

INTERNAL AUDIT REPORT

Processes related to Market Shaping
October 2020



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Conclusion

Our audit procedures were designed to provide assurance to management and the Gavi Board on the design and operating effectiveness of the key controls in the processes related to Market Shaping in order to ensure sufficient and secure supply of innovative, quality vaccines at appropriate and sustainable prices.

Market shaping is one of Gavi's strategic goals with four main strategic objectives in the 2016-2020 period, i.e. to achieve moderate or high levels of healthy markets dynamics in six markets; ensuring adequate and secure supply; reducing prices to an appropriate and sustainable level; and incentivising development of suitable and quality products (innovation). Market shaping activities include vaccines and other immunisation products such as Cold Chain Equipment (CCE). To achieve these objectives, Gavi works closely with key alliance partners and vaccine manufacturers.

We assessed the design and operating effectiveness of key controls relating to the Market Shaping process and concluded that internal controls, governance and risk management practices are adequately designed and generally well implemented. However, some medium risk rated issues were identified that may present a moderate risk to the achievement of the objectives some of which are summarised below.

Summary of Key Audit Findings

Ref	Description	Rating*
Supply and Procurement Strategy		
1.1	There is need to enhance the definition of some of the strategic goal indicators	
Memorandum of Understanding (MoU) between Gavi and the Procurement Agency		
1.2	There is need to review Gavi's authority as defined in the MoU and strengthen the Secretariat's oversight during implementation	
Implementation and monitoring of the vaccine supply and procurement roadmaps		
1.3	Improvement is required in documenting progress of the roadmap action plans	
Policies and procedures		
1.4	There is need for documented standard operating procedures for market shaping processes and activities	

** The audit ratings attributed to each section of this report, the level of risk assigned to each audit finding and the level of priority for each recommendation, are defined in annex 2 of this report.*

1. Summary of findings

Through our audit procedures, we have identified four medium risk issues relating to the Market Shaping process as summarised below.

1.1 Supply and Procurement Strategy

There is need to enhance the definition of some of the strategic goal indicators

A monitoring framework has been developed as part of the supply and procurement strategy (2016-2020). The framework consists of strategic and operational indicators to measure progress in the achievement of the objectives defined in the strategy. There are currently four strategic goal indicators in the framework: healthy markets dynamics; sufficient and uninterrupted supply; change in vaccine price; and innovation. According to the strategy, the Alliance was supposed to integrate into its roadmaps the milestones towards limiting market shaping interventions to active procurement only (objective 4.1). However, there was no indicator defined for monitoring performance against this key objective. Additionally, we noted that there is room for improvement in the definition of the Healthy Markets dynamics indicator (measures the 'number of Gavi vaccine markets with moderate or high levels of healthy market dynamics (HMD) as measured through the Healthy Markets Framework') and Sufficient and uninterrupted supply indicator (measures the 'number of Gavi vaccine markets with sufficient and uninterrupted supply of appropriate vaccines').

In our opinion, the definition of the two indicators could be enhanced to consider a stabilisation period in the vaccine market before it is regarded as having achieved the target. For instance, the vaccine market should achieve and maintain the desired state consistently for a period of more than one year to qualify. Through our audit procedures, we observed cases where a vaccine market which had sufficient and interrupted supply in one year failed to meet one of the criteria in the next year e.g. in the Rota and HPV markets.

1.2 Memorandum of Understanding (MoU) between Gavi and the Procurement Agency of Vaccines and vaccine-related supplies and cold chain equipment and associated services

There is need to review Gavi's authority as defined in the MoU and strengthen the Secretariat's oversight during implementation

Management should consider reviewing the terms of the current MoU which was signed between Gavi and the Procurement Agency in March 2016 to give Gavi more authority in decision-making during the procurement process.

In addition, the MoU states that the parties would, within three months of the effective date of the MoU agree on a set of KPIs for each party in the implementation of the memorandum. The parties are supposed to undertake annual consultations in the first quarter of each calendar year to review performance. However, we were not provided with the agreed KPIs and evidence of performance monitoring. There is no specific individual within Gavi who has been tasked with the responsibility of monitoring the Procurement Agency's compliance with the defined reporting requirements.

1.3 Implementation and monitoring of the vaccine supply and procurement roadmaps

Improvement required in documenting progress of the roadmap action plans

We noted inconsistencies in documentation of the progress on the roadmap action plans and interventions. These relate to: delays in updating the status of the interventions, i.e. whether completed, delayed, etc; documentation of supporting explanations for the status of the interventions, for instance where they were not completed or delayed; independent review; and updating the online action plan tool with new interventions identified in the course of implementing the roadmaps. There is therefore need to enhance accountability by ensuring adequate and timely documentation of the progress of the interventions and other relevant information.

1.4 Policies and procedures

There is need for documented standard operating procedures for market shaping processes and activities

We noted that there were no consolidated documented operating procedures for the market shaping processes and activities, including comprehensive roles and responsibilities. Some of the processes and roles had been documented but were disaggregated in various documents and were not comprehensive. There is need to ensure that processes are comprehensively documented and consolidated in standard operating procedures manual for the team.

2. Background

Market shaping activities are guided by a supply and procurement strategy which is developed for each strategic period in alignment with the overall Gavi strategy and the vaccine and investment strategy. The 2016-2020 supply and procurement strategy has identified three main priorities which include: healthy markets; taking a long-term view of the market; and innovation. The scope included the 11 Board-approved antigens and other immunisation products, specifically cold chain equipment. Gavi works closely with the alliance partners who have various roles in the process to facilitate achievement of the objectives.

Supply and procurement roadmaps are developed for each vaccine market with an analysis of the market, prioritised objectives, target outcomes in each of the four strategic areas, action plans and planned interventions. The roadmaps inform the Procurement Agency's procurement strategies which inform tender planning and award decisions. The designated procurement agency leads and manages the procurement process, including contracting with the vaccine manufacturers. The Procurement Agency operates under a framework governed by a Memorandum of Understanding (MoU) signed with Gavi in March 2016 for this strategic period.

A monitoring framework was developed as part of the 2016-2020 supply and procurement strategy and consists of strategic goal and process indicators and targets for the period. As at 31 December 2019, two of the strategic goal indicators were on track while the other two had not been met. Sufficient and uninterrupted supply was achieved in eight out of a target of 11 markets while the healthy markets dynamics was met in three out of six targeted markets. Performance in the two indicators which are closely linked is attributed to challenges in specific vaccine markets for whom interventions are in progress as per the defined roadmaps.

3. Objectives and Scope

3.1 Audit Objective

Our audit assessed the adequacy and effectiveness of the governance, risk management and internal controls in the key processes and activities supporting the achievement of the market shaping objectives defined in the Gavi Supply and Procurement Strategy for 2016–2020 period.

3.2 Audit Scope and Approach

We adopted a risk-based audit approach informed by our assessment of the system of internal controls.

Our audit approach included interviewing relevant Secretariat teams, reviewing Board and committee reports, reviewing relevant policies, operational guidelines, and reviewing, on a sample basis, evidence relating to Market Shaping activities carried during the period under review.

This audit was designed to assess the:

- Design and operating effectiveness, where possible, of the controls;
- Economy and efficiency of the utilisation of resources;
- Quality of implemented governance and risk management practices; and
- Compliance with relevant policies, procedures, laws, regulations and where applicable, donor agreements.

The scope of this audit covered the period from 01 January 2017 to 31 December 2019.

We will continue to work with management to ensure that these audit issues are adequately addressed and required actions undertaken.

We take this opportunity to thank all the teams involved in this audit for their on-going assistance.

Head, Internal Audit

Annexes

Annexe 1 – Methodology

Gavi's Audit and Investigations (A&I) audits are conducted in accordance with the Institute of Internal Auditors' ("the Institute") mandatory guidance which includes the definition of Internal Auditing, the Code of Ethics, and the International Standards for the Professional Practice of Internal Auditing (Standards). This mandatory guidance constitutes principles of the fundamental requirements for the professional practice of internal auditing and for evaluating the effectiveness of the audit activity's performance. The Institute of Internal Auditors' Practice Advisories, Practice Guides, and Position Papers are also adhered to as applicable to guide operations. In addition, A&I staff adhere to A&I's standard operating procedures manual.

The principles and details of the A&I's audit approach are described in its Board-approved Terms of Reference and Audit Manual and specific terms of reference for each engagement. These documents help audit staff to provide high quality professional work, and to operate efficiently and effectively. They help safeguard the independence of the A&I staff and the integrity of their work. The A&I's Audit Manual contains detailed instructions for carrying out its audits, in line with the appropriate standards and expected quality.

In general, the scope of A&I's work extends not only to the Secretariat but also to the programmes and activities carried out by Gavi's grant recipients and partners. More specifically, its scope encompasses the examination and evaluation of the adequacy and effectiveness of Gavi's governance, risk management processes, system of internal control, and the quality of performance in carrying out assigned responsibilities to achieve stated goals and objectives.

Annexe 2 – Definitions: opinion, audit rating and prioritisation

Issue Rating

For ease of follow up and to enable management to focus effectively in addressing the issues in our report, we have classified the issues arising from our review in order of significance: High, Medium and Low. In ranking the issues between 'High', 'Medium' and 'Low', we have considered the relative importance of each matter, taken in the context of both quantitative and qualitative factors, such as the relative magnitude and the nature and effect on the subject matter. This is in accordance with the Committee of Sponsoring Organisations of the Treadway Committee (COSO) guidance and the Institute of Internal Auditors standards.

Rating	Implication
High	<p>At least one instance of the criteria described below is applicable to the finding raised:</p> <ul style="list-style-type: none">• Controls mitigating high inherent risks or strategic business risks are either inadequate or ineffective.• The issues identified may result in a risk materialising that could either have: a major impact on delivery of organisational objectives; major reputation damage; or major financial consequences.• The risk has either materialised or the probability of it occurring is very likely and the mitigations put in place do not mitigate the risk.• Management attention is required as a matter of priority.• Fraud and unethical behaviour including management override of key controls.
Medium	<p>At least one instance of the criteria described below is applicable to the finding raised:</p> <ul style="list-style-type: none">• Controls mitigating medium inherent risks are either inadequate or ineffective.• The issues identified may result in a risk materialising that could either have: a moderate impact on delivery of organisational objectives; moderate reputation damage; or moderate financial consequences

Rating	Implication
	<ul style="list-style-type: none"> The probability of the risk occurring is possible and the mitigations put in place moderately reduce the risk. Management action is required within a reasonable time period.
Low	<p>At least one instance of the criteria described below is applicable to the finding raised:</p> <ul style="list-style-type: none"> Controls mitigating low inherent risks are either inadequate or ineffective. The Issues identified could have a minor negative impact on the risk and control environment. The probability of the risk occurring is unlikely to happen. Corrective action is required as appropriate.

Distribution

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For Information

Title
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