

# **New vaccine introduction in MIC: current initiatives to address financial challenges**

**What is to be done to respond to country needs and comply with WHA and SAGE recommendations?**

# Plan

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- SAGE recommendations revisited
- Global road map and strategy principles and components
- Implementation and coordination dimensions

# 2008 : SAGE recommendation and WHA RESOLUTION

## Strategies

The strategies proposed for assisting LMICs fall under three broad areas:

- 1) providing technical support to develop and enhance the knowledge and skills within LMICs
- 2) raising awareness of the issues among stakeholders and establishing policies to better reflect the issues for LMICs
- 3) promoting an enabling environment to create a healthy market and facilitate access to affordable, high quality, new vaccines and technologies.

SAGE requests that WHO conduct further **situation analysis of financial challenges** for low and middle-income countries and consultation with countries concerned & partners to **distil issues to more actionable activities.**

## 2008 WHA RESOLUTION

**Concerned** that many developing countries are not on track to meet the internationally agreed targets in the health-related Millennium Development Goals, particularly the target of reducing the under-five mortality rate;

**Concerned** that there are insufficient resources available for introduction of new and underutilized vaccines, especially in low-income and middle-income countries, and given the costs related to procurement and introduction of these vaccines, and taking into account the need to expand the number of manufacturers, particularly in developing countries, that can produce to the standards required to attain and maintain WHO-prequalification and to create a competitive market place for these vaccines

### REQUESTS the Director-General:

- (1) to work and increase collaboration with Member States in order to sustain political commitment at all levels for achieving high immunization coverage rates with all available cost effective vaccines;
- (2) to collaborate with international partners and intergovernmental partners in order to provide technical support to expand the number of manufacturers, particularly in developing countries, that can meet the standards required to attain and maintain WHO-prequalification standards;
- (3) to collaborate with international partners, intergovernmental partners and donors as well as vaccine producers to mobilize necessary resources to support low-income and middle-income countries with the aim of increasing the supply of affordable vaccines of assured quality;
- (4) to work with UNICEF and the GAVI Alliance to build on existing international efforts and partnerships and facilitate the development of a consensus among developing and developed countries for meeting the financial gaps and other requirements for the attainment of the health-related Millennium Development Goals through immunization;

# SAGE RECOMMENDATIONS IN 2010

SAGE noted that **price continues to be a major barrier** preventing the introduction of new vaccines in these countries. SAGE emphasized the need for advocacy at national, regional and global levels to support equitable access to new vaccines.

SAGE endorsed the WHO activities in **gathering epidemiological and vaccine-related data at regional and country levels**, and encouraged WHO to assist countries to use data from neighboring countries and their region for decision-making. SAGE recognized that this required strengthening of the WHO country offices in lower-middle-income countries.

SAGE requested that WHO **facilitate the establishment of a partnership** among all relevant stakeholders to consider: **pooled procurement; tiered pricing; greater transparency of pricing; and exploring the role that UNICEF, the Pan American Health Organization and foundations can have in assisting these countries with procuring and financing vaccines.**

# A GLOBAL STRATEGY TO SUPPORT MIC: PRINCIPLES?

Seeking an enabling environment and system strengthening not financial assistance or charity

- Filling out the :
  - Information gap
  - Capacity gap
  - Networking gap
- Promoting **country ownership** and using **comparative advantage** of each and all partners (in line with GVAP)
- Building on existing efforts and capacities but in a more concerted and coordinated manner

# Global Policy for MIC

Creating and promoting an enabling environment and systems building process

**Evidence  
Base &  
Capacity  
Building**

**Policy &  
Advocacy**

**Pricing &  
Financing**

**Supply &  
Procurement**

# R4D Lower Middle Income Country Study

## Priority Recommendations

Theme	Country Level	Regional Level	Global Level
<b>Evidence and capacity building</b>	Strengthen epidemiological and economic analysis capacities	Actively promote and strengthen regional information sharing and joint research on BOD, pricing, cost-effectiveness, etc. (regional clearinghouse)	Create a technical and reliable source for global vaccine market information including vaccine pipe line, vaccine prices, pricing policies, procurement principles and practices
<b>Policy and advocacy</b>	Improve procurement regulation to promote competition, quality and sustainability	Conduct advocacy to strengthen political will and support champions for new vaccines	Conduct advocacy to strengthen political will, regulation and policy development
<b>Financing</b>	Take steps to increase domestic funding and capacities to negotiate with Ministries of Finance and other potential funders	Increase countries' and partners' awareness of the value of vaccination in the broader context of government investment and achievement of the MDGs	Promote transparency and access to comparatively low and affordable vaccine prices with sustainable domestic financing
<b>Procurement and supply</b>	Consider using or joining a pooled procurement mechanism	Develop inter-country and regional processes for achieving pooled procurement, vaccine quality, safety and diversified and sustainable base of supply	Support regional and country activities for efficient and effective procurement systems through assessment, and identification of improvement to current practices and policies

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**Targeted Approach**

**Pragmatic Approach**



# What that mean in practical terms?

- The expansion of available tools to meet the individual specific needs of GAVI graduating countries and MIC
- The revision and adjustment of certain existing mechanisms to better respond to GAVI graduating and MIC contexts
- The design and development of innovative mechanisms in line with the challenges faced by GAVI graduating and MIC

# A PRAGMATIC APPROACH?

## USE EXISTING TOOLS

- expansion of available tools to meet the individual specific needs of GAVI graduating countries and MIC
- Examples: cMYP, EVM, PIE, NITAG, NRA,..

## REVISE EXISTING MECHANISMS

- revision and adjustment of certain mechanisms to better respond to GAVI graduating and MIC contexts;
- Examples: UNICEF procurement services, Procurement regulation, access to favorable pricing,..

## DEVELOP NEW OPTIONS

- design and development of innovative mechanisms in line with the challenges faced by GAVI graduating and MIC.
- UNICEF specific window for MIC, Capital fund, Pooled procurement, explicit tiered pricing,..

# TARGETED APPROACH

## BY PRODUCT

- Combo vaccines
- PCV
- RV
- HPV, IPV,..

## BY PRIORITIZING COUNTRIES

- Graduating countries
- "Threshold" countries
- "Isolated", Island countries
- Populated, local production,..

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**Targeted Approach**

**Pragmatic Approach**

**Priority  
products**

Combo vaccines,  
PCV,  
Rotavirus,  
HPV,  
IPV  
...

**Priority  
countries**

facing significant  
challenges  
eg GAVI  
Graduating,  
“Threshold”  
countries  
developing or  
isolated countries.

**Expanding the  
use of existing  
tools**

to meet the individual  
specific needs of GAVI  
graduating countries  
and MIC, such as  
cMYPs, NITAGs, NRAs,  
disease surveillance,  
forecasting, economic  
analysis, vaccine  
management...

**Revising and  
adapting  
existing tools**

for Graduating & MIC  
context such as  
UNICEF procurement  
service requirements,  
procurement  
regulations, and  
access to favourable  
pricing, regional  
information exchange  
opportunities, country  
networks, advocacy &  
resource mobilisation

**Develop new  
mechanisms**

such as a UNICEF  
specific tendering for  
MIC, a capital fund,  
inter-country pooled  
procurement, explicit  
negotiated prices with  
clear eligibility criteria,  
tech transfer and  
intellectual property,  
research &  
development...

# Coordination and funding are the key missing Implementation requirements

- Coordination among partners and with regions and countries

- An operational task team coordinated by WHO?

- Funding

The assistance needed requires very modest amount of resources compared with those needed to subsidize the procurement of vaccines

➡ Modest investment amount with very significant impact on new vaccine introduction, public health , economic and vaccine market

Global strategy to support MIC: Game changer with a high RoI