

# MI4A Market Information for Access to Vaccines



Improving access to affordable supply  
Fair Pricing Forum, Johannesburg, April 12th, 2019  
Johanna FIHMAN, WHO



**World Health  
Organization**



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# Vaccine price transparency into context

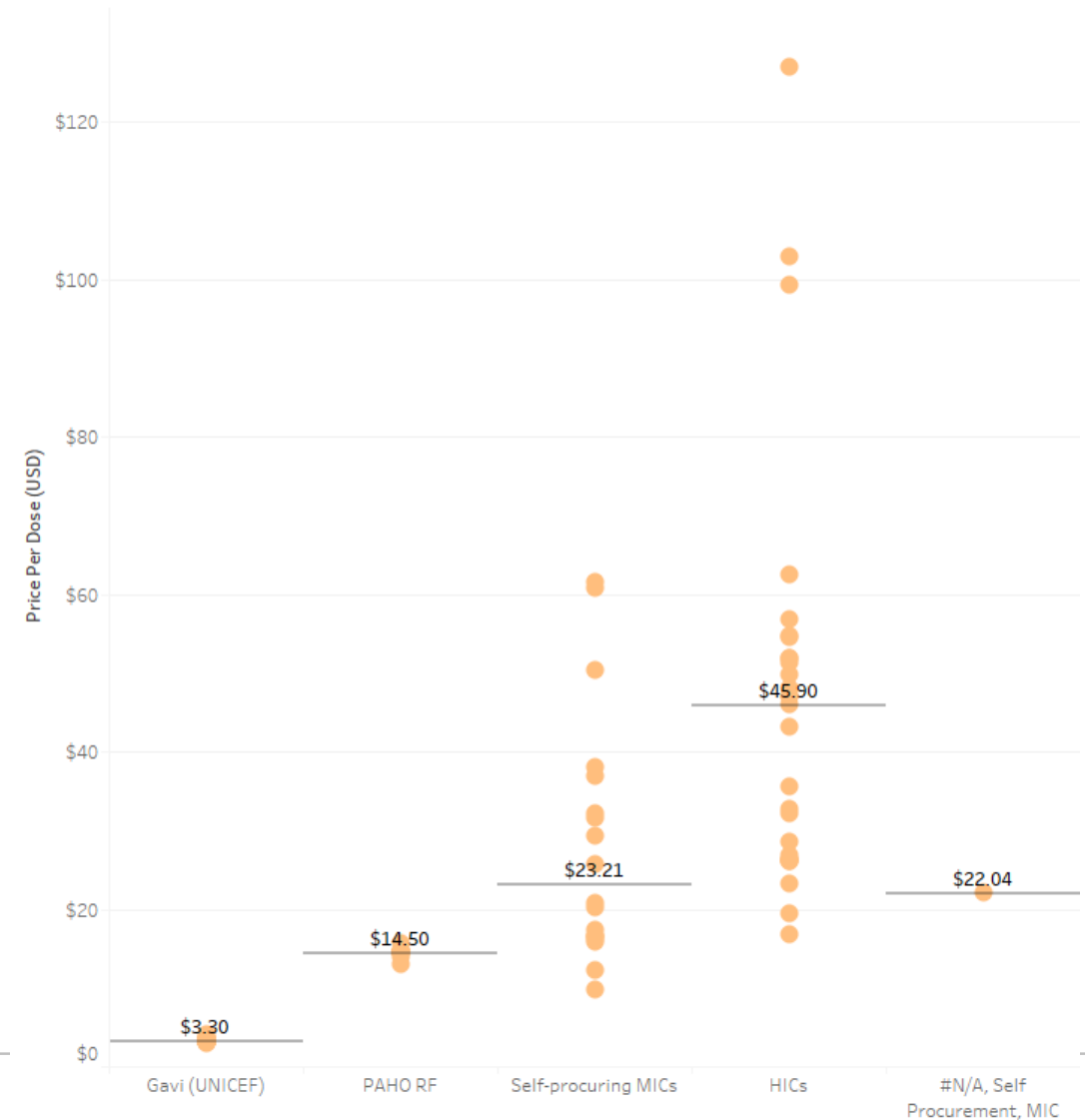
The access landscape for vaccines:

- Gavi the vaccine Alliance support to the poorest countries (73) of the world
- The Bill & Melinda Gates Foundation and other entities (e.g. PATH) are active in market shaping in the Gavi market
- UNICEF & PAHO act as pooled/centralised procurement entities

Vaccine Price is key to sustainable immunization programmes

Yet it remains one of main obstacles to access

2017 Country-reported Prices: PCV



# The WHA has repeatedly called for action on access to vaccine supply



- ❖ Total of 50 WHA Global Resolutions on access to medicines and vaccines + 45 regional Resolutions
- ❖ Over 60 member states spoke at 71<sup>st</sup> WHA on vaccine shortages, high prices, continuous need for information/support
- ❖ WHO Access Roadmap for 2019-2023 to enhance access to medicine and vaccines aligned with GPW13

# MI4A as part of the solution

How do we work?



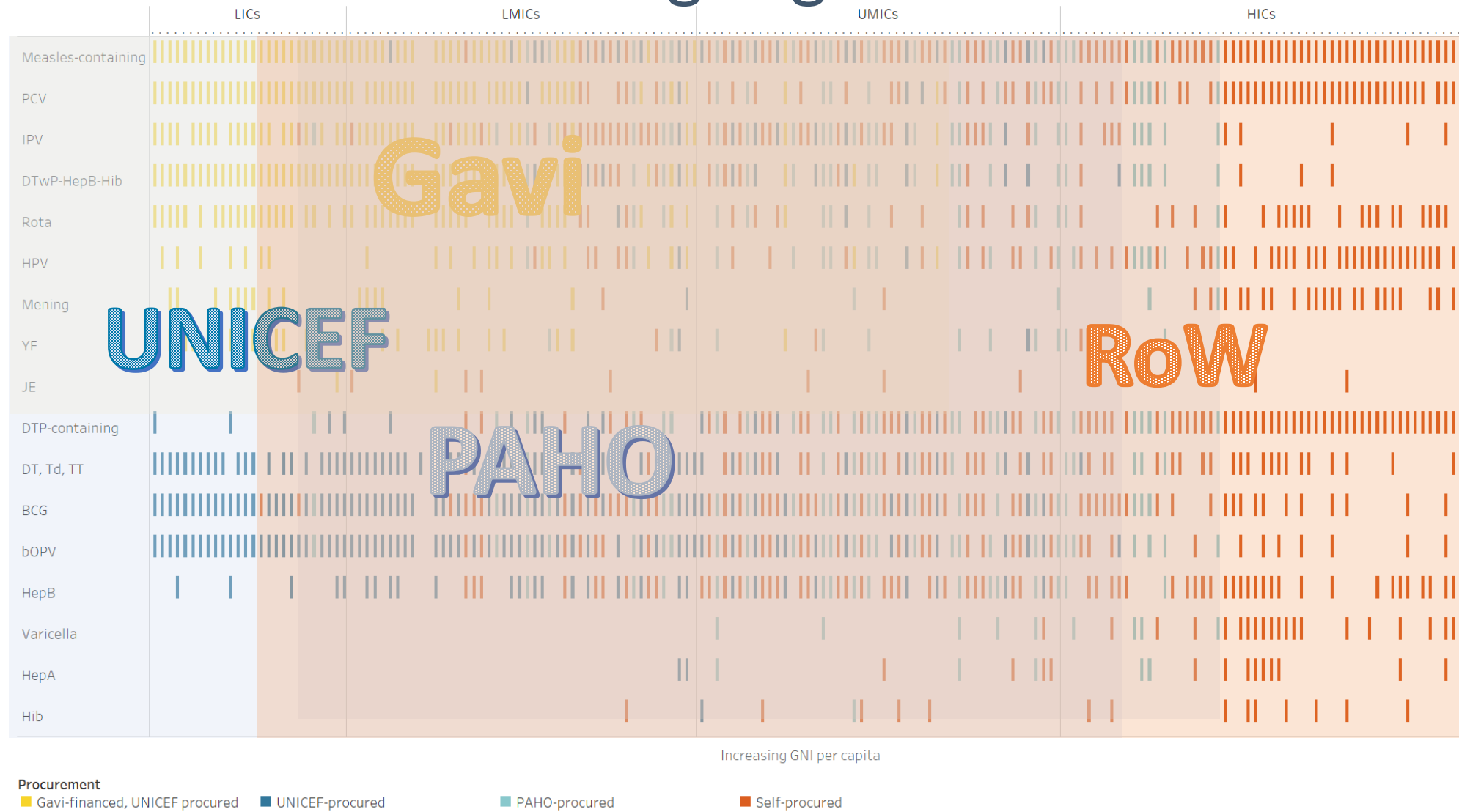
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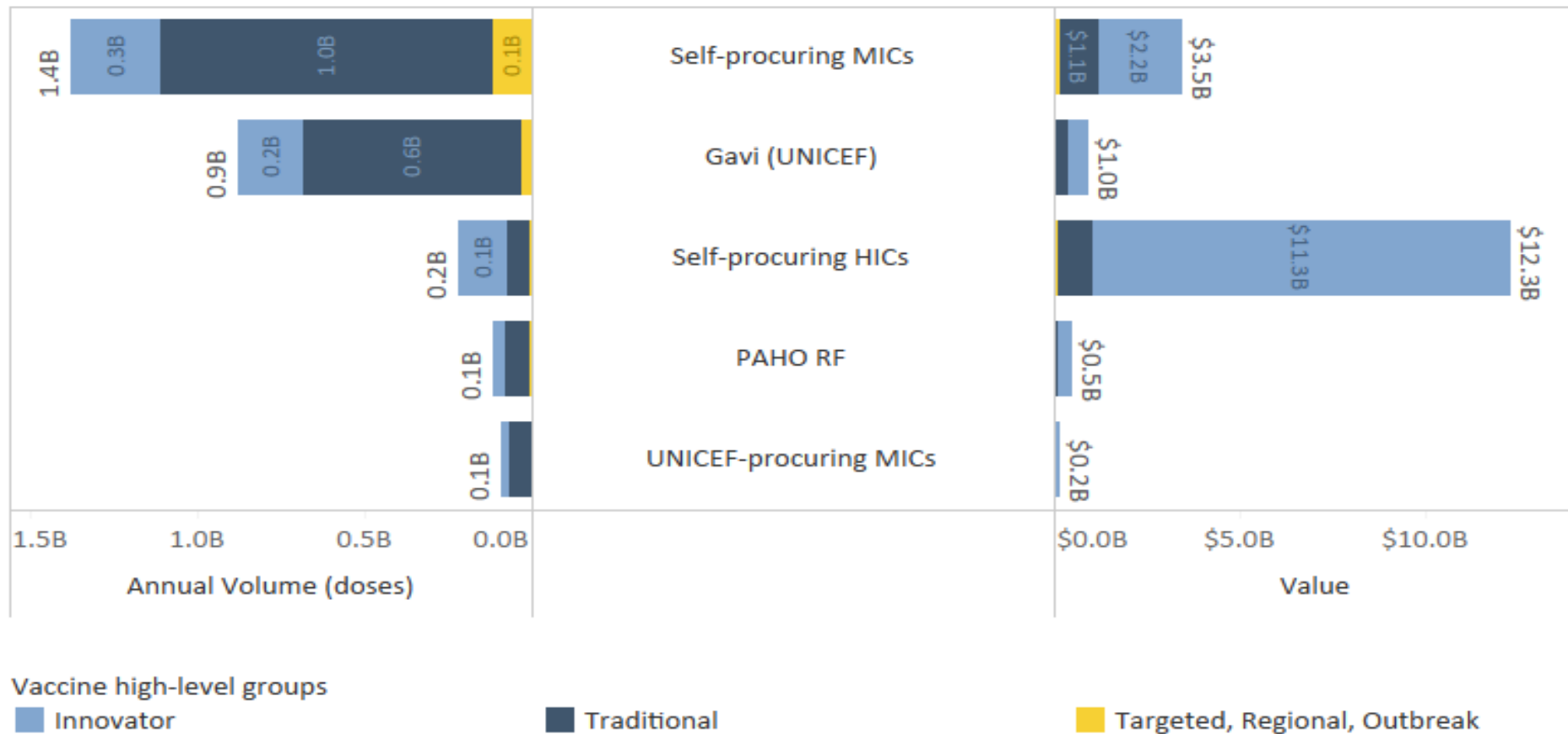
MARKET INFORMATION FOR ACCESS TO VACCINES



# Access efforts: the missing segment



# Self-procured/funded vaccines represent about 60% of market volumes and 90% of the value

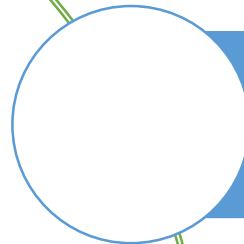


Source: MI4A Global Vaccine Market Report available at : [www.who.int/immunization/MI4A](http://www.who.int/immunization/MI4A)

# MI4A to inform global and local access strategies



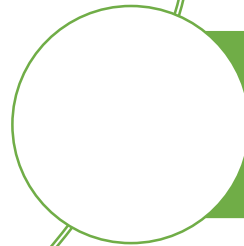
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Enhance the **understanding** of global vaccine demand, supply and pricing dynamics and identify affordability and shortage risks



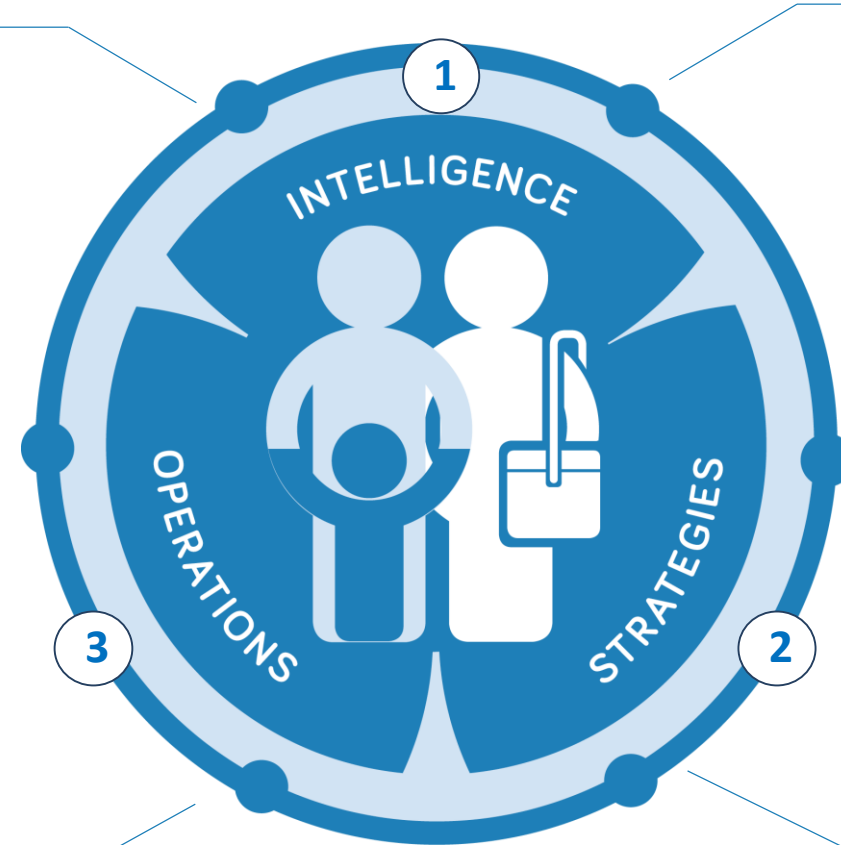
**Convene** global health partners to define strategies and guidance to address identified risks – focus self-procuring/funding countries



Strengthen **national and regional** market understanding for improved access to vaccines supply

*MI4A builds on the success of the V3P project and on 2017 successful BCG and D&T pilots*

# MI4A key areas of action



## 1.A Collection & quality control of **price/procurement/demand/supply data**

*Outputs: yearly updated data set with global vaccine market information made public*

## 1.B In depth global market analysis

*Outputs:  
2 global vaccine specific market studies yearly  
Global vaccine market report  
Study of specific market dynamics*

## 3.B Providing **technical assistance** to countries

*Output: countries supported to make appropriate use of available information*

## 2.A Information sharing ecosystem

*Output: policy makers, regulators, industry, countries, partners use information on relevant market dynamics to inform their actions*

## 3.A Developing **guidelines/tools**

*Output: e.g. transitioning country pricing fact sheet; MI4A country purchase fact sheets; MI4A regional fact sheets*

## 2.B **Guidance & strategies** to enhance affordability and availability

*Output: E.g. TT-Td replacement; SAGE recommendation on best use of scarce HPV supply*



# Key achievements

What progress have we made up to present?



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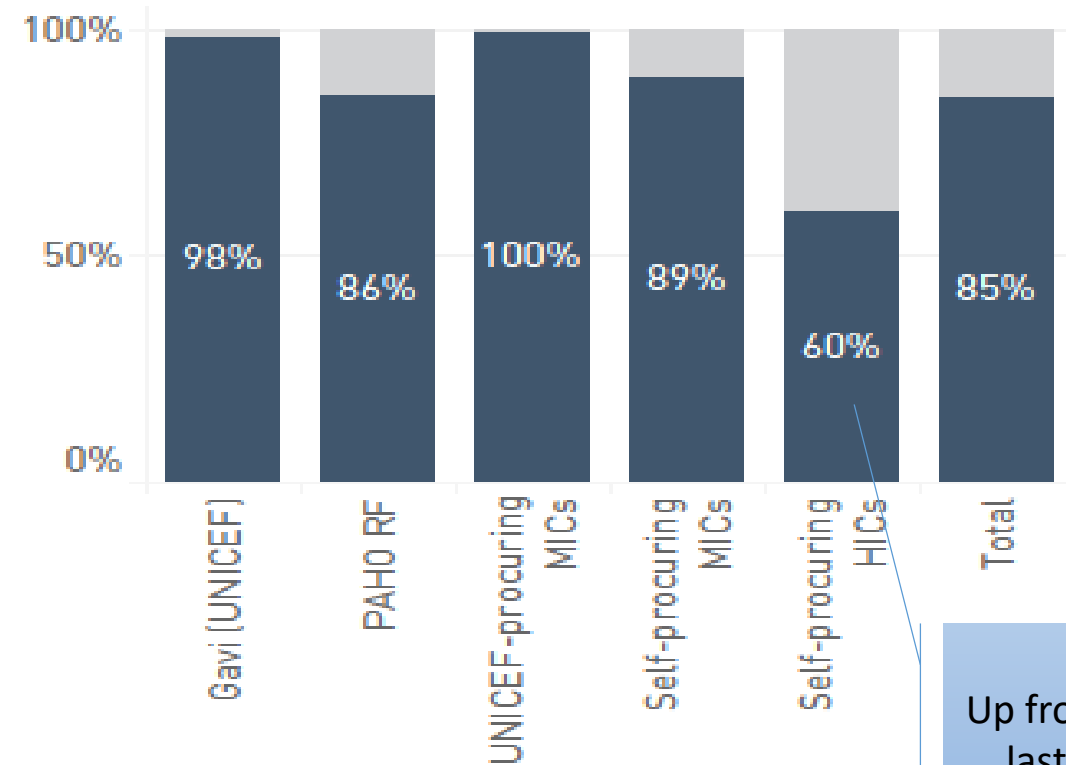
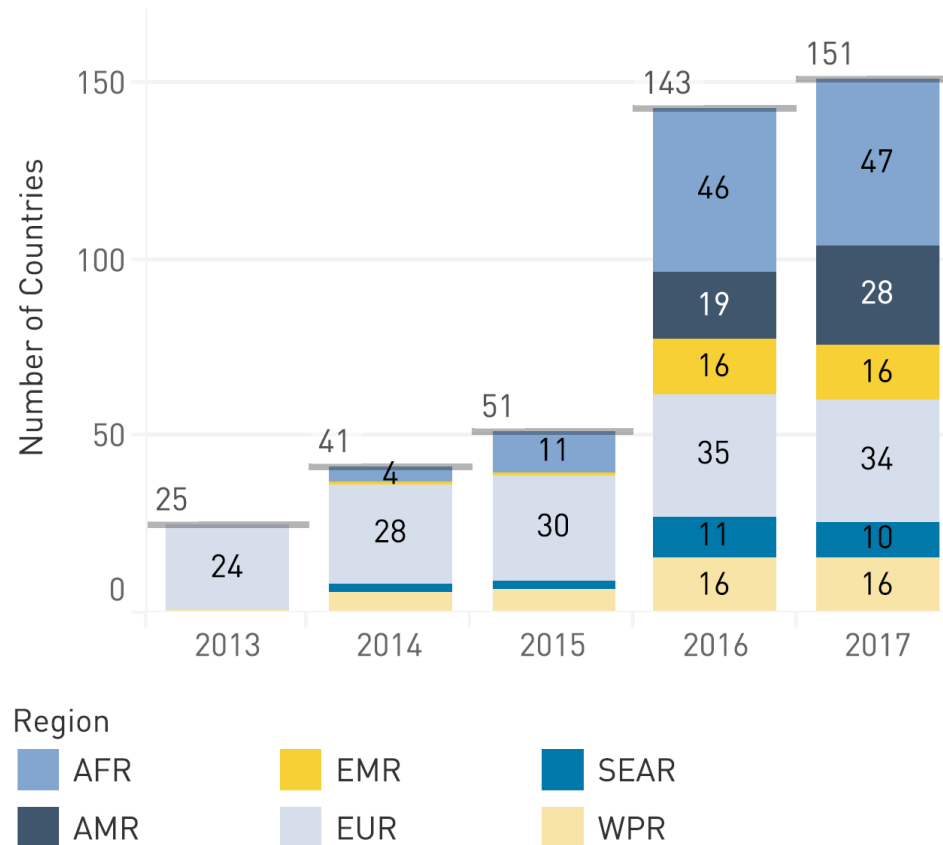


*Health agents are pictured during the first day of the yellow fever vaccination campaign in Kinshasa, on August 17, 2016.*

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# Great advances in vaccine market intelligence

Number of countries reporting over time by region & share by income group



Source: WHO JRF/V3P 2018 – all data available at : [www.who.int/immunization/MI4A](http://www.who.int/immunization/MI4A)

# Improved understanding of cross cutting market dynamics

**Factors that influence price for self-procured purchases - both GNI per capita and volume showed statistically significant associations with price:**



On average, a 1 million-dose increase in the vaccine purchase volume is associated with a 1.7% decrease in the vaccine price



On average, a \$1,000 increase in a country's GNI per capita is associated with a 5.5% increase in the price of a purchased vaccine



The relationship between price and contract length is not significant

Source: MI4A, for more information see Global Vaccine Market Report 2018 available at [www.who.int/immunization/MI4A](http://www.who.int/immunization/MI4A)

# Increase in use of data

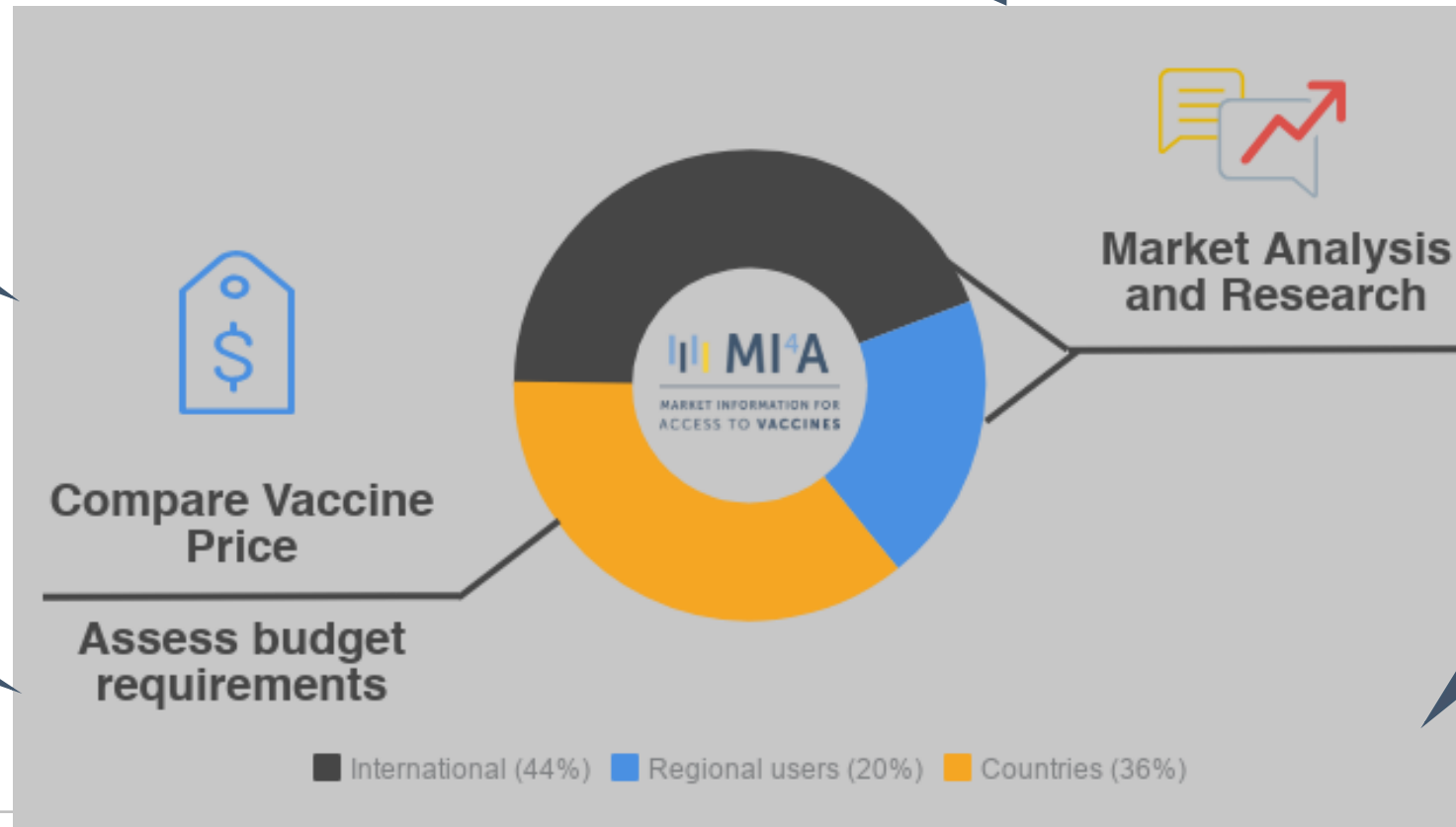
Gavi Market Shaping Externalities project

MI4A database used to inform negotiations in HPV Price

Data used in market research in Baltic States

Use price as input to country wastage calculator

MI4A data to inform decisions on new vaccine introduction in MICS



# Looking ahead

Key priorities



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# Country engagement

## OBJECTIVES

## TARGET

## TACTICS

### ENHANCE DATA COLLECTION

- Ensure continued reporting
- Target non reporting countries
- Move towards prospective data collection

GLOBAL

Outreach, dissemination strategy , communication  
Targeted advocacy  
Process for data collection out of JRF

### ENHANCE AND DOCUMENT USE OF MI4A DATA

- To inform new introductions and product switches
- Support planning and budgeting
- Procurement and negotiations

Self  
procuring  
MICS

Document and analyze use  
Priority countries: new intro, low coverage  
MI4A reports and factsheets, meetings/workshops

**PARTNERS KEY:  
CONTRIBUTION  
Includes**

**MSF, Save the Children – focus on advocacy  
UNICEF – coordinated support to countries  
WHO regional and country support**



Thank you!





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# In depth global understanding of 4 markets dynamics and risks

## GLOBAL MARKET UPDATE BCG VACCINE

### Key Takeaways

- For 2017, BCG vaccine supply is estimated to be 1.5 times greater than forecasted demand. This excess supply is reassuring given the instability of the manufacturing process and is important progress from the restricted supply situation in recent years.
- However, demand flexibility is limited due to product registration constraints and supply is still concentrated, with a few large suppliers with prequalified products serving most countries. Consequently, shortages may still occur.

**QUICK STATS**

**NUMBER OF TYPES**  
1

**TOTAL NUMBER OF SUPPLIERS**  
19

**2017 ESTIMATED MAXIMUM GLOBAL SUPPLY**  
~500M doses

**2017 FORECASTED GLOBAL DEMAND**  
~350M doses

**2015 REPORTED PRICE RANGE**  
US \$0.04-\$15.08 (Median: \$0.52)

### Market Highlights

Over ten years (2005-2015), short-duration stock-outs of BCG (maximum 1.5 months) have been reported across all regions, income groups and procurement methods. The African region, low income countries (LICs) and lower middle income countries (LMICs) were most affected. In 2014 and 2015, average stock-out duration increased. Stock-outs seem to be caused by several factors: production issues, countries having only one product registered, timely availability of financing (national or external), procurement shortcomings, and inefficient vaccine management.

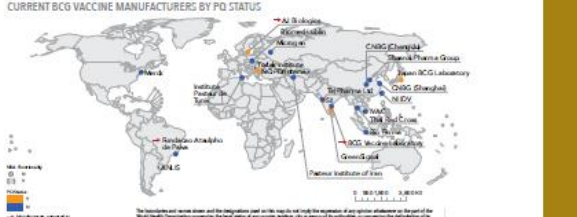
### Global Demand

Annual global demand is forecasted at ~350M doses according to a model based on country reported EPI schedule, UN Population Division (UNPD) population, WHO UNICEF estimated coverage, 50% wastage, and historical procurement data. Information on past country purchases shows that countries may be over-purchasing BCG, possibly due to actual wastage >50%, large country stocks, or country target population greater than UNPD estimator. The greatest difference in forecasted demand and historical procurement is seen for self-purchasing LMICs.



### Global Supply

Between 2013 and 2015, manufacturing issues for most prequalified (PQ) suppliers led to temporary reduced production or suspension of production. Additionally, some non-PQ manufacturers exited the market. Nevertheless, supply increased significantly in 2016, as some of the manufacturers' production issues were resolved and one new supplier, GreenSignal, was PQ'd. In 2017, supply is estimated to reach ~500M doses from 19 suppliers. The suppliers can be split into two groups: (1) four suppliers with PQ'd products that can reach 169 countries (86% of WHO member states) that accept UN procurement or have one of the PQ'd products registered and (2) fifteen suppliers with non-PQ'd products that can serve 52 countries where they have product registered. In 2017/2016, three manufacturers are expected to be back online and additional capacity could be made available from one other currently active manufacturer.

### CURRENT BCG VACCINE MANUFACTURERS BY PQ STATUS



WORLD HEALTH ORGANIZATION / MARKET UPDATE
Working Document – April 2017

## GLOBAL MARKET STUDY DIPHThERIA & TETANUS CONTAINING VACCINES

### Key Takeaways

- WHO recommends six doses of Diphtheria and Tetanus containing vaccines and for all countries to replace use of IT with TD.
- 100 / 194 countries do not meet these recommendations, but due to conducive circumstances, they are now likely to implement WHO recommendations.
- Implementation of the recommendations would increase global demand for all D&T containing vaccines by ~20%.
- Sufficient supply is available to cover both current and future demand for all D&T containing vaccines; TD is the only exception, but in 10-15 years time.
- Supply of all-containing vaccines is currently sufficient to support demand but any significant change (+10% or more) will require adequate warning (up to 18 months) for production adjustment.
- Several countries with only one locally-registered product are at risk of supply shortages, in particular the global supply-demand balance.

**QUICK STATS**

**NUMBER OF VACCINE TYPES**  
16

**TOTAL NUMBER OF SUPPLIERS**  
40 (20 producers, 5 distributors)

**2017 ESTIMATED MAXIMUM GLOBAL SUPPLY**  
> 2 billion doses

**2017 ESTIMATED GLOBAL DEMAND**  
~1 billion doses

**2016 REPORTED PRICE RANGE**  
US \$0.04-\$40.00



### Market Highlights

WHO recommends six doses of Tetanus and Diphtheria – 2 DTaP doses (i.e. 1 dose DTaP in the 2nd year of life, 1 dose DTaP/DT at 4-7 years); 11 dose Td at 9-15 years. WHO also has a long-standing recommendation to transition from IT to TD. Due to an increasing number of reports of outbreaks of diphtheria, increasing recognition of gaps in adult immunity to tetanus, as well as a more enabling environment (second year of life, adolescent, and maternal vaccination platforms), implementation of these recommendations by all WHO member states, will result in vaccination schedule changes that could lead to product access issues. Figure 1 (page 2) shows 115 countries (84% of the global birth cohort) that are likely to modify product choice at their IT schedule for Diphtheria and Tetanus (D&T) to align with WHO policy recommendations.<sup>1</sup> All of these 115 countries are self-producing and lack access to market information. Additionally, some access issues have been already indicated by countries in the European and American regions.

### TABLE 1: D&T-CONTAINING PRODUCTS AND GROUPINGS

Priority	DTaP (Early Childhood Vaccines)	The Adolescent / Adolescent Booster	Preventive / Adult Booster
DTaP	DTaP (aP)	DTaP (aP)	DT
DTaP/DT	DTaP/DT	DTaP/DT	
DTaP/DT/DT	DTaP/DT/DT	DTaP/DT/DT	
DTaP/DT/DT/DT	DTaP/DT/DT/DT	DTaP/DT/DT/DT	
DTaP/DT/DT/DT/DT	DTaP/DT/DT/DT/DT	DTaP/DT/DT/DT/DT	

WORLD HEALTH ORGANIZATION / GLOBAL MARKET STUDY
Working Document – November 2017

## GLOBAL MARKET STUDY HPV

### Key Takeaways

- Twelve years after the first HPV vaccine registration, less than half of WHO Member States have introduced HPV vaccine into the routine national immunization schedule. Introductions are lowest in Gavi countries and non-Gavi, non-PAHO middle-income countries (MICs).
- Supply is currently insufficient to meet demand and some countries have or will have postpone introductions.
- 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 by at least 100M doses over the next 10 years.
- To meet the expected increase in demand due to the cervical cancer elimination initiative, sizeable increases in supply will be required. Constraints are expected until at least 2024, assuming the base case supply scenario. This timing may change depending on selected vaccination strategies and investment decisions of current manufacturers, as well as on the timing of the three programs in advanced stage of clinical development.
- Meeting the projected demand volumes required for multi-age cohort (MAC) introductions (9-14 years of age), as per WHO recommendation, will remain especially problematic in large countries, as well as meeting additional demand generated by implementing gender-neutral HPV vaccination.
- Affordability of HPV vaccines in non-Gavi MICs is a barrier which needs to be addressed to encourage introduction.

**QUICK STATS**

**NUMBER OF VACCINE SUBTYPES<sup>1</sup>**  
3

**TOTAL NUMBER OF MANUFACTURERS<sup>2</sup>**  
2

**2018 ESTIMATED GLOBAL SUPPLY**  
~30 million doses (maximum)

**2018 ESTIMATED GLOBAL DEMAND**  
~30 million doses (supply constrained)

**2017 REPORTED PRICE PER DOSE (RANGE)**  
US \$4.50-\$154.28

### Purpose & Background

Several countries across regions and income groups have notified WHO of constraints to their access of HPV vaccines. The issue of affordability has also been raised, particularly by non-Gavi MICs. Following the announcement of a call for action towards global elimination of cervical cancer by the WHO Director General in May 2018, increasing introduction and coverage of HPV vaccine worldwide will be key. Working to understand current and future global trends and drivers of supply and demand, this study aims to address the current and expected constraints and to serve as an important resource for the development of the cervical cancer elimination strategy.

### Market Highlights

As of May 2018, 81 countries (42% of UN Member States, corresponding to 25% of target population) had introduced HPV into the national routine immunization schedule.<sup>3</sup> Despite carrying the greatest share of disease burden<sup>4</sup>, LICs and MICs are lagging in the introduction of HPV vaccine. To date, the majority of the countries have self-produced HPV vaccines (74% in 2017).

Currently, three HPV vaccine sub-types are available on the market: GSK's Cervix (HPV2), using the proprietary AS04 adjuvant, and Merck's Gardasil (HPV4) and Gardasil 9 (HPV9), both using alum adjuvant. Merck's two products are also commercialized by two licensors (Instituto Butantan in Brazil and Sinergium Biotech in Argentina). Distribution agreements exist

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Working Document – September 2018




## GLOBAL MARKET STUDY MENINGOCOCCAL MENINGITIS

### Key Takeaways

- The meningococcal vaccine market is diverse and complex with regional variations in serogroup epidemiology, significant non-routine use of vaccines, and 29 marketed products targeting various combinations of the six serogroups (A, B, C, W-135, X, Y).
- MNCs have discontinued production of polysaccharide vaccines, reducing country access, particularly for LICs.
- Without increases in production, available supply of conjugate MenACWY-135 will be insufficient to meet demand growth triggered by rising incidence of serogroups C and W and reduced availability of polysaccharide vaccines.
- LICs, MICs and the WHO Global Stockpile struggle to access multivalent and conjugate vaccines due to limited supply and high cost.
- Several multivalent, conjugate vaccines by Indian and Chinese manufacturers are in the pipeline and, if prequalified or widely registered, could provide additional supply.
- The mid- to long-term assessment of this market will be developed following the completion of the Global Roadmap to Defeating Meningitis in 2030 that will provide improved epidemiological data and country-specific goals.

**QUICK STATS**

**NUMBER OF TYPES**  
12 vaccine types

**29 distinct products**

**TOTAL NUMBER OF SUPPLIERS**  
17

**2017 ESTIMATED GLOBAL SUPPLY**  
~200M doses

**2017 FORECASTED GLOBAL DEMAND**  
~170M doses

**2017 REPORTED PRICE RANGE**  
US \$0.51-\$100 (median: \$19.25)

### Context and Rationale

Despite broad and effective engagement from the global health community in Meningitis A (MenA) vaccination in the Meningitis Belt, low manufacturing capacity, increasing demand, and high prices across other meningococcal vaccine types<sup>1</sup> have impeded access to these vaccines over the past several years. These long-standing access issues and the development of the WHO's Global Roadmap to Defeating Meningitis by 2030, which will set goals for disease control and vaccination for meningococcal meningitis on a global level, requires a more in-depth understanding of global demand and supply for meningococcal vaccines. This study seeks to provide a baseline understanding of the global landscape of supply and demand, outline market trends that may impact future supply and demand and identify actions to improve access for meningococcal vaccines in the short term.<sup>2</sup>

For MenACWY-135 specifically, nine products are available across polysaccharide and conjugate, but conjugate products are recommended for use in routine immunization activities, and though the three conjugate products available from MNCs are widely registered, the high price and low manufacturing capacity limits access for countries.<sup>3</sup> In 2017 the median price reported by countries for the three conjugate MenACWY-135 vaccines was \$36.53.

The number of prequalified (PQ'd) products is very limited. Only four vaccine products across two vaccine types (conjugate MenA and

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Working Document – September 2018

Source: MIA4, all studies available at [www.who.int/immunization/MIA4](http://www.who.int/immunization/MIA4)