NVI process (see previous slide), products are selected for introduction following clear, relatively standardized and well-documented steps
- Some variation is expected from product to product



▲ Product selection process triggered by NVI timelines, with partner support (e.g., WHO, CHAI)

For target markets, **conducting country-specific research** to understand **product selection processes** can help shed light on *which stakeholders require product information, and when*

¹National Primary Health Care Development Agency; ²Full portfolio planning; ³Nigeria Immunization Technical Advisory Group

Decision-making may lie within different bodies per country, so suppliers' efforts to share information need to be appropriately targeted



Broadly, countries select products for NVIs in one of three ways:

Approaches to product selection	Example countries	Key decision-making body
(1) EPI bodies make product recommendation, and NITAG reviews and endorses but rarely challenges the recommendation	Ethiopia	National EPI Task Force
	Kenya	EPI leadership and NLWG
	Pakistan	National EPI, including provincial EPI buy-in
	Uganda	Working group in EPI
	Vietnam	EPI and GDMP
(2) NITAGs make specific product recommendation and EPI endorses decision	Indonesia	NITAG (ITAGI)
	Nigeria	NITAG (NGI-TAG)
(3) NITAG sets minimum requirements to allow for competition in RFPs, which select based on price	India	Standing Working Group in NITAG and Vaccine Procurement Cell in MOH

It is important to engage with key data sources and make clear consolidated product data available through them - limited availability of data can hamper decisions



Typical data sources used by country decision-makers to inform product choices include the following:

- [WHO SAGE recommendations](#)
- Gavi [Detailed Product Profile](#) (Gavi Menu)
- Local and regional data

In lieu of information in these sources, decision-makers use other global guidance from trusted partners (e.g., WHO, PATH), especially when based on local or regional evidence

- Examples include the [IVAC PCV Interchangeability Evidence Dossier](#) and [WHO Considerations for PCV Product Choice](#)

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While the process and stakeholders involved in product selection for switches is expected to be similar to NVIs, some key differences have been observed



1. **Loss aversion:** As there is a product already in use, stakeholders may disproportionately focus on avoiding a loss in certain characteristics
 - **Implication:** The attributes of the product initially introduced, may influence countries' preferences for any future switches (e.g., if countries introduce a high valency product, they may not accept lower valency products in the future)

2. **Process:** Unlike for NVIs, processes are less clear - it is not always known *when* countries will look to switch, and *who* is involved in the process

3. **Programmatic interest:** In some instances, there is a greater incentive to prioritize NVIs over optimizing current vaccine portfolios through switches
 - **Implication:** New products may see a delay in demand developing if countries have already introduced the product

Examples of recent switch behavior show that different factors affect country switch decisions - each switch is product and country dependent



Country	Switch	Year	Details
Ghana ¹	GSK Rotarix → BBIL Rotavac	2020	<ul style="list-style-type: none"> Ghana was in preparatory transition phase in 2015, expected to transition to fully self-financing by 2030 NITAG identified rota vaccination as area they could make pre-emptive change to prepare for future NITAG supported and endorsed the recommendation by the Ministry of Health to switch to using ROTAVAC, partly due to lower price and smaller cold chain volume per dose
Uzbekistan ²	Pfizer PCV13 → SII PCV10	2020	<ul style="list-style-type: none"> Uzbekistan fully self-financing in 2022 Vaccine product preference driven by lower price of SII PCV10
Pakistan ²	GSK PCV10 → Pfizer PCV13	2020	<ul style="list-style-type: none"> Pakistan in preparatory transition phase New NITAG recommendations for PCV13
Zambia ³	MR 10-dose vials → MR 5-dose vials	2017/18	<ul style="list-style-type: none"> The recent availability of 5-dose vials from UNICEF prompted a switch to tackle low coverage rates

Not a comprehensive list of switches; ¹More details in PATH study: [“The switch from ROTARIX to ROTAVAC in Ghana: Answers to four key questions”](#); ²More details in [PCV AMC Annual Report, 2020](#); ³More details in [Zambia Mixed-Method Study](#)

Examination of past switch behaviour shows four main drivers can enable product switches: strong incentives, ease of switching, country capacity and triggers



1. **Strong incentives**, (e.g. desire to find lower-priced products for self-financing countries or higher valency products) drive switches
2. **Ease of switching** (e.g. similar products) reduces the ‘cost’ to switch
 - Countries are more likely to switch to products that are more similar to the product currently in use, because those switches are easier to implement, e.g., same dose schedule or presentation
 - Switches in markets where products are highly differentiated (e.g., Rota) are expected to be more costly
3. **Country capacity**
 - Countries with NVIs planned in the next few years are less likely to have EPI capacity to decide to and execute a switch
 - Low DTP3 coverage and/or significant drop in DTP3 coverage can indicate likelihood that country will be prioritizing coverage gains before building switch capacity
4. **Specific time-bound triggers** bring attention to switch options, e.g. tenders, supply shortages

Partner efforts to support country decision-making may increase future switches; suppliers can use tools to ensure relevant framing of messages to stakeholders



PATH Cost Calculators

- Tool is designed to support countries in calculating cost savings for Rota, PCV, and HPV based on country co-financing and product choice
- Relatively widespread use - Gavi recommends use to countries within their published product profiles to support country decision making
- Suppliers can use this tool to communicate potential cost savings using a trusted external resource

CHOICES Core Partners



World Health Organization

CHOICES Grant and CAPACITI Tool

- CHOICES supports countries on decision making on PCV and other vaccines, using CAPACITI tool, as well as preparations for switch
- CAPACITI tool launched 2019/20, but currently CHAI is only seeing use trialed in Indonesia
- As countries have their own tools that require less time and are perceived as sufficiently robust, have not seen substantial demand yet
- Uptake may be limited unless partners push (e.g., if Gavi required CAPACITI tool to approve switches)

Suppliers can proactively engage with countries to provide additional tailored support

Recommendations for suppliers

Understanding

- Examine historical trends to understand the context for a product choice
 - For that product, what attributes have been important in product selection and switch previously?
- Conduct in-country engagement to understand product selection processes and registration requirements
 - *Which* stakeholders require product information?
 - *What* information do these stakeholders require?
 - *When* do these stakeholders require information?

Actions

- Register products appropriately according to the target markets
- Ensure key data sources (WHO SAGE recommendations, Gavi detailed product profile (DPP), local and regional data) include the product, and ensure products are listed on the Gavi DPP as soon as possible; this is a critical tool for country stakeholders to become aware of the product option
- Emphasize the product attributes that will provide incentives to countries to select a product - these can include valency, presentation or administration, and price savings



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