

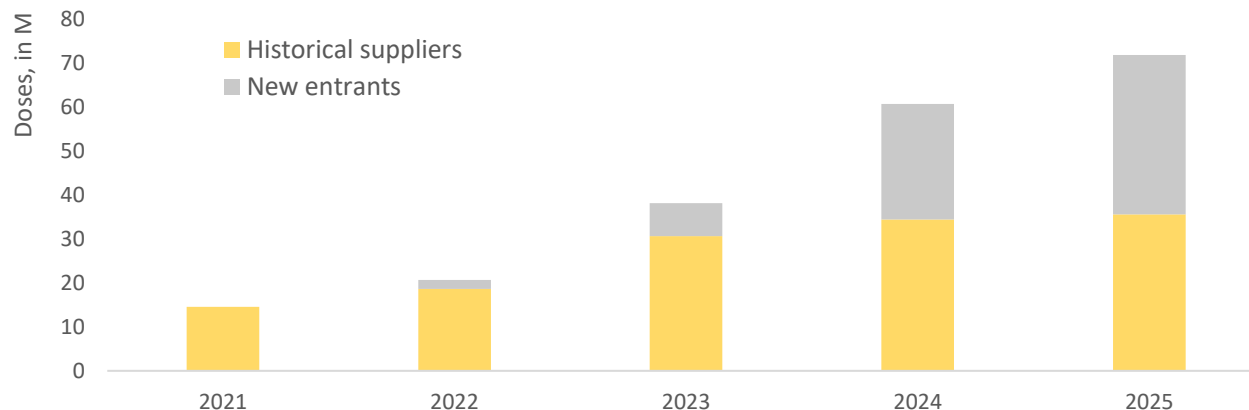
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Annex B: HPV volume forecast scenarios

Current programme design vs programme relaunch

Between 2022-2025, HPV2/HPV4 supply availability is expected to more than triple

Supply projection (base case scenario)



*2023 supply projection includes 6.8m doses offered by MERCK for the introduction of Nigeria (pending award and application review)

Only the supply projection scenario (base case) of HPV2/HPV4 used for the development of the volume scenarios presented in the subsequent slides is represented in chart above. Note that lower/higher alternative scenarios exist.

With the current programme design (2-dose & target age 9-14 yrs), 42m girls will be reached by 2025

Assumptions of current programme design

Schedule: 2-dose

Primary target : 9-14 years old

Vaccine preference: as per country application – no switch to new entrants assumed.

Routine prioritized over MAC support: countries, which have introduced prior <2022, have delayed their MAC due to the limited supply availability, have lost cohort of girls in the primary target 9-14 years old as they have aged out.

Routine coverage:

- First dose: 90% of DTP1 (WUENIC) / or HPV1 (WUENIC) for already introduced countries
- Last dose: 80% of DTP3 (WUENIC) / or HPVc (WUENIC) for already introduced countries
- 1 ppt increase per year, capped at 65%

MAC coverage:

- First dose: 95% of DTP1 (WUENIC) / or HPV1 (WUENIC) for already introduced countries
- Last dose: 85% of DTP3 (WUENIC) / or HPVc (WUENIC) for already introduced countries

Note: DTP1 & DTP3 as default as no accurate proxy currently exists due to lack of historical data on HPV. Methodology will be adapted when more data points will be available.

Implications

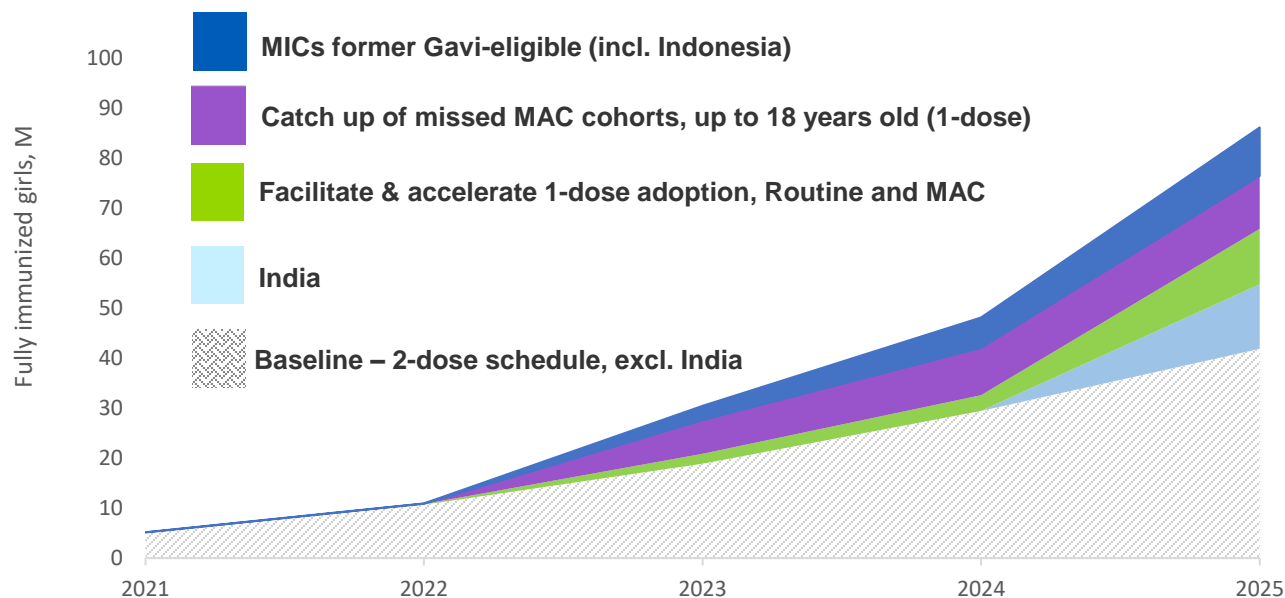
Demand forecast suggests that **most countries will be able to conduct their routine programme**. However, with regards to MAC:

- Countries with delayed MACs, i.e., introduced prior 2022:
 - **Inequity in access** for countries who started their routine at 9 or 10 years old as they would lose cohorts of girls in primary target
 - Countries who are conducting their routine at 14 years old will not lose girls but will experience **delays in implementation** (e.g., Ethiopia, Tanzania), resulting in programme complexity.
- Large countries introducing routine & MAC, may experience **delays in MAC implementation in 2023-2024** considering the base-case scenario of supply projection (e.g., Bangladesh)

Number of girls reached: >86m with programme relaunch

Current strategy vs programme relaunch scenario

Fully immunized girls in Gavi 57, for-eligible MICs, and India



44m additional girls through the relaunch

10m additional girls

10m additional girls

11m additional girls

13m girls

42m girls: baseline

By facilitating & accelerating 1-dose adoption, 11m additional girls could be reached in Gavi57

The additional number of girls reached through the programme relaunch (accelerating update of 1-dose, improve coverage) will only materialize with additional technical assistance, HSS investment, and learning agenda (e.g., out of school girls, delivery strategy etc.)

Assumptions of programme relaunch

Schedule:

- Routine & MAC on similar schedule
- 2023-2024: off-label use of single dose is a country-led decision occurring at different timelines as dependent on review and guidance from EPI, NITAGs and NRA for RI & MAC
- 2025: On-label use of 1 dose for historical manufacturers

Target:

- Primary target: 9-14 years old (1 or 2 doses)
- Extended target: 15-18 years old (only 1-dose) for countries with delayed MACs
- Vaccine preference: Single dose will be considered for HPV vaccine with available data

Routine coverage (9 to 10 years old):

- 10ppt increase for HPV1 and HPVc from methodology used for current programme design – see slide 3. For countries adopting 1-dose, coverage is only linked to HPV1.

MAC coverage:

- 5ppt increase for HPV1 from methodology used for current programme design – see slide 3.

Implications

Scale-up of 1-dose adoption from 2023, notably in large countries such as Nigeria & Bangladesh will:

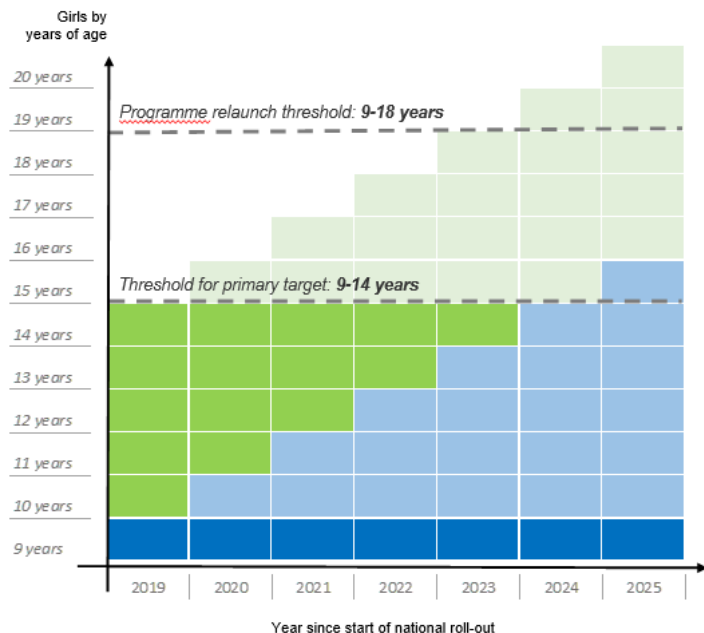
- **Ease supply** for additional RI introductions (e.g., Pakistan) and MAC support within 5.0/5.1 (e.g., Tanzania (+5 cohorts), Bangladesh (+ 1 cohort))
- **Increase coverage** due to the absence of drop-out in countries adopting 1-dose.

Note: Countries with a preference for the 2-dose schedule, could consider **alternative products** which are pending data on 1-dose.

By catching-up MAC missed cohorts, an additional 10m girls could be reached in Gavi57 by 2025

The additional number of girls reached through the programme relaunch (accelerating update of 1-dose, improve coverage) will only materialize with additional technical assistance, HSS investment, and learning agenda (e.g., out of school girls, delivery strategy etc.)

Catch-up of missed cohorts **up to 18 years old** for countries with delayed MACs & entire cohorts of girls that have aged out of the primary target (> 14 years of age)



Implications

- Countries with delayed MACs (see slide 3), i.e., **introduced prior 2022**:
 - Will be allowed to **catch up their missed cohorts** that have aged out of the primary target **up to 18 years old**.
 - Despite this approach will allow to catch up most of the missed cohorts, **some cohorts will still be missed**, as some have aged beyond 18 years, e.g., Senegal, Côte d'Ivoire, Cameroun, Liberia.
- An additional **10m girls could be reached** through the implementation of this strategy **out of the 15m girls estimated to be missed by end of 2025**

MICs (former eligible Gavi, including Indonesia) can reach 10m girls if decision making (product choice, schedule, target) is accelerated

Assumptions of programme relaunch

- **Former-Gavi countries could access Gavi prices and supply if favorable conditions are agreed with suppliers**
- **Former-Gavi countries yet to introduce HPV are:**
 - Angola
 - Azerbaijan
 - Cuba
 - Kiribati
 - Indonesia
 - Mongolia
 - Nicaragua
 - Timor-Leste*
 - Ukraine
 - Viet Nam

Note: The June 2022 Gavi Alliance Board approved 'Middle-Income Countries approach' aims to address access issues, including to sustainable pricing, through a range of support modalities and collaborations with UNICEF Supply Division to facilitate pooled procurement mechanisms.

Implications

- Support is available to former-Gavi countries through Gavi's MICs Approach to accelerate new vaccine introductions (incl. on decision making around products and schedule).
- If former-Gavi countries becomes part of the Gavi supply support, the introduction timeline of routine and MAC support with historical suppliers in 2023 will largely depend on the adoption of 1-dose (both by themselves and by other countries).
- E.g., **Indonesia**, which aims at introducing both routine and MAC in 2023 will have to consider trade-offs in their product choice:
 - *Option 1:* In **Indonesia**, the adoption of permissive 1-dose will have economic benefits. However, within the pre-agreed Gavi supply, **Indonesia** could only introduce with historical suppliers from 2024 (1 year of delay) unless UNICEF SD and manufacturers increase award for 2023 pending application and confirmed demand.
 - *Option 2:* Thanks to their strong school health programme, the 2-dose schedule should have limited impact on their performance. Therefore, opting for new entrants would allow **Indonesia** to introduce as per their initial plan (in 2023) and avoid delays in the implementation of their routine and MAC.

13m girls could be reached in India by accelerating their request for Gavi-supported doses

Background to India's HPV programme

- Introduction of HPV vaccine in the country's Universal Immunization Programme (UIP) has been recommended by the NTAGI of India and has also been approved by the Hon. Health and Family Welfare Minister.
- HPV vaccine introduction will be in a phased campaign mode for girls aged between 9-14 years followed by routine introduction for girls at 9 years of age. Target girl cohort for HPV vaccination campaign is estimated to be around 68 million and target girl cohort (9 years) for routine HPV Vaccination is estimated to be around 11.2 million every year.
- For routine immunization, two dose schedule will be adopted for the indigenous vaccine in the initial years. Subsequently, based on the results of indigenous HPV vaccine single dose trial, a single dose schedule may be adopted for routine immunization in 2026 onwards.

Gavi support

- Per Board approved India strategy, Gavi will provide support for approx. 22m doses between 2024-2026.
- To access these doses, it will be important for country to make a formal request to Gavi (process TBD).
- Request will need to include country level decision making workshop, technical assistance, schedule product preference, target, introduction date, geographical phasing
- Assumption reflected in forecast: National roll-out of the RI and phases 1 & 2 of MAC from 2023 with domestic funding and indigenous doses*. The 3rd phase of MAC will be supported by Gavi and implemented in 2025-26, with vaccines with proven single-dose efficacy, for ~10m doses in 2025 and 2026, respectively**.

*Volume that could be procured with Gavi's support in 2025-2026 will depend on India & other countries' decision on product/schedule. Awards for Gavi supply is not yet granted for 2026. It is thus subject to evolve. Additional supply may be available earlier/later for a varying quantity.

**Indigenous doses are assumed on 2-dose schedule as pending evidence for 1-dose schedule.

Risks

- Schedule, product choice & timing of introduction of large countries as main driver of the number of girls reached (e.g., Pakistan, Indonesia, India)
- Challenges along the **decision pathway** for single dose
- Countries may want to stay on **2-dose for RI and 1-dose MAC**
- Countries product preferences & timeline for the evidence on **1-dose for new entrants** (exp. 2024-27).
 - In the interim, an accelerated adoption of 1 dose schedule may put at risk long-term competition and market health, with higher reliance on historical manufacturers.