7/21/2025

NGI-PV Market Analysis

Methodology and Demand Forecast

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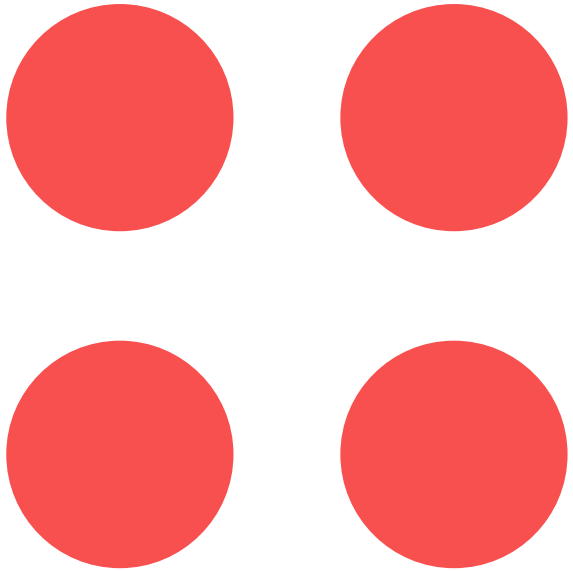
Agenda

- **Project intro**
- **Eradication assumptions**
- **Modeling assumptions**
- **Demand scenarios**
- **Demand forecast**
- **Market risks and opportunities**



Project Introduction

Objective:

To better understand the landscape (i.e. developability, acceptability, and market demand) of potential technologies for manufacturing polio vaccines from non-infectious sources.

Summary of Planned Activities:

- Develop scenarios to reflect potential conditions for next generation injectable polio vaccine (NGI-PV) market introduction.
- Leverage use cases and stakeholder interviews from Workstream #2 to determine which products may be preferred over others based on income level, immunization access, experience with polio elimination, etc.
- Forecast NGI-PV demand by scenario and highlight market risks

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Global Polio Eradication Strategy Assumptions†

Current epidemiological situation

- Wild type 2 and 3 are eliminated, only Wild type 1 remains in Pakistan and Afghanistan
- Circulating vaccine-derived poliovirus type 2 (cVDPV2) outbreaks are still occurring
- Circulating vaccine-derived poliovirus type 1 (cVDPV1) and type 3 outbreaks are also occurring sporadically

Certification of polio eradication resulting in removal of all OPVs will require:

No polio virus cases in the community and no polio virus detected in the environment for a period of time.

Bivalent oral polio vaccine (bOPV) cessation in routine immunization (RI) will require*:

- Certification of eradication of Wild type 1 poliovirus by Global Certification Commission (GCC)
- Certification of elimination of cVDPV2 elimination by GCC as proof that OPV cessation
- No persistence (circulation >6 months) of cVDPV1/3 in the previous 24m period at the time of the decision to proceed with bOPV cessation. will be a pre-requisite
- Available stockpiles of type-specific OPV vaccine (novel or Sabin) in sufficient quantity
- All countries must have established at least two-dose IPV RI schedules for a minimum of 2 years prior to cessation.

† All assumptions taken from the GPEI Strategy 2022-2026 unless otherwise indicated.

* *Notes from SAGE meeting Sept 2024*

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Modeling Assumptions

- NGI-PV products are considered programmatically interchangeable with current IPV products. Countries have no preference for NGI-PV over current products
- NGI-PV products are potentially cheaper than traditional IPV:
    - Gavi-supported countries are indifferent to prices
    - Non-Gavi countries may choose to switch based on price
- The demand forecast is mainly driven by supplier decisions, recommended or mandated by WHO guidance
- GVMM has product-based demand for Gavi suppliers; non-Gavi demand relies on more general assumptions
- Refer to the appendix for definitions of each market segment

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Demand Time Periods

Period A
2025-2034

- cVDPV outbreaks are still occurring
- Initial NGI-PV market introductions expected

No programmatic benefit to NGI-PV usage

Period B
2035-2044*

Modeling assumes bOPV cessation:

- Certified WPV1 and cVDPV2 eradication by GCC
- No persistence of cVDPV1/3 in 24m before decision

NGI-PV is considered crucial for eliminating global containment risks

Period C
2045+

10-years after bOPV cessation

- Potential for Polio eradication

Uncertain need for NGI-PV product post-polio in non-PEF countries

** bOVP cessation in 2035 is a modelling assumption. For the latest Polio eradication timeline estimates, refer to the GPEI website.*

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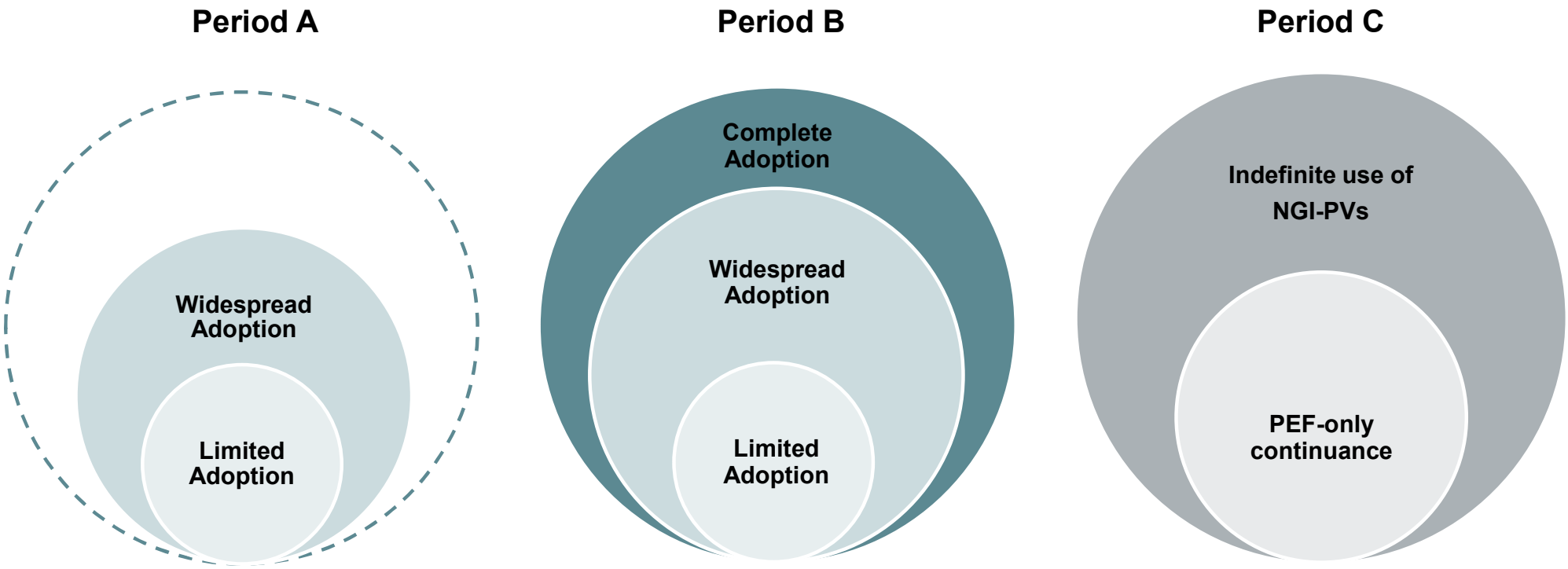
Demand Scenarios

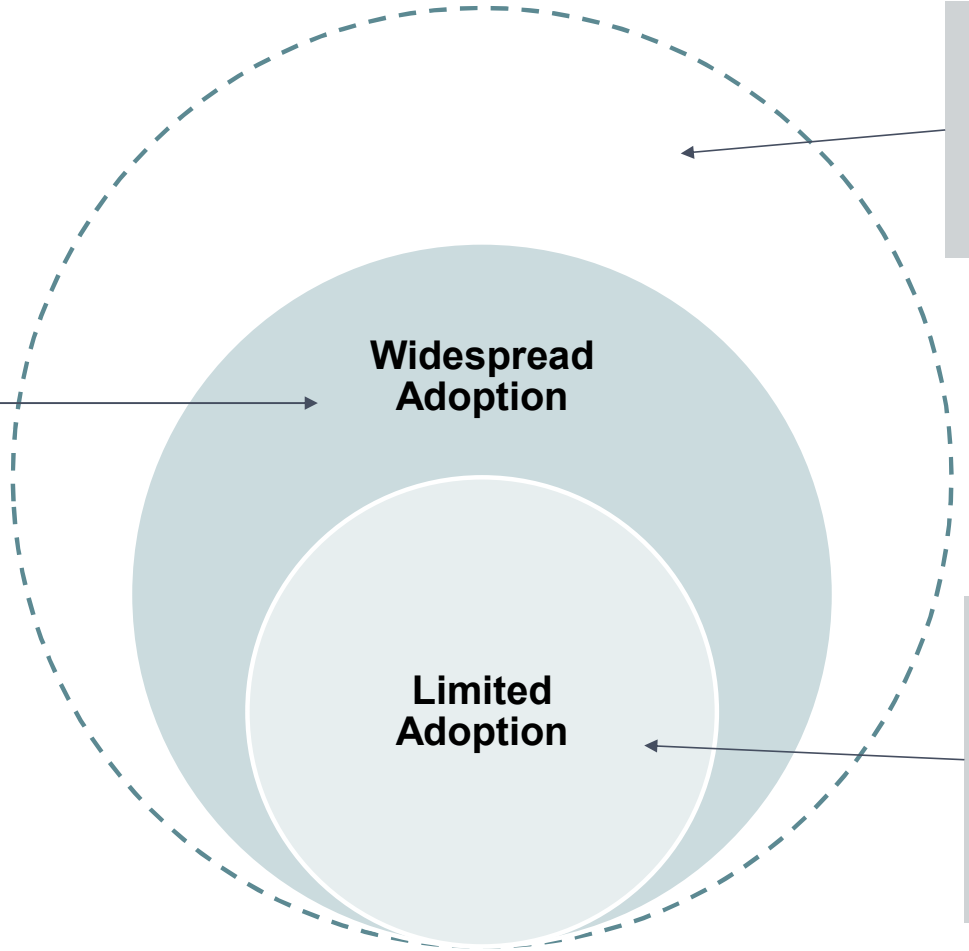


Period A

WHO recommends a switch to NGI-PV use after bOPV cessation:

- Fast-follower manufacturers adopt NGI-PV products 2-3 years after initial developers
- Other DCVMs and Gavi suppliers transition in Period B

HIC manufacturers do not plan an NGI-PV switch



Remainder of global IPV demand

Manufacturers actively developing NGI-PV products enter the market

Price-sensitive non-Gavi countries switch to NGI-PVs over a 3-year period

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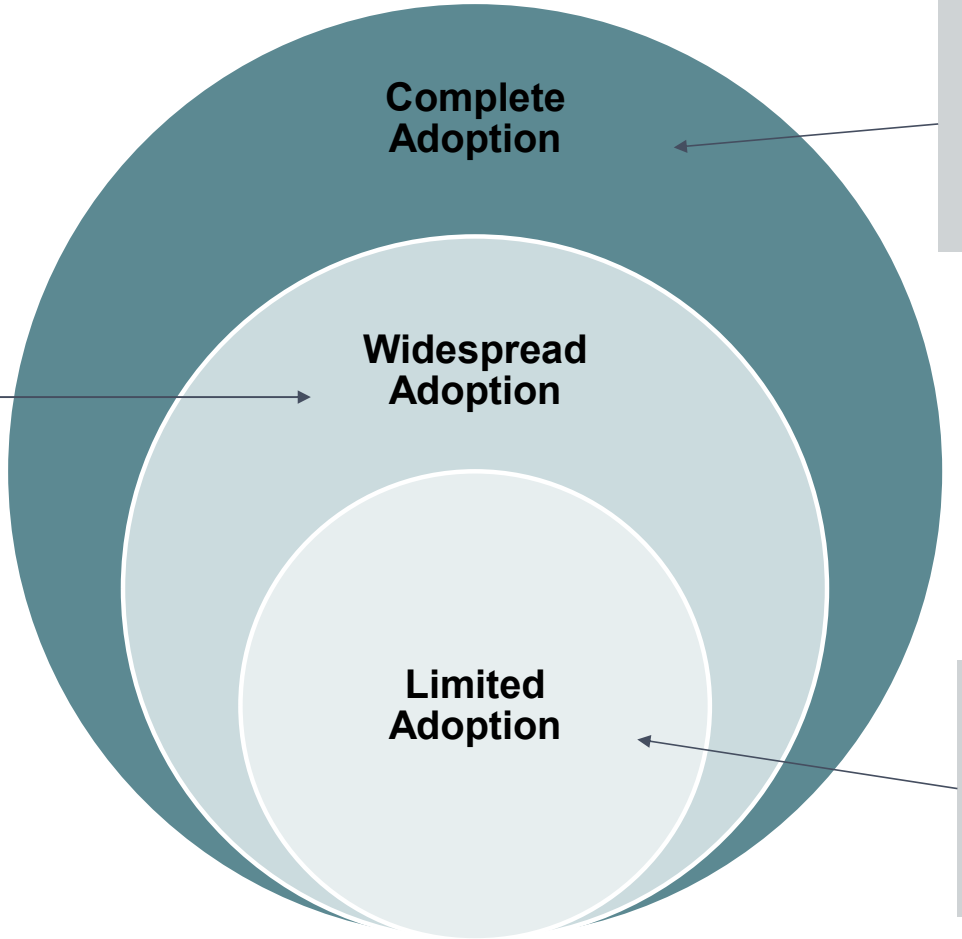
Period B



Containment requirements drive all manufacturers to switch to NGI-PV production

NGI-PV transition takes place over a 5-year period

Remaining DCVMs transition to NGI-PV production over a 5-year period

Initial NGI-PV developers remain the only NGI-PV producers

No additional growth to the NGI-PV market in Period B

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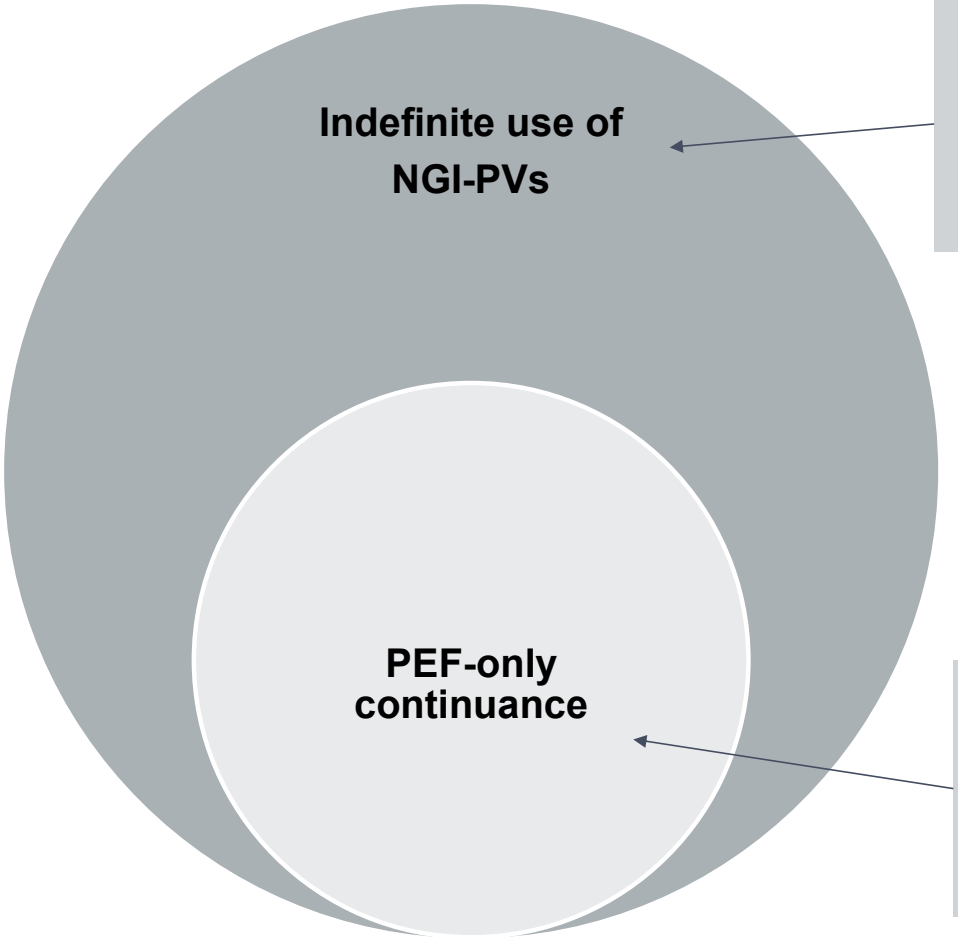
Period C

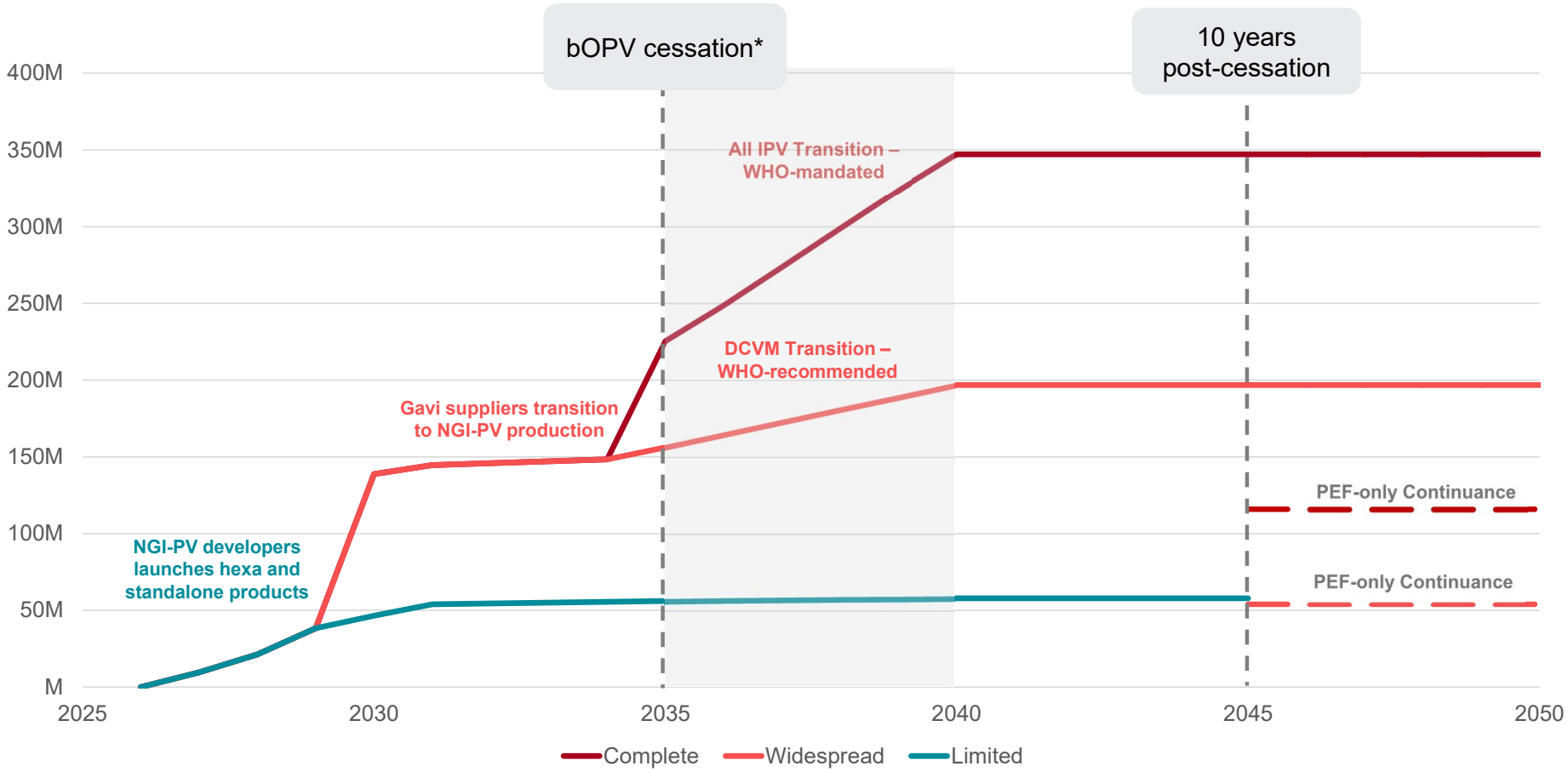


Countries continue to use NGI-PV as in Period B

PEF countries continue NGI-PV usage

Remaining countries cease polio vaccinations

NGI-PV Demand Scenarios



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Market Risks and Opportunities

Potential Risks

- Non-combinability of VLP products for hexa formulation
- Market exits from traditional IPV suppliers if NGI-PV production is required
- Demand for NGI-PV vaccines may outstrip supply until larger manufacturers transition production
- Managing a shrinking IPV market as countries transition to hexa

Potential Opportunities

- Lower-priced IPV-containing vaccines
- Reduced barrier to market entries for DCVMs if PEF requirements are lessened for IPV manufacturing

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Appendix

Market Segment Definitions

NGI-PV scenarios rely on demand forecasts from the Global Vaccine Market Model (GVMM). The following market segments are referenced in the creation of NGI-PV demand forecasts:

Market	Market Segment	Definition
Gavi	Manufacturers actively developing NGI-PVs	Producers with NGI-PV products undergoing clinical trials Market-level demand based on share assumptions for IPV and Hexa markets derived from previous market analysis and partner intel
Gavi	Fast follower manufacturers	Producers communicating an interest in developing NGI-PVs Market-level demand based on share assumptions for IPV and Hexa markets derived from previous market analysis and partner intel
Gavi	Other DCVMs and Gavi suppliers	Remaining Gavi demand for IPV and Hexa
Non-Gavi	Price-sensitive	Country-level demand from the bottom 20% of non-Gavi countries by health spending per capita (WHO 2022)
Non-Gavi	Non-Gavi countries using DCVM polio vaccines	Excluding the price-sensitive segment, countries likely using polio vaccines from DCVMs based on 2024 JRF feedback and partner intel
Non-Gavi	Remaining polio vaccine production	Remaining non-Gavi demand from countries using polio vaccines of any form

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