HPV vaccine product landscape

&
Reflections on supply-demand balance and HPV vaccine market

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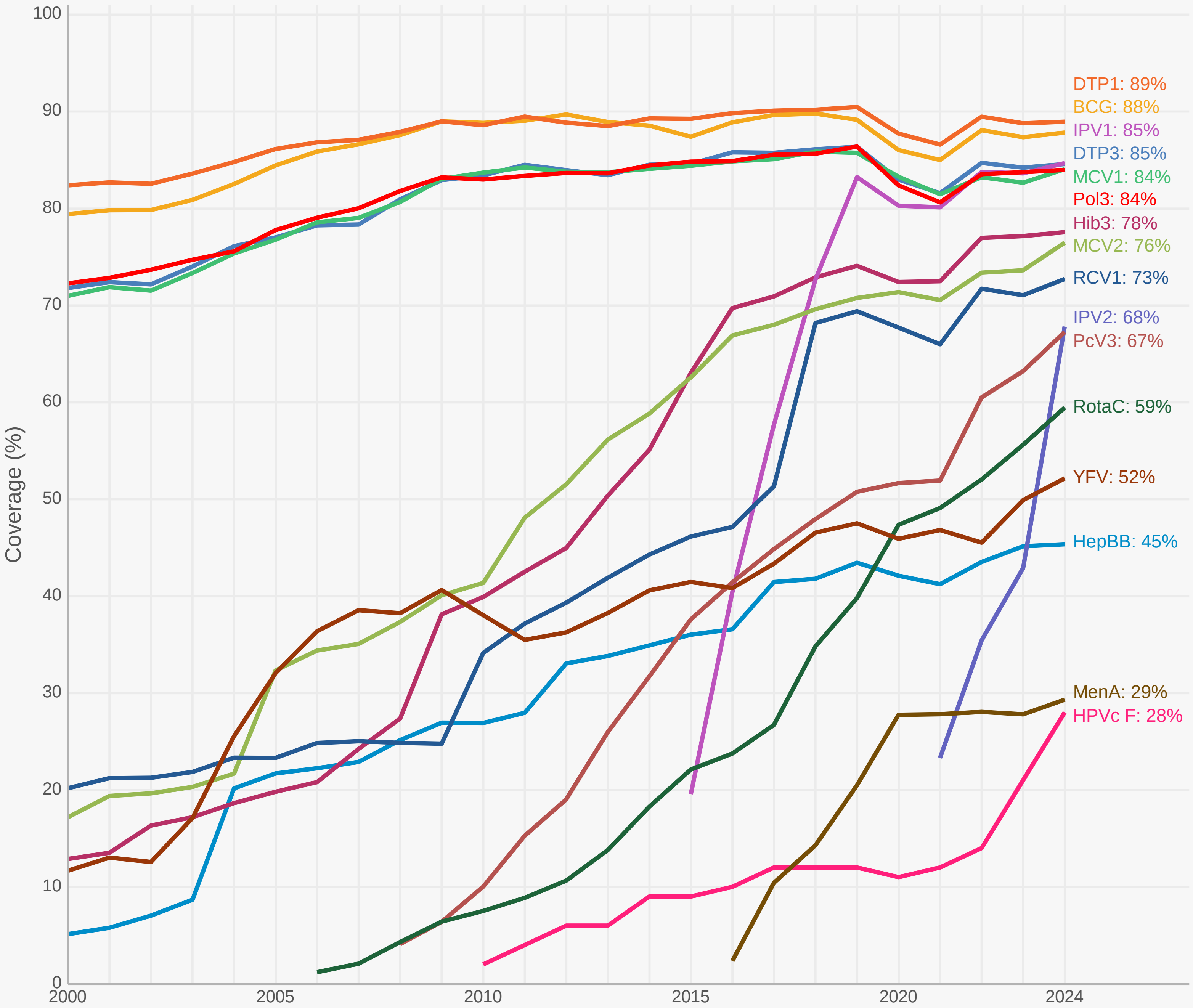
World Health Organization | IVB

Coverage trends for all vaccines with a global estimate

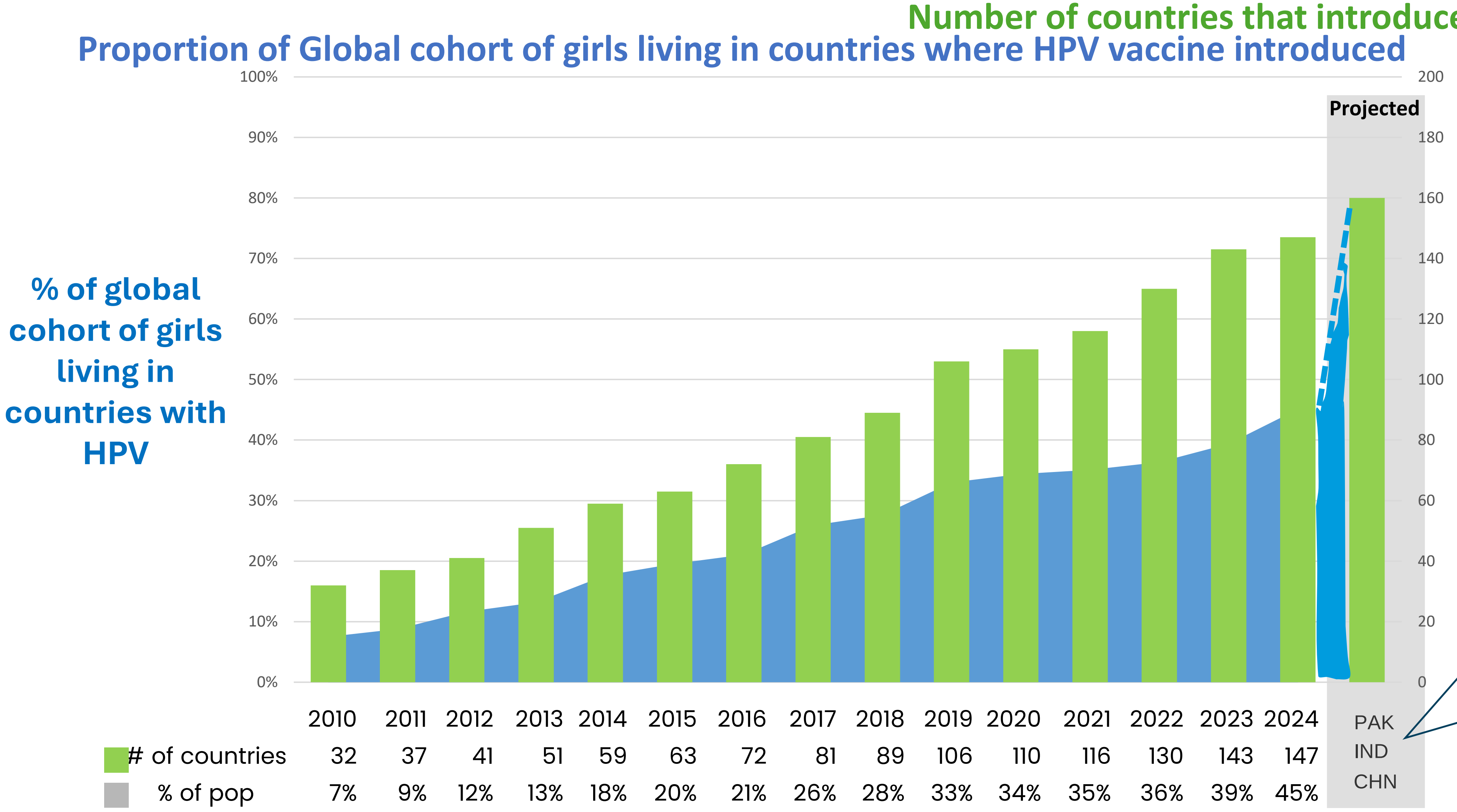
Among other vaccines for which WUENIC estimates are available, the steep increases in IPV2, PCV, Rotavirus and HPV are noteworthy.



World Health Organization unicef

By end 2025, 80% of all WHO Members introduced HPV vaccine

& nearly 80% of girls can access the vaccine



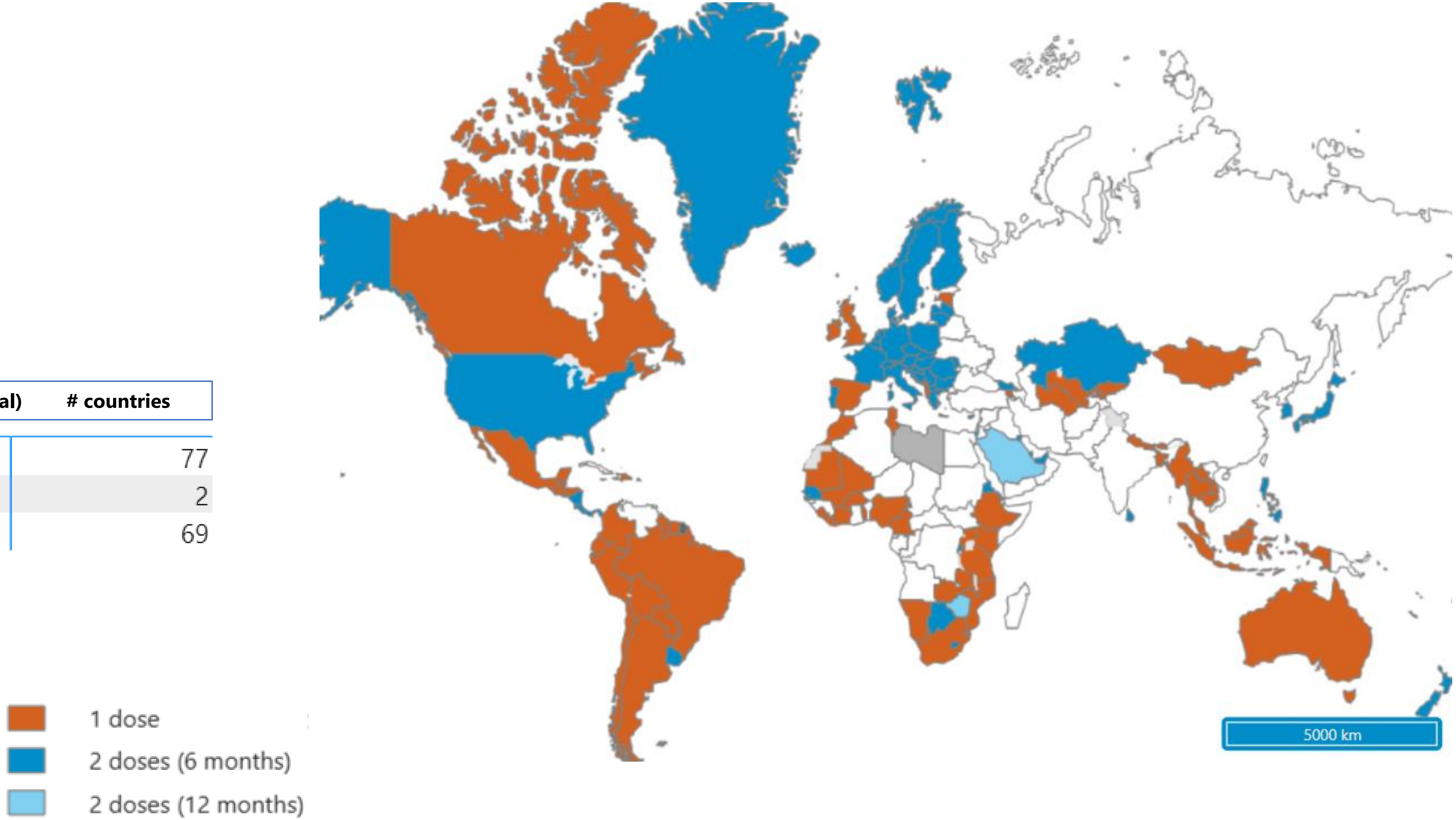
	2010	2011	2012	2013	2014	2015	2016	2017	2018	2019	2020	2021	2022	2023	2024
# of countries	32	37	41	51	59	63	72	81	89	106	110	116	130	143	147
% of pop	7%	9%	12%	13%	18%	20%	21%	26%	28%	33%	34%	35%	36%	39%	45%

Scale up & MACs in very large countries in 2025-26 will strongly increase population of girls protected and peak demand

Single dose HPV schedule adoption

=> drastically changed supply needs

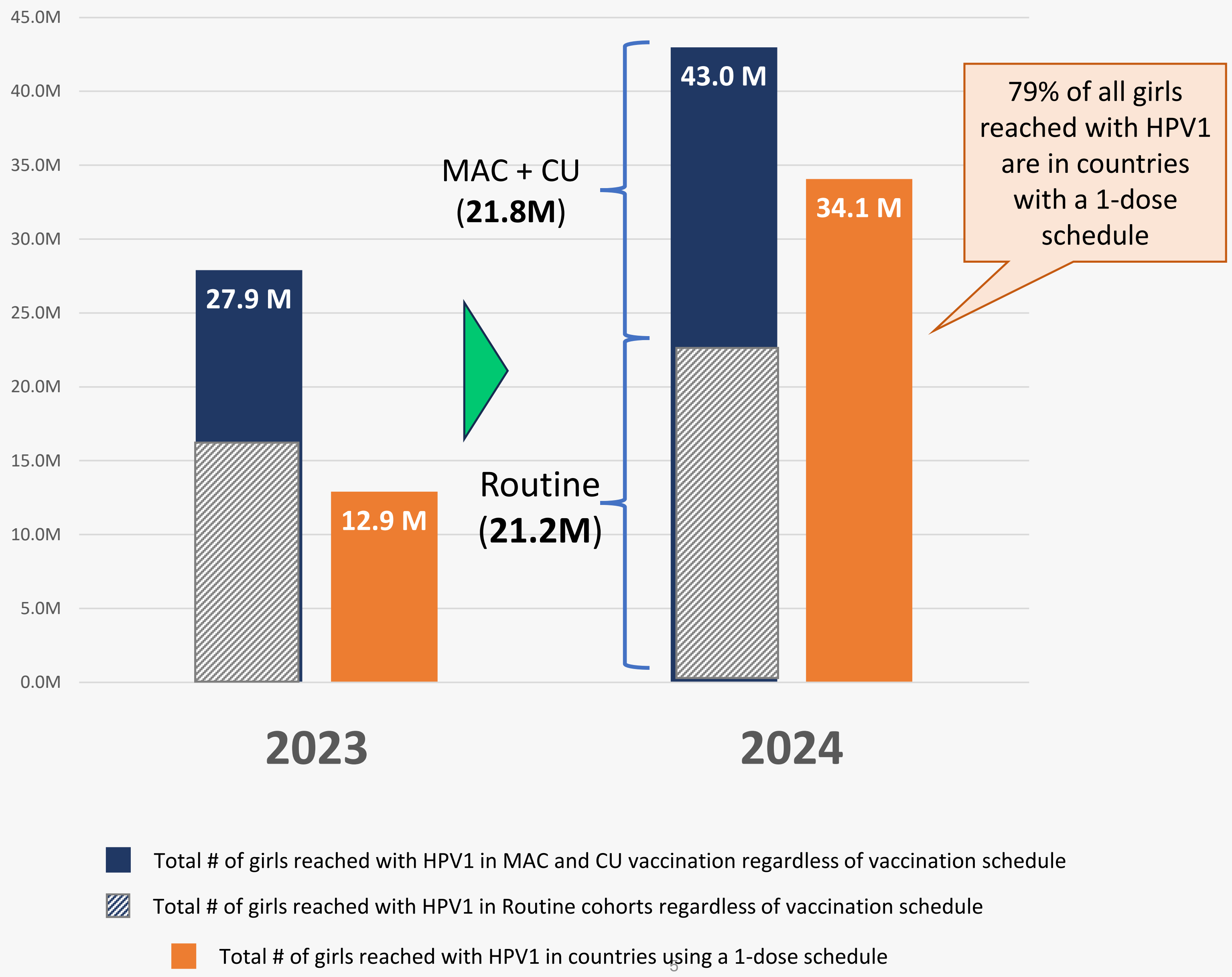
Schedule # doses (interval)	# countries
1 dose	77
2 doses (12 months)	2
2 doses (6 months)	69



Source: WHO HPV Dashboard, Oct 2025

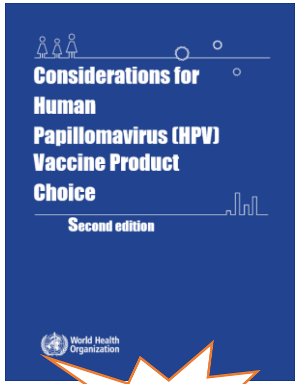
In 2024 a record 43m girls were reached with HPV vaccines - 79% of which on a 1-dose schedule

- National scaling up of phased introductions in two countries with large populations – Nigeria and Bangladesh – reached 4 M girls in routine and 10 M in catch up cohorts (MAC).
- Large MAC campaigns in Ethiopia (5 M) and Tanzania (4.7 M) also contributed to the high overall number of 43 M girls reached in 2024.
- Adoption of a 1-dose schedule has continued to increase to 65 in 2024.



HPV vaccines – overview of manufactures

WHO PQed	Marketed products	1-dose indication	GAVI Price
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	4.5 US$ **4V**
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	5.18 US$
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	2.9 US$
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*		2.8 US$
Serum Institute of India - SII **Cervavac** 4v Under REVIEW	**Licensed in India (March 2023)** *Adjuvant: Alum* *Schedule: 2 doses (girls 9-14) or 3 doses (women 15-26)* *Presentation: 1, 2^doses vial (TBC)*	**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

HPV vaccine – New entrants & higher valency products

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*

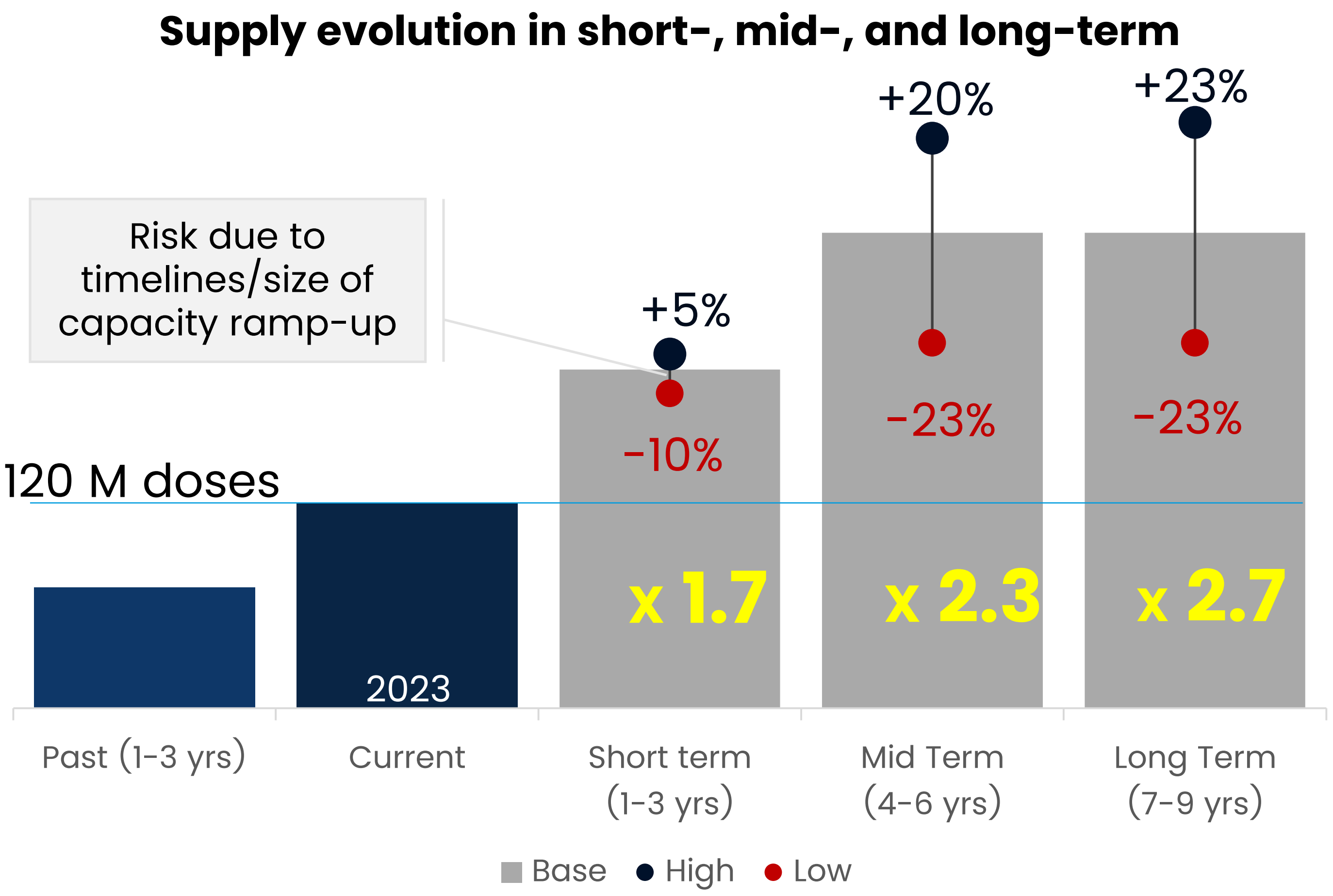
Source: 2023 MI4A Market Intelligence

Other Multi valent products (9+) under development by **SII & MSD**

Implications

- HPV market evolving with new manufacturers and higher valency products
- Not all new 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

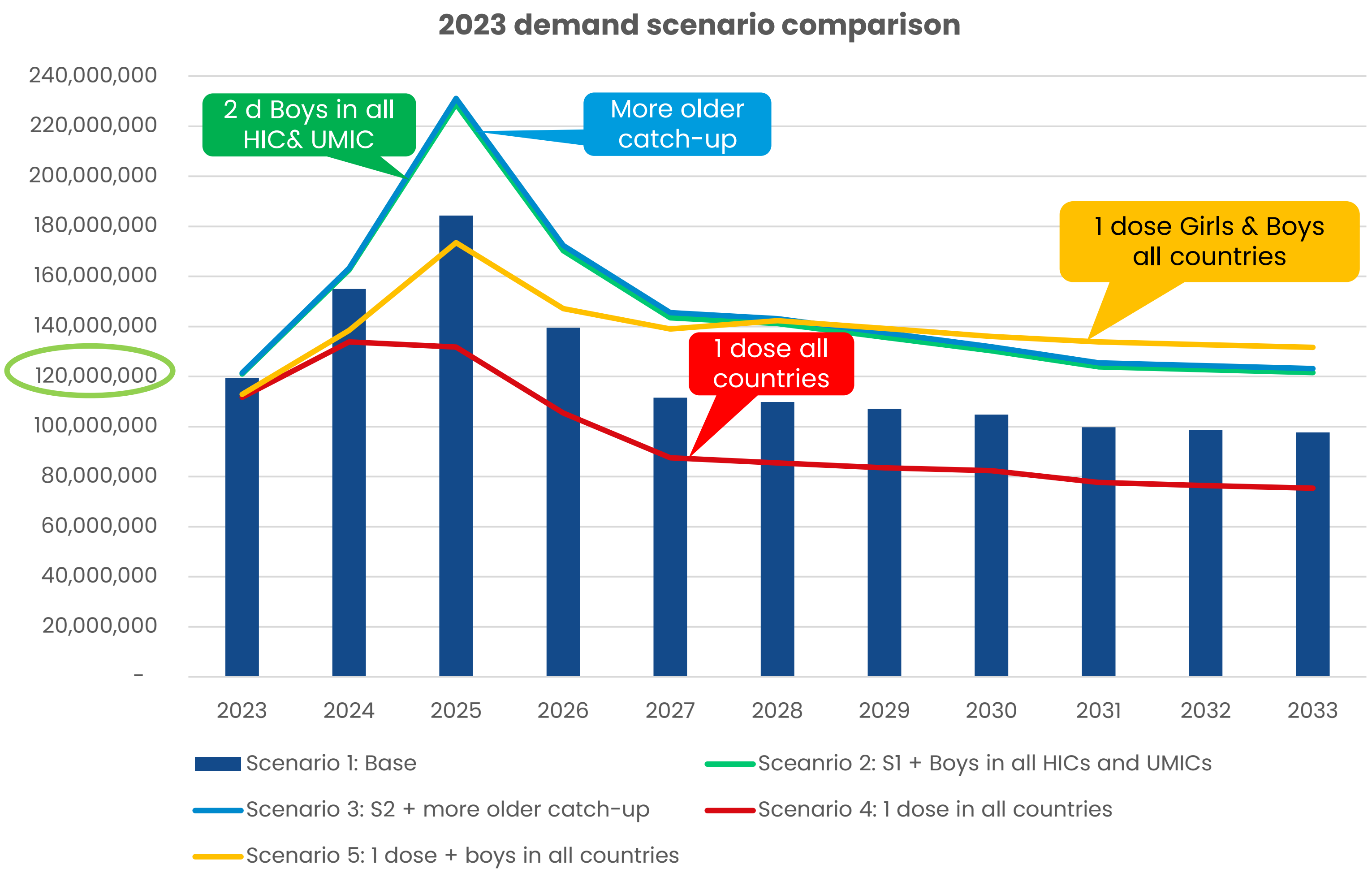
Available supply expected to increase - with steep mid-term ramp-up



- 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 <u>global</u> shortages**. In the <u>short-term</u>, 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 <u>mid-long term</u>, 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

Conclusions

- Increasing # of manufacturers & products in market and production capacity has increased supply availability
  - Risk of global shortages has strongly diminished , even in the light of strong demand
- Growing number of products (including Higher valency) increases choice and competition
  - Availability of lower prices in the market

Source: WHO HPV Clearing house