Global Vaccine Market Report

Executive Summary

In response to repeated calls from WHO Member States, WHO launched the Market Information for Access to Vaccines (MI4A) initiative to enhance vaccine market transparency and understand global vaccine market dynamics.

This report provides a snapshot of the **global vaccine market** covering all vaccines and countries, complementing existing resources focused on specific market segments (see *Annex 1*). The report is divided into five sections: 1. vaccine market transparency, 2. global vaccine market value and volume, 3. vaccine products, 4. vaccine procurement and 5. vaccine price.

Key findings:

- Vaccine market transparency has tripled since 2016, as country reporting increased from 51 to 151 countries in 2018. MI4A data now covers almost all self-procuring MICs and engagement from HICs has improved
- Innovator vaccines, such as PCV, continue to drive global market value while Diphtheria and Tetanus (D&T)-containing vaccines comprise the largest share of global volumes
- Products from DCVMs comprise the majority share of volumes procured
- Countries are primarily self-procuring vaccines, with 60% of volumes reported to be self-procured. MICs represent 91% of self-procured volumes
- Self-procuring MICs pay at least double the PAHO RF price for more than one-third of vaccines
- A richer data set allows this report to further analyze factors associated with price for self-procuring countries – volumes procured, income, and contract length:
 - » An increase of one million doses procured is associated with a 1.7% decrease in vaccine price
 - » Every \$1,000 increase in GNI per capita is associated with a 5.5% increase in vaccine price
 - » Contract length shows no significant relationship with price

These findings can continue to inform dialogue on access in context of WHO's work on Fair Pricing of Medicines.¹

For further information, please contact MI4A@who.int.



Overview of MI4A

MI4A (Market Information for Access to Vaccines), a World Health Organization (WHO) initiative launched in January 2018, aims to:

- Enhance the understanding of global vaccine demand, supply and pricing dynamics and identify affordability and shortage risks;
- Convene all relevant global health partners to contribute to the development of policies, strategies and guidance to address identified risks;
- Strengthen national and regional capacity for improved access to vaccines supply.

MI4A focuses, in particular, on addressing the needs of selfprocuring countries that experience limited benefit from international support.

The initiative builds on the success of the WHO Vaccine Product, Price and Procurement (V3P) project and responds to calls for action from WHO Member States and the Strategic Advisory Group of Experts on Immunization (SAGE) to address vaccine market information gaps.

More information and reports available: http://who.int/immunization/MI4A

¹ http://www.who.int/medicines/access/fair_pricing/en/





Section 1: Vaccine Market Transparency

The MI4A initiative is part of larger efforts by WHO to address affordability and vaccine shortages issues through vaccine market transparency. To enhance the understanding of global vaccine market dynamics, MI4A collects price and procurement data from countries reporting through the JRF.

In 2018, 151 countries reported vaccine purchase data (2017 purchases), reflecting an increase over previous years' responses. This increase includes 19 countries reporting for the first time. Across all years of reporting, MI4A now captures price data for 85% of countries, which represents 95% of the global birth cohort.

Figure 1.1. Countries reporting price data, 2013-17

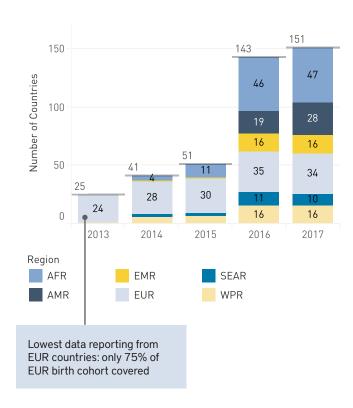
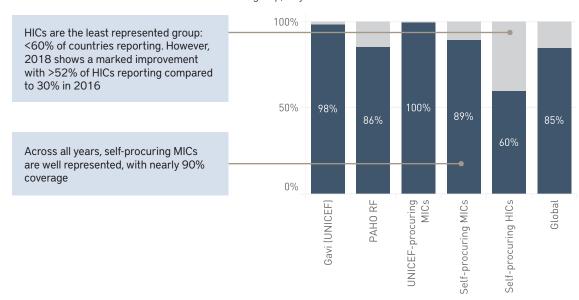


Figure 1.2. Percentage of countries reporting by MI4A country group, all years



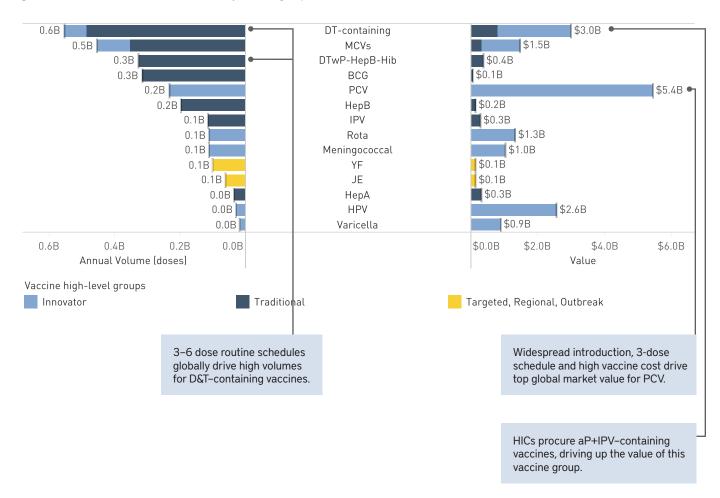


Section 2: Global Vaccine Market Value and Volume

Grouping vaccines in three categories – (1) traditional, (2) innovator [new vaccines] and (3) targeted, regional and outbreak [e.g. YF, JE] – shows that traditional vaccines drive global market volume while innovator vaccines drive global market value. Globally, the highest market value vaccine is PCV. D&T–containing vaccines have the second highest market value and the highest proportion of the market volume.² Measles–containing

vaccines (MCVs) are second in global market volume due to the large volumes required for campaigns. Self-procuring MICs, which include the two most populous countries, dominate 52% of global market volumes but only comprise 20% of global market value. SEAR, AFR and AMR have the greatest share of market volume, driven by very populous countries.

Figure 2.1. Global market volume and value by vaccine group (2017)



² bOPV is excluded from this analysis due to the highly unpredictable volumes required for polio eradication. If included, it would likely be one of the largest volume markets at present.





Figure 2.2. Global market volume and value by MI4A country group (2017)

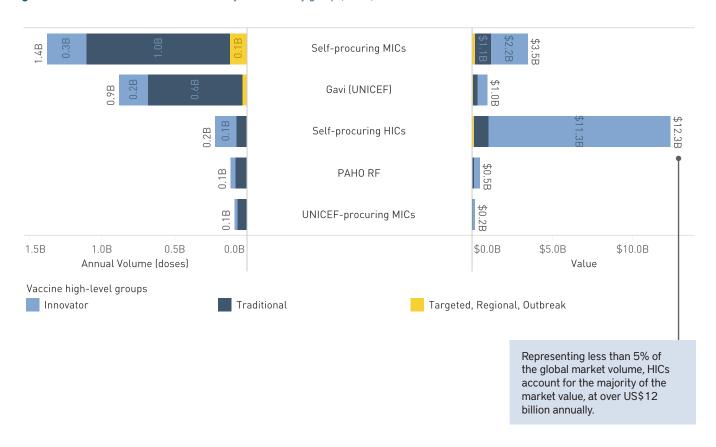
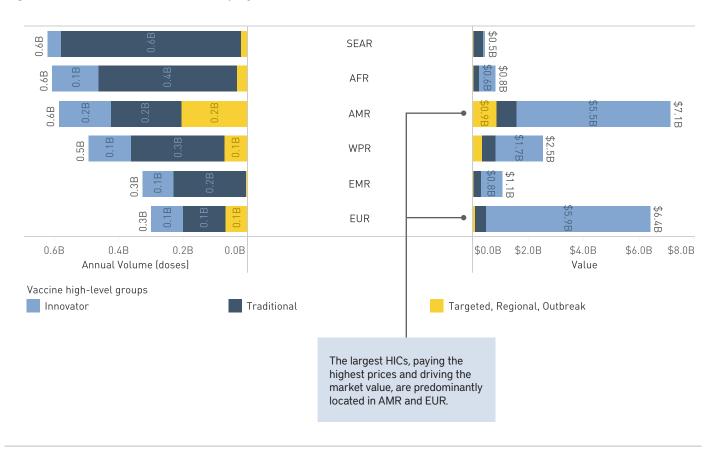


Figure 2.3. Global market volume and value by region (2017)

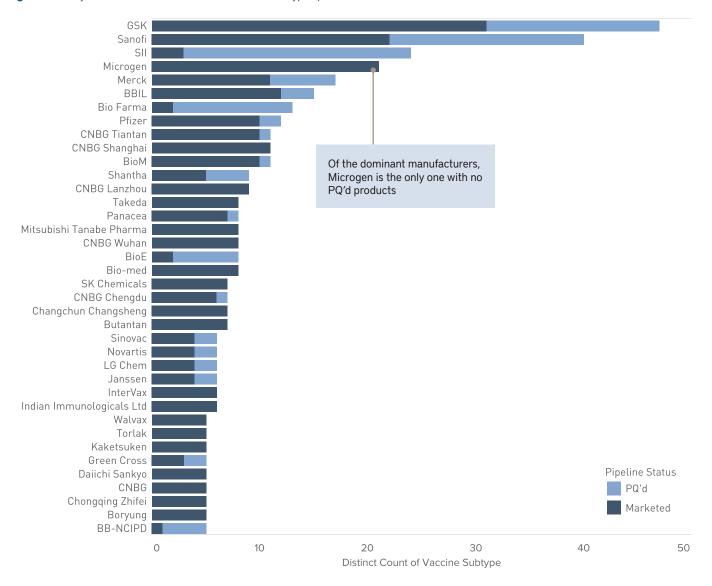


Section 3: Vaccine Products

Although there are many manufacturers engaged in the global market for vaccines, a small group of manufacturers dominate the market with many products: GSK, Sanofi, Serum Institute of India (SII), Microgen and

Merck. Almost all of these dominant manufacturers serve the UNICEF market in some capacity with their pre-qualified (PQ'd) products.

Figure 3.1. Key manufacturers and number of vaccine subtypes produced



Note

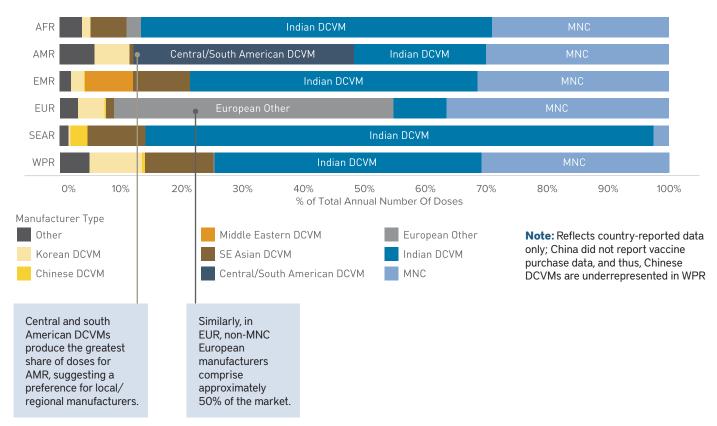
• This figure only lists manufacturers with five or more licensed vaccines in their portfolio



DCVMs claim the majority share of volumes procured, at more than 65% in each region except the European Region (EUR) (Figure 3.2). Indian DCVMs are key in all regions, dominating in African Region (AFR), Eastern Mediterranean Region (EMR), South-East Asian Region

(SEAR) and Western Pacific Region (WPR). Across all regions, countries report roughly 30% of procurement from MNCs, with the exception of SEAR, given the very high volumes procured by India from national manufacturers.

Figure 3.2. Procurement from MNC versus DCVM by region



Box 3.1: Vaccine Product Registration

A key limiting factor to access to vaccines is the availability of registered products in a specific market. If any unforeseen issue arises with the supply of the only registered product, access to alternative vaccine products is more complicated or time-consuming than if several products were registered.

The first MI4A market studies performed in 2017 for BCG and D&T-containing vaccines highlighted single-vaccine product registration as an area of risk to access. For BCG, one-third of countries had only one or no vaccine products registered at time of study. Of those, 21 countries had BCG vaccine in their routine immunization schedule. The situation was equally precarious for D&T-containing vaccines; Td was the most problematic product, with half of the countries using the product in their national programme with only one product registered.

Dialogue between manufacturers, countries and WHO on how to resolve this and related matters is ongoing. Investments have been made to streamline regulatory procedures, encourage the use of reliance and mutual recognition among National Regulatory Authorities, set up regional regulatory networks, enhance the use of the Collaborative procedure for registration of PQ'd products, and develop of guidelines on procedures for post approval changes. Ultimately, it is up to countries' leadership to bring about change.



Figure 3.3 details the numbers of manufacturers active and PQ'd in each vaccine market. Across all vaccines, there are a median of six manufacturers and two PQ'd products. Markets with only one to two manufacturers stand out as a concern for supply security. Some markets may have multiple manufacturers available but only have one or two PQ'd manufacturers, which limits the flexibility of UNICEF Supply Division (SD), as countries are dependent on the performance and price point of those PQ'd manufacturers. Of these markets, MR is of particular importance, given the high volumes of MR campaigns. Other markets, such as those for many traditional vaccines (e.g., BCG), have several suppliers and competition has driven prices to be very low, increasing the chance of market exit.

MenA, TCV, DTwP-Hib, MR and Varicella have only one PQ'd manufacturer.

Figure 3.3. Number of companies and PQ'd product by vaccine market, with forecasted 2019 demand

Total Number of Companies	W/ PQ'd Product	Vaccine	2019 Forecasted Demand
	• 1	MenA	•
1	0	Td-IPV	•
		DTaP-HepB-IPV	•
		Dengue	•
2	2	HPV	•
	1	DTaP-HepB-Hib-IPV	•
	0	MenBC	•
		DTaP-HepB	•
3	0	Tdap	•
		MMRV	•
		DTaP-Hib	•
	1	TCV	•
4	0	DTaP-Hib-IPV	•
	0	Diphtheria	•
5	2	PCV	
	1	DTwP-Hib	•
	0	MenC	•
6	4	YF	•
	3	Cholera	•
		MenACYW-135	•
	0	MenAC	•
		DTaP-IPV	•
7	4	MMR	•
	2	DTwP-HepB	•
8	3	Rota	
9 -	2	DTaP	•
	1	MR	
11	1	Varicella •	
12	5	IPV	•
13	8	DTwP-HepB-Hib	
	7	bOPV	
14	3	DTwP	•
15	2	Measles	•
16	5	Hib •	
17	3	DT	•
	2	НерА	•
22	6	TT	•
	5	Td	•
25	5	BCG	
41	7	НерВ	•

Demand Size



Note

 Excluded from the forecasted demand: bOPV campaigns and stockpile doses (e.g. meningococcal vaccines)





Section 4: Vaccine Procurement

Countries primarily self-procure vaccines (60% of doses). The remaining procurement occurs through UNICEF SD (36% of doses) and PAHO Revolving Fund (RF) (4% of doses). Procurement from MICs comprises 91% of self-procured volumes, highlighting the importance of this group in vaccine markets.

By region, the dominant procurement mechanism varies. Figure 4.1 shows the birth cohort represented by each procurement mechanism.

Figure 4.2 explores how the dominant procurement mechanism varies by vaccine. UNICEF SD procurement is the predominant procurement mechanism for nearly all Gavi vaccines. Procurement patterns for non-Gavi vaccines are less consistent; countries procure more than 50% of BCG and Td volumes via UNICEF SD while DTaP, MMR, Rabies, Seasonal Flu and Rabies are largely self-procured.

Figure 4.1. Procurement mechanism by birth cohort

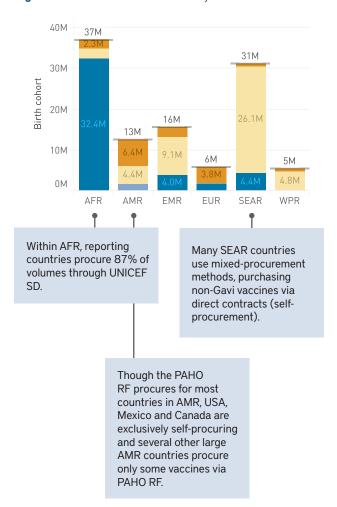


Figure 4.2. Procurement mechanism by vaccine

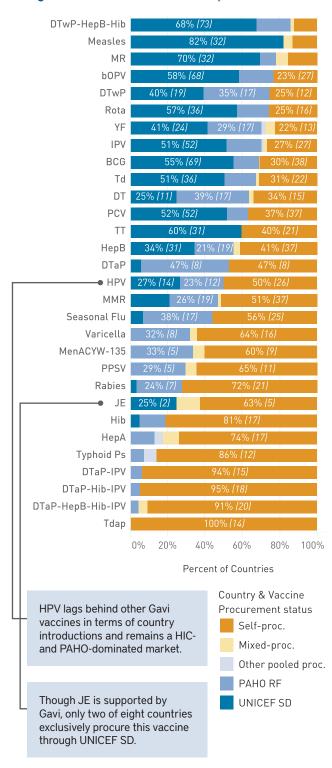


Figure Notes

4.1:

"Mixed-procurement" indicates that a country procured vaccines via multiple procurement mechanisms in 2017

4.2:

- "Mixed-procurement" for a vaccine indicates that a country procured the same vaccine via multiple procurement mechanisms in 2017
- Excluded vaccines with fewer than eight countries reporting





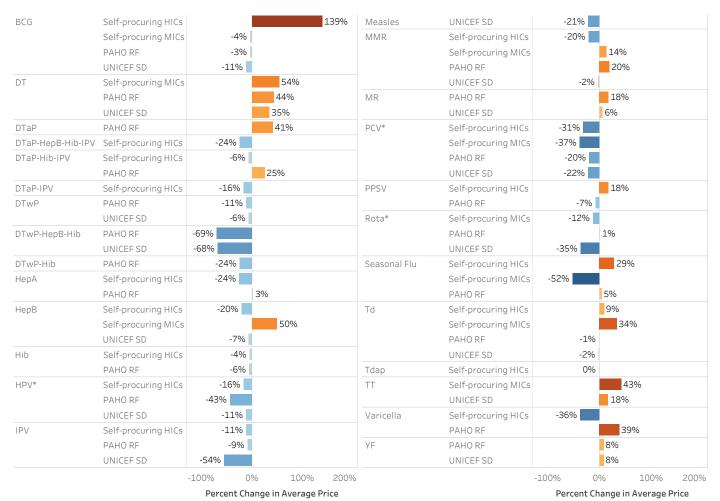
Section 5: Vaccine Price

Evolution of Price over Time

Over time, no clear trend in price is evident by vaccine group (e.g. traditional, innovator, etc.). Some individual vaccines do show conclusions across procurement groups³, namely:

- · Increasing price over time: DT, MR, TT
- · Broadly stable price (less than 15% change): DTwP, Hib, YF
- Decreasing price over time: DTwP-HepB-Hib, HPV, IPV, PCV

Figure 5.1. Percent change in average price over time, 2013-17



 $\hbox{^*UNICEF SD prices for HPV, PCV, and Rota are the price offered to Gavi-supported countries only}\\$

³ Many vaccines in Figure 5.1 have only one procurement group for analysis, either due to vaccine use in certain markets only (e.g. DTaP-IPV) or due to a limited number of country-reported records available for self-procured purchases.





Price by Procurement Mechanism

Across all countries reporting in 2018, the influence of procurement mechanism on price is evident. For 11 vaccines⁴ procured via all three mechanisms, selfprocuring countries pay the highest price, with a median of \$4.79, while PAHO RF and UNICEF SD have median prices of \$0.32 and \$0.25, respectively (Figure 5.2).

Self-procuring HICs pay the highest price for all vaccines, apart from DTaP and Tdap, for which self-procuring MICs pay a higher median price.

Compared with self-procuring MIC prices, UNICEF SD (excluding Gavi-supported countries) or PAHO RF procurement leads to lower prices for 90% of vaccines (27 out of 30). In these instances, the UNICEF/PAHO pool-procured average price per dose is 48% lower than the average self-procured MIC price.

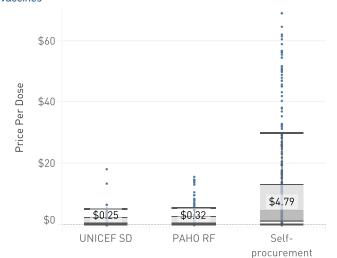
Self-procuring MICs pay at least double the PAHO RF price for more than one-third of vaccines (11/33) in Table 5.1. Though the magnitude of the difference is great, most of these are traditional vaccines for which self-procuring MICs pay less than \$1.25 per dose. There are several vaccines for which the magnitude is not as large, but the additional cost per dose is considerable. Examples are:

DTaP-HepB-Hib-IPV: \$15.86

PCV: \$13.09

DTaP-Hib-IPV: \$9.21

Figure 5.2. Procurement mechanism and price (USD) across 11 vaccines



Note

Eight self-procurement values above \$70.00 are not shown but are factored in to the resulting box and whisker

Table 5.1. Median price per dose (USD) for all vaccines by procurement/income group (2017)

			Self-	Self-
	UNICEF		procuring	procuring
Vaccine Subtype	SD*	PAHO RF	MIC	HIC
BCG	\$0.11	\$0.14	\$0.29	\$1.08
bOPV	\$0.14	\$0.15	\$0.20	\$0.24
Cholera	\$1.50	\$1.85		\$43.86
DT	\$0.16	\$0.17	\$0.34	\$2.69
DTaP		\$15.00	\$16.50	\$14.30
DTaP-HepB-Hib-IPV		\$19.80	\$35.66	\$41.57
DTaP-Hib-IPV		\$13.60	\$22.81	\$24.78
DTaP-IPV		\$11.00	\$16.91	\$19.70
DTwP	\$0.21	\$0.20	\$0.30	\$3.51
DTwP-HepB-Hib	\$0.92	\$1.06	\$2.53	\$3.63
DTwP-Hib		\$2.65	\$2.84	
HepA		\$8.06	\$9.68	\$13.95
HepA (adult)		\$13.20	\$19.43	\$26.47
НерВ	\$0.25	\$0.22	\$1.23	\$5.03
HepB (adult)	\$0.30	\$0.25	\$1.14	\$8.55
Hib		\$2.05	\$4.31	\$8.73
HPV2	\$4.60	\$8.50	\$14.79	\$25.93
HPV4	\$4.50	\$9.80	\$15.55	\$38.25
IPV	\$1.87	\$3.60	\$4.00	\$7.61
JE live attenuated	\$0.42			\$18.77
Measles	\$0.26		\$0.69	\$7.15
Men AC			\$0.89	\$17.59
MenACYW-135		\$20.30	\$10.20	\$29.63
MMR	\$1.97	\$3.57	\$6.04	\$7.81
MR	\$0.61	\$1.43	\$0.93	
PCV10	\$3.05	\$12.85	\$32.16	\$32.41
PCV13	\$3.17	\$14.50	\$21.36	\$48.98
PPSV23		\$6.81	\$11.48	\$15.77
Rabies		\$2.25	\$13.66	\$16.58
Rota	\$2.77	\$6.50	\$7.87	\$14.90
Seasonal Flu		\$1.52	\$4.29	\$7.67
Seasonal Flu (adult)		\$3.91	\$3.38	\$8.08
TBE (adult)			\$6.60	\$36.80
Td	\$0.12	\$0.11	\$0.36	\$9.73
Tdap		\$11.39	\$26.39	\$17.77
TT	\$0.09		\$0.28	\$2.66
Typhoid Ps		\$9.00	\$9.60	\$10.36
Varicella		\$14.85	\$21.76	\$28.56
YF	\$1.05	\$1.17	\$18.05	\$33.97

Notes

*UNICEF SD prices for HPV2, HPV4, JE, PCV10, PCV13, and Rota are the price offered to Gavi-supported countries only

- Color differences are relative to the sum of all prices across the row (by vaccine)
- For MICs and HICs, any vaccines with only one country reporting for that vaccine are excluded
- Vaccines with only one group with a median price are excluded, as price is not comparable across two or more groups





⁴ BCG, bOPV, DT, DTwP, HepB, HPV, IPV, MMR, MR, PCV, Rota

Factors that Influence Price for Self-procured **Purchases**

Given the significance of self-procurement (60% of reported volumes) and markedly higher prices paid, this section further investigates the drivers of price for self-procured purchases. Three key factors are presumed to impact price for self-procuring countries: volumes procured, income, and contract length. Each of these factors was correlated against average prices to understand the effect each has on price. A multiple linear regression including all three variables was then completed. Country-reported data from all years (2013– 2017) is used in all analyses presented.

A correlation of volume against price showed a modest negative association, with higher volumes yielding lower prices per dose. The examination by vaccine revealed that only four out of 58 vaccines showed a statistically significant and negative correlation between volume purchased and price.⁵

The correlation of GNI per capita and price revealed a positive association indicative of higher prices paid by higher income countries. The evident upward trend increased at a faster rate for lower GNI values (\$2,500-\$8,300) and at a slower rate for higher GNI values (\$8,300-\$70,000). This relationship suggests that countries with lower GNIs experience more rapidly increasing prices with only a modest increase in GNI, whereas higher-income countries with dramatically increasing wealth see smaller increases in vaccine prices. In exploring this relationship by vaccine, 27 vaccines have statistically significant positive correlation, of which 11 were strongly positive.6

An examination of price by contract length exhibits no **clear trend in price**, refuting the hypothesis that longer contracts result in lower prices. While the median price per dose shows some differentiation, there is significant overlap in prices paid for different contract lengths. Oneyear contracts show the lowest median price for both HICs and MICs, while single deliveries appear to result in marginally higher median prices for MICs. This may be influenced by variable procurement sizes between contract lengths, as purchases by single deliveries are often for smaller volumes. Analysis of the impact of contract length by vaccine shows no conclusive patterns.

These relationships were further explored through a multiple linear regression of volume, GNI per capita, and contract length on price. Both GNI per capita and volume showed statistically significant associations with price:

- · On average, a one-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 again not significant

These results indicate that the magnitude of impact is greater for GNI per capita than for purchased volumes, suggesting that only very populous countries can take considerable advantage of reduced prices for large volume purchases. The relationship of GNI per capita and price confirms price tiering by income level for selfprocured purchases. Price acceleration may be stronger with increasing income for MICs, suggesting challenges in vaccine affordability. These findings can continue to inform the dialogue on access in the context of WHO's work on Fair Pricing of Medicines.

To illustrate the spread of price data, when plotted by GNI, purchase volume, and contract length, five vaccines with the greatest number of records across self-procuring MICs and HICs are shown in Figure 5.3. Increasing price by GNI, decreasing price by volume, and wide overlap of price by contract length are visible for each vaccine. However, variability by vaccine is also illustrated.

^{6 11} vaccines displayed strong positive (r ≥ 0.6) statistically significant (p ≤ 0.05) correlation: JE, Measles, MenACYW-135, MenACYW-135 Ps, MenB, Rota, Seasonal Influenza, TBE, Td, TT, Varicella,





⁵ The following vaccines displayed negative (r < 0) statistically significant (p ≤ 0.05) correlation: DTaP-HepB-Hib-IPV, DTaP-Hib-IPV, HepB, Typhoid Ps.

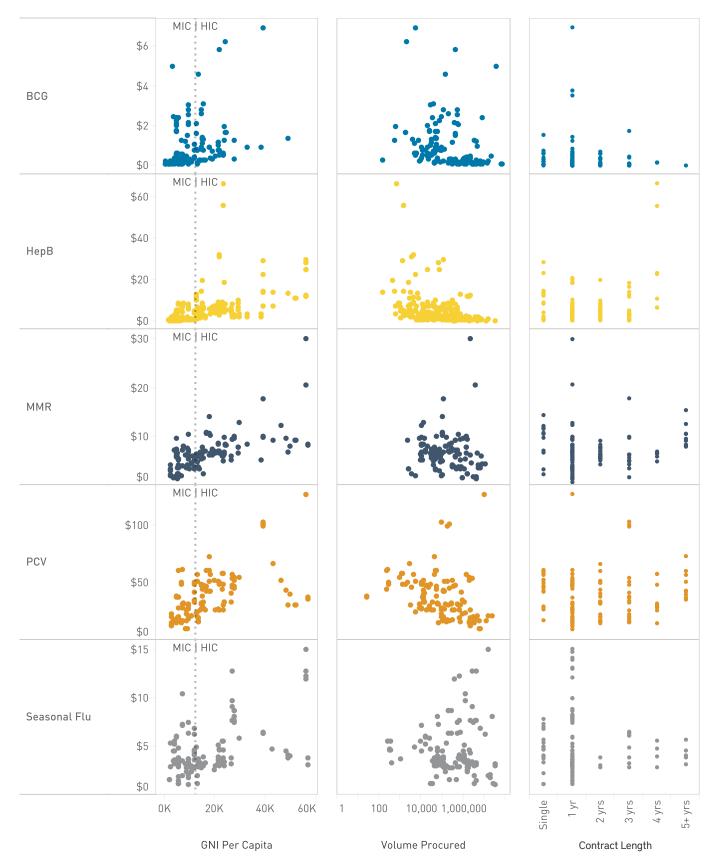


Figure 5.3: Price versus GNI per capita, Volume and contract length for select vaccines

Note

• Volume scatterplots are on log-scale for x-axis to better display data





Annex 1: Additional Resources

Gavi

Vaccine Roadmap public summaries and other supply and procurement related documents:

https://www.gavi.org/library/gavi-documents/supply-procurement/

PAHORF

Vaccine price data (leveraged in this report): https://www.paho.org/hq/index.php?option=com_co ntent&view=article&id=9561:2014-revolving-fundprices&Itemid=40714&lang=fr

UNICEF SD

Vaccine Price Data (leveraged in this report): https://www.unicef.org/supply/index 57476.html

Vaccines Supply and Market Overview for UNICEF markets:

https://www.unicef.org/supply/index_vaccines.html

WHO MI4A

Vaccine purchase data (excel for download): http://www.who.int/immunization/programmes_ systems/procurement/v3p/platform/module1/en/

Global Market Studies on BCG, D&T-containing vaccines and HPV (coming soon):

http://www.who.int/immunization/programmes_systems/procurement/v3p/platform/en/

Annex 2: Data Sources and Methods

Data Sources

The primary data source for the analyses in this report is vaccine purchase data reported by countries through the WHO-UNICEF Joint Reporting Form (JRF). This is supplemented with additional publicly available information from PAHO RF and UNICEF SD, and remaining gaps are filled by leveraging the Global Vaccine Market Model (GVMM). Vaccine prices for PAHO and UNICEF SD used in Section 5 are as reported by these organizations (see Annex 1).

Global Vaccine Market Volume and Value analyses are supplemented with GVMM demand estimates. The GVMM estimates demand, by country and vaccine, across all WHO Member States and markets. It is based on the JRF (all country-reported immunization schedules), MI4A country-reported purchase data,

WUENIC coverage estimates, and UNICEF SD, PAHO RF and US CDC⁷ public pricing. Demand estimates are scrutinized by global vaccine partners, including the Bill & Melinda Gates Foundation (BMGF), CHAI, Gavi, PAHO, PATH, UNICEF and WHO. MI4A supplier consultations conducted as part of specific vaccine market studies (2018: HPV, 2017: BCG and Diphtheria & Tetanus (D&T)-containing) are also incorporated. GVMM is managed by Linksbridge SPC and funded by BMGF.

UN Population Division (UNPD) World Population Prospects (WPP) provides data for birth cohorts. The most recent birth cohort data was used for each country; for six countries, the most recent data available was from 2012.

World Bank provides data for GNI per capita and global cumulative inflation rate.

Methods

Vaccine Market Transparency

In previous years, Gavi and PAHO RF countries were shown as 100% covered in the V3P database. Beginning in 2018, only countries reporting vaccine purchase data via the JRF will be counted. The reduction from 100% for Gavi and PAHO RF are due to one Gavi and four PAHO RF countries never having reported.

Global Markets

For the global analysis (beyond country-reported data), MI4A has categorized countries by their predominant procurement mechanism (e.g. a MIC with 70% of purchased volumes from UNICEF SD and 30% self-procured would be UNICEF-procuring). This categorization is used only in Sections 2 (Global Vaccine Market Value and Volume) and 3 (Vaccine Products).

In 2018, 42 countries, primarily HICs, did not report data to MI4A. To analyze and produce global market views, demand and price data were supplemented for these countries from GVMM, which aggregates data from UNICEF SD, PAHO RF, Gavi, CDC and WHO for pricing and procurement assumptions.

Some vaccines were excluded, as they are not included in GVMM and are commonly procured by high-income countries, and thus, would be underestimated compared to other vaccines: PPSV, Seasonal Flu and Shingles. This global analysis does not include stockpile doses (i.e. meningitis, YF, cholera).

CDC vaccine price list: https://www.cdc.gov/vaccines/programs/vfc/awardees/vaccine-management/price-list/index.html





Evolution of Price

The change in prices over time for countries concentrates on the time frame of 2013–2017. 2014 data is used where 2013 data was not reported. The analysis includes vaccines for which at least three records were registered by the same self-procuring countries in both 2013/14 and 2017. Average price is adjusted for cumulative inflation of the same time period (source: World Bank, 2018).

Self-procured Purchase Correlations and Regression

For analyses that consider statistical significance, a *P* value of < 0.05 is considered significant.

Pearson correlation and linear regression analyses examine the relationship between GNI per capita of the purchasing country, purchase volumes, contract length and the price of the vaccine. For vaccine level, correlation analysis is included only when the number of data points is ten or greater.

GNI versus price: Evaluating the relationship between GNI per capita and price for only self-procured purchases resulted in a statistically significant (p < 0.0001) upward trend. A logarithmic model showed a better fit to these data than a linear model, suggesting that as GNI per capita increases, price increases more quickly for lower GNI values (\$2,500–\$8,300) and then continues to increase at higher GNI values (\$8,300–\$70,000) but at a slower rate. However, the overall fit of the model to these data is poor (R-squared <= 0.2) indicating that other factors are likely influencing price.

<u>Volume versus price</u>: Analysis showed a statistically significant (p < 0.0001) negative relationship, but with low fit to the data (R-squared <= 0.2). The trend model used, a "power model", showed the best fit to the data (R-squared = 0.16) compared to linear, log, or exponential models.

Contract length versus price: The MI4A database captures contract length as a categorical variable, with data values set to single delivery, 1 year, 2 year, 3 year, 4 year, 5+ year, so a correlation analysis was not possible. Instead, the median and variance of prices within each category was examined using boxplots. Overlap and trends across categories was assessed visually.

Multiple Regression: The regression data is based on self-procured purchases for 2013–2017 as reported by countries. For ease of interpretation, GNI per capita is computed by thousands, and purchase volumes by millions. Several regression models were tested, and the linear log-level model was selected as the best fit (R-squared = 0.24, n=1830):

 $In(Price) = 0.43 + 0.054 \times GNI - 0.017 \times Volume + 0.058 \times Contract Length + e$

Both GNI per capita and volume variables are statistically significant. The Contract Length variable is not statistically significant. It is important to note that the given model only explains 24% of the variance in the price of the vaccine, which suggests that there must be several other variables that, if added, could further explain the variance.

Disclaimer

Information contained in the MI4A database is provided by participating countries that have agreed to share vaccine price and procurement data. Participating countries are solely responsible for the accuracy of the data provided.

The information contained in the MI4A database does not in any way imply an endorsement, certification, warranty of fitness or recommendation by WHO of any company or product for any purpose, and does not imply preference over products of a similar nature that are not mentioned. WHO furthermore does not warrant that: (1) the information is complete and/or error free; and/or that (2) the products listed are of acceptable quality, have obtained regulatory approval in any country, or that their use is otherwise in accordance with the national laws and regulations of any country, including but not limited to patent laws. Inclusion of products in the database does not furthermore imply any approval by WHO of the products in question (which is the sole prerogative of national authorities).

WHO will not accept any liability or responsibility whatsoever for any injury, death, loss, damage, or other prejudice of any kind that may arise as a result of, or in connection with the procurement, distribution and use of any product listed in the MI4A database.

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