Global HPV vaccine market

Update on supply & demand of HPV vaccine products

Paul Bloem

WHO IVB

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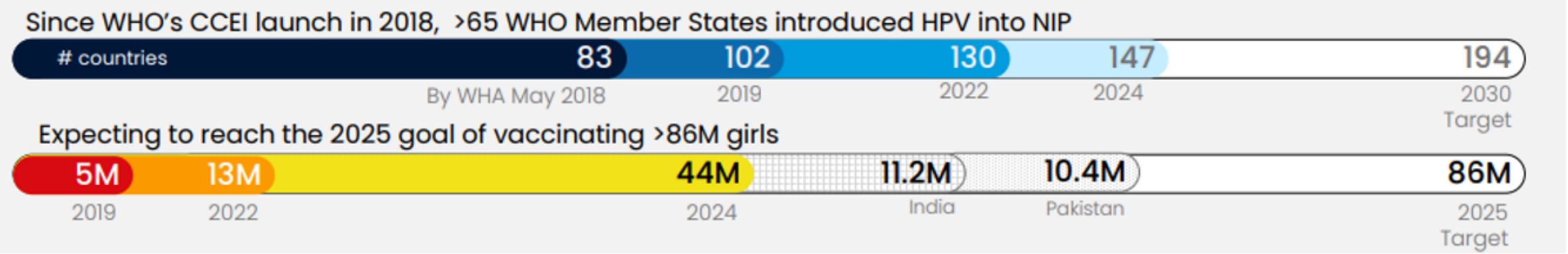
HPV vaccines : Key drivers of demand/supply balance

Cervical Cancer Elimination Initiative & Global Strategy shifted the discussion from *Should we introduce* to *When*?



GAVI HPV programme enabling factor for LMICs

Secondary targets: Catch up & Male vaccination

World Health Organization

Introduction Status | Introduction Year | Delivery strategy | Targeted Sex | HPV1 coverage | HPVc coverage | Schedule (interval between doses)

Global Map area

Country profile area

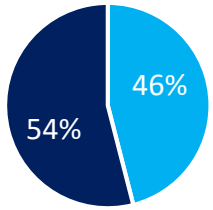
Coverage Analysis Global/Regional

Effectiveness studies

149

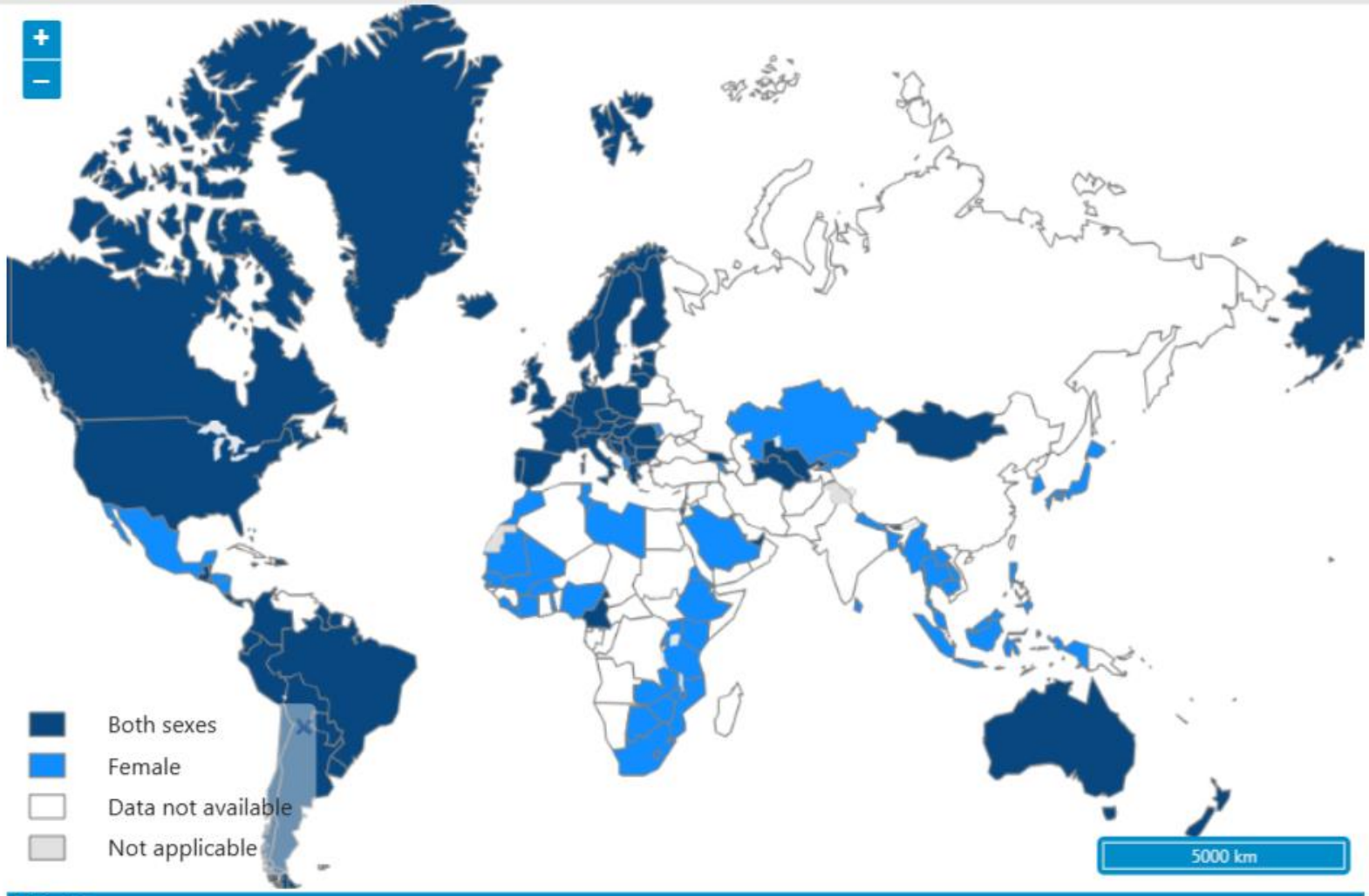
Total countries reported

HPV Sex	No. of countries
Female	68
Both sexes	81

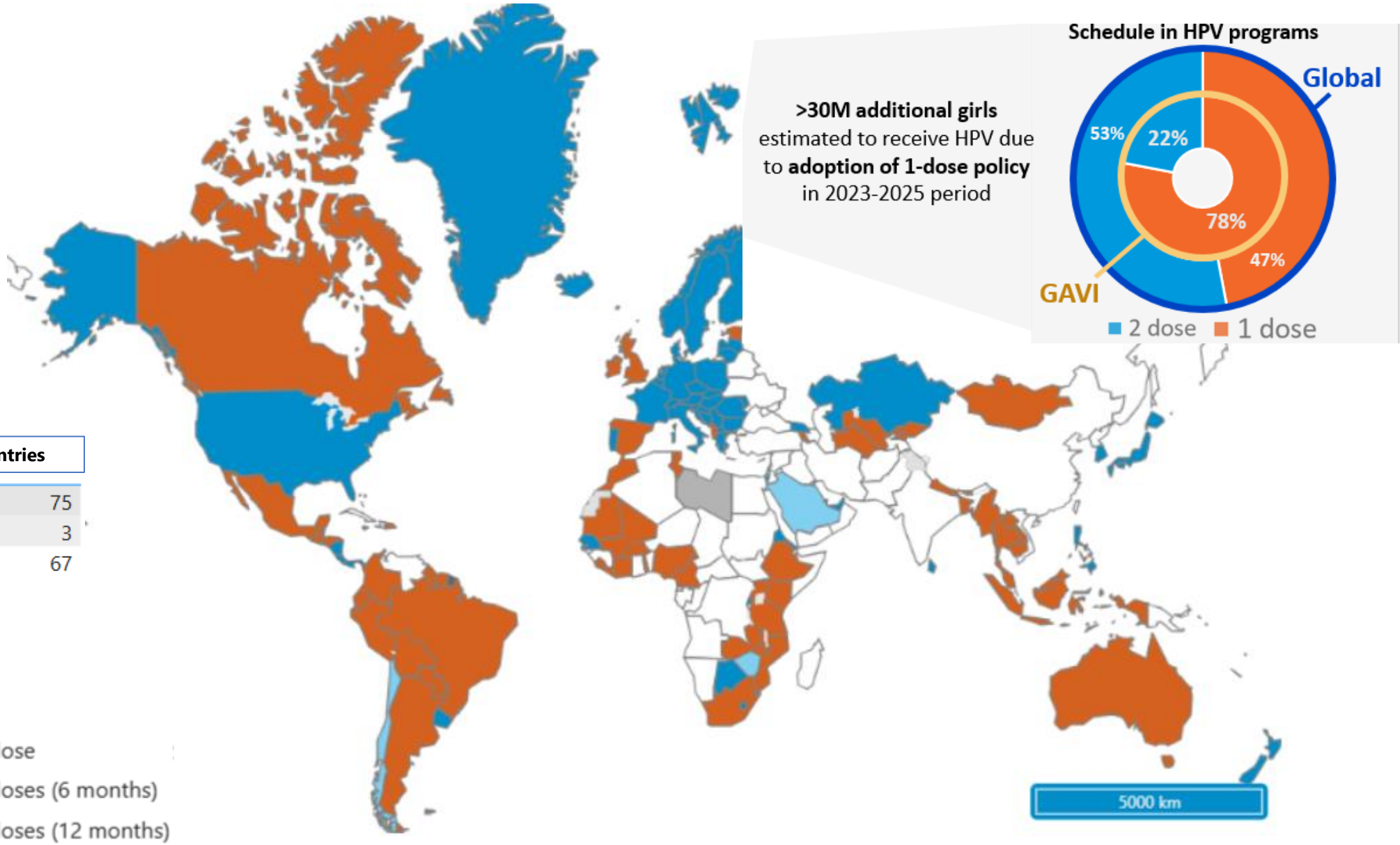


Females Both sexes

HPV vaccine included in national immunization programme, by targeted sex



Single dose HPV schedule adoption (girls 9-14yr) changed the programming landscape



Schedule # doses (interval)	# countries
1 dose	75
2 doses (12 months)	3
2 doses (6 months)	67

>30M additional girls estimated to receive HPV due to **adoption of 1-dose policy** in 2023-2025 period

Source: WHO HPV Dashboard, June 2025

HPV vaccines – overview of manufactures & Tech transfer

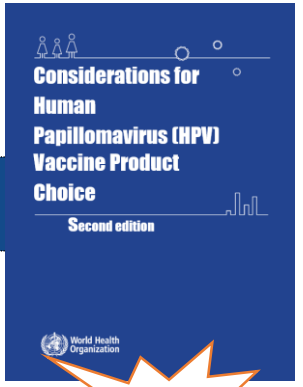
WHO PQed indication	Marketed products	1-dose
Merck/MSD **Gardasil** 4v & 9v	Licensed globally / WHO prequalified Adjuvant: Alum Sched.: 2 doses (9-14) or 3 doses (15+) Pres.: 1 dose vial (PQ) / PFS (non PQ)	1-Dose VE data
GSK **Cervarix** 2v	Licensed globally / WHO prequalified Adjuvant: AS04 Sched.: 2 doses (9-14) or 3 doses (15+) Pres.: 1,2 dose vial (PQ)/ PFS (non PQ)	1-Dose VE data
Xiamen Innovax (Beijing Wantai) **Cecolin** 2v	Licensed in China / WHO prequalified Adjuvant: Alum Schedule: 2 doses (girls 9-14) or 3 doses (women 15-45) Presentation: 1 dose vial / PFS	1-Dose VE data
Shanghai Zerun (Yunnan Walvax) **Walrinvax/Wo Ze Hui** 2v	Licensed in China / WHO prequalified *Adjuvant: Alum* *Schedule: 2 doses (girls 9-14) or 3 doses (women 15-30)* *Presentation: 1 dose vial*	
Serum Institute of India - SII **Cervavac** 4v	*Licensed in India (March 2023)* *Adjuvant: Alum* *Schedule: 2 doses (girls 9-14) or 3 doses (women 15-26)* *Presentation:* 1,2 dose vial	1- dose Trial ongoing
Xiamen Innovax (Beijing Wantai) **Cecolin 9v**	*Licensed China (June 2025)* *Adjuvant: Alum* *Schedule: 2 doses (girls 9-14) or 3 doses (Fem. 15-26)*	1- dose Trial ongoing

NEW

Marketed products - tech transfer	
Incepta (Bangladesh)	*Papilovax 2v* *Licensed from Innovax (TBC)*
Sinergium (Argentina)	*4v* *Licensed from Merck/MSD*
Inst. Butantan (Brazil)	*4v* *Licensed from Merck/MSD*
PT Biofarma (Indonesia)	*4v* *Licensed from Merck/MSD*
Microgen/Rostec (Russian Federation)	*4v* *Licensed from Merck/MSD (TBC)*

Distribution Agreements	
Chongqing Zhifei Biological Products	*China – Merck – Gardasil/Gardasil 9*

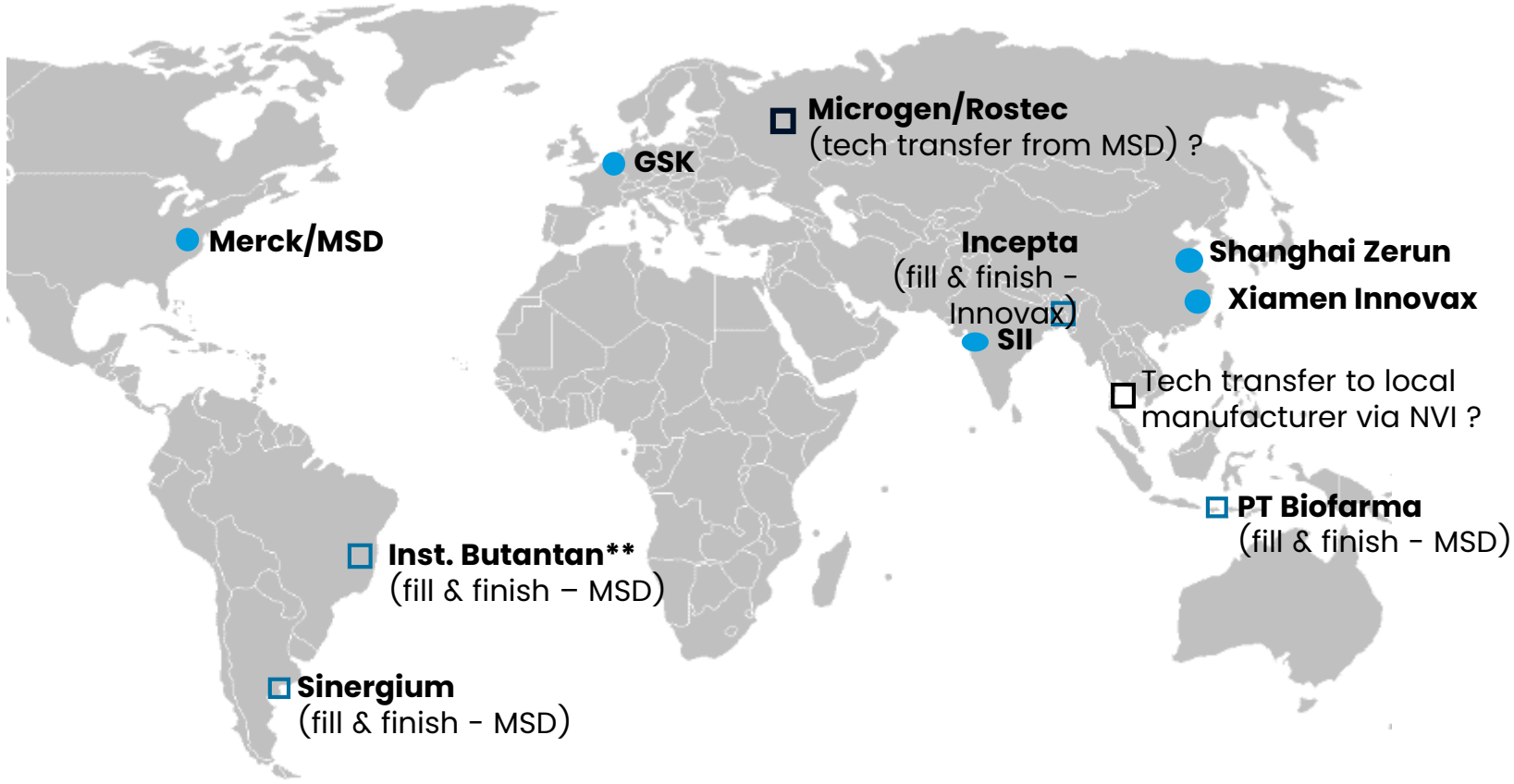
NEW



Source: 2023 WHO MI4A Market Intelligence

In parenthesis the holding company

HPV vaccine - Supply overview (marketed and tech transfers)



Disclaimer: map does not reflect the WHO / UN views
** Immunobridging study is sufficient for licensure in India / CIN2 efficacy is required in China*
*** Product in clinical development based on tech transfer*

Source: 2023 MI4A Market Intelligence

HPV vaccine - Supply overview

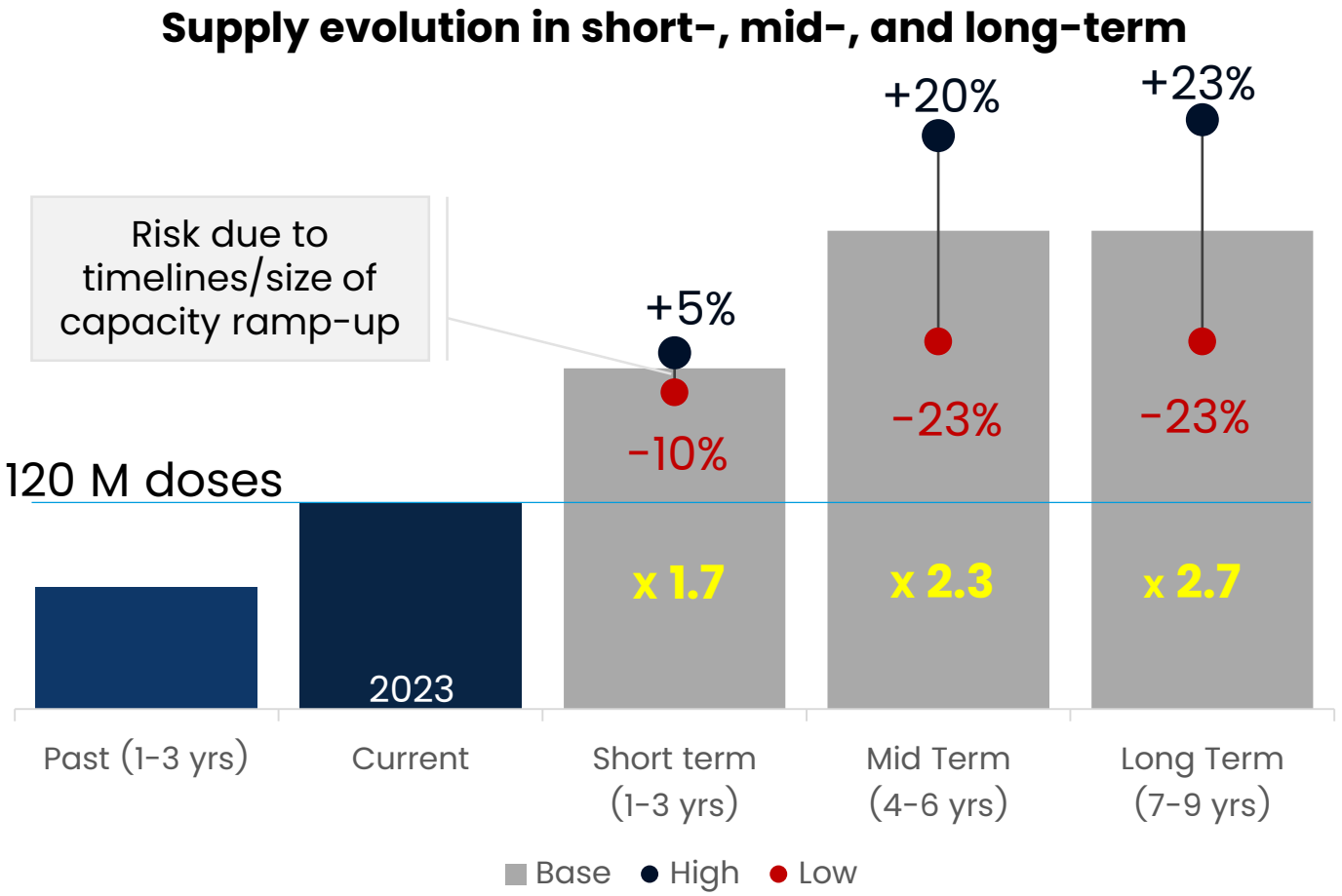
Product in Phase III clinical development	
Sinocelltech **China**	*SCT100 - 14v (female 18-45), NCT06041061 – started 2023* *Expected study completion 2028*
Shanghai Zerun (Yunnan Walvax) **China**	*9v (female 9-45) - started 2021*
RECBIO **China**	*REC603 - 9v (female 9-45) - started 2021* *Expected China licensure: 2026*
China National Biotech Group (CNBG) **China**	*4v (female 18-45) - started 2018*
Beijing Health Guard **China**	*4v (female 20-45) - started 2021*
Bowei Biologics **China**	*4v (female 9-45) - started 2021*

Implications

- HPV market evolving with new manufacturers and higher valency products
- Not all now producers /tech transfers will contribute to global market
- In mid to long term higher valent products (9+) could become more dominant
- This may also lead to higher average prices

Source: 2023 MI4A Market Intelligence

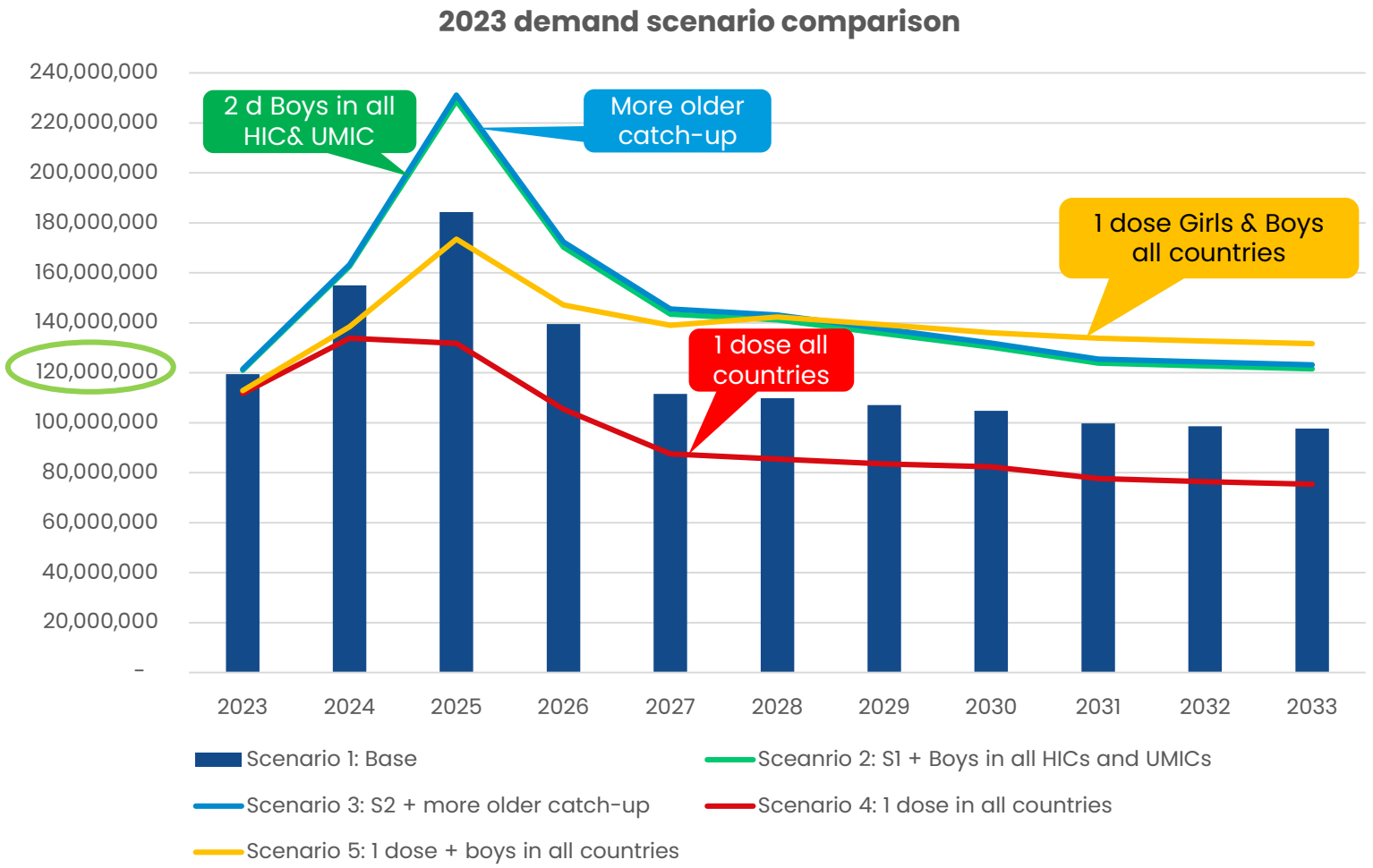
Available supply expected to increase - with steep mid-term ramp-up



- In recent past, **available supply for commercialization (ASC) grew approximately 25% per year to reach current ASC**, but insufficiently to serve demand.
- In **short-term growth will continue** driven by scale-up efforts of production come to market
- In **mid-term, ASC to increase significantly**, driven by manufacturer's development/scale-up efforts of new products primarily from China
- **In long-term, ASC to stabilize on a level defined by demand** dynamics
- Currently, **supply dominated by one manufacturer**. In second half of decade, market will differentiate with multiple suppliers (up to 5 with 4-5 with global focus).
- 9 valent to become dominant with entrance of new manufacturers (up to 4)

Source: 2023 update of WHO Global Market Study on HPV vaccines

Comparison of estimated HPV "Programme Demand" (PDR) between 2023 market study scenarios



Messages

- Demand stabilizes at ~100M doses/year in base scenario
- Gender neutral strategy in all HIC/UMICs results in highest short-term demand, driven by China
- Limited impact on PDR from older age catch-up[1]
- Assuming global transition to 1-dose demand forecasted to decline by ~25% compared to base
- ~130M doses/year required to support 1-dose + gender neutral globally (similar to prior base scenarios)

1. Improved data on extent of older age catch-up ongoing in countries could help to refine forecast assumptions and allow for great exploration of impact on global PDR

Supply demand balance

Supply increases in recent years have led to a **significant reduction in the risk of global shortages**. In the short-term, under the base supply scenario, access risks still exist if target populations significantly expand; in the low supply scenario this could result in shortages. In the mid-long term, excess supply will require appropriate management.

	Base Supply			Low Supply		
Demand Scenarios	**Short-Term (1-3)**	**Mid-Term (4-6)**	**Long-Term (7-9)**	**Short-Term (1-3)**	**Mid-Term (4-6)**	**Long-Term (7-9)**
1. Base (w/MACs)						
2. Base (+ w/boys , MACs)						
3. Base (+w/boys, MACs, older age catch-up)						
4. 1-dose w/MACs						
5. 1-dose w/MACs (+boys)						

*Single dose schedule supporting data assumed available since 2022 only for a limited number of products

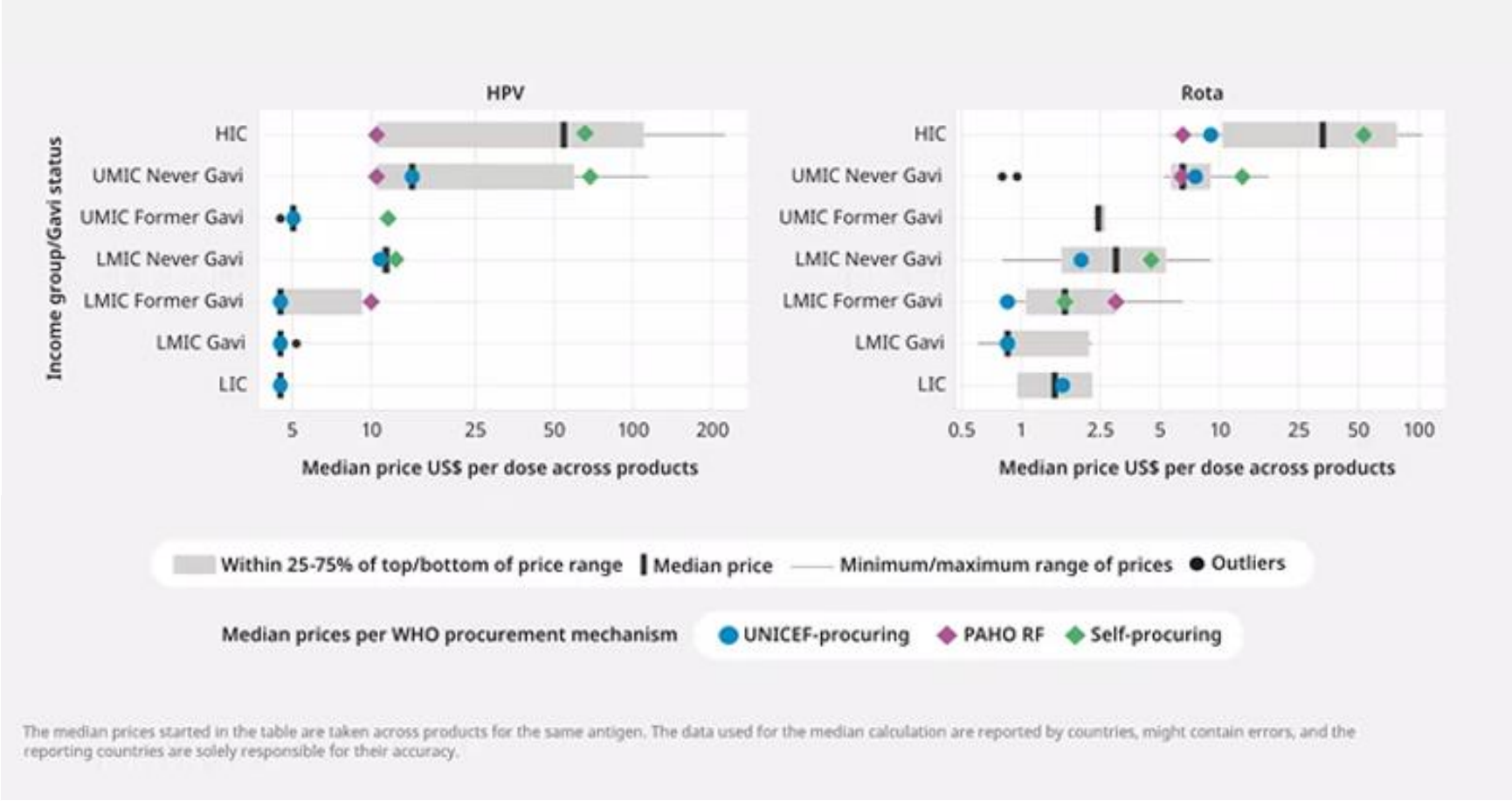
- Insufficient supply — Supply <1.1X Demand
- Some risk of shortages — Supply <1.3X Demand
- No risk of shortages — Supply >1.3X Demand
- Excess supply — Supply > 2X Demand

Source: WHO, MI4A 2023 Market Study

Globally, prices are tiered by income group, with opportunity to streamline

- Prices are tiered by income group
- Pooled procurement agencies are typically offered a single price for a given product for a specific pricing tier, exhibited via narrower price ranges
- Never-Gavi UMICs often exhibit wide price ranges and price overlaps with HICs
- Newer vaccines like HPV and rota, are more expensive and have wider price ranges, potentially due to the several different products on the market

HPV prices show a wide range by type of product, procurement & country



The median prices started in the table are taken across products for the same antigen. The data used for the median calculation are reported by countries, might contain errors, and the reporting countries are solely responsible for their accuracy.