Vaccine market, market shaping and regional initiatives for vaccine production

ARVAC Lecture 9

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What is a market?

- Number of buyers and sellers
- Information availability
- Product variety
- Ease of entry and exit
- Degree of government intervention
- Price mechanisms





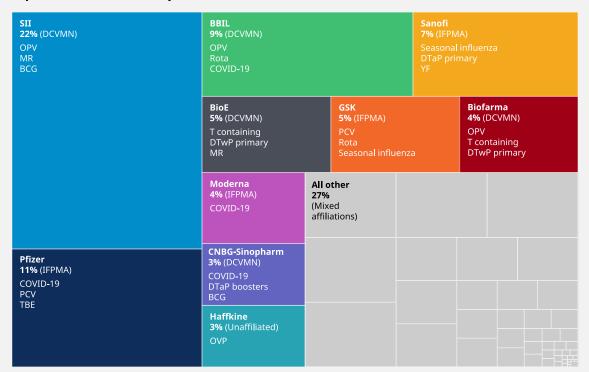
Who sells vaccines?

The great majority of vaccines is sold by a handful of manufacturers. Why?



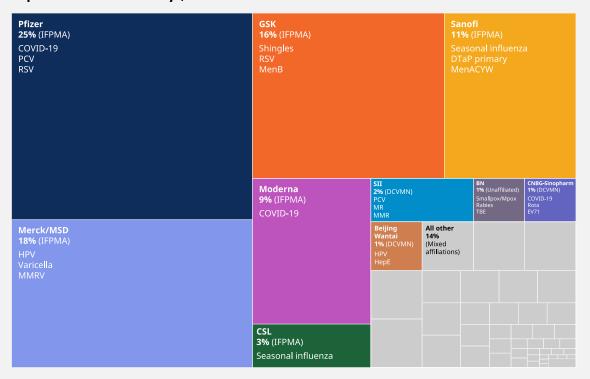
DATA AS OF EOY 2023

Top 10 manufacturers by volume 2023



- ~70% of volume captured by 10 manufacturers, and ~40% captured by three
- DCVMN companies accounted for >50% of volumes sold in 2023

Top 10 manufacturers by \$ value 2023

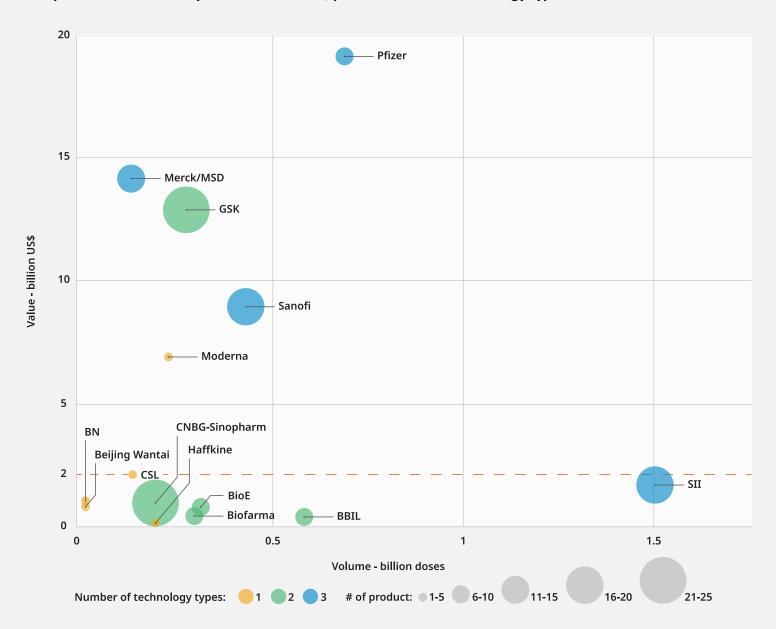


- 85% of value captured by 10 manufacturers, and >40% captured by two
- IFPMA companies captured >80% of total value in 2023

Two main business models co-exist in vaccine supply. How can we explain this?

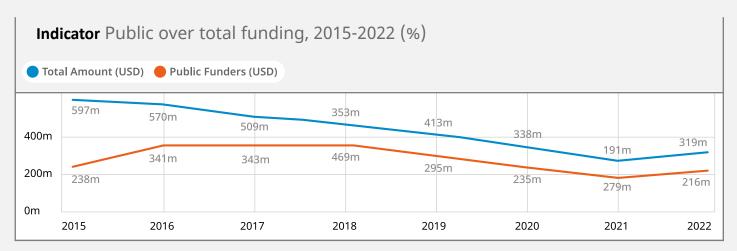
- Below the 2bn USD line (mainly) manufacturers HQ'd in India and China,
 ~70% of total volume
- Above the 2bn USD line five IFPMA-affiliates, ~30% of global volumes and ~80% of total value
- Pfizer and SII outliers from value and volume perspectives

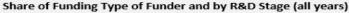
Top 10 manufacturers by volume or \$ value, portfolio size and technology types used



Who funded development of these vaccines? Public funding accounts for a large portion of R&D funding









- 1 Ebola
- 2 Chikungunya
- 3 Crimean Congo Haemorrhagic Fever
- 4 Lassa Fever
- 5 Marburg
- 6 Mpox

- 7 Cholera
- 8 MERS
- 9 Nipah and henipaviral disease
- 10 SARS
- 11 Zika
- 12 Tuberculosis
- Public spending accounts for more than 60% of total R&D funding for listed diseases
- Early R&D stages like discovery & preclinical and Phase I & II clinical are almost exclusively funded by public funders
- Public funding by HICs continues to be the main funding source (60-70% historically), and has increased in value
- 8 out of the 12 listed diseases still do not have an approved vaccine developed

Source: Policy Cures G-FINDER

Different regions of the world display different levels of self reliance. What has changed over time?



DATA AS OF EOY 2023

<5%

The AFR region produces less than 5% of the vaccines it procures; 55% imported from India

<5%

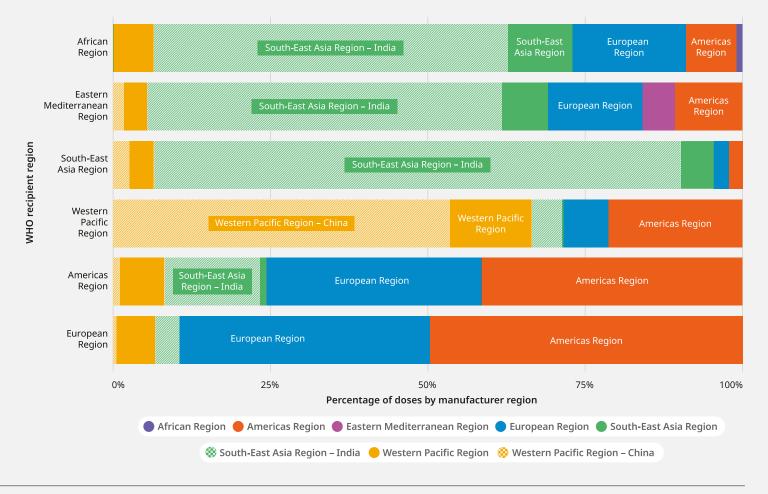
The EMR region also produces less than 5% of the vaccines it procures; 56% imported from India

The SEAR region manufactured 87% of the vaccines it procured, with 84% produced in India

The WPR region manufactured 66% of the vaccines it procured, with 54% produced in China

The EUR and AMR regions exhibit diversification, with some percentage of selfreliance combined with imports from other regions

Source of vaccine volume (%) by manufacturer region to recipient region



Source: WHO MI4A Global Vaccine Market Report 2024

Who buys vaccines?

Vaccine demand is also concentrated. Why?





It is largely governments who provide vaccines to their population free of charge



In low- and middle-income settings remains very unpredictable due to unclear agendas, limited funding, ineffective procurement, weakness of programmes



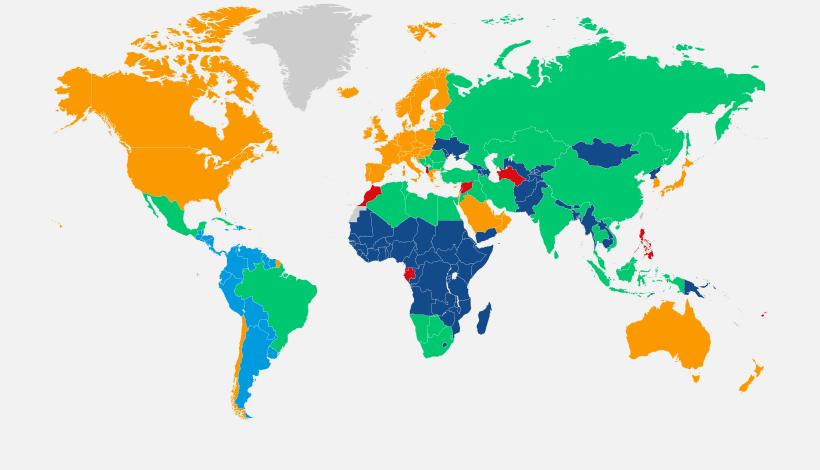
Mechanisms such as UNICEF, PAHO Revolving Fund, Gavi - the Vaccine Alliance - have worked to strengthen demand for lower- and middle-income settings by improving predictability as well as procurement and payment procedures







How do countries purchase vaccines?



● PAHO RF ● Self-procuring HICs ● Self-procuring MICs

● UNICEF SD (Gavi) ● UNICEF-Procuring MICs

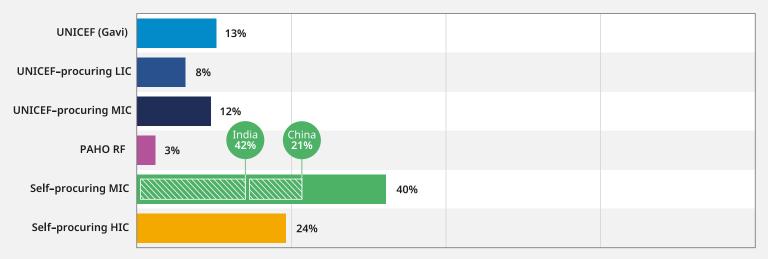


Pooled procurement mechanisms account for an important share of volume, but a small share of \$ value. Is this good or bad?

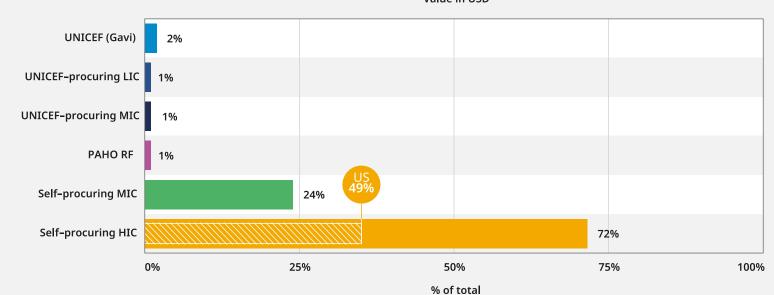
- Most vaccines are self-procured (MICs and HICs)
 ~65% of the market volume and
 ~95% of market value
- Pooled procurement mechanisms have evolved to represent the remaining 35% and 5%, respectively
- Vaccines procured by HICs account for 24% of volume and 72% of value, driven by higher prices
- Vaccine volumes purchased by MICs account for >50% of the total

Source: WHO MI4A Global Vaccine Market Report 2024





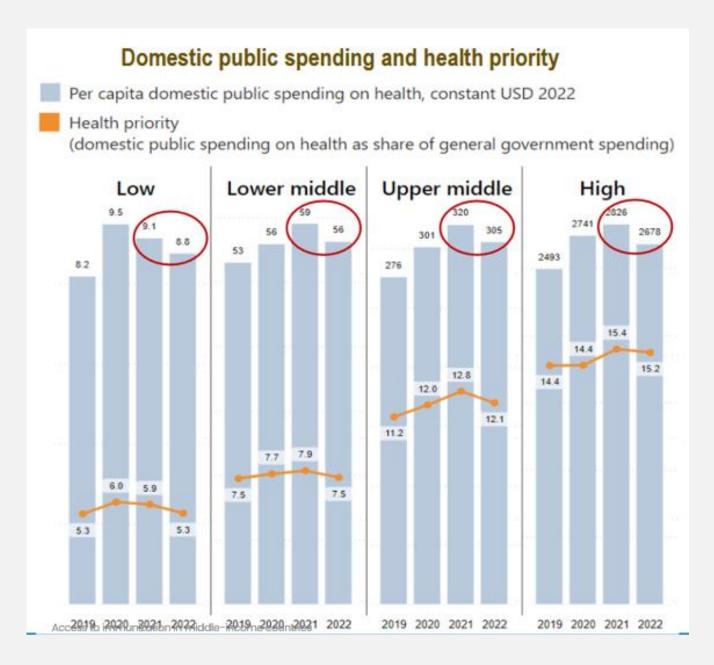
Value in USD



Historically, domestic public spending on health has been increasing, but trend is changing

- Since 1970s, LICs have been spending more and more on vaccines in absolute terms
- Domestic spending increased across all income groups during the pandemic
- Since 2022 it has been decreasing as health is being deprioritized
- Further decline is expected in the future

Source: WHO Global Health Spending Report, 2024



Supply + Demand = Access

What have we achieved?



Reduced timelines for introduction between HICs and LICs;

Increased market transparency;

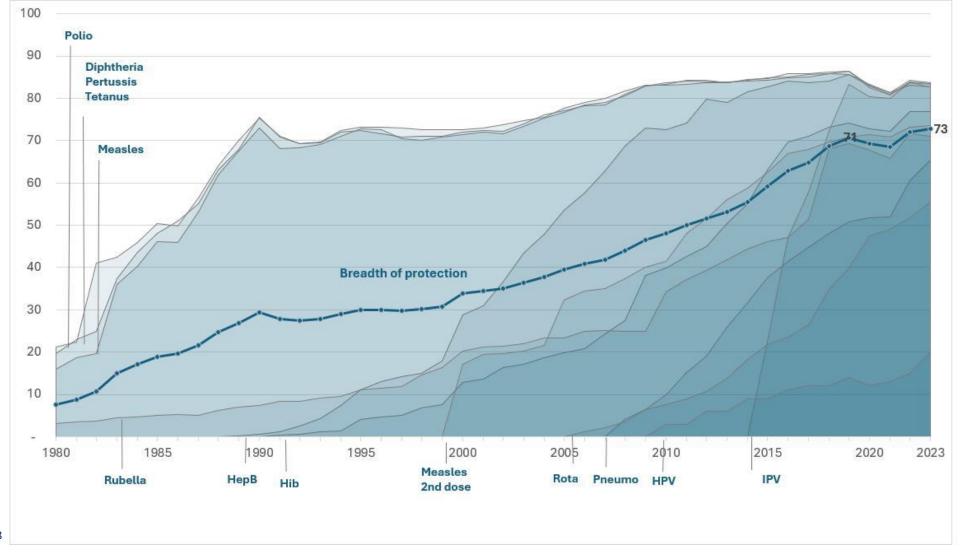
Increased number of manufacturers from developing economies;

Improved affordability for lower income settings;

What else?



We are stuck on DTP3 coverage (systems' reach), but we have succeeded in NVI thanks to a more effective funding and procurement system





Every year countries share data with WHO increasing transparency

- MI4A Vaccine purchase database published in September 2024, with information on 2023 purchases from 169 countries; historical data from 2005
- Table containing price ranges as reported by

countries

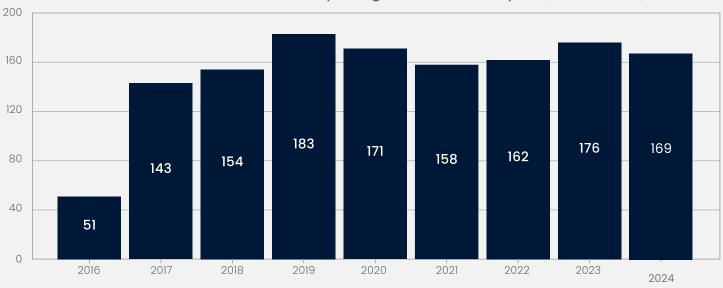
The MI4A vaccine purchase database contains information on vaccines purchased, volumes, price, procurement mechanism



WHO website anonymizes country information in respect of confidentiality



Evolution of number of countries reporting in the indicated year (2016 – 2024)

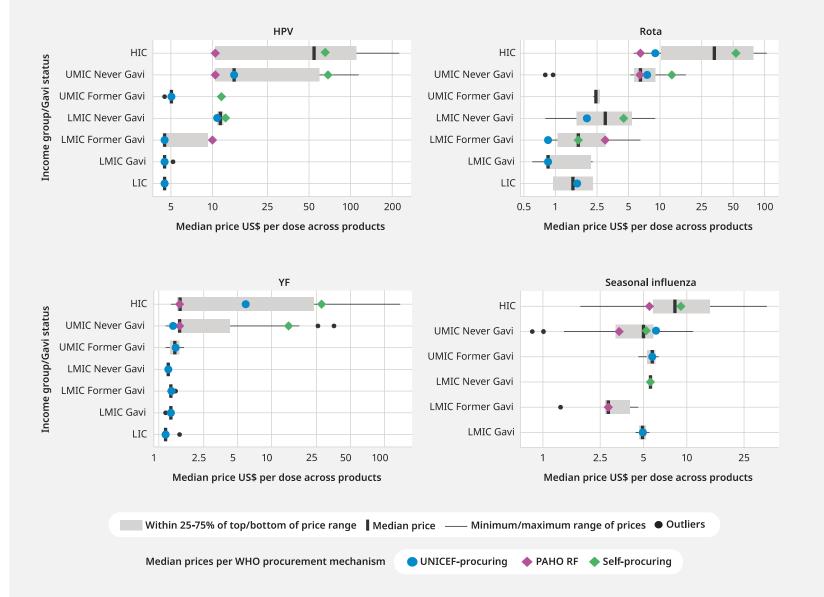


VACCINE	UNICEF Supply Division (incl. COVAX)						PAI	10	Self-procurement					
	Ga	vi	Non-Gavi				Revolving Fund							
			LMIC		UMIC				LMIC		UMIC		HIC	
	Min	Max	Min	Max	Min	Max	Min	Max	Min	Max	Min	Max	Min	Max
BCG	\$0.10	\$0.20	\$0.10	\$0.22	\$0.10	\$0.27	\$0.12	\$0.33	\$0.16	\$0.80	\$0.03	\$1.24	\$0.25	\$29.53
bOPV	\$0.11	\$0.20	\$0.14	\$0.23	\$0.14	\$0.20	\$0.13	\$0.20	\$0.18	\$0.18	\$0.16	\$0.38	\$0.25	\$4.94
COVID-19	\$3.70	\$20.00	\$6.70	\$7.50	\$4.00	\$12.00	\$12.00	\$12.00			\$4.00	\$15.00	\$17.68	\$93.54
Dengue													\$95.18	\$95.18
Diphtheria											\$0.04	\$0.04		
DT	\$0.18	\$0.21	\$0.17	\$0.38	\$0.20	\$0.21	\$0.18	\$0.18	\$0.24	\$0.47	\$0.09	\$1.13	\$0.78	\$1.42
DTaP							\$18.20	\$18.20			\$0.81	\$0.81	\$13.04	\$20.81
DTaP-HepB-Hib-IPV							\$20.00	\$21.54			\$19.92	\$39.20	\$20.99	\$96.86
DTaP-HepB-IPV													\$63.48	\$63.48
DTaP-Hib											\$0.81	\$0.81		
DTaP-Hib-IPV							\$17.61	\$19.00			\$12.75	\$26.41	\$17.75	\$67.11
DTaP-IPV							\$13.49	\$13.66			\$15.47	\$24.50	\$14.08	\$46.52
DTwP	\$0.18	\$0.19	\$0.17	\$0.19	\$0.18	\$0.19	\$0.18	\$0.18	\$0.46	\$0.61	\$0.11	\$0.11	\$0.34	\$0.68
DTwP-HepB	\$0.85	\$0.85									\$1.42	\$1.42		
DTwP-HepB-Hib	\$0.78	\$1.29	\$0.78	\$1.29	\$0.80	\$3.77	\$1.19	\$1.19	\$1.63	\$2.29	\$1.25	\$1.25	\$6.47	\$11.69
HepA (adult)					\$7.45	\$8.30	\$10.99	\$13.50			\$33.13	\$33.13	\$17.50	\$39.11
HepA (ped.)			\$6.99	\$6.99				\$8.03	\$11.09	\$11.09	\$4.13	\$21.08	\$11.42	\$27.71
HepA+B													\$46.65	\$72.05
HepA-Typhoid													\$87.94	\$89.74
HenR (adult)			\$n 7n	\$n 7n			¢ በ 33	\$n 78	\$1 <i>4</i> 0	\$1 <i>/</i> /0	\$n 97	\$7.85	\$2.29	\$7 <i>1</i> 9 <i>1</i>

The table is non-exhaustive and only representative of min-max prices as they are reported by countries. Variations can be attributed to different vaccine presentations, manufacturers and other

Lower income countries pay considerably lower prices, though opportunities for streamlining in MICs

- Prices are tiered by income group
- Pooled procurement agencies are typically offered a single price for a given product for a specific pricing tier, exhibited via narrower price ranges
- Never-Gavi UMICs often exhibit
 wide price ranges and price overlaps with
 HICs
- Newer vaccines like HPV and rota, are more expensive and have wider price ranges, potentially due to the several different products on the market



Source: WHO MI4A Global Vaccine Market Report 2024

But did we change the paradigm or are we tinkering at the margins?



Decisions on vaccine development, production, distribution are largely **driven by private corporations** who respond to shareholders;

Access to vaccines in lower income settings remains second in line to higher income settings;

Continents still rely heavily on a few HICs for research and development and emergency needs;

Investment in R&D for LIC diseases improved but **still insufficient**;

What else?



The examples of TB and RSV. Thoughts?

1. New TB vaccine – M72 example¹

- In the 80's the U.S. Army brings in GSK to work on a malaria vaccine and helped develop an adjuvant (patented by GSK ASO1)
- USD 2 million in federal money (mainly NIH) is invested from 1995 to 2005 to conduct trials for a TB vaccine using the adjuvant
- As the vaccine progressed into testing, BMGF, UK, the Netherlands and Australia contributed. Important role of Areas and IAVI with public funding
- GSK discontinues TB vaccine development. Focus on shingles vaccine using the adjuvant gets FDA approval, focused on the US market, priced between USD 100 – 200 a dose.
- Gates MRI obtains exclusive license to develop and commercialize M72 (<u>licensing agreement confidential</u>)

2. RSV vaccine

- Early investments by the NIH (first in the 60's, then early 00's) in lab work, clinical trials, and issuing of grants to universities, biotechs and manufacturers led to successful vaccine and monoclonal development
- NIH licensed technology
- BMGF stepping in in early to mid 00's to fund universities, small biotechs as well as multinationals like Pfizer to develop RSV vaccines
- Currently only available in HICs by Pfizer, GSK, Astra Zeneca, Sanofi Pasteur, priced between USD 175 – 395 a dose²
- Not yet introduced in LICs and MICs. Recent policy recommendation by WHO SAGE

^{1.} How a Big Pharma Company Stalled a Potentially Lifesaving Vaccine in Pursuit of Bigger Profits — ProPublica

 $^{2. \}qquad https://cdn.who.int/media/docs/default-source/immunization/mi4a/who-global-market-study-on-rsv-immunization-products_november-2024.pdf?sfvrsn=e6ff42a9_3\&download=true$

WHO calls for a new paradigm for vaccine development and access



WHO calls for¹:

- increased investment in & oversight of vaccine manufacturing & distribution, especially when publicly funded;
- international collaboration rules on sharing vaccines equitably;
- improved transparency along value chain by industries (licensing/access agreements?);
- technology transfer to manufacturers in low- & middle-income countries



We will not recover from the historic backsliding in essential immunization if we continue to allow market dynamics alone to shape global vaccine priorities. Nor will we achieve equitable access to vaccines globally unless we have more transparency and active government oversight.

Dr. Tedros Adhanom GhebreyesusWHO Director General

1. https://www.who.int/publications/i/item/9789240062726

The pandemic catalyzed many such changes, even if their scale remains moderate





The draft of the Pandemic Accord, agreed upon by INB (for consideration by WHA 2025) warrants:

- rapid access targeting 20% of manufacturers' real time production
- promotion and facilitation of transfer of technology
- encouragement to publish terms of purchase agreements with manufacturers for pandemic-related health products



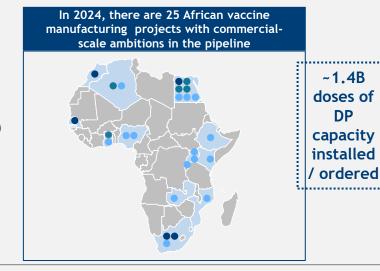
Regional pooled procurement, local manufacturing and regulatory strengthening will mitigate import risks... and ensure that much of the money spent on essential medical products will benefit the countries of the Region¹

DP

Regional flagship initiative 1: Expanding equitable access to medical products

Local production of health products has been on the agenda for years, renewed emphasis with Africa's 2040 vision and partners' support





Segment 1 - AVMs with facilities & TTs signed or started

Segment 2 - AVMs with facilities awaiting TT initiation

Segment 3 - AVMs with facilities in development

Thank you!

Special thanks to:

- Tania Cernuschi
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- Tara Prasad
- Kate O'Brien

Want to learn more?

https://www.who.int/teams/immunization-vaccines-and-biologicals/vaccine-access/mi4a

Want to help our work?

https://www.oneworldhealthforall.org/



Annex