

# Regulation in Gavi's Sustainability and Transition Approach

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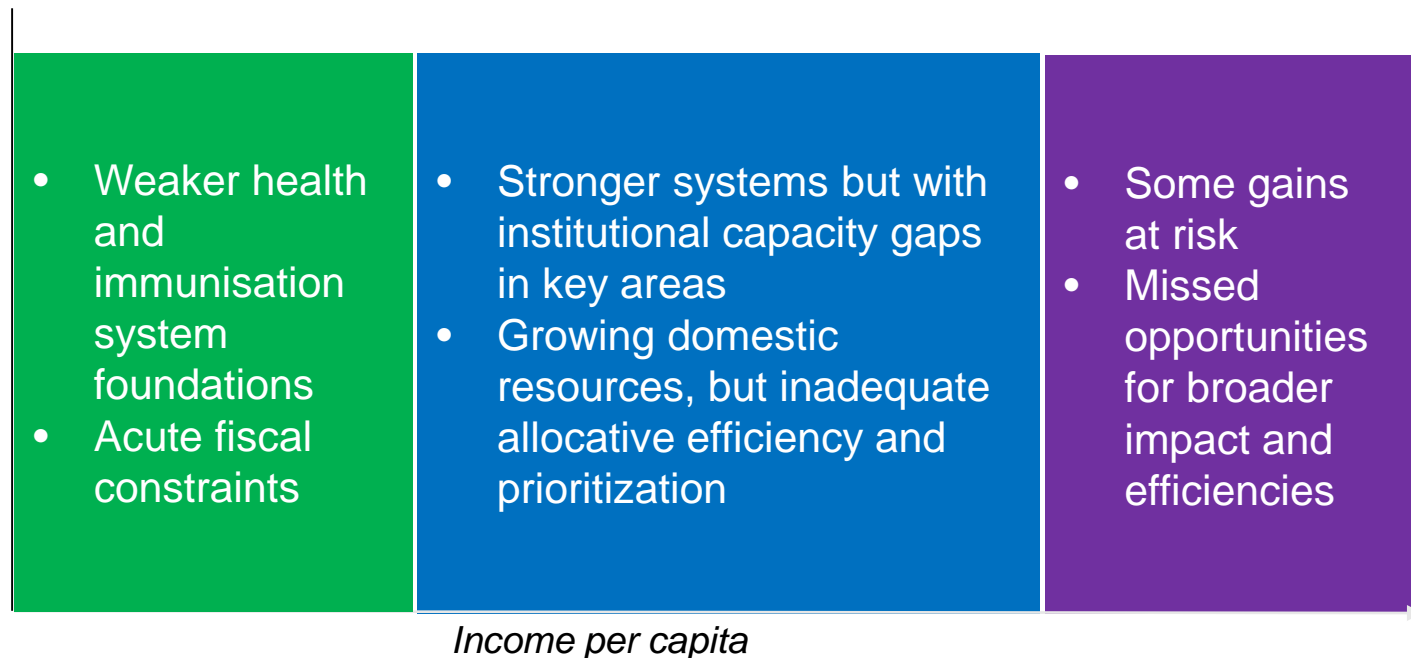
Santiago Cornejo  
Director, Immunisation  
Financing and Sustainability

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# Countries tend to face various programmatic and financing challenges at different development stages...

*Schematic representation of main programmatic and financing bottlenecks to immunisation along the development continuum*

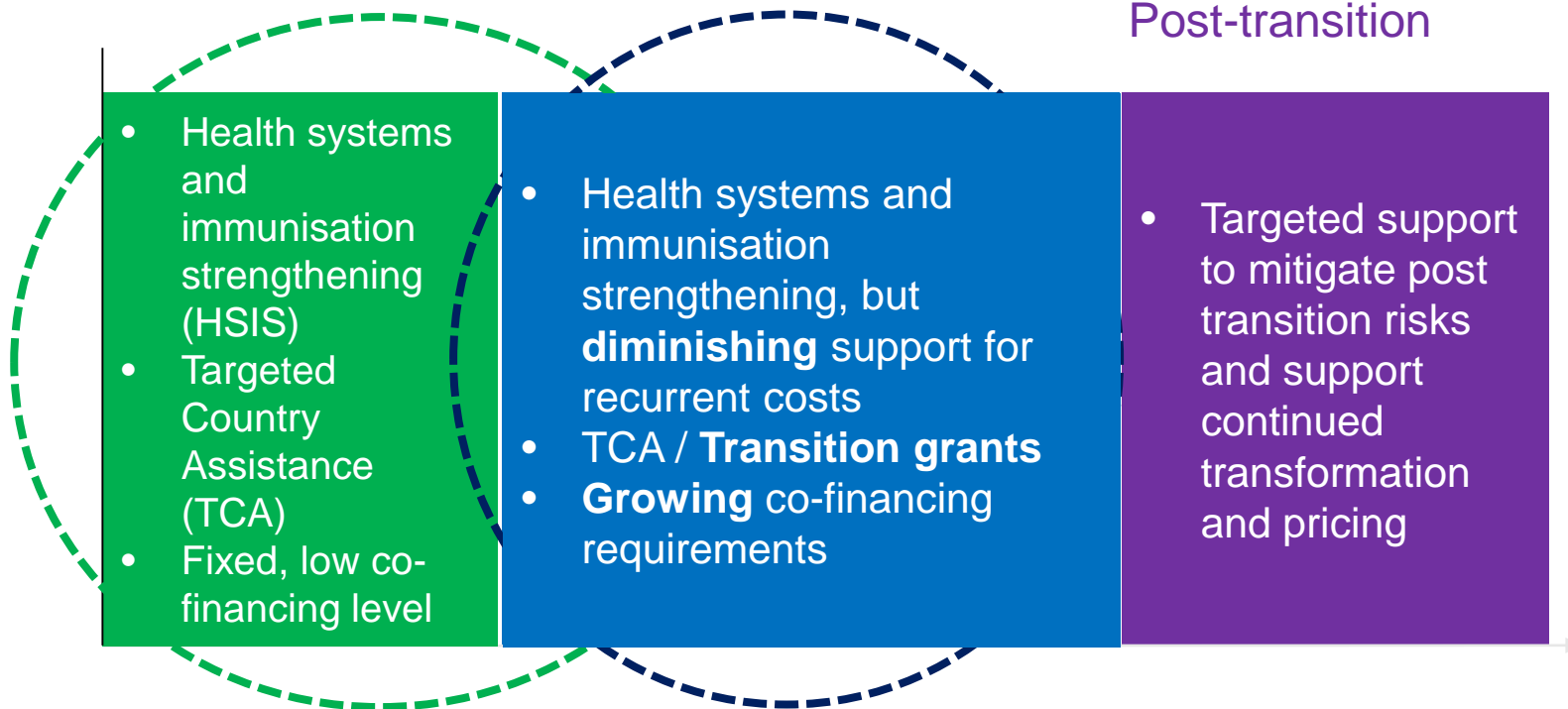


- ❖ These are not absolute categories: actual country realities sit somewhere on this continuum
- ❖ First wave of transitioning countries aligned with this model

# Evolving needs require evolving types of engagement and support

Early engagement :  
Building foundations for sustainability

Post-transition

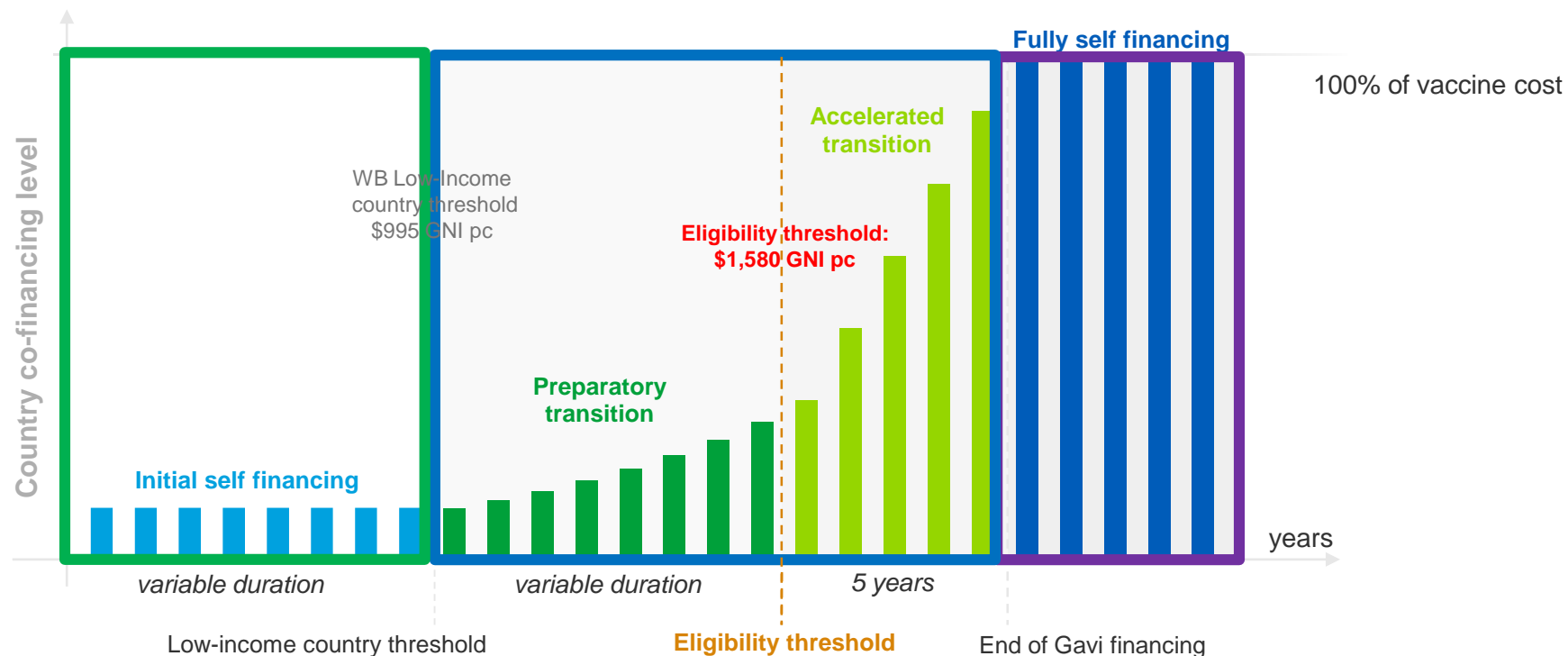


Preparing for transition

# Eligibility, transition and co-financing policies provide the institutional framework for Gavi's engagement...



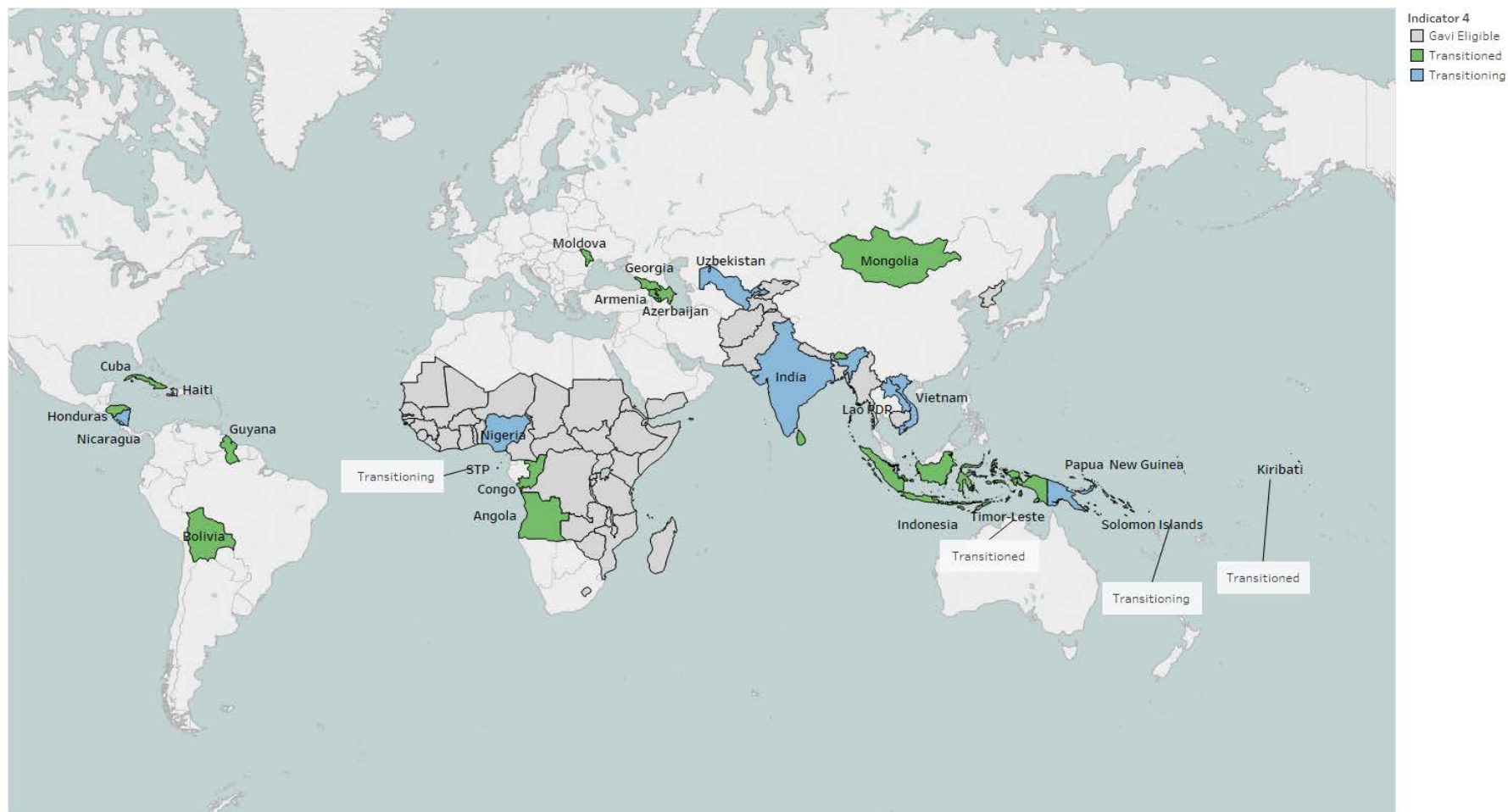
... and serve as key mechanism for domestic resource mobilization and financial sustainability



# Gavi's transition approach: key components

- **Financial and programmatic sustainability**
  - Domestic financing is key, but it is not enough
  - Programmatic sustainability requires critical national capacities, e.g., planning and budgeting, procurement, regulations, etc.
- **Integrate “sustainability” in the design of Gavi’s engagement**
  - Getting the sequencing of interventions right: Addressing systemic bottlenecks early on
  - Adapting support to needs and reflecting the transition status: Reducing support for recurrent costs
- **Conduct transition assessments and plans to mitigate risks**
  - Conduct the assessments and plans before entering transition to guide all Gavi investments
  - Comprehensive approach beyond the programme to leverage all opportunities in the sector

# 16 countries have already transitioned and 9 countries are still in transition

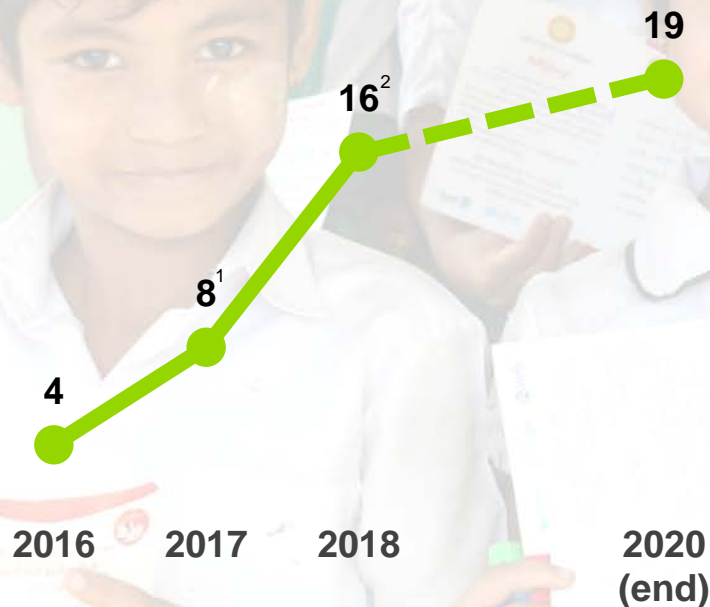


Map based on Longitude (generated) and Latitude (generated). Color shows details about Indicator 4. The marks are labeled by Country. The view is filtered on Indicator 4, which keeps Gavi Eligible, Transitioned and Transitioning.



# 16 transitioned countries have fully transitioned and self-finance 33 vaccine programmes

**Countries transitioned out of Gavi support (end of 2018)**



**Strong performance after more than one year without Gavi support**



## **Sustained or improved coverage**

All countries transitioned for >1 year maintaining or improving coverage



**Fully funding** vaccine programmes  
Avg. investment per child **up >400%**



10 transitioned countries **introduced HPV and Measles-Rubella** with one-time catalytic funding from Gavi

1) 8 countries transitioned before 2017: Bhutan, Honduras, Mongolia, Sri Lanka, Guyana, Indonesia, Kiribati, Moldova;

2) 8 countries transitioned at the end of 2017: Angola, Armenia, Azerbaijan, Bolivia, Congo Rep., Cuba, Georgia, Timor Leste



# The Alliance provides targeted post-transition support

## Bottleneck

## Existing post-transition support

### Vaccine prices



**Predictability and stability for vaccine prices**  
Access to prices similar to those paid by Gavi for a limited duration\*

### Introductions of new vaccines



**Catalytic support to new introductions**  
10 transitioned countries received catalytic funding to incentivise missed introductions

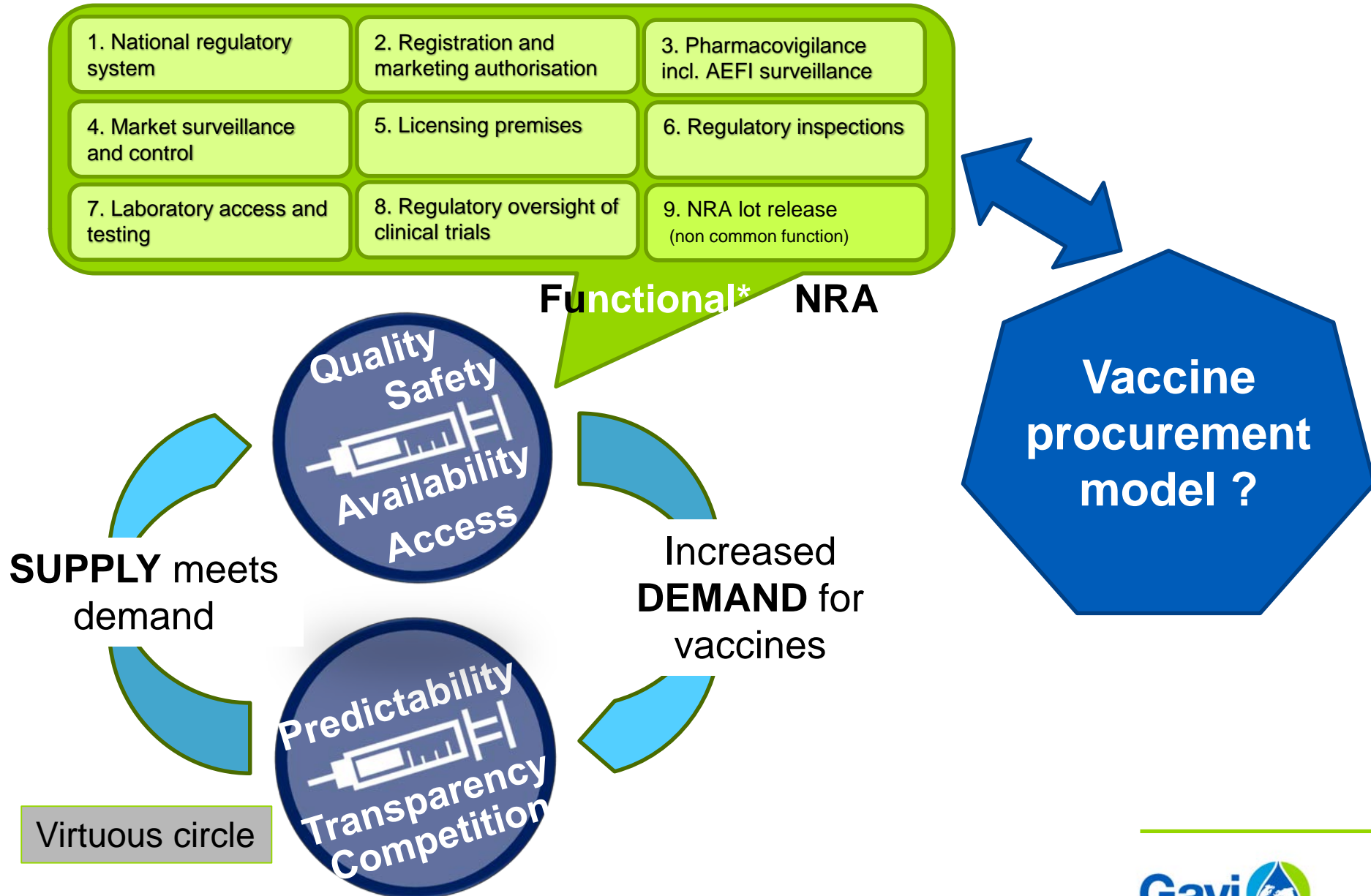
### Programmatic bottlenecks



**Targeted mitigation of specific programmatic bottlenecks**  
Post-transition support for country, regional and global level initiatives to mitigate risks

**Support to post-transition countries provided on a case-by-case basis – a more deliberate approach could be adopted**

# Why does a functional regulatory system matter?



\* According to maturity score developed by WHO = level 4 = well resources regulatory system is operating at advanced level of performance with well and continuous improvement / all 9 functions are meeting high standards

# Different countries need different level of NRA maturity but there is room for improvement

Critical control functions depending on vaccine source

Vaccine source	Licensing	Surveillance	Lot Release	Lab Access	GMP Inspections	Clinical Evaluation
UN agency	x	x				
Procure	x	x	x	x		
Produce	x	x	x	x	x	x

Source: WHO website

Most of Gavi countries	A few Gavi countries*
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\* India, Vietnam, Senegal (and Indonesia and Cuba – former Gavi countries)

- ❖ Gavi countries are almost all procuring through UNICEF SD and /or PAHO. **Most of them were unlikely to have a fully functional NRA.**
- ❖ In 2014, **9% of countries procuring though a UN agency had a functional NRA** (and 41% of countries self-procuring) compared to 83% of producing countries.
- ❖ **Limited support to strengthen regulatory agencies in non-producing countries**
  - In 2018, out of 194 countries, **51% had their regulatory system at level 1** while 26% presented functional (level 3 or 4) NRA.
- ❖ All Gavi countries in transition presented some challenges and need for improved NRA and **approx. 90% of them had identified related activities in their transition plans**

# Gavi engagement in RSS has focused on countries in transition

Risks related to Gavi transition regarding regulatory systems	Actions undertaken so far to strengthen regulatory systems in transitioning countries
<b>Recipient procures non-pre-qualified vaccines since it is not mandatory anymore after transition</b>	<ul style="list-style-type: none"><li>- Conducted country NRA assessment (all transition assessments included a review of the NRA capacity and regulatory system in collaboration with WHO)</li><li>- Provide technical assistance and financial support to strengthen the NRA mainly:<ul style="list-style-type: none"><li>✓ Update of national guidelines and manual of procedures, SOPs, review of standards</li><li>✓ Human resources capacity building, especially in vaccine registration, market authorisation and pharmacovigilance</li><li>✓ Support to modernize registration process</li><li>✓ Training / workshop on AEFI monitoring</li><li>✓ Investment in needed equipment</li><li>✓ Peer-to-peer support (Thailand-Bhutan NRA exchange)</li><li>✓ Others...</li></ul></li></ul>
<b>NRA is not performing well enough to ensure availability of quality and safe vaccines (if poor pharmacovigilance including AEFI monitoring)</b>	
<b>Immature national regulatory processes can impact vaccine procurement: lengthy and cumbersome processes limiting access to competition</b>	

# Gavi engagement in Regulatory System Strengthening: way forward

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- **Short-term: Continue engaging with countries in producing and transitioning to ensure quality vaccines**
- **Start engaging with countries in preparatory phase**
  - NRA assessment (or at least self-assessment) done as soon as the country enters the preparatory phase to support through HSS and TCA
- **Explore to support more on regional and global opportunities**
  - Continue engaging in the harmonisation of regulatory processes across countries (e.g. Medicines Regulation Harmonisation (AMRH) work focusing on Regional Economic Communities)
  - To link with ongoing vaccine procurement capacity building work

# Important lessons

- ❖ **Sustainability has two components: financial and programmatic**
- ❖ **Support the development of national institutions is critical for programmatic sustainability**
  - The main bottleneck is not financial
  - Need to focus and improve how to support institutional development
  - Build political will
- ❖ **Early engagement and planning**
  - Addressing health systems bottlenecks and institutional constraints
- ❖ **Provide predictability and transparency**
  - Flexibility to innovate new approaches (Evolving or learning agenda)



**THANK YOU**

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# Different countries need different level of NRA maturity but there is room for improvement

## Critical control functions depending on vaccine source

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Maturity level	1	2	3	4
ISO	No formal approach	Reactive approach	Stable formal system	Continual improvement emphasized
WHO	Some elements of regulatory system exist	Evolving national regulatory system that partially performs essential regulatory functions	Stable, well-functioning and integrated regulatory system	Regulatory system operating at advanced level of performance and continuous improvement

- ❖ In 2014, **9% of countries procuring through a UN agency had a functional NRA** (and 41% of countries self-procuring) compared to 83% of producing countries.
- ❖ Gavi countries are almost all procuring through UNICEF SD and /or PAHO. **Most of them were unlikely to have a fully functional NRA.**
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