Global Polio Eradication Initiative (GPEI)

The 24th Annual Consultation between the GPEI and Polio Vaccine Manufacturers, National Authorities for Containment and National Regulatory Authorities

Geneva / Virtual, 9 October 2025

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FOREWORD

Polio eradication stands at a pivotal moment. As the world moves closer to interrupting the final chains of transmission, the work of manufacturers, regulators, containment authorities and global partners remains fundamental to sustaining progress. The Annual Consultation provides a dedicated platform for these actors to come together, share experience and align on the steps needed to ensure that safe, affordable and high-quality polio vaccines remain available through eradication and into the post-eradication era.

This year's Consultation was shaped by the continued operationalization of the Polio Vaccine Security Framework, now the central structure guiding long-term vaccine security. Bringing together the technical pillars of manufacturing and supply, containment, and research and development, supported by essential cross-cutting enablers, the Framework provides a shared foundation for coordinated planning. Its implementation will be essential as programmatic shifts, and operational transitions place new demands on the global vaccine ecosystem.

At this moment, our strength lies in partnership. The success of polio eradication has always depended on collaboration across institutions, sectors, and regions. Manufacturers, regulators, national authorities, researchers, and global partners each play an irreplaceable role. By working together with transparency and mutual trust, we can build a vaccine architecture that is resilient for the final phases of eradication and capable of safeguarding future generations.

The priorities agreed during this Consultation will guide the next phase of work: strengthening alignment across the Framework's pillars, reinforcing forecasting and risk management, supporting readiness for bOPV cessation and maintaining high standards in containment and certification. Achieving eradication will require sustained partnership, predictable planning, and shared accountability.

On behalf of the Global Polio Eradication Initiative, I express my appreciation to all participants for their continued commitment. The coming years will be decisive, but with coordinated action and collective resolve, we can deliver on the promise of a polio-free world.

With respect and appreciation,

Director of Polio Eradication, WHO; Chair, GPEI Strategy Committee,

Dr Jamal Ahmed

EXECUTIVE SUMMARY

The 24th Annual Consultation between the Global Polio Eradication Initiative (GPEI), poliovirus vaccine manufacturers, National Authorities for Containment (NACs) and National Regulatory Authorities (NRAs) was convened in a hybrid format on 9 October 2025. The meeting brought together more than 250 participants from 21 countries, reflecting the strong engagement and ongoing commitment of global partners working to secure the polio vaccine ecosystem through eradication and into the post-eradication era.

This year's Consultation centred on operationalizing the Polio Vaccine Security Framework (PVSF), launched in 2024, which provides a common structure for coordinated action across three technical pillars: manufacturing and supply**,** containment**,** and research and development**.** These are supported by cross-cutting enablers on communication, coordination, financing and advocacy. The 2025 meeting reviewed developments across these pillars, examined cross-pillar dependencies, and identified operational priorities to maintain resilient vaccine security in an increasingly complex and resource-constrained environment.

Participants welcomed encouraging news from the global programme, including reductions in wild poliovirus type 1 (WPV1) cases and fewer outbreaks of variant polioviruses. At the same time, continued transmission in specific high-risk areas, persistent access challenges, and fragility in financing and supply underscored the need for sustained collaboration. Updates from GPEI partners and technical experts, manufacturers and regulatory authorities highlighted progress since 2024: expanding manufacturing and supply capacity across a broader vaccine portfolio; improving demand visibility to support timely and predictable procurement; advancing nOPV2 and Sabin IPV platforms; streamlining regulatory pathways; and strengthening readiness for containment requirements.

The Consultation also reviewed planning for the eventual cessation of bOPV, reviewing the pre-conditions endorsed by the Strategic Advisory Group of Experts on Immunization (SAGE) and the implications for manufacturers, regulators and GPEI partners. Continued emphasis was placed on ensuring the integrity of containment certification processes, which remain essential to achieving the certification of eradication. Presentations from industry on novel technologies, including virus-like particle (VLP) platforms, and next-generation Sabin IPV, highlighted the expanding innovation landscape that will shape post-eradication vaccine security.

Across discussions, participants stressed the importance of transparency, predictable financing, and strengthened coordination between the manufacturing and supply, containment, and research and development pillars of the Framework. Key priorities emerging from the meeting included: advancing work on a harmonized Framework workplan; maintaining regular cross-pillar coordination; reinforcing early communication of policy and regulatory guidance; strengthening forecasting and risk management processes; and sustaining progress in containment and certification.

The Consultation reaffirmed the collective commitment of the global community to deliver on the final stages of eradication and to secure a stable and sustainable vaccine architecture that will protect future generations against all polioviruses.

OPENING REMARKS FROM THE DIRECTOR OF POLIO ERADICATION

The 24th Annual Consultation opened with remarks from Dr Jamal Ahmed, Director of WHO's Polio Eradication Programme, who welcomed participants joining both in person and online. He acknowledged the presence of vaccine manufacturers, NACs, NRAs, technical experts and GPEI partners, and expressed appreciation for their continued engagement in an increasingly demanding operating environment.

Dr Ahmed situated the meeting within the broader context of the Polio Vaccine Security Framework (PVSF), emphasizing its role as the central organising structure for the partnership's collective work. He noted that the Framework's three pillars, manufacturing and supply, containment**,** research and development, together with the cross-cutting enablers of financing, coordination, communication and advocacy, provide the shared language, governance backbone and strategic direction required to secure a stable and reliable vaccine ecosystem through eradication and beyond.

Reflecting on progress since the 2024 Consultation, Dr Ahmed highlighted the progress achieved by the global programme. The number of WPV1 cases continued to decline, supported by strengthened surveillance and targeted operational approaches in Afghanistan and Pakistan. Nevertheless, he cautioned that the epidemiological landscape remains dynamic, requiring continuous vigilance and adaptability. He underscored that the persistence of transmission in specific corridors, the operational disruptions caused by conflict and fragility, and the uneven recovery of routine immunization services create vulnerabilities that could undermine progress if not addressed collectively.

Central to his remarks was the message that the vaccine ecosystem remains fragile. Production capacity, manufacturing continuity, regulatory timelines and financing flows all depend on coordinated action across multiple technical and institutional actors. Dr Ahmed emphasized that even a single point of failure, whether in containment compliance, regulatory readiness, procurement cycles or bulk availability, could have system-wide consequences. He called for transparency, predictability and consistent communication between partners to mitigate risks and ensure continuity of supply.

Dr Ahmed reiterated the importance of robust and forward-looking forecasting as a tool not only for procurement and supply planning, but also for strategic risk management. He commended the progress made on consolidating forecast inputs across GPEI agencies and manufacturers and stressed the need for continuous refinement as the programme approaches bOPV cessation and transitions into the post-eradication phase.

He further highlighted the role of NACs and NRAs in maintaining global confidence in the safety and security of poliovirus handling. Strengthened containment compliance and timely certification, he noted, remain essential prerequisites for achieving global eradication certification, as endorsed by the Global Commission for Certification of the Eradication of Poliomyelitis (GCC). Ensuring that national authorities have the resources,

political support and technical guidance needed to fulfil these responsibilities was identified as a continuing priority for WHO.

Dr Ahmed closed by emphasizing that eradication cannot be achieved by any single institution acting alone: it requires the sustained engagement of manufacturers, regulators, research institutions, technical partners and national authorities. He encouraged participants to use the Consultation as an opportunity to jointly assess progress, identify operational challenges and chart a coordinated path forward that ensures vaccine security in both the eradication and post-eradication eras.

SESSION I: PROGRAMME UPDATE, GLOBAL ACTION PLAN & GPEI ADAPTATIONS

The first technical session was opened by Dr Arshad Quddus, who provided a comprehensive overview of the global epidemiological situation and the strategic direction of the GPEI in 2026-2027. He noted that, despite significant operational pressures and a tightening financial landscape, the global programme continues to make tangible progress against both wild poliovirus and circulating variant polioviruses (cVDPVs). The number of WPV1 cases reported globally had declined, supported by strengthened surveillance and more targeted strategies in key transmission corridors.

Dr Quddus highlighted that transmission persists primarily in limited areas of Afghanistan and Pakistan, where complex access challenges, security constraints and population movement continue to impede consistent immunization coverage. He emphasized that while the epidemiological picture is improving, sustained investment in surveillance, supplementary immunization activities and community engagement remains essential to interrupt the remaining chains of transmission. He also underlined the need for flexible, risk-based approaches as the programme navigates shifting geopolitical and humanitarian conditions.

Turning to variant polioviruses, Dr Quddus reported a notable reduction in cVDPV2 detections following intensified outbreak response activities, including expanded use of nOPV2. While the declines are encouraging, he cautioned that the risk of seeding new outbreaks persists in areas with low routine immunization coverage. Strengthening routine services therefore remains a core priority in the 2026-2027 period, especially in regions where immunization systems have been slow to recover from the impacts of conflict, displacement and global health emergencies.

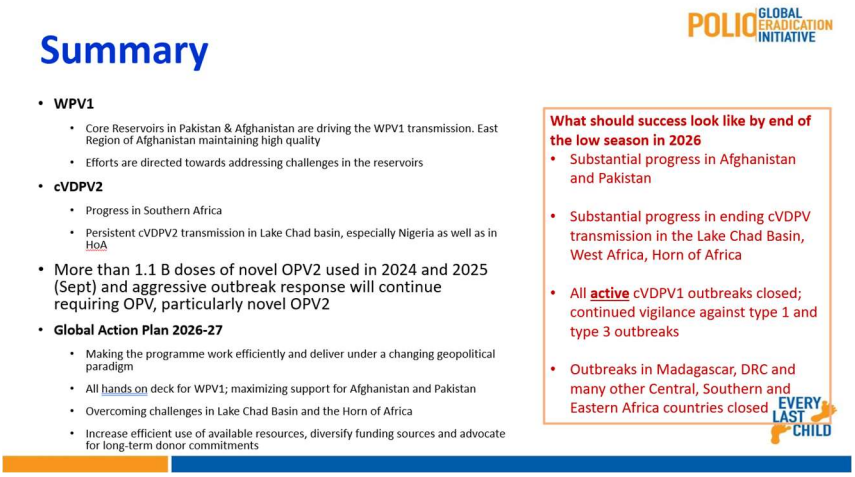
Dr Quddus then outlined key details of the GPEI Action Plan 2026-2027, noting also the endorsed budget for 2026 of USD 786 million. The plan reflects both fiscal constraints and a renewed emphasis on strategic prioritization. Key priorities include focusing resources where they will have the greatest impact, reinforcing technical support in high-risk geographies, and strengthening integration with essential health services to drive more sustainable immunization gains. The programme's strategic direction also seeks to enhance efficiency, streamline operational planning and strengthen accountability across all levels of implementation.

He reaffirmed that the goals remains unchanged:

1. Interruption of WPV1 transmission in Afghanistan and Pakistan; and
2. Cessation of all variant poliovirus outbreaks globally.

Dr Quddus concluded by emphasizing the continued importance of partnership, transparent information-sharing and strong alignment across operational, technical, regulatory and supply actors. He underscored that success requires coordinated action,

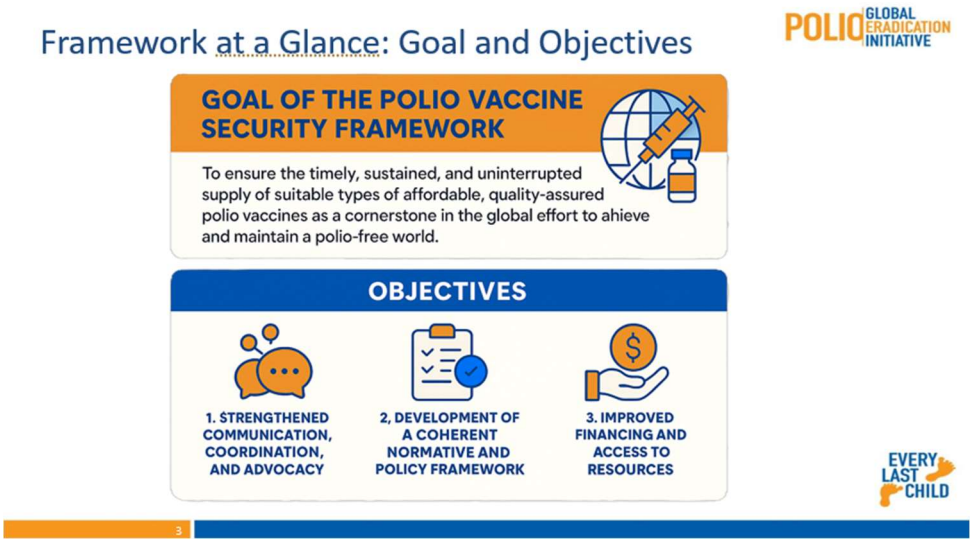
particularly as the programme prepares for milestones related to containment, certification and vaccine transitions in the post-eradication landscape.



Summary slide from Dr Quddus' Global Programme Update presentation.

SESSION II: POLIO VACCINE SECURITY FRAMEWORK

The second session, led by Dr Vachagan Harutyunyan, provided a detailed update on progress made under the Polio Vaccine Security Framework (PVSF) one year after its launch. The Framework, which provides the organising structure for ensuring a secure, resilient and sustainable polio-vaccine supply through eradication and into the post-eradication era, is built around three operational pillars, manufacturing and supply, poliovirus containment, and research and development, supported by cross-cutting enablers spanning financing, policy and regulatory alignment, coordination, communication and advocacy.



Goal and objectives of the Polio Vaccine Security Framework.

Dr Harutyunyan opened the session by reflecting on the positive reception the Framework has received across partners, noting that it has strengthened alignment, clarified roles and responsibilities, and provided a more systematic foundation for cross-pillar cooperation. He emphasized that maintaining a resilient vaccine ecosystem requires visibility, predictability and shared accountability across a wide network of actors, including manufacturers, regulators, procurement partners, technical agencies and policy stakeholders.

He noted that vaccine security is not solely a matter of supply availability, but of system resilience, requiring active risk management, clear governance roles and timely policy signals. The Framework's implementation is being integrated into 2026–2027 GPEI workplans to support bOPV cessation readiness, align financing and regulatory milestones, and ensure coordinated mitigation of emerging risks across the three pillars.

Under the manufacturing and supply pillar, Dr Harutyunyan highlighted improvements in forecasting and coordination achieved since 2024. He emphasized that the consolidated forecast, developed collaboratively by GPEI partners, is intended to support risk

mitigation and market sustainability, particularly as the OPV market contracts and preparations accelerate for bOPV withdrawal. He reinforced the importance of early and structured engagement with manufacturers to ensure continuity during major programmatic transitions.

He underscored progress under the Containment pillar, noting that global efforts to advance containment certification continue under GCC oversight. However, challenges remain in ensuring that National Authorities for Containment have the technical capacity, institutional authority, and political support needed to meet certification timelines.

Dr Harutyunyan outlined progress under the R&D pillar, including developments in virus-like particle (VLP) platforms, expansion of Sabin-IPV production capabilities, and research on antivirals and monoclonal antibodies that may play a role in mitigating long-term risks. He highlighted that innovation will be increasingly important as programme needs shift after eradication certification and as manufacturing and regulatory environments evolve.

He stressed that the PVSF has strengthened coherence across the partnership, but that continued communication and structured coordination are needed to ensure that technical, regulatory, supply and containment milestones are aligned. At the end, he encouraged participants to contribute actively to the development of the forthcoming harmonized workplan and monitoring framework, which will serve as a practical tool for tracking progress, aligning execution across all three pillars, and ensuring continuity of collective action as the programme advances toward eradication and beyond.

SESSION III: VACCINE MANUFACTURING & SUPPLY

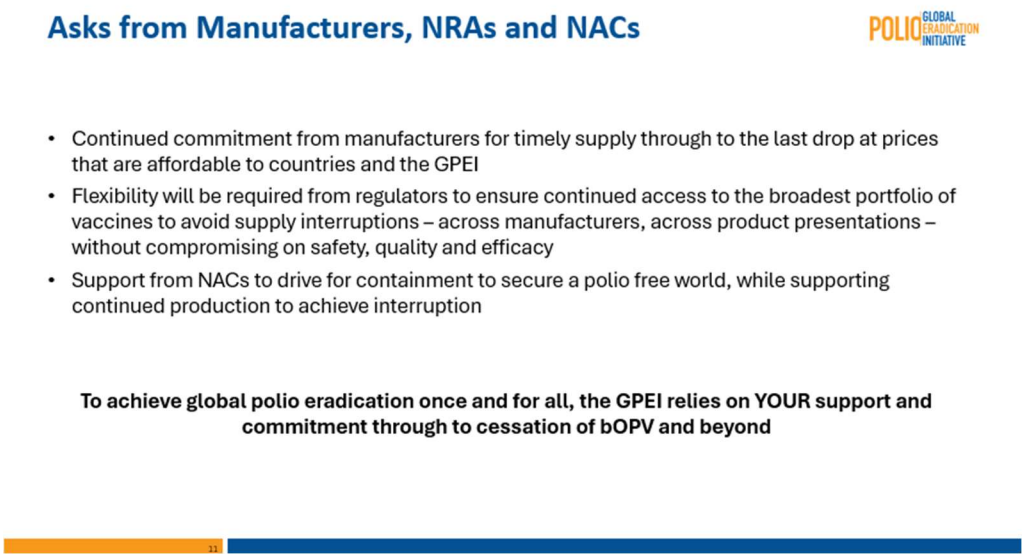
Update on Oral Polio Vaccines

The third session focused on the current status of Oral Polio Vaccine (OPV) availability, stockpile management and supply dynamics, with the presentation led by UNICEF Supply Division. The session provided a detailed assessment of recent developments across the OPV market, including production trends, procurement forecasts, stockpile utilization and manufacturer planning.

Ann Ottosen of UNICEF opened the session with an update on global OPV supply since the last meeting in 2024 and through 2026, covering bOPV, and nOPV2. Demand for bOPV remains significant, though the long-term trajectory reflects an expected decline as outbreak response requirements are reducing as WPV1 is anticipated to be eradicated, as we move closer to the eventual withdrawal of bOPV. A considerable demand driver leading up to cessation is immunity boosting activities that will be required in 37 countries in advance of withdrawal. Ms Ottosen acknowledged the changes in demand requirements and appreciated collaboration with manufacturers to adjust supply to meet the demand as it continues to evolve.

Several manufacturers noted that while the market remains stable, the contracting OPV landscape poses medium-term planning challenges, as investments must be aligned carefully with expected demand to maintain economic viability. They emphasized the importance of early and clear communication on policy decisions that have supply implications, particularly related to bOPV cessation.

A substantial portion of the discussion focused on nOPV2, which is the backbone of outbreak response activities against cVDPV2. UNICEF reported that global nOPV2 supply has remained stable since the middle of 2024, with manufacturers demonstrating strong performance in meeting delivery timelines. The session emphasized that continued, predictable demand forecasts, particularly the 2026-2030 consolidated forecast presented later in the Consultation, are critical for sustaining production capacity and avoiding risks of market contraction during a period when outbreak risks remain real.



Key asks of manufacturers, NACs and NRAs from Ms Ottosen's presentation.

Ms Ottosen noted that the Global OPV2 Stockpile continues to be maintained at levels sufficient to respond to cVDPV2 outbreaks, although actual utilization and phasing of demand throughout 2025 was below the initial forecast UNICEF highlighted the continuous year on year increase in cVDPV2 outbreak response, which based on the 2026 approved budget is projected to decline for the first time since 2016.

Ms Ottosen highlighted the GPEI requirement to maintain the broadest possible OPV portfolio towards eradication and encouraged manufacturers to maintain national licensures and prequalification of Sabin vaccines in case of delays in nOPV development.

Participants also discussed regulatory considerations, shipping pathways and the impact of global logistics pressures on OPV delivery timelines. UNICEF emphasized the importance of predictable shipping windows, particularly for minimizing disruptions in outbreak response contexts.

The presentation concluded with a discussion on preparations for the eventual withdrawal of bOPV, noting that clear timelines, communication and coordinated planning between manufacturers, NRAs, and the GPEI are essential. Participants affirmed that early signal-sharing and structured coordination mechanisms will be key to enabling a smooth transition and avoiding stranded stocks or gaps in outbreak preparedness.

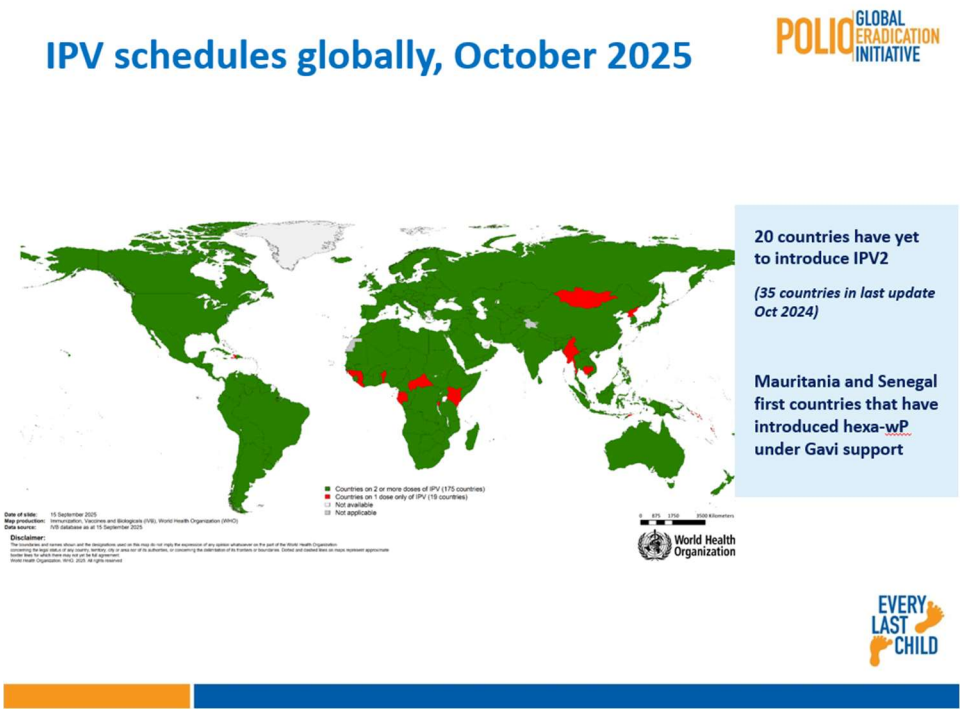
IPV, Routine Immunization and Vaccine Supply Update

The next presentation reviewed global developments in Inactivated Polio Vaccine (IPV) supply, routine immunization trends, and the introduction of IPV-containing combination vaccines. The session included presentations from WHO, UNICEF and Gavi, as well as points made by manufacturers involved in producing IPV and IPV-containing vaccines.

Ian Lewis of UNICEF began by providing an update on global IPV supply, noting that production capacity has improved considerably since the shortages experienced between 2014-2018. Both Salk-IPV and Sabin-IPV manufacturers have expanded output, and several new producers have advanced progress through technology transfer programmes. Mr Lewis emphasized the importance of continued diversification of IPV supply sources to strengthen long-term resilience, particularly in the context of post-eradication needs and manufacturing transitions associated with containment requirements.

Alejandro Ramirez Gonzalez of WHO summarized progress on IPV introduction globally, noting that all countries now use at least one dose of IPV in their routine schedules. The introduction of IPV2, the second routine IPV dose recommended by SAGE, has expanded steadily, although several countries continue to face operational and financing constraints that affect uptake. At the time of the meeting, 20 countries globally had yet to introduce IPV2. Participants discussed the importance of maintaining high IPV coverage as a core pillar of post-eradication immunity.

Specific attention was given to combination vaccines, such as pentavalent and hexavalent formulations. Participants noted the continued demand for hexavalent vaccines, particularly in middle-income countries transitioning away from donor support.



Map of routine schedules globally, delineating IPV1 and IPV2 rollout.

Elie Akiki of Gavi presented an overview of financing considerations for IPV and IPV-containing vaccines, outlining support for countries expanding IPV2 introduction and strengthening routine immunization systems. Mr Akiki highlighted the need to ensure

that IPV financing remains robust and predictable, especially as health systems face competing priorities and broader fiscal pressures.

Discussions also addressed the evolving landscape of IPV production, highlighting the growing importance of Sabin-IPV as a more containment-aligned production platform compared with traditional Salk-IPV.

Participants reaffirmed the importance of maintaining strong integration between IPV supply planning, routine immunization strengthening and outbreak response strategies. The session emphasized that IPV will remain essential well into the post-eradication era, underscoring the need for continued investment in manufacturing capacity, regulatory readiness and programme financing.

Forecasting of global polio vaccine requirements

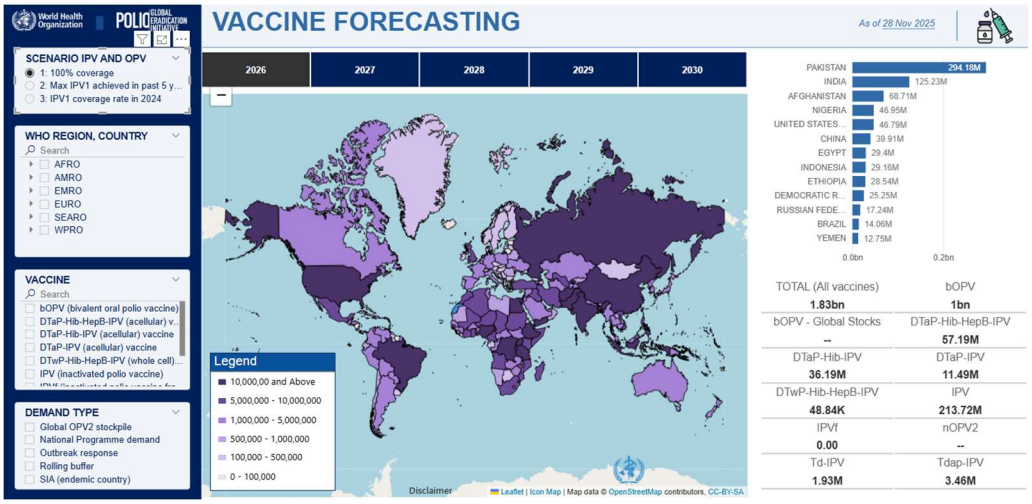
David Woods presented the 2026-2030 global forecast for polio vaccine requirements, building on the initial version shared at the 2024 consultation. The forecasting model has been substantially expanded to include the full suite of polio vaccines and to provide a multi-year, scenario-based view of global demand. The tool will be publicly available shortly, with stakeholders invited to explore the dashboard and provide structured feedback.

Mr Woods began by outlining the evolution of the model. Last year's version focused narrowly on routine immunization needs for bOPV and IPV-containing vaccines within a single year. The updated model now incorporates nOPV2 forecasting, bOPV requirements for outbreak response and endemic SIAs, and estimates for pre-cessation activities. The forecast spans 2026 to 2030 and integrates several significant methodological enhancements.

He explained that the model remains anchored in four key inputs: population, national immunization schedule, coverage, and wastage. Population projections draw on UN Population Prospects for each year of the forecast period. Vaccine schedules are based on 2025 country-level data, given the stability of national immunization schedules year-to-year. Coverage estimates rely on WHO-UNICEF (WUENIC) data, while wastage assumptions use a simplified income-based proxy (5% for high-income, 10% for middle-income, and 15% for low-income countries). SIA demand, both for nOPV2 and bOPV, is derived from separate methodologies, including pre-cessation planning work currently underway.

Three demand scenarios provide a realistic range of forecast outcomes: (1) 100% coverage; (2) each country's highest IPV1 coverage in the past five years; and (3) each country's IPV1 coverage in 2024. Mr Woods noted that the variance across scenarios all three scenarios is modest (on average circa 10-15% of a delta between the highest and lowest scenarios) and stressed that forecasting accuracy ultimately depends on the quality of underlying data and the reasonableness of assumptions.

He then demonstrated the Power BI dashboard, which offers country- and region-specific forecasts for routine and SIA demand, with disaggregation by vaccine type. Users can filter by scenario, geography, and year, and download the full dataset for further analysis. He highlighted plans to integrate additional features based on feedback, including alignment with manufacturer needs and potential incorporation of recent procurement data.



Snapshot of the polio vaccine forecasting dashboard.

Mr Woods concluded by emphasizing that the forecast is a component of the Polio Vaccine Security Framework and is intended to complement rather than replace other demand forecasting tools used across the GPEI partnership. He invited manufacturers and partners to provide feedback once the dashboard link is circulated.

SESSION IV: RESEARCH AND DEVELOPMENT

Update on bOPV Cessation Planning & SAGE recommendations

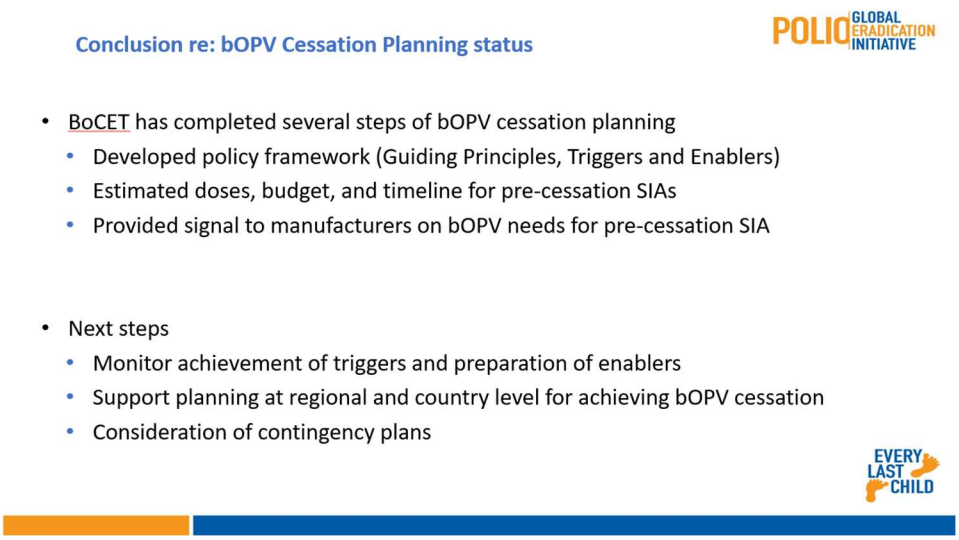
Dr Mach opened the session by presenting the current status of bOPV cessation planning. He recalled that the SAGE reaffirmed two preconditions for global bOPV withdrawal including:

- Certification of global WPV1 eradication, and
- Sustained interruption of variant poliovirus outbreaks, particularly type 2.

While progress toward these objectives continues, Dr Mach stressed that the operational and regulatory preparations required for withdrawal are complex and must begin well before certification is achieved. He noted that bOPV cessation will represent one of the most consequential operational shifts since the global withdrawal of type 2 OPV in 2016, involving simultaneous action by countries, manufacturers, procurement agencies, regulators and containment authorities.

He outlined several areas requiring early and coordinated effort:

Manufacturers will need sufficient advance notice to adjust production planning, manage procurement of starting materials, plan workforce allocations, coordinate facility shutdowns or transitions and ensure regulatory approvals for post-cessation product lines. Many facilities currently producing bOPV will be expected to shift toward other vaccines or scale up IPV/Sabin-IPV capacity. Dr Mach emphasized the importance of predictable timelines to avoid supply disruptions or stock imbalances.



Overview of the status of bOPV cessation planning.

Engagement between manufacturers and National Regulatory Authorities (NRAs) will be crucial. For some countries, the withdrawal of bOPV may require relicensing or delisting processes, revisions to product licenses and updates to package inserts. Regulators may also need to review dossiers related to alternative products or modified production processes. Dr Mach encouraged early, proactive interaction between NRAs, WHO and industry to avoid bottlenecks during the cessation period.

Dr Mach presented work underway to refine the size and composition of the mOPV and/or nOPV stockpiles that will be required after cessation. Because OPV will no longer be used in routine immunization, outbreak-response planning must be precise and ensure that appropriate quantities of OPV2 and additional monovalent OPVs are maintained under strict containment and regulatory oversight.

At national level, Ministries of Health will need to update EPI policies, revise immunization schedules, re-train staff, manage inventories and ensure systematic withdrawal and destruction of remaining bOPV stocks. Lessons from the 2016 switch highlighted the operational challenges involved in synchronized cessation, including the importance of strong monitoring, post-withdrawal verification and communication strategies.

Across all components, Dr Mach emphasized that bOPV cessation represents both a technical and a political milestone, requiring coordination across the entire global polio ecosystem.

Update on GPEI's product development programme

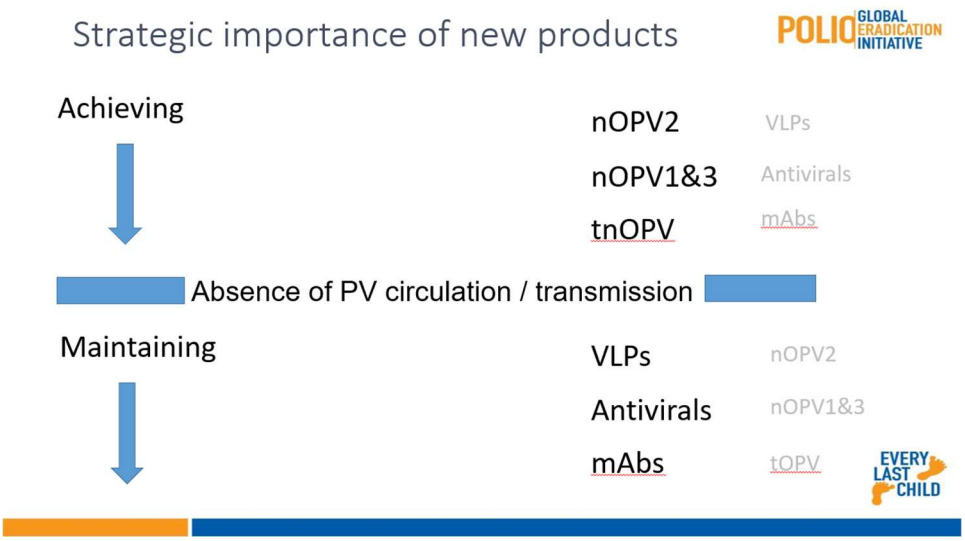
Dr Martin Eisenhawer then provided an update on the GPEI product development programme, underscoring the growing importance of innovation as the programme approaches eradication and transitions toward the post-OPV era.

Dr Eisenhawer highlighted progress in several priority domains, including that of Virus-Like Particle (VLP) Vaccines. VLP technology continues to show promise as a safer alternative for polio immunization in a world where production using live virus poses significant containment challenges. VLP platforms create non-infectious particles that mimic the poliovirus structure to induce immunity while removing the risks associated with handling infectious virus. Dr Eisenhawer noted:

- Encouraging immunogenicity data from proof-of-concept studies.
- Cost advantages given simpler containment needs.
- Potential for future integration into combination vaccines.
- Interest from multiple manufacturers in partnering on product development.
- VLP technology is viewed as a cornerstone of long-term vaccine security strategies.

The expanding portfolio of Sabin-IPV producers reflects both improved production processes and progress in facility upgrades aligned with containment requirements. Newer manufacturers have made strides in technology transfer.

The programme is exploring delivery innovations, such as microneedle patches, jet injectors and intradermal dose-sparing approaches, that could improve reach, acceptability and efficiency. These technologies may reduce operational complexity, support campaigns in insecure areas and minimize cold chain demands. Dr Eisenhawer emphasized that innovations must be assessed not only for feasibility and cost, but also for regulatory pathways and programmatic integration.



Summary of the strategic importance of new products.

Research continues on antiviral agents and monoclonal antibodies that could be used as the most effective approach to stop iVDPV excretion in immune deficient individuals. These tools may become increasingly relevant in the post-OPV era, providing an additional layer of protection.

Dr Eisenhawer concluded by stressing that innovation will be central not only to strengthening eradication readiness, but to shaping a sustainable vaccine security environment for decades to come.

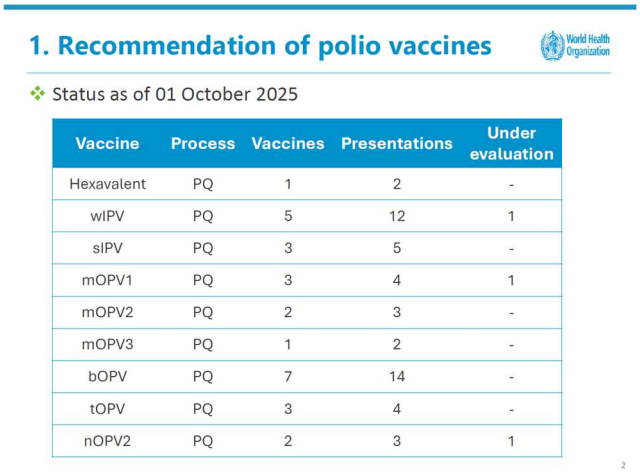
Update on polio-related activities from WHO Vaccine Prequalification Team

Mathias Janssen provided an update on polio-related activities within the WHO Vaccine Prequalification (PQ) Team, focusing on current PQ status, changes since the previous consultation, ongoing evaluations, inspections, stockpile release activities, and work related to polio vaccines in development.

He began by presenting the current PQ portfolio (as of 1 October 2025), highlighting that bOPV, mOPVs, wIPV, sIPV, and nOPV2 constitute the majority of prequalified or

under-evaluation vaccines. The slides show detailed counts of vaccines and presentations per category, including one prequalified hexavalent vaccine and active reviews in wIPV, mOPV1, and nOPV2. Since the last consultation, Serum Institute of India's bOPV (10- and 20-dose presentations) was accepted for review, while Sanofi Pasteur withdrew its bOPV and mOPV2 products

Mr Janssen summarized ongoing evaluations, including SII's adjuvanted IPV (filling only), the withdrawal of Bharat's mOPV1/mOPV3 dossiers, and the medium-priority status of SII's mOPV1, which remains delayed due to resource constraints that require the PQ team to prioritise high-priority products such as nOPV2, cholera, malaria, and rabies vaccines. He also described the continuing review of Biological E's nOPV2 phase-2 submission, involving transition to in-house bulk manufacturing and finalization of the neurovirulence testing framework by the NCL.



1. Recommendation of polio vaccines

World Health Organization

Status as of 01 October 2025

Vaccine	Process	Vaccines	Presentations	Under evaluation
Hexavalent	PQ	1	2	-
wIPV	PQ	5	12	1
sIPV	PQ	3	5	-
mOPV1	PQ	3	4	1
mOPV2	PQ	2	3	-
mOPV3	PQ	1	2	-
bOPV	PQ	7	14	-
tOPV	PQ	3	4	-
nOPV2	PQ	2	3	1

Overview of the recommendation of polio vaccines from WHO-PQ.

He then reviewed polio-related inspections conducted since 2024, including follow-up inspections at PT Bio Farma, a QC-related IPV inspection at AJ Vaccines, and SII's initial inspection for its adjuvanted IPV. Several inspections remain in CAPA status. Initial testing of Biological E's nOPV2 phase-2 material has been satisfactorily completed, while testing for SII's IPV is pending.

In the area of stockpile batch release, Janssen outlined the standard PQ verification process: packaging checks, shelf-life confirmation, and trend analysis of manufacturer and NRA data. Since 2020, 2.7 billion doses of polio vaccines have been released to the global stockpile, including 894 million nOPV2 doses since 2024.

Finally, he reported the progress on nOPV1/nOPV3 and VLP-based vaccines, with submissions pending further clinical development and ongoing discussions on regulatory pathways (PQ vs. EUL).

SESSION V: CONTAINMENT

The fifth session, led by Dr Arlene King, provided an in-depth overview of global poliovirus containment and certification activities. Dr King began by reiterating that containment remains a critical prerequisite for global eradication certification and for maintaining long-term safety in a world where wild poliovirus no longer circulates.

She noted that significant progress has been made since 2024, with countries advancing through the steps required under the Global Action Plan for Poliovirus Containment (GAPIV) and preparing for alignment with the forthcoming second edition of the Global Poliovirus Containment Certification Scheme (CCS). Dr King highlighted that several Member States have strengthened their national containment systems and improved oversight of poliovirus-essential facilities (PEFs), including through enhanced risk assessments, training of personnel and upgrades to facility infrastructure.

Country progress towards poliovirus containment certification

Data as of 1 October 2025

WHO Region	Country	No of facilities designated	No of facilities with/without valid CP (expired, never applied)	No of facilities with plans to pursue ICC/CC	No of facilities with valid/expired ICC	No of facilities with CC
WHO Region of the Americas	Canada	1			1	
	Cuba	1	1	1		
	USA	22	19	8	3	
	Regional Total	24	20	9	4	
WHO Eastern Mediterranean Region	Islamic Republic of Iran	1	1	1		
	Regional Total	1	1	1		
WHO European Region	Belarus	1	1	1		
	Belgium	2		1	1	1
	Denmark	1				1
	France	10	6	4	4	
	Hungary	1			1	
	Netherlands	4	3	3	1	
	Romania	1	1	Not known		
	Russian Federation	7	7	7		
	Serbia	1	1	1		
	Sweden	1	1	0	N/A	
	United Kingdom of Great Britain and Northern Ireland	1	1	1		
	Regional Total	30	1+19+1	18	7	2
WHO South East Asia Region	India	3	3	3		
	Regional Total	3	3	3		
WHO Western Pacific Region	Australia	1	1	1		
	China	7	1+6	7		
	Indonesia	1			1	
	Japan	3			3	
	Republic of Korea	1				1
	Regional Total	13	2+8	8	4	1
	Global	71	1+45+7	39	15	3

For No of Facilities with/without valid CP:

Numbers in **black** = with valid CP; **purple** = expired CP and **red** = never applied for CP

Data represents facilities retaining poliovirus serotypes 1 to 3.

Data as of 6 October 2025.

Available at: Containment-progress-table-20250922.pdf

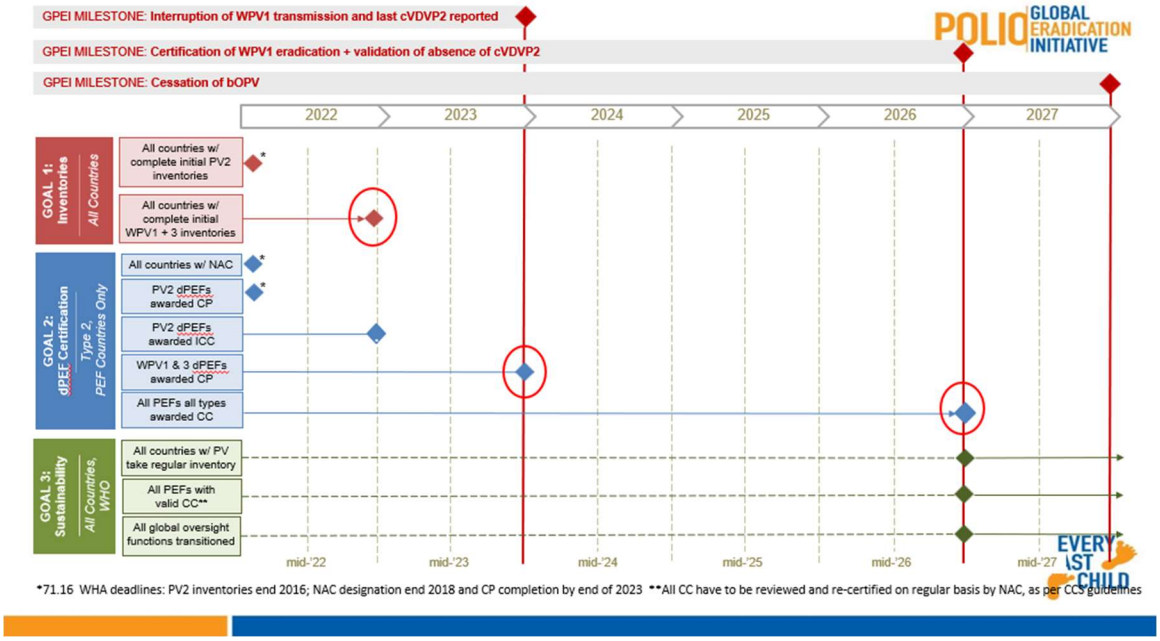
The global status of containment certification.

Despite this progress, persistent challenges remain. Dr King emphasized that in many countries, National Authorities for Containment (NACs) continue to face resource constraints, insufficient institutional authority or limited political support. These factors have slowed certification timelines and created uncertainty for manufacturers and research institutions relying on clear regulatory direction for facility transitions. Strengthening NAC capacity and ensuring sustained political commitment were therefore emphasized as urgent priorities.

Dr King also underscored the importance of effective engagement between NACs, NRAs, manufacturers and WHO. She encouraged early communication on planned changes to facility status, production activities, licensure requirements and stockpile-

related decisions. She noted that alignment is particularly essential as countries and manufacturers prepare for bOPV cessation, which will require coordinated relicensing, containment adjustments and new documentation pathways.

The session included updates on the global status of containment certification (above), including the number of facilities currently progressing toward PEF certification, expected timelines for compliance and key milestones required for endorsement by regional and global bodies (below).



Facilities currently progressing toward PEF certification, expected timelines for compliance and key milestones required for endorsement by regional and global bodies.

Adherence to the timelines for verification of containment, established by the GCC and before certification of eradication is expected, was emphasized. Poliovirus eradication can only be sustained in the presence of safe and secure containment of polioviruses in the fewest possible facilities. The history of smallpox virus containment offers many lessons for countries and facilities retaining polioviruses. Ten months after the last endemic smallpox case in the world had been detected in 1977, and before certification of eradication, the failure of containment in a laboratory in the UK resulted in the death in 1978 of a 40-year-old medical photographer and transmission to her mother.

Although the eradication of WPV2 and WPV3 were certified in September 2015 and October 2019, respectively, reports of inadvertent facility-associated releases of polioviruses from laboratories and manufacturing facilities have continued to be reported, some resulting in infections. Infections due to breaches are reportable under the International Health Regulations. Releases require extensive facility and community investigations which can be costly, disruptive and may result in high public health impacts.

The session also enabled clarification on the use of novel poliovirus strains. Although the view is that containment is required for all live poliovirus strains, implementation of "temporary waivers" on the use of these novel strains has worked to avoid programme interruptions. The achievement of key milestones and other issues affecting future use of this waiver (e.g., eradication, elimination, OPV cessation, global eradication of cVDPV, stockpile requirements, outbreak responses) may extend the use of these waivers. Current direction is unlikely to change until after all OPV use ceases.

Participants reaffirmed their commitment to maintaining strict standards in poliovirus handling and containment, recognizing that breaches, even in the post-eradication context, could lead to significant consequences requiring costly public health interventions. WHO encouraged all stakeholders to maintain close communication, ensure timely reporting of progress and challenges, and actively participate in the refinement of the updated containment guidelines.

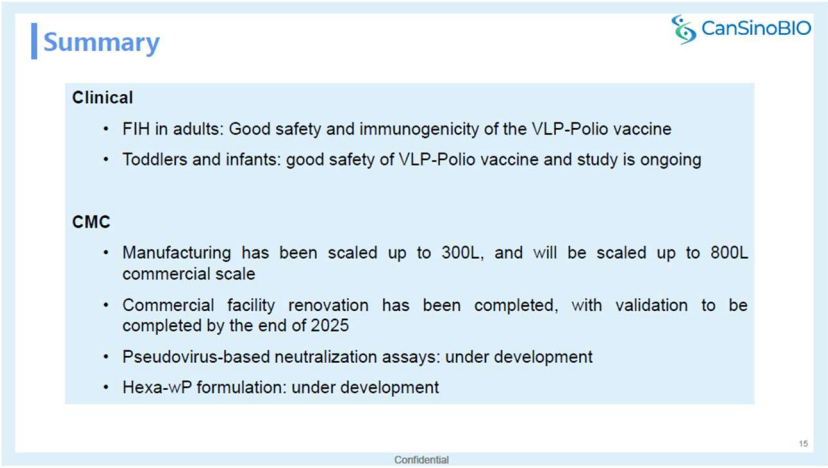
SESSION VI: INDUSTRY INNOVATIONS

Update from CanSino Biologics

CanSino presented updates on its trivalent VLP-based polio vaccine candidate, which is manufactured without any live poliovirus and therefore fully aligned with long-term containment objectives. Clinical development has progressed from a first-in-human adult study in Australia to Phase 1/2 evaluation in Indonesian infants and toddlers, and the manufacturing process has been scaled up to 800L using repurposed COVID-19 facilities in China.

The VLP-Polio programme now includes seven Gates Foundation-funded academic partners developing controlled-release and mucosal formulations, and five manufacturers exploring VLP-based Hexavalent (DTwP-IPV-Hib-HepB) concepts. These efforts provide early evidence for post-eradication product design and ensure future VLP-Polio solutions suit LMIC needs.

CanSino has created a pseudovirus-based neutralization system for VLP-Polio, enabling immunogenicity testing and potential lot-release without infectious poliovirus. This containment-aligned approach supports readiness for a post-polio world without reliance on poliovirus-essential facilities.

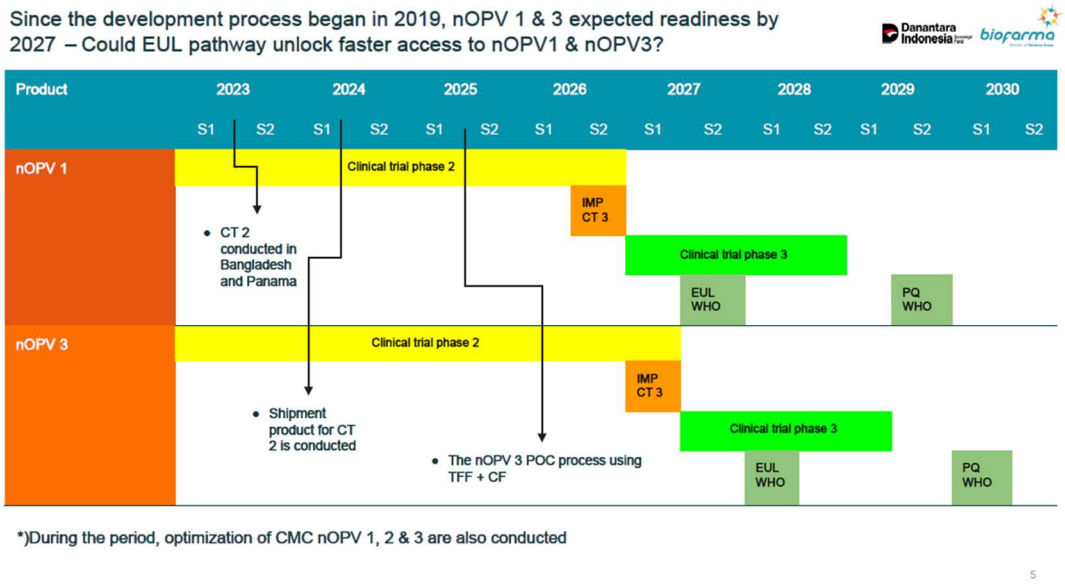


Summary slide from CanSino's presentations on VLPs.

Update from Bio Farma

Bio Farma presented recent achievements in strengthening its polio vaccine portfolio, including progress on nOPV, facility modernization and enhanced quality systems. The company highlighted its continued support to the GPEI through the provision of OPV and nOPV products, including contributions to global stockpiles and outbreak readiness.

Bio Farma also outlined its work on new formulations and technologies aimed at increasing manufacturing efficiency, reducing costs and meeting future programmatic needs. Efforts include infrastructure upgrades aligned with containment and PQ requirements, as well as steps to optimise supply continuity during global vaccine market transitions.



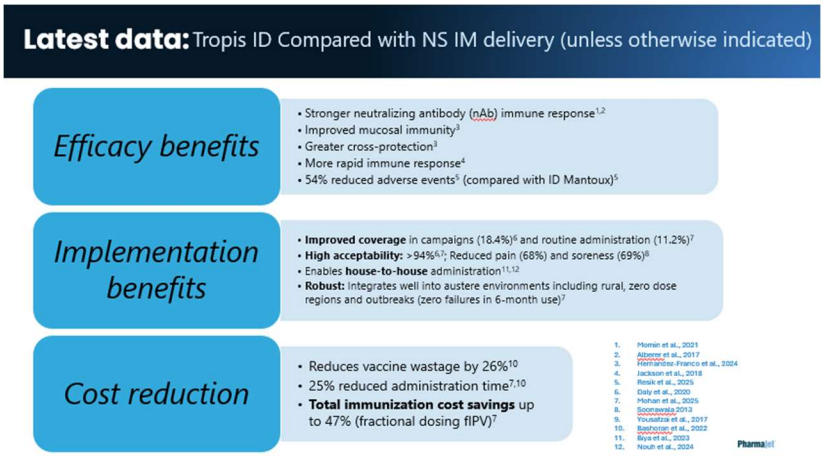
Slide from Bio Farma's presentation detailing nOPV1/3 development.

Update from PharmaJet

PharmaJet presented advances in its needle-free injection systems, which offer potential programmatic benefits, including:

- Improved coverage in campaign and routine immunization settings.
- Cost savings compared with full dose IPV delivery.
- Improved safety by eliminating sharps waste.
- Easier administration in mass vaccination campaigns.
- Reduced risk of needlestick injuries.
- Enhanced acceptability among certain populations.

Field evaluation results were shared, demonstrating high usability and potential operational advantages for both outbreak response and routine immunization contexts. The company expressed interest in further collaboration with WHO and Member States to expand the evidence base for integrating needle-free technologies into polio and broader immunization programmes.



Comparison of Tropis with NS IM delivery.

CONCLUSION OF TECHNICAL SESSIONS

The presentations reflected a dynamic and forward-looking industry landscape, marked by innovation in vaccine platforms, delivery systems and manufacturing approaches. Participants noted that such innovations will be vital in shaping a sustainable polio vaccine security architecture, particularly in the post-eradication era when containment requirements will be more stringent and OPV use will be discontinued.

Across the session, stakeholders emphasized the need for continued collaboration between manufacturers, regulators, GPEI agencies and research partners to support development pipelines, ensure technical alignment and accelerate regulatory processes where appropriate. WHO encouraged ongoing engagement to ensure that innovation pathways are aligned with public health needs, global standards, and the operational realities of polio vaccination programmes.

CROSS-CUTTING THEMES

Across all the technical sessions, several cross-cutting themes emerged, underscoring the interdependence of programme, regulatory and manufacturing systems that collectively underpin global polio vaccine security.

A central theme was the need for strengthened coordination across the PVSF's three technical pillars. Participants emphasized that manufacturing and supply, containment and research and development activities are increasingly interconnected, particularly as programme milestones approach and as the global vaccine landscape evolves. Early communication of policy changes, such as bOPV cessation timelines, regulatory requirements, and containment standards, was repeatedly highlighted as essential for ensuring stable production planning, procurement continuity and risk mitigation.

Another recurrent theme was predictable and sustainable financing. Several discussions underscored that the polio vaccine market remains highly sensitive to funding fluctuations and programme-level uncertainties. Predictable financing for both OPV and IPV is required to sustain manufacturing capacity, support facility upgrades aligned with containment requirements and ensure uninterrupted supply for both routine immunization and outbreak response. Gavi and UNICEF highlighted their continued efforts to support countries and procurement planning, while manufacturers stressed the importance of visibility on future demand.

Communication and transparency were identified as critical enablers across all sessions. Whether in forecasting, containment, regulatory processes or policy development, timely information-sharing between the GPEI, manufacturers, NRAs and NACs was repeatedly emphasized as necessary to avoid delays, bottlenecks or misaligned expectations. Several participants noted improvements since 2024 but encouraged further strengthening of systematic information flows across the partnership.

A further theme concerned the transition to the post-eradication era. Discussions pointed to the need for technologies, processes and regulatory pathways that support a world in which OPV is no longer in use and where containment requirements will be central to all poliovirus handling. Innovations in Sabin-IPV, VLP platforms, delivery technologies and antivirals were noted as important components of the future landscape, reinforcing the role of R&D as a core pillar of long-term vaccine security.

Finally, the Consultation highlighted the importance of global equity and resilience, particularly in maintaining routine immunization services. Strengthening country-level immunization systems remains vital both for preventing variant poliovirus outbreaks and for enabling smooth transitions in vaccine schedules. WHO reaffirmed its commitment to supporting countries through technical assistance, data systems strengthening and integration of polio assets into broader health systems.

THE WAY FORWARD

The Consultation concluded with broad agreement on priority actions required to sustain momentum toward eradication and secure a stable vaccine supply architecture. While discussions highlighted positive progress across the PVSF's technical pillars, participants recognized that the coming years will be decisive and will require coordinated execution of several key tasks.

1. Advance development of a harmonized PVSF workplan and monitoring framework

WHO will initiate work with the Vaccine Supply Group, Containment and R&D teams to develop a unified workplan that aligns activities, milestones and indicators across all three pillars. The harmonized framework will serve as the operational backbone for tracking progress, identifying interdependencies and ensuring that partners have a shared understanding of priorities and timelines.

2. Maintain strong focus on bOPV cessation readiness

Further refinement of bOPV cessation planning will be essential. WHO and the GPEI at large will continue working with manufacturers, regulators and procurement partners to define clear communication milestones, regulatory pathways and stockpile requirements. Manufacturers emphasized the importance of predictable timelines to ensure smooth transitions in production planning and facility management.

3. Strengthen forecasting and risk management

Forecasting will remain a central tool for risk mitigation and supply security. GPEI committed to regular updates of the consolidated forecast, with structured opportunities for manufacturers to contribute data and validate assumptions. Strengthened risk logs and early warning mechanisms will support more agile responses to potential disruptions.

4. Support containment and certification processes

The meeting underscored the importance of sustained investment in NAC capacity, political commitment and regulatory readiness. The GPEI will continue providing technical guidance and capacity-building support, while encouraging early engagement between NACs, NRAs and manufacturers on facility transitions, licensure and compliance planning.

5. Foster innovation and accelerate regulatory alignment

Participants agreed that innovation, including Sabin-IPV scale-up, VLP platforms, improved delivery systems and antiviral development, will be critical for the post-eradication landscape. The GPEI will continue working with industry partners to align

R&D pathways with public health needs and regulatory frameworks, ensuring that new products enter the market efficiently and safely.

6. Strengthen communication and transparency across partners

Clear, predictable and timely communication across the GPEI, manufacturers, NRAs and NACs will remain a priority. Participants emphasized the benefits of improved information flows observed in recent years and encouraged further institutionalization of communication channels.

ANNEX 1: AGENDA

Annual Consultation between the GPEI and the Poliovirus Vaccine Manufacturers, NACS & NRAS

9 October 2025 | 09.00-17.15 (CET / Geneva time)

WHO Headquarters (Salle T, B Building, Room) & online (Zoom)

Chair	Jamal Ahmed and Arshad Quddus
Goal	Enable the implementation of the Polio Vaccine Security Framework, ensuring resilient supply through eradication and beyond.
Objectives	Brief on the status of the programme, showcase the Global Action Plan, and outline how GPEI is adapting to a rapidly evolving public-health landscape. Update on the Polio Vaccine Security Framework and its role in securing a resilient vaccine supply. Highlight and discuss the Framework's operational pillars, Containment, Supply, and Research, alongside other priority issues.

AGENDA		
08.30-09.00	Welcome tea & coffee	
09.00-09.20	Opening remarks and orientation	
Welcome and opening remarks		Jamal Ahmed
Introduction and orientation		David Woods (WHO)
09.20-10.15	SESSION I: Programme update, Global Action Plan, GPEI adaptations	
Brief on the status of the programme, showcase the Global Action Plan, and outline how GPEI is adapting to a rapidly evolving public-health landscape *Develop a shared understanding of the status of the programme, the Global Action Plan, adaptations to the GPEI, and progress since Consultation 2024*		Arshad Quddus (WHO)
10.15-10.30	Break	
10.30-11.00	SESSION II: The Polio Vaccine Security Framework	
Briefing on the Polio Vaccine Security Framework *Update on the Framework and its component parts*		Vachagan Harutyunyan (UNICEF)

11.00-12.30 SESSION III: Vaccine Manufacturing & Supply	
Update on OPVs *Present on the market and way forward in OPVs*	Ann Ottosen (UNICEF)
IPV Routine Immunization and Vaccine Supply Update *Present the supply and demand landscape at the global and regional levels, and the activities of GPEI partners in IPV, including Gavi Board recalibration decisions*	Ian Lewis (UNICEF), Alejandro Ramirez Gonzalez (WHO), Elie Akiki (Gavi)
Forecasting of global polio vaccine requirements *Present the dashboard for global estimates of dose requirements*	David Woods (WHO)
12.30-13.30 Lunch	
13.30-14.30 SESSION IV: Research & Development	
Update on bOPV Cessation Planning & SAGE recommendations *Ensure manufacturers are briefed on the status of planning for the cessation of OPV use (currently focused on bOPV)*	Ondrej Mach (WHO)
Update on GPEI's product development programme *Enable manufacturers to plan their R&D and production*	Martin Eisenhawer (WHO)
14.30-14.50 Break	
Update on polio-related activities from WHO Vaccine Prequalification Team *Brief on key regulatory developments in polio vaccines*	Mathias Janssen (WHO)
15.30-16.30 SESSION V: Containment	
Global update on progress towards the certification of poliovirus containment *Update on notable developments in poliovirus containment*	Arlene King (Global Certification Commission)
16.30-17.00 SESSION VI: Updates from Manufacturers	
Update on manufacturing developments from CanSino, BioFarma and PharmaJet	CanSino, BioFarma and PharmaJet

Update on notable developments in manufacturing	
17.00-17.15 Wrap-up	
Summary comments and wrap-up	Arshad Quddus

ANNEX 2: PARTICIPATION

Countries represented (21): Belgium, Brazil, Canada, China, Denmark, France, Germany, India, Indonesia, Iran, Japan, Pakistan, Korea, Russia, South Africa, Switzerland, Thailand, The Netherlands, UK, USA, Vietnam.

Manufacturers represented (32):

- AJ Vaccines A/S
- Bharat Biotech International Limited
- The Research Foundation for Microbial Diseases of Osaka University (BIKEN Foundation)
- Bilthoven Biologicals B.V.
- Biological E. Limited
- Bio-Manguinhos / Fiocruz
- BioNet-Asia Co., Ltd.
- The Biovac Institute (Biovac)
- CanSino Biologics Inc. (CanSinoBIO)
- Center for Research and Production of Vaccines and Biologicals (POLYVAC)
- Central Institute for Experimental Medicine and Life Sciences
- Chumakov Federal Scientific Center for Research and Development of Immune-Biological Products of the Russian Academy of Sciences (Chumakov Center, FSC R&D IBP RAS)
- GCB Vaccines
- GlaxoSmithKline Biologicals S.A.
- Haffkine Bio-Pharmaceutical Corporation Limited
- Institute of Medical Biology, Chinese Academy of Medical Sciences (IMB-CAMS)
- Janssen Vaccines & Prevention B.V.
- KM Biologics Co., Ltd.
- LG Chem, Ltd.
- Panacea Biotec Ltd.
- PharmaJet, Inc.
- Poonawalla Science Park
- PT Bio Farma (Persero)
- Razi Vaccine & Serum Research Institute
- Reliance Life Sciences Pvt. Ltd.
- Sanofi Pasteur S.A.
- Serum Institute of India Pvt. Ltd.
- Sinopharm, China National Biotec Group Company Limited (CNBG)
- Sinopharm, Beijing Institute of Biological Products Co., Ltd. (BIBP)
- Sinovac Biotech Ltd.
- Temptime Corporation (a Zebra Technologies company)
- Viroclinics-DDL (now Cerba Research)

NACs represented (13):

- Kingdom of Belgium
- Canada
- People's Republic of China
- Kingdom of Denmark
- French Republic
- Republic of India
- Republic of Indonesia
- Islamic Republic of Iran
- Japan
- Kingdom of the Netherlands
- Republic of Korea
- Russian Federation
- United Kingdom of Great Britain and Northern Ireland

NRAs represented (6):

- Kingdom of Belgium
- People’s Republic of China
- French Republic
- Republic of India
- Republic of Indonesia
- Russian Federation