

## Annex C: Proposed innovation approach for Gavi 5.0

*This annex is an extract of Section 2 of the May 2022 PPC paper*

- 2.1 **Innovation in Gavi 5.0 will be defined as new products, practices and services that unlock more efficient and effective ways to accelerate countries' immunisation objectives in line with Gavi's mission.** Rather than a radical shift, the approach is an evolution of Gavi's existing innovation model and is intended to help accelerate progress towards reaching its ambitious strategic goals for Gavi 5.0 and beyond<sup>1</sup>.
- 2.2 **A Theory of Change describes how the innovation approach will contribute to Gavi's four strategic goals** including access to COVID-19 vaccines<sup>2</sup> (see Figure 1). The key expected outcomes of the innovation approach are to accelerate the restoration of routine immunisation, reach more zero-dose children, and help scale-up COVID-19 vaccination in an integrated way. This will be achieved using new products, practices, and services across priority programmatic areas at the country level. Gavi also expects innovations to increase the effectiveness, efficiency, and sustainability of immunisation programmes. An example of an innovation that helped improve programmes' effectiveness and efficiency is the eVIN<sup>3</sup> platform in India. eVIN was designed to record supply chain transactions and collect data on vaccine stock and storage temperatures up to last-mile health facilities and led to significant savings in vaccine utilisation (30%) and reduced stock-outs (by 40%)<sup>4</sup>. Building on eVIN and with Gavi support, the Government of India built a new tool, called CoWIN integrating the tracking of COVID-19 vaccine beneficiaries. Applied to routine immunisation, CoWIN could have a tremendous impact in reducing the number of zero-dose and under-immunised children.

---

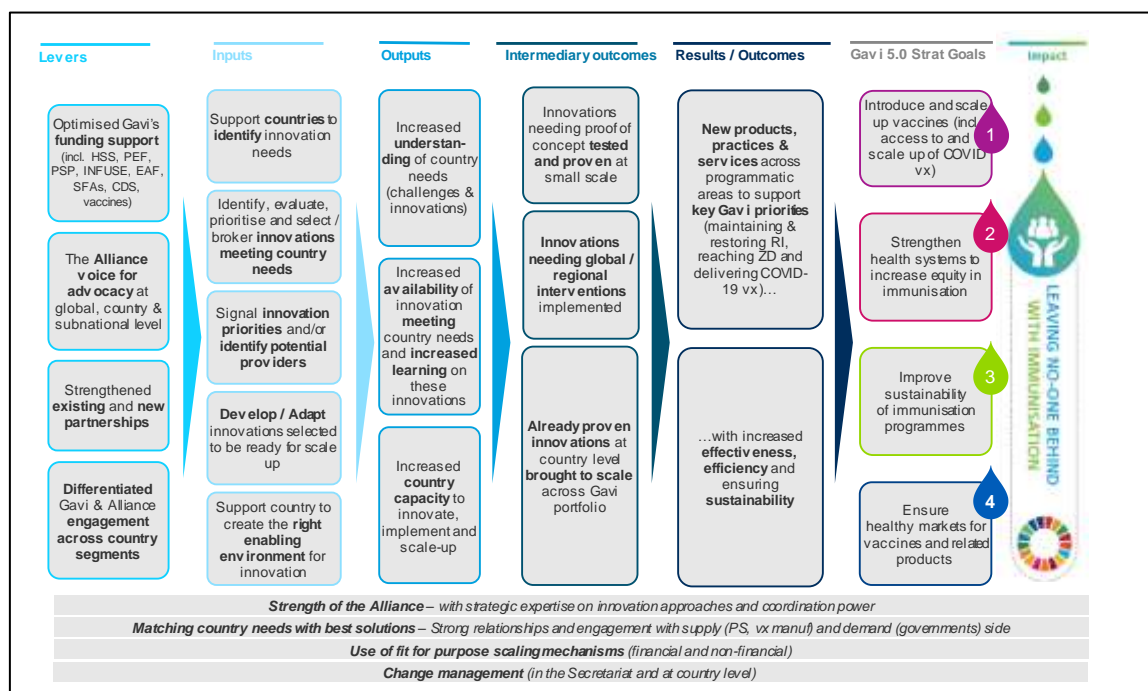
<sup>1</sup> Innovations linked to Gavi's operating model, policies, and processes are not part of this approach

<sup>2</sup> At its December 2021 meeting the Board reconfirmed that ensuring access to COVID-19 vaccines are part of the recalibrated Gavi 5.0 priorities

<sup>3</sup> Electronic Vaccine Intelligence Network

<sup>4</sup> eVIN 2018 Assessment report

Figure 1: Theory of Change for innovation approach in Gavi 5.0



2.3 To achieve these outcomes, Gavi will invest in three categories of innovations. These are described as intermediary outcomes in Figure 2 and detailed in section 2.5. Progress will be enabled by the Alliance through an increased understanding of country needs, increased availability of innovations to meet these needs and a higher country capacity to implement and scale up innovations. To get there, Gavi will – as all innovations will be grounded in country needs – support countries to identify innovation needs; select/broker innovations meeting country needs; signal innovation priorities to providers or identify providers; support development/adaptation of innovations where there are gaps; and support countries to create the right enabling environment for scaling up innovations. This will be fuelled by Gavi's main engagement levers including optimised funding streams that support innovations (e.g., HSS), the Alliance's voice to advocate at global, regional, and country levels, strengthening existing and new partnerships, as well as differentiating its focus and engagement across country segments.

2.4 Six key shifts vis-à-vis the Gavi 4.0 model will be needed to deliver on the Theory of Change. These address the lessons learnt from the previous strategic period as illustrated in

2.5

2.6

- 2.7 *Figure 2 below. While lessons learnt, including successes and failures, are described in more detail in Annex A, the shifts are detailed out in the following sections.*

*Figure 2: Overview of lessons learnt and associated shifts*

Lessons learnt	Associated shift in new approach
Different perceptions & understanding of <b>Gavi vision, positioning and risk appetite</b> within the Secretariat and across partners	Provide a <b>clear articulation of Gavi's role</b> along the innovation value chain
Supply and demand requires putting <b>country needs and perspectives first</b> , then looking for suitable solutions matching country requirements	Ensure <b>country needs</b> guide the identification and prioritisation of innovations
Gavi should focus on <b>specific programmatic priorities</b> where innovations are most needed to accelerate progress on 5.0 ambitious agenda	Focus innovations that <b>support specific programmatic priorities</b> , in line with Gavi's strategic goals, grounded in country needs
Need to launch <b>experimental innovations quickly</b> and have improved mechanisms for <b>testing, learning and iterating fast</b>	Establish a mechanism to <b>'try fast, iterate fast, learn fast'</b> for innovations needing proof of concept (category 1 innovations)
Scale-up of proven innovations at country level often <b>suffered from under-investment</b> with lack of ownership and sustainability over time.	Incentivise countries to <b>accelerate scale-up of proven innovations</b> and improve sustainability of these innovations
Management of innovation across the Secretariat was sometimes <b>fragmented</b> , with <b>lack of lessons learning</b> , cross-organisational coordination	Improve <b>end-to-end portfolio management of innovations</b> through better <b>assessment, monitoring, learning, coordination and decision making</b>

## 2.8 **Shift #1: Provide a clear articulation of Gavi's role along the innovation value chain**

2.5.1 **Gavi operates in an innovation environment alongside multiple other actors with different roles**, as described in Figure 3Error! Reference source not found.. Its comparative advantage lies in its ability to work with countries to surface their needs and signal those needs to shape the market, supplemented by its convening power among countries, partners, and providers across the innovation value chain. Gavi's other engagement levers (e.g., funding, advocacy, and the diverse set of partners in the Alliance), unique in their combination, support the adaptation of promising innovative solutions at country level, and most importantly, the work with countries to scale-up innovations.

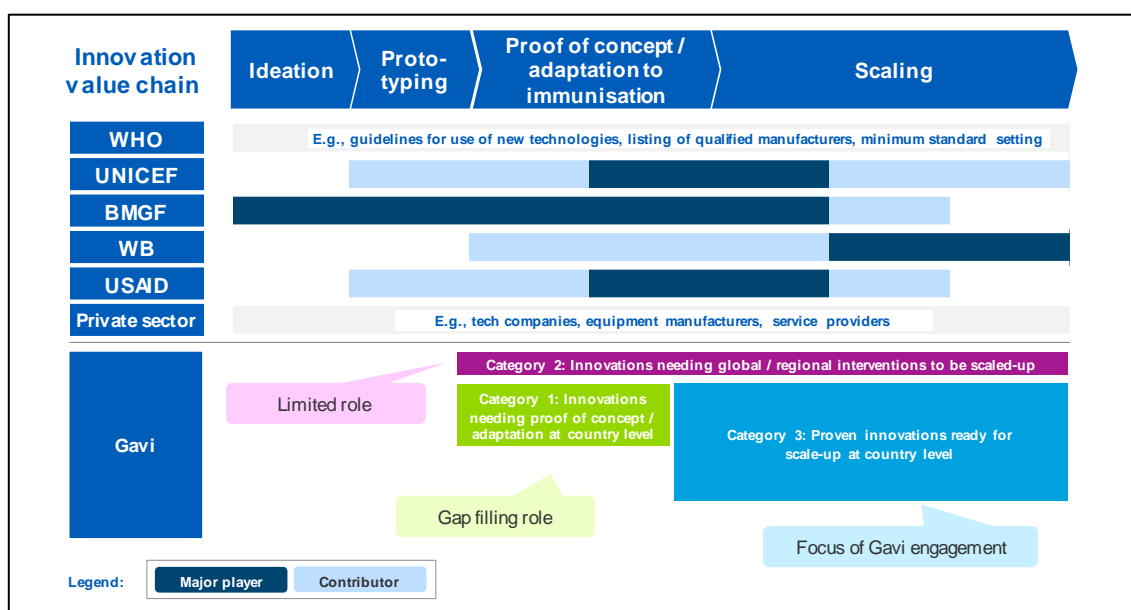
2.5.2 As introduced in section 2.3, within this environment and building on its comparative advantage, **Gavi will play a role in three categories of innovation situated across the innovation value chain** (see Figure 3):

- **Category 1: Potential 'breakthrough' innovations needing proof of concept/ adaptation at county level to address needs in Gavi-supported countries.** Gavi will have a limited gap-filling role to support maintenance of a healthy pipeline of potentially scalable innovations addressing country needs.

- **Category 2: Innovations needing global / regional interventions to enable scale up.** Similar to Gavi 4.0, the Alliance will make some investments into innovations requiring global and/or regional interventions to enable future scale up at country level.
- **Category 3: Proven innovations ready for scale up at country level.** This will be by far the largest focus of Gavi's investments.

Gavi's future positioning in the immunisation innovation landscape does not represent a major deviation from its current role, it rather delineates Gavi's focus more clearly.

*Figure 3: Positioning of Gavi and other key actors in the innovation value chain (non-exhaustive).*



*Note: the size of the three boxes in the Gavi line represents the relative weight of each category for Gavi's future focus<sup>5</sup>*

**2.5.3 Category 1 (innovations needing proof of concept / adaptation at country level):** Gavi will continue to play a limited role in testing and supporting proof of concept for innovations with scale up potential where there is a gap. This is critical to ensure that a healthy pipeline of potentially scalable innovations is maintained. Complementing other actors and based on a deep understanding of country needs (see section 2.6), it will signal to the market which types of innovations countries need most. Gavi would opportunistically fund the development of proof of concept for promising breakthrough innovations with scale up potential when a funding gap has been identified. A rigorous and systematic assessment of the effectiveness of new concepts will be essential to lay the groundwork for scale up. An example of an innovation in this category are remote temperature sensor technologies. Based on the evidence that remote sensor technology, coupled with data analytics and human-centred design can reduce the freezing of vaccines, the INFUSE platform mobilised private capital to fund a nationwide rollout of remote temperature monitoring in

<sup>5</sup> The future indicative split of investments between categories would be approximately ~15% (cat. 1), ~15% (cat. 2), ~70% (cat. 3)

Tanzania, through Nexleaf Analytics. Based on this experience as well as a deeper understanding of the technology and its use-case, it has since then been deployed in Kenya and Mozambique. These learnings enabled INFUSE to also support another remote temperature sensor organisation, Parsyl, thereby diversifying supplier base. Category 1 innovations require a higher risk appetite than other Gavi investments and will continue to be mainly funded through INFUSE and a subset of Private Sector Partnerships.

**2.5.4 Category 2 (innovations needing global / regional interventions to enable scale up):** Some innovations require global and/or regional interventions to enable future scale up at country level. Gavi will continue to play a role in this category. This includes convening actors around ways to shape markets for new health technology products. An example of this is the Vaccine Innovation Prioritisation Strategy (VIPS)<sup>6</sup> which evaluated, prioritised vaccine product innovations and now drives these innovations forward. Since its inception, VIPS has transitioned to develop and implement roadmaps for each of the three prioritised innovations to accelerate their availability and future uptake in L(M)IC. An example of the VIPS innovations is bar coding, where global convening and market shaping are needed to develop a fit-for-purpose technology solution before scaling up widely in Gavi-supported countries (please see Appendix 2 for an update on VIPS). Moreover, Gavi will continue to support global or regional standards setting, guidance and technical support to enable future innovation scale-up at country level through a subset of more experimental and transformative PEF SFA investments<sup>7</sup> (see agenda item 3 on how PEF SFA is pivoting to support its objectives more effectively). Examples for PEF SFA investments include setting standards and piloting methods to target subnational populations and missed communities through digital immunisation microplanning.

**2.5.5 Category 3 (proven innovations ready for scale-up at country level):** Finally, building on its history and unique positioning as the main funder for scaling up immunisation interventions, the Alliance will focus on scaling up clearly defined, pre-existing, mature innovations in Gavi-supported countries. The Alliance will use various levers to enable scale-up of proven innovations in country, including advocacy, technical assistance (PEF TCA), and funding (HSS, Equity Accelerator Funding (EAF), CCEOP, COVID-19 vaccine Delivery Support (CDS)). Past examples of innovations that Gavi helped to scale up include geospatial identification of missed communities, and real time planning and monitoring for immunisation campaigns. COVID-19 has also accelerated the roll-out of innovations: for example, DHIS2 surveillance modules for COVID19 have been scaled up in more than 40 countries in a few weeks at the start of the pandemic based on the routine VPD surveillance module, when it used to take several years to modernise information system. The delivery of COVID-19 vaccines was also made possible by an unprecedented scale up of new Ultra Cold Chain equipment in more than 45 AMC countries, allowing them

<sup>6</sup> VIPS has prioritised three innovations (micro-array patches, heat stable and controlled temperature chain qualified vaccines, and barcodes) to better meet country needs and help reach zero-dose children. It is now defining and implementing strategies for each innovation.

<sup>7</sup> SFAs include zero-dose, demand & vaccine hesitancy, gender, civil society engagement, leadership/management/health workforce performance, sustainable financing for immunisation, comprehensive vaccine management, vaccination targeting, measurement & learning.



to use mRNA vaccines. Integrating innovations from the COVID-19 response within routine immunisation offers additional opportunities for impact.

## 2.9 **Shift #2: Ensure country needs guide the identification and prioritisation of innovations**

**2.6.1 Gavi will systematically engage with countries and Alliance partners to surface, understand, and signal country needs.** Country needs encompass both the understanding of specific immunisation related challenges that could be solved through innovative approaches as well as specific innovation asks from countries. To surface these needs, Gavi will leverage both pre-defined touchpoints with countries such as the Full Portfolio Planning (FPP) process for Gavi support, the annual Gavi Joint Appraisals in Gavi-supported countries and other touchpoints as needed (for example, dedicated workshops or surveys, other existing country and partner processes, leveraging their presence on the ground). This will include engagement at different levels of government (from EPI manager to leadership level), within the Alliance and with a broader set of stakeholders such as Civil Society Organisations. The engagement will focus primarily on critical countries with significant impact on Gavi 5.0 goals including but not limited to those in the High Impact and Fragile & Conflict segments.

**2.6.2 Understanding country needs and identifying associated innovative solutions will be an iterative process between countries, Alliance partners, the Secretariat, and the providers.** Needs surfaced will be captured on an on-going basis across the portfolio and inform the prioritisation of investments across the various Gavi funding streams used for innovation. The identification and understanding of country needs will be the pre-requisite to prioritise those innovations that support specific programmatic priorities in line with Gavi's strategic goals (see section 2.7).

## 2.10 **Shift #3: Focus on innovations that support specific programmatic priorities in line with Gavi's strategic goals, grounded in country needs**

**2.7.1 Desk review of country reports<sup>8</sup> and engagement with country representatives and Alliance partners have shown strong country demand for innovations,** for example for new technologies to identify and reach zero-dose children. Based on these needs, Gavi has consolidated seven focus areas. The prioritised areas will contribute to reaching Gavi's strategic goals, and more particularly its ambition to maintain and restore routine immunisation, accelerate the identification, and reach of zero-dose children and missed communities, the integrated delivery of COVID-19 vaccines, as well as enhancing the efficiency of immunisation programmes. They include improving vaccine products, optimising supply chain, improving service delivery, building vaccine confidence, improving health workforce performance, Digital Health Information and addressing gender-related barriers.

**2.7.2 The focus areas will be refined and further prioritised** as country needs are regularly surfaced to provide a sharp, limited set of sub-topics which Gavi's investments will focus on (see section 2.6 on how needs are surfaced). This exercise has already been completed for VIPS which has identified country

<sup>8</sup> Includes reports from Joint Appraisals, Independent Review Committee meetings, Multi Stakeholder Dialogues

needs for product improvements and prioritised three innovations to meet those needs: micro-array patches, heat stable and controlled temperature chain qualified vaccines, and barcodes (see section 254). Similar work has been launched for Digital Health Information, defining three cross-country priorities: identification and reaching zero-dose children with digital tools, digital supply chain information and real-time planning and monitoring of immunisation campaigns. Annex B includes a first draft of prioritised innovation areas.

**2.11 Shift #4: Establish a mechanism to ‘try fast, iterate fast, iterate fast’ for innovations needing proof of concept / adaptation at country level (‘category 1’ innovations)**

**2.8.1 As laid out above, Gavi-supported countries have historically demonstrated strong interest to implement proven innovations to strengthen their immunisation programmes.** However, the global health community has not always been able to meet this demand with proven innovations ready to scale for multiple reasons, one being a lack of a systematic approach to rapidly test, learn and generate evidence for the effectiveness of innovation pilots. Therefore, many innovations have not progressed beyond pilot stage.

**2.8.2 In 2016, Gavi launched INFUSE to improve vaccine delivery systems by connecting potential high-impact innovations with the countries that need them most to proof the concept.** Focusing on scale-ready solutions with strong potential but requiring proof of concept in the immunisation space, the most promising innovations were selected as ‘INFUSE Pacesetters’ to receive Gavi and partner support. Consultations led over the past months surfaced that the INFUSE mechanism has potential to strengthen its grounding in country needs, the selection and interaction with ‘first mover’ countries, to test innovations needing proof of concept more quickly, and that it could provide stronger monitoring and evaluation during implementation to better learn from successes and challenges, stop interventions or build pathways to scale.

**2.8.3 Building on its experience, its community, and its recognised track record, Gavi will strengthen INFUSE improving its ability to ‘try fast, iterate fast, learn fast’** and be the main funding mechanism for ‘category 1’ innovations alongside Private Sector Partnerships (INFUSE 2.0). In collaboration with partners and countries, INFUSE 2.0 will evolve into a platform to transform how countries and innovators connect needs to solutions. It will focus on three main activities:

- Identify, adapt, and expand existing innovations that require proof of concept / adaptation to immunisation and respond to the pre-identified needs and priorities (see sections 2.6 and 2.7);
- Create a platform for matching catalytic support with the most promising innovations and ‘first mover’ countries having a clear need and demand to test these innovations; and

- Accelerate its learning approach through the identification of a few assessment criteria and learning questions that can be easily and regularly monitored to take 'stop or go' decisions for innovations quickly

**2.8.4 To further improve Gavi's ability to flexibly and rapidly invest into potential high impact 'category 1' innovations, INFUSE 2.0 will add a catalytic funding stream of not more than US\$ 20 million for Gavi 5.0.** This will build on the critical role that risk-tolerant and flexible capital has had in the innovation environment. Operationalising the new stream will be grounded in new partnerships with strategic investors, bringing external expertise and capacity, with new funding sourced from both public and private donors.

**2.12 Shift #5: Incentivise countries to accelerate scale-up of proven innovations and improve sustainability of these innovations**

**2.9.1 Scaling-up proven innovations will be at the heart of Gavi's innovation approach.** Historically, countries have continuously expressed significant interest to Gavi in scaling up proven innovations. They have included for example, remote temperature monitoring to reduce stock wastage, innovative capacity building, geospatial tools, and most recently COVID-19 response innovations such as ultra-cold chain equipment, and electronic information system to report and manage adverse events following immunisation (AEFI). However, they have not always prioritised this in programming Gavi funding. In addition to the challenges in demonstrating 'proof of concept' of innovations including the health and economic value add (see section 2.8), this was driven by concerns about the potential risks of failure, competing priorities within a limited funding envelope and deficits in the enabling environment at country level to sustain innovations (see Annex A for more details). While Gavi's new programme funding guidelines have already shifted towards encouraging countries to invest into scaling up proven innovations<sup>9</sup>, this will not resolve the funding gap, ownership and sustainability issues limiting scale up.

**2.9.2 To provide additional funding for countries interested in scaling up critical innovations, the Board is asked to approve US\$ 50 million in additional funding for HSS in Gavi 5.0 in addition to the existing HSS envelope of US\$ 1.2 billion.** This additional HSS funding could be accessed by all Gavi-eligible countries on a needs' basis when sufficient HSS to support their innovation priorities is not available. To access this additional funding for innovation, countries would have to demonstrate clear needs and strong commitment in specific innovations. Countries would be strongly encouraged to co-invest parts of their HSS or other domestic or donor funding to demonstrate ownership of the innovation and increase its sustainability. The additional amount would depend on country context, with guardrails potentially ranging from 5% of the HSS ceiling for larger countries up to 15% for smaller countries. The funding would be exclusively used for innovations that have proven their scale-up potential and meet country needs, for example eLMIS solutions, or ensuring that the enabling environment at country level is fit-for-purpose (e.g., technical support and capacity). This mechanism would be accompanied by a learning agenda to understand the demand from countries

<sup>9</sup> [https://www.gavi.org/sites/default/files/support/Gavi\\_Programme\\_Funding\\_Guidelines.pdf](https://www.gavi.org/sites/default/files/support/Gavi_Programme_Funding_Guidelines.pdf)



to access it and its relevance for supporting scale up of proven innovations (see section 2.10 and Annex C). This is the only recommendation for approval for this PPC meeting that entails an additional investment need. As per the latest financial forecast to be reviewed by the AFC at its May 10<sup>th</sup> meeting, US\$ 247 million will remain available for future investments for Gavi 5.0.

**2.9.3 To further increase country ownership the Alliance will be more deliberate in its dialogue with countries to match their needs with proven solutions** (see section 2.6 for country touchpoints to do so). This will include data-driven dialogues on the effectiveness of proven innovations as part of its broader engagement with country governments on promoting domestic public resources for health<sup>10</sup>.

**2.13 Shift #6: Improve end-to-end portfolio management of innovations through better assessment, monitoring, learning, coordination, and decision making**

**2.10.1 At a portfolio level: Gavi's innovation approach will be monitored through a results framework and an associated learning agenda.** The results framework will assess progress of specific indicators at each step of the Theory of Change. Through the learning agenda, lessons learnt across the innovation portfolio will be captured and used to continuously improve the implementation of the overall innovation approach. Annex C provides more details on the draft results framework and draft learning questions.

**2.10.2 At the level of individual innovations: an investment framework comprising of a set of criteria common to all innovations accompanied and tailored indicators will be used to assess potential impact, maturity, and feasibility.** The framework will serve as a basis for 'go' investment decisions on new innovations with an initial priority on category 1 (see section 2.8), enabling improved comparison across the portfolio<sup>11</sup>. To accelerate the learning approach and allow for rapid 'stop' or 'continue' decisions, it will also be used to swiftly monitor implementation progress alongside additional process indicators (see annex C for the draft framework).

**2.10.3 An internal oversight group composed of Gavi leadership team members will guide and coordinate the innovation approach across Secretariat teams.** Supported by a small central coordination function (see section 3.1), the group will conduct periodic progress reviews at portfolio level applying the results framework and learning agenda and ensure that the innovation approach is adjusted accordingly. In addition, it will keep track of the consolidated country needs, and review the innovation priorities on an ongoing basis.

**2.10.4 Investment decisions in categories 2 and 3 will continue to be guided by the existing independent mechanisms<sup>12</sup>. In addition, independent experts will guide category 1 investments<sup>13</sup>.** They will rapidly validate investment

<sup>10</sup> The 'Gavi Innovation Catalogue' (see appendix 3) launched in 2020 is a first tool enabling to go into that direction.

<sup>11</sup> A rollout to the full innovation portfolio will be considered as the approach is implemented

<sup>12</sup> For example, in accordance with the Programme Funding Policy, the IRC recommends decisions for allotting funding for HSS, EAF and PEF TCA (category 3), and the Partnerships Team for SFA (category 2) to the Gavi Secretariat

<sup>13</sup> Dedicated pool of experts to build on existing INFUSE advisory group and its members

decisions for innovations in this category by making recommendations to the Gavi CEO as and when needed. They will include external technical innovation experts with a strong understanding of country realities and needs, innovation leaders and Board or Board committee members with a strong innovation background. The experts will also provide advice on potential investment priorities to the internal oversight group, contribute to sourcing innovations, and give feedback on successes, failures, and potential adaptations of specific innovations.

**2.10.5 Regular updates on the implementation of the innovation approach will be brought to the PPC for discussion** twice during the strategy period (including on the activities of the independent mechanisms).

**2.14 The innovation approach is fully aligned with the Private Sector Engagement Strategy approved by the Board in December 2021.**

**2.11.1 As outlined in the Private Sector Engagement Strategy, innovation is broader than private sector and private sector is broader than innovation.** Yet, an overlap exists between the two approaches. Private sector investments, along with INFUSE 2.0, will remain a critical funding lever for innovation particularly for category 1 (see sections 2.8). Similarly, innovation is a core component of Gavi's Private Sector Engagement Strategy.

**2.11.2 Hence, for where they intersect, both approaches have been fully aligned with similar principles.** Both approaches are grounded in country needs (see section 2.6) and cover the same investment priorities (see section 2.7) with the objective to accelerate the reach of Gavi 5.0 strategic goals. In addition, a joint mechanism to manage the portfolio of innovations will be used for the overlap between the two approaches. Existing Secretariat advisory / decision making groups will be streamlined and integrated (see section 2.10).