

SAGE April 2016

Preempting and responding to vaccine supply shortages

Introduction

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Objectives of the session

- Present the situation regarding shortages, including main reasons behind shortages
- Present initiatives in place to pre-empt and respond to these shortages
- Discuss the role of WHO on this issue, within the scope of the WHA resolution 68.6 on the GVAP urging WHO to address factors that can detrimentally impact vaccine availability.



Outline of the introduction

1. Background

2. What are the main causes?

3. What is being done?



1. Background



In 2015, stories about vaccine shortages have multiplied, leading to increased attention on vaccine security



Vaccine security:

“the sustained, uninterrupted supply of affordable vaccines of assured quality”¹

1 – UNICEF definition

Several vaccines are currently in short supply or at risk of a shortage

Vaccines in the WHO Model List of Essential Medicines:

Traditional vaccines	BCG
	MR, MMRV
	DTP
	* tOPV
Newer vaccines	aP-containing
	IPV
	HPV
	PCV
Vaccines with specific recommendations	Rotavirus
	Yellow Fever
	** Meningococcal
	Hep A
	Japanese Encephalitis
Vaccines with no known issues	Cholera

Vaccines with no known issues

Measles ; Hib ; HepB; DTP-HepB-Hib ; TT ; Td ; Rabies ; Typhoid ; MMR, Seasonal influenza

Legend:

- Known shortages in several countries and regions
 - Known shortages in a few countries, or vaccine at risk of shortage (eg. with 2 or less manufacturers)
- * Due to the switch to bOPV
** Short supply of multivalent vaccines

- 15 out of 25 vaccines in shortage or at risk of a shortage (60%).
- Issues for newer vaccines are mainly linked to mono/duopoly situations.
- Issues are more complex for traditional vaccines and vaccines with specific recommendations.
- Other biologicals also in shortages (e.g. diphtheria antitoxin, snake antivenoms).



Vaccine shortages can lead to stockouts

Shortage

There is a vaccine shortage when a vaccine cannot be obtained by a country in sufficient amount to cover the full population at risk.

Global shortage



Country shortage



Stockout

There is a stockout of vaccine when stocks at the national or district levels have been depleted¹. Vaccines are not available to anyone anymore.

1 - GVAP Secretariat, Global Vaccine Action Plan Monitoring, Evaluation & Accountability, Secretariat Annual Report 2015.



Global concerns over shortages are being brought to WHO's governing bodies

MEDICINES

138th WHO
Executive Board
January 2016

69th World Health
Assembly
May 2016



WHO Member States underscored the need for public health approach to world drug problem



Preparation of a resolution on “Addressing the global challenges of medicines shortages”

VACCINES

68th World Health Assembly
May 2015



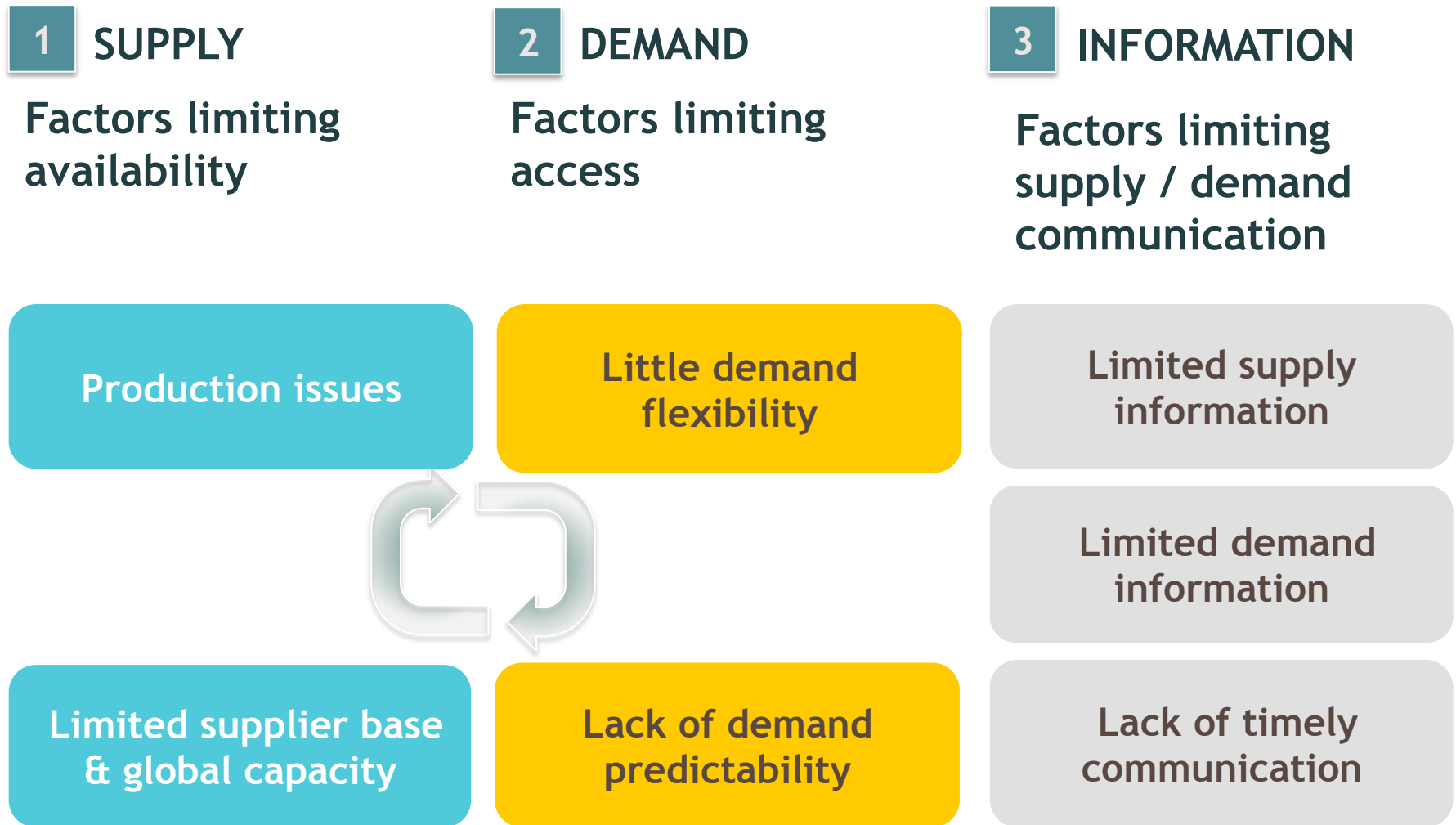
Resolution 68.6 on Global Vaccine Action Plan (GVAP):

“[...] the establishment of effective and sustainable vaccine production, supply, procurement and delivery systems is essential to ensure access to all the necessary vaccines of assured quality at the right time”

2. What are the main causes?



There are several known causes behind shortages



Causes of shortages: BCG example

1 SUPPLY

Factors limiting availability

- 4 manufacturers with prequalified products in 2015 (+1 in 2016)
- Technical issues at manufacturing sites
- Low market attractiveness

2 DEMAND

Factors limiting access

- Fluctuations in demand
- Lack of knowledge on alternative solutions

3 INFORMATION

Factors limiting supply / demand communication

- Countries expressing concerns about lack of availability
- Countries not informed about upcoming risk of shortage



Main area of concern



Causes of shortages: aP containing vaccines example

1 SUPPLY

Factors limiting availability

- Only 2 manufacturers (0 prequalified)
- Complex manufacturing process. Long production time. Manufacturing delays and quality testing issues

2 DEMAND

Factors limiting access

- Safety concerns leading countries to switch from wP-containing vaccines to aP-containing vaccines
- Steady increase in global demand, particularly coming from MICs

3 INFORMATION

Factors limiting supply / demand communication

- Lack of information on demand evolution, leaving manufacturers with little time to ramp up capacity
- Lack of communication on reasons for supply issues and timeline for re-supplying leading to ad-hoc mitigation actions and distrust



Main area of concern

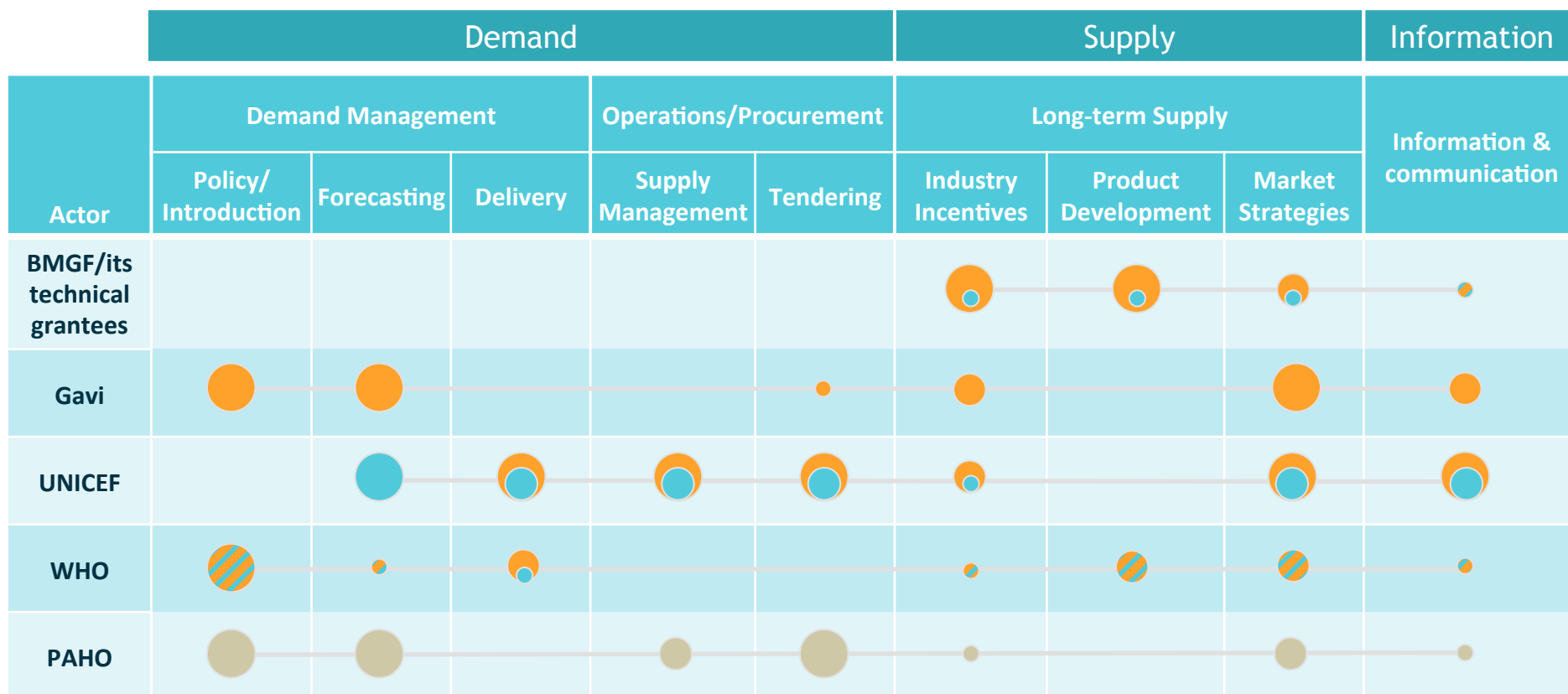


3. What is being done?



There are several actors working on supply and demand

Main international partners



- Several global actors across areas
- Most actors have a specific focus (e.g. PAHO on PAHO countries, Gavi on Gavi countries/vaccines)

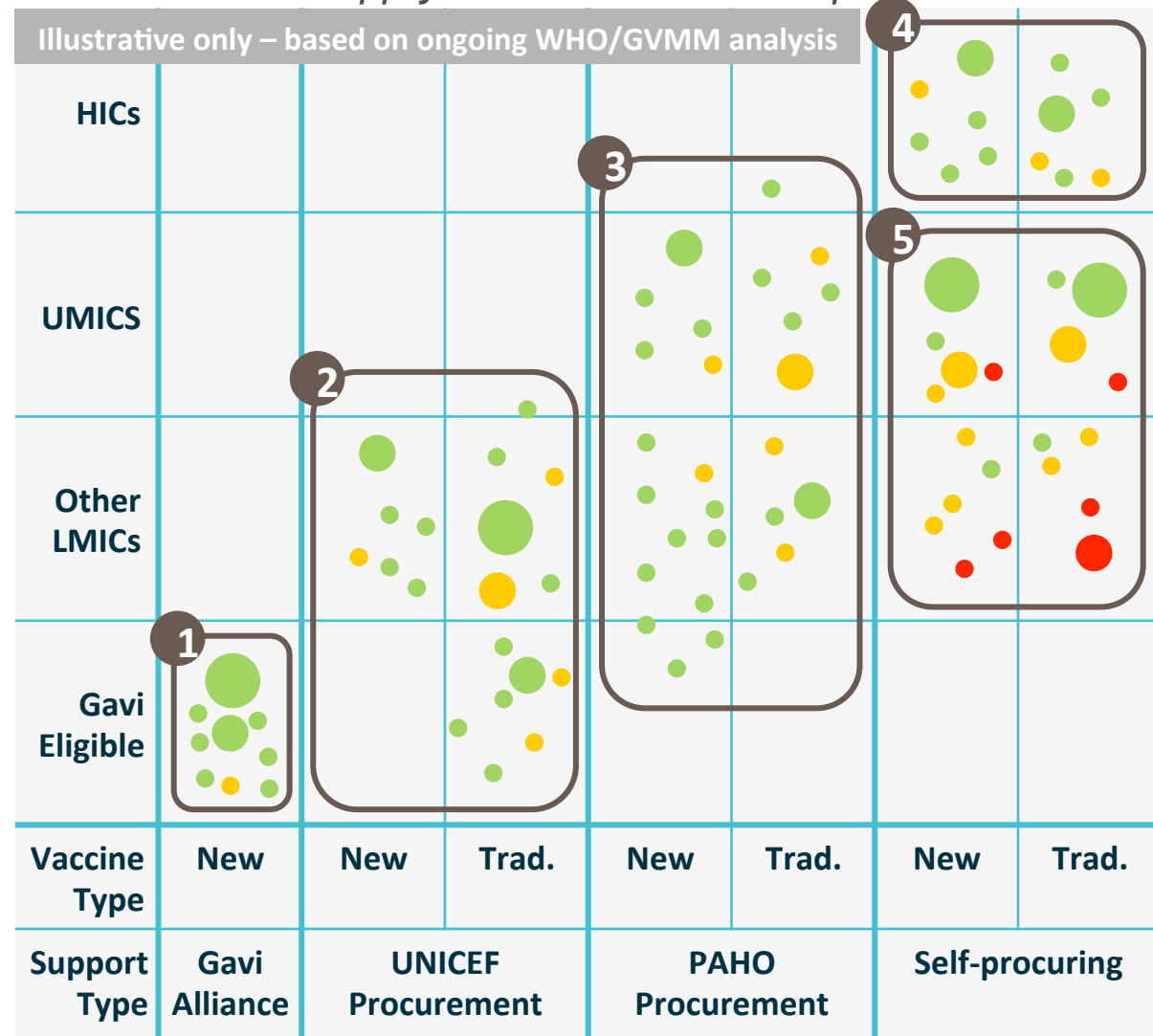


Size of circle indicates level of focus



Supply/demand risk is highest in self-procuring Middle Income Countries (MICs)

Vaccine markets supply/demand risk landscape:



5 Self-procuring MICs have mixed prospects. With several countries vulnerable to markets not being able to meet their demand at affordable prices.

Country demand vs. supply risk: ● Lower ● Medium ● Higher
Size of circle indicates demand volume

Outline of the session

- Dealing with vaccine shortages
 - **Oleg Benes, WHO EURO:** Impact of shortages and solutions set up by countries
 - **Michael Sulzner, European Commission DG SANTE:** Vaccine shortages: Improving cooperation, communication and management in the European Union
 - **Ann Ottosen, UNICEF SD:** Global operational procurement planning and long-term strategic supply security
- Statements & discussion



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Thank you!

