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[6]:

- Need for more formalised representation of demand
- Ambiguity in assessing the individual market attributes
- Lack of clarity on the inclusion of innovation
- Varying applicability across markets
- Masking of variability in health and progress across markets

The HMF is updated to address the above limitations and to align with the Gavi 5.0 market shaping priorities.

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.

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 the other attributes 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.

Detailed HMF attributes and attribute drivers

| HMF Attributes			Drivers	
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) and their timeliness support demand materialisation and/or predictability?
			Donor funding policies and processes	Do donor funding policies, guidelines, processes and decision/approval timelines impact demand materialization and/or predictability?
			Country capacity to effectively prioritise across vaccines and public health interventions	Do countries have sufficient capacity to make vaccine introduction prioritisation decisions, based on available data and considerations appropriate to their context?
	Predictability of demand	The degree to which both the quantity and timing of demand can be accurately predicted and sustained by countries	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?
	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	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)?

HMF Attributes			Market Rationale	
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?
	Geopolitical & regulatory 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?
	Supplier base risk	The magnitude of risk that a supplier will be unable to supply expected doses	Supplier diversity	Does the market overly rely on specific suppliers for fill/finish or bulk capacity?
			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?
	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?
			Buffer capacity	Are there additional supply available to meet unforeseen increase in demand or decrease in supply?
	Supply meets demand	The magnitude of risk that a supplier will be unable to supply expected doses	Global demand level	Is supply sufficient to meet demand at the global level, including non-Gavi MICs and HICs?
			Meeting Gavi demand	Is the volume of doses offered to Gavi supported countries ≥ the volume of demand required by Gavi supported countries?

HMF Attributes			Market Rationale	
Innovations	**Incentivising & Scaling Up Innovations**	The degree to which ongoing innovations address countries' unmet needs and may be adopted by countries in the future	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?
			Clear country needs	Do innovations in the pipeline address clear country needs not met by available products?

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.

Illustrative examples of potential market-specific HMF structures
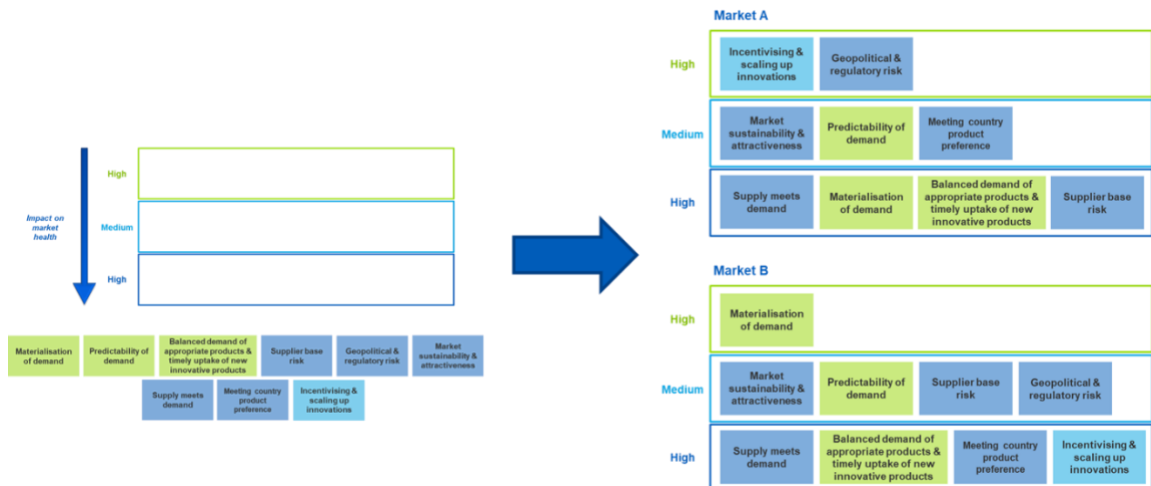
The flexibility in attribute structure allows the HMF to clearly signal within the context of specific markets whether market challenges are detrimental to market health and require urgent intervention or are within the limits of acceptable risks and thus require no intervention. Market health categories 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.

<u>Unacceptable and requires further intervention</u>:
- Majority of high and medium impact attributes are unmet
- No improvement is expected without further Alliance intervention

<u>Unacceptable with conditions for improvement</u>:
- Majority of high and medium impact attributes are unmet
- Improvements possible and expected with lead time to materialise

<u>Acceptable with risks</u>:
- Majority of high and medium impact attributes are fully met or partially met
- Interventions are required to mitigate risks

<u>Acceptable and sustainable</u>:
- Majority of high and medium impact attributes are fully met or partially met
- Monitoring required to ensure risks to not increase

Updated market health categories