NOVEMBER 2025

Global market landscape of vaccine manufacturing and procurement

World Health Organization

WORKING DRAFT

NOVEMBER 2025

Global market landscape of vaccine manufacturing and procurement

World Health Organization

Contents

Cover:
© WHO / Ain Media

Abbreviations

WHO	World Health Organization
PQ	prequalified
HICS	high-income countries
LICS	low-income countries
MICS	middle-income countries
mRNA	messenger RNA
R&D	research and development
DS	drug substance
DP	drug product
HQ	headquarters
PAHO	Pan American Health Organization
PAHO RF	Pan American Health Organization Revolving Fund
EU	European Union
LMIC	lower-middle-income country
UMIC	upper-middle-income country
PCV	pneumococcal conjugate vaccine
HPV	human papillomavirus
OPV	oral polio vaccine
Td	tetanus and diphtheria
BCG	Bacillus Calmette-Guérin
MR	measles-rubella
DTwP	tetanus and whole-cell pertussis
IPV	inactivated polio vaccine
GPEI	Global Polio Eradication Initiative
YF	yellow fever
sIPV	Sabin inactivated polio vaccine
UNICEF	United Nations Children's Fund
AMC	advanced market commitment
IP	intellectual property
MPP	Medicines Patent Pool
AVMA	African Vaccine Manufacturing Accelerator
PAVM	Partnership for African Vaccine Manufacturing
ODA	official development assistance
PI	product insert
cGMP	current good manufacturing practices
PHAHM	Platform for Harmonized African Health Products Manufacturing
AFRICA CDC	Africa Centres for Disease Control and Prevention
RVMC	Regionalized Vaccine Manufacturing Collaborative
CEPI	Coalition for Epidemic Preparedness Innovations
GCC	Gulf Cooperation Council
ASEAN	Association of Southeast Asian Nations
APPM	African Pooled Procurement Mechanism
GTH-B	Global Training Hub for Biomanufacturing
MI4A	Market Information for Access to Vaccines
GVMD	Global Vaccine Market Dataset
eJRF	electronic Joint Reporting Form
GVMR	Global Vaccine Market Report
AFR	WHO African Region
AMR	WHO Region of the Americas
EMR	WHO Eastern Mediterranean Region
EUR	WHO European Region
SEAR	WHO South-East Asia Region
WPR	WHO Western Pacific Region
MMR	measles, mumps and rubella
DTaP	diphtheria, tetanus, pertussis and polio
TDaP	tetanus, diphtheria, and pertussis
PPV23	pneumococcal polysaccharide vaccine (23-valent)

Executive summary

Achieving equitable global vaccine access requires available, accessible, affordable, quality-assured vaccines reaching all countries globally where there is need. Important steps have been taken in this direction over the last decades, resulting in countries accessing an increasing portfolio of life-saving vaccines. This positive outcome is attributed to many developments, including the adoption of market-shaping mechanisms, greater information transparency, effective pooled procurement channels and an increased number of manufacturers with World Health Organization (WHO) prequalified (PQ) products.

Many countries and partners have highlighted the significance of building vaccine manufacturing capacity across different regions following the COVID-19 pandemic experience. Related initiatives have been met with enthusiasm and material support. This development can further contribute to the expansion and diversification of the global manufacturing landscape and country procurement patterns. Understanding the trends that shape this landscape and patterns is important in identifying global and regional access barriers, opportunities and actions for countries, vaccine manufacturers and international organizations.

The analyses and related findings in this report provide insights into the current state of the global vaccine ecosystem and geographic distribution of key capacities, identify actions needed to improve equitable access and monitor trends over time as more regional manufacturing is established.

Key findings from the report analysis

- All WHO regions[1] are interdependent with other regions for vaccine supply. Country-level data show that no country meets its vaccine needs solely through vaccines produced in the region.
- In addition, countries in all regions purchase vaccines that have production stages located in multiple regions.
- The WHO African Region sources less than 5% of its vaccines from companies headquartered within the region, relying heavily on manufacturers based in the WHO South-East Asia Region. In contrast, South-East Asia is the most self-reliant, sourcing 89% of its vaccines from within the region, followed by the WHO Western Pacific Region (67%) and the WHO European Region (54%).
- Domestic manufacturing capacity can strengthen a country's supply security, and regional manufacturing can be an important source of supply for countries in the region. However, having vaccine production capacity in a country does not guarantee supply security in emergencies. As demonstrated during the COVID-19 pandemic, ensuring the availability of raw materials and capacity for all stages of manufacturing is needed to ensure supply security during health emergencies.
- Vaccine production often occurs within the same region from end to end, indicating that manufacturers tend to carry out all stages of production in a single, integrated location. The WHO European Region and the WHO Region of the Americas are exceptions, as vaccines manufactured in these areas are more likely to involve production steps spanning both regions.
- High-income countries (HICs) tend to purchase vaccines from manufacturers headquartered in high-income countries, while low-income countries (LICs) rely on manufacturers headquartered in HICs and middle-income countries (MICs). If vaccine suppliers prioritize more profitable markets when supply is constrained, this creates an access risk for LICs.

1 WHO regions are defined in Annex 1.

- A concentration of suppliers in a market is more likely to result in supply disruptions, with limited alternative sources or buffer capacity available to fill supply gaps. The root causes for the concentration can vary. For example, markets may have few suppliers due to low commercial attractiveness (due to structural factors such as demand unpredictability or markets that serve populations in low-income settings) or markets may have several suppliers, yet with high volume concentration among a small subset of suppliers resulting in oligopolistic dynamics (due to delayed entry of competitors and limited market share, product preferences, price dynamics, etc.). Markets with secure supply typically have in common a diverse, distributed supplier basis, and stable and high demand for routine use.

- There is a skewing of vaccine manufacturers' distribution by market share, both in terms of volume and financial value. A few large companies sell over 400 million doses and exceed US$5 billion in financial value. In contrast, 75–85% of manufacturers are small to medium-sized, with over 30% selling fewer than 5 million doses annually and over 20% capturing less than US$5 million in financial value.

- The majority of vaccine producers use traditional technology platforms (live attenuated or inactivated virus, polysaccharide, toxoid) for vaccine production. Modern technologies (protein-based, conjugation) are less accessible to regions with limited capacity. Innovative platforms like messenger RNA (mRNA) or viral vectors are limited mainly to production in the United States and Europe.

These findings reveal a global vaccine supply ecosystem that is geared towards commercially viable markets that target large populations and have predictable demand, rather than markets for health emergencies. Even the more predictable markets face demand and supply imbalances due to the nature of vaccine production and the market dynamics inherent to these products. Within this ecosystem, countries employ a mix of strategies to secure vaccine access. HICs routinely source from multiple suppliers for the same vaccine, while LICs and some MICs rely on pooled procurement to manage costs. Some countries produce vaccines, so they are largely self-reliant to meet their population's needs, but they still import at least some vaccines. During a pandemic, limited availability of raw materials and other constraints due to reductions in the movement of goods may impact their supply security. During health emergencies more broadly, the inability to scale or switch production rapidly enough has also impacted supply.

↓ **Below**

Strategic discussion on regional vaccine manufacturing

> For regions embarking on developing regional manufacturing capacity, there is an opportunity to pursue end-to-end investments, to ensure true supply security and to support regional priorities.

Based on current initiatives that support development or expansion of regionalized vaccine manufacturing, it is expected that more countries will be able to purchase regionally manufactured vaccines, particularly countries in regions that previously did not have capacity. WHO has historically supported efforts towards geographically diversified vaccine manufacturing, given its importance for regional supply security. At the same time, WHO proposes several key aspects that need to be considered.

- **Manufacturing in a region may not guarantee supply for all countries of that region during an emergency;** commitments between countries, and between manufacturers and countries in a region, will be essential to ensure equitable distribution during emergencies, especially if supply is constrained.

- **For regions embarking on developing regional manufacturing capacity, there is an opportunity to pursue end-to-end investments** – from research and development (R&D) and clinical trials to production and distribution – to ensure true supply security and to support regional priorities.

- **To enable this, public investment in regional product development and production from countries in the region is needed**, **with access terms negotiated more effectively.** Through this, countries can incentivize R&D for unmet regional needs and promote local clinical trials.

- **Switching to regionally manufactured vaccines may result in increased vaccine costs**. Initial infrastructure investments, biomanufacturing workforce training and technology transfers may add additional costs to the cost of manufacturing and increase vaccine prices. Over time and as manufacturing is scaled up, these costs will be amortized, but in a globalized and competitive economy, regional manufacturing may result in higher prices for some time. However, the investment can be overall beneficial if guided by an industrial policy that promotes regional and national socioeconomic growth.

- Besides socioeconomic growth, **regional manufacturing can help serve neglected markets of limited commercial interest, delivering health impact for local populations.** Past experience shows that emergencies can create momentum for vaccine manufacturing initiatives. However, to establish a viable business case, manufacturers need to include products for routine immunization, and work towards reaching economies of scale.

- **Several regional manufacturing business models exist and should be explored.** Besides the dominant model of publicly traded private-sector companies, successful state-owned enterprises in different countries demonstrate the value of alternative models. Different models have their own advantages and disadvantages related to the objectives they serve.

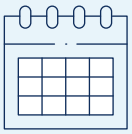
- Regardless of the manufacturing business model of choice, **regional manufacturing requires a whole-of-ecosystem approach**. This includes national and regional commitment to buy locally/regionally, demand certainty offered by national governments and regional entities, strengthened regulatory systems, comprising the strengthening of national regulatory authorities, regional regulatory harmonization and regulatory reliance for countries that do not have the manufacturing capacity, and investments in infrastructure and workforce, across sectors. Multilateral development actors, manufacturers, countries and regions with successful regional production models can all offer support and share knowledge with countries and regions that are in early stages.

01 Introduction

This landscape analysis aims to present a current picture of the global vaccine ecosystem from the purchaser (country) and supplier (manufacturer) perspectives to help global, regional and country stakeholders understand the current distribution of global manufacturing and procurement for different markets, technologies and regions.

The messages highlighted in this report help identify opportunities and risks that exist in the current vaccine manufacturing landscape.

Countries can use this landscape to understand regional vaccine manufacturing patterns and guide strategic procurement action. For international organizations, the report clarifies where there are access risks. Vaccine manufacturers can identify opportunities to strengthen future supply chains. Establishing an understanding of the current landscape can also help stakeholders understand trends over time, as the vaccine manufacturing and procurement ecosystem continues to evolve.



2023
data

204
countries

>20,000
data points

98
manufacturers, across four production stages (116 including subsidiary companies)

The report broadly addresses the following questions.

1. What is the geographic distribution of vaccine manufacturing across all production stages at the regional level? What trends are emerging?
2. How is regional manufacturing related to supply security and pandemic preparedness? What can be learned from different regions' and countries' experiences?
3. How do links among manufacturers across production stages affect supply security?
4. What is the geographic distribution of vaccine technology platforms?

To address these questions, data reported in 2023 from 204 countries and 98 vaccine manufacturers are analysed (details on the data are provided in Annex 5).

1. Firstly, a **regional view** is adopted, through which vaccine procurement patterns across all vaccines are examined. Here, analyses showcase the region of manufacturing and the region of procurement. Regional production patterns across four manufacturing stages – drug substance (DS) production, drug product (DP) formulation, filling and packaging (see Annex 2 for definitions) – are studied to answer the question of where vaccines are manufactured and how the manufacturing stages are linked. Analysis of country archetypes examines the relation between domestic manufacturing capacity and the ability to secure supply in emergencies.
2. Second, in the **vaccine view** analysis, a list of high-volume vaccines is selected, and their procurement and production patterns are analysed, pointing to characteristics relevant to supply security considerations.

3. Third, the **manufacturing view** is investigated, looking into market shares and technology platforms that manufacturers use for DS production and DP lyophilization and filling by region. This view provides a map of the relative size of different companies and their technological capabilities, features that are critical when dealing with emergencies in a regional setting.

4. Finally, the report draws on the insights generated through the analysis and dives into a discussion of **broader strategic considerations surrounding regional vaccine manufacturing**. These include the distinction between local and regional production capacity and their respective implications for supply security; the opportunity for regions initiating manufacturing efforts to pursue public investments that strengthen access outcomes; and the critical importance of an enabling ecosystem to ensure the sustainability and success of regional manufacturing initiatives, while monitoring for potential externalities affecting global vaccine access.

↓ **Below**

02 Analysis

2.1 THE REGIONAL VIEW

BOX 1

Key messages

1. **Diverse regional buying patterns in terms of location of manufacturing**, with the WHO African Region sourcing less than 5% of vaccines from companies headquartered within the region, relying heavily on manufacturers based in the WHO South-East Asia Region. In contrast, South-East Asia is the most self-reliant, sourcing 89% of its vaccines from within the region, followed by the WHO Western Pacific Region (67%).
2. **Domestic manufacturing can strengthen national vaccine security**, and regional manufacturing is an important source of supply for countries in the region. However, having vaccine production capacity in a country does not guarantee supply security in emergencies.
3. **Across all regions, the variation in production location remains small**, suggesting that manufacturers tend to implement all stages of production in an integrated location. The WHO European Region and the WHO Region of the Americas constitute exceptions as they are more closely integrated with each other through production stages.

2.1.1 Regional procurement patterns by sources of vaccine supply

Seven billion vaccine doses were procured globally in 2023, with a total financial value[2] of US$78 billion. Fig. 1 shows procurement patterns for each region based on the supplier headquarters (HQ) location, including the dose volume, financial value, number of suppliers procured from and number of vaccines procured.

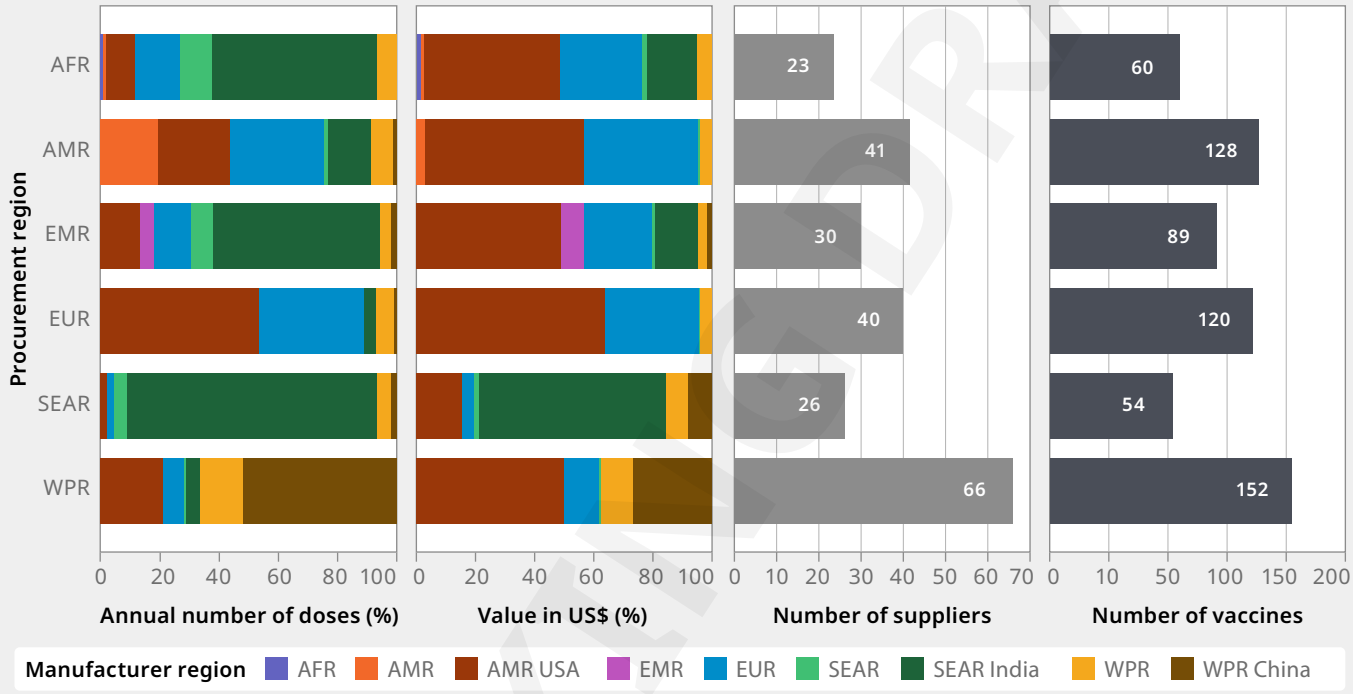
The data indicates that the WHO Africa Region procured less than 5% of its vaccine doses from manufacturers with business headquarters within the region. More than 50% of vaccine volumes were procured from suppliers headquartered in India, and 50% of financial value was procured from suppliers headquartered in the United States. Similarly, the WHO Eastern Mediterranean Region procured 5% of vaccine volume from suppliers headquartered in the region and 50% of the volume from suppliers located in India. The WHO South-East Asia and Western Pacific regions, on the other hand, exhibit a very different pattern. The South-East Asia Region procured nearly 90% of its vaccines from domestic suppliers, and the Western Pacific Region procured 67% of its vaccines from domestic suppliers. Both regions' high self-reliance is driven by the respective self-reliance of big countries located within their borders, namely India (99% self-sufficiency) and China (90% self-sufficiency). Taking those countries out, the procurement patterns of other countries in the regions are more diverse (34% regional self-sufficiency for the Western Pacific Region and 55% for the South-East Asia Region). Another characteristic that differentiates the South-East Asia Region from the Western Pacific Region is the supplier base, with the entire South-East Asia Region procuring from 26 manufacturers, a rather consolidated base, and the Western Pacific Region having a significantly more diversified supplier base of 66.

2 The financial value is calculated as volume (number of doses) x price per dose (US$). The financial value can be different from revenues reported by individual companies.

Finally, closer inspection of the Region of the Americas indicates that it has a more uniform distribution of supply-sourcing from different regions, when compared to the rest. When this observation is investigated in more depth, one concludes that this "diversity" is an outcome of the United States hosting several of the world's largest vaccine manufacturers, along with the fact that Latin American and Caribbean countries have limited domestic suppliers and rely primarily on procurement through the Pan American Health Organization Revolving Fund (PAHO RF), which engages a wide range of global manufacturers. The combined effect makes the Region of the Americas appear most diverse in terms of supply base, while in practice, individual countries in Latin America and the Caribbean remain structurally dependent on a small number of external suppliers.

FIG. 1

Global procurement by WHO region



Note: AFR: WHO African Region; AMR: WHO Region of the Americas; EMR: WHO Eastern Mediterranean Region; EUR: WHO European Region; SEAR: WHO South-East Asia Region; WPR: WHO Western Pacific Region.

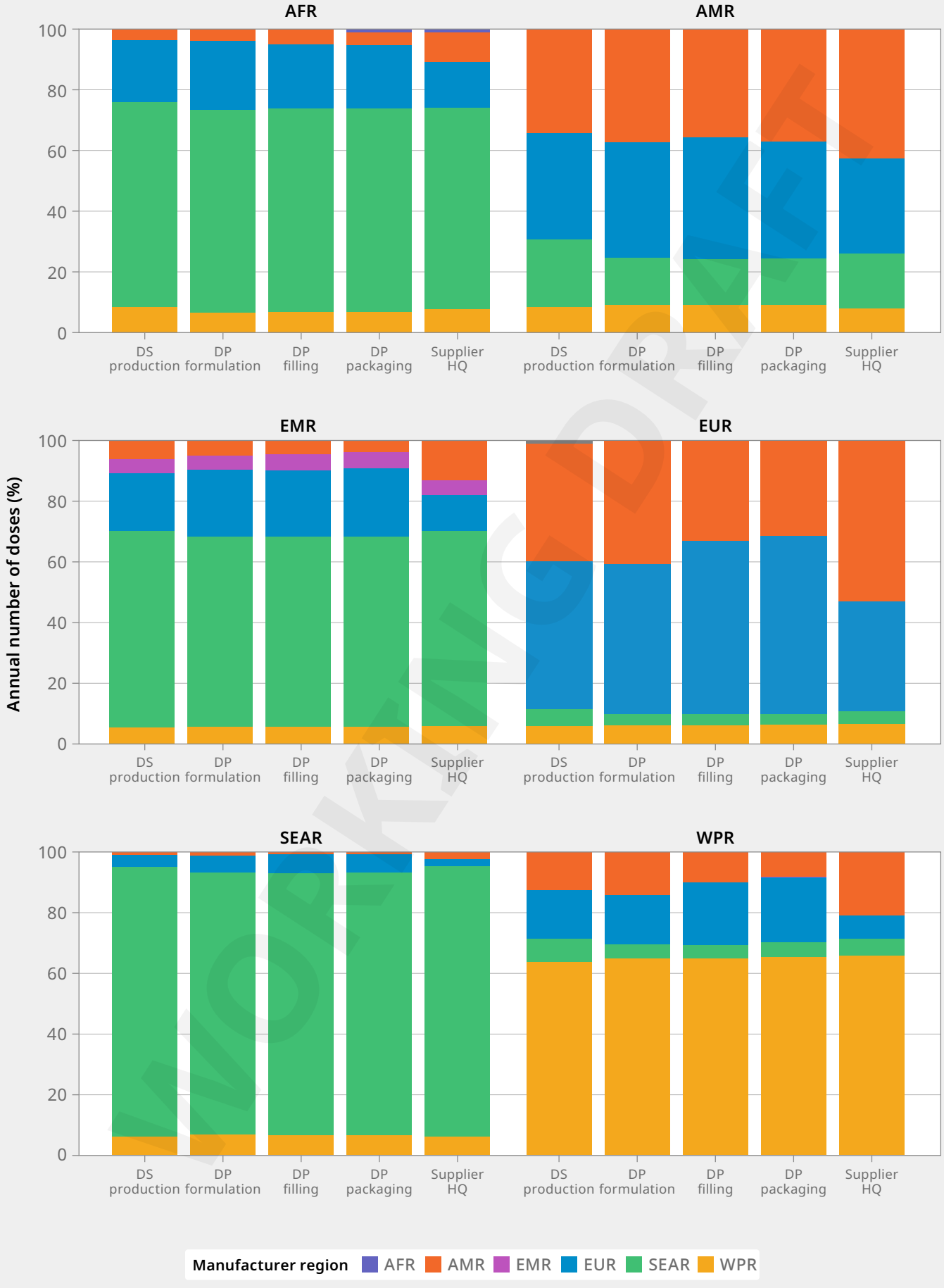
Looking at the location of each of the production stages reveals the more complex supply chain of vaccine production. Fig. 2 shows data based on the total volume of procured doses and where those doses underwent each stage of production.

The conclusions drawn about the procurement patterns of the African, the South-East Asian and the Western Pacific regions (Fig. 1) apply to vaccine production across all stages. Interestingly, the European Region and the Region of the Americas are highly dependent on each other with respect to the location of DS production, while volumes of DS transferred between other regions are small. For example, of all the doses procured by the European Region in 2023, the DS production and DP formulation were completed nearly equally in the Region of the Americas and the European Region; DP filling and packaging, however, were more skewed towards the European Region. Several large manufacturers have filling/packaging operations in the European Region, though they are headquartered in the Region of the Americas. Those patterns are driven primarily by large multinational manufacturers with headquarters in the United States and the European Union (EU) that have production operations across the two regions.

Overall, there is a high degree of interdependency for vaccine supply in all WHO regions, even if not all regions and not all vaccines are subject to the same production dynamics.

FIG. 2

Regional procurement by location of manufacturing stage



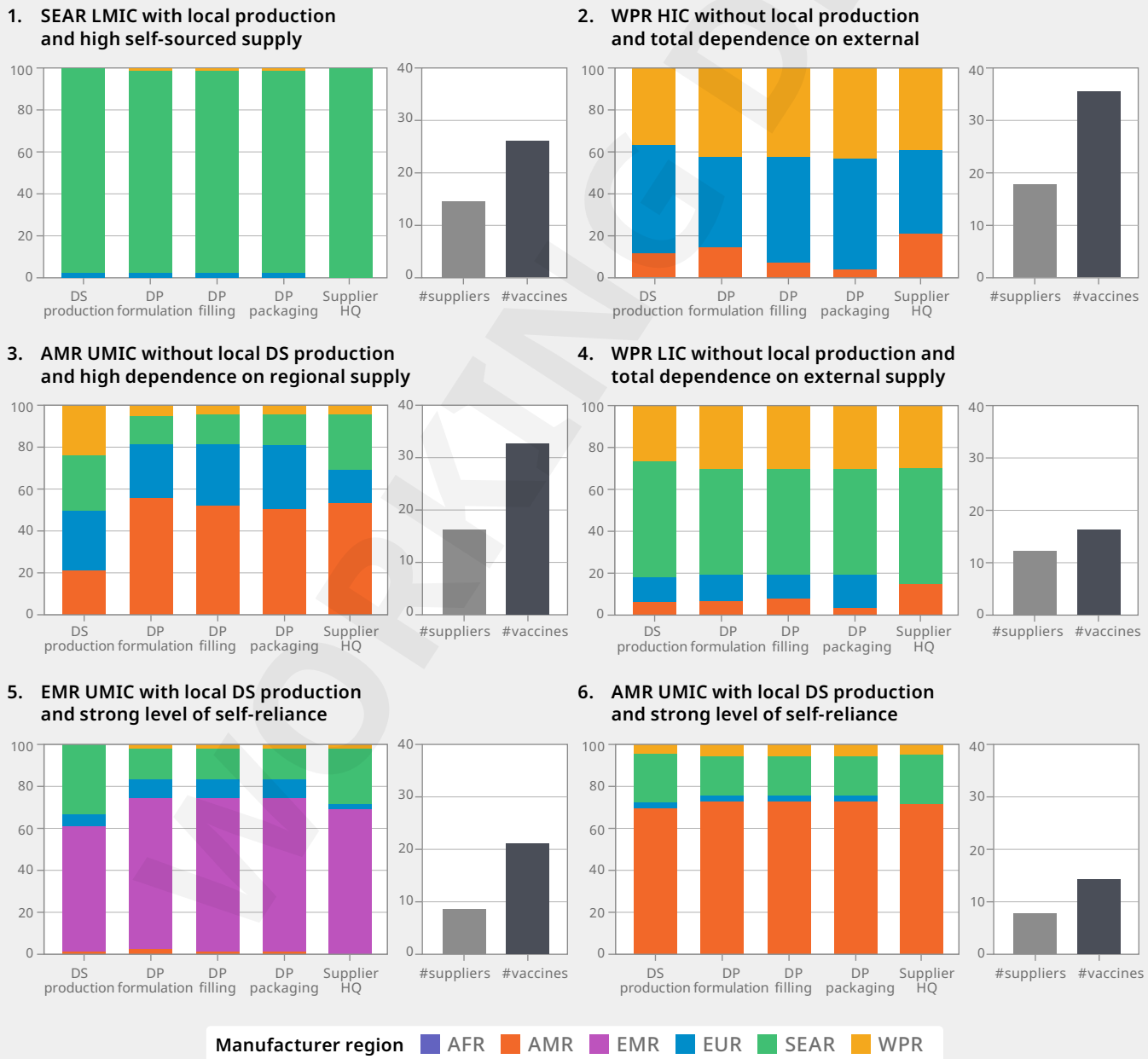
2.1.2 Exemplar country procurement patterns by sources of vaccine supply

There is a wide variation in the procurement patterns of different countries and the related impact on national supply security. Six exemplar countries are considered in Fig. 3[3], where the production stages and the variety of the procured vaccines are illustrated as a case in point. The exemplar countries were selected to capture diversity in geography, income group and procurement approach, while ensuring that their COVID-19 response, in terms of coverage, was well-documented. These cases illustrate substantial variation but are not intended to be exhaustive, regionally or globally representative.

3 The data presented in the figure are as of end-of-year 2023; however, additional facts and historical references are presented to draw a more complete picture of the country's security status.

FIG.3

Exemplar country procurement by location of manufacturing stage (% volume)



1. A lower-middle-income country (LMIC) located in the South-East Asia Region with domestic manufacturing that procured over 1 billion doses valued at more than US$1.5 billion in 2023, shows a high degree of self-reliance through all stages. Given the high volume, the country procures from a relatively small number of suppliers, and it successfully produced its own vaccine during the COVID-19 pandemic, which was also exported. Nevertheless, during the COVID-19 pandemic, it faced raw material shortages as those were mainly sourced from the United States and Europe.

2. An HIC located in the Western Pacific Region that procured over 3.5 million vaccine doses valued at over US$100 million during 2023, relies primarily on vaccines filled and packaged in the European Region and the Western Pacific Region and has no domestic manufacturing. Given the associated volume, it procures a relatively significant number of vaccines from a large number of suppliers. There have been no reports indicating that the country faced specific COVID-19 vaccine supply issues during the pandemic.

3. An upper-middle-income country (UMIC) located in the Region of the Americas that procured more than 40 million doses, valued at over US$350 million in 2023. The country relies on vaccines packaged in the Region of the Americas for more than 50% of the vaccine volumes, with a more diversified sourcing of drug substance. With only limited domestic fill-finish capacity, the country used a diversified procurement strategy during the COVID-19 pandemic, achieving relatively high COVID-19 vaccine coverage, which was also attributed to strong demand.

4. An LIC in the Western Pacific Region that procured 3.5 million doses valued at over US$4 million in 2023, relies strongly on vaccines produced in the South-East Asia Region, with diversity of supply coming from the Western Pacific and the European Regions. The country depended heavily on COVAX and donations from China and the United States during the COVID-19 pandemic.

5. A UMIC located in the Eastern Mediterranean Region that procured more than 152 million doses, valued at over US$246 million in 2023. The country exhibits strong self-reliance via state-backed manufacturing, procuring only a few vaccines from India that are not produced domestically. Despite domestic production of COVID-19 vaccines, scale-up delays and raw material shortages caused major supply constraints during the COVID-19 pandemic, which were gradually addressed. The country achieved among the highest COVID-19 vaccine coverage rates in the Eastern Mediterranean Region and globally by January 2022, with almost 65% of the population having been vaccinated. Additionally, the country had fostered strong demand for the vaccine.

6. A UMIC located in the Region of the Americas, presented last in Fig. 4, procured 33 million doses valued at US$91 million in 2023. The country has very little reliance on other countries for vaccines and has good health infrastructure, a factor that generally enhances access. The country developed its own vaccines during the COVID-19 pandemic, which were also exported, achieving very high coverage rates. Nevertheless, raw materials shortages and limited ability to scale up manufacturing caused supply constraints.

In summary, the examples demonstrate that countries without a local vaccine supply often rely on products from multiple regions. While HICs typically secure supply through diverse sourcing and pre-purchasing, others enhance security via domestic production, pooled procurement and multi-manufacturer relationships. Where a country has domestic production capacity, it is more self-reliant, and this was showcased during the COVID-19 pandemic through several examples detailed above. However, many of those countries faced challenges in sourcing raw materials and hence had to also rely on imports. Therefore, while domestic manufacturing can strengthen national supply security, and regional manufacturing is an important source of supply for countries in the region, the availability of raw materials and capacity for all stages of manufacturing is needed to ensure supply security during health emergencies. At the moment, there is no country or region that can be, or chooses to be, fully self-reliant.

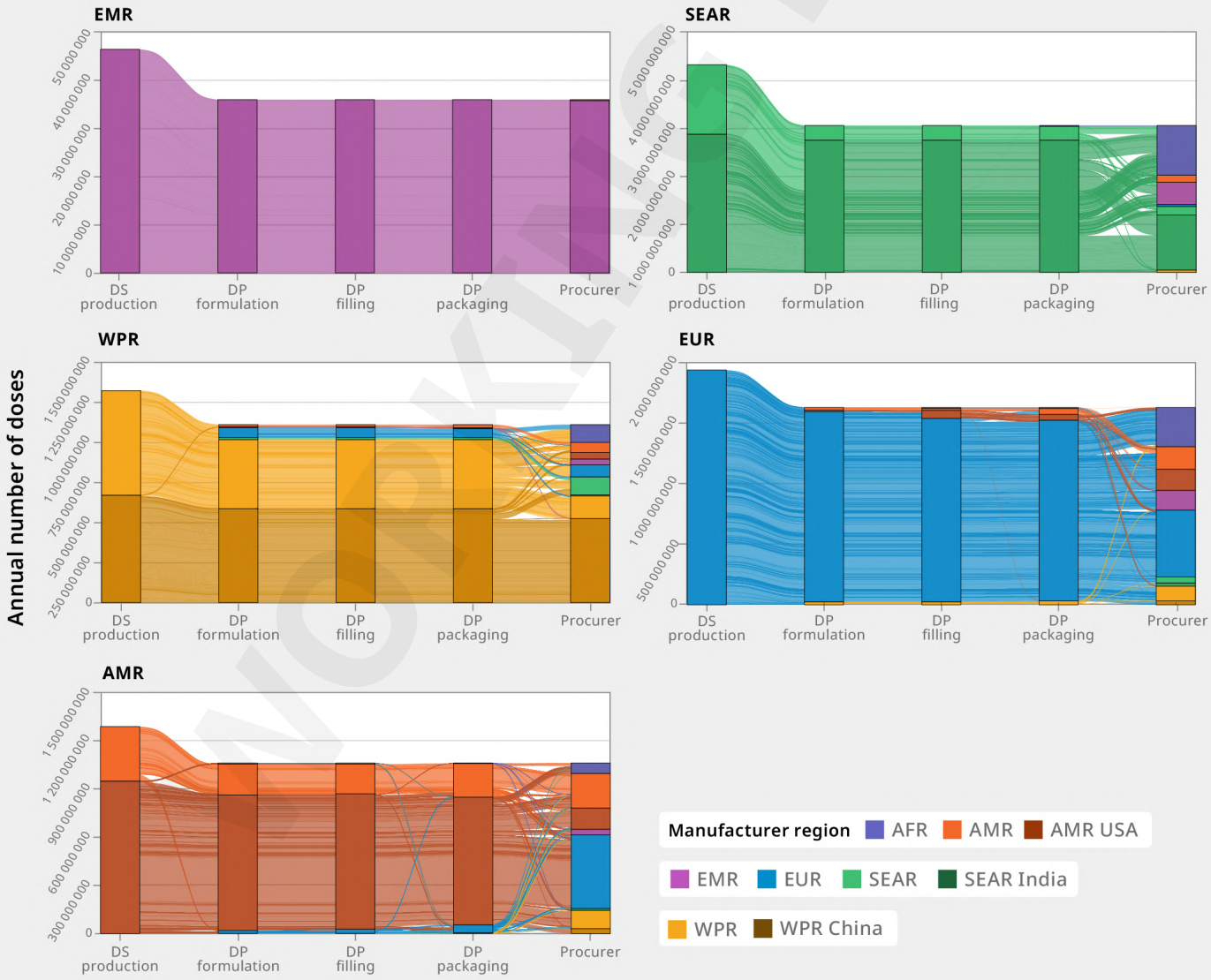
2.1.3 Regional production patterns by production stage

Globally, the geographic location of vaccine production can be broken down by stage of vaccine production. Fig. 4 displays where DS is produced in a region (first bar of each regional Sankey plot) and where subsequent production stages occur. The DS production bar extends higher, as it separately counts the components of combination vaccines, which are then formulated into a single dose in subsequent steps.

For most regions, the variation in production location remains small, suggesting that manufacturers tend to implement all stages of production in the same region. DS produced in the Eastern Mediterranean Region and the South-East Asia Region has fewer interdependencies with other regions since most manufacturers centralize their production, whether through their own operations or partnerships, with less dependence on other regions. DS produced in the Western Pacific Region, the European Region and the Region of the Americas is more tightly integrated across these regions in later production stages. It is also clear that India and China obtain nearly all of their DS from domestic production, while the United States sources roughly equal amounts from domestic producers and the European Region, with smaller volumes coming from the Western Pacific Region.

FIG.4

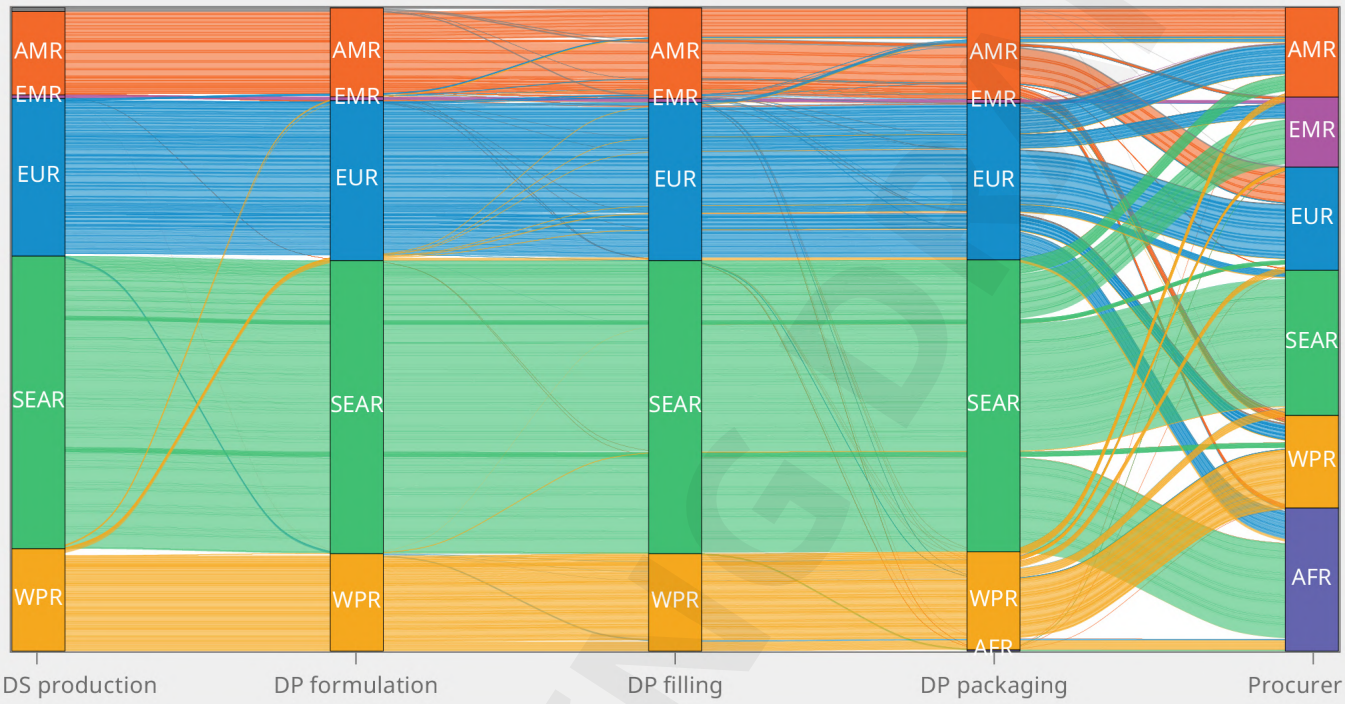
Location of production stages for drug substance produced by region (volume in number of doses)



Similarly, Fig. 5 shows global vaccine production by the region of each stage of production for all doses globally, by volume. Focusing on the last stages between packaging and procurement, vaccines packaged in the European and the South-East Asia regions drive the majority of global volumes and are procured broadly across all other regions.

FIG.5

Doses by production location through to procurement



2.2 THE VACCINE VIEW

BOX 2

Key messages

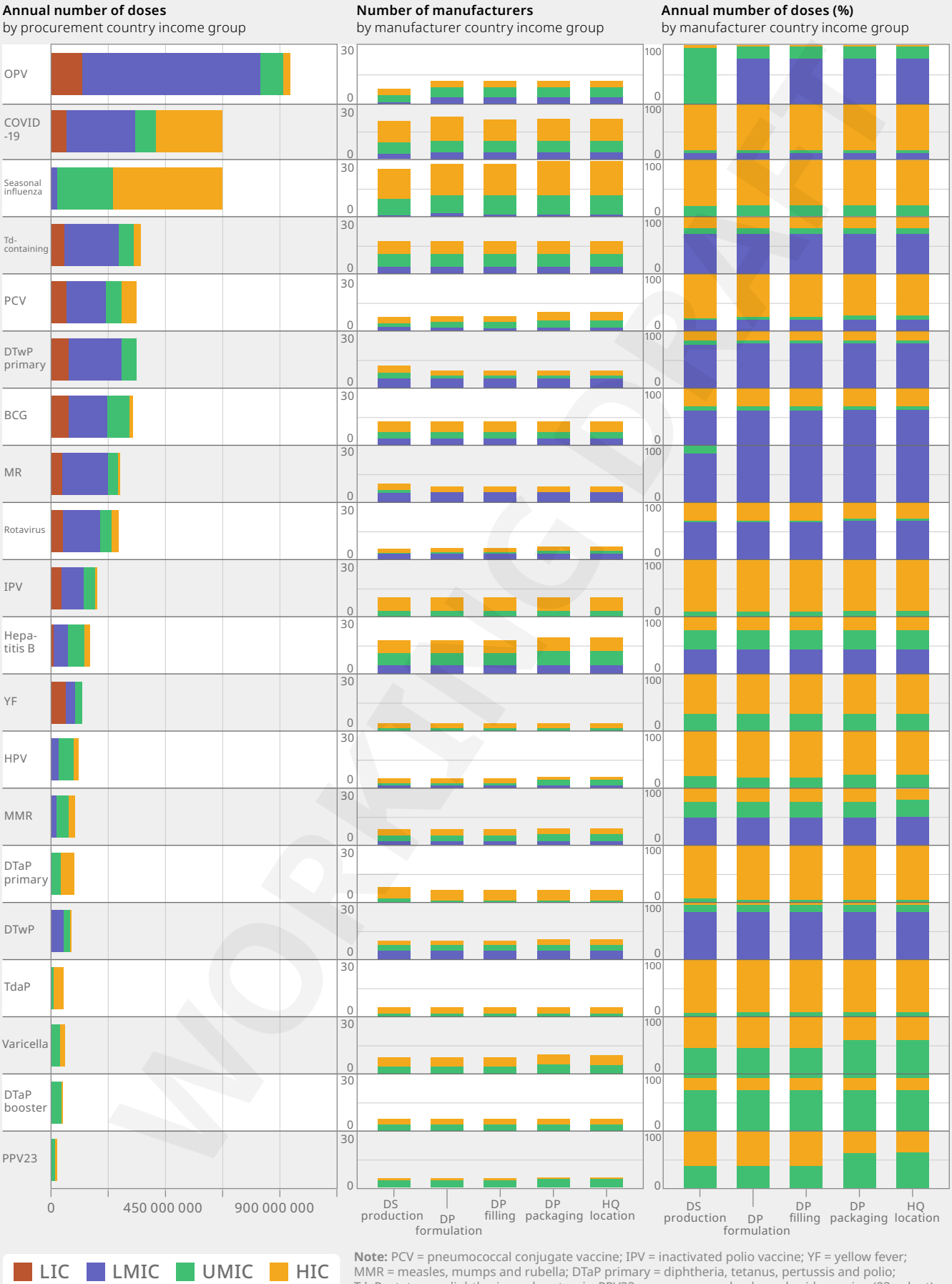
- **HICs tend to procure vaccines manufactured in other HICs,** while it is common to see manufacturers based in HICs producing vaccines that are highly used in lower-income countries, such as pneumococcal conjugate vaccine (PCV), human papillomavirus (HPV) vaccines and COVID-19 vaccines.
- **Vaccines predominantly sold in HICs tend to have many manufacturers,** largely because they maintain steady, high demand – either due to their seasonal nature (such as influenza vaccines) or their relatively higher prices compared with routine vaccines (such as COVID-19 vaccines).
- **A concentration of suppliers in a market is more likely to result in supply disruptions.** Root causes for the concentration can vary. For example, some markets may have few suppliers because they offer limited commercial incentives, while others have several suppliers but still show high concentration of sales among a few dominant players, leading to oligopolistic dynamics. Markets with secure supply typically have in common a diverse supplier basis and stable, high demand for routine use.

2.2.1 Location of production stages by vaccine

This section maps the dependencies of sources of vaccine supply globally for the 20 vaccines used by the largest number of countries in 2023. In Fig. 6, information is analysed based on the income level of the country where production takes place. It shows the number of doses procured, the number of manufacturers and the percentage of production performed at each stage for each vaccine market. It is evident that vaccines purchased mainly in HICs have many manufacturers (COVID-19 and seasonal influenza). The steady, seasonally recurring demand for influenza vaccines – maintained by national immunization policies and government support – has fostered a sizable yet stable base of manufacturers. In contrast, the COVID-19 vaccine market remains in a transitional phase, still reflecting the high level of concentration that emerged during the COVID-19 pandemic. DS production across the 20 vaccines is also driven by manufacturers located in HICs, with some important exceptions like oral polio vaccine (OPV), tetanus and diphtheria (Td)-containing vaccine, Bacillus Calmette-Guérin (BCG) vaccine, measles-rubella (MR) vaccine and diphtheria, tetanus and whole-cell pertussis (DTwP) vaccine. More generally, procuring countries tend to belong to the same income group as the manufacturing countries, with the exception of LICs that largely access their vaccines through Gavi, the Vaccine Alliance and pooled procurement mechanisms. At the same time, it is also common to see manufacturers based in HICs producing vaccines mainly used in LICs. Notable examples include the COVID-19 and, where most manufacturers supplying LICs and LMICs are headquartered in HICs.

FIG.6

Vaccines by income group of procurement, number of manufacturers and location of production stages



Note: PCV = pneumococcal conjugate vaccine; IPV = inactivated polio vaccine; YF = yellow fever; MMR = measles, mumps and rubella; DTaP primary = diphtheria, tetanus, pertussis and polio; TdaP = tetanus, diphtheria, and pertussis; PPV23 = pneumococcal polysaccharide vaccine (23-valent)

↑ **Above**
© WHO / Igor Sergienko

2.2.2 Vaccine exemplars

Relationships among manufacturers across the stages of production of a specific vaccine can contribute to supply security considerations. For example, global over-reliance on a few manufacturers for a critical vaccine production stage can create risks for supply security.

This section is an in-depth analysis of the manufacturing aspects of the six vaccines depicted in figures 7a and 7b, showing how supply security is linked to geographic production patterns, and, ultimately, market status. Fig. 7a illustrates manufacturers' volume market shares by production stage of a given vaccine. The manufacturers' names are removed to maintain confidentiality. The colours correspond to the region where the manufacturer is headquartered. Fig. 7b demonstrates the reliance of the countries in a given region on a specific manufacturer (fraction) for a given vaccine. The vaccines were selected to be representative of a variety of vaccine-use archetypes (outbreak-prone versus routine), geographies (regional versus global) and market conditions (number of manufacturers and their concentration).[4]

The examples illustrate market dynamics that lead to a limited number of suppliers, often due to low commercial interest. Such cases are typically found in outbreak-driven or geographically constrained markets, such as oral cholera or yellow fever vaccines. In routine markets, like HPV, initial oligopolies emerge because the manufacturing process is highly complex, slowing the market entry of additional manufacturers. Regardless of the underlying driver, concentrated supply among a few manufacturers results in supply-security risks. Conversely, it is observed that markets with secure supply typically have in common a diverse supplier basis, and stable, high demand for routine use.

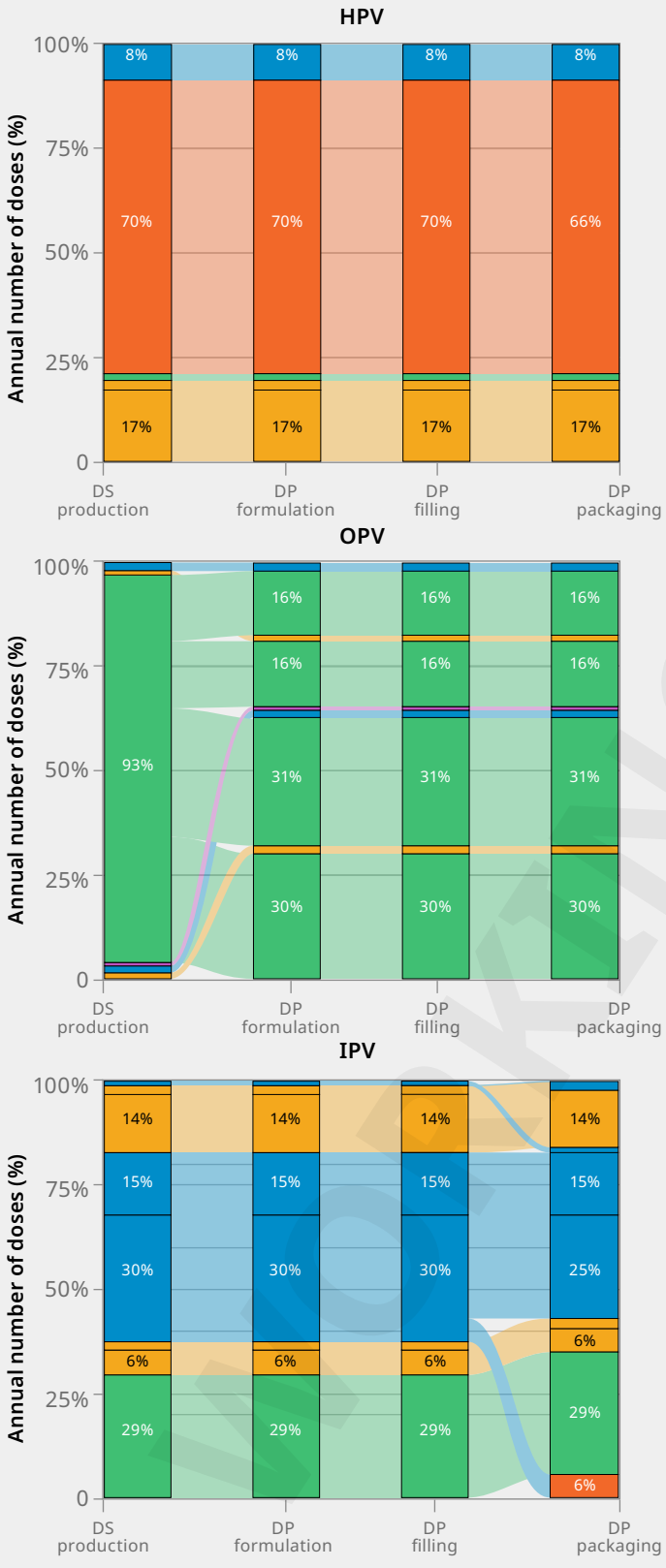
4 The data presented in the figure are as of end-of-year 2023; however, additional facts are presented and historical references made to draw a more complete picture of the market's health.

FIG.7

Manufacturer market share across production stages for a selection of six vaccine

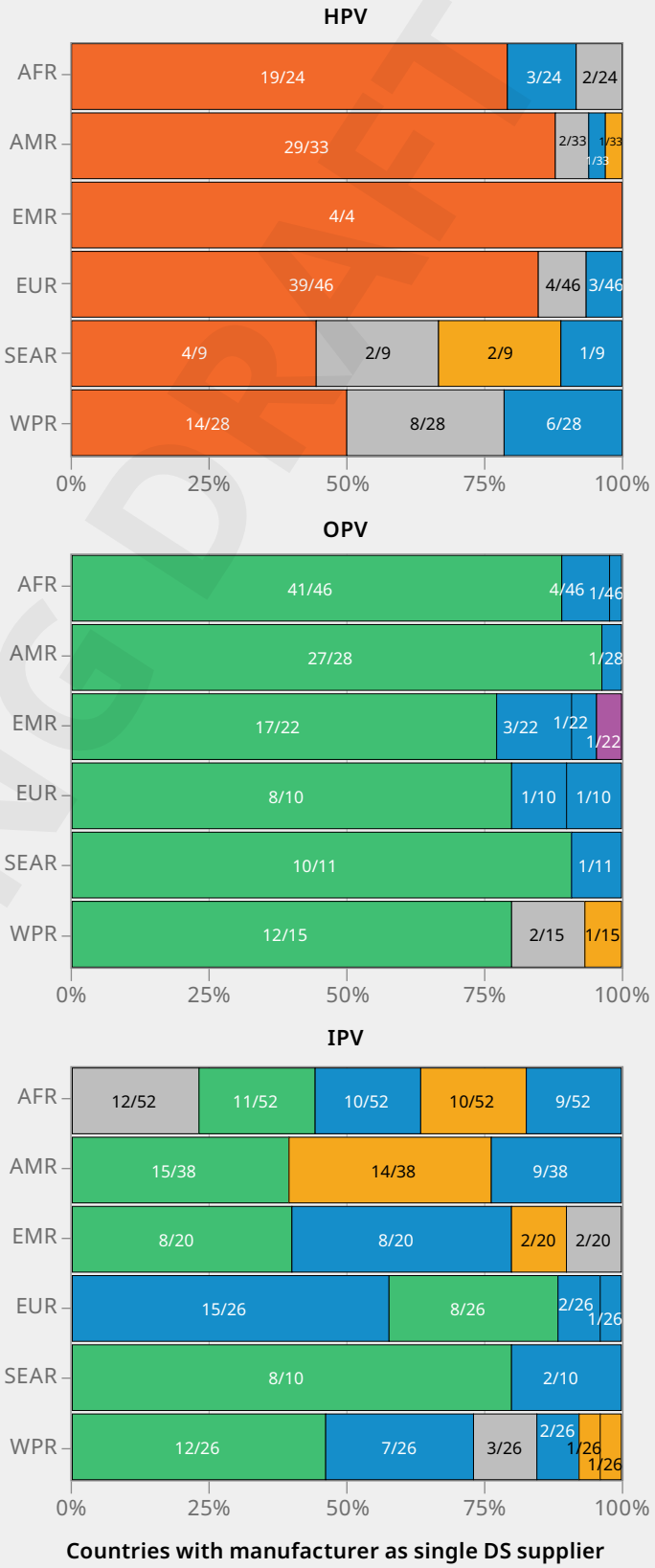
7a

Manufacturers market shares for key vaccines by region and by production stage (% volume)



7b

Manufacturer market share by region of DS production for key vaccines (in number of countries)



Countries with manufacturer as single DS supplier

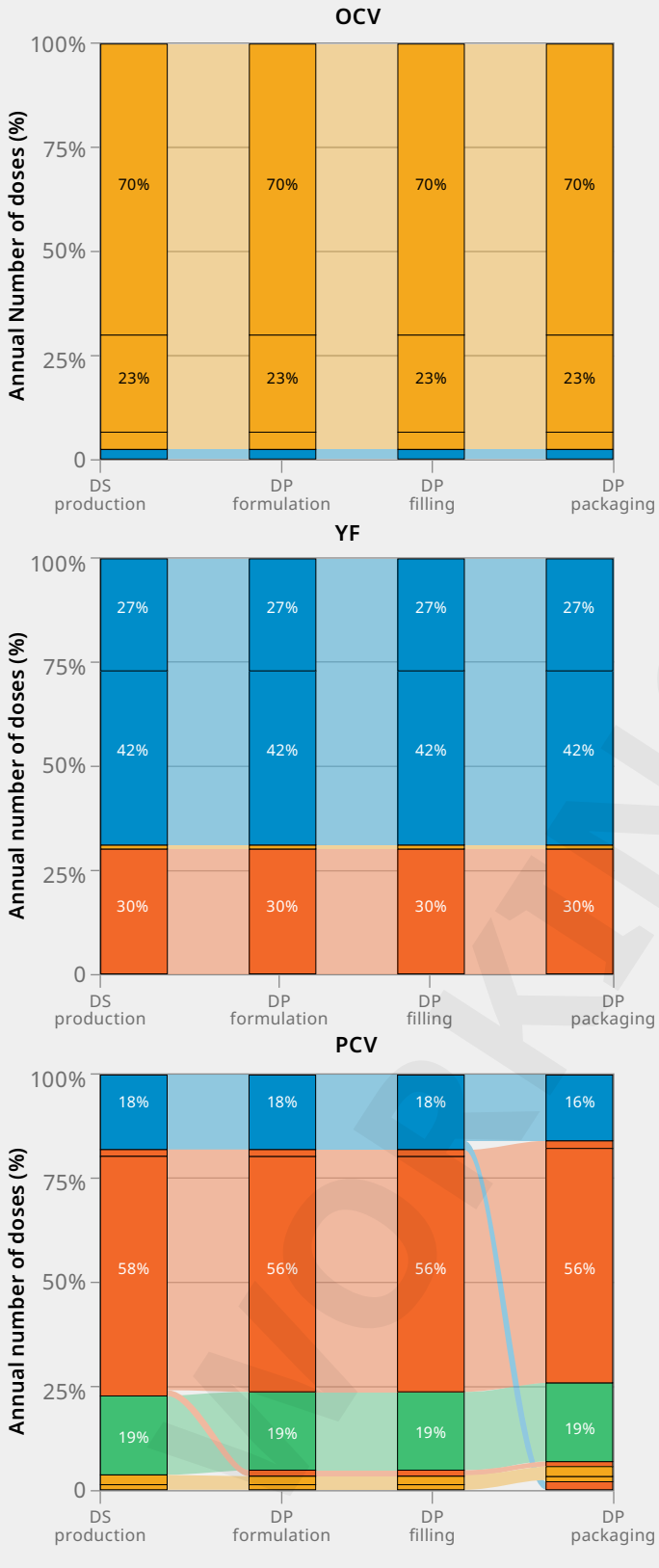
Manufacturer HQ region AFR AMR EMR EUR SEAR WPR

FIG.7

Manufacturer market share across production stages for a selection of six vaccine (Continued)

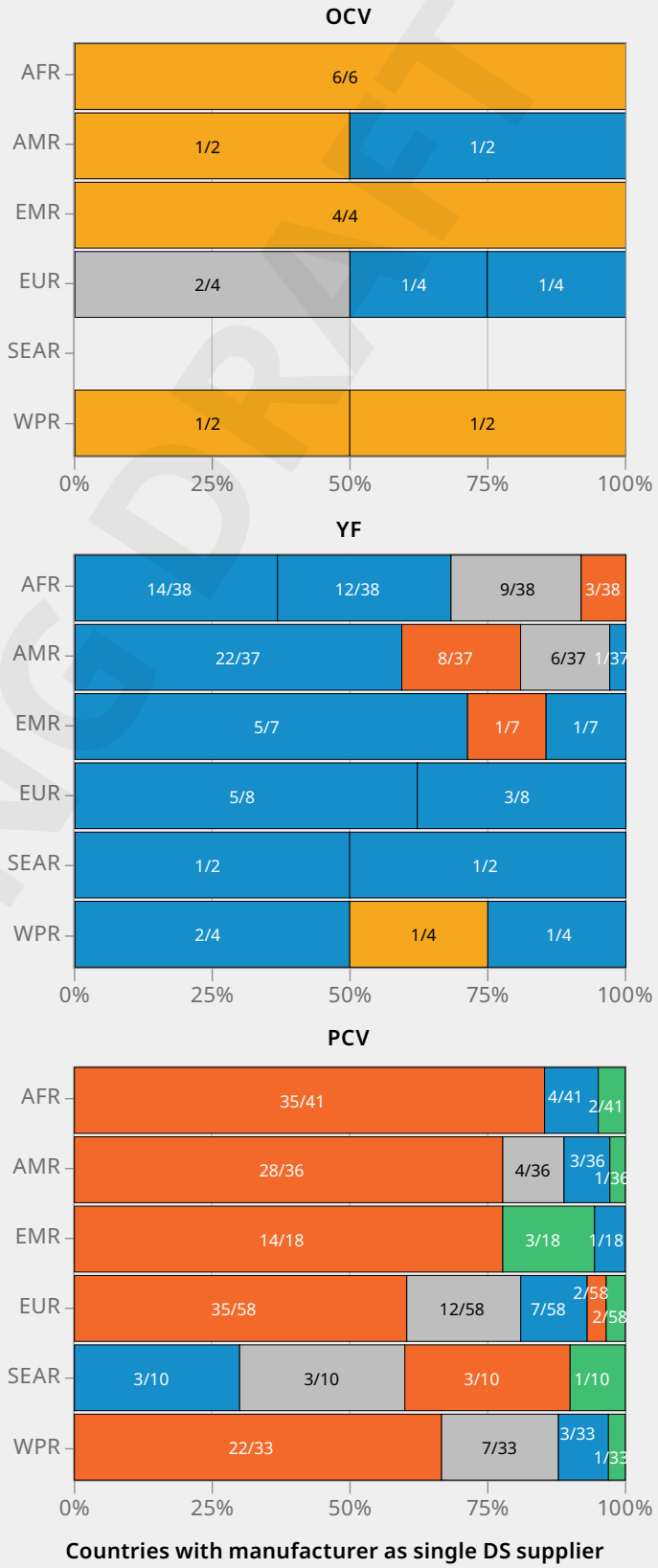
7a

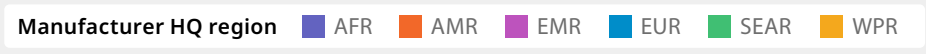
Manufacturers market shares for key vaccines by region and by production stage (% volume)



7b

Manufacturer market share by region of DS production for key vaccines (in number of countries)





HPV vaccine

Until recently, only two suppliers, based in the United States and Europe, manufactured HPV. Two additional suppliers, headquartered in China and India, have now entered the market. In 2023, as illustrated in Fig. 7a, one manufacturer produced 70% of the DS procured and the second largest produced 17%. This market concentration on one supplier is evident across all regions, with the South-East Asia and the Western Pacific regions exhibiting a more diversified profile (Fig. 7b suggests that, of the 24 countries of the African Region that purchased HPV in 2023, 19 sourced their doses from a single supplier, while the South-East Asia and the Western Pacific regions purchased HPV doses from a higher number of manufacturers.) This high concentration led to supply disruptions that hit Gavi-supported lower-income countries the hardest, causing delays in vaccine introductions and campaigns in recent years.

OPV

As part of the OPV cessation strategy of the Global Polio Eradication Initiative (GPEI), OPV is intended to be phased out following eradication *(1, 2)*. There continues to be a need for outbreak response OPV doses. As such, it is expected that the market should progressively shrink in volume as milestones towards eradication are achieved. Based on this, commercial incentives for new manufacturers to enter this market are limited *(3)*. The market is also characterized by a high degree of product segmentation, with the vast majority of HICs procuring IPV, whereas LMICs continue to procure OPV along with IPV.

IPV

IPV is produced using a traditional manufacturing process based on virus inactivation. However, DS production for IPV requires a very high degree of biocontainment and limits DS production to specific locations. This constitutes a substantial barrier for new producers. Therefore, new producers have concentrated on the production of Sabin IPV (sIPV), which uses inactivated live-attenuated poliovirus strains. This approach considerably reduces the risks associated with handling poliovirus and requires less stringent biocontainment.

In 2023, there were 12 producers of DS, with headquarters in countries across all income groups and distributed geographically over three WHO regions.

OCV

There are five producers of the cholera vaccine DS. One vaccine that was licensed and prequalified in 2015 accounts for more than 90% of procured dose volume (Fig. 7a). Two of the DS producers serve markets in HICs exclusively due to product characteristics, and two DS producers supply locally. High-volume demand is limited to the low-income countries market, with the African Region demand being served by only one producer (Fig. 7b).

The market has been supply-constrained since 2021, affecting several LICs. There are a number of reasons for this, primarily the unpredictable demand spikes driven by outbreak response, and increasing demand for preventative vaccination.

DS production is highly concentrated in one country, with the exception of very small quantities of OPV being locally produced. The majority of OPVs undergo filling and packaging in two countries (Fig. 7a). With four of the six OPV suppliers headquartered in one country, any regulatory disruption could compromise the global supply of OPV, while a production issue with one DS producer could also threaten the security of global supply.

Yellow fever (YF) vaccine

The market for the YF vaccine is limited geographically, primarily to the African and Americas regions, where the vaccine is recommended for routine preventive use in endemic countries and for outbreak response. Being a vaccine largely limited to the LMIC market, and demand is unlikely to expand beyond this. Sporadic outbreaks of disease require vaccination campaigns, potentially with a large number of doses, prompting the establishment of a vaccine stockpile in 2001, which currently reserves 6 million doses a year *(4)*. About 70% of the 120 million doses purchased in 2023 were procured in the Africa region.

There were four DS producers globally in 2023; only three of the four supplied the vaccine that year (Fig. 7a). Despite the relatively diversified distribution of supply in the African region (Fig. 7b), the small number of suppliers means that a potential market exit could undermine supply security, causing concern over the health of the YF market.

PCV

In 2023, 179 countries procured PCV. Of these, 37% were LICs or LMICs, 23% were UMICs, and 39% were HICs. PCV coverage among all countries in each group reached 86%, 81% and 95%, respectively. Given the number of antigens and the conjugation technology involved, DS production is limited to suppliers with moderate to high technical capability and capacity.

In 2023, there were 1a1 suppliers of PCV, two from LMICs, four from UMICs and five from HICs. Of these, seven produce DS (two LMICs, two UMICs and three HICs), as depicted in Fig. 7a. Two HIC suppliers and two UMIC suppliers perform formulation and/or subsequent downstream production stages with DS from two HIC suppliers.

The diversity of suppliers has helped address global shortages. In 2020, one of the two HIC suppliers faced production issues, resulting in a large LMIC facing a dose shortage. The country switched to the second HIC supplier, and the disruption was mitigated.

Although the PCV market is global, suppliers are nevertheless concentrated in UMICs and HICs because of the sophistication required to produce DS. In addition, and despite the relatively wide supplier base, two suppliers represent approximately 75% of the global market share, with one of them dominating DS supply across regions (Fig. 7b). PCVs are not directly interchangeable, and procurement decisions are strongly influenced by strain composition. United Nations Children's Fund (UNICEF) notes that since the advanced market commitment (AMC) subsidies for PCV ended in 2022, there has been sufficient global supply, stable pricing and diversification of suppliers, although challenges related to the end of the subsidies may still emerge *(5, 6)*.

2.3 THE MANUFACTURING VIEW

BOX 3

Key messages

- **There is a significant gap between a few large companies and all other manufacturers regarding market share by volume of doses.** A small number sells over 400 million doses and exceeds US$5 billion in financial value. In contrast, 75–85% of manufacturers are small to medium-sized, with over 30% selling fewer than 5 million doses annually and over 20% capturing less than US$5 million in financial value.
- **Most companies of moderate size** (i.e. less than US$500 million in financial value and 50 million doses in sales) **are in the Western Pacific Region**, specifically China, and are pursuing a national/regional market model.
- **Traditional technologies dominate production globally.** Both the South-East Asia Region and the Western Pacific Region contribute to the production of vaccines with modern technologies, such as protein and conjugation. Modern technologies are less accessible to regions with limited capacity. Innovative platforms like mRNA are currently limited to the United States and Europe.

2.3.1 Manufacturers profiles

A variety of manufacturer profiles exist among the 98 parent companies captured in this data (the total number climbs up to 116 when subsidiaries are considered). Here, manufacturers are analysed by volumes of production, by the financial value they generated from vaccine sales, and by the breadth of their product portfolio. This analysis allows for the comparison of regional production ecosystems and identifies how the scale of manufacturing may contribute to the security of supply. Fig. 8 shows aggregated data for volume, financial value and portfolio breadth across all manufacturers by HQ region.

Financial value: The data shows that about 20% of companies fall below US$5 million in financial value. Several of those "small" suppliers are in the Eastern Mediterranean Region, also capturing less than US$5 million in financial value annually. About 85% of companies have a financial value of less than US$500 million, while most companies are within a range of US$50 million to US$500 million. Those companies are mainly concentrated in the Western Pacific Region, more specifically, China.

Volume of production: Annual output in number of doses is more concentrated than financial value, giving rise to a few large outliers. More than 80% of companies sell fewer than 50 million doses annually, and over 30% sell fewer than 5 million doses. This shows that a substantial share of manufacturers operate at relatively small production volumes. In addition, the distribution of manufacturer volumes is skewed. Around 20% of manufacturers sell between five and 100+ times the number of doses produced by the median manufacturer (9.8 million doses). This observation is further elaborated on in Fig. 9.

Products portfolio: About 35% of companies sell five or more products, with similar numbers of these multi-product companies found in the Western Pacific, European and Americas regions. Nearly one in five companies (17%) have only one product in their portfolio. Most of those companies manufacture relatively high-market-value seasonal vaccines, like influenza.

Fig. 9 illustrates the large gap between the few companies that sell more than 400 million doses and have a market value above US$5 billion and the rest. Fig. 9 shows that most companies are in the Western Pacific region, specifically China. This suggests that many small companies have a regional market model, often with few products in their portfolio.

FIG.8

Cumulative histogram of the number of companies by vaccine sales, volumes and product portfolio size

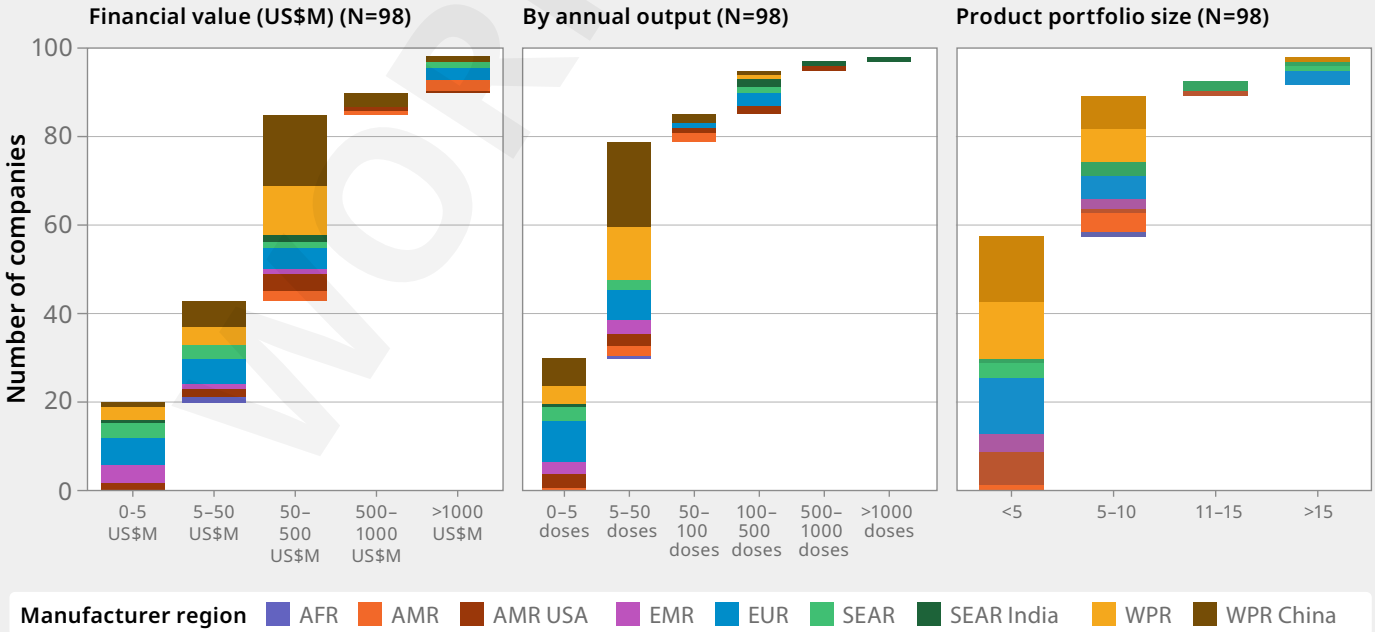
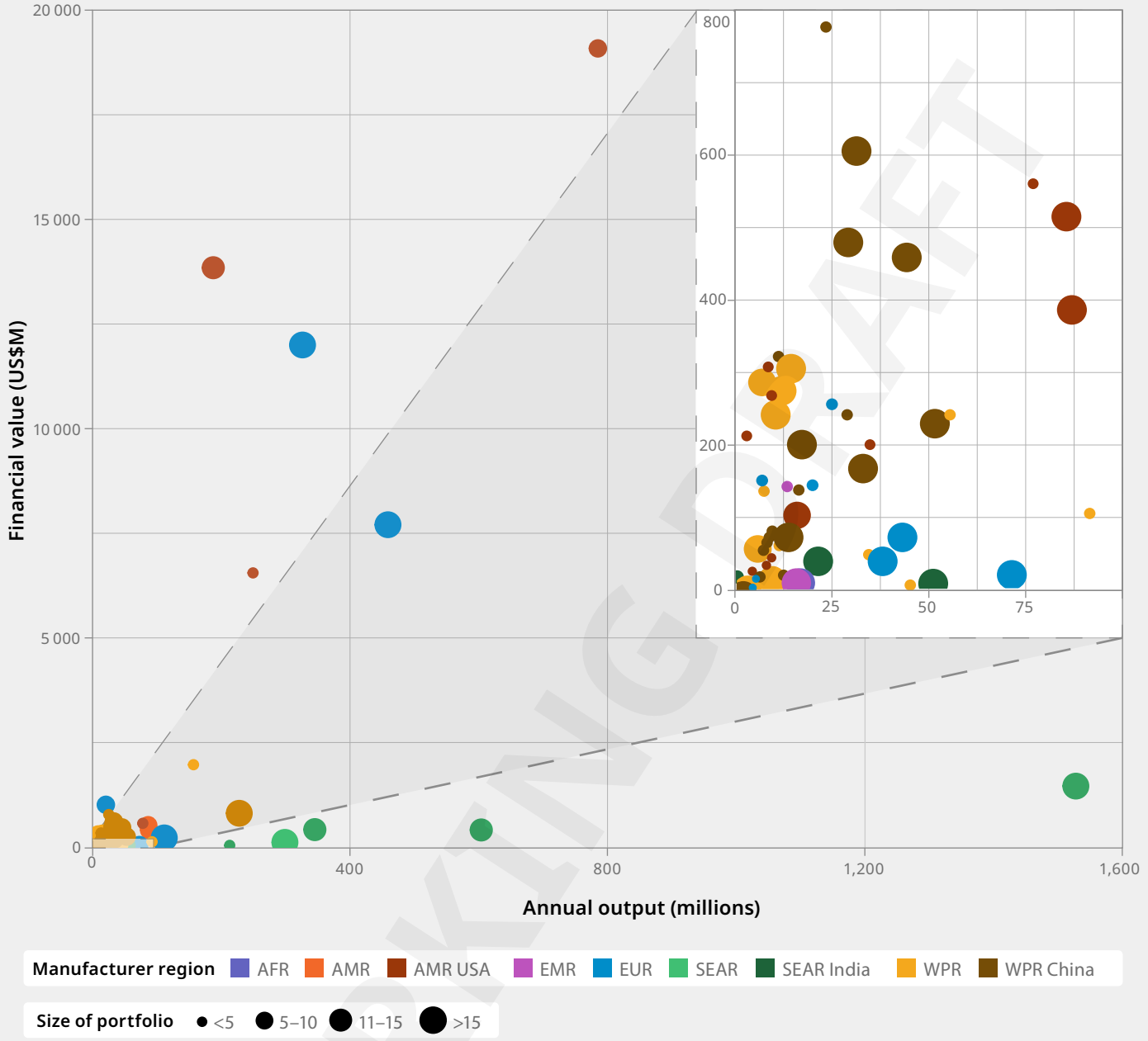


FIG.9

Distribution of manufacturers by volume and financial value, portfolio size and region of HQ



2.3.2 Location of vaccine manufacturing stages by production technology

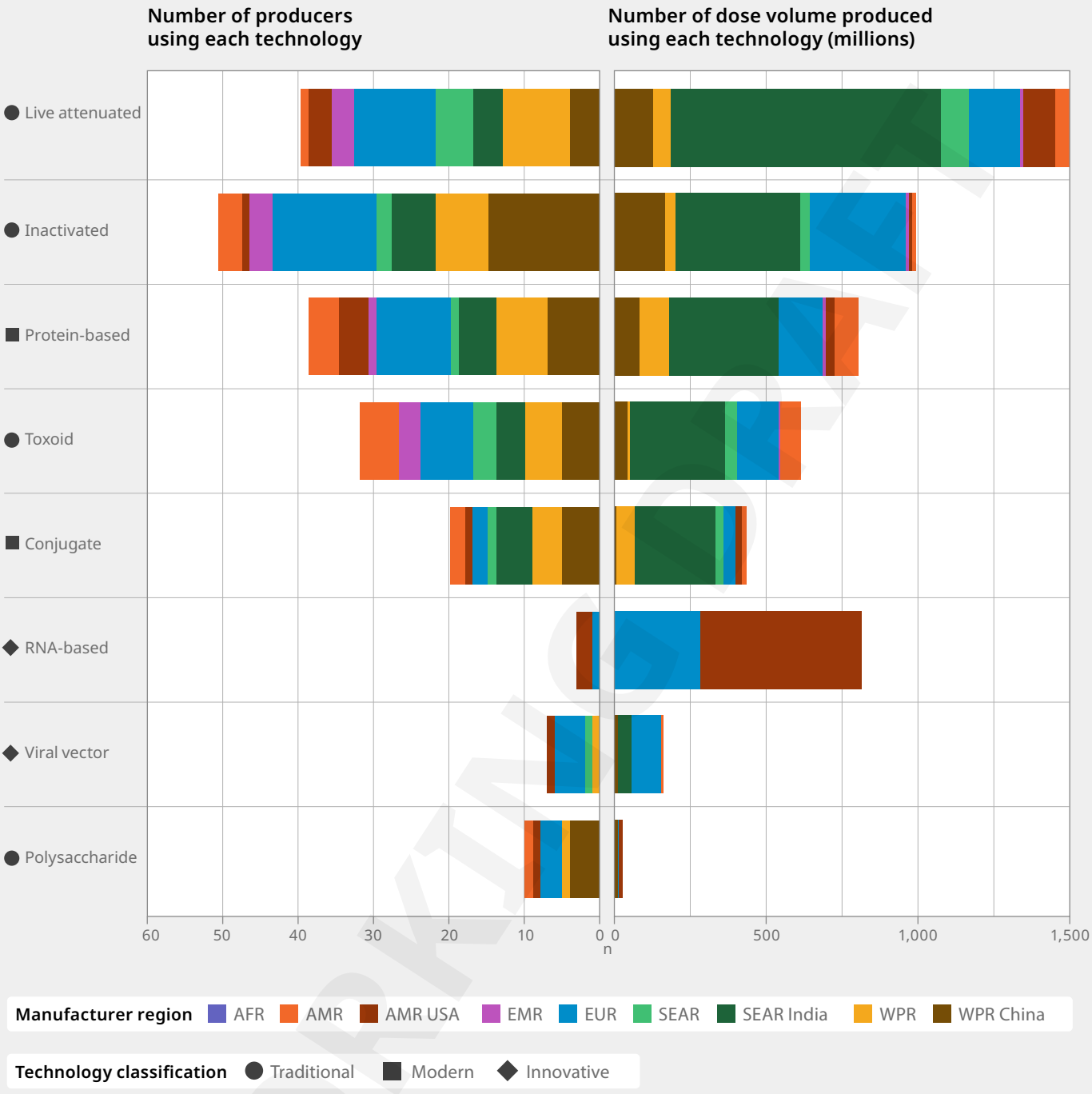
The location of DS production and filling is revealing for countries and regions that wish to assess the diversification and the level of production capacity available in their geography, compared with the global total.

Fig. 10 illustrates the geographic distribution of DS production technology, presenting the number of DS producers using each platform by location of DS production and the total volume of DS produced using each technology.[5]

5 Vaccine platforms represent different ways of making and manufacturing a vaccine. In this report, vaccines are classified as follows: (a) toxoids, polysaccharide, live-viral and inactivated vaccines = traditional platforms group; (b) protein-based and conjugate vaccines = modern platforms group; (c) nucleic acid (e.g. mRNA) and viral vector vaccines = innovative platforms group.

FIG.10

Producers and dose volume by technology



The data shows that most producers employ traditional technologies (e.g. inactivated, live attenuated). Both the South-East Asia Region and the Western Pacific Region contribute meaningfully to the production of vaccines using modern technologies, like protein-based and conjugate vaccines. Innovative technologies like RNA-based are produced by relatively few manufacturers. Despite the suitability of mRNA and viral vector platforms for pandemic response due to rapid scale-up capacity, current production is concentrated only in the United States and Europe, pointing to opportunities to expand the adoption of these newer technologies globally. A rich pipeline of over 50 candidates in clinical or advanced preclinical development exists, but financing gaps, intellectual property (IP) complexity, regulatory readiness, cold-chain limitations and input dependencies are key bottlenecks that need to be addressed to enable LMIC manufacturing capacity.

BOX 4

mRNA vaccine manufacturing

mRNA vaccines represented the highest market value in 2023, contributing substantially to doses and value of the adult and outbreak-driven market categories in the analyses. Beyond COVID-19 vaccines, over 50 candidates are advancing globally, but commercial-scale production remains concentrated in the United States and Europe, with very limited presence in LMICs.

Major bottlenecks constrain wider adoption.

- High upfront R&D and facility costs make sustainability difficult without dedicated financing.
- Patent complexity for lipid nanoparticles and nucleoside modifications limits transfer.
- Regulatory gaps persist, with only 34 RNAs at maturity level 3 or above able to oversee mRNA dossiers.
- Cold-chain requirements remain beyond most LMIC systems despite improving stability profiles.
- The supply of key inputs (lipids, enzymes) is concentrated in a handful of HIC suppliers, and cautious uptake in large markets may delay regional adoption.

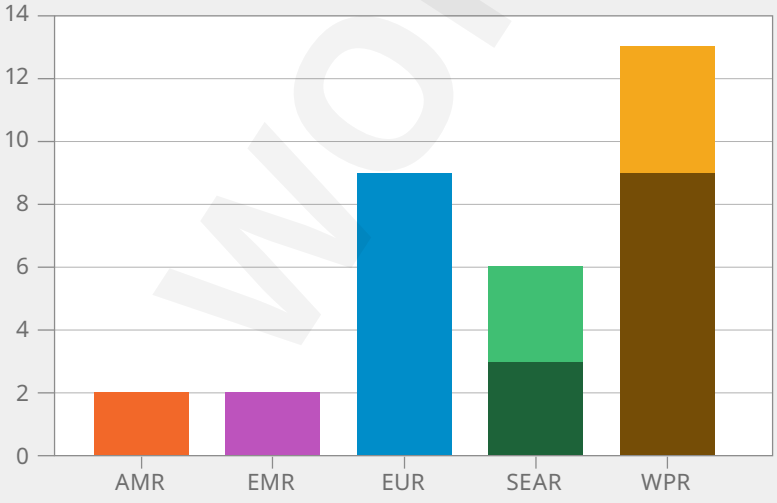
The WHO/Medicines Patent Pool (MPP) mRNA Technology Transfer Programme addresses some of these gaps by providing an IP-independent platform, supporting regulatory capacity and enabling LMIC partners to establish manufacturing for regionally relevant products. This approach complements the African Vaccine Manufacturing Accelerator (AVMA) and Partnership for African Vaccine Manufacturing (PAVM) (see Annex 3), and aims to diversify supply and strengthen pandemic preparedness.

Lyophilization is primarily used to enhance the stability of vaccines and prolong their shelf-life, yet the technology can create bottlenecks at the finishing stage. The lyophilization stage becomes important for pandemic preparedness when a vaccine being produced requires freeze-drying. Regions with producers that are able to lyophilize will be better prepared than others. Fig. 11 shows the number of manufacturers performing lyophilization by region of production and lyophilisation performed per region by percentage of global lyophilization.

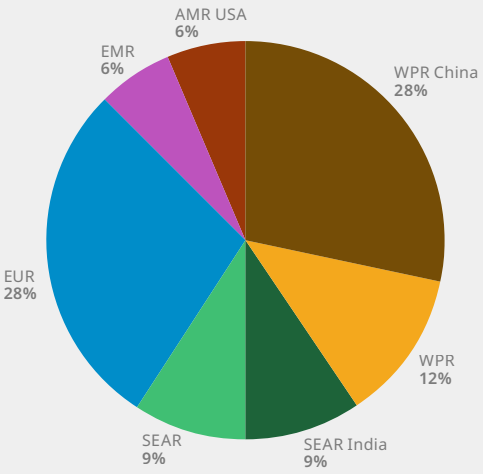
FIG.11

Producers performing lyophilization by region

Number of producers performing lyophilization by region



Doses volume lyophilized by region of production

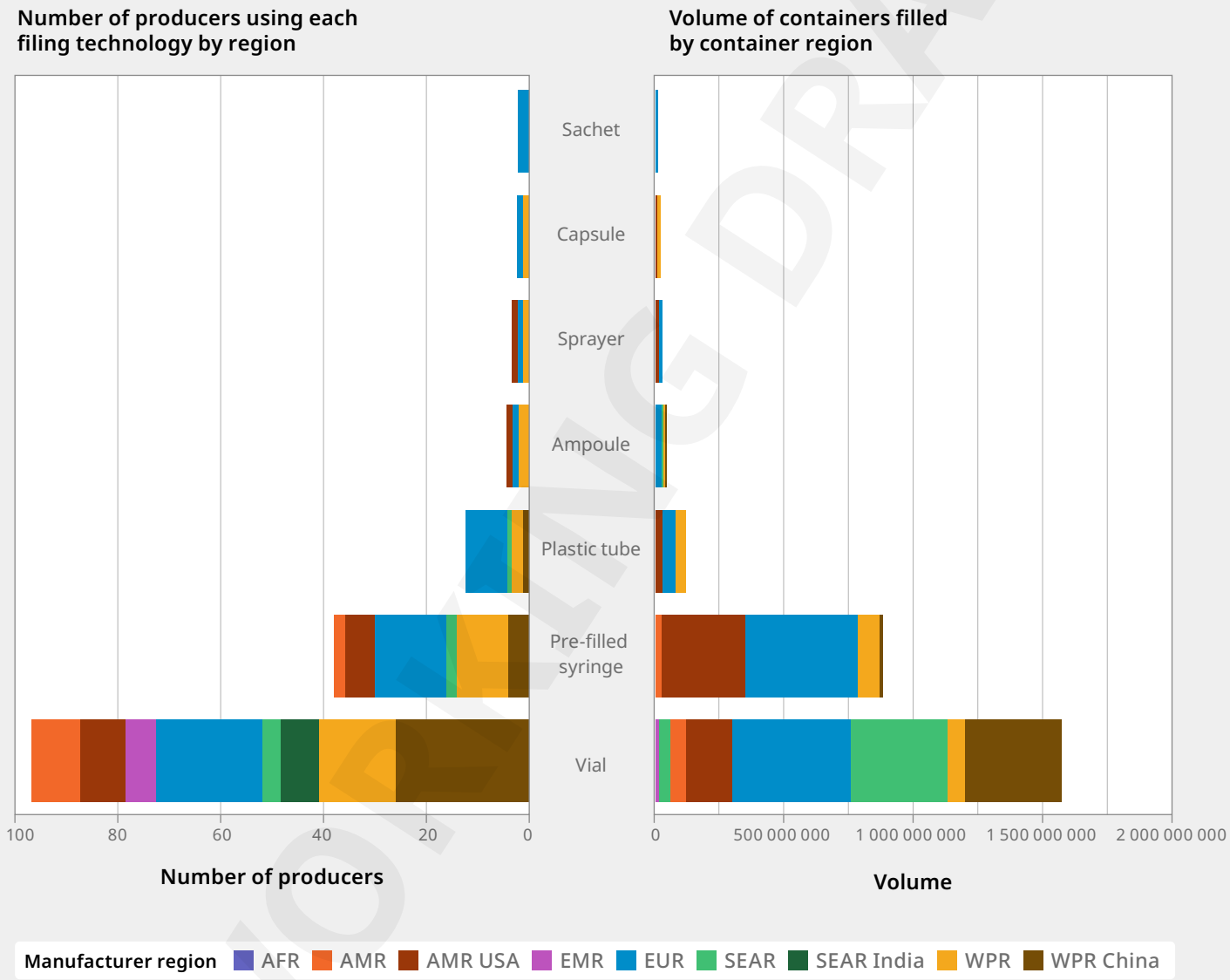


The data shows that producers in the Western Pacific region lyophilize more doses than producers in other regions, whereas producers in the Americas and the Eastern Mediterranean region perform very little lyophilization.

Filling is another potentially critical step for pandemic preparedness, as often a country (or region) that can import DS and has the ability to perform this last step locally can respond more efficiently. Fig. 12 shows the total number of manufacturers performing filling by type of container and by region, and the associated volumes.

FIG.12

Producers filling by container type



The analyses show that both vials and prefilled syringes are the predominant container types filled by producers. However, fewer than half as many producers fill vaccines into prefilled syringes as those that fill into vials. Likewise, the producers of the Americas and the European Region fill substantial volumes in both vials and prefilled syringes.

03 Strategic discussion on regional vaccine manufacturing

This section builds on the observations derived from the report's analysis and draws on them for a discussion of broader strategic considerations related to regional vaccine manufacturing. The report brings forward evidence that has implications for the regional vaccine manufacturing agenda, including the diverse ways in which countries currently secure access to vaccines, as a basis to consider the evolution of the landscape. Countries without local manufacturing capacity (the majority) depend on importing products manufactured in multiple regions, regardless of income group.

Global supply capacity is generally adequate to meet demand for routine vaccines, and most countries do not face access barriers. As such, the global vaccine supply ecosystem is geared towards commercially viable markets that target large populations and have predictable demand, rather than markets for health emergencies. Often, even the more predictable markets face demand and supply imbalances due to the nature of vaccine production and the market dynamics inherent to these products. LMICs are more frequently affected, and key initiatives and partnerships (market-shaping efforts and pooled procurement) monitor the market and intervene as needed to ensure a healthy market, ensuring that supply meets demand and products remain affordable.

> There is no one recipe for creating a sustainable business case. Several manufacturing business-model approaches exist and should be explored.

However, when looking at outbreak vaccine markets, experience from the COVID-19 pandemic demonstrated that rapid vaccine deployment is critical for effective outbreak response. Countries with greater financial resources secured early access to those initial supplies due to greater economic leverage. These countries typically host vaccine manufacturers within their region, creating greater access to novel candidate R&D, as well as manufacturing and supply chains. It is worth noting that in some countries with production capacity, despite the improved self-reliance, raw material shortages and difficulty in scaling up production were factors that limited access even in those countries, In practice, full self-reliance currently does not exist, and may not be the objective for many countries, a fact that is pointing to the importance of building global and regional supply-chain resilience. Despite the challenges faced by countries with production capacity, most countries with limited economic leverage and no regional capacity experiences even slower access to vaccines during COVID-19. Consequently, LMICs could benefit from increased regional production of vaccines for supply security during outbreaks or pandemics. Following the COVID-19 pandemic, a number of organizational and regional initiatives aligned in the call to strengthen regional manufacturing for improved access (*7*). Key initiatives are listed in Annex 3.

As these initiatives gain traction, stakeholders will need to explore how to balance increased regional vaccine manufacturing with economic viability for suppliers and countries, while ensuring global vaccine access. Declining official development assistance (ODA) in the coming years is another factor that adds to the uncertainty. Domestic manufacturing could increase ownership and reduce dependence on aid over the long term, but increased prices and upfront investment costs might be too costly for countries in the short term, especially in the current context. In order to be sustainable, regionalization of production needs to be founded on a suitable business model, to consider the right portfolio mix and guided by an industrial policy that promotes both national and regional growth.

WHO proposes several key considerations for the development of a regional manufacturing ecosystem.

First, **regional manufacturing may not guarantee national supply security for all countries in the region during an emergency**. Commitments between countries and manufacturers in a given region will be essential to ensure equitable distribution during emergencies, especially if supply is constrained. Besides equity in distribution, country commitment is critical for establishing the necessary enablers for successful domestic and regional manufacturing: adequate demand, a strong regulatory environment, comprising regulatory strengthening (including Maturity Level 3 attainment for National

Regulatory Authorities), regional regulatory harmonization and regulatory reliance for countries that do not have the manufacturing capacity, as well as effective procurement. Regional manufacturing cannot succeed in isolation from its enabling ecosystem, and failure to create the latter might have repercussions on global supply and equity.

Second, **switching to regionally manufactured vaccines may result in increased vaccine costs**. Initial investments in human and physical capital and technology transfers may add high initial costs to the cost of manufacturing. As manufacturing is scaled up, these costs will be amortized faster, but initially, countries in the region purchasing these vaccines may need to absorb some of the additional costs, creating a trade-off. In a globalized and competitive economy, regionalization will not necessarily result in lower prices, but the investment can be beneficial overall if guided by an industrial policy that promotes regional and national socioeconomic growth (*8*). In addition, better demand forecasting and predictability within the region could lead to achieving economies of scale in production that could yield cost savings. Finally, better epidemic or pandemic response can yield additional cost savings by reducing the potential losses to the economy and public health.

Besides socioeconomic growth, and when connected to a regional R&D ecosystem, **regional manufacturing can help serve neglected markets of limited commercial interest, delivering health impact for affected populations**. As a secondary effect, this expansion to regional and underserved markets can help create a more viable business case. Experience shows that emergencies can create momentum for vaccine manufacturing initiatives, while demand and (initially) limited competition help establish a viable business case. Producing routine vaccines for domestic use could be a viable model going forward. When this is achieved, suppliers are better positioned to respond to sudden demand surges, improving pandemic preparedness due to the installed industrial infrastructure and skilled workforce. Past successes, like the 2001 Meningitis Vaccine Project (*9*), can serve as examples. In this project, the developing country manufacturer, although not located in the same region, was incentivized to develop the new vaccine by gaining capital for expansion of its infrastructure, the prospect of a big new market, the acquisition of technology and skills and WHO accreditation.

> Public investment by countries in the region is necessary, with access terms negotiated more effectively, to ensure long-term equitable access, both for routine use and in emergencies.

There is no one recipe for creating a sustainable business case. Several manufacturing business-model approaches exist and should be explored. Besides the dominant model of publicly traded private-sector companies, successful state-owned enterprises in different countries demonstrate the value of alternative models. Different models have their own advantages and disadvantages related to the objectives they serve.

Regardless of the manufacturing business model of choice, **regional manufacturing requires a whole-of-ecosystem approach**. This includes national and regional commitment to buy locally/regionally, demand certainty offered by regional and national governments, strengthened regulatory systems and investments in infrastructure and biomanufacturing workforce training. Multilateral development actors, countries and regions with successful regional production models should be consulted during this process.

Finally, it is worth mentioning that **regions embarking on the development of regional manufacturing capacity have an opportunity to pursue end-to-end investments** – from R&D and clinical trials to full access to raw materials, production and distribution. Developing R&D capability is critical for the development of products to meet regional unmet needs. Establishing DS production capacity supports long-term sustainability. Investing in all those stages results in improved pandemic preparedness and ensures true supply security.

This highlights the need for **public investment by countries in the region** – from R&D to manufacturing – with more effective negotiation of access terms to ensure long-term equitable access, both for routine use and in emergencies. For regions that are in the early phases of building a regional manufacturing ecosystem, increased public investment should be encouraged as it can incentivize R&D for unmet regional needs, local clinical trials and provisions for technology transfer.

It will be critical to continue assessing the ecosystem as regional production and procurement efforts translate into tangible shifts to ensure equitable vaccine access is at the centre of these efforts. Ongoing monitoring should consider global impacts to ensure that regional efforts support, rather than hinder, global vaccine access.

References[6]

1. OVP Cessation [website]. Global Polio Eradication Initiative; 2025 (https://polioeradication.org/polio-today/preparing-for-a-polio-free-world/opv-cessation/).

2. Planning for IPV Introduction FAQ. Geneva: World Health Organization; 2013 (https://terrance.who.int/mediacentre/data/sage/SAGE_Docs_Ppt_Nov2013/4_session_polio/Nov2013_session4_img_ipv_faq.pdf).

3. Bivalent Oral Polio Vaccines: Supply and Demand Update. Geneva: United Nations Children's Fund (UNICEF); 2024 (https://www.unicef.org/supply/media/21676/file/OPV-Market-Note-MSFC-April-2024.pdf).

4. Yellow fever vaccines stockpiles [website]. World Health Organization; 2025 (https://www.who.int/groups/icg/yellow-fever/stockpiles).

5. Vaccine Market Update PCV. United Nations Children's Fund (UNICEF); 2023 (https://www.google.com/url?sa=t&source=web&rct=j&opi=89978449&url=https://www.unicef.org/supply/media/18906/file/UNICEF-VIC2023-Session15-PCVupdate-UNICEF-2023.pdf&ved=2ahUKEwjk5eexiuWOAxXTCTQIHUdzLcYQFnoECBoQAQ&usg=AOvVaw0gXHjHt0us0zxIGU6JFkSq).

6. Market & Supply Update: Pneumococcal Conjugate Vaccine (PCV). United Nations Children's Fund (UNICEF); 2023 (https://www.google.com/url?sa=t&source=web&rct=j&opi=89978449&url=https://www.unicef.org/supply/media/19016/file/VIC-MarketUpdate-Poster-PCV-2023.pdf&ved=2ahUKEwjk5eexiuWOAxXTCTQIHUdzLcYQFnoECB4QAQ&usg=AOvVaw2CpU_mt8_BGmXyLu7ROfAW).

7. WHA74.6: Strengthening local production of medicines and other health technologies to improve access. Seventy-fourth World Health Assembly, Geneva, 24 May–1 June 2021. Geneva: World Health Organization; 2021 (https://apps.who.int/gb/ebwha/pdf_files/WHA74/A74_R6-en.pdf).

8. United Nations Conference on Trade and Development. Building the case for investment in local pharmaceutical production in Africa: A comprehensive framework for investment policymakers. United States of America: United Nations; 2025 (https://unctad.org/system/files/official-document/diae2024d5_en.pdf).

9. LaForce F M, Konde K, Viviani S, Préziosi M-P. The Meningitis Vaccine Project. Vaccine. 2007; 3;25 Suppl 1:A97-100. (https://doi.org/10.1016/j.vaccine.2007.04.049).

6 All references were accessed 23 October 2025.

Annex 01 WHO regions

WHO African Region

Algeria, Angola, Benin, Botswana, Burkina Faso, Burundi, Cabo Verde, Cameroon, Central African Republic, Chad, Comoros, Congo, Côte d'Ivoire, Democratic Republic of the Congo, Equatorial Guinea, Eritrea, Eswatini, Ethiopia, Gabon, Gambia, Ghana, Guinea, Guinea-Bissau, Kenya, Lesotho, Liberia, Madagascar, Malawi, Mali, Mauritania, Mauritius, Mozambique, Namibia, Niger, Nigeria, Rwanda, Sao Tome and Principe, Senegal, Seychelles, Sierra Leone, South Africa, South Sudan, Togo, Uganda, United Republic of Tanzania, Zambia, Zimbabwe.

WHO Region of the Americas

Antigua and Barbuda, Argentina, Bahamas, Barbados, Belize, Bolivia (Plurinational State of), Brazil, Canada, Chile, Colombia, Costa Rica, Cuba, Dominica, Dominican Republic, Ecuador, El Salvador, Grenada, Guatemala, Guyana, Haiti, Honduras, Jamaica, Mexico, Nicaragua, Panama, Paraguay, Peru, Puerto Rico (*Associate WHO Member State), Saint Kitts and Nevis, Saint Lucia, Saint Vincent and the Grenadines, Suriname, Trinidad and Tobago, United States of America, Uruguay, Venezuela (Bolivarian Republic of).

WHO South-East Asia Region

Bangladesh, Bhutan, Democratic People's Republic of Korea, India, Indonesia, Maldives, Myanmar, Nepal, Sri Lanka, Thailand, Timor-Leste.

WHO European Region

Albania, Andorra, Armenia, Austria, Azerbaijan, Belarus, Belgium, Bosnia and Herzegovina, Bulgaria, Croatia, Cyprus, Czechia, Denmark, Estonia, Finland, France, Georgia, Germany, Greece, Hungary, Iceland, Ireland, Israel, Italy, Kazakhstan, Kyrgyzstan, Latvia, Lithuania, Luxembourg, Malta, Monaco, Montenegro, Netherlands, North Macedonia, Norway, Poland, Portugal, Republic of Moldova, Romania, Russian Federation, San Marino, Serbia, Slovakia, Slovenia, Spain, Sweden, Switzerland, Tajikistan, Türkiye, Turkmenistan, Ukraine, United Kingdom of Great Britain and Northern Ireland, Uzbekistan.

WHO Eastern Mediterranean Region

Afghanistan, Bahrain, Djibouti, Egypt, Iran (Islamic Republic of), Iraq, Jordan, Kuwait, Lebanon, Libya, Morocco, Oman, Pakistan, Qatar, Saudi Arabia, Somalia, Sudan, Syrian Arab Republic, Tunisia, United Arab Emirates, West Bank and Gaza Strip (*Non-Member area), Yemen.

WHO Western Pacific Region

Australia, Brunei Darussalam, Cambodia, China, Cook Islands, Fiji, Japan, Kiribati, Lao People's Democratic Republic, Malaysia, Marshall Islands, Micronesia (Federated States of), Mongolia, Nauru, New Zealand, Niue, Palau, Papua New Guinea, Philippines, Republic of Korea, Samoa, Singapore, Solomon Islands, Tokelau (*Associate WHO Member State), Tonga, Tuvalu, Vanuatu, Viet Nam.

Annex 02 Vaccine manufacturing and procurement primer

Vaccine manufacturing involves a series of complex steps performed by one or more organizations in one or more locations or countries.

The descriptions and vocabulary used here are provided to align vocabulary as much as possible with other organizations and to explain the method of analysis.

DS production: The stage of production where a vaccine component is produced/manufactured from raw ingredients. This stage is also called "bulk antigen manufacturing". In this instance, DS can contain an antigen or be an adjuvant. DS in bulk format can be sold and bought among producers of vaccines, whereby one organization produces the DS, sells and ships it to the other

organization for DP formulation or to be filled into the primary container.

DP formulation: The stage of production where DP in bulk format is produced. This stage is also called "formulation" and can involve mixing the DS with other components, such as preservatives or adjuvants, or mixing multiple DS together. DP in bulk format can be sold and bought among producers of vaccines, whereby one organization produces the DP, sells and ships it to the other organization to be filled into the final primary container.

Filling: The stage at which the DP is filled into its final primary container for sale (e.g. vial, ampule or pre-filled syringe). In the case of lyophilized products, the lyophilization process occurs as a part of filling in that the DP is filled into the primary container.

Packaging: The stage of affixing a label to the final primary container and placing the final primary containers and a product insert (PI) into the secondary container (the package). This stage is also called "finishing".

Lot release: The stage of submitting a product to the regulatory authority for their review of the manufacturing data and their verification of product consistency and compliance with current good manufacturing practices (cGMP), and for their laboratory testing of the product for potency and other regulated product characteristics. If compliant with all regulatory requirements, the regulatory authority will authorize the manufacturer to release the product for sale.

Location of DS production: The WHO region where the DS is produced. In some cases, when multiple DSs are combined into one DP, these substances may be manufactured in multiple locations.

Location of DP formulation: The WHO region where the DP is formulated. In some cases, DP for the same vaccine can be formulated in more than one location, and each location is typically associated with regulatory approval of the product in specific countries.

Location of filling: The location at which DP is put into the primary container. This can be the same location as DP formulation or a different location. In some cases, the same vaccine can be filled in more than one location, and each filling location is typically associated with regulatory approval of the product.

Location of packaging: The location at which primary containers are packaged into a secondary container (e.g. a box holding 10 vials).

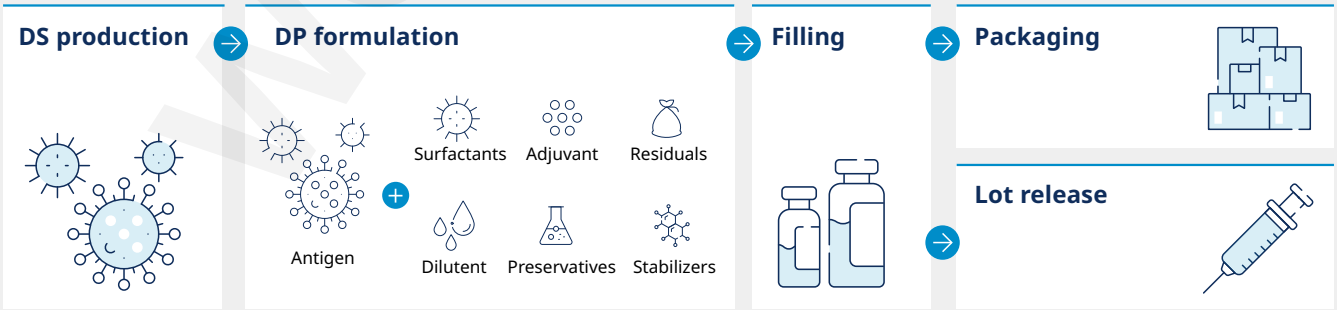
Manufacturer/producer: An organization that has performed one or more stages of vaccine production/manufacturing. If an organization is structured to have subsidiaries, all production activity of the subsidiaries is captured as individual organizations.

Supplier: The organization that has sold/supplied the vaccine to a customer. If an organization is structured to have subsidiaries, all sales are captured under a single organization.

Location of supplier HQ: The location of the HQ of the organization responsible for supplying or selling the vaccine.

FIG. A2.1

The four stages of vaccine production



Annex 03

Key initiatives to support regional vaccine manufacturing in Africa

PAVM *(1)*, now upgraded to Platform for Harmonized African Health Products Manufacturing (PHAHM), aims to safeguard Africa's health by reducing reliance on vaccine supply from other WHO regions from the current 99% to 40% by 2040. Drawing from the experiences in other WHO regions, particularly the South-East Asia Region and the Region of the Americas, where local manufacturers have enhanced vaccine supply regionally, the initiative underpins a strategy where vaccines of high or predominant priority to Africa (HIV, Shigella, etc.) and vaccines for some regional-specific diseases (Lassa fever, Rift Valley fever, etc.) could become available.

Also focused on the African continent and launched by Gavi in June 2024, AVMA is a landmark financing instrument originally designed in consultation with the African Union and Africa Centres for Disease Control and Prevention (Africa CDC). It aims to strengthen and expand Africa's vaccine manufacturing capability *(2).* With up to **US$1.2 billion** committed over 10 years, the AVMA employs a "pull financing" model by providing downstream incentives to manufacturers to help offset initial costs of development and production.

The Regionalized Vaccine Manufacturing Collaborative (RVMC), established in 2022 and hosted by Coalition for Epidemic Preparedness Innovations (CEPI), aims to enhance vaccine equity and global health security by promoting regional vaccine manufacturing and supply chain networks. Its goal is to promote a shared global vision by improving access to information and aligning regional efforts.

References

1. Partnership for African Vaccine Manufacturing (PAVM) From Aspiration To Action [website]. Africa Centres for Disease Control and Prevention; 2025 (https://africacdc.org/event/partnership-for-african-vaccine-manufacturing-pavm-from-aspiration-to-action/).
2. African Vaccine Manufacturing Accelerator (AVMA) [website]. Gavi, the Vaccine Alliance; 2025 (https://www.gavi.org/programmes-impact/types-support/regional-manufacturing-strategy/avma).

Annex 04

Regional enablers

Regional pooled procurement mechanisms have increased over the years. To date, the PAHO RF is the largest regional pooled procurement mechanism for countries procuring with domestic resources (not donor-funded), and PAHO serves 41 countries in Latin America and the Caribbean. Although procurement from Latin American manufacturers has not been the largest part of the PAHO RF, the participation of Latin American manufacturers has been increasing. In addition, countries in the region have benefited from pooled demand, which provides manufacturers with stronger incentives than individual country orders. They have also benefited from assistance in vaccine demand forecasting and access to regional expertise on vaccine markets and manufacturers. In the Eastern Mediterranean Region, there have been efforts at both regional and sub-regional levels, notably with the Gulf Cooperation Council (GCC) pooled procurement for medicines and vaccines. Recently, the WHO Regional Office for the Eastern Mediterranean (EMRO) launched a

flagship initiative to enhance equitable access to essential medical products, which includes the establishment of a regional pooled vaccine procurement mechanism to improve access, reduce costs and boost countries' negotiating power *(1)*. The Association of Southeast Asian Nations (ASEAN) region's vision to ensure timely access to vaccines dates to 2014. The ASEAN Vaccine Self-Sufficiency Initiative *(2)* includes proposals on regulatory collaboration, pooled procurement and strategic investment in vaccine production capabilities. Finally, Africa CDC is developing the African Pooled Procurement Mechanism (APPM) to "lower the cost of pharmaceutical products and harmonize regulations that will enhance quality and safe medical supplies for the continent" *(3)*.

Capacity building and regulatory strengthening: In 2023, the WHO established the Biomanufacturing Workforce Training Initiative *(4)* to address the global shortage of skilled professionals in quality biomanufacturing. The three pillars of the initiative form a synchronized network to enhance access to biomanufacturing training, especially for countries in need. One pillar is WHO's capacity building activities *(5)*, including flagship training programmes such as the Virtual cGMP Training Marathon, Week of Quality and Holistic Training Workshops. These programmes provide a comprehensive range of training for both private and public sectors to meet WHO quality standards and achieve sustainable local production and technology transfer. Another pillar is the Global Training Hub for Biomanufacturing (GTH-B), hosted by the Republic of Korea. Established under a signed Memorandum of Understanding between the Ministry of Health and Welfare of the Republic of Korea and WHO in 2023, the GTH-B has been providing didactic and hands-on training in good practices and the development and production of biopharmaceuticals to professionals, particularly from LMICs. The last pillar concerns establishing regional training centres to enhance access to biomanufacturing training that is tailored to the region's needs and contexts (e.g. language).

References

1. World Health Organization Regional Committee for the Eastern Mediterranean. Regional flagship initiative 1: Expanding equitable access to medical products. Geneva: World Health Organization; 2024 (https://applications.emro.who.int/docs/Flagship-Initiative-Expanding-Access-Medical-Products-eng.pdf).

2. ASEAN Vaccine Security and Self-Reliance (AVSSR): Equitable access to quality vaccines on an affordable and timely basis [website]. International Vaccine Institute; 2025 (https://www.ivi.int/asean-vaccine-security-and-self-reliance-avssr-equitable-access-to-quality-vaccines-on-an-affordable-and-timely-basis/).

3. An African Pooled Procurement Mechanism will enhance quality and safe medical supplies for a resilient continent [blog]. United Nations Economic Commission for Africa; 2024 (https://www.uneca.org/stories/an-african-pooled-procurement-mechanism-will-enhance-quality-and-safe-medical-supplies-for-a#:~:text=Mombasa%2C%20Kenya%2C%2015%20May%202024,Commission%20for%20Africa%20(ECA)).

4. WHO Biomanufacturing Workforce Training Initiative [website]. World Health Organization; 2025 (https://www.who.int/initiatives/biomanufacturing-workforce-training-initiative).

5. Capacity building and technical assistance [website]. World Health Organization; 2025 (https://www.who.int/teams/regulation-prequalification/lpa/capacity-building-and-technical-assistance).

Annex 05

Existing work and datasets

WHO publishes an annual dataset of vaccine market information. In 2024, the Market Information for Access to Vaccines (MI4A) Public Vaccine Purchase Dataset was published based on data collected from 168 countries on their 2023 purchases. In addition, WHO publishes case studies describing how countries have used vaccine purchase data and their related outcomes.

For a comprehensive understanding of the global vaccine market, WHO developed the internal Global Vaccine Market Data (GVMD), which supplements the country-reported data from the MI4A Public Vaccine Purchase Dataset by estimating global totals of all vaccine supply and financial value. This study builds on the GVMD by associating vaccine procurement with manufacturing location for each stage of production, which is provided confidentially by vaccine manufacturers to WHO and supplemented with public information. Data in this report respects the confidentiality of the reporting and provides aggregated data only.

To mitigate supply security risks to Member States and WHO regions, it is important to know where interdependencies of manufacturing exist by geographic location. By better understanding their supply risks, Member States or WHO regions can determine how best to secure supply, whether through greater diversification of the supplier base and/or through increased dependency on localised production. Through the collection of vaccine procurement and pricing data in the UNICEF and WHO electronic Joint Reporting Form (eJRF), WHO makes available two data sources to Member States for this purpose:

1. the MI4A Vaccine Purchase Database; and
2. the Global Vaccine Market Report (GVMR).

These are both updated on an annual basis, and Member States should regularly consult these sources for the latest vaccine market data.