

Global vaccine market report 2024

Preface

This year marked the 50-years anniversary of the Expanded Programme on Immunization: over 150 million lives have been saved over these past 50 years and 40% of the reduction in infant deaths globally has been due to vaccination.⁽¹⁾ Recently, the World Health Organization (WHO) and the United Nations International Children's Emergency Fund (UNICEF) published the 2023 WHO/UNICEF Estimates of National Immunization Coverage (WUENIC) results indicate some recent positive trends, such as a coverage increase for global human papillomavirus vaccine (HPV) among girls, and coverage gains in the Africa region. Despite important progress in some areas, there is widespread concern in the immunization community that childhood immunization coverage levels have been stalling for many years now, leaving many children unprotected year after year. ⁽²⁾ In 2023, vaccination coverage was below the 90% Immunisation Agenda 2030 (IA2030) target for several important vaccines across the life course. ⁽³⁾ Insufficient vaccination coverage against measles, whose progress has also stalled, has led to outbreaks in 103 countries over the last five years. ⁽⁴⁾ Of the many challenges countries face, access to timely, affordable, assured quality and sustainable vaccine supply continues to be a critical issue. The 2022 global vaccine market report (GVMR) identified key areas that governments, industry, international institutions and partners need to act on to improve sustainable and equitable access to vaccines, which remain relevant today.

The 2024 GVMR is a unique source of information that provides a snapshot of vaccine markets globally in 2023, covering 88 vaccine products sold in 207 countries and procurement channels by 116 manufacturers. Understanding vaccine markets is a key input to increasing access to vaccines and a critical component to improving immunization coverage. The report also analyses market trends between different country income groups and regions and over time using historical data, to support an improved understanding of individual vaccine markets as well as cross-cutting issues. The market intelligence from this report supports governments, industry, global public health agencies and other decision-makers to identify challenges and opportunities to accelerate equitable access to vaccines globally.

Key takeaways

This year's GVMR assesses vaccine procurement data from the year 2023. Short-term evolution of the market is analysed through comparisons to data from 2022. Trends compared to 2019 are also analysed to enhance understanding of pre-pandemic and post-pandemic market dynamics.

The detailed analysis is organized into the following sections:

- 1 Volume and financial value
- 2 Manufacturing and supply
- 3 National stock-outs
- 4 Vaccine specific supply dynamics and supply security
- 5 Procurement and pricing
- 6 Vaccine regulation



The Market Information for Access Initiative (MI4A) was launched in 2018 to contribute to the achievement of Sustainable Development Goal 3.8 (Universal Health Coverage target) by enhancing access to safe, effective, quality and affordable vaccines for all. This important issue was highlighted by the World Health Assembly in 2019 with the endorsement of a Roadmap for access to medicines and vaccines, and the adoption of resolution WHA72.8 on improving the transparency of markets for medicines, vaccines and other health products.

MI4A is a peer platform that leverages data collected from countries and provides the data publicly to inform product choice, conduct financial planning, optimize budgets, enhance procurement, and strengthen national, regional, and global capacity for improved access to vaccines. Vaccine manufacturers also participate by sharing information on their late-stage pipeline and available supply, as well as by engaging in dialogue to inform investment decisions.

More information on MI4A can be found at: [Immunization, Vaccines and Biologicals \(who.int\)](https://www.who.int/immization-vaccines-and-biologicals)

The corresponding **key takeaways** are:

1 Volume and financial value

Aggregate global vaccine market volumes in 2023 stabilized at a level similar to pre-COVID, due to reduced procurement of COVID-19 vaccines. Total global market volumes were approximately 7 billion doses in 2023, almost half of the 2022 volumes, a notable decrease due to reduced purchases of COVID-19 vaccines. In total, 50% of volumes were accounted for by three vaccines: oral polio (OPV), COVID-19 and seasonal influenza vaccines. Big volume increases were observed in HPV and smallpox/mpox vaccine due to programme expansion and increased outbreak response respectively. The compound average growth rate (CAGR) of the global vaccine market in volumes was 3% over the past five years (2019-2023) and was mainly driven by demand for COVID-19 vaccines.

The global vaccine market's financial value experienced a larger growth of 15% CAGR over the past five years.

The relatively high increase in financial value is driven by increased procurement of higher priced adult vaccines in high-income countries – e. g. COVID-19, pneumococcal conjugate vaccine (PCV) and shingles – and the purchase of novel respiratory syncytial virus (RSV) vaccines (for adults and maternal use) and monoclonal antibodies (mAb) for protection of infants. Moreover, significant financial value growth in China, driven primarily by private market procurement of PCV and HPV vaccines, has contributed to the overall growth. COVID-19 remained the vaccine accountable for the highest global financial value, at US\$ 20 billion and 27% of total market value in 2023.

2 Manufacturing and supply

The global vaccine market remains highly concentrated between a limited number of manufacturers, with the largest 10 manufacturers accounting for 73% of vaccine dose volumes and capturing 85% of global financial value. More than 90 manufacturers account for the remaining global volumes. Manufacturers affiliated with the Developing Country Vaccine Manufacturers Network (DCVMN) sold more than 50% of vaccine doses procured globally, representing 11% of the global financial value, while manufacturers affiliated with the International Federation of Pharmaceutical Manufacturers & Associations (IFPMA) accounted for approximately 85% of financial value, representing 34% of total volume.

Dependence on a few large manufacturers – Pfizer, the Serum Institute of India (SII), GSK, Sanofi, Merck/MSD, Bharat Biotech (BBIL) – **with broad portfolios and use of multiple technology types is evident,** with Pfizer and SII being outliers from financial value and volume perspectives.

3 National stock-outs

National stock-outs have remained a problem for many countries, with 68 countries reporting at least one stock-

out at the national level in 2023. The number of national stock-outs reported has ranged between 67-88 in the past 5 years, mostly in the same countries.

4 Vaccine specific supply dynamics and supply security

Countries in the WHO African and Eastern Mediterranean regions continued to procure vaccines manufactured almost entirely outside their respective regions. Efforts to expand local production in these regions, with support from the international community are underway but will take time to materialize.

The WHO South-East Asia region and the WHO Western Pacific region look highly self-sufficient, with the former self-supplying 87% of vaccines procured, and the latter self-supplying 66% of vaccine procured. Nevertheless, this picture can be mostly attributed to India and China, with the former providing 84% of the doses procured in its region and self-supplying 99% of its own procurements, and the latter providing 54% of the WHO Western Pacific region and self-supplying 90% of its own procurements.

5 Procurement and pricing

Self-procuring middle-income countries (MICs) represented approximately 40% of market volumes, followed by pooled procurement initiatives (UNICEF and PAHO), which represented 36% of globally procured volumes in 2023 with self-procuring high-income countries (HICs) accounting for the remaining 24% of the volumes. From a financial value perspective, HICs continue to dominate with 72% of the financial value, up from 65% in 2022, while MICs account for 24% and pooled procurement accounts for the remaining 4% of the financial value.

Globally, vaccine prices have remained relatively stable in the last years. Vaccine prices within individual markets tend to be tiered across countries based on their income group, similar to previous years. Likewise, prices paid by self-procuring countries exhibited greater variability than prices paid by countries who used pooled procurement mechanisms, underlining the importance of UNICEF Supply Division (SD) for Gavi supported countries and PAHO Revolving Fund (RF) for access to vaccines for self-financing countries.

6 Vaccine regulation

In 2023, no additional **national regulatory authority** has achieved a maturity level sufficient to regulate vaccine production, leaving the global total at 34 authorities with maturity level (ML) 3 or higher for vaccine manufacturing. To support regional diversification of manufacturing, the growth of national regulatory authorities of a sufficient ML to regulate vaccine production will be a critical factor. National authorities in countries where vaccine manufacturing is a priority are working towards higher ML, supported by WHO and partners.

Analysis

1 Volume and financial value

The global vaccine market size in 2023 was seven billion doses (Fig. 1a), corresponding to a financial value^a of US\$ 77 billion (Fig. 1b), defined as the volume multiplied by the acquisition cost/price of the vaccine by the end purchaser. This number corresponds to approximately 5% of the total

pharmaceutical market revenue measured in US\$ in 2023. (5) The market size fell by US\$ 47 billion (corresponding to a volume of 6 billion doses) compared with 2022, almost entirely resulting from the purchase of fewer COVID-19 vaccine doses.

Fig. 1a: Vaccine volume (doses) from 2019–2023, showing the top 10 vaccines by volume

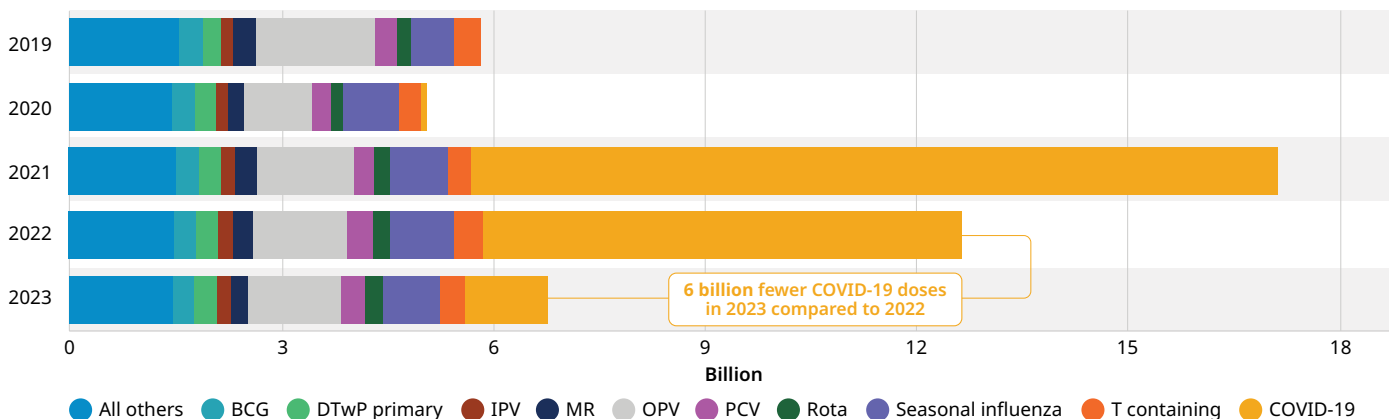
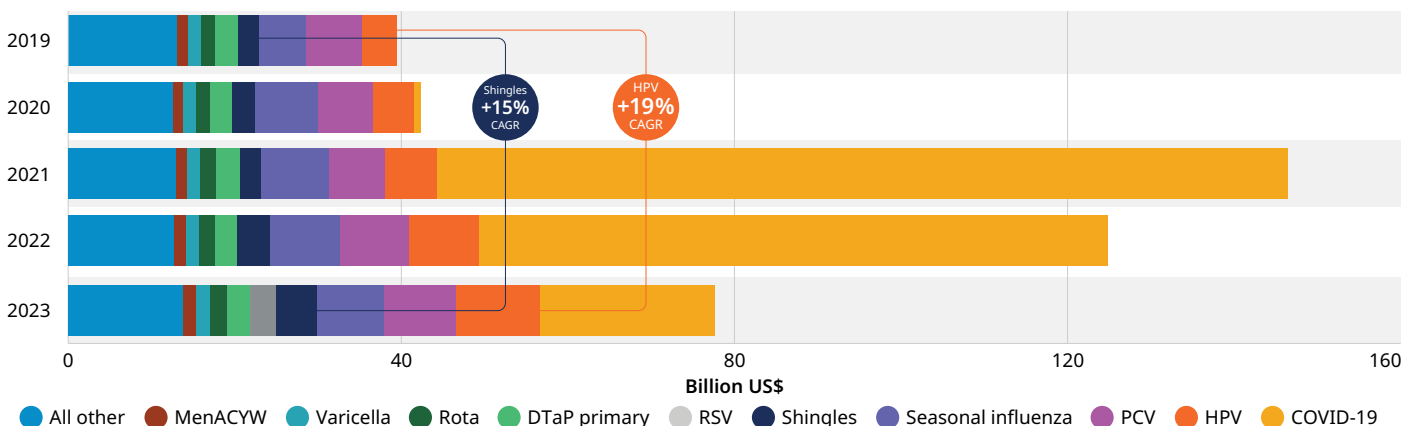


Fig. 1b: Vaccine value (US\$) from 2019–2023 showing the top 10 vaccines by value

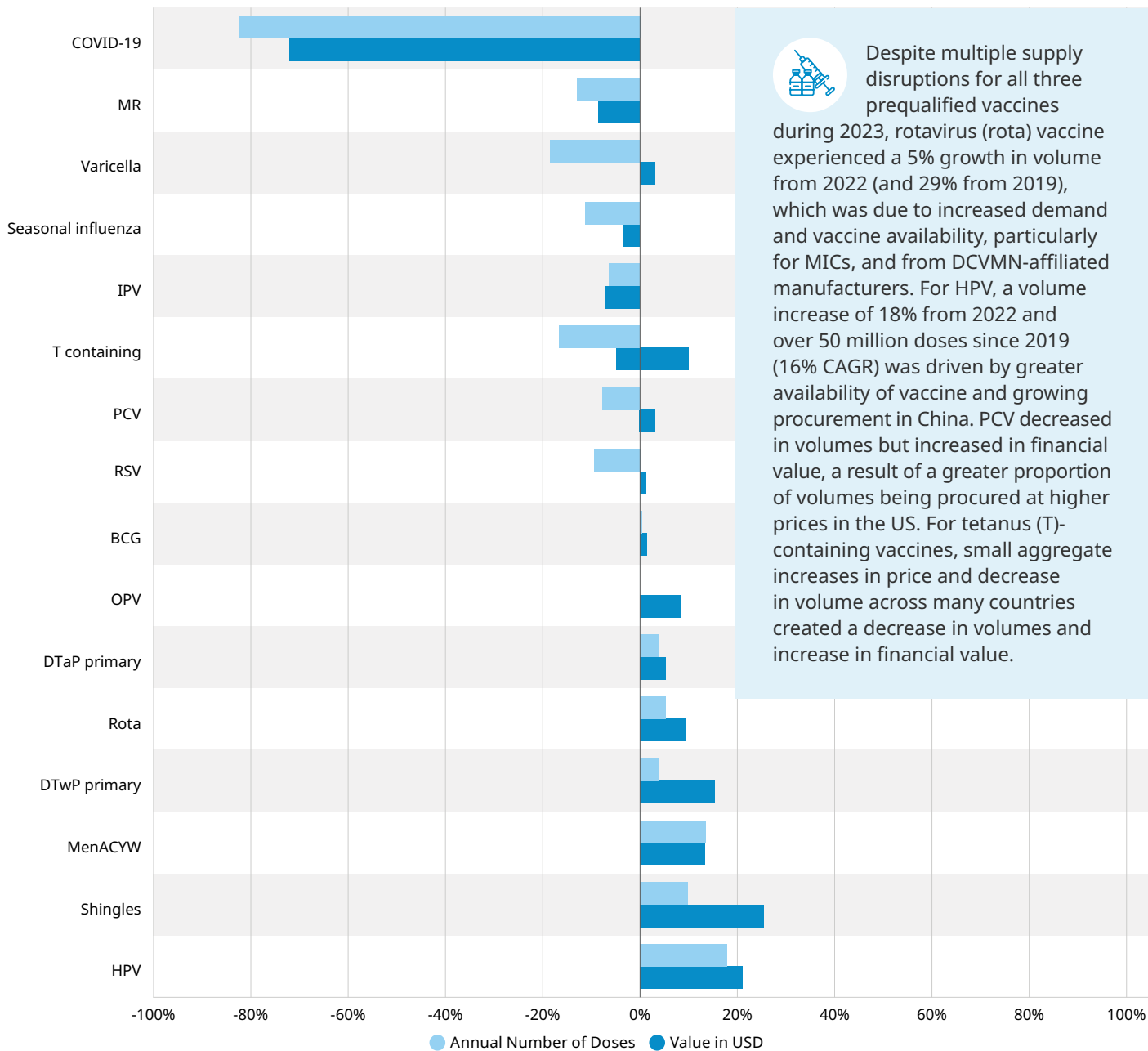


High volumes of sales of COVID-19 vaccines combined with relatively high prices resulted in it being the vaccine with the highest dollar market value in 2023 at US\$ 20 billion (27% of total across all vaccines). This was more than twice the financial value of the next vaccine on the list, when ranked by financial value. As seen in Fig 1b, the vaccines with the highest dollar value in 2023 were COVID-19, HPV, PCV seasonal influenza and shingles. When compared to

2019, the HPV market grew by the largest percentage in financial value, with a 19% CAGR, followed by shingles with a 15% CAGR. Strong demand and greater availability of HPV and shingles vaccines drove this growth. RSV vaccines and mAbs combined were the sixth most valuable market due to relatively high prices and relatively high early demand in their first year of sales, following marketing authorization in several HICs.

a. Differences in the timing and recording of purchase and sales data for 2023 are not fully aligned across all sources and are approximated.

Fig. 2: Percentage change in the top 10 vaccine markets by volume or financial value in 2023, showing change between 2022 and 2023



Despite multiple supply disruptions for all three prequalified vaccines during 2023, rotavirus (rota) vaccine experienced a 5% growth in volume from 2022 (and 29% from 2019), which was due to increased demand and vaccine availability, particularly for MICs, and from DCVMN-affiliated manufacturers. For HPV, a volume increase of 18% from 2022 and over 50 million doses since 2019 (16% CAGR) was driven by greater availability of vaccine and growing procurement in China. PCV decreased in volumes but increased in financial value, a result of a greater proportion of volumes being procured at higher prices in the US. For tetanus (T)-containing vaccines, small aggregate increases in price and decrease in volume across many countries created a decrease in volumes and increase in financial value.

Fig. 2 illustrates how the ten vaccines with the highest volume or financial value in 2023 have changed compared to 2022. Changes in volume and financial value across each market were within the limits of normal annual variability except for the 83% decrease in volume, and 72% accompanying financial value, for COVID-19 vaccines. There are a few other trends worth highlighting. Despite multiple supply disruptions for all three prequalified vaccines during 2023, rotavirus (rota) vaccine experienced a 5% growth in volume from 2022 (and 29% from 2019), which was due to increased demand and vaccine

availability, particularly for MICs, and from DCVMN-affiliated manufacturers. For HPV, a volume increase of 18% from 2022 and over 50 million doses since 2019 (16% CAGR) was driven by greater availability of vaccine and growing procurement in China. PCV decreased in volumes but increased in financial value, a result of a greater proportion of volumes being procured at higher prices in the US. For tetanus (T)-containing vaccines, small aggregate increases in price and decrease in volume across many countries created a decrease in volumes and increase in financial value.



Fig. 3 contrasts volume and financial value in 2023 for the same vaccines as in Fig. 2, overlaying regional details. The volume is the reported sales while the financial value is the volumes sold multiplied by the price, across each country for all products. Five categories of vaccines were identified when analysing this information according to the volume-value lens. The below figure is illustrative: it helps identify the underlying rationale for the aggregate financial value in each market, based on total volumes. Volumes and financial value are characterized as “high”, “medium” or “low”. The volumes sold and corresponding prices across specific countries and regional segments can vary.

1 High volume, low financial value: OPV remains a cornerstone of the Global Polio Eradication Initiative (GPEI) strategy. Every year billions of doses of this vaccine are administered to large portions of the world’s children, but given the average price point, the OPV market has a relatively low financial value.

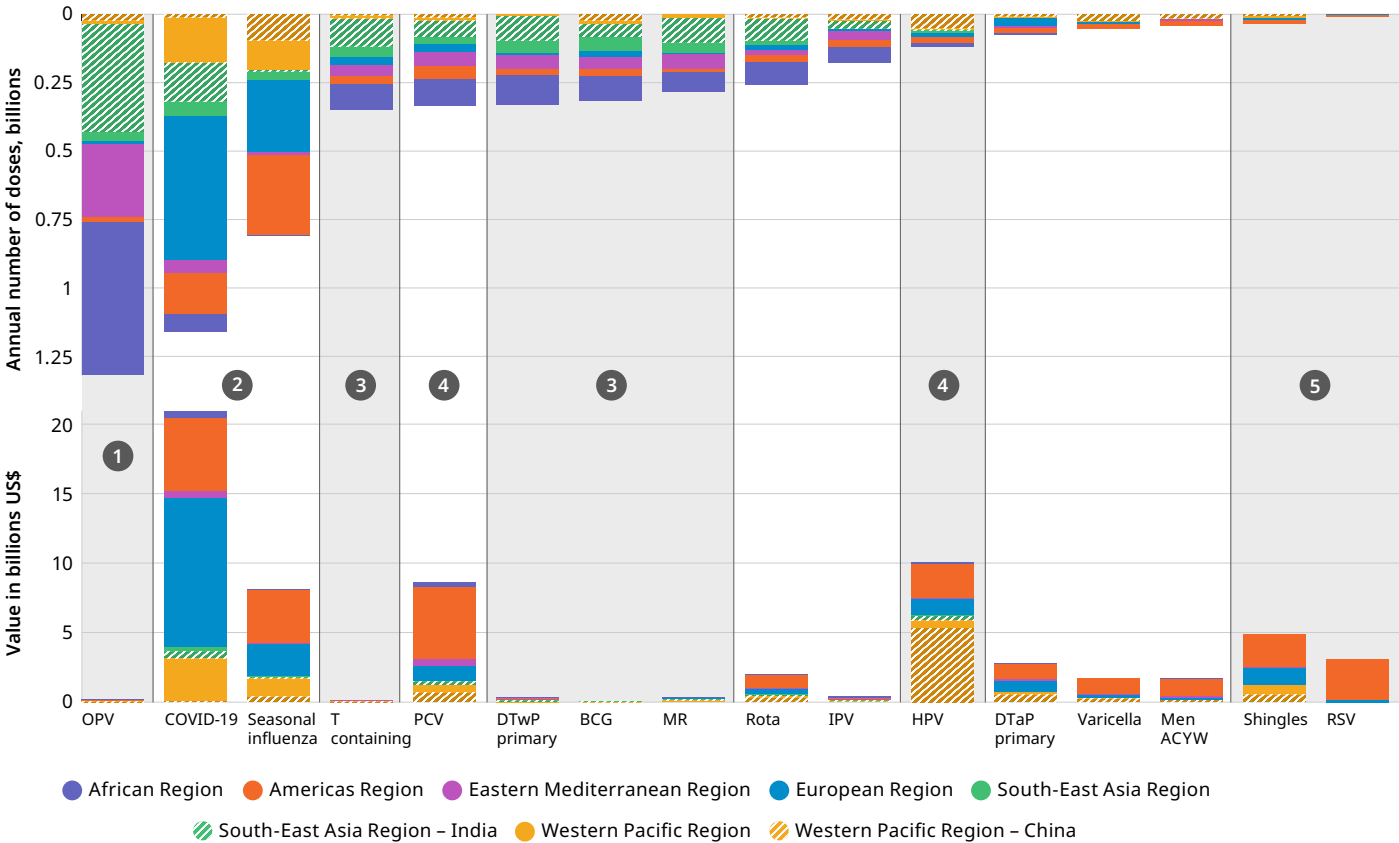
2 High volume, high financial value: COVID-19 and seasonal influenza vaccines are sold annually or bi-annually in a large number of countries. As the majority of doses are sold in HICs, this category has a relatively high financial value.

3 Moderate volume, low financial value: Vaccines that were mainly procured in lower income countries such as T-containing, Diphtheria, tetanus whole cell pertussis combinations (DTwP), Bacillus Calmette–Guérin (BCG), measles rubella (MR), resulting in a low total financial value.

4 Moderate volume, high financial value: The fourth category included vaccines like PCV and HPV, with modest volumes and high financial value, attributable to higher prices in UMICs and HICs.

5 Low volume, moderate financial value: Finally, vaccines purchased mainly in HICs like shingles and the newly introduced RSV immunization products had high financial value, despite relatively small volumes procured in 2023.

Fig. 3: Vaccine volumes (doses) and financial value (US\$) during 2023 by vaccine and region, showing top 10 vaccines by volume or value



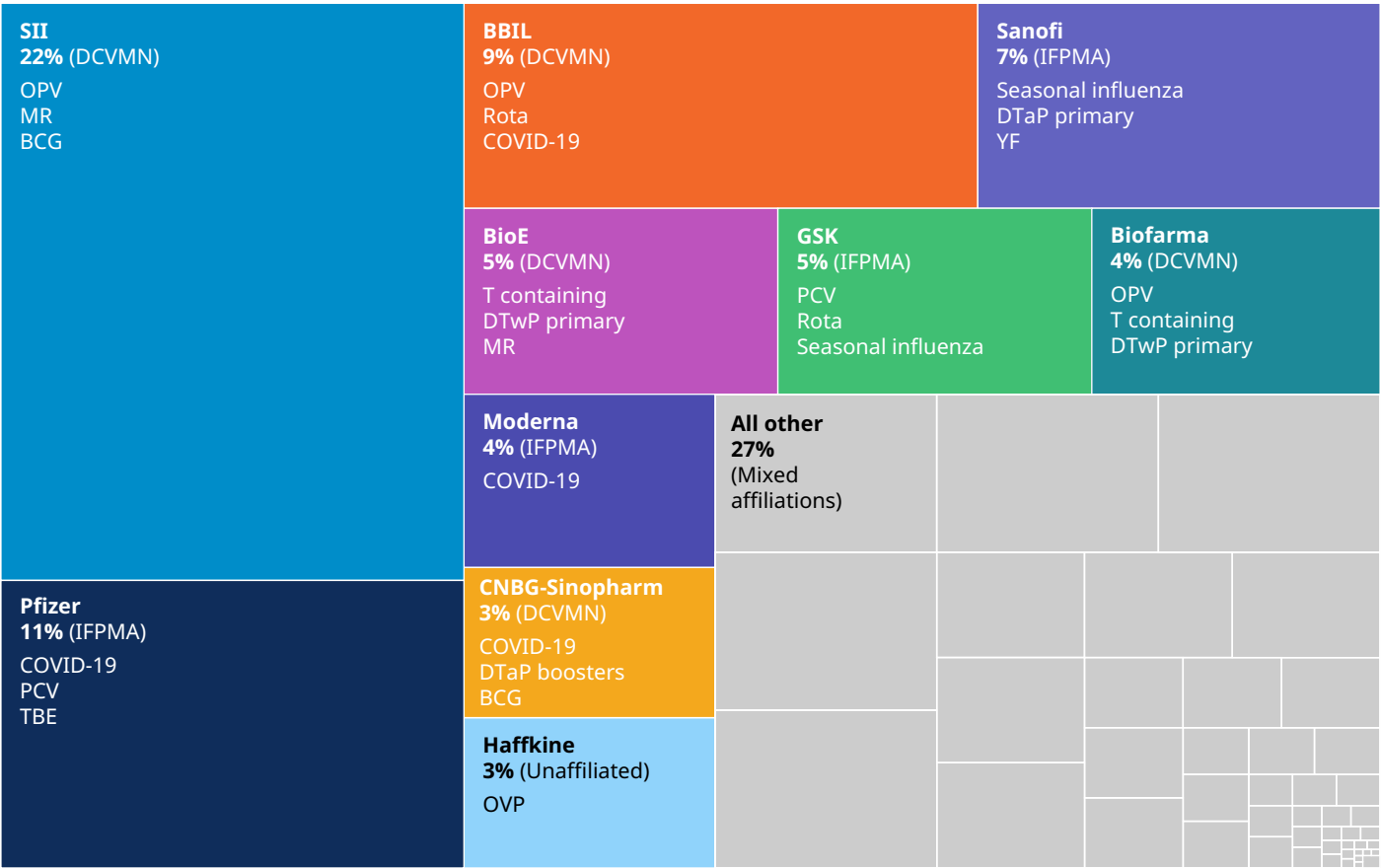
2 Manufacturing and supply

The leading vaccine manufacturers in 2023, defined as those with the greatest financial value and/or highest volumes procured, were largely unchanged from 2022. However, the sizable reduction in COVID-19 vaccine procurement from 2022 to 2023 resulted in a decreased share of global volumes for Pfizer (11% in 2023 versus 26% in 2022). This also resulted in SII returning to its pre-pandemic position as the largest volume manufacturer with 22% of total global market (Fig.5a).

The total number of manufacturers in the market is relatively stable compared to 2022. However, six manufacturers who entered the market in 2021 and 2022 to produce COVID-19 vaccines exited in 2023, while two new entrants came into the market for non-COVID vaccines.

Manufacturers affiliated with the DCVMN accounted for 54% of volumes sold in 2023 and those affiliated with the IFPMA accounted for 34%.

Fig. 5a: Share of market of volume by manufacturer in 2023



The global vaccine market remained concentrated and highly dependent on the ten highest volume manufacturers, who sold 73% of vaccine volumes purchased in 2023. An additional 90 manufacturers contributed to the remaining quarter of the total doses procured in the market in 2023.

Consistent with trends in previous years, the market's financial value was even more concentrated than in 2022, with 85% of the global financial value accounted for by 10 manufacturers. There are no significant variations for

these manufacturers compared to 2022. Moderna only had COVID-19 vaccines in its portfolio so the company's share of global vaccine market's financial value has decreased from 15% in 2022 to 9% in 2023 (Fig. 5b). Pfizer remained the manufacturer that captured the largest share of financial value, i.e. 25% of the total financial value of the global market. Manufacturers affiliated with the IFPMA continued to maintain high share of market value, capturing about 83% of total financial value in the market in 2023, which is an increase from 80% in 2022.

Fig. 5b: Share of market by financial value in 2023

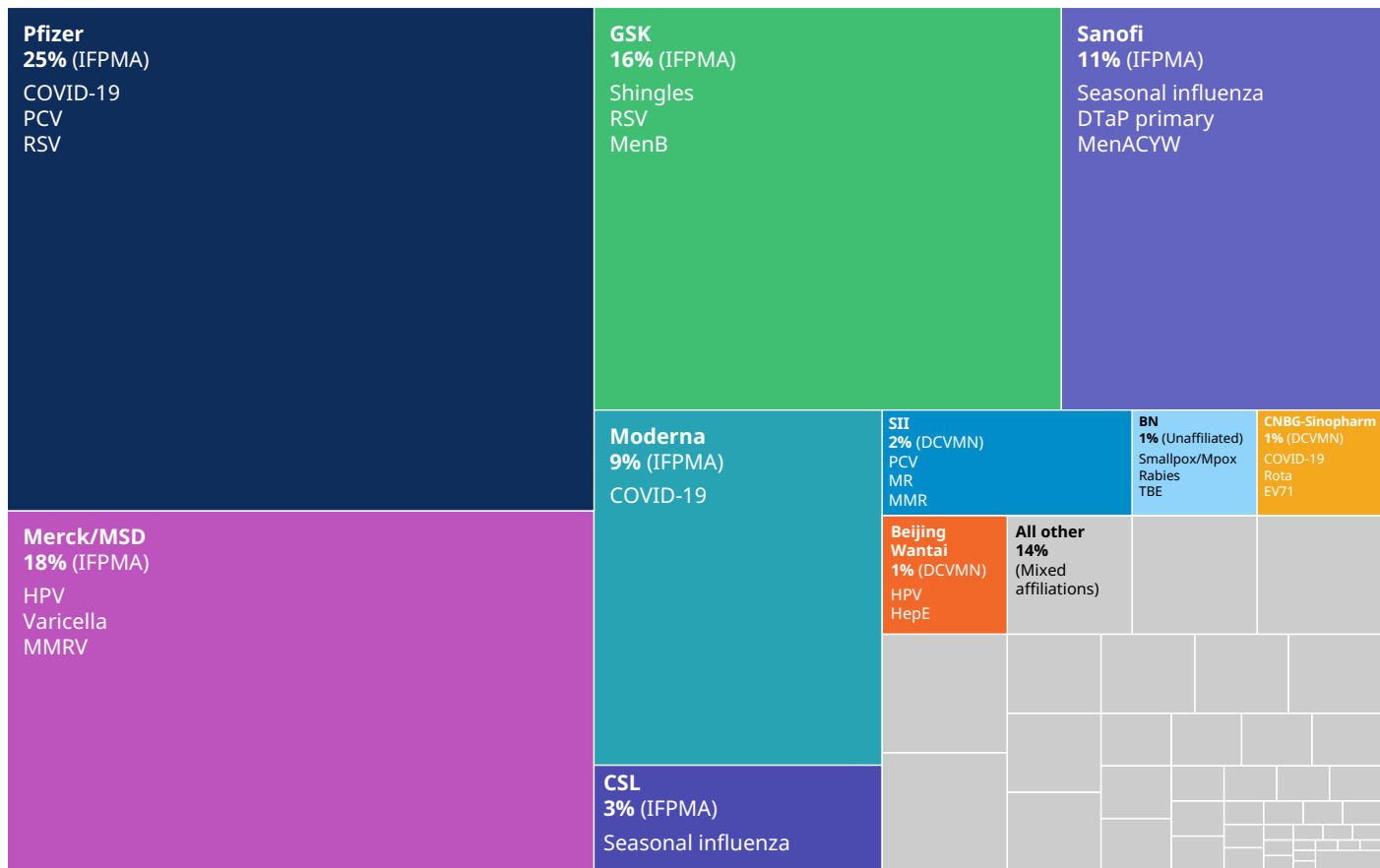
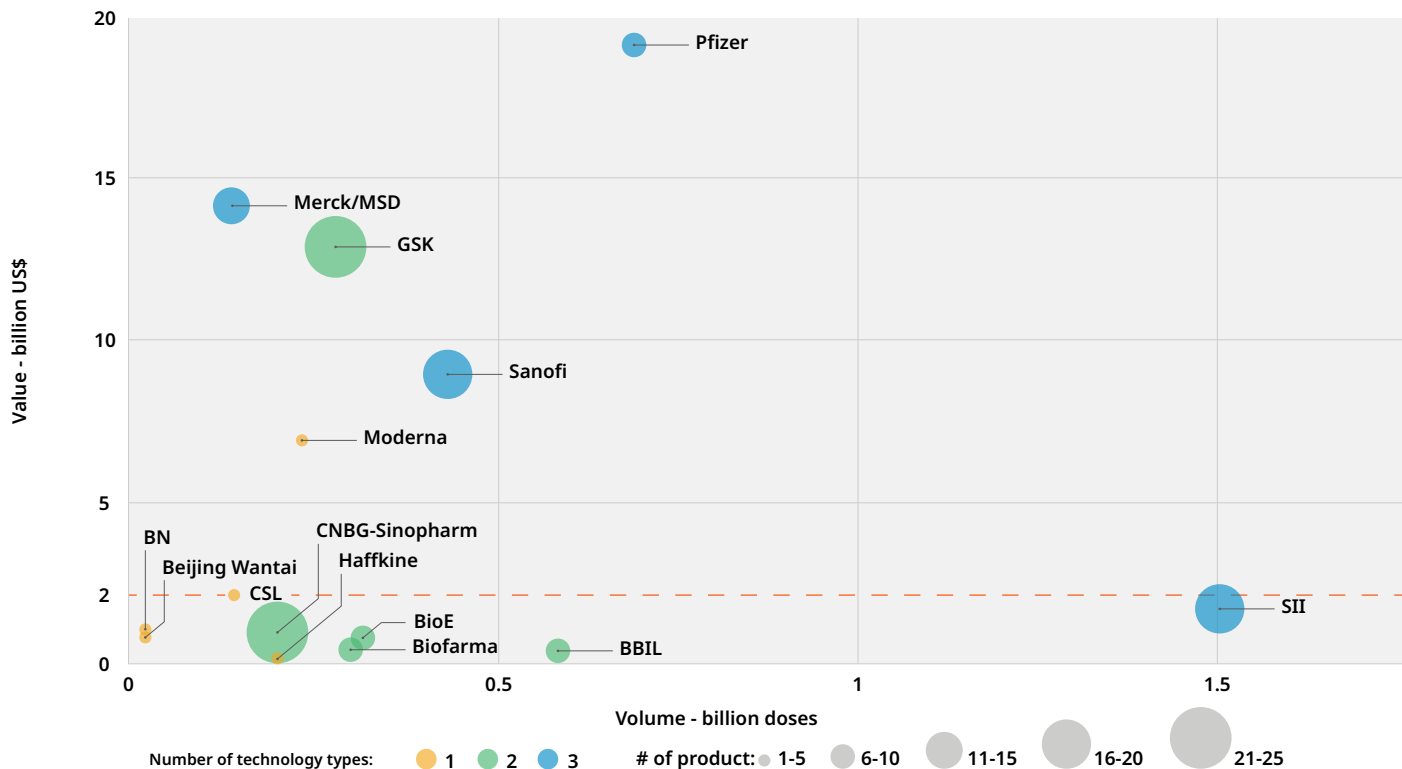


Fig. 6: Top 10 manufacturers by volume or financial value, portfolio size and technology types used



The dominant position of the top financial value manufacturers was confirmed by a more in-depth analysis that combines financial value, number of products and number of technology types^b used (Fig. 6). Dependence on a few large manufacturers (Pfizer, SII, GSK, Sanofi, Merck/MSD) with broad portfolios and use of multiple technology types is evident, with Pfizer and SII being outliers from financial value and volume perspectives.

The horizontal line at 2 billion US\$ in financial value demarcates a split between manufacturers. Below the line are mainly manufacturers headquartered in India and China, accounting for approximately 70% of the total volume. Above the line are the five manufacturers affiliated

with IFPMA, amounting for approximately 30% of global volumes but capturing almost 80% of total financial value.

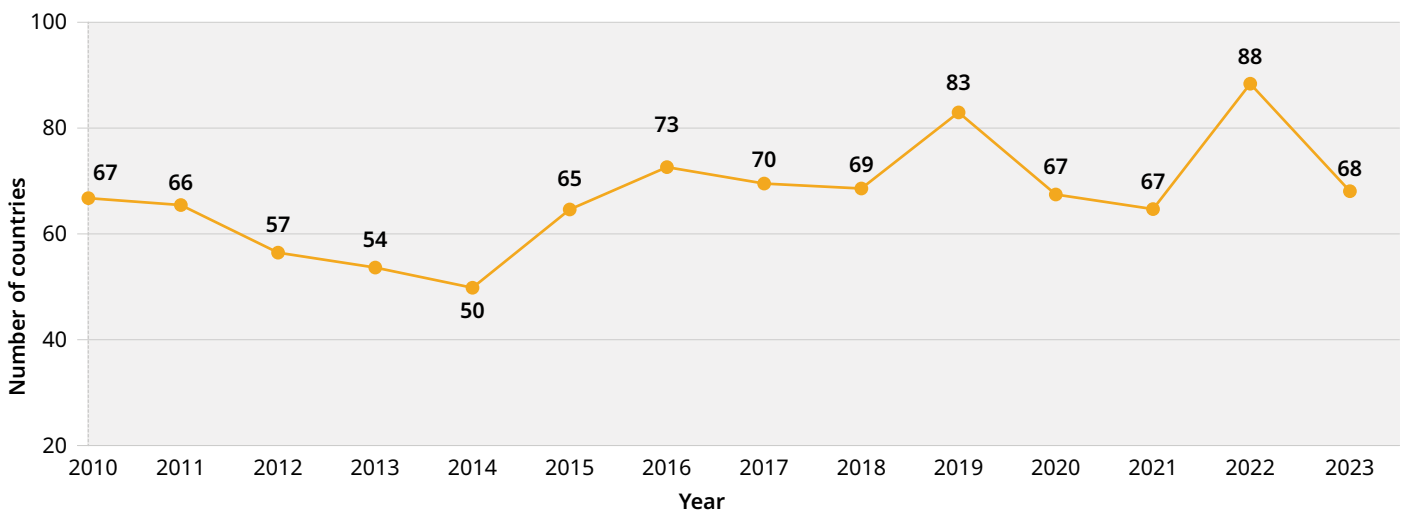
Manufacturers affiliated with the DCVMN including SII, BBIL, Biological E (BioE) and PT Biofarma (Biofarma) have broad vaccine portfolios with multiple technologies. These companies primarily sell their products to low-income countries (LICs) and low middle-income countries (LMICs). Beyond the largest manufacturers that sell more than 100 million doses annually, the number of manufacturers selling between 10 and 100 million doses annually has increased by 14 from 28 in 2019 to 42 in 2023 with half of the increase being manufacturers in China.

3 National stock-outs

At the global level, supply constraints due to manufacturing disruptions or lack of adequate supply allocated to LICs and LMICs can limit availability and reduce access to vaccines. In addition, national stock-outs have historically remained a problem for many countries, with 68 countries globally reporting at least one national stock-out in 2023. The number

of annual national stock-outs reported has ranged between 67-88 in the past five years (Fig. 7), occurring mostly in the same countries each year. Procurement and funding delays were the two most frequently reported causes of a national stock-out for each year since 2019 are often causally related, with delays in funding creating delays in procurement.

Fig. 7: Countries reporting a national stock-out of at least one vaccine

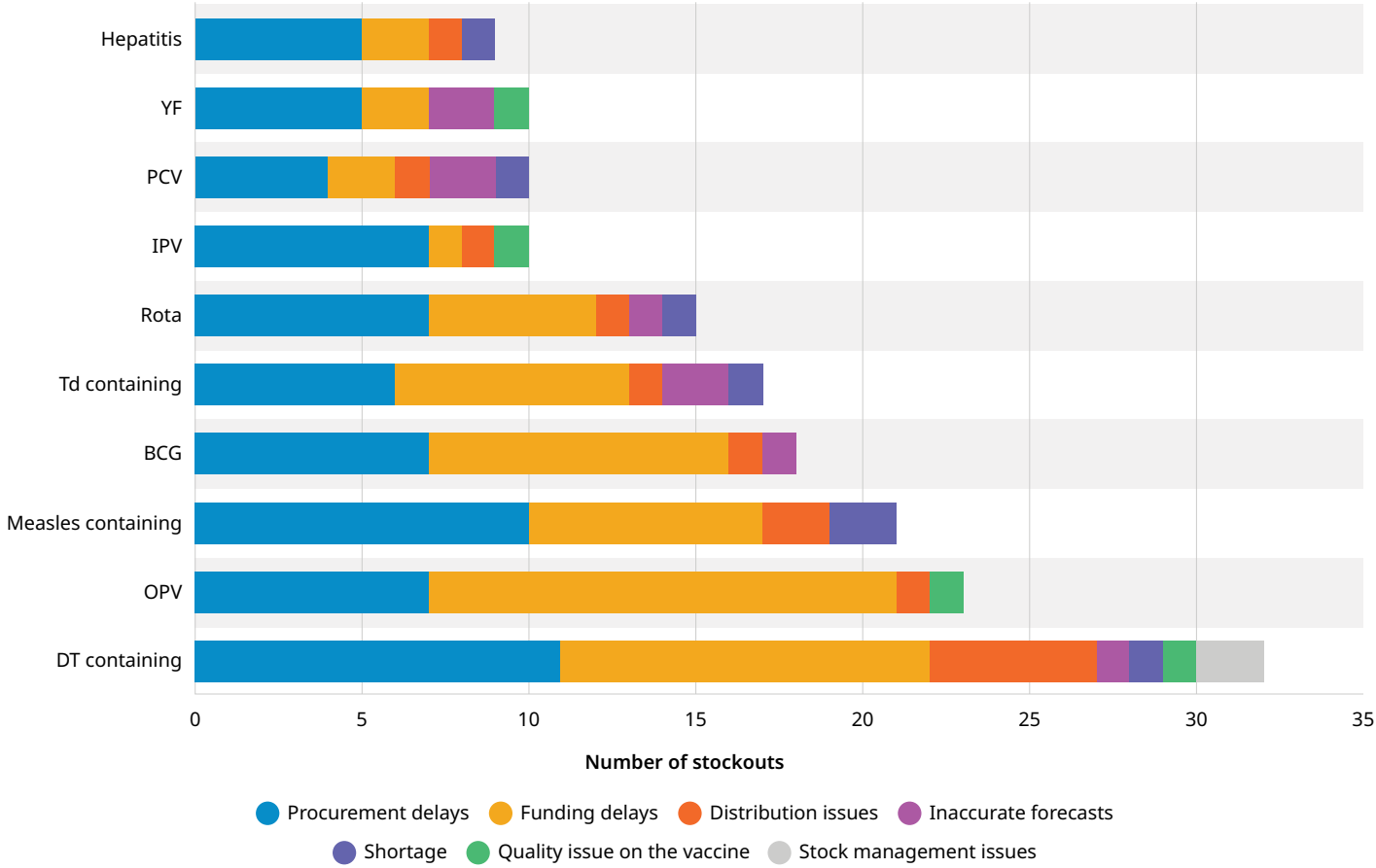


Countries reported stock-outs for all vaccine types, with most occurring for the most frequently procured vaccines: diphtheria and tetanus (DT)-containing, OPV, measles-containing and BCG. Similar to the general analysis on frequent causes discussed above, procurement and funding delays were also the most frequently cited causes of stock-

out of the top 10 vaccines with reported stock-outs (Fig. 8). A limitation of the country-reported data is that global shortages of vaccines exclusively deployed through a global stockpile mechanism (e. g. OCV) are not captured in the analysis, while still experience by serious access challenges largely related to under-supply.

^b. Technology types are classified by production platform as traditional (inactivated, live-attenuated, polysaccharide and toxoid), modern (combination, conjugate and protein-based) and innovative (viral vector, nucleic acid, mRNA). Multiple technology types can be associated with the ability of a manufacturer to efficiently develop and sell a range of vaccines.

Fig. 8: Reasons for stock-out reported by vaccine in 2023 for the 10 vaccines with the highest number of stockouts

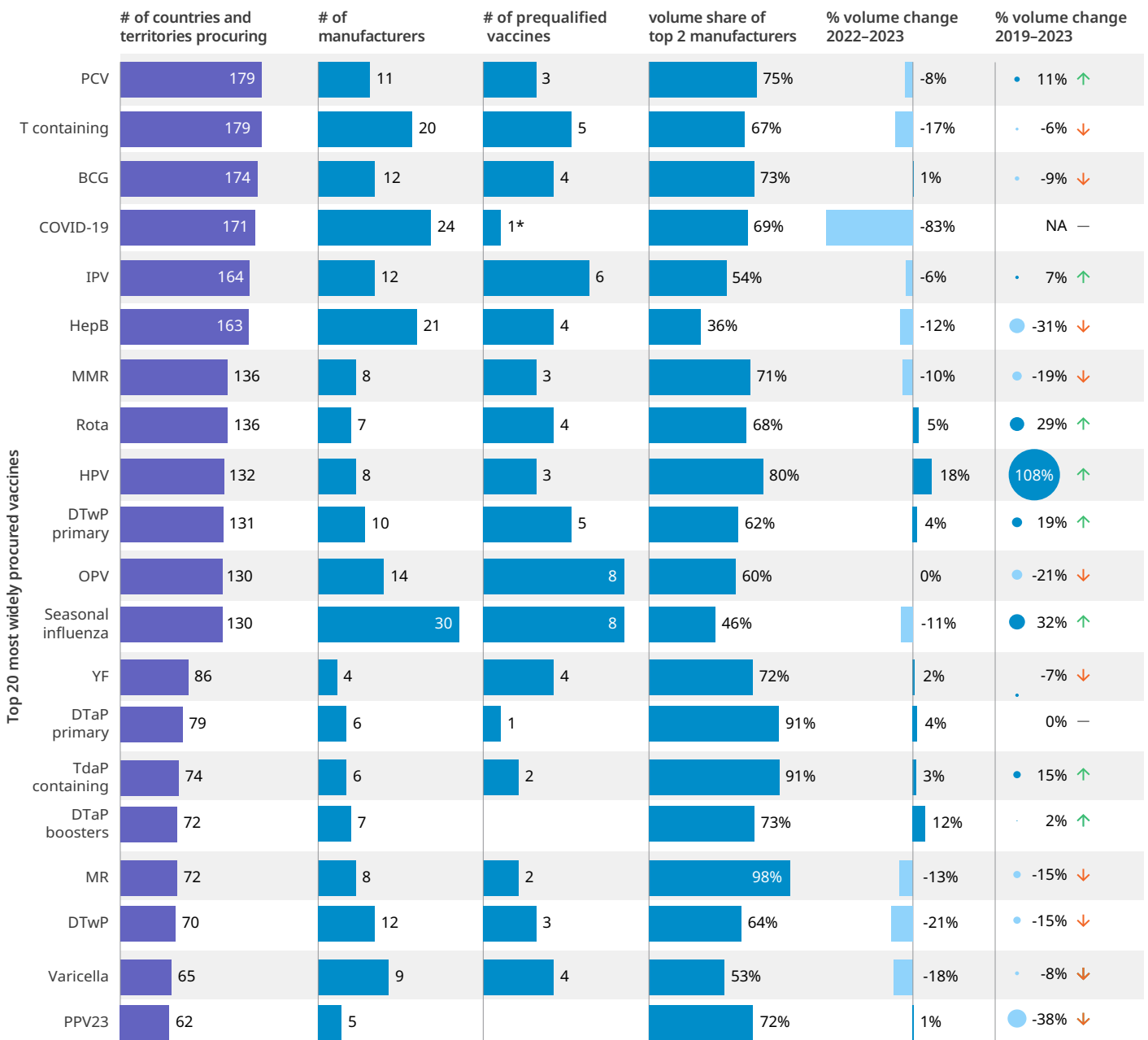


4 Vaccine specific supply dynamics and supply security

Each vaccine market has specific supply dynamics that can facilitate or hinder access and supply security. Given available information at the global level, four supply-related market characteristics were analysed across the 20 vaccine markets with more than 60 country buyers.


For each market, the characteristics analysed are 1) the number of manufacturers, 2) the number of prequalified vaccines, 3) the concentration of supply among the top 2 manufacturers, and 4) the trends over time in volumes purchased.

Fig. 9: Supply-related market characteristics for the 20 most widely procured vaccines in 2023



Note: *Additionally, 12 EUL vaccines from 9 producers.

A higher number of manufacturers (more than five) and greater diversification of the manufacturer base (defined as the top 2 manufacturers market share < 50% of global volumes) results in more sources of supply, which can mitigate supply disruptions should there be production issues. Similarly, the number of prequalified vaccines increases the probability of alternate supply sources for United Nations (UN) procurement agencies. Volume growth from one year to the next most commonly reflects greater access and coverage but this varies at the national level according to each country's national programme policy decisions and programme performance.



The 29% increase for rotavirus vaccine and 32% growth for seasonal influenza vaccine volumes from 2019 to 2023 are driven by more countries introducing or expanding use of the vaccines (e. g. changes to recommendations for use in China). The 108% increase in HPV vaccine volumes between 2019 and 2023 was driven predominantly by new countries introducing the vaccine, and several countries include multiple “catch-up” cohorts.

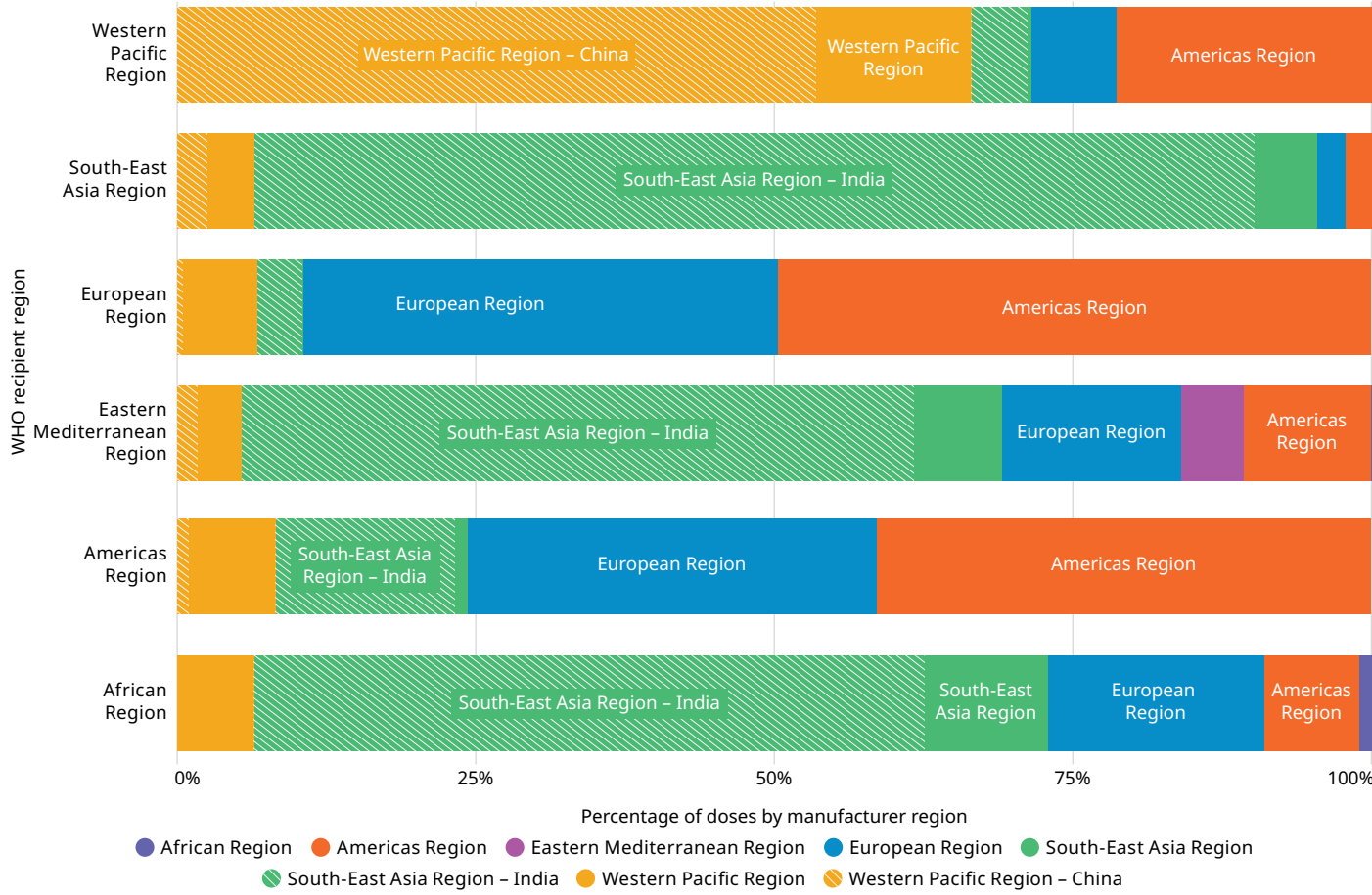
In total, 19 markets (of the 20 analysed) in 2023 had more than five manufacturers. However, only two had enhanced diversification of supply, based on the market share by volume of the top two manufacturers (Fig. 9). These two markets, hepatitis B (HepB) and seasonal influenza, have developed over decades, primarily driven from multiple technology transfers from technology originators. (6) (7)

In most of the markets analysed, there were no significant volume changes, as would be expected. Many mature

vaccine markets are characterized by consistent volumes from year to year, varying only through slowly evolving population and programmatic changes (i.e. vaccination coverage and schedule adjustments).

Achieving market characteristics that support global supply security and access are critical, and market shaping interventions are often required to achieve them. This can prove especially important for the WHO regions that rely primarily on vaccine supply from outside their region.

Fig. 10: Global distribution of vaccine volumes (%) based on WHO region where manufacturer is headquartered (Y-axis) and WHO Region where doses are procured (X-axis)



The WHO African and Eastern Mediterranean regions produced less than 5% of the vaccine procured in their respective regions in 2023 (Fig. 10). The WHO African region was highly dependent on vaccines sourced from manufacturers in India (55%) and Indonesia (10%), and the Eastern Mediterranean region likewise depended on vaccines sold by manufacturers headquartered in India (56%), as well as the US (11%). In contrast, the WHO South-East Asia region self-supplied 87% of vaccines procured (with 84% of those produced by companies in India and with India self-supplying 99% of vaccines procured), and the WHO Western

Pacific region self-supplied 66% of vaccine procured (with 54% of volumes produced by companies in China and with China self-supplying 90% of vaccine procured). Following the COVID-19 pandemic, there have been increased efforts to develop and expand regional manufacturing so that each region has local manufacturers that can supply vaccines, in service of equitable access, (8) regional supply security and economic development, (9) health emergency preparedness and response and supply chain resilience. (10) As these efforts come to fruition, a shift in the regional distribution of manufacturing is expected.

5 Procurement and pricing

As shown in Fig. 11, when analysing vaccine volumes procured based on country income-level and procurement mechanism, vaccine volumes self-procured by MICs accounted for the largest share in 2023 (40% of volumes), as has historically been the case. China, India and Indonesia were the main drivers because of the population sizes and scope of their immunization programs. Together, these three countries were responsible for 27% of procured vaccine volumes in 2023. Volumes procured through UNICEF (across country income-levels) was the next largest category, accounting for 33% of the total global volumes (Fig. 11), making UNICEF the single largest buyer of vaccines globally. (11) When considering vaccines within the Vaccine Alliance

(Gavi) portfolio, 13% of global volumes were procured by UNICEF for Gavi-eligible countries. Gavi's provision of vaccines to countries protects half the world's children. (12)

When looking at financial value, in 2023, vaccines self-procured by HICs represented 72% of the market's value, up from 65% in 2022 and regaining the pre-pandemic share. This share, much larger than its volumes share (24%), was driven by higher prices typically paid by HICs. The particular drivers in 2023 were the significant procurement of COVID-19 vaccines during 2023 and the increase in financial value attributed to PCV, HPV, shingles and RSV vaccines, as explained in previous sections.

Fig. 11: Vaccine volumes (doses) and financial value (US\$) during 2023 by WHO procurement mechanism and country income group

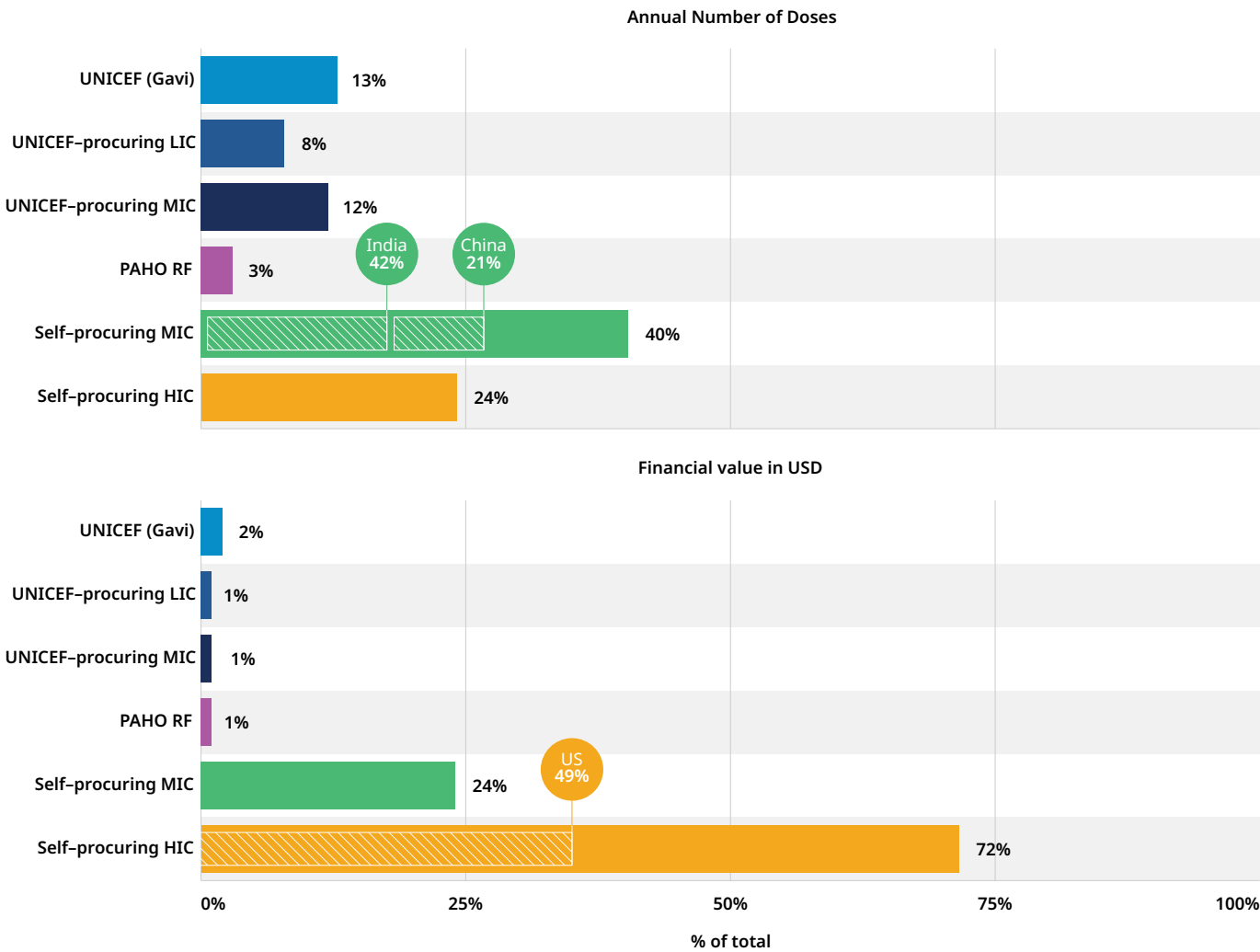


Fig. 12 provides a stratified analysis for individual vaccine markets of prices by procurement mechanism and country classification (i.e. World Bank income group and Gavi eligibility status). The vaccines were selected to represent a broad range of uses and income groups. These include: vaccines procured globally with a variety of product choices (e. g. HPV, PCV); vaccines with widespread procurement among LIC and LMIC where the choice of manufacturers available has increased (e.g. rotavirus vaccine); vaccines used routinely by LIC and in HICs as traveller vaccines (e. g. YF vaccine); and vaccines rarely procured by LIC and LMIC (e. g. seasonal influenza). The main results, listed below, are similar to previous years with no substantial variations in specific vaccine prices.

1. HICs continue to pay the highest prices across all vaccines, while pooled procurement mechanisms continue to negotiate lower prices for countries that go through them.
2. For a given product, manufacturers often use tiered pricing to offer price levels that vary based on a

country's income level, with lower prices offered to countries with lower income levels (i. e. LIC and LMIC).

3. Pooled procurement agencies are typically offered a single price for a given product for a specific pricing tier (e. g. Gavi-eligible country price). Prices offered to self-procuring countries that negotiate procurement bilaterally are highly variable.
4. Newer vaccines, for example HPV vaccine, PCV and rotavirus vaccine, are more expensive than those that have been marketed for longer time periods. These vaccines also recorded the widest price ranges in 2023, potentially due to the several different products on the market (PCV10 to PCV20, HPV2 to HPV9).

For a comprehensive overview of price ranges paid for different vaccines by different countries in 2023, including the minimum and maximum price per dose, based on data collected and published as part of the MI4A 2024 Vaccine Purchase Dataset, the reader can refer to the [MI4A webpage](#).

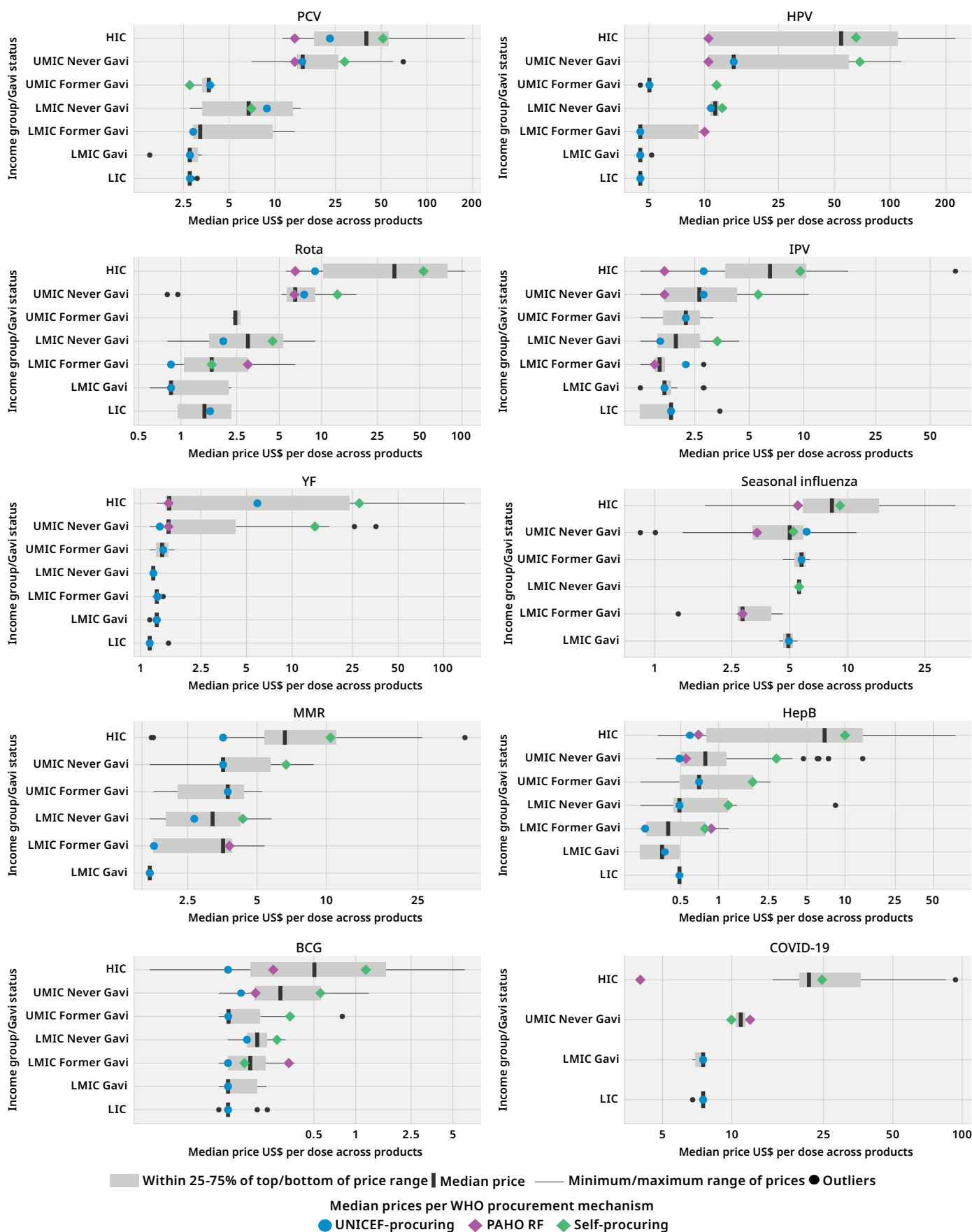


Country grouping for the “procurement and pricing” section

- **Procurement mechanism (UNICEF, PAHO RF, self-procuring):** Refers to the mechanism by which the vaccine was purchased.
- **Country classification by World Bank (LIC/LMIC/UMIC/HIC):** Country categorization into income levels is conducted according to gross national income (GNI) per capita in US dollars.
- **The six categories that appear in Fig. 11** are defined as follows:
 - UNICEF (Gavi): (Volume and financial value of) Gavi-eligible vaccines purchased through UNICEF for Gavi-eligible countries.
 - UNICEF-procuring LIC / MIC: (Volume and financial value of) vaccines purchased through UNICEF by LICs / MICs.
 - PAHO RF: (Volume and financial value of) vaccines purchased by countries through the PAHO RF
 - Self-procuring MIC / HIC: (Volume and financial value of) vaccines purchased by countries through bilateral procurement.
 - **Within the LMIC and UMIC categories of Fig. 12, Gavi eligibility status (never, former, current) is defined** according to country's eligibility to receive Gavi support for vaccines in 2023 or prior.^c

c. Does not include MICs eligible for Gavi support.

Fig. 12: Vaccine prices by procurement mechanism (US\$ per dose) by World Bank income group and Gavi status, 2023



6 Vaccine regulation

To provide regulatory oversight of vaccine development, manufacturing, and deployment, a country’s national regulatory authority needs to reach the required ML 3, represent a stable, well-functioning and integrated regulatory system, or be a WHO-listed authority (WLA). (13) (14)

While ML 3 has been the gold standard, the inclusion of the WLA framework started in 2023 and the first group of countries were listed in October 2023. The framework aims to provide a transparent process for global recognition for regulatory authorities operating at a higher level of regulatory performance.

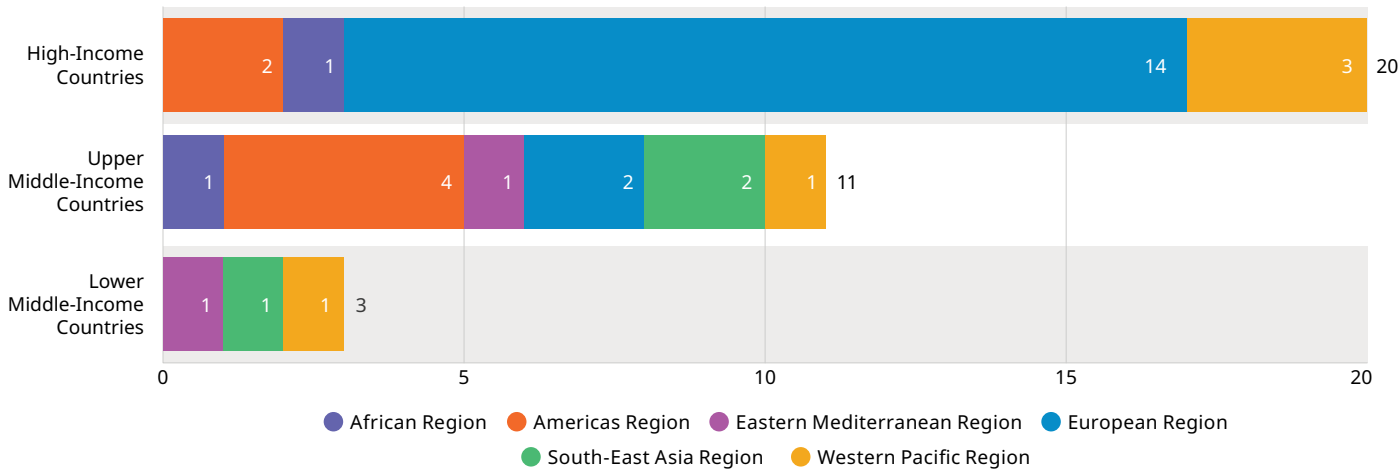
As of September 2024, 34 vaccine-producing countries are considered by WHO to have reached ML 3 for vaccine production or a higher ML. Several countries have been supported by WHO to enhance their regulatory capacity to meet the ML 3 requirement. Of the 34 countries meeting the ML 3 requirement for vaccine manufacturing in 2022, two have moved from UMIC to HIC, and one country moved from LMIC to UMIC. No new country has achieved this milestone in 2023^d. (15) Notably, only 3 out of 34 countries with ML 3 or

above are lower middle-income countries and no low-income countries have reached this maturity level as of 2023.

Due to changes in the vaccine production landscape, (e. g. mRNA vaccine technology transfer hub and Partnership for African Vaccine Manufacturing), the focus of the WHO Regulatory Systems Strengthening programme (16) has been expanded to include countries that are planning to produce vaccines in the coming years. Most of these countries have been supported to enhance their regulatory capacity; some have achieved ML 3 for medicines regulation. This will facilitate the expansion of the scope of the work to vaccine regulation when production starts.

Compared to 42 countries in 2022, 67 countries and one regional economic community are participating in the WHO collaborative registration procedure for prequalified vaccines as of August 2024. The procedure ensures timely approval of quality-assured vaccines to countries and allows manufacturers to streamline their effort, by facilitating country access to evaluation and inspection reports from WHO Prequalification or stringent regulatory authorities.

Fig. 13: Vaccine-producing countries considered ML3 or ML4 in 2023 for vaccine manufacturing (n=34)



In addition to facilitating marketing authorisation of vaccines through evaluation of regulatory agency maturity and the WHO collaborative registration procedure, WHO provides a prequalification service for UN procurement agencies. During 2023, WHO prequalified seven new

vaccines from five manufacturers, resulting in 158 prequalified vaccines being available from 44 manufacturers in total, as of end 2023. In total, 65% of vaccine volumes procured in the market in 2023 were prequalified by WHO.

d. Based on internal RSS database of WHO Member States and their respective ML (actual, based on benchmarking exercises or estimated, based on historical data).

Annex 1

Vaccines included in the Global Vaccine Market Report (GVMR) dataset

Abbreviation of the vaccine used in the GVMR	Long name of vaccine and detailed types of vaccine abbreviation of detailed vaccines when different than vaccine
Anthrax	Anthrax: live attenuated, subunit
BCG	Bacillus Calmette-Guérin (for tuberculosis)
Cholera	Oral cholera vaccine: OCV
COVID-19	COVID-19 (C-19): C-19 Inact.(inactivated), C-19 mRNA, C-19 nRVV (non-replicating viral vector), C-19 Subunit, C-19 VLP (virus like particle)
Dengue	Dengue
DT	Diphtheria and tetanus
DTaP boosters	Diphtheria, tetanus acellular pertussis and combinations used as boosters: DTaP, DTaP-IPV
DTaP primary	Diphtheria, tetanus acellular pertussis combinations used as the primary series: DTaP-HepB-IPV, DTaP-HepB-Hib-IPV (hexa), DTaP-Hib, DTaP-Hib-IPV
DTwP	Diphtheria, tetanus, and whole cell pertussis: DTwP
DTwP primary	Diphtheria, tetanus whole cell pertussis combinations used as the primary series: DTwP-HepB-Hib (penta), DTwP-HepB-Hib-IPV (hexa), DTwP-HepB
Ebola	Ebola
EV71	Enterovirus 71
HepA	Hepatitis A
HepA+B	Hepatitis A and B combined
HepB	Hepatitis B
HepE	Hepatitis E
HFRS	Haemorrhagic Fever with Renal Syndrome
Hib	Haemophilus influenzae type B
HPV	Human papillomavirus: HPV2, HPV4, HPV9
IPV	Inactivated polio
JE	Japanese encephalitis: inactivated, live attenuated
Leptospirosis	Leptospirosis
Malaria	Malaria
Measles	Measles
Men5CV	Meningococcal A, C, Y, W, X conjugate
MenA	Meningococcal A, MenA conj. (conjugate), MenA Ps (polysaccharide)
MenAC	Meningococcal A and C : MenAC conj. (conjugate), MenAC Ps (polysaccharide)
MenACYW	Meningococcal A, C, Y, W-135: MenACYW-135 conj. (conjugate), MenACYW-135 Ps (polysaccharide)

Abbreviation of the vaccine used in the GVMR	Long name of vaccine and detailed types of vaccine abbreviation of detailed vaccines when different than vaccine
MenB	Meningococcal B
MenC conj.	Meningococcal C conjugate; MenC conj., Hib-MenC conj.
MM	Measles, mumps
MMR	Measles, mumps, rubella
MMRV	Measles, mumps, rubella, varicella
MR	Measles and rubella
Mumps	Mumps
OPV	Oral polio (all types)
Plague	Plague
PCV	Pneumococcal conjugate: PCV10, PCV13, PCV14, PCV15, PCV20
PPV23	Pneumococcal polysaccharide 23-valent
Rabies	Rabies
RSV	Respiratory syncytial virus: RSV, RSV mAb (monoclonal antibodies)
Rubella	Rubella
Rota	Rotavirus: RV1, RV5
Seasonal influenza	Seasonal influenza; HD-IV (high dose inactivated), IIV-Adj. (inactivated, adjuvanted), IIV-QIV (inactivated, quadrivalent), IIV-TIV (inactivated, trivalent), LAIV-QIV (live attenuated, quadrivalent), LAIV-TIV (live attenuated, trivalent), Subunit-QIV (subunit, quadrivalent)
Shingles	Shingles (aka Varicella zoster): live attenuated, subunit
Smallpox/Mpox	Smallpox/Mpox
T-containing	Tetanus: Td, Td-IPV, TT
TBE	Tick-borne encephalitis
Tularemia	Tularemia
Typhoid	Typhoid: TCV (conjugate), Typhoid Ps (polysaccharide)
Tdap containing	Tetanus, diphtheria, acellular pertussis: Tdap, Tdap-HepB, Tdap-IPV
Tularemia	Tularemia
Varicella	Varicella
YF	Yellow fever

Annex 2

Data sources

The electronic Joint Reporting Forms (eJRFs) were the primary source of country-reported information, including for vaccine stock-out data. Data on procurement and prices of vaccines are submitted annually to WHO by Member States. The data include information on the types of vaccines procured, the presentation size and format, the names of the vaccine manufacturers, the number of doses procured, the procurement mechanism, the price per dose of vaccine, and other information on the nature of the procurement contract. eJRF data are reported by countries and, as such, might contain errors. The reporting countries are solely responsible for their accuracy. [\(17\)](#)

The Global Vaccine Market Model (GVMM) was used to supplement volume information where not reported elsewhere. [\(18\)](#)

China lot release data were accessed from public websites of the releasing regulatory authorities in China and translated. In a few cases where no lot size data were available, an average was used based on other vaccines from the same manufacturer. [\(19\)](#)

UNICEF pricing information was used to supplement price, [\(20\)](#) while procured volume information was used to validate the annual number of doses. [\(21\)](#) Market-based information contained in market notes was used as part of the data validation activities. [\(22\)](#)

PAHO Revolving Fund pricing information was used to supplement price information where not reported in the eJRF. [\(23\)](#)

International Coordinating Group (ICG) for vaccine provision volume shipped data for cholera, meningococcal, Ebola and yellow fever vaccine were used to supplement country-reported vaccine use. [\(24\)](#)

Publicly reported sales for 2023 were sourced directly from reports of 32 companies.^e

World Bank gross national income (GNI) per capita data were used to determine the country income level. The most recently income level classification is used for the country even if it has changed between 2019 and 2023. [\(25\)](#)

Gavi, the Vaccine Alliance (Gavi) eligibility criteria for 2023 were used to determine the status of each country. [\(26\)](#) [\(19\)](#) Gavi Market Shaping Roadmaps were used as part of the data validation activities performed during data validation. [\(27\)](#)

US Centers for Disease Control Vaccines Price List for US public and private sector prices. The final list published in each calendar year was referenced. [\(28\)](#)

United Nations Office for Project Services (UNOPS) exchange rates for converting prices to US\$ were sourced from exchange rates for 31 December 2023. [\(29\)](#)

e. Abbott, Adimmune, Aim Vaccine Co., AZ, Beijing Wantai, BN, BioNTech, CanSino, CDBio CSL, Daiichi Sankyo, Dynavax, Emergent, Fosun Pharma, GSK, Hualan, KMBio, Moderna, Merck/MSD, Mitsubishi Tanabe, Novavax, Pfizer, Sanofi, Sinovac, Shenzhen Kangtai, SK Bioscience, Takeda, Valneva, VBI Vaccines, Walvax, Zhifei.

References

- Shattock AJ, Johnson HC, Sim SY, Carter A, Lambach P, Hutubessy RCW, et al. Contribution of vaccination to improved survival and health: modelling 50 years of the Expanded Programme on Immunization. *Lancet*. 2024;403(10441):2307-16. <https://pubmed.ncbi.nlm.nih.gov/38705159/>.
- WHO/UNICEF estimates of national immunization coverage 2024 [website]. WHO/UNICEF; n.d. <https://www.who.int/teams/immunization-vaccines-and-biologicals/immunization-analysis-and-insights/global-monitoring/immunization-coverage/who-unicef-estimates-of-national-immunization-coverage>.
- Scorecard for Immunization Agenda 2030 (IA2030) [website]. World Health Organization; 2024 <https://scorecard.immunizationagenda2030.org/ig2.1>.
- Global childhood immunization levels stalled in 2023, leaving many without life-saving protection [press release]. Geneva/New York: UNICEF; 14 July 2024 <https://www.who.int/news/item/15-07-2024-global-childhood-immunization-levels-stalled-in-2023-leaving-many-without-life-saving-protection>.
- Mikulic, M. Revenue of the worldwide pharmaceutical market from 2001 to 2023 [database]. Statista; 2024 <https://www.statista.com/statistics/263102/pharmaceutical-market-worldwide-revenue-since-2001/>.
- Chadwick C, Friede M, Moen A, Nannei C, Sparrow E. Technology transfer programme for influenza vaccines - Lessons from the past to inform the future. *Vaccine*. 2022;40(33):4673-5. <https://pubmed.ncbi.nlm.nih.gov/35810059/>.
- Increasing access to vaccines through technology transfer and local production [website]. World Health Organization; 2011. (<https://www.who.int/publications/i/item/9789241502368>).
- African Vaccine Manufacturing Accelerator (AVMA): What is AVMA? [website]. Gavi; n.d. <https://www.gavi.org/programmes-impact/types-support/regional-manufacturing-strategy/avma>.
- Partnerships for African Vaccine Manufacturing (PAVM) Framework for Action [website]. AfricaCDC; 2022. <https://africacdc.org/download/partnerships-for-african-vaccine-manufacturing-pavm-framework-for-action/>.
- About us [website]. RVMC; n.d. <https://rvmc.net/about-us>.
- Transforming global access to vaccines: Five reasons why UNICEF's pooled procurement approach is crucial to deliver vaccines affordably and on time [website]. UNICEF; 2023. <https://www.unicef.org/supply/stories/transforming-global-access-vaccines>.
- Vaccine Alliance reaches more than one billion children [website]. Gavi; 2023. <https://www.gavi.org/news/media-room/vaccine-alliance-reaches-more-one-billion-children>.
- Manual for benchmarking and formulation of institutional development plans. Geneva: World Health Organization; 2023. Report No. <https://iris.who.int/bitstream/handle/10665/376137/9789240087637-eng.pdf?sequence=1>.
- GPW Impact Measurement Metadata [website]. World Health Organization; 2024. <https://www.who.int/publications/m/item/gpw-impact-measurement-metadata>.
- WHO/UNICEF Joint Reporting Process. WHO/UNICEF; 2024. <https://www.who.int/teams/immunization-vaccines-and-biologicals/immunization-analysis-and-insights/global-monitoring/>
- Our Work [website]. Linksbridge; n.d. <https://linksbridge.com/our-work>.
- WHO/UNICEF Joint Reporting Process. WHO/UNICEF; 2024. <https://www.who.int/teams/immunization-vaccines-and-biologicals/immunization-analysis-and-insights/global-monitoring/>
- Our Work [website]. Linksbridge; n.d. <https://linksbridge.com/our-work>.
- Resources: Database [online database]. National Medical Products Administration; 2024. <https://english.nmpa.gov.cn/database.html>.
- Vaccines pricing data [online database]. UNICEF; 2024. <https://www.unicef.org/supply/vaccines-pricing-data>.
- Gavi shipment reports [online database]. UNICEF; 2024. <https://www.unicef.org/supply/documents/gavi-shipment-reports>.
- Gavi shipment reports [online database]. UNICEF; 2024. <https://www.unicef.org/supply/documents/gavi-shipment-reports>.
- PAHO Revolving Fund Vaccine Prices for 2023 [website]. Pan American Health Organization (PAHO); 2023. <https://www.paho.org/en/documents/paho-revolving-fund-vaccine-prices-2023>.
- International Coordinating Group (ICG) on Vaccine Provision [website]. WHO; n.d. <https://www.who.int/groups/icg>.
- World Development Indicators database: Gross national income 2023, Atlas method [online database]. World Bank; 1 July 2024. <https://datacatalogfiles.worldbank.org/ddh-published/0038127/DR0046432/GNI.pdf?versionId=2024-07-01T12:42:55.5218615Z>.
- Programmes & Impact: Eligibility [website]. Gavi; n.d. <https://www.gavi.org/types-support/sustainability/eligibility>.
- Our Alliance: Market Shaping roadmaps [website]. Gavi; 2024. <https://www.gavi.org/our-alliance/market-shaping/market-shaping-roadmaps>.
- Archived CDC Vaccine Price List as of December 19, 2023 [database]. Centers for Disease Control and Prevention (CDC); 2023. <https://archive.cdc.gov/#/details?q=>.
- UN Operational Rates of Exchange [database]. United Nations; n.d. <https://treasury.un.org/operationalrates/OperationalRates.php>.

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