

DCVMN – General Meeting

Impact of C-19 on RI and mitigation strategies

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**World Health
Organization**

Outline

- **Global vaccine markets**
- C-19 impact on supply and demand for other antigens
- C -19 impact on Routine Immunization
- Mitigation strategies

Countries worldwide, through WHO processes, are calling for enhancing access to vaccines



- ❖ **Total of 50 WHA Global Resolutions** on access to medicines and vaccines + 45 regional Resolutions
- ❖ **WHA72 adopted a Resolution on improving the transparency of markets** for medicines, vaccines, and other health products
- ❖ WHA73 endorsed the **Immunization Agenda 2030 (IA2030)** with **Strategic Priority 6 on supply** and adopted a resolution recognizing **extensive immunization against COVID-19** as a global public good for health.

How does WHO influence access to vaccine supply?



**72nd WHA - May 2019 – adopted a
Roadmap on access to medicines
and vaccines 2019-2023**



Establish global
immunization
**agenda &
strategies** to
build and
harness
commitment to
action

**Inform
demand:**
develop policies
for optimal use
of vaccines &
advance
evidence-based
introduction of
vaccines

**Promote
research and
innovation** to
increase impact
of vaccines,
technologies,
and practices

Provide
regulatory
support to
accelerate
authorization

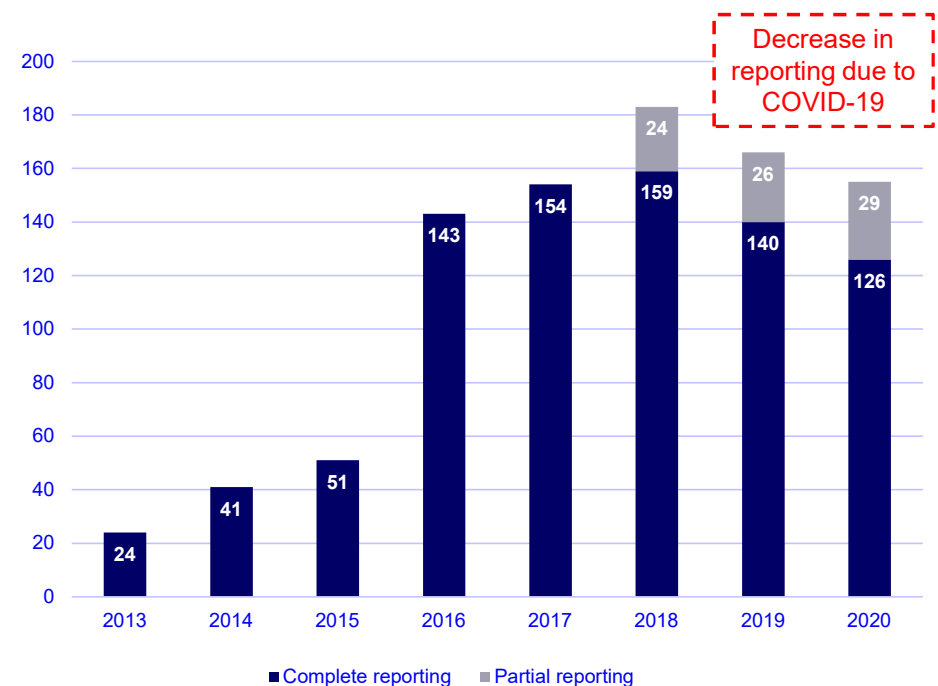
**Enhance
market
transparency**
to ensure all
options towards
equitable
access are
evident to both
buyers and
sellers

Key resource: market intelligence and analysis for increased access

Market Information for Access (MI4A)

- **Increased engagement of countries** sharing information on products purchased, however recent difficulties due to Covid-19. Vaccine Purchase Data is updated annually and publicly available:
<https://www.who.int/teams/immunization-vaccines-and-biologicals/vaccine-access/mi4a/mi4a-vaccine-purchase-data>
- Considerable progress in engagement of manufacturers with **37 main producers** providing yearly update – representing of **~90% of global supply for key vaccine markets**. Covid-19 now provides an opportunity to go even further.
- Industry engagement has increased over time but **only 30% of DCVMN members participate in the annual data survey**.

Number of countries reporting Vaccine Purchase Data over time



Partial reporting: countries reporting vaccines procured but not prices
Member States report vaccine purchase data through the WHO/UNICEF JRF
2020 data as of 31st September – further updates expected

Policy influences demand for vaccines and intelligence is used to inform strategic understanding of market dynamics, e.g. Malaria



Key Takeaways

- A first malaria vaccine is currently implemented in a pilot programme in selected areas of Ghana, Kenya and Malawi. Data from the programme will be reviewed by WHO in the last quarter of 2021 to inform a potential recommendation for broader use of the vaccine in children in sub-Saharan Africa.
- The first vaccine could be WHO pre-qualified in the first half of 2022. A second vaccine started Phase 3 trials in mid-2021.
- It is expected there will be high demand for a malaria vaccine. However, supply will be the constraining factor through the medium term (4-6 years from the expected first introductions in 2023). Moreover, there is risk of supply concentration with one main supplier in the long term. Finally, as these malaria vaccines are being developed specifically for use in children in sub-Saharan Africa, they do not have a market in high income countries. This is a challenge for recovering past and ongoing investment costs.
- Action is required by WHO and other global and regional partners, manufacturers and countries in order to address market imbalances, support development of a healthy malaria vaccine market and ensure timely access. Actions include supporting countries' decision making, planning and preparations, and working with manufacturers, procurement and financial schemes to increase supply capacity.

Purpose & Background

Much progress has been achieved in terms of malaria disease reduction in the last 20 years, by layering different malaria control interventions. However, progress has plateaued since 2015¹. WHO estimates that there were 21.5 million malaria cases and 384,000 deaths in sub-Saharan Africa in 2019, 70% of deaths were in children under the age of five.

A malaria vaccine added to existing malaria prevention and treatment tools is expected to considerably reduce morbidity and mortality. The first malaria vaccine (RTS,S/AS01E) is currently implemented in routine immunization programmes in selected areas of Ghana, Kenya and Malawi as part of the Malaria Vaccine Implementation Programme (MVIP). Data from the MVIP will be reviewed by the Strategic Advisory Group of Experts on Immunization (SAGE) and the Malaria Policy Advisory Group (MPAG) in Q4 2021 to inform a potential WHO recommendation for broader use of the vaccine in children in sub-Saharan Africa.

Meanwhile, there are another 102 studies underway for malaria vaccine development, although most (91/102) are in the discovery, pre-clinical or Phase 1 stage.

This market study was initiated in order to help establish a common understanding of the malaria vaccine market in the near and long term (2022-2036) and to support timely access to the vaccine should there be a WHO recommendation for broader use of RTS,S/AS01E. The study focuses on vaccines targeting *Plasmodium falciparum* (the deadliest species for humans).

¹ Based on the data in the market study.
² WHO, World malaria report 2020.

QUICK STATS

NUMBER OF VACCINE PRODUCTS ¹	2
NUMBER OF VACCINE PRODUCTS WHO PRE-QUALIFIED	0
TOTAL NUMBER OF MANUFACTURERS	2
2021 ESTIMATED GLOBAL SUPPLY	1.4M doses
2021 ESTIMATED GLOBAL DEMAND	1.3M doses
ESTIMATED STEADY STATE DEMAND	~110M doses per year
EXPECTED PRICE PER DOSE	US\$ 2.00-10.00

October 2021, following SAGE recommendation on Malaria Vaccine RTS'S, WHO recommended that *“the vaccine be used for the prevention of *P. falciparum* malaria in children living in regions with moderate to high transmission as defined by WHO.”*

WHO Global Market Study feeds into programmatic discussions and define required action by WHO in collaboration with partners to ensure timely access including:

- **Support countries on decision-making**, planning and introduction.
- Provide visibility into supply outlook and **develop an approach to prioritizing distribution of limited supply** in initial years.
- Work with manufacturers, governments, procurement and financing schemes **to incentivize an increase in supply capacity**.

<https://www.who.int/publications/m/item/who-malaria-vaccine-global-market-study-september-2021>

This work happens in full collaboration with partners

WHO's ongoing assessment of the global market for COVID-19 vaccines to understand Covid-19 vaccine market dynamics and related risks

MULTILATERAL LEADERS TASK FORCE ON COVID-19 VACCINES, THERAPEUTICS, AND DIAGNOSTICS

A global effort to help developing countries access and deliver COVID-19 vaccines, testing, and therapeutics, as they work to end the pandemic and boost economic recovery.



Market Information for Access (MI4A) Advisory Group



IMF



Global Market Assessment (GMA)

Coalition of partners



BILL & MELINDA
GATES foundation

IMF



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- Global vaccine markets
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Understanding risks for access to key vaccines due to COVID-19 impact

- Potential **supply issues due to both pandemic & COVID-19 vaccine production** need to be investigated (e.g. linked to manufacturing processes, constraints in the release and distribution of the vaccines)
- **Evolution of programmatic dose requirements/demand due to both pandemic & COVID-19 vaccine introduction** requires study (e.g. coverage, postponement of NVI, postponement of campaigns, outbreak response, etc)

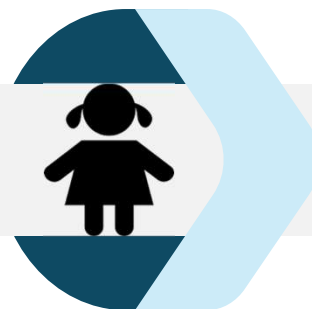
Objective: highlight risks for access to key vaccines and identify potential actions



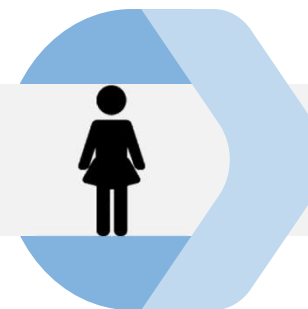
Indicative: BCG vaccine



D&T containing vaccines*
Pneumococcal vaccines



Measles containing vaccines
D&T containing vaccines**



HPV vaccine
D&T containing vaccines**

Influenza, Polio, Rotavirus
input included in the supply analysis based on specific input from WHO & UNICEF

COVID-19 increases risks of supply-demand unbalances for MCV and PCV

Measles

PCV



BALANCED (MR) WITH RISKS

Supply sufficient to meet baseline global demand, but risks linked to highly variable doses requirements (coverage gaps triggering large SIAs) and highly concentrated market

BALANCED WITH RISKS

Growing supply to meet global demand through rich pipeline, but market fragmentation carry risks linked to mismatch of country product preferences with supply



Demand

Moderate risks of change

Potential increase in demand unpredictability due to reduced coverage and delayed planned SIAs

Available Supply for Commercialization

Moderate to high risks of decrease

Very concentrated supply base, involved in C-19 + one NRA (MR); possible delays in pipeline / capacity scale up

Demand

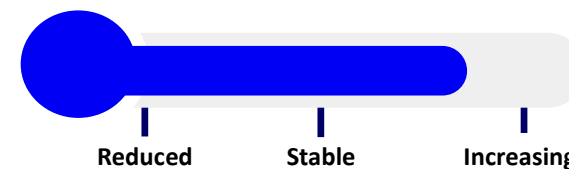
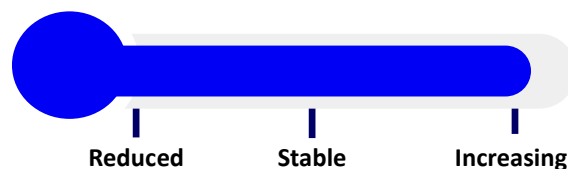
Low risks of change

Potential decrease due to drops in coverage; potential increase because respiratory disease similar to COVID-19

Available Supply for Commercialization

Moderate to high risks of decrease

Existing production processes shared with C-19: delays may affect capacity scale-up and pipeline



*Per WHO MI4A market studies 2020

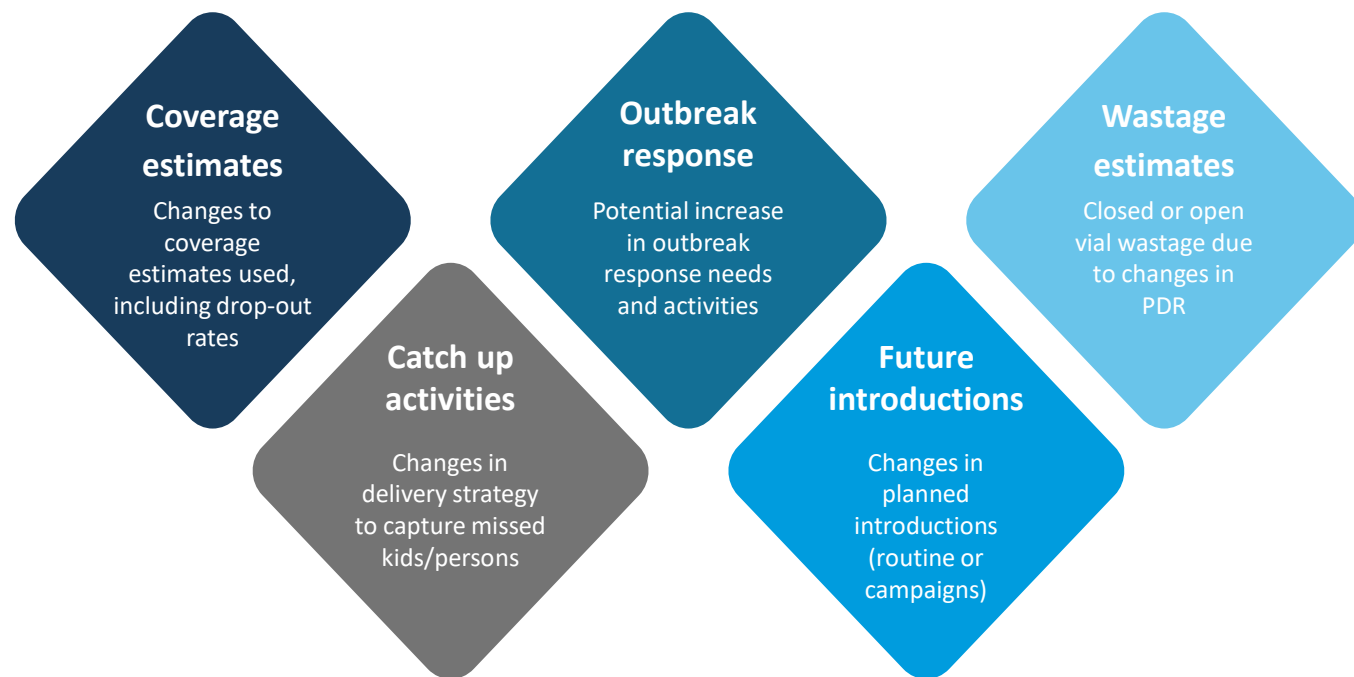
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5 areas related to demand that were potentially impacted due to COVID-19 pandemic

Experts indicated there were **several factors that could impact global mid- to long-term demand forecasting** :

- Stopping of immunization services
- Changes in health seeking behavior
- Disruption of staff and workforce
- Inefficiencies in cold chain and logistics systems
- Financing and economic downturn

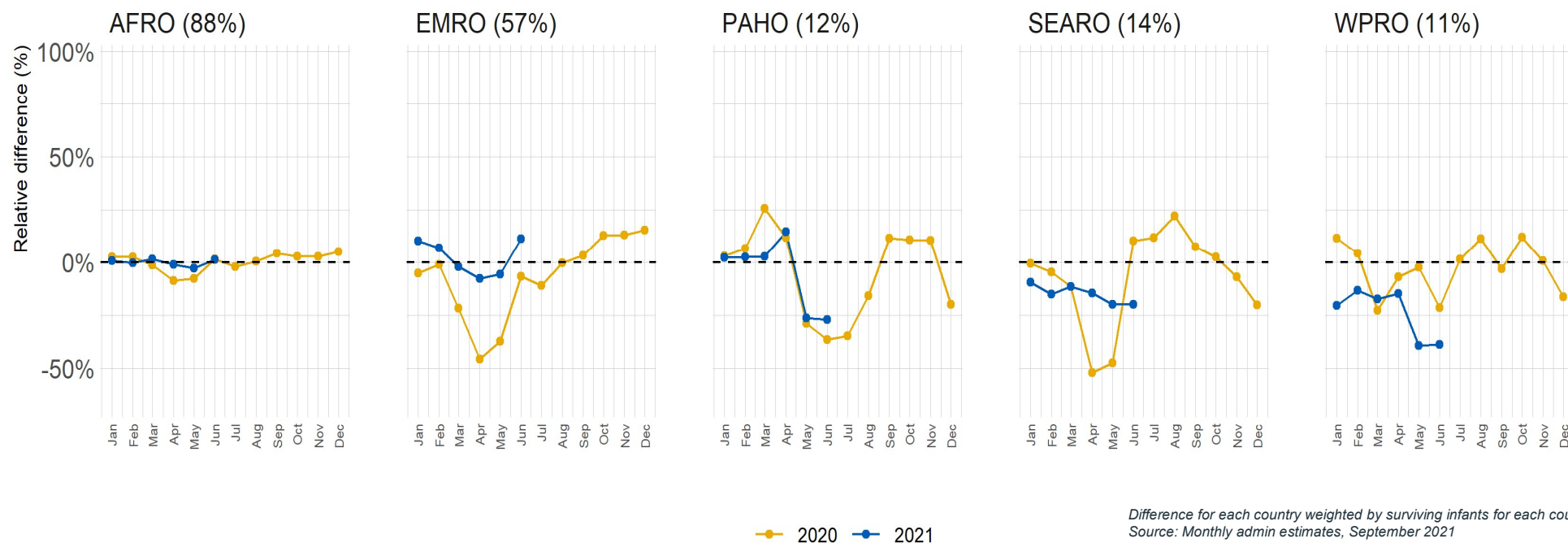


Level of RI disruption varies by region and continues into 2021

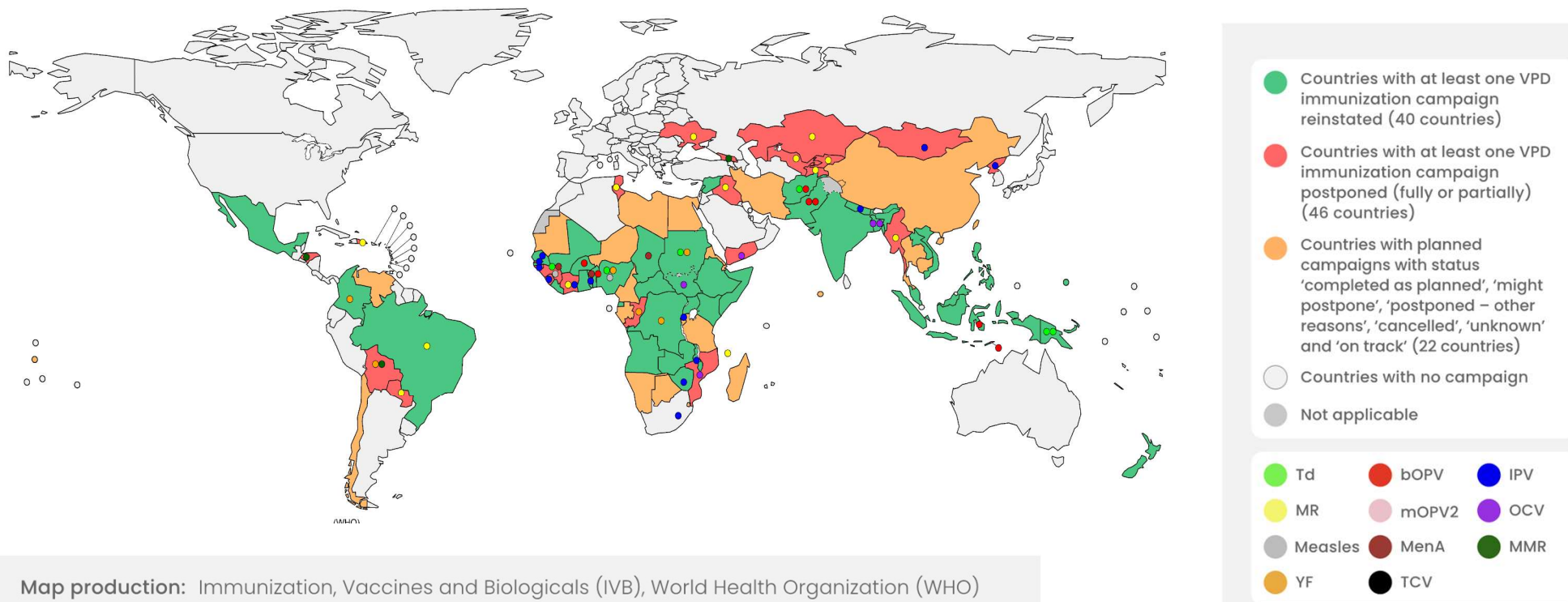
Weighted relative difference in #DTP3 vaccinated in 2021 and 2020, compared to 2019

Countries that have consistently reported data through June 2021

(%) is the proportion of surviving infant population in the region represented by the countries reporting through last month



46 Countries with VPD campaigns postponed due to COVID-19, by antigen



Map production: Immunization, Vaccines and Biologicals (IVB), World Health Organization (WHO)

Data source: WHO/IVB Repository, 1st September 2021

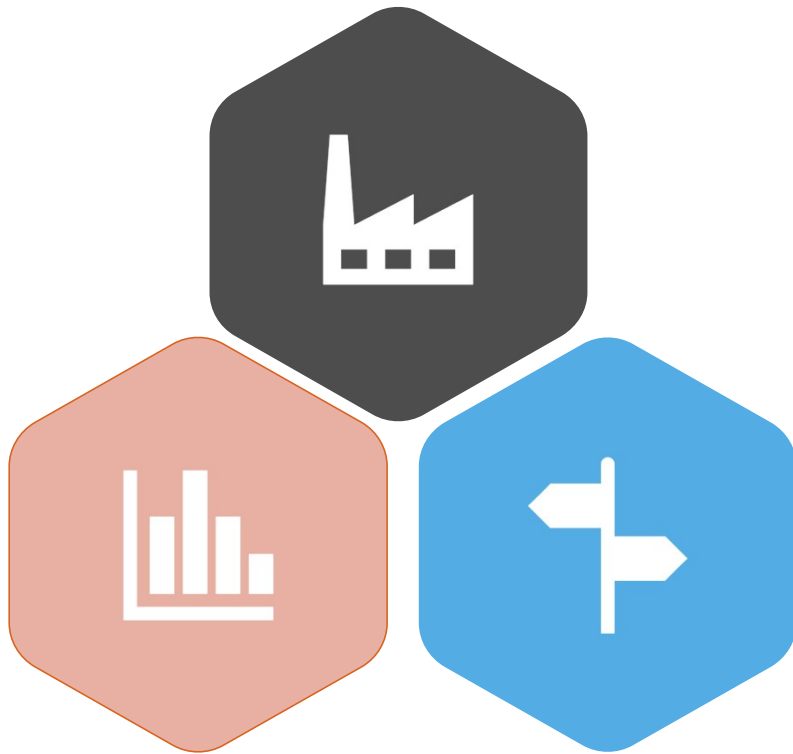
The boundaries and names shown and the designations used on this map do not imply the expression of any opinion whatsoever on the part of the World Health Organization concerning the legal status of any country, territory, city or area nor of its authorities, or concerning the delimitation of its frontiers or boundaries. Dotted and dashed lines on maps represent approximate border lines for which there may not yet be full agreement. World Health Organization, WHO, 2021. All rights reserved.

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Mitigating action for C-19 impact on market for other antigens

Cross-cutting actions:



Manufacturer engagement

Continue engagement with manufacturers:

- Bilateral discussions
- Continue data collection
- Debrief on 2021 findings and conduct information sessions

Information for access

- With UNICEF, monitor shipment trends and country implementation plans
- Monitor coverage estimates and introduction dates, particularly for new vaccines (HPV and PCV) + measles outbreaks
- Monitor timeliness of DCGI lot release and new vaccine registrations

Demand shaping

- Implement flexibilities to meet short-term country demand (e.g., product presentations, country preferences, shelf life)
- WHO keeps working to expand reliance on PQ and SRAs marketing authorisation across all vaccines

NIGERIA: LEVERAGING THE CVDPV OUTBREAK RESPONSE TO SUPPORT COVID-19 VACCINE ROLLOUT

Sensitizing communities to build confidence in the COVID-19 vaccine, leading to an increase in vaccination coverage

Using polio surveillance tools and applications (e.g. AVADAR) for case detection, reporting, monitoring COVID-19 vaccine uptake

Technical support to cold chain management – resulting in significant reductions in wastage

Supporting national deployment plans through capacity building (e.g. using smartphones for e-registration of vaccine recipients, AEFI training)





Assessment of mid-to long-term risks of COVID19 impact on demand changes

