

## Healthy Markets Framework

The Healthy Markets Framework (HMF) is a key strategic tool developed by Alliance partners in 2015 to enable a clear and consistent definition of what constitutes market health. The main aims of the HMF were to: (i) have a common way of thinking about market health; (ii) better communicate how the Alliance assesses individual markets; and (iii) improve how potential trade-offs between different market elements are analysed.

Based on experience from Gavi 4.0, the HMF has been regarded by Alliance partners and wider stakeholders as being an important first step in taking a comprehensive perspective towards identifying market issues and solutions. Learnings from 2016-2020 have also identified the key limitations of the HMF:

- Need for more formalised representation of demand
- Ambiguity in assessing the individual market attributes
- Lack of clarity on the inclusion of innovation
- Limited applicability of predefined attribute priority level for some markets
- Measure of progress does not take into account individual market needs

The HMF is updated to address the above limitations and to align with the Gavi 5.0 market shaping priorities. Additionally, as part of Gavi's regional manufacturing strategy the HMF was updated in 2024 to include a new dimension on the degree to which regional diversification across suppliers mitigates geopolitical and health security risks in each market.

## Healthy market attributes reflecting market shaping priorities

The new iteration of the HMF is designed to represent the three market shaping priorities by aligning healthy market attributes with the priority pillars, thus ensuring market health considerations reflect Gavi's objectives for the 2021-2025 period. Updated HMF attributes capture market conditions from demand health, supply dynamics, and innovation perspectives. Additionally, a fourth dimension has been added in 2024 on geopolitical and regional diversity risk.

The addition of demand health attributes is a key change for the new HMF iteration, and allows the framework to be more comprehensive by also identifying market challenges rooted in demand side dynamics. While attributes pertaining to supply dynamics and innovation already existed in the previous iteration, they have been reframed to better reflect the concept of supplier sustainability and to clearly align with Gavi's overall 5.0 innovations strategy. These updates also address some of the key limitations identified through 4.0 lessons learned.

In December 2022 the Gavi Alliance Board approved a four-pillar **regional manufacturing strategy** to support strengthening vaccine supply resilience at regional levels. Pillar 2 of the strategy sought to adapt the HMF and Gavi's Product Menu Criteria to facilitate the listing and adoption of new regional products. This strategic priority was implemented by adding a new dimension to the HMF on geopolitical and health security exposure. Within this dimension, a new HMF attribute was defined on **geopolitical and regional diversity risk**, defined as "the degree to which regional diversification across suppliers mitigates geopolitical and health security risks".

## Detailed HMF attributes and attribute drivers

| HMF Criteria   | HMF Attributes   |   | Market Rationale   |   |
|--|--|---|--|---|
| Demand health  | Materialisation of demand  | The degree to which country introductions and campaigns materialise   | Global disease management (and CCE) guidelines   | Do Global guidelines (i.e. vaccination strategy / schedule guidelines, SAGE recommendations, CCE guidelines) & their timeliness support demand materialisation and/or predictability? |
|  |  | Predictability of demand  | The degree to which both the quantity and timing of demand can be accurately predicted and sustained by countries  | Donor funding policies and processes  |
|  | Balanced demand of appropriate products & timely uptake of new innovative products   |   | The degree to which country product choices are data-driven, value-based; leading to balanced demand for appropriate products & timely uptake of new innovative products | Country capacity to effectively prioritise across vaccines and public health interventions  |
|  |  | Country regulatory system functionality & harmonisation   |  | Do regulatory process inefficiencies impact demand materialisation (due to delayed access to vaccines/products)?  |
|  |  | Country availability and sustainability of funding for vaccine/CCE programmes   |  | Do country funding availability or sustainability issues impact (or are they expected to impact) demand materialization or predictability over time?                                  |
|  |  | Country capacity to effectively plan and implement introductions/campaigns  |  | Do countries have sufficient capacity to effectively implement program (disease/CCE) strategies/ guidelines/ decisions?   |
|  | Capacity to accurately forecast needs and demand dynamics over time  | Are country forecasting capacities sufficient to predict future demand for products (antigens / presentations / CCE)? Are global demand forecasts well coordinated? |  |   |
|  | Country capacity to effectively assess value of product choices & implications   | Do countries have sufficient capacity to make evidence-based product choice decisions (intro/switch), based on available data and rational considerations?          |  |   |
| Country willingness to use and pay for available products (including appetite to consider switching) | Is there political will to implement evidence-based product switch or introduction decisions, and pay for value-add innovations? Are there other factors or stigmas impacting usage (e.g., origin of vaccine, vaccine hesitancy, national policies, or religious beliefs)? |   |  |   |
| Supply dynamics  | Market sustainability & attractiveness   | The degree to which the market remains sufficiently attractive for incumbent suppliers to remain or for new suppliers to enter                                      | Potential market size  | Is the maximum potential market size, independent of current supplier landscape, attractive for incumbent and new entrant suppliers?  |
|  |  |   | Long-term incentives   | Does the market present sufficient incentives, given its current supplier and pipeline landscape, to keep incumbent and attract new entrant suppliers?                                |
|  |  |   | Sustainable competition  | Is the supplier competitive dynamics sufficient and can it be sustained for the long-term?  |
|  | Regulatory / NRA risk  | The magnitude of risk that doses cannot be released or exported from the country of production  | Policy & legislation   | Does the country of production have laws that allow the export of doses produced in the country and have a positive track record of lot releases?                                     |
|  |  |   | NRA risk   | Are NRAs functional with low risk of changing status due to technical or political reasons?   |

| HMF Criteria                             | HMF Attributes                            |  | Market Rationale                            |  |
|--|---|--|---|--|
| Supply dynamics<br><i>(continued)</i>    | Supplier base risk                        | The magnitude of risk that a supplier will be unable to supply expected doses  | Supplier diversity                          | How concentrated is the market's supplier base (for fill/finish and bulk sourcing)?  |
|  | Meeting country product preference        | The degree to which available supplies can meet countries' product choices   | Supplier technical risk                     | Do suppliers have strong technical capabilities with low track record of production interruptions or shipment delays?                                  |
|  | Supplier sustainability                   | Are suppliers' overall business across their portfolios viable?  | Supplier sustainability                     | Are suppliers' overall business across their portfolios viable?  |
| Supply meets demand                      | Meeting country product preference        | The degree to which available supplies can meet countries' product choices   | Products meeting country programmatic needs | Are the characteristics of available products programmatically suitable for countries?   |
|  | Supplier sustainability                   | Are suppliers' overall business across their portfolios viable?  | Buffer capacity                             | Are there additional supply available to meet unforeseen increase in demand or decrease in supply?   |
|  | Supply meets demand                       | The degree to which the overall supply can meet total forecasted demand  | Global demand level                         | Is supply sufficient to meet demand at the global level, including non-Gavi MICs and HICs?   |
| Innovation                               | Incentivising & Scaling Up Innovations    | The degree to which ongoing innovations address countries' unmet needs and may be adopted by countries in the future | Meeting Gavi demand                         | Is the volume of doses offered to Gavi supported countries $\geq$ the volume of demand required by Gavi supported countries?                           |
|  |   |  | Clear pathway to country uptake             | Is the pathway to country uptake for the innovations is clearly defined? (e.g., SAGE policy, procurement / financing mechanism, introduction pathway)? |
|  |   |  | Clear public health value / impact          | Do innovations provide a clearly articulated public health value / impact, i.e., expected benefits / trade-offs?                                       |
| Geo-political & health security exposure | Geo-political and regional diversity risk | The degree to which regional diversification across suppliers mitigates geopolitical and health security risks       | Clear country needs                         | Do innovations in the pipeline address clear country needs not met by available products?  |
|  |   |  | Regional diversity                          | Does the market have a high degree of regional diversification for drug substance limiting geographical supply security exposure?                      |

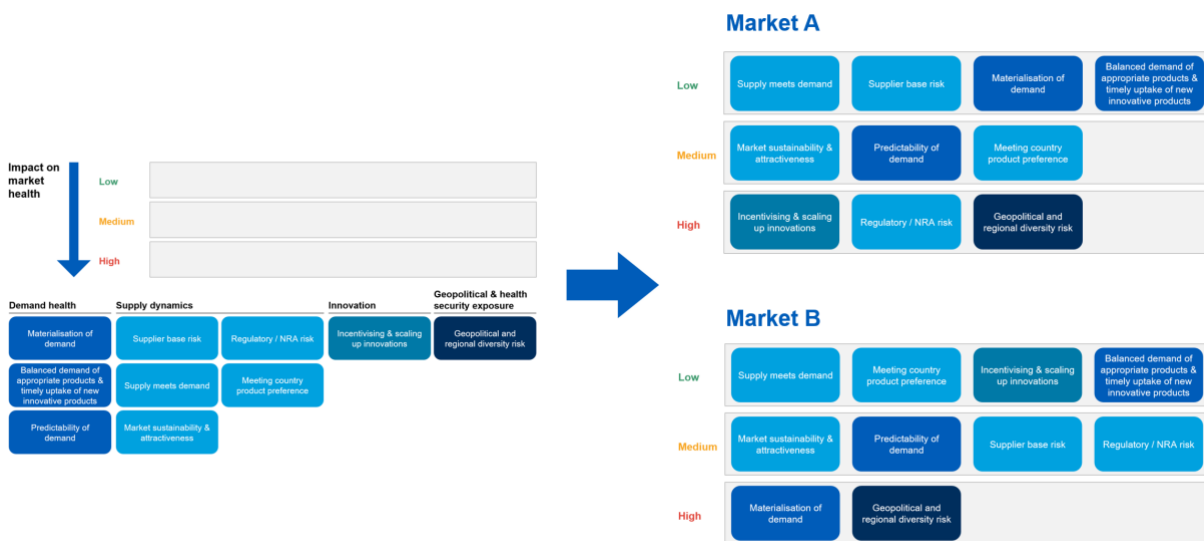
## Diversity of market conditions that define market health

Vaccine markets evolve along different trajectories, and the markets that Gavi operates in are in varying stages in their evolution towards market maturity. Different types of markets (e.g., routine versus outbreak vaccine markets) will also vary in their conditions and needs, even when in the same stage of market maturity.

In order to provide the flexibility needed for a single framework to capture the nuances of different market types and market maturities, attributes may be assigned different priority levels specific to each market.

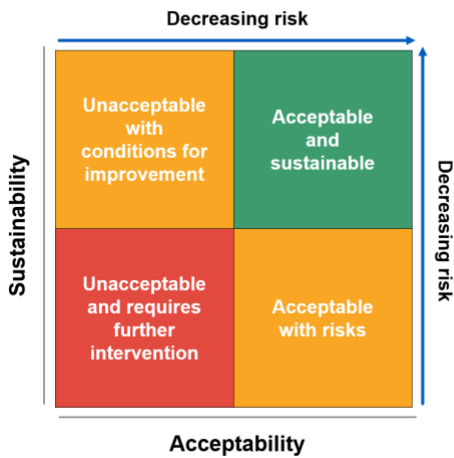
The flexibility in structuring market attributes by level of impact on market health allows the HMF to clearly signal within the context of specific markets the level of relative importance of each attribute and associated challenges that may require market interventions.

### Illustrative examples of potential market-specific HMF structures



Indicators of market health have also been redefined based on acceptability of market conditions and risks, so a portfolio view of all markets within which Gavi operates can better communicate the relative health amongst markets.

Updated market health categories



**Unacceptable and requires further intervention**

- Majority of high and medium impact attributes are unmet
- No improvement is expected without further Alliance intervention

**Unacceptable with conditions for improvement**

- Majority of high and medium impact attributes are unmet
- Improvements possible and expected with lead time to materialise

**Acceptable with risks**

- Majority of high and medium impact attributes are fully met or partially met
- Interventions are required to mitigate risks

**Acceptable and sustainable**

- Majority of high and medium impact attributes are fully met or partially met
- Monitoring required to ensure risks to not increase