Gavi Market Shaping Externalities

March 2018

Gavi
The Vaccine Alliance

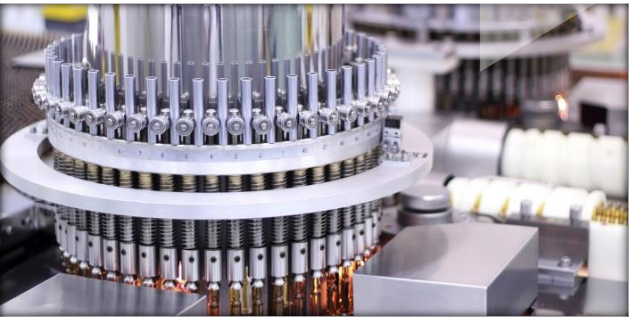
Reach every child
www.gavi.org

What is the context of this project?

- Gavi has helped enable **remarkable progress in immunization** over the last 17 years, including fostering significant improvements in market dynamics
- While Gavi has been highly effective in achieving its core objectives, discussions have been ongoing for some time about the extent to which Gavi's **market shaping work may create both positive and negative** externalities (or unintended consequences) for stakeholders in the vaccine landscape. This includes effects on countries (both Gavi-supported and other middle-income countries), manufacturers, and other partners
- Externalities can have important consequences. It is therefore **important to fully understand what externalities exist, their relative importance**, and how they can be measured
- Through this effort, we have identified key potential externalities and developed a **framework to monitor them**, including indicators to measure them. At this stage, we will not focus on mitigation actions but only on tracking these unintended consequences

Why does this framework matter?

- **Create a common understanding of:**
  - What are the potential and realized unintended consequences of Gavi market shaping
  - Which externalities are priorities to monitor
  - What are the drivers behind these externalities
  - How may the agreed-upon framework look
- Understand the “long-list” of potential positive and negative **externalities from the point of view of different stakeholders and what matters to them**
- **Measure the size of the impact and trends over time to gain insights and potentially adjust** (e.g., reprioritize)
- **Provide a fact base for decision making**, e.g., future market shaping strategy and actions, how to balance the three different market shaping objectives of balanced supply and demand, affordability, and innovation



What is an externality?

What it is…

- **An unintended consequence (positive or negative) of Gavi's market-shaping activities** for vaccines or other immunization related products, that:
  - may affect Gavi-supported countries, non-Gavi-supported countries, manufacturers, or other partners
  - may impact products or services that are part of Gavi's portfolio or others e.g., health systems, vaccines or immunization-related products outside Gavi's priorities
- This unintended consequence may **have already materialized or may be considered a future risk** to monitor

What it's not…

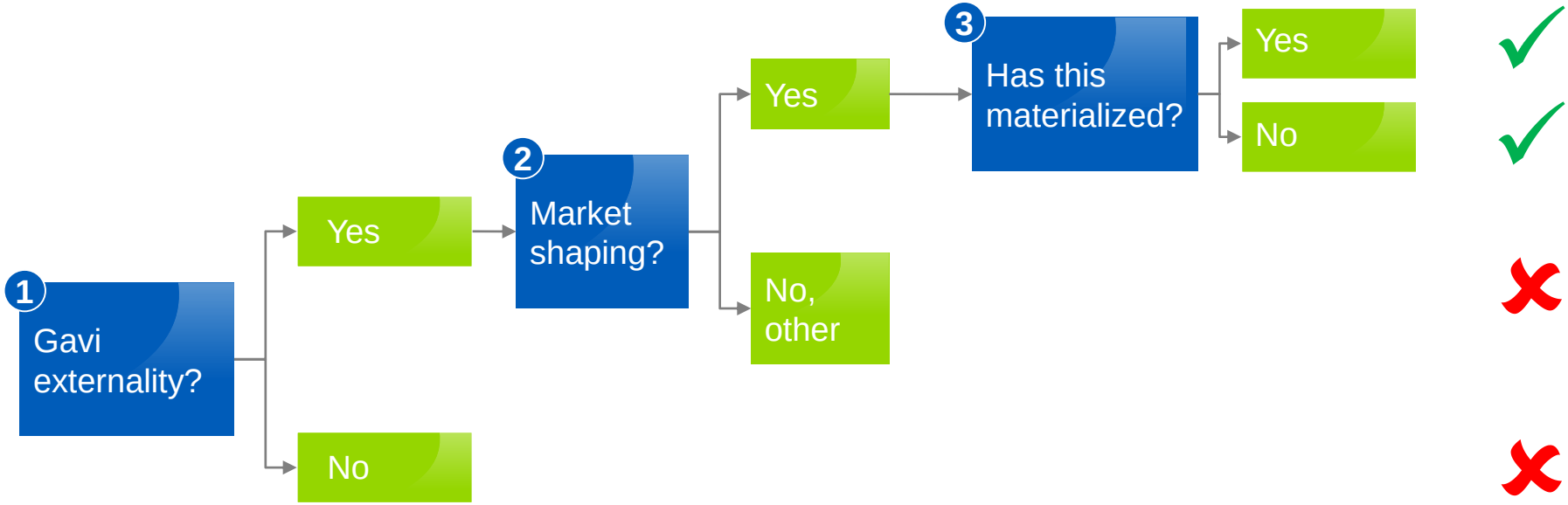
- **An intended consequence of Gavi's (market-shaping) activities**, which is part of Gavi's mission (e.g. reduced prices to a sustainable level for Gavi-funded vaccines and products)
- A negative consequence of **market dynamics, political or economic context** that is not meaningfully influenced by Gavi's market shaping activities
- **Something that Gavi has tried to do but not fully succeeded** in doing (e.g. perception that Gavi should negotiate lower prices for a particular antigen)

Note on "core" externalities

- Certain externalities relate to the **"core" of Gavi's market shaping work,** i.e., relate to Gavi-funded products in Gavi-supported countries
- A negative trend in one of these could indicate that **one market shaping objective had outweighed another** (e.g. over-emphasis on affordability could result in a negative externality relating to supply security)
- **A positive trend would not indicate an externality**, but could indicate success towards Gavi's goals

The monitoring framework will consider observed and potential externalities of Gavi's market shaping activities

Decision tree



Questions to consider

1. *Is this a potential unintended consequence of Gavi's activities?*[1]
   If this were to occur, would Gavi be a primary driver?

2. *Is this externality specifically due to market shaping, or to other Gavi activities (e.g. VIS, policies, existence of Gavi funding)?*

3. *Is there evidence that the consequence has already occurred? Is it something that is a future risk but has not yet materialized?*

1 If a "core" externality, the presence of an externality could indicate that one objective (e.g., affordability) had been prioritized at the expense of another objective (e.g., supply security)

We developed and refined the framework for monitoring externalities through a collaborative process

Gavi's public consultation

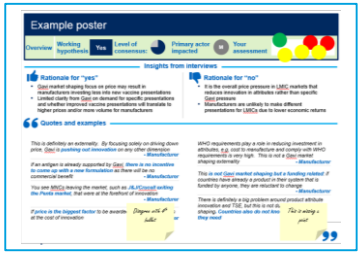
- Collected wide range of views on potential externalities & indicators through 10 individual submissions representing a broad constituency
- Developed long-list of externalities based on public consultation and insights from other experts

Stakeholder interviews

- Assessed completeness, validity and degree of alignment around identified externalities through 28 stakeholder interviews
- Identified additional externalities and specific case examples

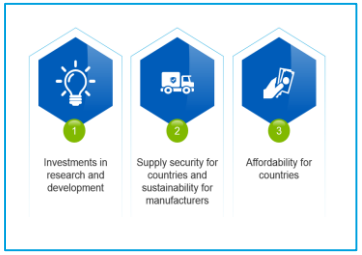
Stakeholder workshop

- Reviewed proposed long-list of externalities and classification with 8 workshop participants
- Identified final amendments and disagreements
- Prioritized externalities to monitor
- Began to identify indicators



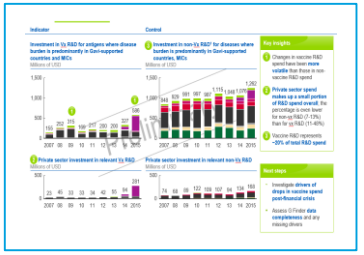
Finalize framework

- Finalized prioritization of externalities into framework based on feedback
- Conducted additional interviews as needed to refine framework



Develop indicators and guidelines

- Defined which indicators will be used to monitor the externalities
- Consulted with additional stakeholders to refine the indicators
- Developed guidelines for how to interpret the indicators



We interviewed 28 stakeholders among the below organisations through this process

	Organization/ Country			
Manufacturers	Sanofi Pasteur		Serum Institute of India	
	GSK		Vaccine Business Unit, LG Chemicals	
	Merck		Biological E	
	Pfizer		Walvax Biotechnology Co	
Partners and country representatives	IVI		PAHO	
	JSI		Independent (ex CDC)	
	PATH		Independent (ex WHO)	
	CHAI		Independent (ex Gavi)	
Countries/ Country viewpoints	Equatorial Guinea		Gabon / WHO AFRO	
	Capo Verde		Rwanda	
	Angola		Thailand	
	DRC		Sri Lanka	
	Gavi			
Academia	Rochester Institute of Technology			

Through a workshop conducted in November 2017, a diverse set of stakeholders[1] shared views on the initial "long list" of externalities

Initial review and voting

- Through a gallery walk exercise, participants reviewed the "long list" externalities
- Participants voted on whether or not proposed externalities were valid externalities
- Participants identified new externalities, refined proposed externalities, and shared comments

Reframing of externalities as neutral

- Participants suggested that instead of having externalities be framed as negative or positive, they should be framed neutrally in order to allow data to show direction of trend

Debate on whether to include "Core" externalities

- Participants debated whether to include potential externalities that are part of the "core" of Gavi's market shaping mission, i.e. externalities relating to Gavi-supported countries, Gavi-funded products, and Gavi's market shaping objectives
- Participants decided most "core" externalities identified should be included in the framework as they could result from an imbalanced focus between market shaping objectives (e.g. prioritizing affordability over supply security)
- It was agreed that collection of indicators for "core" externalities should be harmonized with existing Gavi M&E indicators

Debate and voting on remaining externalities

- Participants debated whether remaining externalities were valid externalities
- Through a voting exercise, participants selected which remaining externalities should be monitored

1 Workshop participants included: Marion Menozzi-Arnaud (Gavi), Melissa Malhame (Gavi Alumna), Andrea Ware (William Davidson Institute at the University of Michigan), Philipp Kalpaxis (UNICEF SD), Robyn Iqbal (BMGF), Tania Cernuschi (WHO), Corinne Bardone (IFPMA / Sanofi), James Droop (DFID)

The externalities monitoring framework is divided into three categories

Investments in research and development

Supply security for countries and sustainability for manufacturers

Affordability for countries

Framework overview

Category	Externality: Gavi's market shaping activities may result in unintended changes in …
1 Investments in research and development	A Investment in vaccine development for antigens where disease burden is predominantly in Gavi-supported countries and middle-income countries
	B Investment in improvements to existing vaccines in Gavi portfolio, e.g. investments in thermo-stability
	C Investment in development of new cold chain equipment
2 Supply security for countries and sustainability for manufac-turers	A Manufacturer diversity for Gavi-funded products[1], including overall number and geography
	B Global capacity to produce and availability of Gavi-funded products
	C Global capacity to produce and availability of non-Gavi-funded products targeted at low- and middle-income countries
	D Range of presentations of existing products available to Gavi-supported countries
3 Affordability for countries	A Price trends and price volatility for Gavi-funded products in non-Gavi-supported countries

1 All references to products in the framework refer to vaccines and CCE

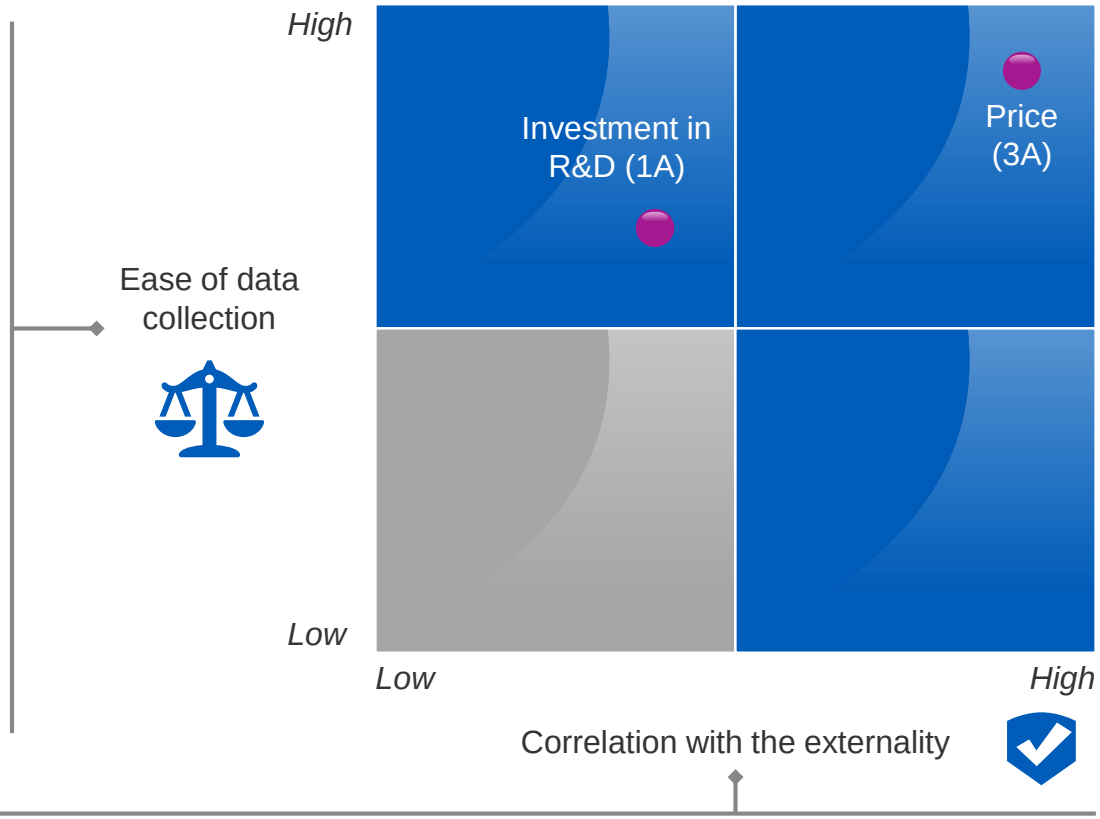
We selected indicators for each externality based on their correlation with the externality and the ease of data collection

Excluded from consideration | May be considered as indicators

Initially prioritized indicators use secondary data sources, thereby improving ease of data collection

- Indicators could ultimately use **secondary data, proxy data[1], or primary data;** initially prioritized indicators use secondary data that is relatively easy-to-access
- It was decided that **no new data collection** will be conducted during the initial period. Over time, it may be decided that **primary or proxy data collection** is needed
- In the case of "core"[2] externalities, **data collection will be harmonized with existing Gavi data collection**

Indicators can be assessed along two axes …



The level of correlation between the externalities and indicators will vary

- Some externalities have perfectly-correlated indicators
- For others, it is necessary to look at more than one indicator and to carefully **interpret imperfect indicators**

1 Calculated data using existing data sources and expert-driven assumptions
2 "Core" externalities refer to Gavi-funded products in Gavi-supported countries

Draft overview of prioritized indicators – to be further amended based on data analyses and insights

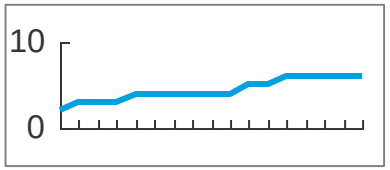
Category	Externality	Indicator(s)[1]	Control or counterfactual indicator
1 Investments in research and development	A Investment in vaccine development for antigens where disease burden is predominantly in Gavi-supported countries and middle-income countries	i Total vaccine R&D spend and manufacturers' self-reported R&D spend	• Total non-vaccine R&D spend and manufacturers' self-reported R&D spend for diseases predominantly in low-income countries (G Finder)
		ii Number of newly launched vaccine development efforts iii Number of vaccines in development iv Pace of progression of vaccine development pipeline	
	B Investment in improvements to existing vaccines in Gavi portfolio, e.g. investments in thermo-stability	i Number of products with improved characteristics procured	• Number of improvements launched to non-Gavi vaccines (UNICEF)
	C Investment in development of new cold chain equipment	i Number of CCE products available on the market that are in the scope of the CCEOP	• TBD
2 Supply security for countries and sustainability for manufacturers	A Manufacturer diversity for Gavi-funded products, including overall number and geography	i Number and geographic location of manufacturers for each antigen	• Manufacturer diversity for non-Gavi-funded vaccines (UNICEF)
	B Global capacity to produce and availability of Gavi-funded products	i Number of vaccine markets with sufficient and uninterrupted supply ii Global percent of countries reporting shortages at national level	• Global capacity to produce and availability of non-Gavi funded products targeted at low- and middle-income countries (2C)
	C Global capacity to produce and availability of non-Gavi-funded products targeted at low- and middle-income countries	i Estimates of supply / demand balance ii Global percent of countries reporting shortages at national level	• Global capacity to produce and availability of non-Gavi funded products targeted at low- and middle-income countries (2B)
	D Range of presentations of existing products available to Gavi-supported countries	i Number of distinct product presentations offered for Gavi-supported antigens	• Number of distinct product presentations offered for non-Gavi-supported antigens (UNICEF data)
3 Affordability for countries	A Price trends and price volatility for Gavi-funded products in non-Gavi-supported countries	i Price trends for Gavi-funded products; calculated price volatility of Gavi-funded products	• Price trends and price volatility for non-Gavi-funded vaccines in non-Gavi-supported countries (GVMM data)

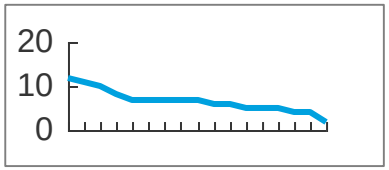
1 For some externalities, indicators relating to CCE will not be collected during the initial phase of monitoring, but may be added in the future

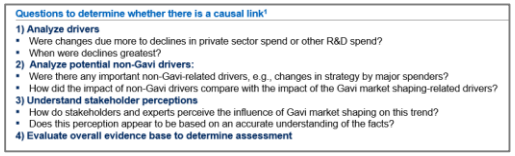
We can understand trends in the externalities and interpret indicators using a four step process

Through four steps, we can assess trends and conduct qualitative analysis…

1. Analyze indicator trends
2. Analyze control or counter-factual trends
3. Conduct additional qualitative and quantitative analysis as needed to understand causality
4. Make overall assessment of whether changes seen were caused by Gavi market shaping






Questions to determine whether there is a causal link[1]

1) Analyze drivers
- Were changes due more to declines in private sector spend or other R&D spend?
- When were declines greatest?

2) Analyze potential non-Gavi drivers:
- Were there any important non-Gavi-related drivers, e.g., changes in strategy by major spenders?
- How did the impact of non-Gavi drivers compare with the impact of the Gavi market shaping-related drivers?

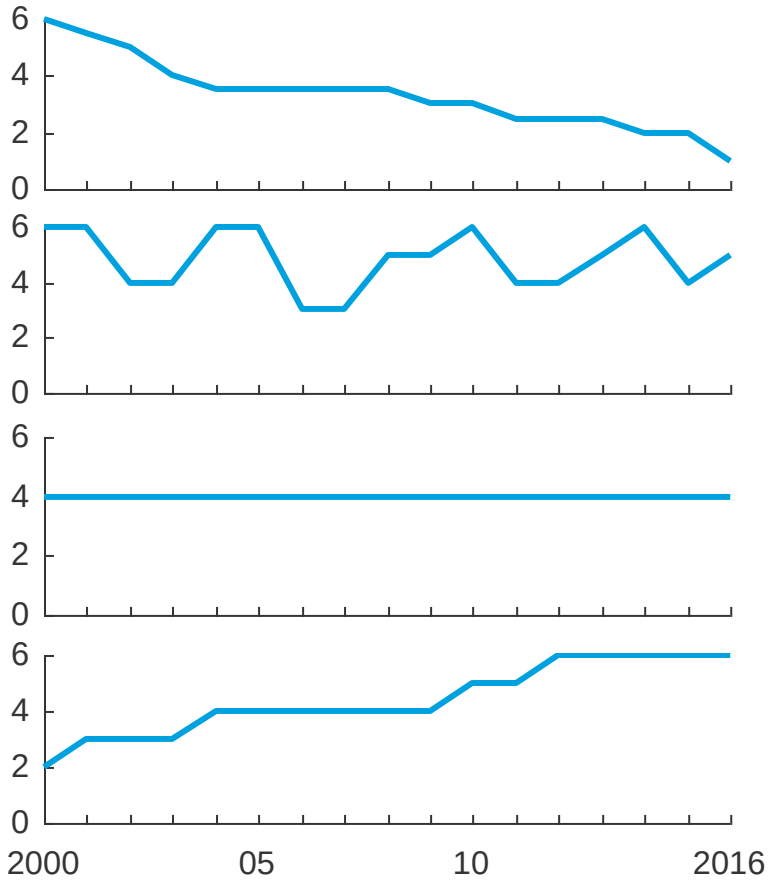
3) Understand stakeholder perceptions
- How do stakeholders and experts perceive the influence of Gavi market shaping on this trend?
- Does this perception appear to be based on an accurate understanding of the facts?

4) Evaluate overall evidence base to determine assessment

… which can be used to assess externalities through a decision tree approach

1 Through an initial analysis of indicators, we can determine whether trends are consistent with a potential externality

Illustrative example: Price trends and price volatility for Gavi-funded products in non-Gavi-supported countries



If prices for most Gavi-funded vaccines in non-Gavi supported countries are…

This would indicate…

Declining	**No evidence of negative externality; may indicate positive externality**
Variable, flat or mixed results for different vaccines	**Uncertain; assess counterfactual and investigate further to understand trend and causality**
Increasing	**May indicate a negative externality; investigate further to assess causality**

2 Where available, we can compare control or counter-factual data with the trends observed in the indicators

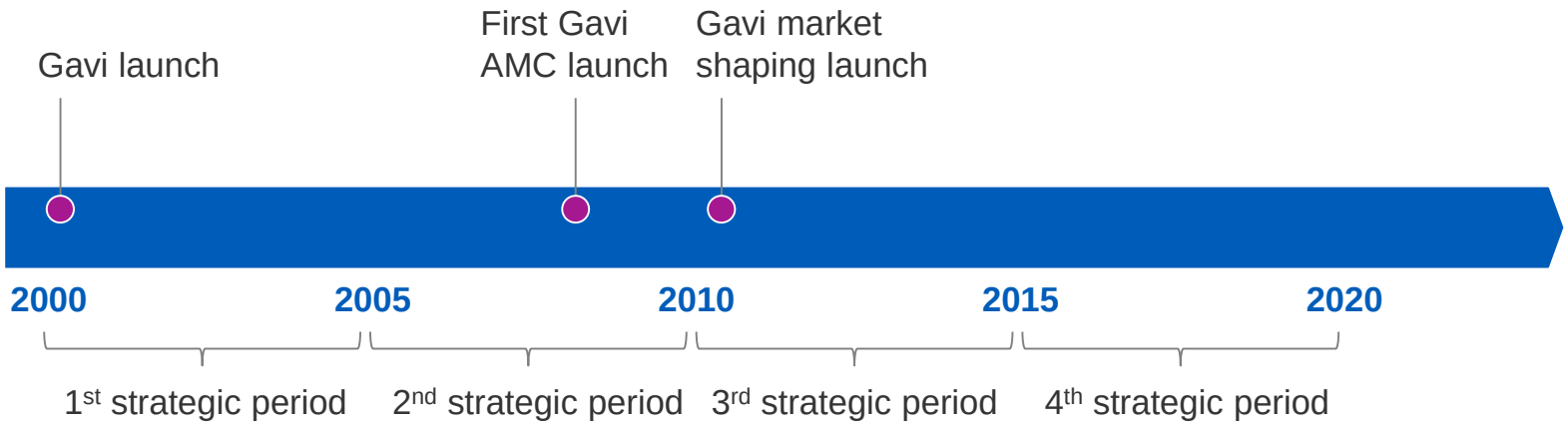
To assess whether there is a causal link between Gavi market shaping and a trend in indicators that would suggest such a link, we can consider…

Time series (forward-looking)	• What trends do we observe in the data over time (beginning now)? • How (if at all) do trends in the indicator change when aspects of the market shaping strategy change?
Historical perspective / counterfactual	• What were trends in the indicator before and after Gavi market shaping-related "inflection points"? – Gavi launch – Gavi market shaping launch • From the changes in trends, can we assess what may have happened in the absence of Gavi market shaping?
Control or counter-factual data	• What are the trends in a comparable data set that was not influenced by Gavi market shaping? • How do the trends differ from trends in the indicator?

- We will look at **retrospective and prospective changes in all indicator trends**, but historical data is not available for many, e.g., some goes back only to 2007
- Where a **useful control data set** is available, we will also consider this data

We can assess whether there are any changes in trend in the indicators near certain Gavi-related “inflection points”

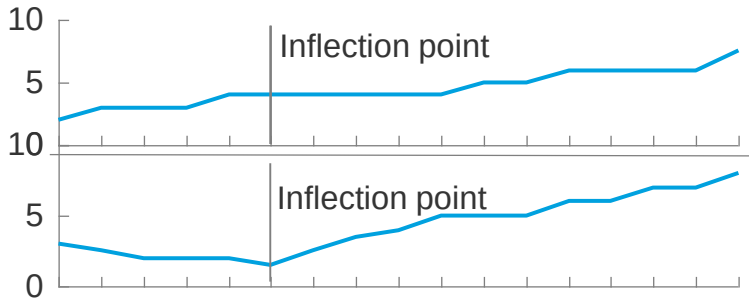
Basic outline of inflection points



Additional details needed

- A basic timeline of key inflection points will need to be **overlaid with additional details**, including but not limited to:
  - Vaccine-specific tender calendars (as applicable)
  - Major market shaping decisions taken that relate to specific products
- To define the key inflection points, it will be important to **consult with additional stakeholders** both within and outside of Gavi

2 Analysis of trends can help to determine whether an externality may be present…

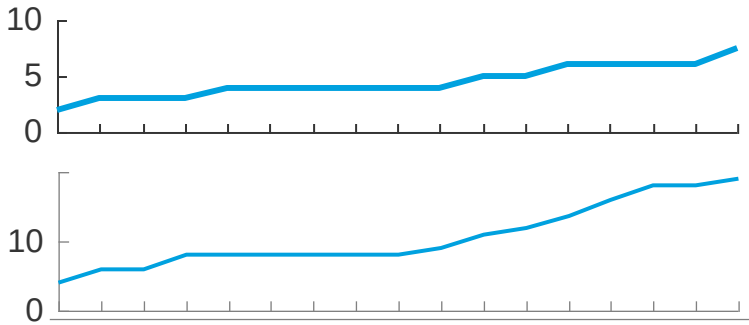


Trend before inflection point is similar to trend after inflection point

May indicate there is a **non-Gavi secular trend**

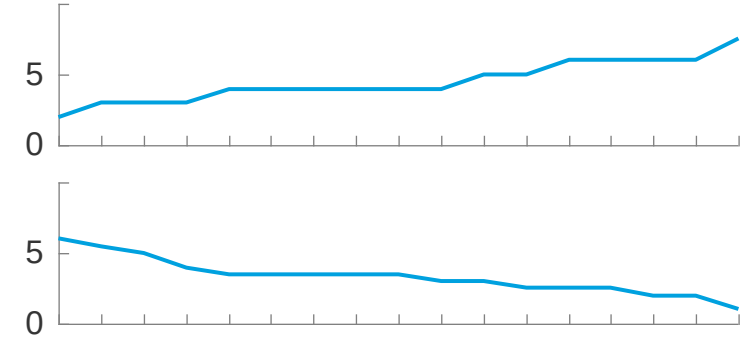
Trend after inflection point is markedly different from before

May indicate trend is driven by Gavi-related factors; investigate further



Trends in control are similar to trends in indicator

May indicate there is a **non-Gavi secular trend that affects both the indicator and the counterfactual,** e.g., increasing production costs



Trends in control differ from trends in indicator

May indicate trend is driven by Gavi-related factors; investigate further

3 4 …but additional analysis is required to assess causality

Illustrative example: Upward price trends and increasing price volatility for Gavi-funded products in non-Gavi-supported countries

3A Analyze potential market shaping-related upward price drivers

- Manufacturers may charge higher prices to non-Gavi-supported countries to compensate for lower returns in Gavi-supported countries
- Gavi market shaping for LICs may limit the negotiation impact of MICs
- Downward price pressure may cause manufacturers to leave the market or not enter, thus reducing competition and increasing the risk of future price increases

Is there evidence to suggest these Gavi market shaping drivers are influencing the trend?

3B Analyze potential non-Gavi drivers

- API or other input costs may have increased
- Production costs may have increased
- Manufacturers' pricing strategy may have changed
- Competition may have decreased for non-Gavi-related reasons, leading manufacturers to increase prices

How did the impact of non-Gavi drivers compare with the impact of the Gavi market shaping-related drivers?

3C Understand stakeholder/expert perceptions

- How do stakeholders and experts perceive the influence of Gavi market shaping on this trend?
- Does this perception appear to be based on an accurate understanding of the facts?

How do stakeholders and experts weigh the relative importance of different drivers?

4 What is the overall assessment?