

Annex B: Gavi 6.0 approach to Fragile and Humanitarian settings

1. Theory of Change for the F&H approach

- a. **The Theory of Change (ToC) articulates the tailored approach for driving impact towards Gavi 6.0 strategic goals in F&H settings.** It is closely aligned to the 6.0 Health Systems Strategy ToC. The ToC is accompanied by an F&H measurement framework that is integrated into the broader Gavi 6.0 Execution Framework and will be further refined (see Annex A).

2. Key shifts for the F&H approach

The F&H approach entails six key shifts. The funding is part of the Gavi 6.0 indicative strategic cost estimate except where called out.

Shift 1: Focus on context-appropriate vaccines including ‘traditional’ vaccines. Gavi 6.0 will prioritise equitable coverage increases with a country’s current portfolio of vaccines over new vaccine introductions, recognising the challenge of doing both simultaneously is particularly pronounced in F&H settings. To achieve this, the Alliance will strengthen vaccine prioritisation and optimisation support. Moreover, in humanitarian settings Gavi will prioritise a pragmatic routine and catch-up immunisation package. **Context-appropriate vaccines may include ‘traditional’, non-Gavi funded vaccines¹ in exceptional circumstances.** Only countries with co-financing waivers will be eligible to request Gavi support for traditional vaccines. This approach minimises the risk of displacing domestic financing and ensures prudent use of Gavi resources. This aligns with PPC feedback that any Gavi support for traditional vaccines should be exceptional and not displace existing resources. Providing this additional support is estimated to cost US\$ 40-90 million. The impact of this investment translates to >250-600k lives saved during the 2026-2030 period. Additionally, where Gavi engages directly with humanitarian partners and traditional vaccines from the national vaccine supply cannot be made available, Gavi will provide support for traditional vaccines and work with the Alliance to enable access by these partners.

- a. **Shift 2: Drive new programmatic approaches to reach missed communities and zero-dose children including catch-up immunisation**

Provide differentiated support to health systems to reach and meet the needs of missed communities and zero-dose children. The effort to increase coverage in missed communities in F&H settings requires agile and resilient health systems. As highlighted by the PPC, community health workforce, community engagement and cold chain must be tailored to the specific needs of each community to help overcome barriers.

¹ Non-Gavi supported vaccines, e.g. BCG, OPV, maternal Td or vaccines part of Gavi portfolio but country not eligible for support (e.g., MCV1)

Reduce the number of zero-dose children by systematically providing catch-up vaccination to children ages 1 to 5. Many communities in F&H settings have been missed for years, leaving a growing number of zero-dose and under-immunised children in clusters that risk high mortality and fuel outbreaks. In Gavi 6.0, the Alliance will build on strategies developed by 'ZIP: Gavi's Humanitarian Partnerships' and the 'Big Catch-up' to systematically immunise older children in missed communities. Additional vaccines are anticipated to cost US\$ 40-70 million. They are expected to avert approximately 50-80k² additional deaths, as well as reducing the risk of outbreaks.

b. **Shift 3: Institute new ways to direct immunisation resources to missed communities and zero-dose children.** In F&H settings, missed communities require tailored approaches. Under Gavi 5.0/5.1, the success of the CSO mechanism³ and learnings from 'ZIP: Gavi's Humanitarian Partnerships' have highlighted the critical role of CSOs and humanitarian actors in vaccinating missed communities. A persistent challenge has been establishing reliable access to immunisation resources, including the country's vaccine supply. To address this challenge, Gavi will adopt a set of tailored delivery approaches:

- **Strengthened advocacy with governments** to promote the systematic inclusion of missed communities in national immunisation plans. This includes efforts to ensure vaccines are directed to these communities and to build acceptance for the complementary role of CSOs and humanitarian partners. In most F&H contexts, the 10% minimum Board-mandated funding allocation for CSOs will be exceeded to enable access where national immunisation programmes face barriers they cannot overcome.
- **Gavi Secretariat-directed delivery outside national plans** to reach missed communities through two distinct but complementary approaches:
 - **Targeted equity programming** in limited cases where national plans do not include missed communities. In these cases, the Secretariat may allocate vaccines and earmark cash support within the country's consolidated cash grant or via the Gavi Resilience Mechanism, with implementation support from Alliance partners and CSOs where needed.
 - **Support to humanitarian partners** in contexts where programming must adhere to humanitarian principles. Here, Gavi will use the same approach as above but direct the support to humanitarian actors. Gavi will also develop mechanisms to deliver and safeguard vaccines through UNICEF Supply Division or other trusted channels.

To date, Gavi's operating model has been designed for engagement with a single, recognised national government. In disputed territories or contexts

² An indicative estimate derived from extrapolating the impact of infant-targeted vaccinations, incorporating an approximate adjustment to account for the reduced effectiveness when vaccinating older children

³ Board decision requiring countries to allocate at least 10% of their combined Health Systems Strengthening (HSS), Equity Accelerator Funding (EAF) and Targeted Country Assistance (TCA) ceilings for CSO implementation

governed by 'de facto' authorities or Armed Non-State Actors (ANSA), Gavi will institutionalise differentiated operating procedures, including not requiring legitimisation of Gavi grants by 'de facto' authorities and limiting the sharing of information where required for the safety of Alliance staff.

- c. **Shift 4: Support sub-national fragile settings in non-fragile countries and fragile & humanitarian settings in catalytic phase countries⁴.** Large sub-national fragile settings often face challenges similar to those in fragile countries yet lack tailored support. Under Gavi 6.0, these settings are proposed to be recognised under the FED policy, enabling more responsive approaches⁵. **Additionally, emergency and fragility support for countries in the catalytic phase will be fully integrated into the Gavi 6.0 F&H approach.** Catalytic phase countries facing fragility and/or emergencies will be able to request time-limited support for routine immunisation vaccine procurement, critical technical assistance and vaccine and operational cost for outbreak response⁶. The funding for this is included in the 'Gavi Resilience Mechanism' (see shift 6).
- d. **Shift 5: Establish immunisation as humanitarian health practice.** The Alliance will enhance its collaboration with the humanitarian sector through key mechanisms, such as the Global and Country Humanitarian Health Clusters, to improve the coordination between Expanded Programme on Immunisation (EPI) efforts and humanitarian responses. Where appropriate, the Alliance will advocate for the inclusion of routine immunisation in these responses. Gavi will build on its ongoing collaboration with GPEI to amplify results. This is in-line with the PPC's recognition that engagement with humanitarian partners and global partners such as GPEI are critical to successfully reach and immunise children in fragile and humanitarian settings.
- e. **Shift 6: Create a dedicated 'Gavi Resilience Mechanism' (GRM).** When unforeseen needs arise, Gavi often relies on reallocating or reprogramming underspend which can cause critical delays in response times. To address this challenge, the Board provided guidance in December 2024 to establish a dedicated agile funding mechanism. The proposed GRM will swiftly respond to unforeseen needs including for i) Newly-arising needs in chronically fragile countries and sub-national pockets (see shift 4); ii) Emergencies including outbreak support not covered through existing mechanisms; iii) Settings requiring humanitarian programming (i.e. ZIP-like; see shift 3); and iv) Catalytic phase countries facing fragility or emergencies (see shift 4). The GRM will build on the Board-approved higher risk appetite under the FED policy and tolerate higher programmatic and financial risk to enable rapid responses. The total cost of the GRM is estimated at US\$ 405-415 million, entailing a reallocation of

⁴ Lower-middle income or IDA-eligible countries

⁵ Subnational fragile settings will have access to relevant FED flexibilities and ways of working, e.g., allow scope for implementing partners to over/underspend on budgets to more flexibly manage shifting needs

⁶ If strong rationale is provided, exceptional support possible for i) outbreak response support for countries in the catalytic phase not facing fragility or emergencies; or ii) For pre-emptive vaccination (vaccination to prevent anticipated outbreaks in emergency settings, e.g., pre-emptive measles campaign upon influx of displaced populations). This will align with the support for outbreaks provided by the International Coordination Group (ICG) for stockpile vaccines in humanitarian emergencies

US\$ 135 million from the previously presented Gavi 6.0 HSS funding (see Annex A).

- f. **Shift 7: Ensure a better equipped Gavi Secretariat.** The Gavi Secretariat will streamline policies, grant management processes and strengthen capacities⁷ to ensure it is equipped to navigate complex F&H settings.

3. Indicative costs and health impact

- a. **Significant impact is expected from the F&H approach in Gavi 6.0 with over 2.8-3.2 million lives saved.** The Gavi 6.0 strategy is expected to save 8-9 million lives, including ~2.4 million in fragile countries. An additional 0.4-0.8 million lives could be saved through the key shifts. The estimated cost for F&H settings in Gavi 6.0 is ~ US\$ 3.7-3.8 billion⁸, of which US\$ 485 - 575 million reflects the additional cost to fully deliver on the new ambition versus previous ways of working⁹. This includes US\$ 290-380 million not included in the indicative Gavi 6.0 strategic cost estimate in June 2024 (see Annex A to Doc 10).

⁷ This is part of the ongoing organisational review of Gavi Secretariat

⁸ Total costs of US\$ 3.7-3.8 billion have increased by ~ US\$ 370 million since the PPC paper due to external factors leading to updates in expected vaccine consumption and refer to the core cost of engaging in F&H settings. The updated costs are included in Gavi 6.0 'recalibration baseline' for discussion by Audit & Finance Committee at its meeting on 17 July 2025

⁹ Of the US\$ 485-575 million, US\$ 195 million was already included in the June 2024 Gavi 6.0 strategic cost estimate – of which US\$ 135 million for FED and ZIP like investments and US\$ 60 million for Diphtheria and Typhoid outbreak responses. The additional US\$ 290-380 million are also included in the latest Gavi 6.0 'recalibration baseline' (see above), taking the mid-point of the ranges in this paper