CLINTON HEALTH ACCESS INITIATIVE

Indonesia Country Profile

2023

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With a birth cohort of almost 5M, Indonesia is one of the largest countries to transition out of Gavi support and has been fully self-financing since 2017

Indicators	Status (2022)
Population	274M
Birth Cohort	4,462,212
Under 5 Mortality Rate (# per 1,000 live births)	23 (2020)
EPI Coverage	• Coverage of complete immunization (i.e. BCG, HB birth dose, Measles, and three doses each of DPT and polio vaccine) in Indonesia currently sits at 80% - a drop of 15% from 2019 • Indonesia introduced IPV1 in 2016 and MR in 2017. PCV, HPV, and JE were introduced in select provinces starting 2017. • In 2022 rotavirus vaccine was introduced in 21 districts in December 2022, PCV was scaled up nationwide in 2022 and IPV2 was introduced • In 2023, national scale-up is expected for IPV2, HPV and RV
GNI per capita (USD)	$4140 (2021)
Government Health Spend (% per GDP)	3.41% (2020)
Gavi Country Status (Y/N, Year of Transition)	• Y, 2017 • Indonesia continues to have access to PCV AMC prices as a transitioned country • Indonesia has been selected as one of four former-Gavi eligible countries to be eligible to receive targeted support to help mitigate backsliding in vaccine coverage through Gavi's Middle-Income Strategy
COVAX country (Y/N)	Yes

SOURCE: Gavi; World Bank; CHAI Insight

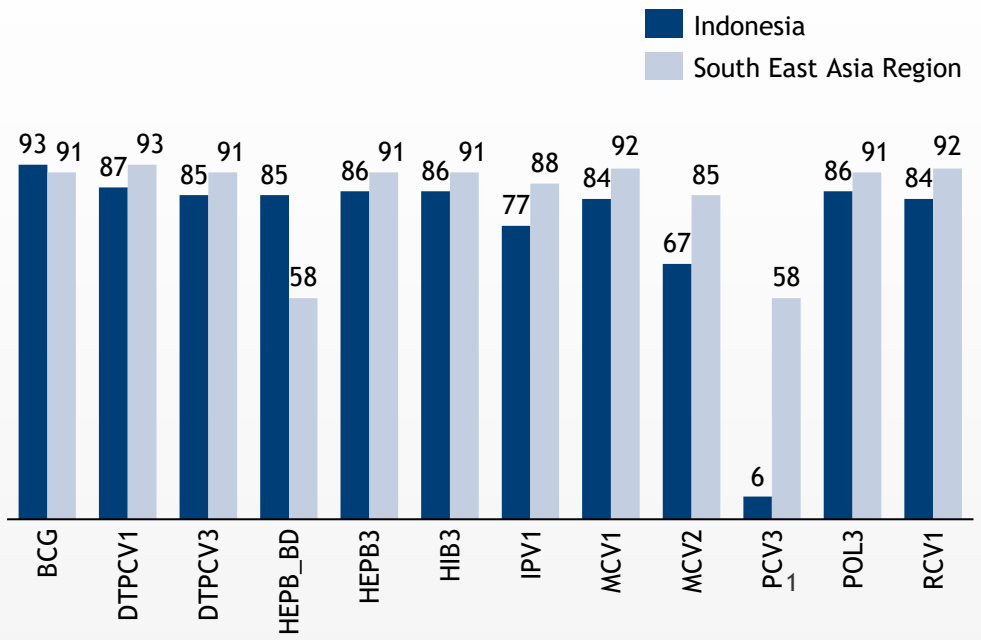
Indonesia has implemented 9 vaccines in its national immunization schedule and 3 vaccines in select geographies

Vaccine	Vaccine abbreviation	Year of Introduction	Scale	Age of Administration
Hepatitis B vaccine	HepB	1997	National	Birth 0-24 hours
Bacillus Calmette–Guérin vaccine	BCG	1999	National	Birth
Pentavalent vaccine	DTP-Hib-HepB	2013	National	2M, 3M, 4M, 18M
Diphtheria-Tetanus	DT		National	6 to 7Y
	Td	2016	National	7 to 8Y, 9 to 10Y, 15 to 39Y (Childbearing women)
Oral polio vaccine	bOPV	2016	National	1M, 2M, 3M, 4M
Inactivated polio vaccine	IPV1 IPV2	2016 2022	National 3 Provinces	4M 9M
Measles Rubella	MR	2017	National	9M, 18M, 7Y
Pneumococcal conjugate vaccine	PCV	2017	National	2M, 3M, 12M
Human Papillomavirus	HPV	2017	9 provinces	11Y, 12Y
Japanese Encephalitis	JE	2018	Bali	10M
Rotavirus vaccine	Rota	2022	21 districts	2M, 3M, 4M

SOURCE: WHO: Indonesia factsheet 2020

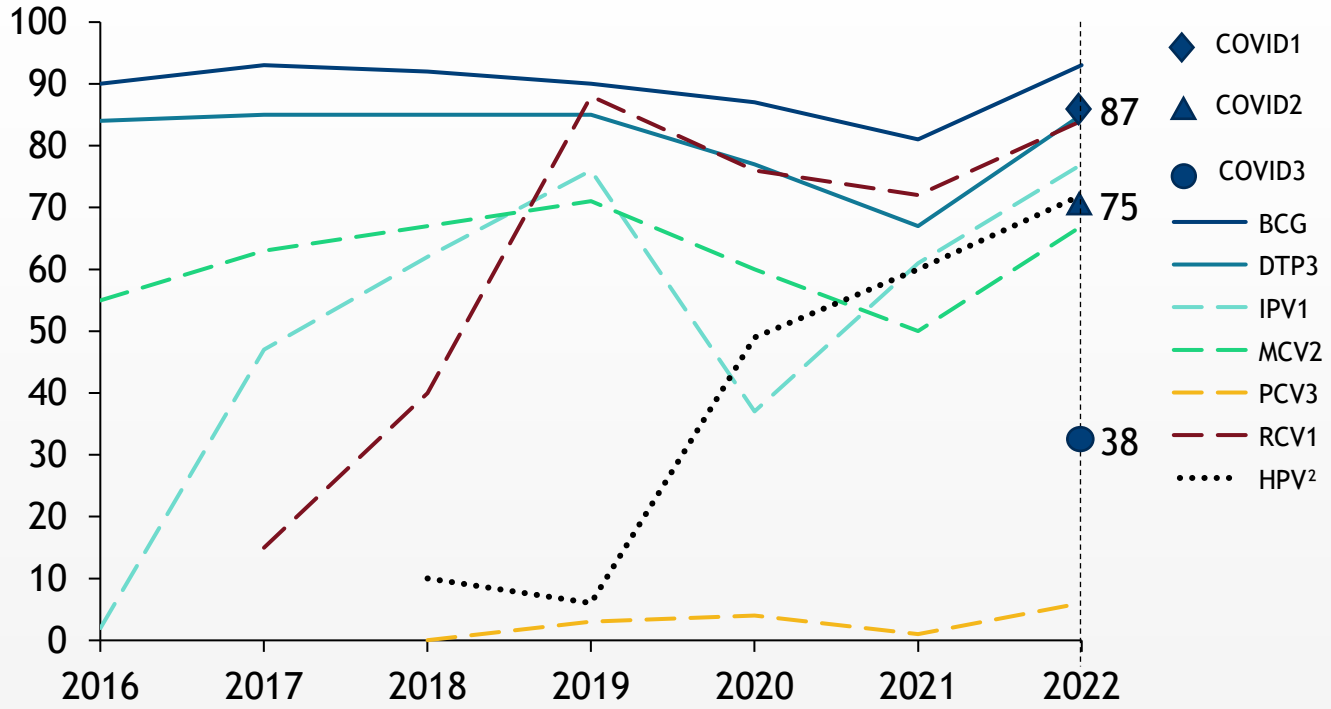
Indonesia has lagged on coverage compared to the regional average, still recovering to reach pre-pandemic coverage levels as of 2022

Regional Coverage (%) comparison, 2022



- Indonesia's coverage is below the regional average for most vaccines due to inequities driven by socioeconomic and demographic factors or due to hesitancy

Indonesia RI Vx Coverage %



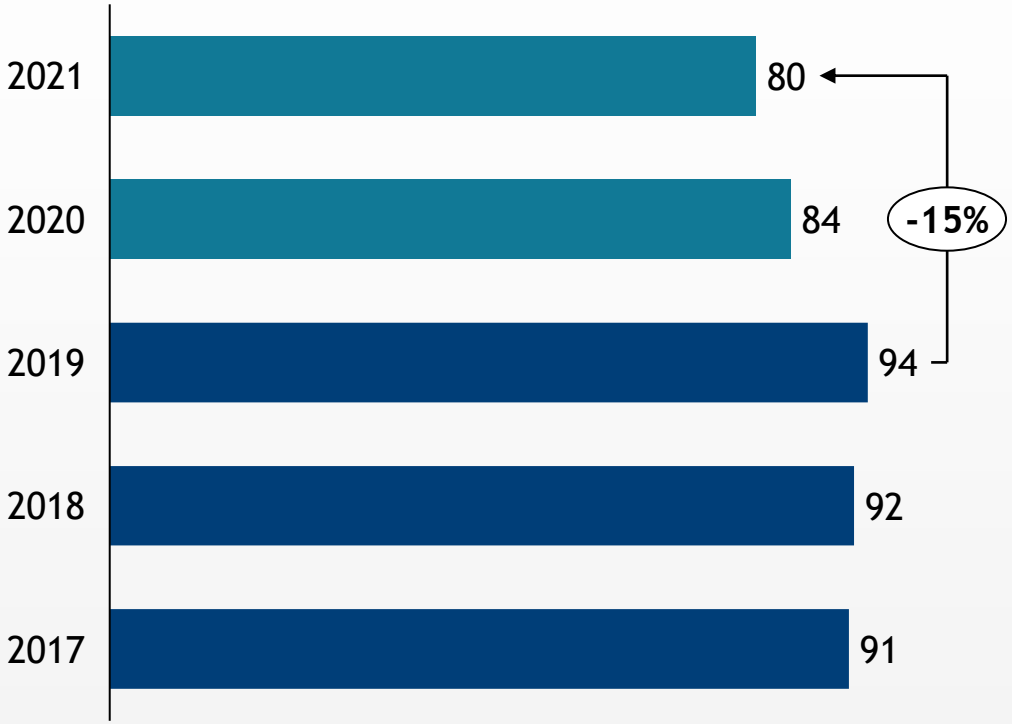
- Pandemic related disruptions in outreach caused coverage to fall below 2016 levels
- DTP3 dropped from 85% (2019) to 67% (2021)
- 2022 coverages for DTP and MCV are still below the pre-pandemic (2019) figures

[1]Introduced in limited geographies; [2]Official country data

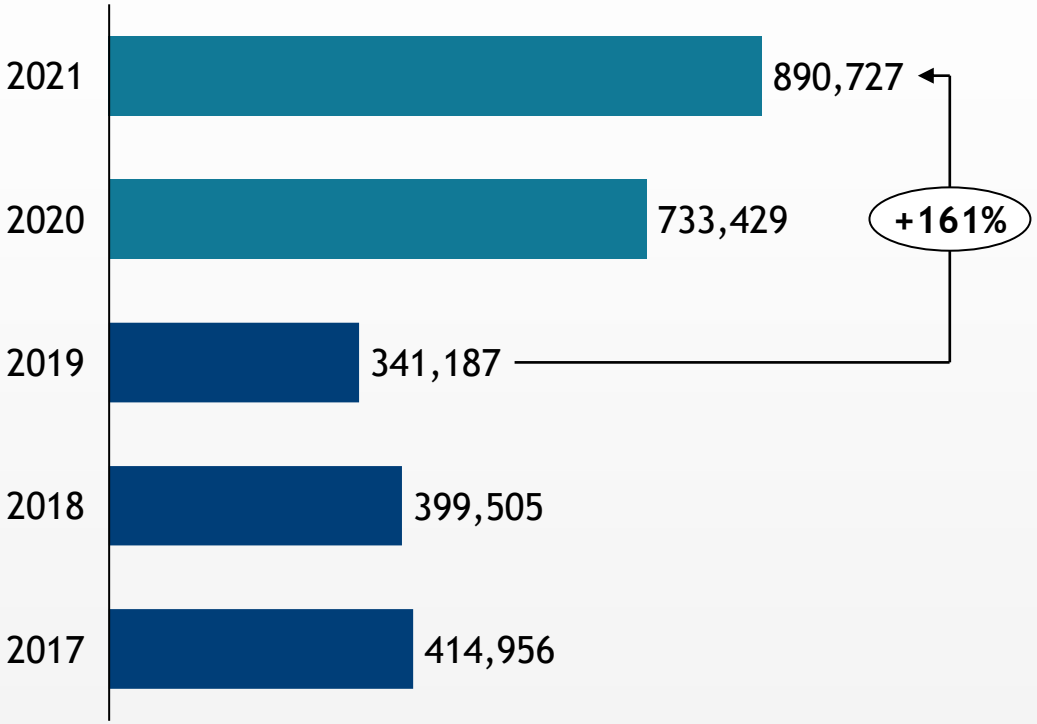
SOURCE: WHO: Indonesia factsheet 2020; https://vaksin.kemkes.go.id/#/vaccines; WUENIC data; Impact of COVID-19 on Routine Immunization services in low- and middle-income countries

Significant coverage drops in 2020-21 due to COVID-19, which more than doubled the number of unvaccinated/partially vaccinated children compared to 2019

Coverage of complete basic immunization[1]



Number of unvaccinated/partially vaccinated children



- Increase in zero dose children (i.e., those not receiving a first dose of DTP and other RI vaccines) has resulted in rising outbreaks/cases of Diphtheria, Measles, Rubella and neonatal TT

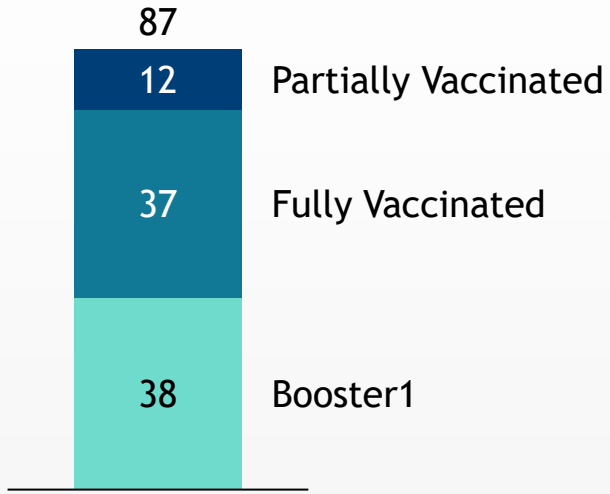
[1]Basic Immunization: BCG, HB birth dose, Measles, and three doses each of DPT and polio vaccine

SOURCE: IDN EPI Interim report to Gavi

As of July 2023, 87% of people have had at least 1 dose of the Covid-19 vaccine with Chinese vaccines dominating the market through a technology transfer with Sinovac

C19 Coverage

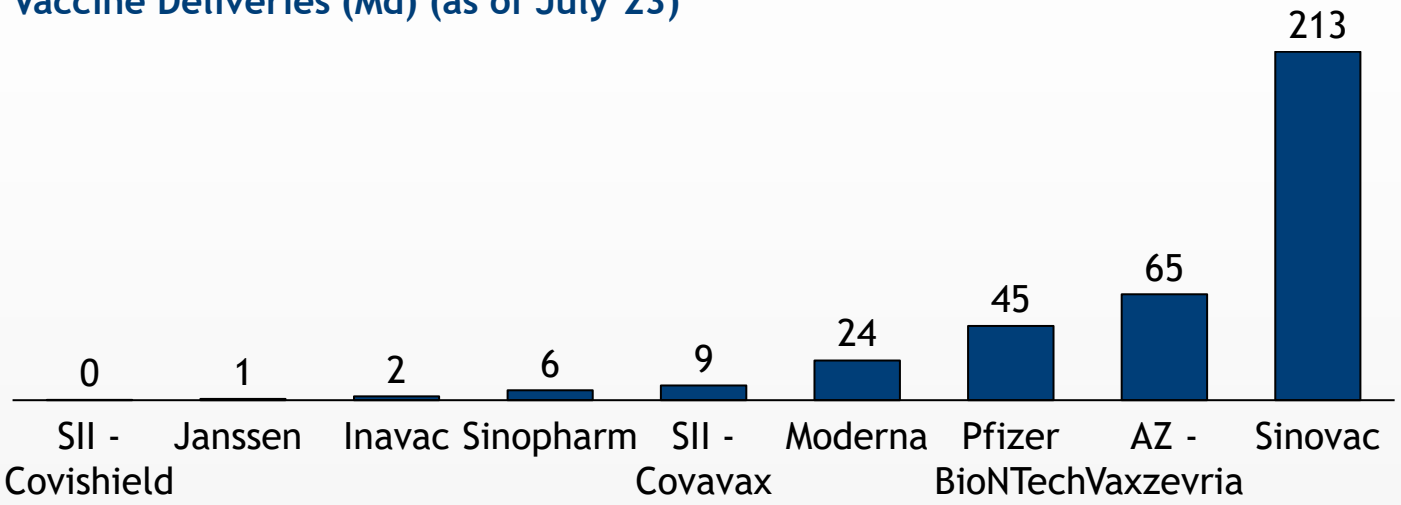
% people vaccinated (as of July'23)



- C19 Vx coverage is at par with major countries in the region
- Initiated booster vaccination program in late 2021 targeted 70% coverage
- Booster dose coverage reached 38% in Jul 2023; plans to introduce 2nd booster dose after first booster reaches 50%

C19 Procurement

Vaccine Deliveries (Md) (as of July'23)



The Food and Drug Supervisory Agency in Indonesia (BPOM) has issued emergency use permits for eleven COVID-19 vaccines[1]

- Chinese C19 vaccines dominate with >60% of total volumes
- Supply, local production and technology licensing agreement between Bio Farma PT and Sinovac Biotech Ltd. for CoronaVac in 2020; Corbevax vaccine licensed for production to BioFarma in Dec 2021
- Etana Biotech acquired a tech transfer from Abogen for mRNA-based C19 vaccine co-developed with Walvax in Aug 2022

[1]Sinovac, COVID-19 Vaccine PT Bio Farma, AstraZeneca, Sinopharm, Moderna, Pfizer, Sputnik V, Zifivax, Janssen, Convidecia, and Covovax.
SOURCE: Ourworldindata; UNICEF Database; Indonesia COVID-19 Response Situation Report

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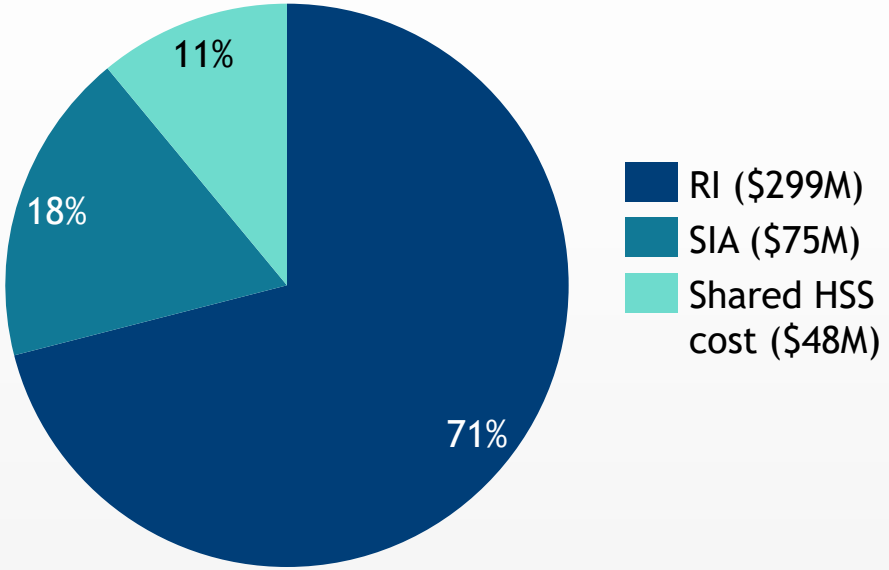
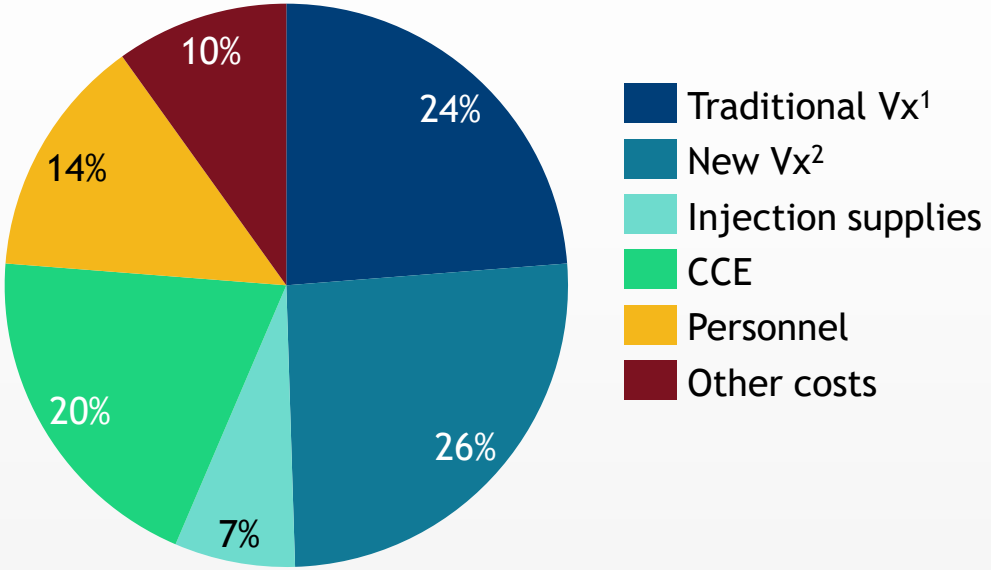
EPI spent $422M on immunization in 2018 including Routine Immunization, Supplemental Immunization Activities and Shared Health Strengthening Systems costs

Total Immunization Expenditures ($422M)



Routine Immunization Expenditures ($255M)

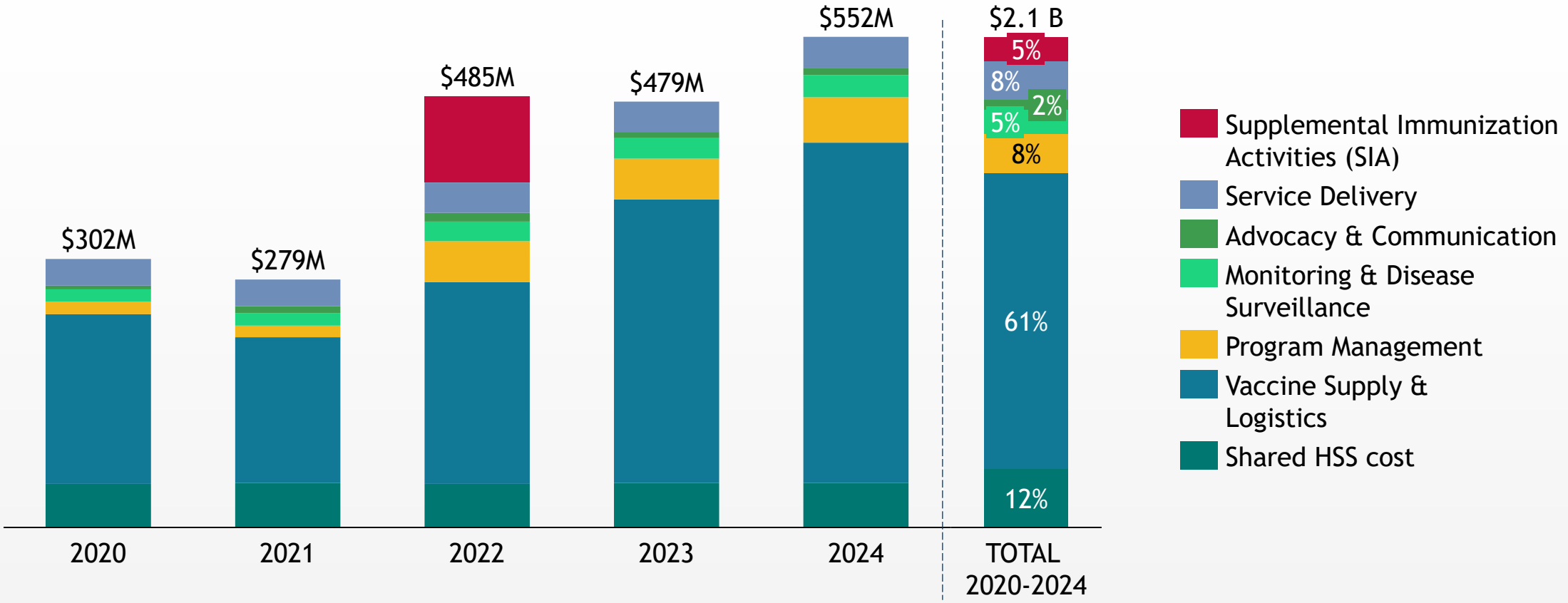


- Cost of a fully immunized child in 2018 was US$ 68 ($1.11/ capita)
- Vaccines and injection supplies was the major cost driver accounting for 57% ($170M) of RI expenditure, followed by Cold-Chain Equipment costs 20% ($60M) and personnel 14% ($41M)
- Domestic funding was the major source for immunization accounting for 92% of total

[1]Traditional vaccines: BCG, Pentavalent, Hep B, OPV, IPV, DT, Td and MR vaccines; [2]New vaccines: HPV, JE and PCV vaccines.

SOURCE: National Statistics Bureau- Indonesia

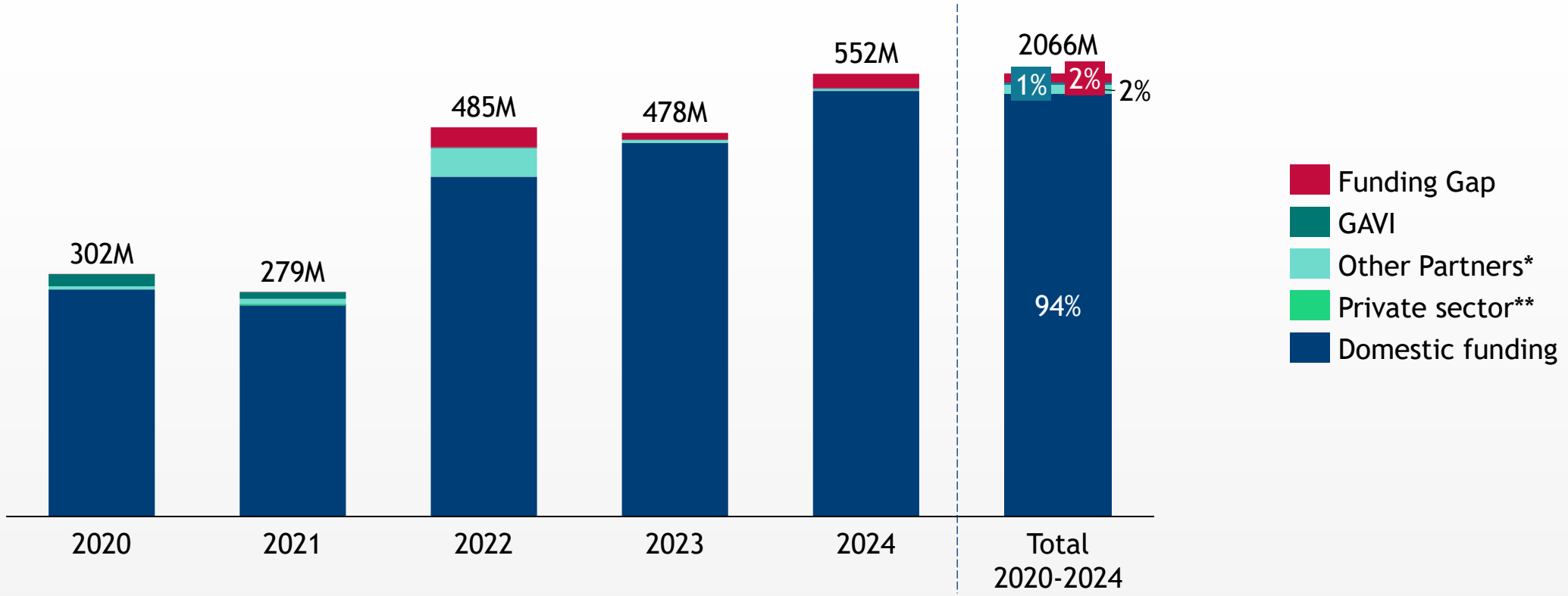
The total resource requirements for EPI during the period 2020-2024 were estimated at $2.1 billion including shared health system costs



- Lower resource needs in 2020 was attributable to no SIAs and corresponding decrease in vaccine supply, service delivery, management and other areas
- Increase in 2021 was attributable to planned SIAs for MR and JE, while in 2022-2024 it is due to introduction and expansion of PCV and other new vaccines

SOURCE: Comprehensive Multi Year Plan National Immunization Program Indonesia, 2020 - 2024

Domestic funding is sufficient to cover 94% of the total resource requirements of the EPI program ($2.1Bn) in 2020-2024



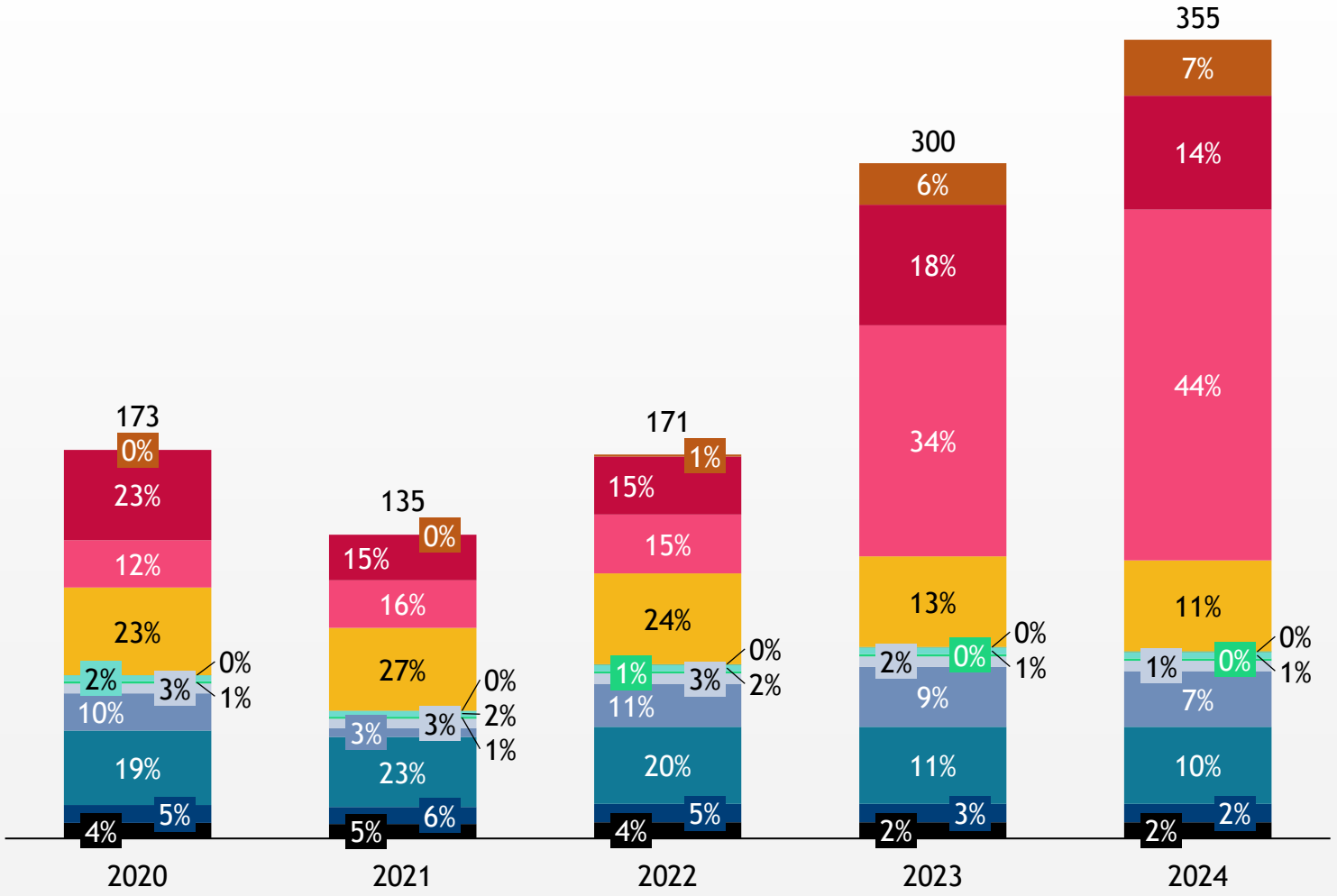
- Analysis of the funding gap structure shows that SIAs, logistics (vehicles, CCE) and other activities would suffer the most if only domestic financing is available for immunization program implementation
- The main strategy for ensuring financial and programmatic sustainability of the EPI Indonesia during the cMYP 2020 – 2024 period is to procure PCV at a lower price (estimated at 3.2 US$ per dose)

*Other partners: WHO, UNICEF, UNDP, and CHAI; **Private sector: Unilever, EMS, BioFarma

SOURCE: Comprehensive Multi Year Plan National Immunization Program Indonesia, 2020 – 2024

Owing to IDN's aggressive NVI and expansion plans, cMYP estimates 65% of total procurement spending on newer Vx including HPV, PCV, and Rota in 2024

Proportion of Vaccine and Injection Supply Cost Projections for RI by antigen



- Proportional spending expected to **shift drastically towards newer vaccines** such PCV, HPV, and Rota from 35% in 2020 to 65% in 2024
- Amongst newer vaccines, **HPV and PCV are expected to be the largest cost drivers accounting for ~58% of total procurement costs** in 2024, as IDN plans to eventually shift to a local rotavirus vaccine from BioFarma

[1]Accounts for <1%

SOURCE: Comprehensive Multi Year Plan National Immunization Program Indonesia, 2020 – 2024

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Owing to high political will, Indonesia has ambitious plans for new vaccine introductions and scale ups over 2022-24

	PCV	HPV	ROTA	IPV2
Year of Introduction	• 2017	• 2017	• 2022	• 2022
Current status/ population covered (as of June 2023)	• National	• Scaled up in 132 district in 9 provinces, targeting 900K girls, ~30% of total cohort)	• Introduced in 21 districts in December 2022	• Introduced in 3 provinces in December 2022
Scale up plan	• N/A	• 2023: National scale up targeting 2.9M girls	• 2023: National scale up • 2024: Phased switch to Biofarma RV3 Vx	• 2023: National scale up
Current product	• Pfizer Prevenar 13	• Merck Gardasil	• BBIL Rotavac frozen	• TT from Shantha with Biofarma
Dose schedule	• 3-dose: 2M-3M-12M	• 2-dose: at least 5 months interval	• 3-dose schedule: 2M-3M-4M	• 2nd dose at 9 M

SOURCE: WHO; cMYP 2020-2024

IDN prioritizes domestic products either through local manufacturing or drug product technology transfers, with only a few international suppliers for vaccines

	Vaccine	Intro year	Scale up year	Supplier	Presentation	WHO PQ
Domestic product	BCG	1999		Bio Farma	20-dose	No
	DT			Bio Farma	10-dose	Yes
	DTP-Hb-Hib	2013		Bio Farma	5-dose	Yes
	Hep-B	1997		Bio Farma	10-dose	Yes
	bOPV	2016		Bio Farma	10-dose	Yes
Domestic product through technology transfer	IPV1/IPV2	2007	**2023**	Shantha -BioFarma	5-dose	Yes
	MR	2017	2018	SII-BioFarma	10-dose	Yes
	HPV	2018	**2023**	Merck- BioFarma (in progress)	1-dose	Yes
International product	PCV	2017	**2022**	Pfizer	1-dose	Yes
	JE	2018	Campaign	Cheng Du	5-dose	Yes
	Rota	2022	**2023**	BBIL (Rotavac frozen)	5-dose	Yes

1 UNICEF SD prices do not include tax or service delivery costs from the port of arrival; Indonesia costs are fully loaded; prices from 2018

SOURCE: -UNICEF SD prices, e-catalogue, in-country interviews ^ Biofarma's RVV is now in Phase3, expected to available by 2024

Besides local manufacturing, quality and cost-effectiveness, IDN shows strong preference for products with Halal certification owing to its religious/social context

Attribute	Insights	Implications for new suppliers
Quality	Majority (9/10) of products in the EPI have WHO PQ, signalling a high-quality standard	Highly recommended to seek WHO PQ for all products
Valency	Preference for valency is highly dependent on cost-effectiveness of the product, as seen with PCV13 that was chosen for scale up following recommendation from ITAGI based on cost-effectiveness analysis	There is a need to establish cost-effectiveness analysis for ITAGI recommendation
Local manufacturing	High preference for locally manufactured product for all traditional Vx or tech transfer in case of lack of products in pipeline (IPV, MR, C19)	Opportunities to pursue technology transfer agreements for vaccines not yet manufactured locally
Country of origin	Openness to Chinese manufacturers given >60% volumes of C19 vaccines are from Sinovac, especially due to lack of domestic product	IDN may be a potential market for Chinese suppliers across other antigens not yet manufactured locally
Other	While not a regulatory requirement, Halal certification is essential to ensure public uptake of the vaccine (for example Mening switch)	A phased implementation of mandatory halal certification through the Halal Product Guarantee Agency, or BPJPH. Indonesian Ulema Council (MUI) certifies vaccines as Halal.

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Indonesia's National Agency of Drug and Food Control (BPOM) has a two-step regulatory process that can take from 100 to over 300 business days for marketing authorization

Required Steps	Timelines (business days)	Details
1. Pre-registration Process	40	• Involves screening of the documents to determine the pathway • The classification depends on the risk assessment and the case built for categorization
2. Evaluation Process	100	**Intended for, but not limited to, one of the following:** • Lifesaving therapy, highly transmissible/very few diseases with no alternative therapies with proven safety and efficacy • Orphan Diseases • Vaccine For National Health Program, supported by the appropriate document or WHO PQ Document • Newly developed vaccine in Indonesia, produced locally, with at least one local clinical trial
	120	• For products that have gained approval from at least one stringent regulatory authority
	300	• For new vaccine registration outside the above two categories

All drugs/vaccines to be distributed in Indonesia must be locally registered except for drugs/vaccines that qualify for Special Access Scheme (SAS). That applies for drugs/vaccines either through donations or which are directly purchased by the government without going through the formal Badan POM process.

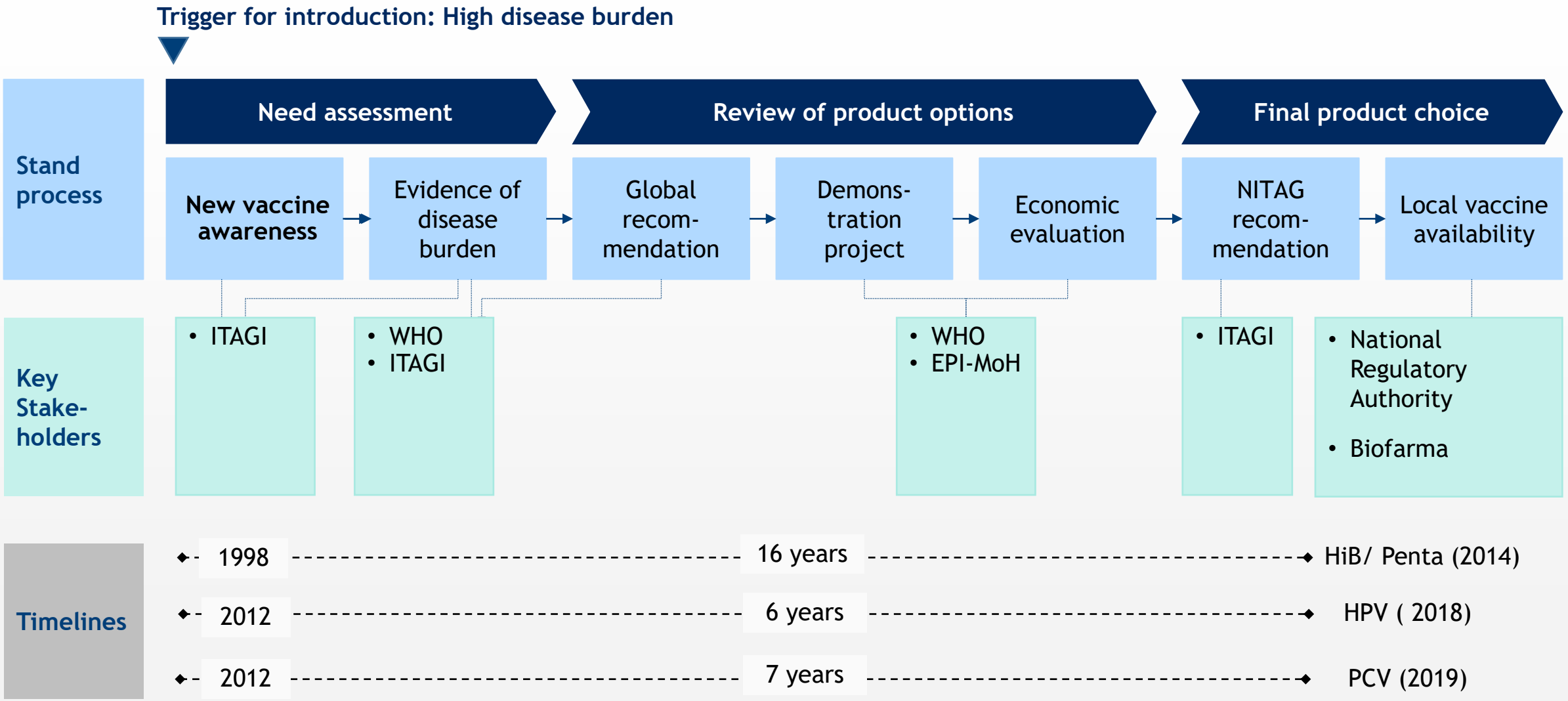
SOURCE: BPOM website

Over the pandemic, BPOM sped up registration for new drugs and biological products intended for use in COVID-19

	PRE-REGISTRATION	REGISTRATION PROCESS	EVALUATION PROCESS	REQUIRED DOCUMENTS	DECISION
NON-COVID-19 DRUGS		40 business days	100, 120 or 300 business days (based on risk assessment)	Complete clinical and non-clinical documents required	Approval only upon full documentation and assessment
COVID-19 DRUGS & VACCINES		6 hours	Maximum 20 business days	May use existing clinical data and existing PSUR^	Conditional Approval

- **Use of drugs:** Limited to hospitals appointed to ensure monitoring of safety and effectiveness
- **Confirmation:** Upon approval of registration, clinical trial must be done in Indonesia using existing clinical data
- **Re-evaluation:** BPOM has the right to re-evaluate the effectiveness and safety of products as new evidence is found

A product is selected for use as part of NVI planning, a process involving multiple stakeholders and can take several years



There are several stakeholders involved in product selection and procurement in Indonesia

Key National Stakeholders[1]	Role	Critical Responsibilities
National Immunization Technical Advisory Group (NITAG)	Body of national experts **providing evidence-informed advice to EPI on immunization policy**	• Evaluate epidemiological research and provide recommendations for national immunization policy • *Critical interface and gateway for suppliers to supply product profiles and clinical data*
Lembaga Kebijakan Pengadaan Baramg dan Jasa Pemerintah (LKPP)	**National procurement regulator**; reporting directly to Head of State	• Regulates products and suppliers on e-Catalogue and controls vendor/product evaluation criteria • Negotiates and finalizes contracts with suppliers awarded tenders
Binfar (ULR)	**Procurement agent** for Indonesian Ministry of Health products, commodities and supplies via e-Catalogue	• Manages direct purchasing for GOI health products listed on e-Catalogue • Develops, evaluates and awards tenders for commodities not listed on e-Catalogue
EPI	Indonesian Ministry of Health unit **leading implementation of Expanded Program on Immunization**	• Manages national immunization program and supports state program delivery • Develops product specification for procurement in coordination with NITAG recommendations
Biofarma	Indonesian **state-owned vaccine manufacturer** and distributor	• WHO PQ manufacturer producing vaccines for public/private Indonesian markets and for export including bOPV, Penta, Measles and DT • Primary local vaccine distributor on behalf of GoI

There are two primary methods by which the Government of Indonesia procures medical commodities – direct and indirect procurement[1]

Direct Procurement

- LKPP evaluates suppliers and relevant antigen based on internal criteria
- LKPP registers suppliers/antigens meeting criteria on to e-Catalogue enabling eligibility for government procurement
- Binfar advertises, evaluates and awards tenders in collaboration with Subdit
- LKPP negotiates contract with selected supplier

Supplier must have strong reputation and will need relationship with LKPP to understand product/vendor criteria for e-Catalogue

Indirect Procurement: Option A

- Biofarma purchases antigen directly from supplier
- Biofarma locally registers antigen product on e-Catalogue
- Government procures antigen directly from Biofarma

Supplier will need contractual agreement with Biofarma with clear stipulations on supply availability in public/private markets

Indirect Procurement: Option B

- Supplier negotiates tech transfer agreement directly with Biofarma
- Biofarma performs fill and finish procedures for specific antigen tech
- As a registered e-Catalogue vender, Biofarma meets Binfar tender requirements

Supplier will need to be cognizant of potential longer timeframes depending on the type of tech transfer negotiated

- Suppliers will **need to develop relationships with local decision-making bodies and collaborate closely** with them in order to successfully navigate each of Indonesia's procurement methods
- GoI's preference to work directly with Biofarma will necessitate suppliers wishing to enter Indonesian market to work directly with **Biofarma through distribution agreements, direct sales or tech transfers**

1 Tendering processes are currently under review; Manual procurement and direct appointment procurement methods also exist but are utilized very infrequently

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