HPV vaccine supply landscape: current scenario and future perspective

HPV Board Technical Meeting
''Impact of COVID-19 on Cervical Cancer Screening, Treatment and Vaccination'' - 12 November 2020

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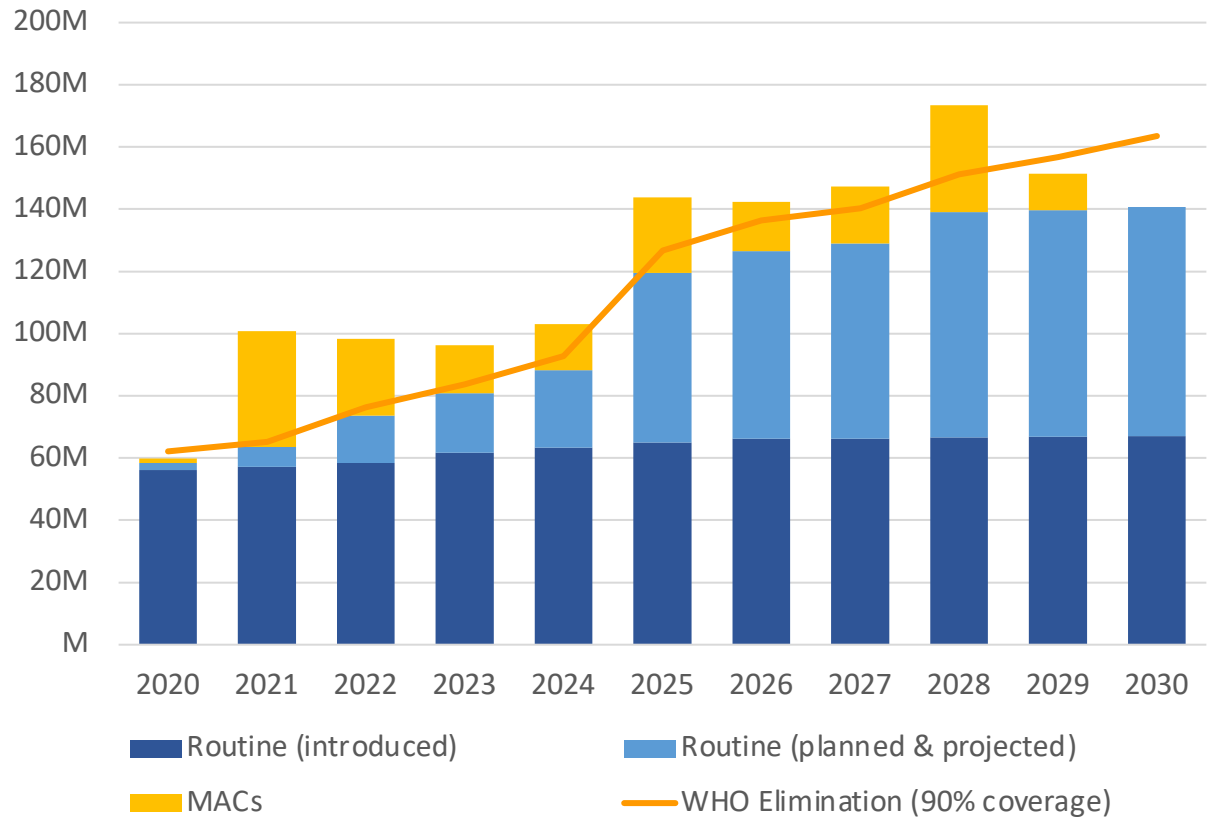
Recap of the HPV vaccine market situation: demand

The factors that led to sharp increase in demand curve for HPV vaccine

- A rapid shift from pilots to national programmes by countries receiving support for HPV vaccination from Gavi
- A recommendation by WHO to immunize a multi-age cohort (MAC) when introducing HPV vaccine
- A rapid shift by high-income countries from vaccinating adolescent girls to also vaccinating boys and adults

In 2020 WHO Member States have adopted the Global Strategy towards the elimination of Cervical Cancer: through national introductions in all countries and increased coverage, demand to reach **160M doses or more per year by 2030**



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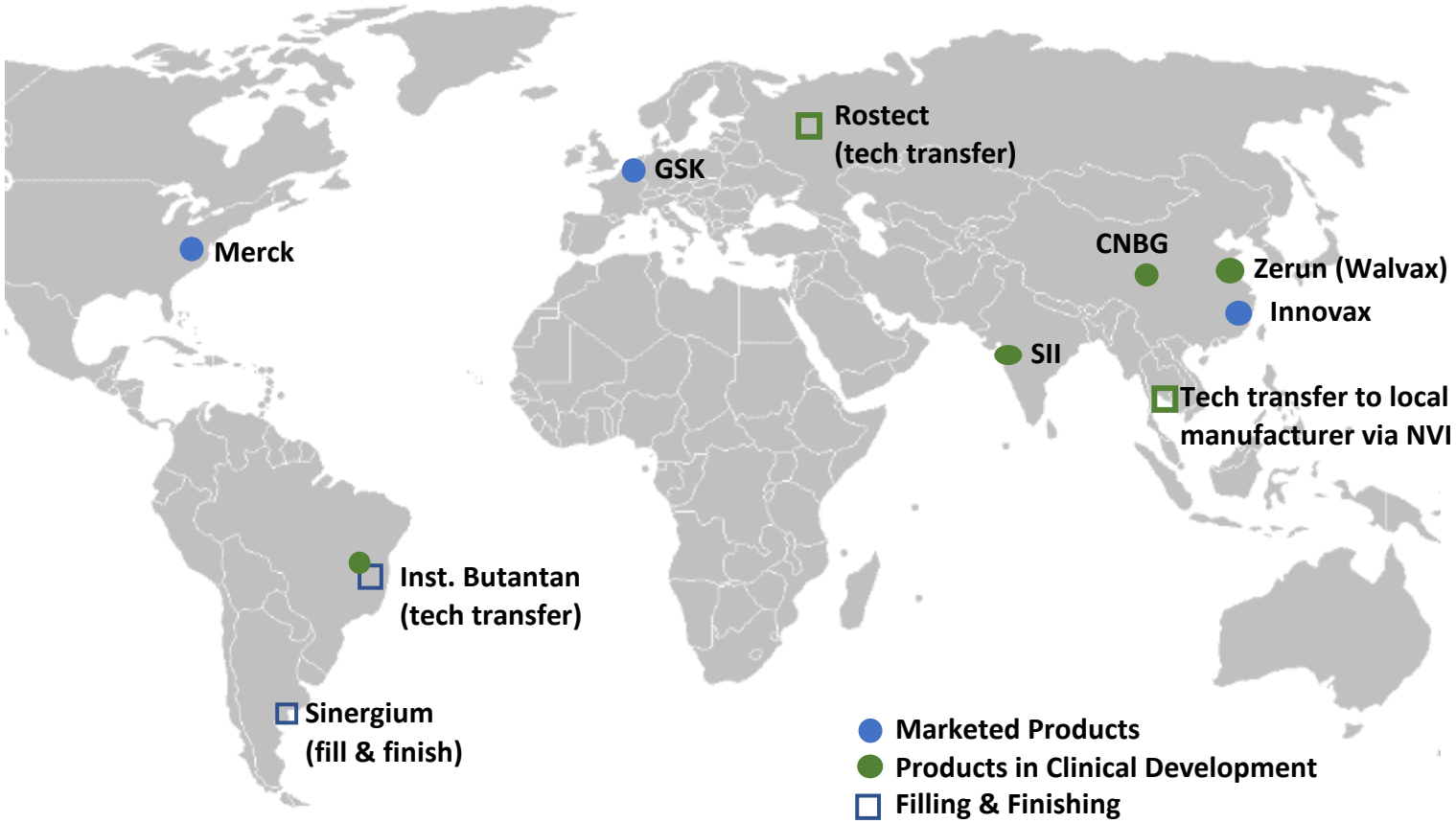
Recap of the HPV vaccine market situation: supply

Despite investments in in production, supply has fallen short of demand

- Supply constraints began in 2017/18: investment have been unable to keep up with sharp increase in demand
- Due to overriding country preferences for one product, one supplier reduced investments and considered market exit
- New market player joined since late 2019: currently there are 3 manufacturers with 2,4,9 valent products. 2 selling internationally
- 3 companies have products in phase III (2 and 4 valent)
- At least 2 more companies are working on tech transfers
- Price range reported: US 4.55 to US$178



Disclaimer: map does not reflect the WHO / UN views

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Short term perspective

- **Over the past 18 months, countries have calibrated their demand** - based on projected vaccine supply and in line with the WHO SAGE recommendation. For instance, they have mostly excluded immunizing multi-age cohorts (MACs) and postponed introductions.
- **Because of this and because of the downward pressure of Covid-19 on immunization rates, WHO estimates there is currently enough HPV vaccine, *in principle.***
- **However,** *in practice* there can still be mismatch between supply and demand and some countries may still be unable to serve their populations. This can be due to i) country preference for one specific vaccine product, ii) supplier allocation decisions, as well as iii) country plans to catch up on missed vaccination rounds due to COVID-19.
- In short, **demand and supply will require close calibration/management until around 2024.**

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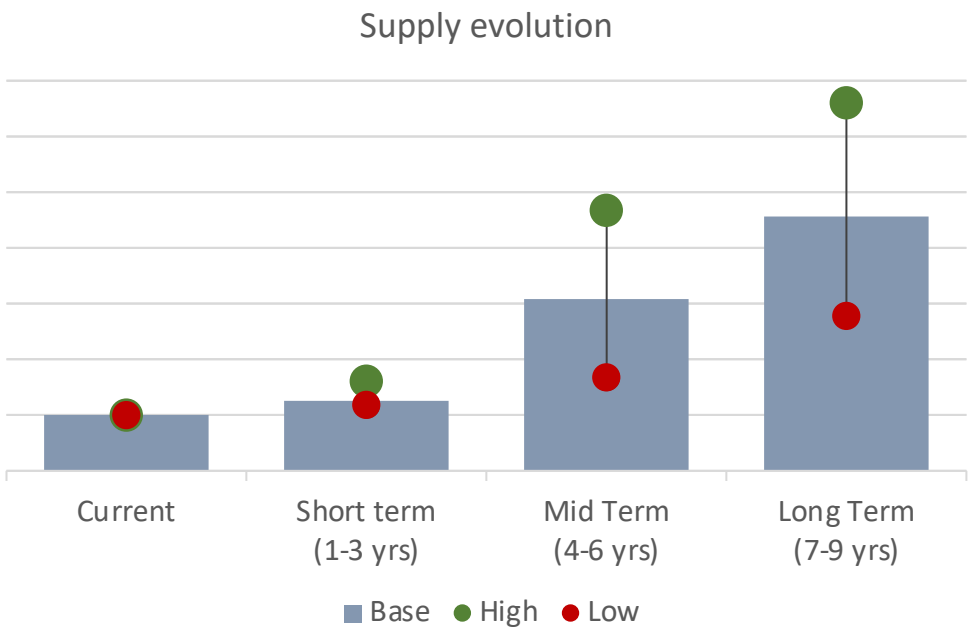
Long term perspective

- Supply to slowly grow in the short term, followed by steep ramp up from year 4-5
- Available supply for commercialization may vary by +/-50% driven by manufacturers decisions and success in development/scale-up
- **By 2024, the increases in production capacity should be in effect and the supply shortages resolve. Nevertheless, the ability to serve all countries and meet Global Elimination goals will depend on**
  a) success of development and investment efforts by companies and
  b) countries following through on their plans to introduce HPV vaccine, despite the numerous challenges raised by COVID-19 and
  c) country acceptance of different vaccine products.



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What's next?

The below factors will be key in optimizing access in 2021 and the scale-up of production through 2024:

- Acquiring visibility on COVID-19 impact on global HPV vaccine demand as well as supply and manage continuous alignment of supply and demand
- Advocating for country consideration of all available, quality-assured HPV vaccines;
- Enhancing the success, time to registration and prequalification as well as level of available supply from the manufacturers with licensed products and programmes in advanced stage of clinical development.
- Continue exploring opportunities to increase supply flexibility through optimized schedules

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HPV

GLOBAL MARKET STUDY
HPV

Key Takeaways

- Thirteen years after the first HPV vaccine registration, **53% of WHO Member States have introduced HPV vaccine** into their routine national immunization schedule. Supply constraints to low- and middle-income countries have resulted in a slower introduction pace in those geographies.
- WHO issued a call for action towards **global cervical cancer elimination** in May 2018 which, through national introductions in all countries and increased coverage, is estimated to increase total demand for HPV vaccines to 120M doses or more per year after 2025. Sizeable increases in supply will be required to serve this level of demand.
- **Supply is currently insufficient to meet demand.** According to the MI4A base case scenario, supply constraints are expected **until at least 2023/24.** This situation may change depending on: (a) operational programmes shifting to alternative vaccination strategies, as recently recommended by SAGE;[6] (b) country acceptance of all available HPV vaccines; (c) the pace of implementation of the investment decisions of current manufacturers; (d) the success, time to registration, prequalification and available supply from the three new manufacturers with programmes in advanced stage of clinical development.
- To address short-/mid-term supply constraints, SAGE recommended that all countries should temporarily **pause implementation of gender-neutral, older age group (>15 years) and multi-age cohort** HPV vaccination strategies as well as consider possible alternative strategies.
- In MICs not supported by Gavi or PAHO Revolving Fund, HPV vaccine can account for up to 56% of a country's total vaccine expenditure. **Affordability is frequently cited by such countries as a barrier** to introduction and to the sustainability of the programme.

QUICK STATS

NUMBER OF VACCINE SUBTYPES[1]
3

TOTAL NUMBER OF MANUFACTURERS[2]
2

2019 ESTIMATED GLOBAL SUPPLY[3]
~50M doses (maximum)

2019 ESTIMATED GLOBAL DEMAND[4]
~50M doses (supply constrained)

2018 REPORTED PRICE PER DOSE (RANGE)[5]
US $4.50–$168.00

6 Meeting of the Strategic Advisory Group of Experts (SAGE) on Immunization, October 2019: conclusions and recommendations. WHO Weekly epidemiological record, 22 November 2019, No. 47, 2019, 94 - https://apps.who.int/iris/bitstream/handle/10665/329962/WER9447.eng.pdf?ua=1 accessed November 26, 2019.

1 Vaccine subtypes differentiate by the antigen content of the various HPV vaccines; in this case, there are three distinct vaccine subtypes available on the market: HPV2 (16,18), HPV4 (6,11,16,18) and HPV9 (6,11,16,18,31,33,45,52,58).

2 This number indicates only the companies that have full manufacturing capacity and does not include licensed companies providing a portion of the manufacturing process or distributors that simply commercialize the product in some locations.

3 This is the "Available Supply for Commercialisation", defined as the number of doses available for sale at the global level in one typical year with normal production facilities utilization across the various vaccines (not factoring in special market, regulatory or technical events). This differs from the manufacturing capacity or the plant yearly throughput.

4 Demand refers to programmatic dose requirement.

5 The highest publicly reported price is the CDC posted private market price. Available at: https://www.cdc.gov/vaccines/programs/vfc/awardees/vaccine-management/price-list/index.html

WORLD HEALTH ORGANIZATION / GLOBAL MARKET STUDY 1 WORKING DOCUMENT / December 2019

WHO convenes a Global Dialogue as a multilateral discussion fora identifying specific actions to reduce supply risk, and contributing alignment of supply and demand

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WHO Global Market Study for HPV vaccines – 2020 Update (available as of November 17th): www.who.int/immunization/MI4A

Thank you!

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