IPV Programme Implementation and Supply Update

Q3 2022 (data as of 13 October 2022)

Outline

- ***Programme implementation update***
  - Reminder of SAGE recommendation on IPV
  - Implementation update – roll-out of IPV2 and coverage estimates
- ***Update on the IPV supply and demand scenario for 2022-23***
- ***Gavi programme update***
  - Overview of Gavi support
  - Status of missed cohorts catch-up activities
  - Gavi IPV demand forecast until 2030
- ***Take away messages***

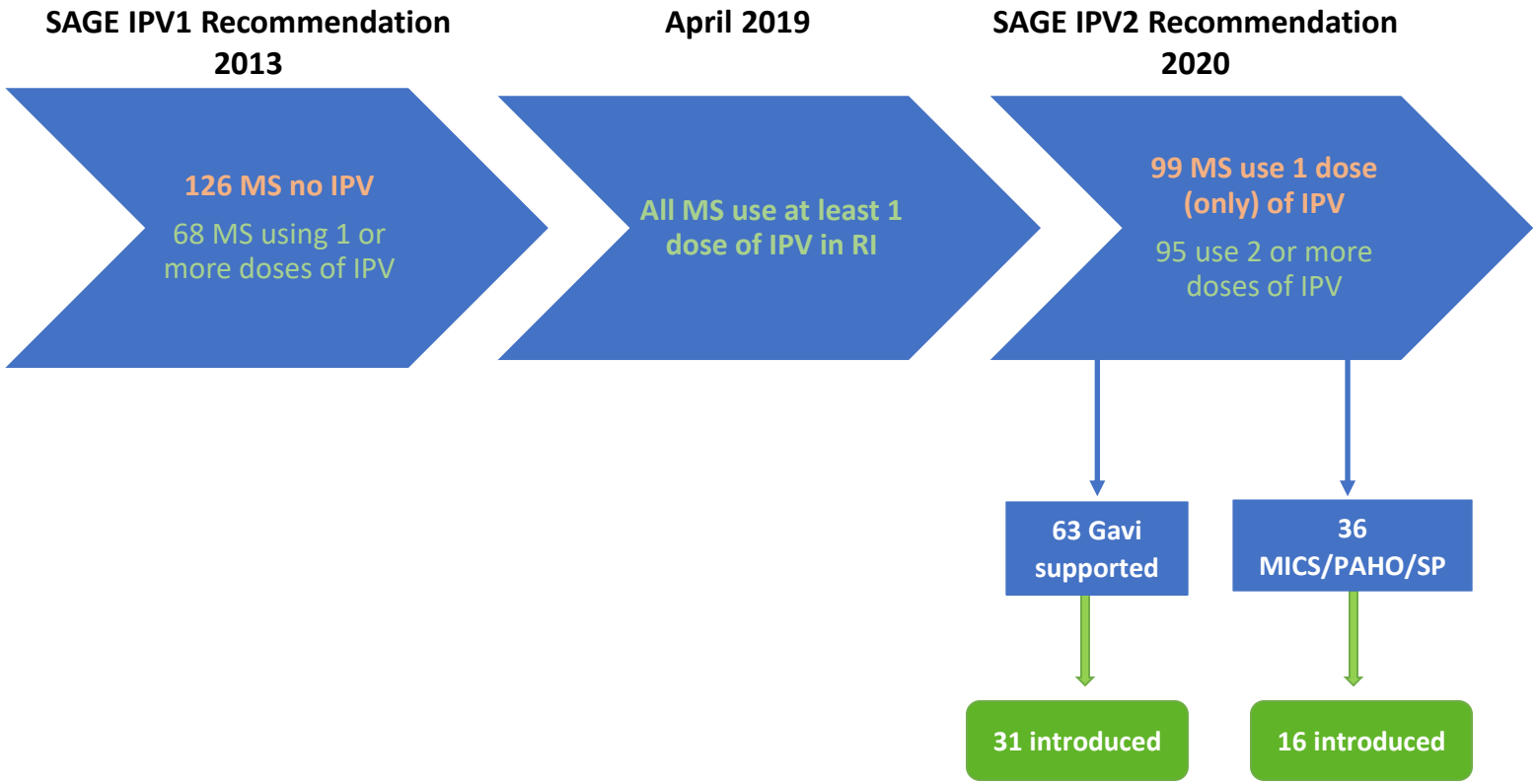
Programme Implementation update

Policy Context

- **SAGE recommended the introduction of a second dose IPV (IPV2) in Oct 2020**
  - Best immunogenicity with IPV at 14 wks and at least 4 ms later – full or fractional dose
  - Early-in-life schedule IPV at 6 and 14 wks, could be also considered under certain epidemiological circumstances
- **Polio Vaccination Position Paper (24 June 2022)**
  - All children should be fully vaccinated against polio, and every country should achieve and maintain high levels of coverage with polio vaccines in support of the global commitment to eradicate polio
  - For all countries using OPV in their national programme, WHO recommends 3 doses of bOPV and 2 doses of IPV as the vaccination schedule
    - Birth dose recommended in polio endemic and high-risk countries
    - IPV can be administered full intramuscularly or fractional intradermally
    - IPV1 should be administered from a minimum of 14 wks of age, with IPV2 given at least 4 ms later. This schedule provides the highest immunogenicity, either using full or fractional dose without loss of immunogenicity
    - Alternative early IPV schedule with IPV1 at 6 wks of age and IPV2 at 14 wks, offers the advantage of early-in-life protection, but with a lower total immunogenicity. If this schedule is chosen, full IPV should be used rather than fIPV due to lower immunogenicity of fIPV at early ages
  - For countries using IPV only schedules, WHO recommends a primary 3-dose series of IPV beginning at 6/8 wks of age, with a minimum 4-wk interval between doses.
    - If the primary series begins at 6 wks, a booster dose should be given 6 ms or more after the third dose. Alternatively, a 2-dose or fractional dose IPV schedule, starting at 14 wks of age or older, with a second dose 4 ms or more later can be considered. This schedule is currently recommended for use after OPV cessation

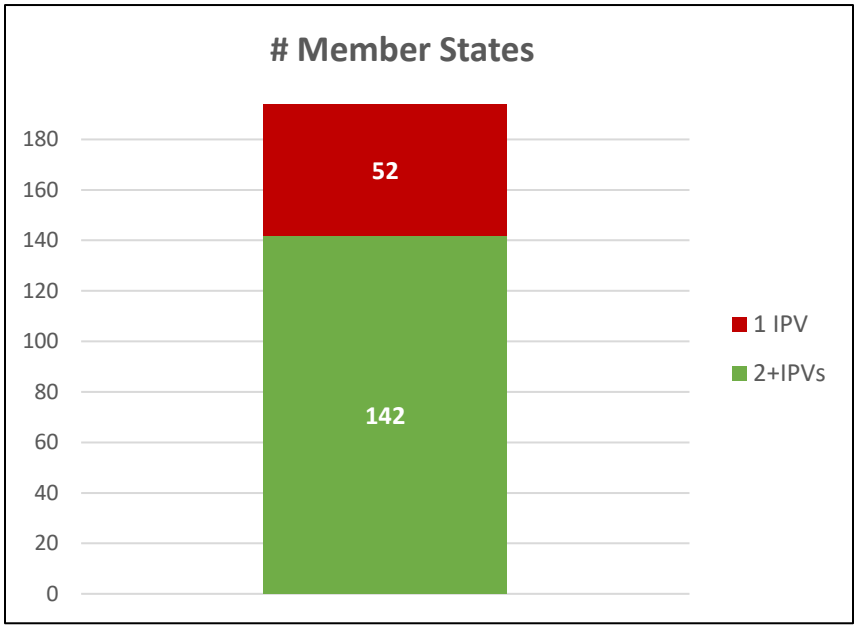
IPV recommendation implementation status

For 194 WHO Member States

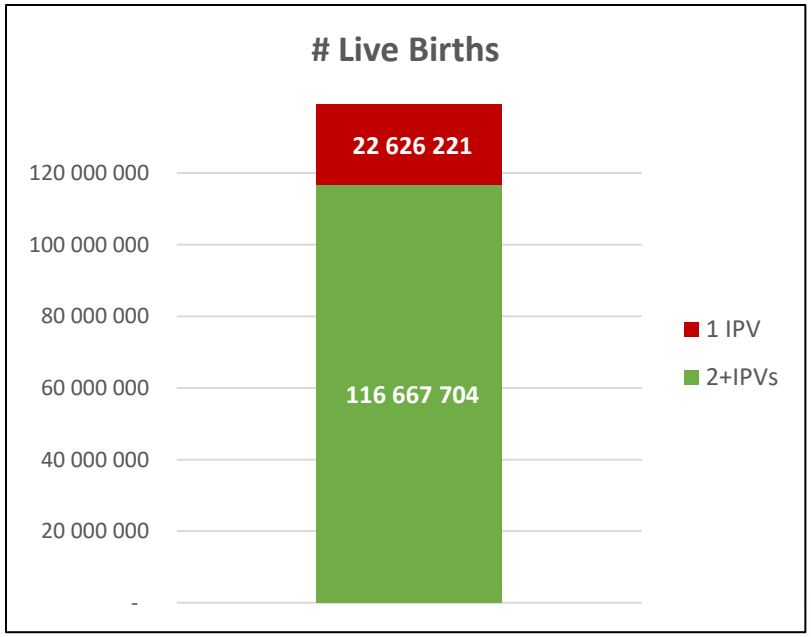


Gavi63 support excludes the 10 Gavi IPV eligible countries that have already adopted a 2-dose schedule with fractional IPV (Bangladesh, Cuba, India, Nepal, Sri Lanka) or introduced a second dose without Gavi support (Guyana, Honduras, Syria) or switched to an aP-Hexavalent product (Armenia and Georgia)

Overview of IPV in immunization schedules



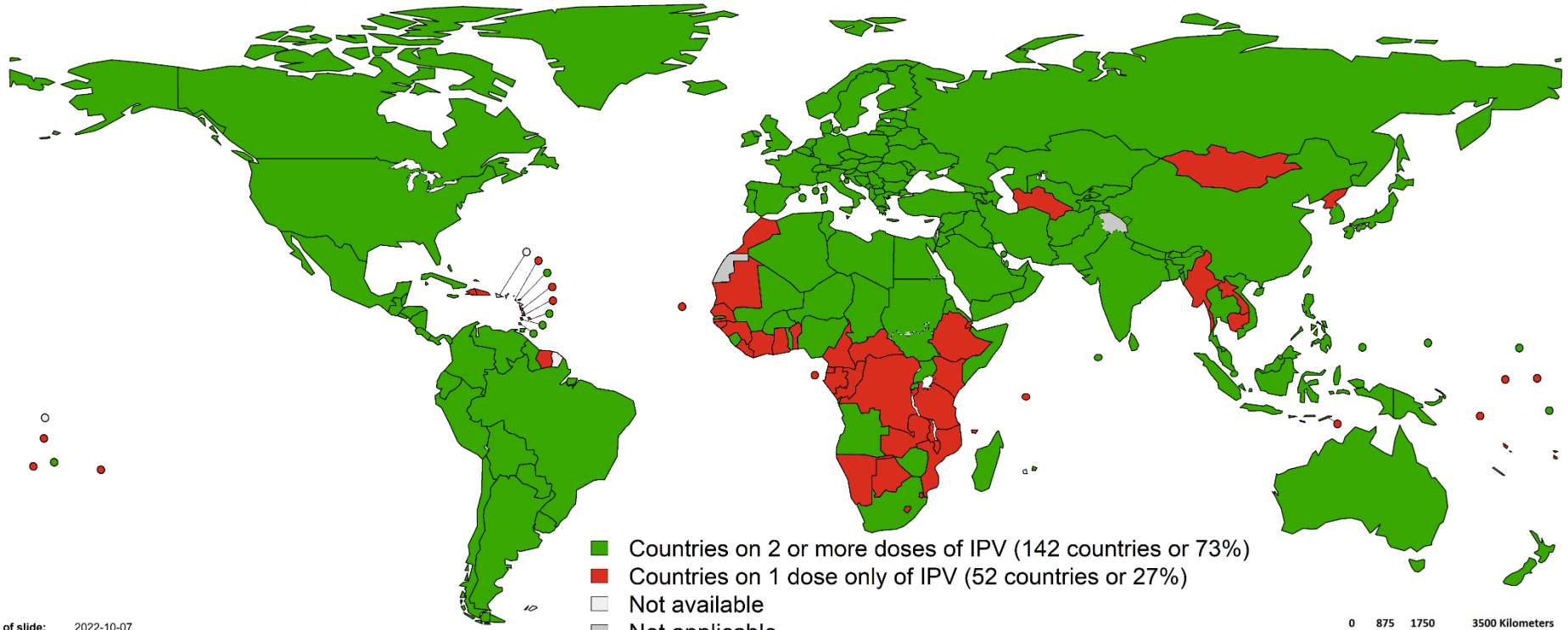
194 WHO Member States



UNDP Pop Reference 2019. LB Cohort for year 2020 = 139M, for 194 Member States

Data as of 7 October 2022

Geographic distribution of IPV in immunization schedules

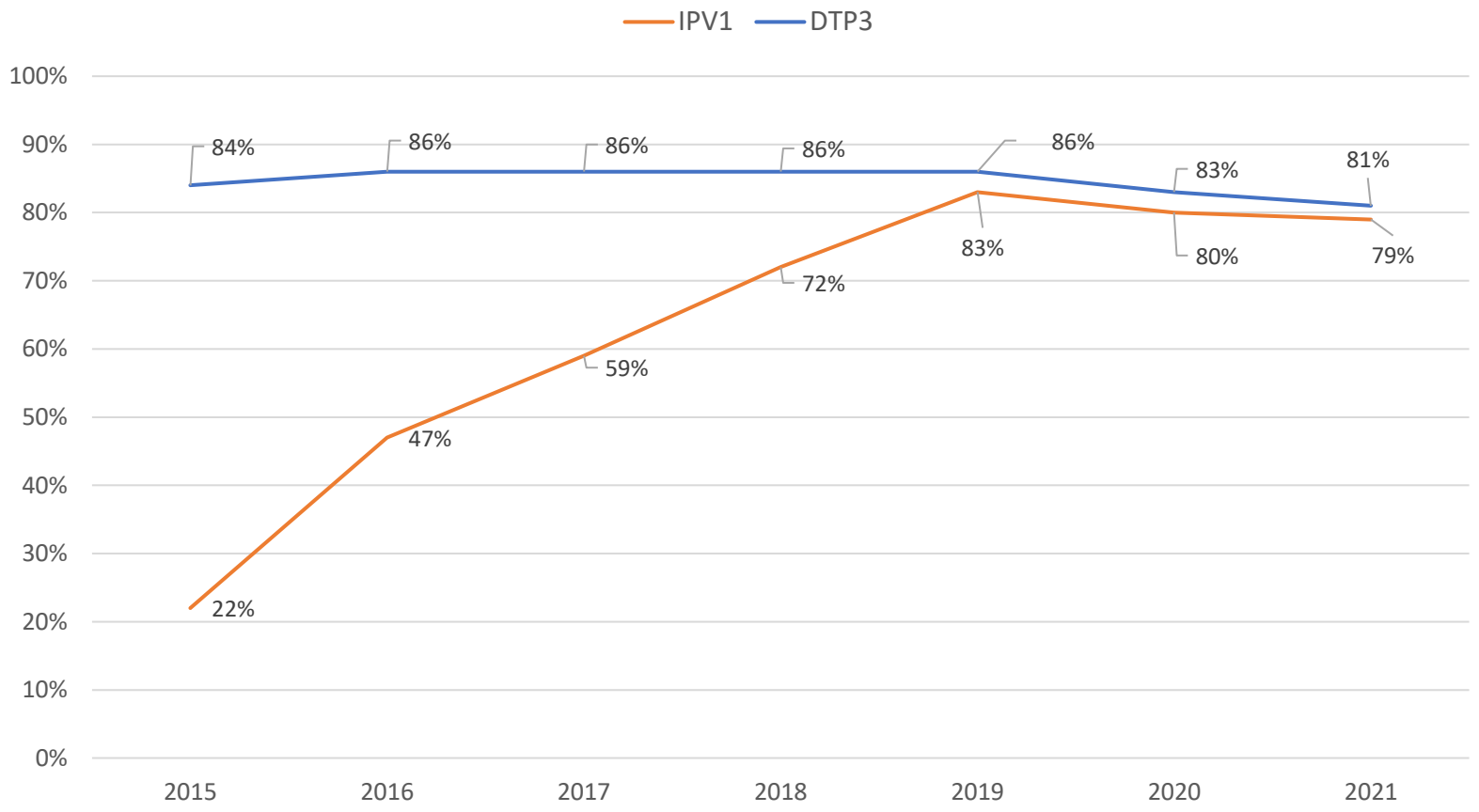


Date of slide: 2022-10-07
Map production: Immunization, Vaccines and Biologicals (IVB), World Health Organization (WHO)
Data source: IVB database

Disclaimer:

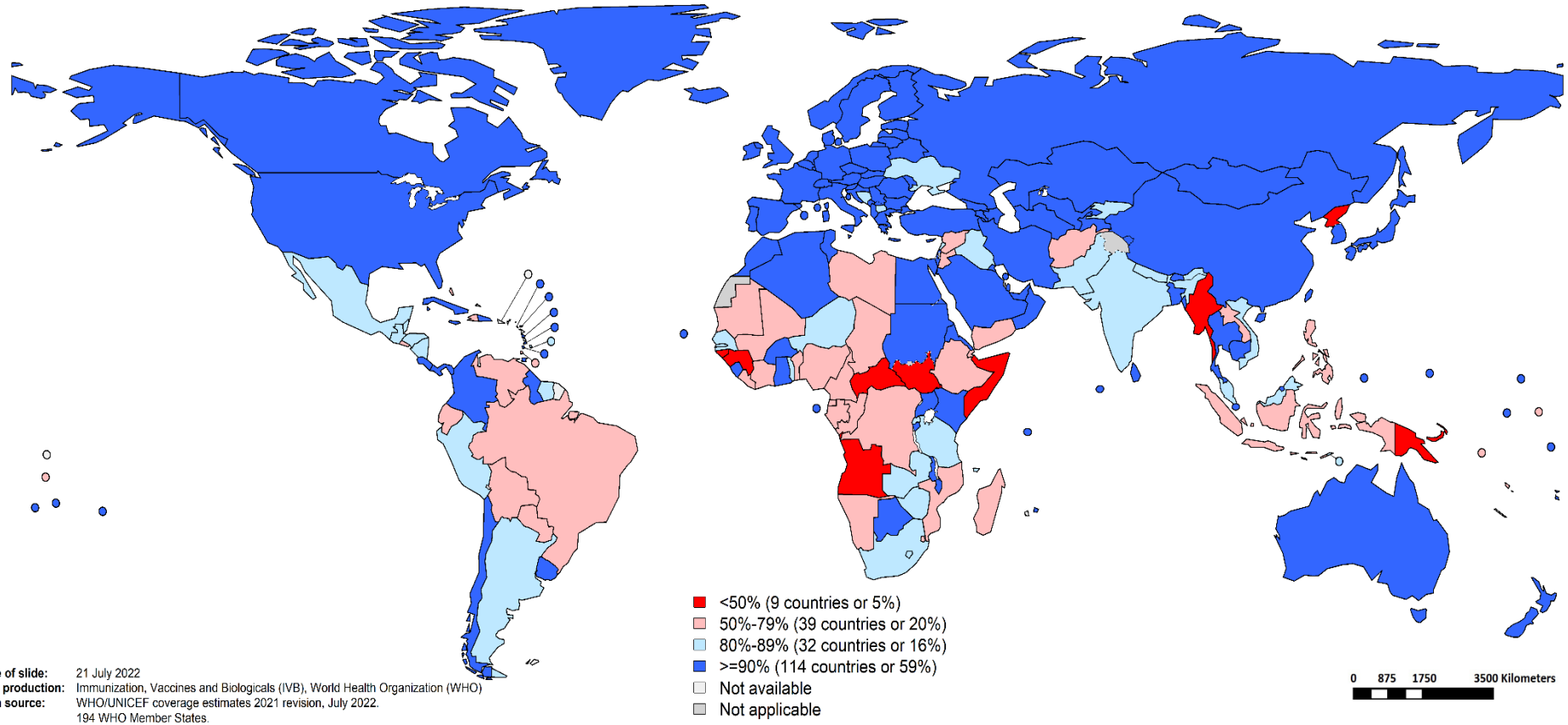
The boundaries and names shown and the designations used on this map do not imply the expression of any opinion whatsoever on the part of the World Health Organization concerning the legal status of any country, territory, city or area nor of its authorities, or concerning the delimitation of its frontiers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

IPV1 Global coverage estimates 2016-2021



Data source: WHO and UNICEF estimates of immunization coverage: 2021 revision, 15 July 2022

Immunization coverage with IPV1 in infants, 2021



Date of slide: 21 July 2022
Map production: Immunization, Vaccines and Biologicals (IVB), World Health Organization (WHO)
Data source: WHO/UNICEF coverage estimates 2021 revision, July 2022.
194 WHO Member States.

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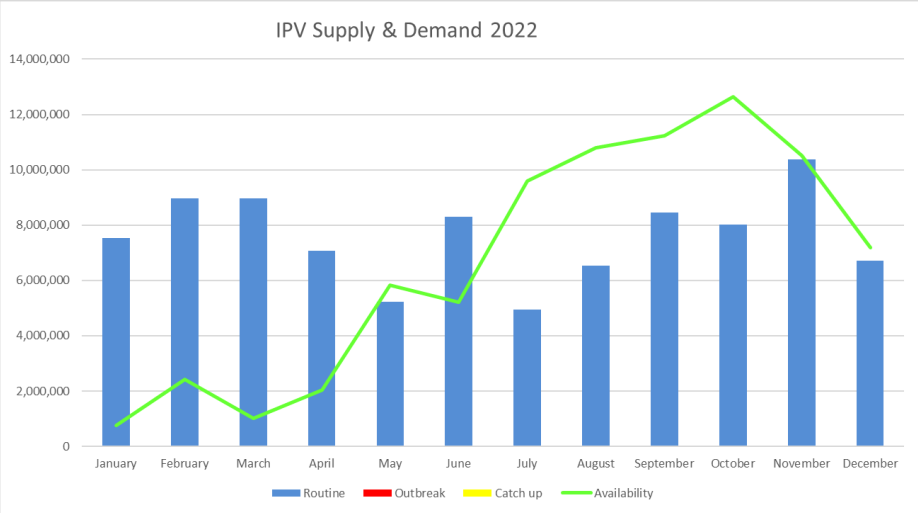
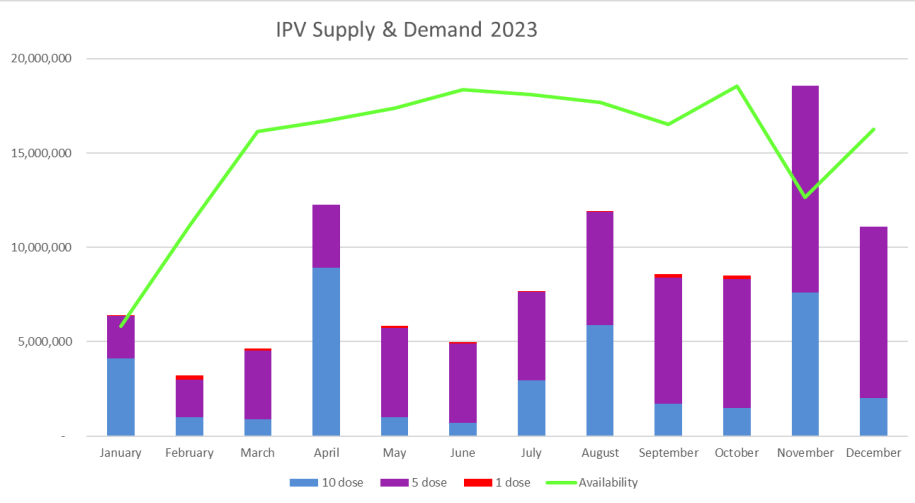
Supply Update

IPV SUPPLY AND DEMAND FOR 2022 AND 2023





5 manufacturers supplying to UNICEF

- Sanofi (France)
- Sanofi Healthcare (India)
- Bilthoven (Netherlands)
- AJ Vaccines (Denmark)
- LG Chem (Korea)

Supply and demand

- Awards have been made based on **all countries** introducing IPV second dose by 2023
- Demand forecast includes Gavi supported countries (based on current allocation) and MIC – No forecast for IPV use in outbreak response
- Suppliers have overcome the production challenges following global introduction recommendations for IPV in 2014
- COVID has had an impact on IPV supply

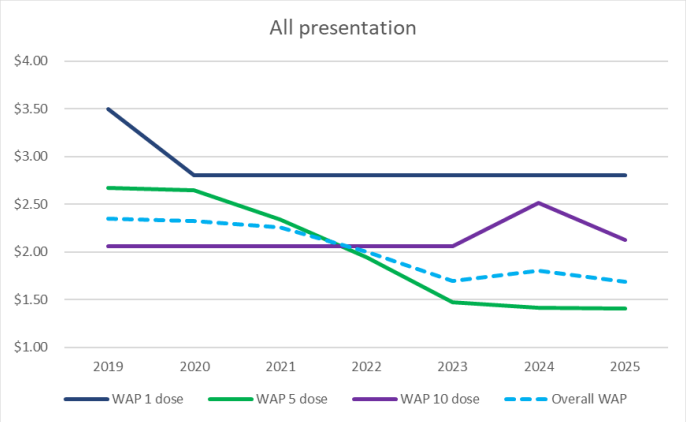
OUTCOME OF THE IPV TENDER FOR 2023 TO 2025

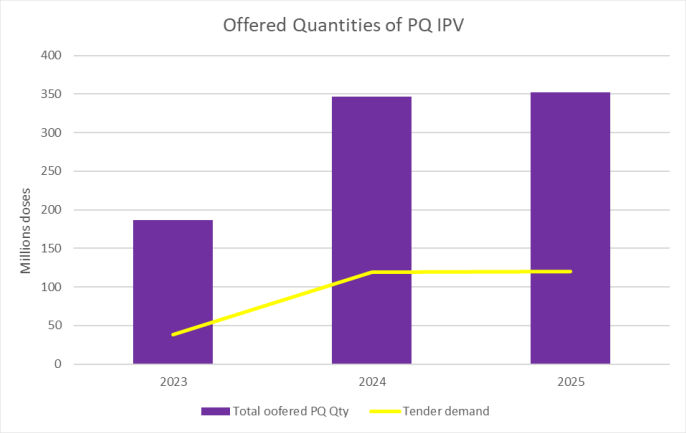
	2023			2024			2025		
	Number of suppliers	Quantities (doses)	WAP per dose	Number of suppliers	Quantities (doses)	WAP per dose	Number of suppliers	Quantities (doses)	WAP per dose
1 dose	1	2,000,000	$2.80	1	2,000,000	$2.80	1	2,000,000	$2.80
5 dose	2	33,500,000	$1.74	3	79,100,000	$1.42	3	70,600,000	$1.41
10 dose				3	40,000,000	$2.50	3	40,000,000	$2.12

For 2023 awards have already been made under current tender for the 10-dose demand and part of the 5-dose demand

- Outcome of the tender communicated to all manufacturers that made a proposal and tender debrief done
- LTA are being concluded with manufacturers that received an award
- Manufacturers who have a product in development meeting established to monitor milestones and progress to WHO PQ
- Some unawarded demand in 2025 for possible switch to a hexavalent product

OUTCOME OF THE IPV TENDER FOR 2023 TO 2025





35% reduction in the Weighted Average Price for IPV over the period

Lower prices could have been achieved but this would have been at the risk of NOT having multiple suppliers for each presentation

Second supplier for the 10 dose presentation to improve supply security

2 new Chinese manufacturers had a sIPV product prequalified by WHO in 2022. No awards have been made as offers were for single dose presentation and inability to assess compliance to GAPIII/IV due to the absence of NAC?

Offered supply is 3 times higher than the demand through UNICEF

IPV market is now considered healthy but with overcapacity which could be a challenge moving forward

Gavi programme Update

Overview of Gavi support for IPV

IPV first dose (IPV1) in 73 Gavi IPV eligible countries*

- Exceptions from co-financing and eligibility policy until OPV cessation
- 1 full or 2 fractional doses of IPV
- Board review of IPV support approach in Dec 2022

IPV second dose (IPV2) in 73 Gavi IPV eligible countries

- Exceptions from co-financing and eligibility policy apply also to IPV2
- Support for IPV2 introduction and schedule changes

IPV catch-up in 33 Gavi IPV eligible countries

- Targeting children missed due to global supply constraints (2016-19)
- Encouraging catch-up vaccination integration with other activities

* Excluding Ukraine (self-financed), Armenia and Georgia (aP-Hexavalent) and India (separate decision)

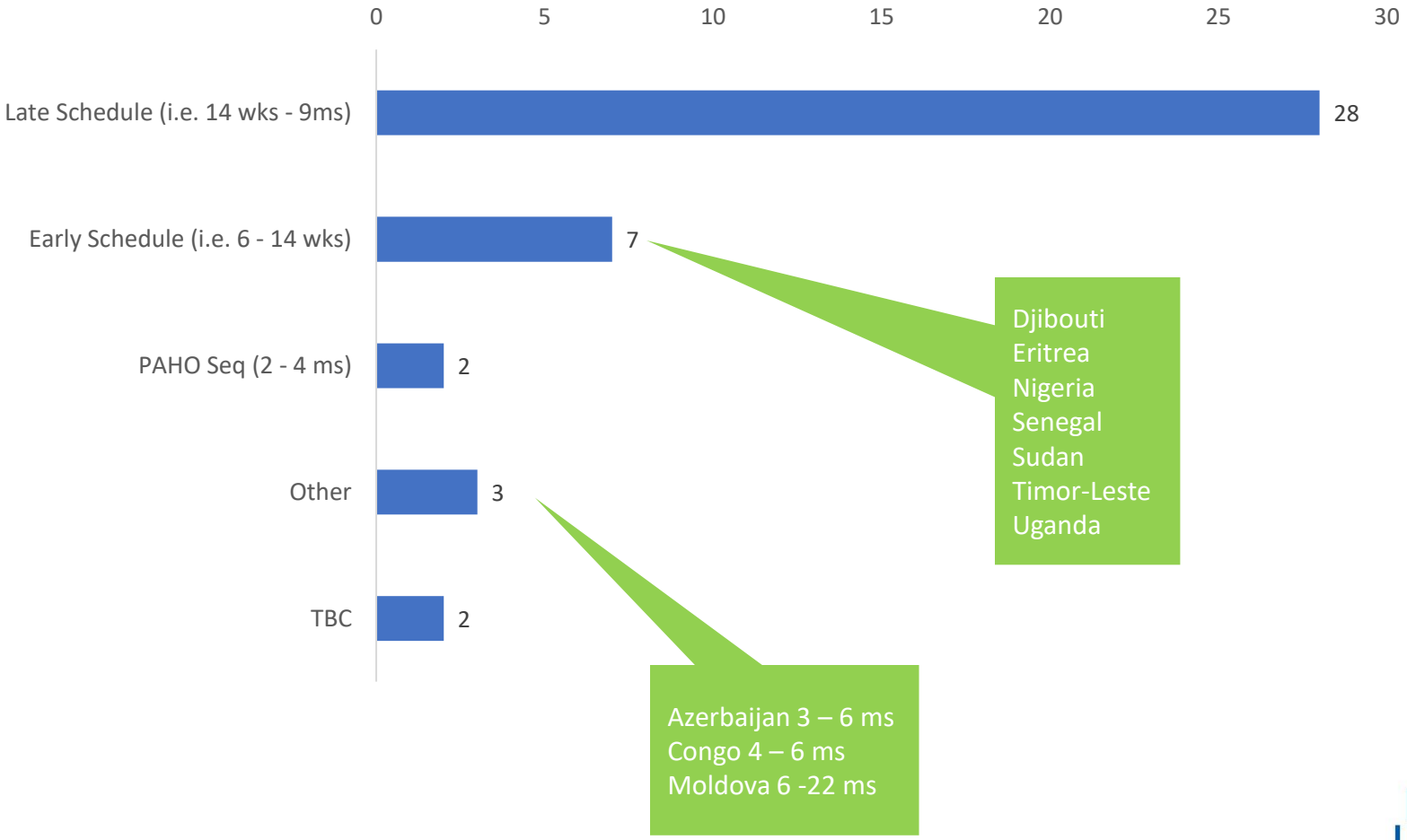
Gavi supported countries without plans for IPV2 implementation

Of the 18 countries without IPV2 introduction plans, some are at high risk under the current epidemiological situation, specially in the African region

Region	Country	Risk
AFR Central	**Burundi**	**Border DR Congo**
	Sao Tome and Principe	
AFR East & South	Comoros	
	Lesotho	
	Malawi	**WPV1**
	Tanzania, United Republic of	**Border with Malawi, Kenya and Mozambique**
	Zambia	**cVDPV2; border with Malawi and Mozambique**
AFR West	**Benin**	**cVDPV2**
	Guinea-Bissau	**cVDPV2**
	Liberia	**cVDPV2**
	Mauritania	**cVDPV2 (ENV)**
PAHO	Haiti	
SEAR	DPR Korea	
WPR	Cambodia	
	Kiribati	
	Lao People's Democratic Republic	
	Mongolia	
	Solomon Islands	

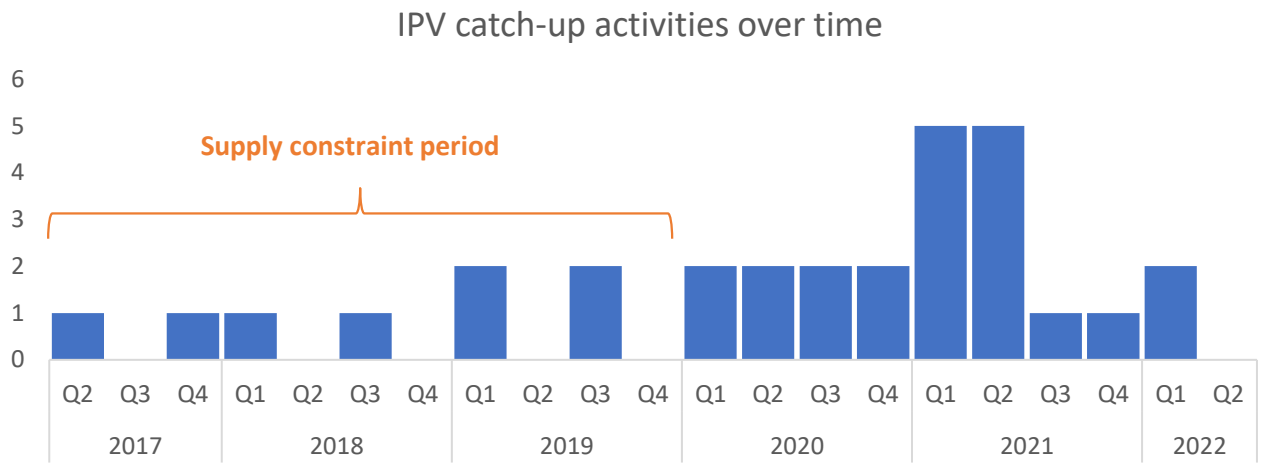
Data as of 7 October 2022

Schedule summary 42 Gavi countries introduced or applied



IPV catch up activities

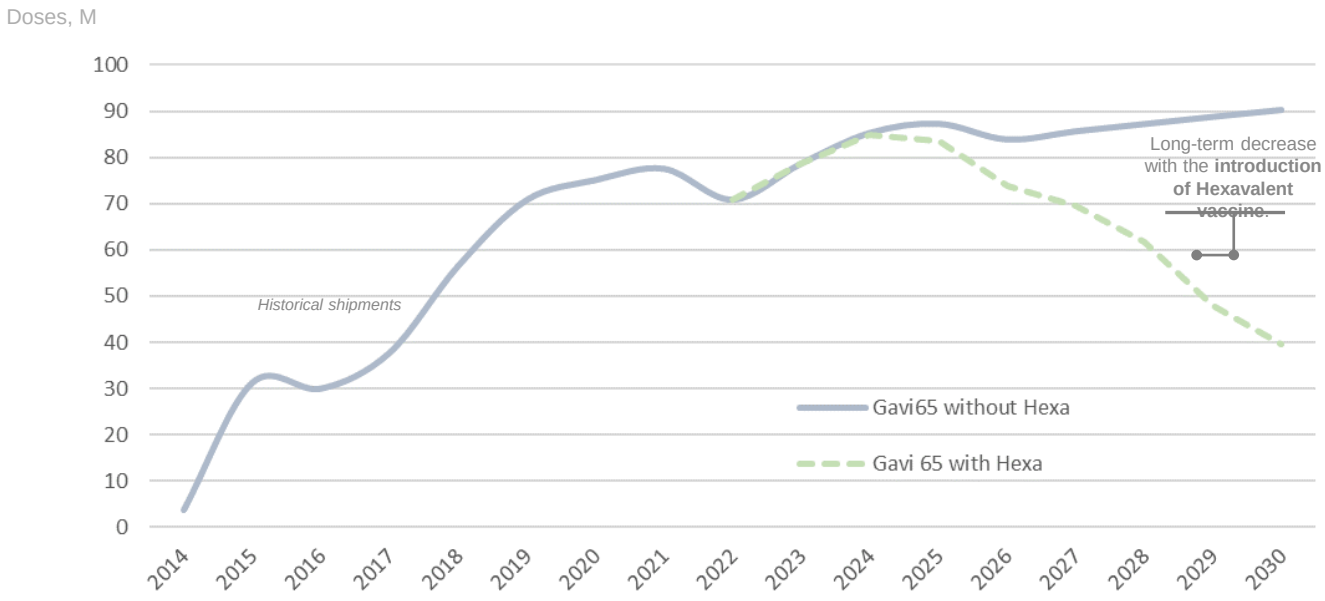
- **Between April 2016 and April 2019 over 43 million children were missed in 36 countries due to global supply constraints**
- **COVID-19 pandemic impacted planned implementation of catch ups in 2020, most of which were delayed to 2021 but have been now implemented and bringing the total of children reached to 40.5 million (95% of the missed cohort)**



- **6 countries have yet to vaccinate 2 million missed children, of which 5 have yet to request Gavi support to do so**
  - ***Applied:*** *Guinea-Bissau;* ***Planned****: DPRK, Djibouti, Gambia;* ***Forecasted****: Lesotho, Nepal*

IPV demand Forecast – Gavi 65* scope

Slight increase in volumes during 2022-25 driven by switch of countries to 2-dose schedule



***2nd dose introductions*:**

- 31 countries have already introduced 2nd dose schedule
- A total of 42 countries are approved for 2-dose schedule by 2023
- All remaining countries assumed to switch to the 2 doses schedule by 2024.

IPV containing wP-Hexavalent vaccine had received the **in-principle approval** from Gavi Board in November 2018 subject to the availability of WHO prequalified products and conditions supporting its successful implementation. Volumes shown in graphic correspond to a Gavi forecasted scenario where Hexa starts to be introduced in certain countries from 2024 onwards

*Notes:
Gavi 65 represents all Gavi 74 except India, Indonesia, Ukraine and six PAHO countries.
Within Gavi 65, Armenia and Georgia have already self-introduced Hexa therefore there are no forecasted IPV volumes for those 2 countries

Take away messages

- **Supply of IPV is sufficient and countries are encouraged to plan and implement IPV2 introduction as soon as possible**
  - As of October 2022, 47/99 countries have introduced IPV2 since 2021
  - A number of high-risk countries remain on 1-dose schedules and should move to a 2-dose schedule, this is particularly relevant for countries at high risk of poliovirus transmission
  - Amidst multiple competing priorities, an evolving COVID-19 pandemic and poliovirus epidemiology, countries are encouraged to prioritize IPV2 introduction into their immunization schedules

- **Appreciating the Oct 2021 SAGE recommendation for all countries to complete IPV catch-ups, 5 Gavi eligible countries remain to plan their catch-up**

Thanks