



Developing Countries Vaccine
Manufacturers Network

Protecting people against known and emerging infectious diseases globally

18 October 2017
SAGE – Geneva

By
Mahima Datla
President, DCVMN

Agenda

- **Introduction to DCVMN**
- **DCVMN's contributions**
- **Suggested areas for engagement**

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DCVMN: An Introduction

DCVMN was established in the year 2000 with the mission of increasing the quality and availability of vaccines affordable to all

The network is a public health driven, international alliance of manufacturers. It currently has **50 member organizations** from **17 countries/territories**

Objective of the Network:

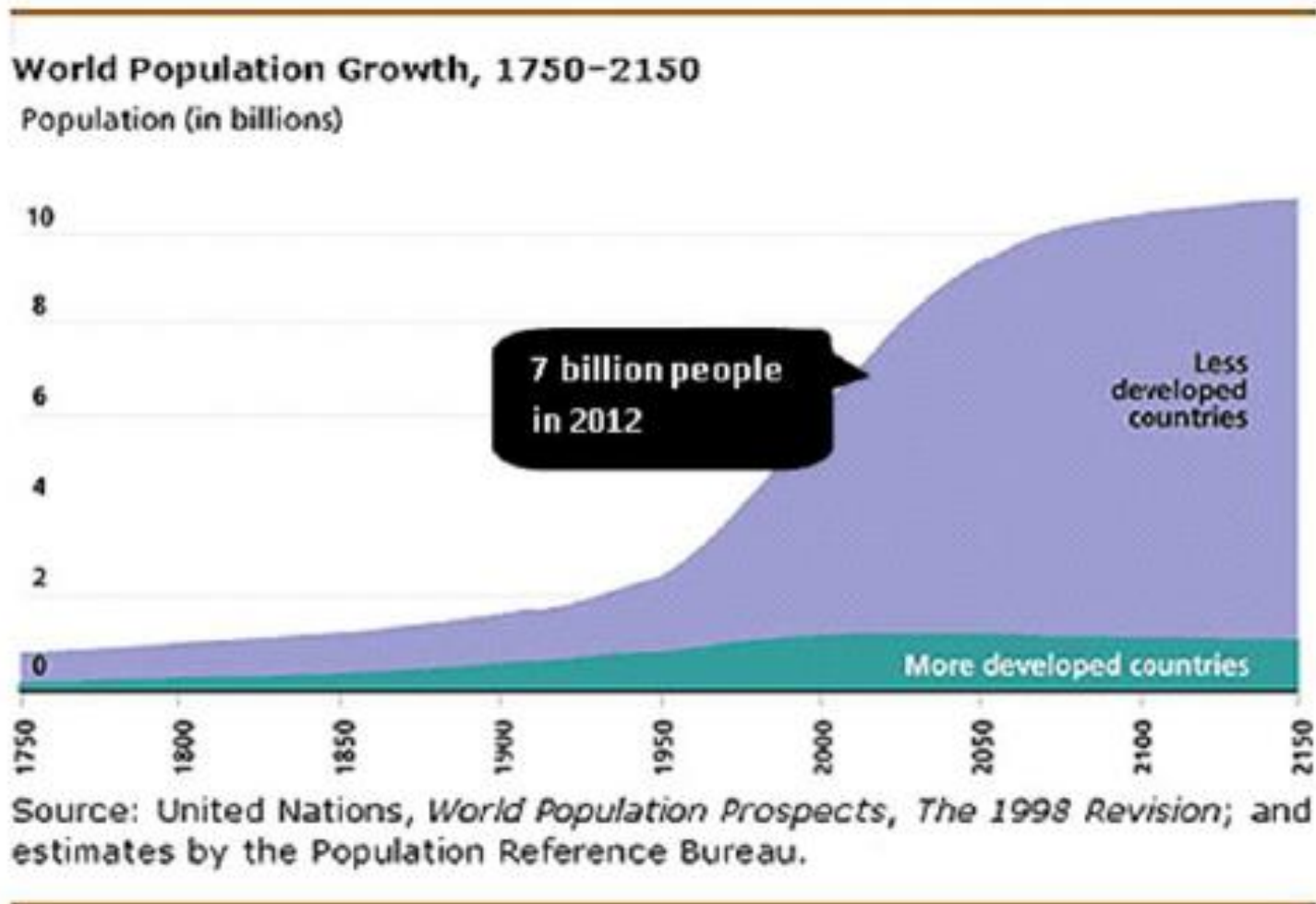
- To provide a consistent and sustainable supply of quality vaccines at an affordable price to developing countries

Following are the ancillary objectives and goals:

- To form a voluntary public health driven alliance of vaccine manufactures from developing countries
- To strive for an International recognition such that developing country vaccine manufactures have an essential role in assuring the availability of quality vaccines for national immunization programs
- To encourage continuation of Research and Development efforts to meet the emerging vaccine needs in the developing world
- Foster the development of members of the network to attain the status of WHO pre-qualification
- Foster collaboration and communication amongst members of the network and actively participate in the international vaccine community to accomplish network specified goal

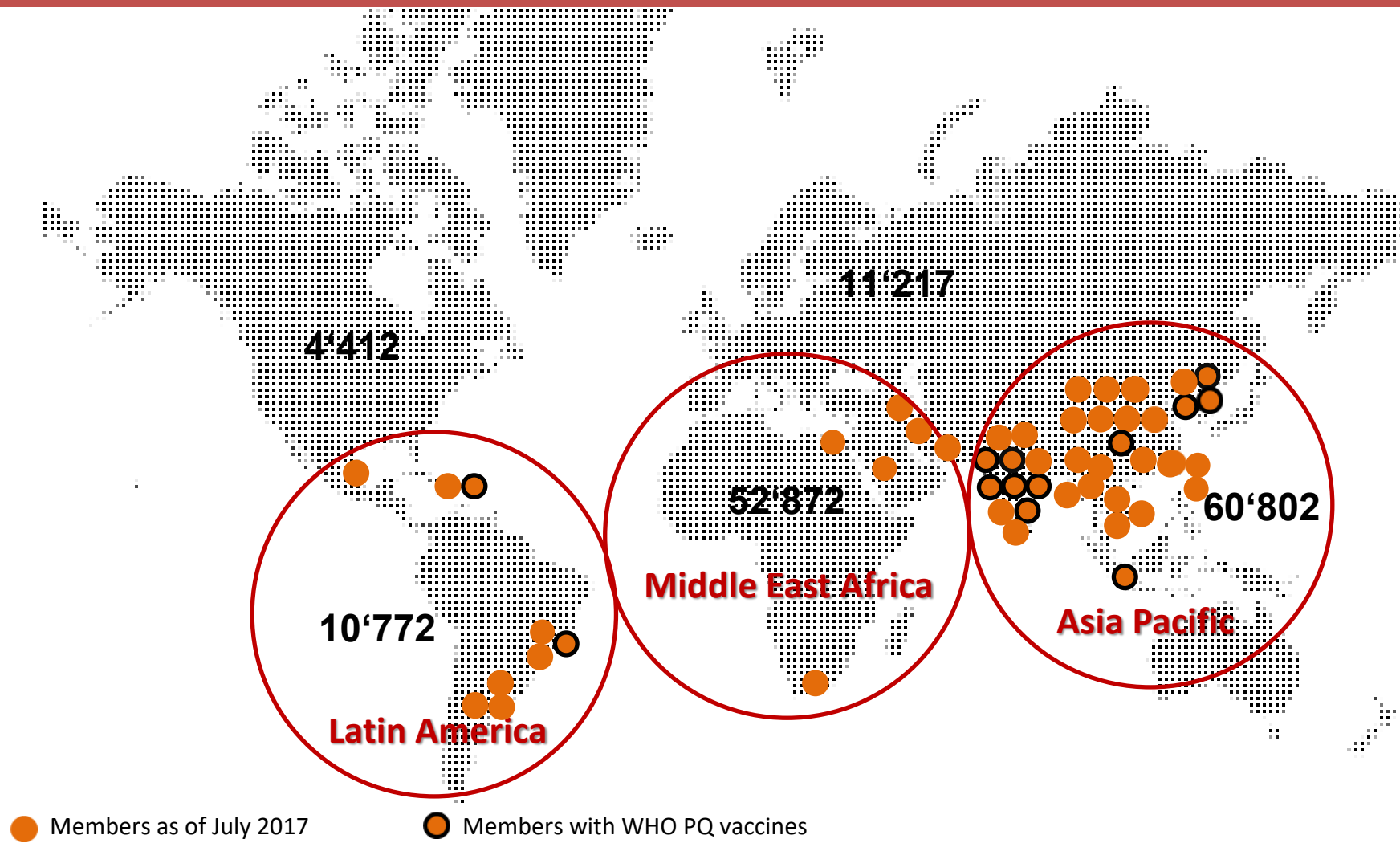
Our Challenge: vaccination to all people

The developing world needs affordable vaccines



DCVMN 2017:

50 manufacturers from 17 countries/territories

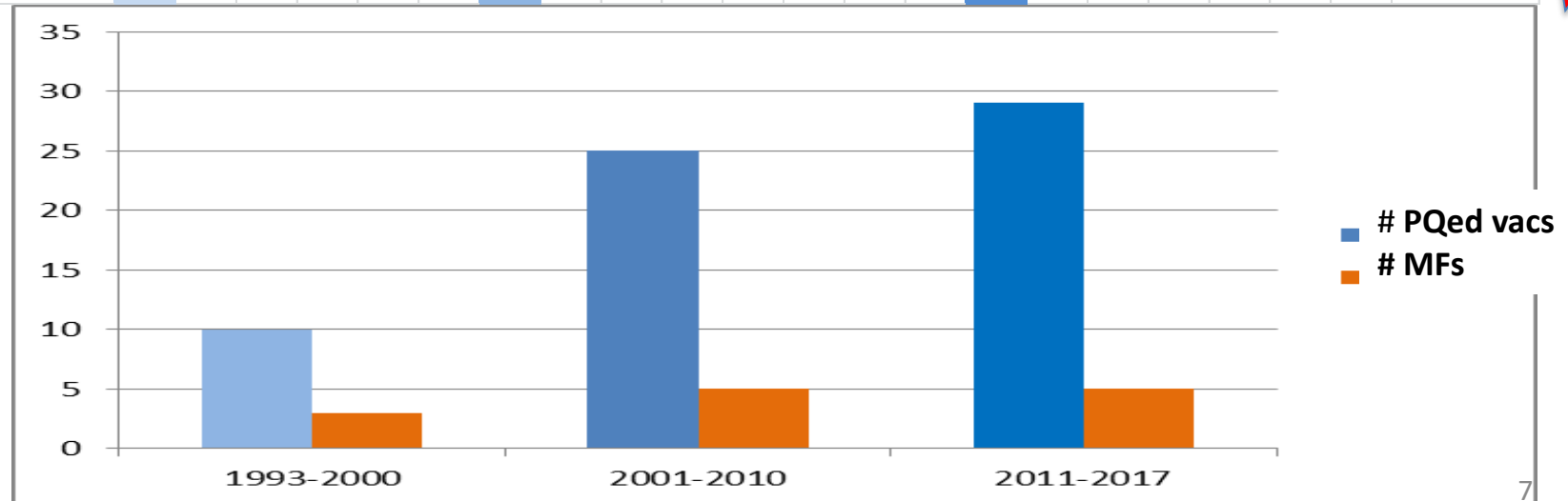


number of birth cohorts 2015 regionally are indicated in black (x1000)

http://www.who.int/immunization/monitoring_surveillance/data/en/

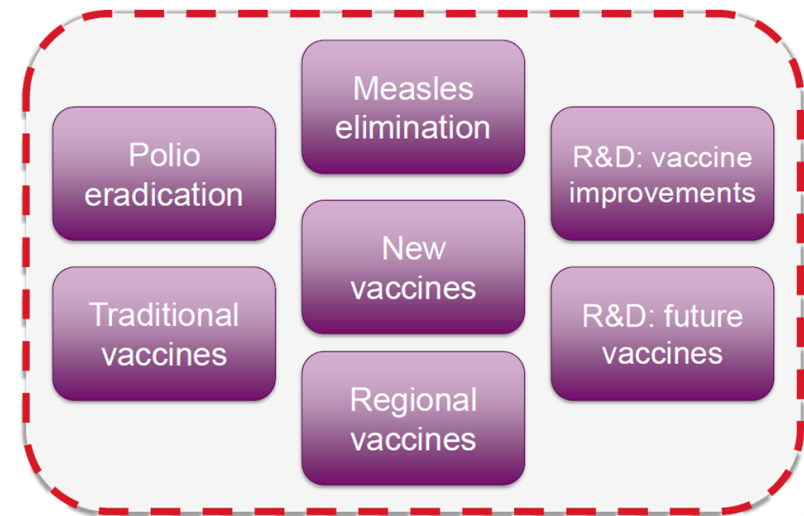
DCVMs increasing public health engagement with 64 PQed vaccines over 25 years

Manufacturer/Year	1993	1995	1996	1997	1999	2000	2001	2003	2004	2006	2007	2008	2009	2010	2011	2012	2013	2014	2015	2016	2017	PQ vaccines	
Bharat/India																			1		1	2	
BioE/India													1		1	2	1	2		1		8	
BioM/Brazil							1				1											2	
CNBG/China																	1					1	
CIGB/Cuba							1							1								2	
EuBiologics/Korea																			1		1	2	
GreenCross/Korea														1	1	1				1	1	5	
Green Signal/India																			1			1	
Haffkine/India										1			1	1								3	
LG Chem/Korea			1														1			1		3	
Panacea/India																		1				1	
Biofarma/Indonesia				2	2		1	1	2	1			1	1	1			1	1			14	
Serum Institute/India	1	3				1		2	1	2		1		3		1	1	2	1	1		20	
Total	13	1	3	1	2	2	1	3	3	3	4	1	1	3	7	3	5	4	5	5	4	3	64
		10						25								29						from 145*	



Role of DCVMN in ensuring vaccines availability across all categories

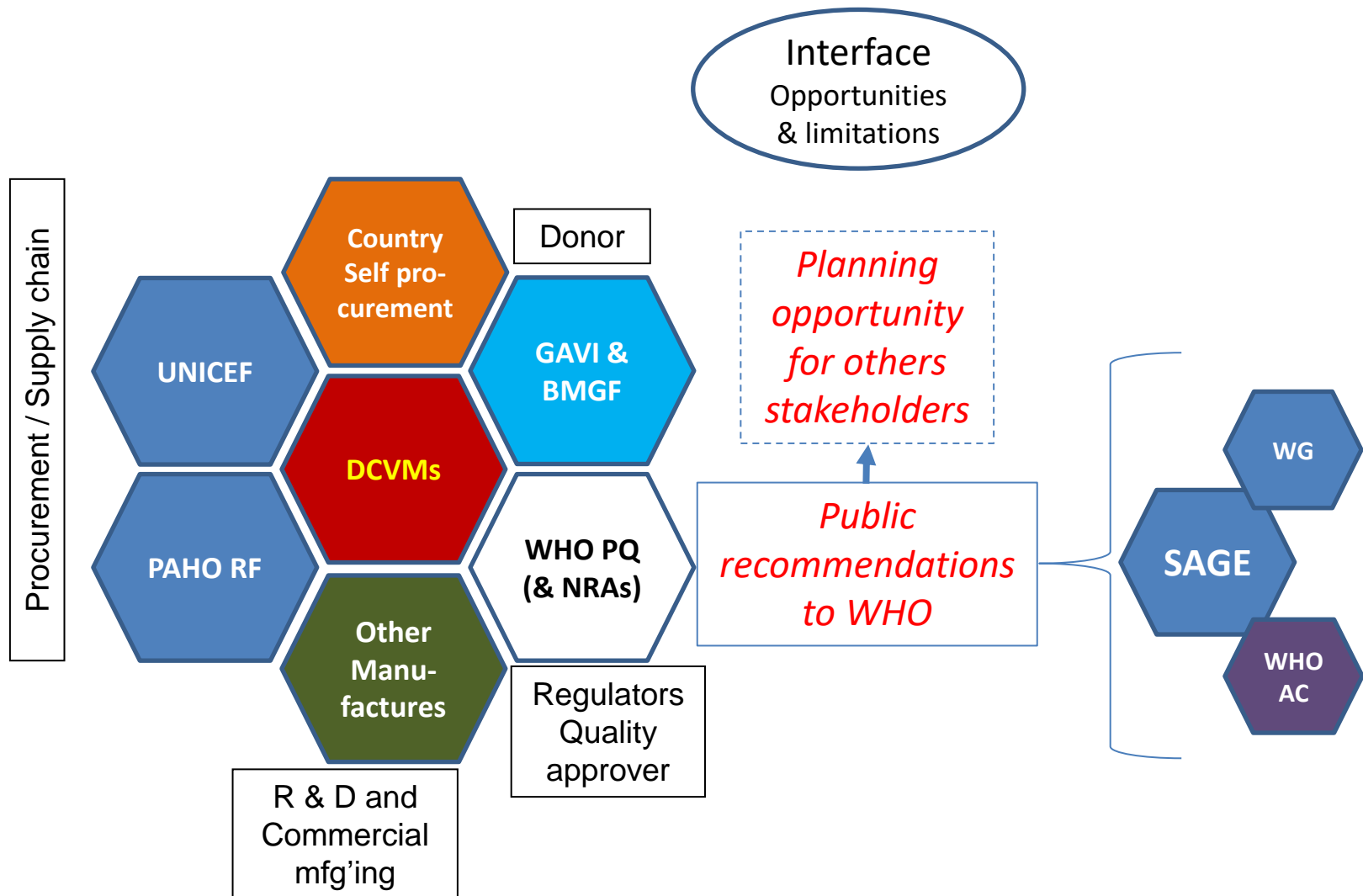
Disease	# of vaccines by DCVMs				# of vaccines by non-DCVMs			
	PQed	Local license	Under development	Total	PQed	Local license	Under development	Total
Endemics								
Pentavalent	5	2	2	9	3	-	-	3
HPV	-	-	8	8	2	-	1	3
JE	2	3	2	7	1	1	-	2
M/MR/MMR	3	4	6	13	1	1	1	3
Meningitis	1	4	2	7	2	2	1	5
PCV	13	-	-	13	2	-	1	3
Rota	-	2	9	11	2	-	1	3
YF	1	1	1	3	3	-	-	3
Cholera	1	1	1	3	2	2	-	4
Typhoid	-	1	6	7	-	-	-	-
Rabies	-	6	4	10	1	1	1	3
Dengue	-	-	6	6	-	1	2	3
Malaria	-	-	1	1	-	1	-	1
RSV	-	-	1	1	-	-	2	2
Hep B	-	4	1	5	-	1	-	1
Hep E	-	1	1	2	-	-	-	-
Hep A	-	3	1	4	-	1	1	2
Epidemics								
Ebola	-	-	1	1	-	-	3	3
Zika	-	-	2	2	-	-	1	1
Chikungunya	-	-	1	1	-	-	1	1
Other vaccines								
IPV	2	2	7	11	1	1	2	4
Flu	1	4	2	7	3	1	1	5



DCVMN collaborative approach with Global Health Agencies

- Regular participation, **as observers**, in various WHO vaccine-related activities and advisory meetings, including PDVAC, ECBS, IPAQ/PSPQ SC, IVIR-AC, GVSII, WHO PQ, WHO D&T Advisory Group, and SAGE.
- Standing seat at the board of Gavi, the Vaccine Alliance, and Gavi Program & Policy Committee and Governance Committee.
- *ad hoc* participation at Unicef meetings.
- Endorsement of CEPI Partners' Forum.

SAGE interface with other stakeholders incl. DCVMN



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Contribution to UNICEF supplies

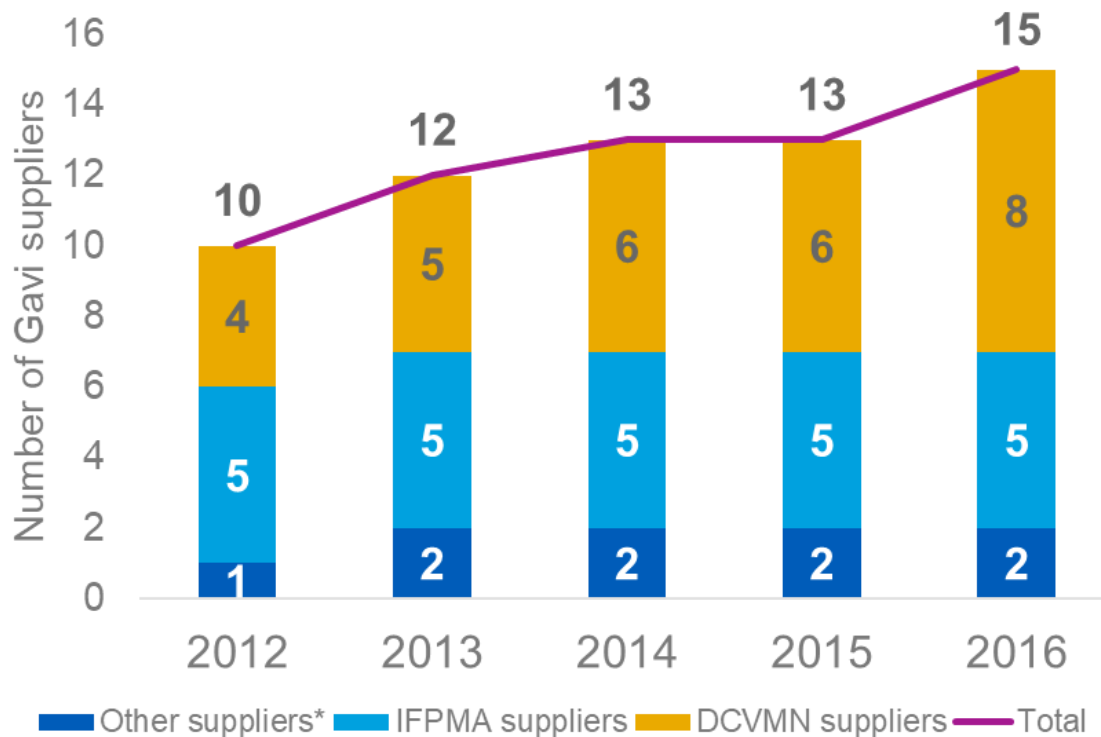
Number of Developing Countries Vaccine Manufacturers contributing to UNICEF supplies has increased significantly in the last 15 years and DCVMs are today major contributors towards UNICEF's supply security:

Country	No. of DCVMN members* supplying to UNICEF	
	2001	2016
Brazil	-	1
China	-	1
India	1	7
Indonesia	1	1
Republic of Korea	1	2
Total # of DCVMN members	3	12
Total # of organizations supplying to UNICEF	15	21

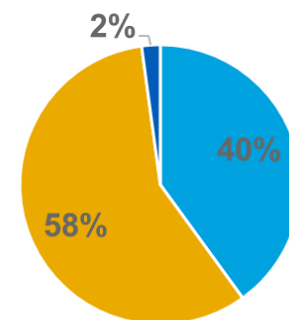
Source: UNICEF Supply Division

* Members as of now

Contributing to a broad basis of vaccines supply to GAVI countries



% of Gavi supplied doses 2012-2016

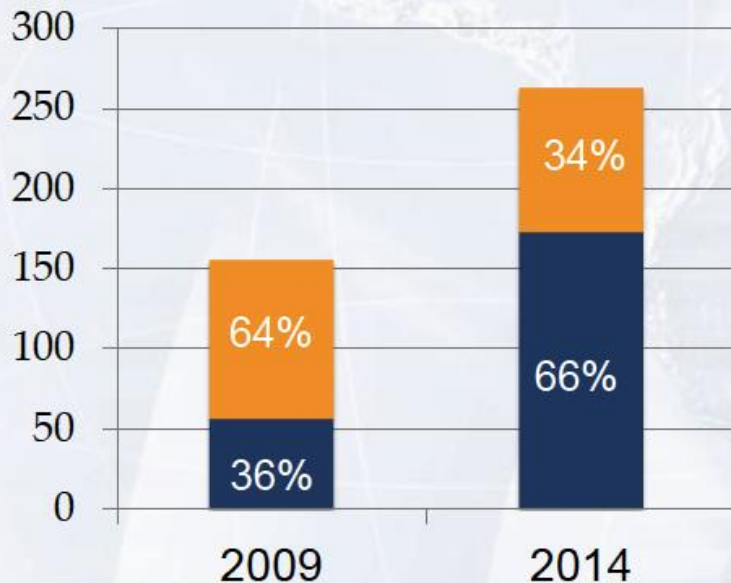


DCVMN supplied Gavi with 1.5bn doses over 2012-2016

DCVMN supplies through PAHO

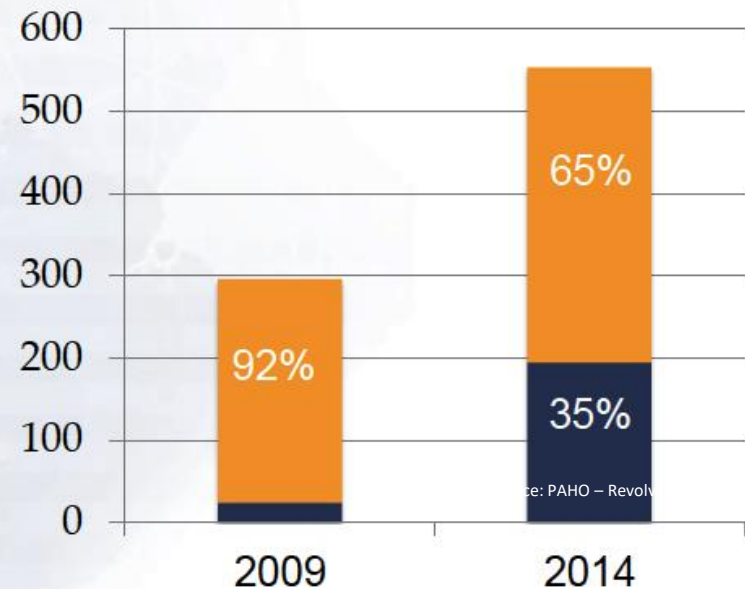
“Every year more vaccines are delivered by DCVMN manufacturers through PAHO Revolving Fund”

Volume (Million doses)



■ DCVMN ■ Others

Procured Value (US\$ Million)



Pan American
Health
Organization



World Health
Organization
REGIONAL OFFICE FOR THE
Americas

The case of wP based Pentavalent

- With GAVI's efforts and DCVMs' supplies, Pentavalent coverage has increased from 1% in 2000 to 78% in 2016 in GAVI supported countries
- Since 2007, global demand for wP-based pentavalent vaccines has increased rapidly from <100Mio to ~300Mio doses per year
- DCVMs have partnered with GAVI in improving the affordability of the vaccines globally

DCVMN members success stories towards achieving GVAP goals

- Oral Polio Vaccines – Bio Farma & Filling Partners (Haffkine, Bharat, SII, others)
- Inactivated Polio Vaccine (IPV) – Serum Institute of India/Bilthoven Biologicals and Sabin IPV available in China since 2015 – IMBCAMS and CNBG
- Pentavalent, MR & Tetanus – Biological E, LGChem, Panacea, Biofarma, SII,
- MenAfriVac – Serum Institute of India
- Japanese Encephalitis Pqed vaccines – Chengdu Institute Biological Products & Biological E
- Oral Cholera Vaccine PQed and available in new plastic presentation - EuBiologics
- Novel Rota and typhoid conjugated vaccines available in India – Bharat Biotech
- Novel thermo stable rotavirus vaccine available since February 2017 in India – Serum Institute of India

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Suggested areas of engagement

- SAGE product-related and other recommendations impact vaccine supply and demand scenarios and hence SAGE's recommendations can use current market context while providing recommendations.

Examples

- wP vs. aP
- IPV: 1 dose to 2 doses
- SAGE could encourage improved procurement policies and processes which are transparent and sustainable for Developing Countries Manufacturers
 - More accurate forecasts & Rolling updates
 - Increasing regulatory requirements and pressure from procurement agencies adversely impacting long term sustainability of DCVMs

Suggested areas of engagement

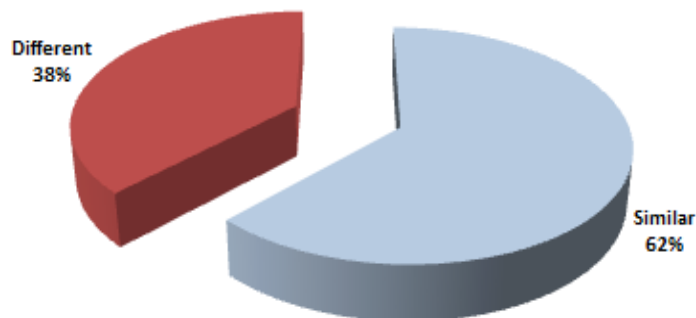
- Access to some of the critical vaccines could be improved by recognizing safer strains which would have different safety and containment requirements (e.g. Polio strains)
 - Example: Polio strains
- SAGE can advocate for improvements in WHO PQ process:
 - Concurrent or prospective validation for manufacturing processes
 - Rolling or parallel submissions for PQ
 - Reducing the complexities of the lot release processes to reduce the lead times and variability in test results
- Convergence of regulatory requirements (discussed in the following slides)

Vaccine Registration Experts Meeting

May 15 and 16, 2017, in Geneva

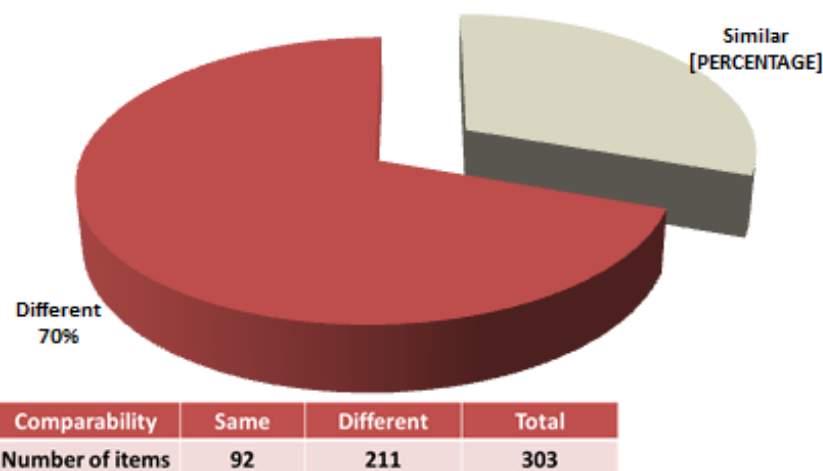


COMPARISON OF CTD MODULE 1 CONTENT FROM AUSTRALIA, CHINA, EUROPE, GCC, INDIA, JORDAN, PAHO, TANZANIA, THAILAND, US AND WHO



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COMPARISON OF CTD MODULE 1 NUMBERING FROM AUSTRALIA, CHINA, EUROPE, GCC, INDIA, JORDAN, PAHO, TANZANIA, THAILAND, US AND WHO

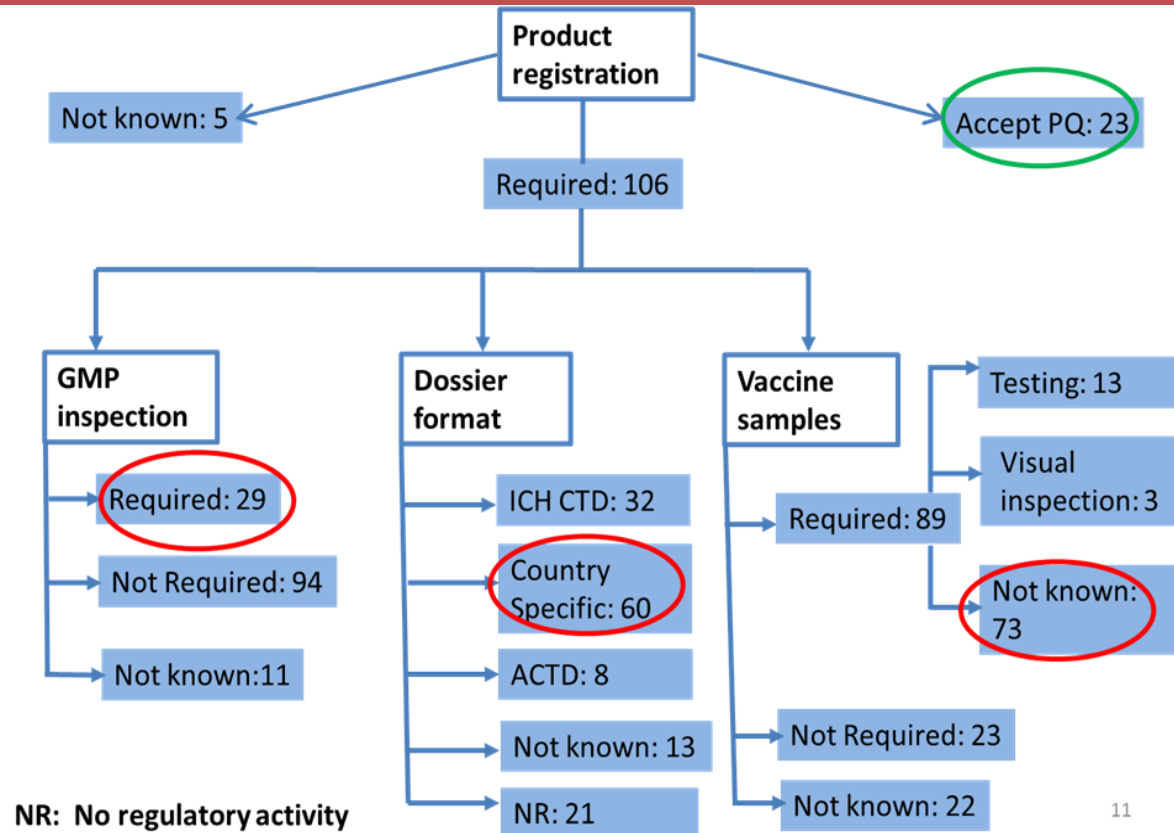


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Advocating for **convergence of registration processes** and **alignment of registration dossiers** will go a long way in ensuring faster supply of vaccines

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Divergent vaccine registration requirements in 134 countries



SAGE can advocate for recognition of WHO PQ as an accreditation for vaccines registration so that country specific requirements are waived or are much quicker, if required (e.g. for GAVI countries)

Thank you



Individually we are one drop, together we make an ocean .

Ryunosuke Satoro

www.dcvmn.org