

CONSOLIDATED COMMENTS FROM THE PUBLIC CONSULTATION ON EXTERNALITIES OF GAVI MARKET SHAPING ACTIVITIES

INTRODUCTION

In June 2017, Gavi, the Vaccine Alliance launched a public consultation process on externalities of market shaping. The consultation was open from 26 June 2017 to 02 August 2017. This document provides an overview of the process, as well as a summary of the main themes that emerged from the comments received. It does not necessarily reflect the views of Gavi, the Vaccine Alliance.

In the second half of 2017, Gavi will prioritise these externalities and establish a framework for monitoring them, taking into consideration inputs received through the public consultation. This summary will be posted on the Gavi website. The final list of prioritised externalities will also be posted on the Gavi website when developed.

DESCRIPTION OF THE CONSULTATION

Lessons learned from the first 10 years of Gavi's existence suggested that market forces alone would not sufficiently improve supply security and pricing for low-income country markets. Drawing from these lessons, Gavi shifted to a more explicit and proactive approach to shaping vaccine markets with the development of a [Supply and Procurement Strategy \(SUPPRS\)](#), which sets out the strategic framework to deliver on our ambitions.

While primarily intended to benefit the countries that Gavi supports, the ultimate goal of Gavi's market shaping work is to improve the health of markets as a whole – for manufacturers, countries and partners. But in doing so, our market shaping activities may have unintended consequences. Such consequences, or externalities, can be both positive and negative, short- and long-term.

In [SUPPRS 2016-20](#), Gavi committed to monitoring the unintended consequences of its activities in Gavi-supported and non-Gavi-supported countries, and on manufacturers and partners.

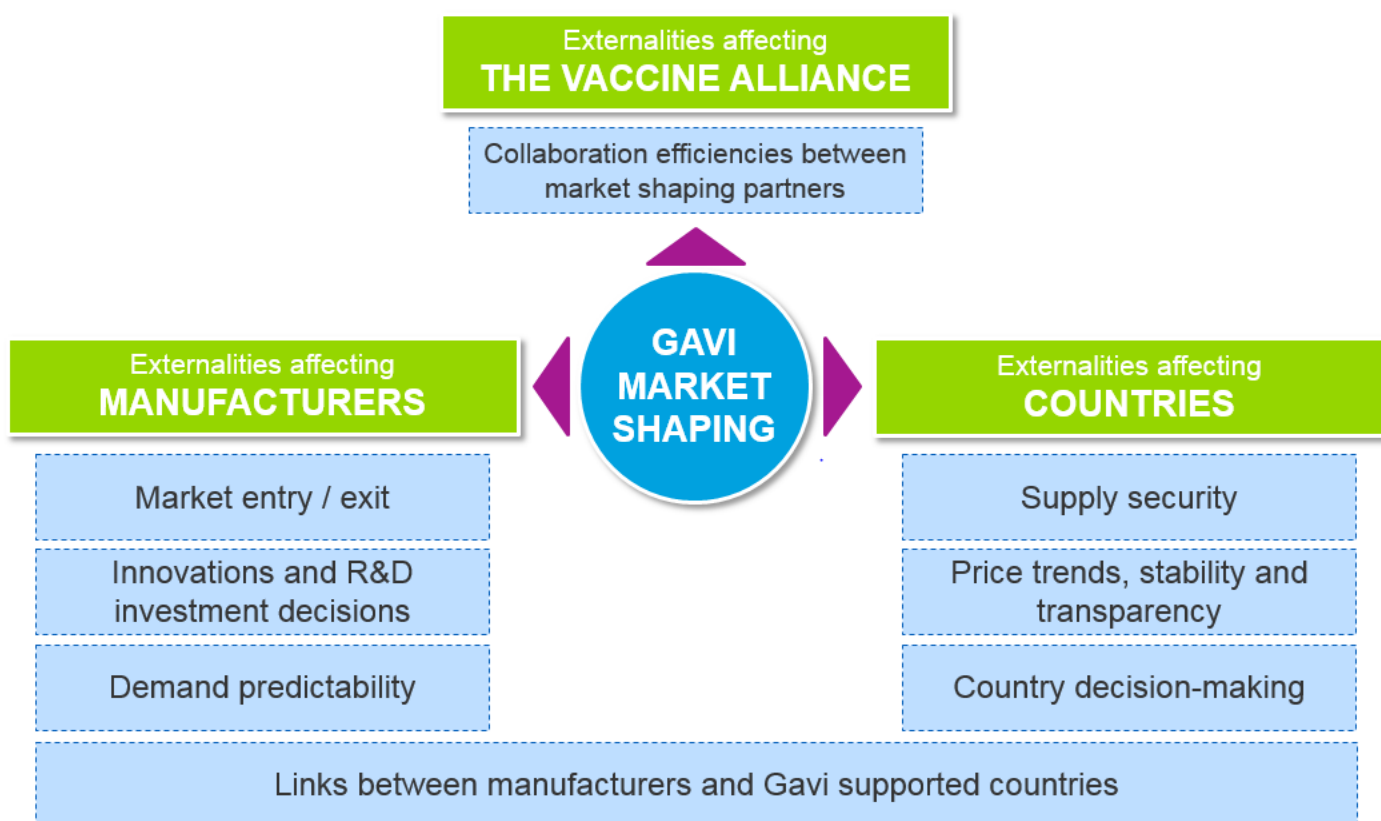
To inform this process, Gavi solicited public input on examples of externalities and suggestions on how to monitor them. The consultation aimed to be inclusive in its approach to soliciting and consolidating feedback on the question of externalities of market shaping. In addition to advertising on the Gavi website, the Gavi LinkedIn page, and on the website of the [Immunisation Economics- Community of Practice](#), the Secretariat also reached out to Alliance members, market shaping intermediaries, vaccine manufacturers, independent experts, and research organisations with an interest in Gavi activities.

The consultation generated 218 visits to the on-line feedback form, with 10 forms submitted from individual respondents representing a broad constituency: Individuals (2), Alliance partners (5), Vaccine manufacturers (3). The majority (>90%) of received text is reproduced in this summary. The remainder was edited out to keep only the most relevant portion of feedback. Some feedback was edited or broken into smaller pieces for clarity, keeping as close as possible to the original text to ensure good interpretation.

KEY THEMES

This section consolidates the comments received, grouping them per affected stakeholder group (in green in picture below) and key themes (in blue in picture below); describing first the suggested externality, illustrating it with quotes from the respondents in order to contextualise the theme and highlight the various viewpoints (in blue boxes below) and then listing the respondents' suggestions for ways to monitor the suggested externality (in tables below).

KEY THEMES OF EXTERNALITIES FROM PUBLIC CONSULTATION



EXTERNALITIES AFFECTING MANUFACTURERS

MARKET ENTRY/EXIT

Several respondents highlighted market entry and exit decisions made by manufacturers as an externality to monitor in Gavi supported and non-Gavi supported countries. A few respondents noted that Gavi, as a major funder of vaccine procurement, incentivises manufacturer entry in previously neglected markets. Others suggested that pressures for lower priced vaccines may affect supplier decisions to remain in the market. While some responses suggested that this situation was more untenable for multinational manufacturers with higher overhead costs to cover, others noted that Gavi's engagement with such manufacturers might be leaving local manufacturers at a disadvantage.

Respondents suggested a variety of ways to monitor these externalities, for example, tracking and publishing historical vaccination rates in countries to understand the size of vaccine markets; tracking and comparing prices over time against supply availability; or monitoring the total number of vaccine suppliers and total production on a yearly basis, while holding exit interviews with those that are leaving the Gavi market to record the reasons behind their exit.

"[Industry manufacturers] ... only [invest] when a market exists..." (Alliance partner)

"Gavi always pushing for lower prices may dis-incentive manufacturers to enter the market as they would feel their benefit is too low (ROI for R&D investments)" (Alliance partner)

"Decisions to exit a market or to limit presence in a market linked to market shaping impact or to market shaping decisions (such as push funding creating an uneven playing field)." (Alliance partner)

"Downward pressure on pricing impacts international R&D-focused companies a lot more. These organisations are usually located in more stringent jurisdictions with higher set of requirements which result in higher costs. The value proposition

should go beyond pricing to enable internal decision making that support investment to support public health goals without compromising viability of "Gavi" supplied vaccines." (Vaccine manufacturer)

"Displacing domestically produced vaccines out of priority: Market shaping efforts tend to focus on major manufacturers that can provide for multiple countries, leaving domestic manufacturers at a disadvantage." (Alliance partner)

Suggested indicators
<i>"Historical vaccination rate of each vaccine in Gavi countries should be monitored and published [as it] has positive consequences for manufactures to clearly understand Gavi market size thus to decide the strategy of entering this market. " (Anonymous)</i>
<i>"Compare existing manufacturers of one specific vaccine and the ones that have agreement with Gavi and comparing the prices these manufacturers offer to their different clients." (Alliance partner)</i>
<i>"Withdrawal of a R&D manufacturer from the Gavi UNICEF market i.e., the inverse of the Metrics in Place for SG. 4." (Vaccine manufacturer)</i>
<i>"Exit interviews with vaccine manufacturers to understand what pressures the Gavi model created for their business that were deemed unsustainable, including the extent to which the prices decreased to the point that it was no longer possible to supply Gavi." (Vaccine manufacturer)</i>
<i>"Number of vaccine suppliers and total production capacity remaining year on year in each vaccine market." (Alliance partner)</i>
<i>"Number of new manufacturers and NRAs that have entered and supply to Gavi markets" (Alliance partner)</i>
<i>"Identify market exits/limitations, identify root causes, evaluate impact through resulting balance of supply and demand (potential shortage), resulting long-term competition (number of remains competitors), and resulting WAP (reduction/increase)." (Alliance partner)</i>
<i>"Gavi to continue to assess impact of large domestic markets and vaccine introductions on incentives to manufacturers." (Alliance partner)</i>
<i>"Track domestically produced vaccine availability." (Alliance partner)</i>

INNOVATIONS AND R&D INVESTMENT DECISIONS

Several respondents suggested the monitoring of innovation and R&D activities related to preventing diseases relevant to Gavi-supported countries, highlighting the impact of Gavi market shaping activities on manufacturer decisions to invest in research and development, and innovative products for the needs of countries supported by the Alliance. For some, this externality is positive as Gavi funding decisions encourage vaccine development. For others, the unintended consequences are negative, as the push for lower priced vaccines dis-incentivises R&D focused international manufacturers from investing in innovative products as well as manufacturers from investing in diseases only endemic in Gavi-supported countries.

Indicators suggested for monitoring the aforementioned externalities include tracking the number of innovations that are brought to market to meet the needs of Gavi supported countries.

"R&D decisions linked to Gavi market shaping activities." (Alliance partner)

"The influence on manufacturers [to invest in] priority vaccines and presentations." (Alliance partner)

"Role of Gavi's programming to create markets through vaccine introductions...The recent discussions with Indian manufacturers of the pneumococcal vaccine shows the potential value of large domestic markets, incentivising vaccine development. Gavi's strategic approach to vaccine introductions can have a significant effect on creating/shaping markets in a

positive way.” (Alliance partner)

“International R&D-focused companies are largely self-financing compared to low cost competitors receiving funding to bring significant capacity to the market. In addition, they invest more in new diseases versus low cost competition who develop more “me too” products.” (Vaccine manufacturer)

“There is a possible negative consequence for diseases that are principally endemic in Gavi countries that the low price focus could drive suppliers away from such disease areas and potentially create long-term issues in sustainable supply and quality. That is noted in the Gavi report with yellow fever, [and] could apply similarly to malaria, dengue...” (Vaccine manufacturer)

Suggested indicators
“[Monitor R&D decisions linked to Gavi market shaping activities] through a periodic (every 5 years?) survey with manufacturers.” (Alliance partner)
“Number of innovations in existing vaccines to make them most suitable for Gavi context.” (Vaccine manufacturer)
“Number of innovations to develop new vaccines to prevent diseases relevant to Gavi countries.” (Vaccine manufacturer)
“Include a human-centred design approach with a feedback loop to UNICEF/Gavi/manufacturers... [to understand the influence on manufacturers, priority vaccines and presentations].” (Alliance partner)
“If prioritized list of innovations was communicated by Gavi, it could then be understood over time which mechanisms would seek to encourage/discourage these innovations from being invested in.” (Vaccine manufacturer)
“[Track] manufacturer participation / innovation regarding vaccines principally endemic in Gavi countries.” (Vaccine manufacturer)

IMPACT OF GAVI INVESTMENT STRATEGY ON R&D DECISIONS

Some feedback highlighted the impact of fundamental investment decisions on vaccine funding made by the Gavi Board on the prioritisation of vaccine development by manufacturers. By committing to fund certain vaccines (but not others) through the Vaccine Investment Strategy and other off-cycle board decisions, Gavi incentivises investments in these vaccines that are prioritised, to the disadvantage of those that are not.

To understand the impact of such an externality, the respondent suggested that diseases for which a vaccine could be brought to market (but is not) be tracked.

“Gavi is a/the major funder of vaccines for developing countries. Gavi agenda is dictated by its donors and the board that includes pharma and its main donors that approve the strategy. Is it normal that the funders define where investment should be made? This is the typical question one can reasonably make in the areas of neglected tropical diseases or non-communicable disease that have been said for years to be major threats on poor country health systems and where there is no appropriate funding.” (Alliance partner)

Suggested indicators
“BOD for a disease for which we know a vaccine could be developed (or candidate vaccines already exist) and not having a vaccine readily available on the market.” (Alliance partner)

DEMAND PREDICTABILITY

The issue of demand predictability was recurrent in responses to the public consultation. Respondents noted the impact that Gavi activities have on manufacturers' ability to plan production adequately, recoup manufacturing costs and plan long term investment, especially as countries transition out of Gavi's financial support. Notably, manufacturers mentioned the discrepancy between Gavi strategic demand forecasts (SDF) and procurement outcomes and the lack of firm procurement commitments, which respondents argued, prevents adequate production planning. They also highlighted the Alliance's focus on meeting country preference which can contribute to suboptimal market conditions; and the transition policy which introduces an additional risk on the financial ability of countries to independently fund vaccine procurement and thus may impact demand and supply.

To assess this set of externalities, respondents suggested that Gavi should track volumes of vaccines procured compared to volumes forecasted.

"SDF offers a good perspective on future demand but is not backed by realities of supplies year on year (Gavi/UNICEF yearly demand usually over-optimistic, impacting supply planning and resulting in unfulfilled demand, or unnecessary over-commitments by manufacturers to Gavi)." (Vaccine manufacturer)

"UNICEF LTA and annual forecast do not provide guarantees that allow adequate supply planning. Firm volume commitments should be considered for wider use to secure supply, particularly on a 12 - 18 month horizon." (Vaccine manufacturer)

"...country preference needs to be balanced more carefully to consider public health impact of delayed launches/switches to another vaccines, particularly if this undermines the viability of a manufacturer to stay in the market." (Vaccine manufacturer)

"Concern that country transitions out of Gavi support will impact volume forecast reliability further due to uncertainty on financial ability of countries." (Vaccine manufacturer)

"As more countries transition, it will be harder to aggregate demand, which could lead to issues with supply." (Alliance partner)

Suggested indicators
<i>"By measuring percent of forecasted doses that are purchased, the prices that are paid, the percent of time the co-financing obligations are met and the timeframe in which the doses to that are financed specifically by the Ministers of Health are purchased and noting any delays between the purchase date and expected purchase date by manufacturer" (Vaccine manufacturer)</i>
<i>"In addition to tracking production by antigen or product (and by manufacturer), tracking the actual distribution of vaccine AND actual administration of vaccine can provide insight into the health of the market and the manufacturers. In retrospect, it can also provide insight into the accuracy of forecasting of market changes." (Other)</i>
<i>"Deploy a multiparty discussion including manufacturers to review the yearly demand assumptions and agree on a yearly demand that sets the base line. Compare the base line number to end year delivery. This should be > 90% accuracy." (Vaccine manufacturer)</i>
<i>"Measure the end of the year supply reality with the publicized, forecasted report done at the beginning of the year and note any discrepancies." (Vaccine manufacturer)</i>
<i>"Measure the existence of the long-term plan in place for a particular vaccine, i.e., roadmap, as well as the demonstrated link between strategic demand forecast & near-term operational commitment." (Vaccine manufacturer)</i>
<i>"Identify the vaccine markets where insufficient investment resulted in insufficient supply for a vaccine. Evaluate root-causes (price/profit levels, demand unclear, competition, allocation of tender volumes, etc.). Evaluate impact through volume undelivered over a period of time and public health impact." (Alliance partner)</i>
<i>"Identify the vaccine markets where high investment resulted in over-capacity and waste. Evaluate root-causes. Evaluate impact through interaction with relevant manufacturers." (Alliance partner)</i>
<i>"[Percentage of] doses procured versus [percentage of] doses forecasted" (Vaccine manufacturer)</i>

<i>"[Percentage of] doses procured versus manufacturer offered doses" (Vaccine manufacturer)</i>
<i>"Impact of country switch in volume year over year (to demonstrate volatility)." (Vaccine manufacturer)</i>
<i>"Measure how much advance notice [a] manufacturer is given for a country switch." (Vaccine manufacturer)</i>
<i>"Pull through of existing dose commitments and related prices as signal that Gavi model is reliably signalling the direction of a particular vaccine market so manufacturers can adequately plan." (Vaccine manufacturer)</i>
<i>"[Monitoring] country forecasted graduation date vs actual [and] doses ordered per year before and after graduation." (Vaccine manufacturer)</i>

EXTERNALITIES AFFECTING COUNTRIES

SUPPLY SECURITY

A manufacturers' decision to enter, exit, invest or divest from a vaccine market (as discussed previously) can have a direct consequence on supply security and stability for countries, including in Middle Income Countries (MICs) not supported by Gavi. Some respondents suggested that the push for lower vaccine prices might drive supply insecurity, and recommended that price trends and supply availability be monitored for correlation. The examples of the inactivated poliovirus and yellow fever vaccines as markets for which demand was created without enough incentives in place to ensure production stability were mentioned. Finally, respondents suggested that market trends including supply security/ stability and market entrance and exit be monitored in MICs not financially supported by Gavi, to understand the consequences of Gavi's market shaping activities on countries outside of its scope.

In addition to monitoring the correlation between price levels and supply security, respondents also recommended recording and investigating instances of supply insufficiency, and keeping track of manufacturers supplying non-Gavi MICs.

"While price is generally the focus for vaccine markets, the bigger issue can be production stability." (Other)

"Impact of the short-term Gavi market shaping "win", including to reach price metric on longer-term availability of supply." (Vaccine manufacturer)

"Certain markets have been negatively impacted by past market shaping, cf. Public Roadmap Yellow Fever. Gavi efforts to "correct" through "positive "market shaping to encourage stability and therefore sustained supply should be included as an externality." (Vaccine manufacturer)

"IPV fractional dosing and Yellow Fever global stock-outs are two examples of creating a high demand yet an inconsistent supply." (Alliance partner)

"Availability of new suppliers to non-Gavi MICs." (Alliance partner)

Suggested indicators

"...Price reductions over time against supply availability over time, split between R&D companies versus low-cost manufacturers." (Vaccine manufacturer)

"[Measure manufacturer] investment level in manufacturing equipment, processes, and capacity." (Alliance partner)

"Identify the vaccine markets where insufficient investment resulted in insufficient supply for a vaccine. Evaluate root-causes (price/profit levels, demand unclear, competition, allocation of tender volumes, etc.). Evaluate impact through volume undelivered over a period of time and public health impact." (Alliance partner)

“Measure percent of time supply didn’t meet demand and percent of time quality issues surfaced that delayed dose delivery.” (Vaccine manufacturer)

“Review reason for presence or non-presence [of new suppliers in non-Gavi MICs]. [Measure] non-Gavi MIC price trends correlated to ... other market shaping outcomes (new entrants, higher capacity, other TBD).” (Alliance partner)

PRICE TRENDS, STABILITY AND TRANSPARENCY

Respondents suggested that Gavi market shaping work influences price trends, stability over time, including after transition, and transparency in Gavi supported and non-Gavi supported countries beyond the intended impact. While some respondents suggested that negative pricing pressure may lead to price erosion over time, others pointed to pricing evolutions after countries have transitioned from Gavi’s support or due to market entries or exits. Additional comments noted that pricing accessed and published by Gavi has the potential to affect markets outside the scope of the Alliance; for example, when stockpiles vaccines are procured at low prices intended to serve Gavi countries, but are used for non-Gavi countries, or when non-Gavi countries reference the ‘Gavi-price’ in procurement negotiations.

Suggestions for monitoring include tracking price trends and making comparisons across times, vaccine markets, types of manufacturers, and stages within the Gavi transition process.

“Negative pricing pressure and price erosion.” (Vaccine manufacturer)

“Price of vaccines paid by countries that have graduated from Gavi and are fully self-financing” (Alliance partner)

“Once countries are no longer able to access Gavi’s pricing for vaccines, there is a risk that they will [be] liable to pay significantly higher prices.” (Alliance partner)

“The number of manufacturers for each product line and when they enter (or leave) the market appears to be a major driver of price points and price stability and should also be tracked along with price” (Other)

“Market shaping impact and/or support for non-Gavi eligible countries, including procurement of doses for vaccine stockpiles at Gavi prices for non-Gavi eligible countries. Gavi should actively support that the price from their unique arrangement, with individual manufacturers, should not be an expectation of acceptable price in non-Gavi markets.” (Alliance partner)

“Price influence on non-Gavi MICs” (Alliance partner)

Suggested indicators

“To the extent possible, an attempt to track ‘real’ price trends in all sectors.” (Other)

“[Monitor] price trends for Gavi-supported vaccines.” (Vaccine manufacturer)

“[Percentage] price increase that [countries that have transitioned from Gavi support] will face after graduation” (Alliance partner)

“Compare existing manufacturers of one specific vaccines and the ones that have agreement with Gavi and comparing the prices these manufacturers offer to their different clients” (Alliance partner)

“[Monitor] Gavi participation in procurement discussions and/or negotiations in non-Gavi eligible countries; formal price referencing of Gavi prices by non-Gavi countries; [and] all signals of intervention in free market outside of Gavi context.” (Alliance partner)

“Review reason for presence or non-presence [of new suppliers in non-Gavi MICs]. [Measure] non-Gavi MIC price trends correlated to Gavi price trends and other market shaping outcomes (new entrants, higher capacity, other TBD). [Compare] to previous price trends.” (Alliance partner)

COUNTRY DECISION-MAKING

A few respondents raised the fact that Gavi market shaping activities influence national decision-making by emphasising focus on new vaccine introduction to the disadvantage of vaccines already in the immunisation schedule, and other more traditional health services. They noted that this may have consequences on countries ability to sustain new vaccine immunisation programmes in the long term.

The recommended indicators for this externality involve monitoring country budgeting for vaccine procurement, and tracking vaccine procurement before and after countries transition from Gavi's financial support.

"Effect on health budgets: particularly NVI are outside of traditional government budgets, complicating the longer-term planning required for Gavi transition/graduation or integrating into essential health packages." (Alliance partner)

"Market shaping activities around new vaccine introduction can displace focus on routine immunization and overwhelm already-fragile health systems. The speed of NVI is being set more by Gavi than by countries themselves without considering the overall system and long-term support options. [Gavi should] Encourage NVI to be incorporated into routine immunization as much as possible and as early as possible (example—distribution of new vaccines through regular distribution channels instead of an initial one-time introduction); financial support for routine immunization strengthening built into NVI." (Alliance partner)

"Countries also need a better understanding of true costs related to immunization activities in order to better plan." (Alliance partner)

Suggested indicators

"Through World Bank mechanisms, review MOH budget lines to verify if vaccines and their related costs are included." (Alliance partner)

"[Monitor] country forecasted graduation date vs actual [and] doses ordered per year before and after graduation." (Vaccine manufacturer)

EXTERNALITIES AFFECTING MANUFACTURERS AND COUNTRIES

LINKS BETWEEN MANUFACTURERS AND GAVI SUPPORTED COUNTRIES

Gavi is a relatively new organisation. Some respondents have wondered whether Gavi (through its market shaping department) does not displace, disrupt and/or destroy existing links between developing countries and the vaccine industry. They therefore recommended for Gavi to confirm whether manufacturers have reduced their engagement in Gavi supported countries after they have become suppliers of the Vaccine Alliance.

"The R&D Industry provides much 'indirect' support in Gavi countries (cf. ATVi); reduction in this could be an indication of a negative externality" (Vaccine manufacturer)

Suggested indicators

"Reduced indirect company engagement [in Gavi supported countries], [measured] through audit/ questionnaire [to] verify with companies any connection to the Gavi Supply and Procurement strategy 2016-2020" (Vaccine manufacturer)

EXTERNALITIES AFFECTING THE VACCINE ALLIANCE

COLLABORATION EFFICIENCIES BETWEEN MARKET SHAPING PARTNERS

Gavi, the Vaccine Alliance is one of the youngest global health organisations, having been created in 2000. Market shaping activities officially started in 2011 with the publication of the first Supply and Procurement Strategy. Activities to shape markets therefore happen within a global health and vaccine procurement systems that have been in place longer than the two decades of Gavi's existence. One respondent noted that Gavi's entry into markets for Cold Chain Equipment (CCE) could result in the duplication of the work already implemented by other partner organisations.

Respondents recommended for Gavi to assess any duplication of work or activities after the Vaccine Alliance starts shaping markets to the benefit of the countries it supports.

"The Supply and Procurement Strategy (SUPPRS) states that 'Gavi's overall 2016-2020 expands the scope of market-shaping to include CCE as a means of achieving gains in coverage and equity'. Gavi entering this market could affect other partners that currently procure or engage in market shaping activities for CCE." (Alliance partner)

Suggested indicators

"Gavi to work with partners to assess whether there is duplication or other adverse market impacts as a result of its involvement in CCE." (Alliance partner)

MISCELLANEOUS COMMENTS

Some comments, though not directly related to an externality of market shaping and its measurement, are still of relevance for market shaping activities as potential ways to address an externality, or for Gavi.

"...Industry has repeatedly underlined the importance of longer term horizons for planning, development, investment. Gavi has the potential to provide this visibility. Recent example of a positive evolution: meningitis 1 year tenders to multiyear 4year tenders; this is unfortunately very late and the meningitis stockpile is in a very difficult situation but is an example of improvement being possible. Proposal: Develop with Procurement agencies instruments for longer-term supply security in future tenders. [The] availability of those tender improvements and manufacturer commitments would be a measure of the impact." (Vaccine manufacturer)

"Develop a type of Vaccine Visibility and Analytics Network (VxVAN) that can provide more in-depth analytics to understand true country demand to help better plan supply side." (Alliance partner)

"The core issue is how to achieve actual market transparency...Working with manufacturers, distributors, and providers of vaccines has many sensitive issues for all stakeholders. However, to the extent possible, increased transparency of data components should be sought through exploring confidentiality issues and aggregation of data for reporting. This is a challenging process and requires resources, time, and communication. Finally, a valid process for commitments to actually use the data to improve the market for all stakeholders is essential and generally overlooked." (Other)

"... in the U.S influenza vaccine market over the past 2 decades, it was possible to track by product and manufacturer: production (by month), distribution (daily), and vaccination rates (by month). This had the potential to provide transparency across the system providing insight into the changing health of the manufacturers and demand in the market as well as potential inefficiencies across the system. Unfortunately, this evaluation process was not vigorously pursued (and was challenging to implement)." (Other)

"As a large number of high birth cohort Gavi countries enter accelerated transition and Gavi graduation, it is important to have an increased focus on sustainable immunization financing and strengthening of procurement systems to ensure successful transition from Gavi support." (Alliance partner)