Subject	Strategy, Programmes and Partnerships: Progress, Risks and Challenges
Agenda item	02b
Category	For Information

Section A: Executive Summary

Context

This report provides a progress update on the implementation of Gavi 5.0 and associated risks1. WHO-UNICEF coverage estimates (WUENIC) for 2021 confirmed the Alliance's expectations that 2021 would continue to see ongoing disruption of routine immunisation (RI), largely related to the COVID-19 pandemic. The number of zero-dose children in Gavi-supported countries has increased by 5% to 12.5 million, and routine immunisation coverage (diphtheria, tetanus, and pertussis third dose -DTP3) decreased by another percentage point (pp) in 2021 compared with 2020. At the same time, there are signs of resilience and recovery. Gavi-supported countries delivered ~3.5 times more vaccines in 2021 alone, than in 2020. The rate of DTP3 coverage decline slowed when compared to 2020. Further, one third of Gavi-supported countries saw a DTP3 increase in 2021. Positive trends in administrative data from a subset of countries from the first half of 2022 suggests more children are being reached with DTP3 than in the same period in 2019 (pre-pandemic). In addition, countries managed to expand breadth of protection² whilst also delivering 1.65 billion COVID-19 vaccine doses. This is a testament to the hard work of countries and the Alliance, and the critical role of the Alliance's long-standing investments in strengthening health and immunisation systems, especially so, in the wider context of the pandemic.

Questions this paper addresses

How is the **Alliance performing against its mission, strategic goals and indicators**, and how has the context of the COVID-19 pandemic impacted progress?

What are the **key risks and challenges** being seen across the Alliance's strategic performance, programmes and partnerships, and what **actions** are being taken to address these?

¹ Associated risks refer to the top risks in the Risk & Assurance Report 2022 (see Doc 5).

² This measures the extent to which countries have introduced and scaled up Gavi-supported vaccine. For further information see Annex A

Conclusion

There has been mixed performance against the Alliance's 5.0 targets. At mission level, the Alliance remains on track for most indicators, supporting countries to reach 65 million unique children with routine immunisation and averting over 1.2 million future deaths in 2021³. In terms of its strategic goals (SGs), the Alliance is also largely on track towards supporting countries to introduce and scale up new vaccines (SG1), foster sustainable financing for immunisation (SG3), and ensure healthy vaccine markets (SG4). However, given the challenges many Gavi-eligible countries faced during the COVID-19 pandemic, progress on equity-related outcomes under SG2, such as reducing the number of zero-dose children, took a step back.

The Alliance is therefore accelerating its support to countries in responding to these challenges by providing differentiated programmatic support, streamlining processes and policies, and strengthening its partnerships. The Alliance is optimistic that immunisation systems can be reinvigorated and get back on track in expanding coverage to meet the Gavi 5.0 targets by 2025. However, many uncertainties remain, including on the future trajectory of the COVID-19 pandemic as well as countries' fiscal constraints.

Section B: Facts and Data

The Alliance measures its progress against its vision of "leaving no one behind with immunisation" against a set of six mission indicators, four SGs (and 21 associated indicators), as well as Strategy Implementation Indicators⁴.

- 1. Progress against Gavi 5.0 mission indicators
- 1.1 Despite the COVID-19 pandemic, the Alliance remains on track to reach the majority of its mission indicator targets by the end of the 2021-2025 period⁵. The Alliance helped countries immunise 65 million unique children, avert 1.2 million future deaths and 59 million future disability-adjusted life years (DALYs) in 2021 alone. This has generated more than US\$ 18.9 billion in economic benefits.
- 1.2 The latest WUENIC estimates confirm that the Alliance was making steady progress towards many of its Gavi 4.0 coverage and equity goals before the pandemic hit, with the number of zero-dose children in Gavi-supported countries decreasing by 20% from 2015 to 2019 (from 11.7 million to 9.3 million). However, the pandemic reversed these gains leading to an increase in zero-dose children to 12.5 million in 2021 (34% increase vs. 2019). Zero-dose children continue to account for nearly three quarters of under-immunised children

³ Target for unique children immunised with Gavi support of 300m by 2025; target of 7-8 million future deaths averted by 2025. Please see section 1.1 for full update on mission indicators

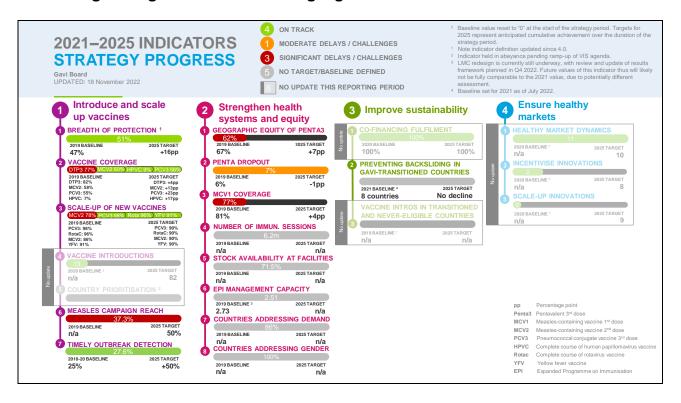
⁴ For the full Gavi 5.0 dashboard see Annex A. Note that strategy implementation indicators (SIIPs) replace the Alliance KPIs from Gavi 4.0.

⁵ Note that the updated estimates on Under-5 Mortality will only be available in December 2022.



in Gavi-supported countries. These children are at the highest risk of disease outbreaks. Therefore, reaching them and setting them on a pathway to full immunisation remains the Alliance's highest priority.

2. Progress against the four strategic goals



Strategic Goal 1: Introduce and scale up vaccines

- 2.1 In 2021, Gavi-supported countries delivered more vaccines than any year in history, and 3.5 times more vaccines than in 2020. With the help of the Alliance, Gavi-supported countries administered over 231 million vaccinations through routine programmes and 184 million vaccinations through campaigns. In addition, 90 countries introduced the COVID-19 vaccine with Gavi support, delivering a total of 1.65 billion doses.
- With regards to the Human Papillomavirus (HPV) vaccine, three more 2.2 countries successfully launched their HPV national vaccine programme with Gavi support, reflecting strong political will to introduce this critical vaccine despite the ongoing challenges of reaching girls during the COVID-19 pandemic. HPV remains one of the most impactful vaccines in the portfolio and yet coverage rates are lagging. With supply constraints expected to decrease, Gavi 5.1 will bring a renewed and heightened focus on increasing HPV coverage through a relaunch (see Doc 07).

- 2.3 **Despite the pandemic, breadth of protection**⁶ **rose by four** pp **since 2019 to reach 51% in 2021.** This indicator reflects countries' ability to both introduce new routine vaccines and scale them up⁷.
- 2.4 A new strategy indicator in Gavi 5.0 measures the rate of coverage scale-up of newly introduced vaccines⁸. It shows that despite the pandemic Gavisupported countries were able to scale up most newly introduced vaccines at pace. Only measles-containing-vaccine second dose (MCV2) scale-up is delayed. This is in part due to existing challenges faced by countries in targeting older children, as MCV2 is given in the second year of life. These challenges were then further compounded by the pandemic since several countries introduced the vaccine just before the pandemic.
- 2.5 While the Alliance was on track with its 5.0 target for vaccine introductions in 2021, recent data suggests a risk of falling behind in 2022. In 2022, of 15 planned routine introductions, only 119 had occurred by mid-November. This is in part due to competing priorities from the scale up of COVID-19 vaccination. In line with the Board's guidance to continue vaccine introductions at pace, the Alliance will accelerate its support to help countries optimise their vaccine portfolio and prioritise introductions based on their specific context.
- Outbreaks requiring internationally supported vaccination responses are on the rise and continue to be a top risk needing close monitoring. The increase in outbreaks across diseases such as measles, cholera, ebola, as well as the resurgence of polio, highlights the importance of further strengthening immunisation and health systems, including strengthening diagnostics and surveillance systems, and having mechanisms to rapidly detect and respond to outbreaks. The 2022 increase in outbreaks was particularly stark for measles, with its effects often compounded by malnutrition, and risk of measles-related mortality. Since January 2022, WHO has identified 25 large measles outbreaks in Gavi-supported countries (compared to 18 in 2021). Efforts are ongoing to increase the timeliness, quality, targeting and integration of measles supplementary immunisation activities (SIAs) to optimise the use of resources and reduce the need for outbreak response. However, sub-optimally planned campaigns remain a top risk. This highlights the continued need to systematically carry out robust post-campaign coverage

⁶ For Gavi 5.0, the definition of breadth of protection (BOP) was updated to include coverage of the second dose of inactivated polio vaccine (IPV2) and the last dose in the schedule for human papillomavirus vaccine (HPVC).

⁷ Improvements in rotavirus vaccine coverage were a key driver, with an increase of 12 pp among Gavisupported countries between 2019 and 2021. A key driver of this improvement came from progress in the Democratic Republic of Congo (DRC) which achieved an increase of 4 pp from 48% to 52% between 2019 and 2021

⁸ This indicator measures coverage of routine vaccines (polio Containing virus third dose (PCV3), Rotavirus (Rotac), Measles containing Vaccine second dose (MCV2) and yellow fever) relative to benchmark vaccines (i.e., Diptheria Tetanus Pertussis third dose for PCV3 and Rotac; Measles containing Vaccine 1 for MCV2 and yellow fever), within reference time frame for new introductions.

⁹ Data as of 18 November 2022; includes 2 routine introductions that were initially unplanned.

surveys (PCCSs)¹⁰ to help evaluate the impact of campaigns and provide learnings to help inform future SIAs. The Alliance will also continue to work with countries to further optimise the SIAs to catch up on missed children and reach zero-dose children.

2.7 Among 2021 outbreaks with internationally-supported response vaccination campaigns, 28% were detected and responded to in a timely manner, on par with the Gavi 5.0 target. For yellow fever outbreaks specifically, timely outbreak detection and response increased from 17% in 2017 to 50% in 2021, thanks in part to the Alliance's efforts to improve country yellow fever diagnostic testing capacity since 2018. Aided by the Board's December 2021 decision to expand the scope of Alliance diagnostic testing efforts from yellow fever to other diseases with targeted vaccines, the Alliance is working to further increase the proportion of outbreaks with timely detection and responses.

Strategic Goal 2: Strengthen health systems to increase equity in immunisation

- Immunisation systems in Gavi-supported countries showed encouraging signs of resilience during the pandemic. Countries were able to deliver more vaccines than ever before in history¹¹ (see 2.1). Gavi's support through its Health System Strengthening (HSS) and Partners' Engagement Framework (PEF) investments have contributed to these achievements. In fact, before the pandemic many of SG2 indicators for Gavi 4.0 were on track. For example, the Alliance's investments into cold chain and institutional capacity (well over ~US\$ 200 million) were critical to deliver COVID-19 vaccines¹². Despite this progress and signs of resilience, the pandemic, as well as other factors such as socio-political events, continued to disrupt routine immunisation services in 2021, with coverage for DTP3 decreasing by one pp in 2021. Geographic equity of DTP3 coverage fell by 5 percentage points¹³ in the lowest coverage districts, indicating the deepening of existing geographic inequities within countries.
- 2.9 There is substantial variation in coverage patterns across countries in 2020 and 2021. Whilst 22 countries suffered coverage declines from 2020 to 2021, this is an improvement when contrasted with 36 countries that suffered a DTP3 coverage decline from 2019 to 2020. Moreover, 19 out of 57 Gavi-eligible countries increased their DTP3 coverage in 2021 and 16 countries managed to prevent

¹⁰ Out of the 10 campaigns launched from early 2021 to mid-2022, only four have produced a post campaign coverage survey (PCCS) following WHO guidelines. As of September 2022, 4 were in process, 1 was granted an exceptional waiver, and 1 Post Campaign Evaluation was done but did not follow WHO guidelines

¹¹ This includes both routine and COVID-19 vaccine doses administered in Gavi eligible countries

¹² Composite Effective Vaccine Management score increased from 67% in 2015 to 72% in 2021. Aggregate Institutional Capacity Building score increased from 2.2 in 2017 to 2.6 in 2020 for countries with Leadership and Management Capacity support provided.

¹³ By focusing on performance among the lowest coverage districts, this indicator measures how well Gavi-supported countries are able to increase coverage in areas with limited access to immunisation services. Geographic equity dropped to 62% in 2021, down from 67% in 2021

backsliding but were unable to outpace growing birth cohorts¹⁴. Recent monthly administrative data reported by a subset of Gavi-supported countries are encouraging, as they suggest that from January to May 2022 countries reached more children with DTP3 than they did during the same time period in 2019, and substantially more than in 2020 and 2021.

- 2.10 COVID-19 response, and in particular, the scale-up of COVID-19 vaccination, remained a key driver of RI disruption. It continued to impact service delivery for childhood vaccines, absorbing immunisation resources at all levels, and in some cases, contributing to vaccine hesitancy. This was reflected in a reduction in institutional capacity to manage RI, with countries having difficulties managing competing priorities, and country management capacity still being a top risk for the Alliance going forward¹⁵. As reflected in the related top risk, this has contributed to delayed implementation of Health System Strengthening (HSS) grant activities, slower HSS disbursements¹⁶, accumulation of funding in countries, especially from COVID-19 vaccine Delivery Support (CDS) and a delay in applications for HSS and the Equity Accelerator Fund (EAF).
- 2.11 To mitigate the risk of not reaching its ambitious equity goals, in 2022 the Alliance is further increasing its focus on execution, working with countries to prevent further backsliding, catch up missed children and accelerate efforts to reach additional zero-dose children. This will remain the key focus in Gavi 5.1 (see Doc 06). Accelerated action is taking place at three levels described below:
- a) Programmes: strengthening the programmatic focus on catching up missed children and reaching additional zero-dose children, and further differentiating and tailoring engagement to the context of each country
- 2.12 The Secretariat is accelerating programming of funding, working with partners and countries to ensure all available funding levers are leveraged in targeting zero-dose children and addressing gender related barriers. Full portfolio planning (FPP) processes are being accelerated, with six countries expected to complete submissions in 2022, and 19 in 2023. The new application kit used in FPP processes includes new programme funding guidelines with gender mainstreamed throughout which have allowed countries to develop more robust and detailed gender interventions (see Appendix 3). For countries not undergoing FPP, existing funds are being reallocated and targeted to ensure a stronger focus on the zero-dose agenda. Four countries have completed EAF funding requests, with seven more expected to submit in 2022, and 20+ more are expected by end of

¹⁴ Noting that for seven countries, two WUENIC flatlines coverage by assumption due to data quality concerns.

¹⁵ This is illustrated by a drop in the aggregate Institutional Capacity Score (from 2.73 in 2019 to 2.51 in 2021), suggesting a diversion of country institutional capacity. This indicator is the combination of the EPI management capacity and the Interagency Coordination Committee/ Health Sector Coordinating Committee coordination functionality score. It highlights that strengthened institutional capacity for programme management and monitoring is on the critical pathway to programmatic and financial sustainability

¹⁶ Currently 34% of the latest HSS annual forecast for 2022 has been disbursed as at 30 September 2022

- 2023. Countries can also use CDS to strengthen RI. CDS funding is increasingly being focused on integrating COVID-19 vaccination into RI mechanisms, reaping mutual benefits for COVID-19 vaccination and stronger RI. Of note, the new CDS3 funding envelope (total US\$ 718 million¹⁷) includes a specific focus on supporting further integration of COVID-19 vaccination into RI (see Doc 09).
- 2.13 Campaigns are also being leveraged to reach missed communities and continue serving them through routine immunisation services. 2022 has seen an accelerated engagement from the Alliance to catch-up missed children through catch-up campaigns and Periodic Intensification of Routine Immunisation (PIRIs) to improve coverage as well as consolidating efforts to reach zero-dose children in communities that have consistently been missed even before the pandemic¹⁸.
- b) Processes: streamlining portfolio management processes and implementing policy flexibilities
- 2.14 The Secretariat is streamlining its portfolio management processes and adapting funding policies to facilitate more efficient access to funding in light of limited country bandwidth. The recently concluded 'FPP step-back' exercise led to a series of simplifications that have been launched in Q4 2022. The ambition is to reduce the length of the FPP process from the current nine to 22 months, closer to six months. Through the EVOLVE project, the Secretariat will undertake a substantial overhaul of its cross-functional portfolio management processes to make these more efficient and effective.
- 2.15 Gavi is implementing the Fragility, Emergencies and Displaced People (FED) policy, recently approved by the Board. This allows for bespoke flexibilities such as streamlined application requirements, provision of vaccines to partners to reach populations outside government control, outreach campaigns to missed populations, and extend thresholds for Human Resource costs due to dire economic situations. The devastating floods in Pakistan for instance, leveraged the emergency component of the FED policy for the first time, allowing rapid access to US\$ 10 million to protect routine vaccination services.
- c) Partnerships: implementing strengthened and context-appropriate partnerships
- 2.16 To mitigate the top risk on partner capacity, the Alliance focuses on strengthening and expanding partnerships at global, regional, national and sub-national levels. Having brought on board ~70 new partners since 2016, Gavi is exploring ways to complement the partner landscape by bringing a context appropriate mix of skills and competencies to countries. For example, the Alliance is now working with the International Organisation for Migration (IOM) across

¹⁷ Sum of ceilings for Gavi 57 countries, excludes US\$ 30 million Emergency funding provided to UNICEF ¹⁸ India for example, submitted a proposal to concentrate its efforts on clusters of select districts which together host 50% of zero-dose children, and decrease the number of chronically missed children by 30% by 2026 vs. 2019 levels.

- several countries to reach mobile populations. The US\$ 100 million Zero-dose Immunisation Programme (ZIP; part of the EAF) in the Sahel and Horn of Africa regions is set to launch this month, aiming to provide a full suite of vaccines to marginalised zero-dose children in cross-border, fragile and conflict settings.
- 2.17 As part of this effort, the Secretariat is adapting its ways of working to enhance its ability to partner with Civil Society Organisations (CSOs). The new Civil Society and Community Engagement (CSCE) approach requires countries to allocate at least 10% of combined HSS, EAF and PEF Technical Country Assistance (TCA) funds to civil society partners. Additionally for PEF TCA, it is aspired that 30% of funds will be allocated to local partners over the course of Gavi 5.0, in recognition of the critical role these organisations play in reaching zero-dose children and missed communities. To implement this approach, the Alliance has begun to shift its ways of working to foster a stronger enabling environment for CSOs and local partner engagement. However, in 2021, only 3% of TCA funding is allocated to local partners. Progress needs to be significantly accelerated to achieve these targets for funding to CSOs and local partners. To support this, a call for proposals is about to be launched to help test, learn, and scale up government and CSO partnership models.

Strategic Goal 3: Improve Sustainability of Immunisation Programmes

- 2.18 Despite slow economic growth, inflation and increasing debt, 2022 cofinancing payments are ahead of the levels seen in previous years. As of end of September 2022, 88% of all outstanding co-financing obligations had been met, compared to 68% at the same point in 2019. This shows an impressive commitment from countries as well as the Alliance in ensuring a strong focus on the financial sustainability of routine immunisation services.
- 2.19 While the overall picture on co-financing is encouraging, the risk of default is increasing in a deteriorating macroeconomic situation and sustainable transition remains a top risk. Payments for 25% of Gavi-supported countries were fully outstanding at the end of October compared to 19% at the same time in 2019. Of particular concern is the fragile and conflict country segment where eight of 12 countries have yet to meet their co-financing obligations. Building on the co-financing flexibilities approved by the Board in June 2022 for countries facing humanitarian crisis or severe fiscal distress, waivers have been approved for Somalia and North-West Syria. Countries entering or currently in Accelerated Transition (AT) are also facing transition risks, which is why the Funding Policy Review (see Doc 10) recommends an extension of AT from five to eight years and the introduction of a 35% co-financing threshold for countries to enter AT.
- 2.20 The scale of the pandemic's impact on routine immunisation programme performance has varied across former-Gavi eligible countries. Of the 17 countries¹⁹ that had transitioned as of 2021, seven were able to sustain DTP3

¹⁹ Former-Gavi eligible as of 2021 include: Angola, Armenia, Azerbaijan, Bhutan, Bolivia, Cuba, Georgia, Guyana, Honduras, Indonesia, Kiribati, Moldova, Mongolia, Sri Lanka, Timor-Leste, Ukraine, Vietnam

coverage above 90% from 2019 to 2021. Among the remaining ten countries, declines in DTP3 coverage ranged from two to 18 pp. The Alliance has prioritised support to mitigate the risk of backsliding in four of these countries through the Middle-Income Countries (MICs) approach²⁰. Whilst implementation of the support was initially slower than anticipated due to constraints by the pandemic, proposals for support in three of these countries have now been approved.

- 2.21 Following the Board-approved special strategy, Nigeria is now scheduled to transition from Gavi support in 2028, extending the original transition date from 2021. It has maintained a positive trend in immunisation coverage in recent years and avoided backsliding during the COVID-19 pandemic²¹. The Alliance has worked with the Government to update the accountability framework to better reflect Gavi 5.0 priorities²² (see Appendix 1). The framework will continue to be used to monitor joint commitments and guide implementation of Nigeria's 2018-2028 NSIPSS²³. A summary of the NSIPSS mid-term review findings will be shared with the Board in May 2023.
- 2.22 Papua New Guinea (PNG) also operates under a US\$ 60 million Board-approved special strategy approved in 2019 that granted an extension of the original transition date from 2020 to 2025. It is becoming apparent that the country will not be fully ready to transition from Gavi support in 2025 due to profound and protracted challenges in its immunisation system. To strengthen RI and prepare for a successful transition, the government has developed a detailed implementation plan and accountability framework. However, DTP3 coverage has dropped further from 35% in 2019 to 31% in 2021. Gavi is working with the country to programme US\$ 45 million of support through its upcoming FPP process. Given these challenges, the country is likely to request Board approval of a no-cost extension of the transition support in 2023 (see Appendix 2).

Strategic Goal 4: Ensure healthy markets for vaccines and related products

- 2.23 SG4 indicators for 2021 were shared at the June 2022 Board meeting and an update on the top risk of global supply shortages is available in the Risk & Assurance report (see Doc 05). Therefore, this update is focused on changes since the update in June on two specific markets: rotavirus and malaria.
- 2.24 Supply disruptions in the rotavirus vaccine market led to a deterioration of the market's capacity to meet country product preferences. While the health of the rotavirus market was initially considered acceptable in 2021 the situation worsened in 2022. Constrained supply resulted in five to six months of stockouts

²⁰ Countries initially prioritised for support include: Angola, Bolivia, Indonesia and Honduras.

²¹ As confirmed by recently released 2021 Multiple Indicator Cluster Survey/National Immunization Coverage Survey and WUENIC data. The latter indicates the number of zero-dose decreased by 77,000 between 2019 and 2021 and DTP1 coverage increased slightly, from 68% in 2019 to 70% in 2021

²² Updates include refined indicators, definitions and data sources and a greater emphasis on subnational performance and key Gavi 5.0 priorities such as advancing co-financing releases to avoid stockouts and reaching zero-dose children nationally and in the prioritised LGAs.

²³ Nigeria Strategy for Routine Immunisation and Primary Health Care Systems Strengthening.

during 2022 across seven countries²⁴. Rotavirus vaccination is set to resume in those countries this year, thanks to the availability of alternative vaccine presentations and product switches. The switches to cheaper alternatives provide an estimated ~40-60% saving on vaccine costs to countries in 2023.

The Alliance has defined market shaping actions to address the limited initial 2.25 production capacity in the malaria vaccine market. Since the Board approval of the malaria vaccine programme in December 2021, the Gavi Independent Review Committee (IRC) recommended the applications for pilot countries Ghana, Kenya and Malawi, for approval. An additional 20 countries have submitted a formal expression of intent to Gavi to introduce the malaria vaccine. UNICEF issued the first award in August to GSK for 18 million doses over the period of 2023-2025, at an initial price of EUR 9.30 per dose²⁵. More contract awards are expected as additional vaccines receive licensure and WHO prequalification. In the meantime, the Alliance is working to operationalise the allocation framework for the limited number of vaccine doses. In parallel, the Alliance has developed a market shaping strategy roadmap to improve the health of the malaria vaccine market. The roadmap has a strong focus on addressing supply constraints in the short to medium term (0-6 years) and dramatically reducing the vaccine price; a feasible and confidential price target range has been agreed with market shaping partners. It also covers the need for multiple products in the market, as well as continued product improvements to first and next generation malaria vaccines and outlines the importance of demand interventions to achieve timely country introductions and sustained routine programmes.

Section C: Actions requested of the Board

This report is for information only.

Annexes

Annex A: Gavi 5.0 Mission and Strategy indicator dashboard and Strategy Implementation Indicators update

Additional information available on BoardEffect

Appendix 1: Nigeria Accountability Framework

Appendix 2: Papua New Guinea update

Appendix 3: Annual report on the implementation of the Gender Policy

²⁴ Cameroon, Kenya, Senegal, Sudan, Tanzania, Zambia, Zimbabwe.

²⁵ The vaccine is a 4-5 dose full course.