



ASEAN VACCINE SECURITY & SELF-RELIANCE (AVSSR) National Vaccine Institute (NVI), Thailand

7th ASIAN VACCINE CONFERENCE 2019

Lotte Hotel Yangon, Myanmar

14th September 2019



History & Background of the AVSSR

2014

NVC Advises NVI to bring to attention vaccine security in the ASEAN Platform

2014 & 2015

NVI, in partnership with WHO SEARO, brings together ASEAN vaccine stakeholders to discuss regional collaborations for vaccines

2015

The regional collaboration for vaccine security (AVSSR) is proposed by NVI and endorsed by the ASEAN Senior Officials Meeting on Health Development

2016

AVSSR is endorsed by the ASEAN Health Ministers & adopted into the ASEAN Health Priority Issue Work Plan



Areas for collaboration identified by ASEAN stakeholders

- System Development for Vaccine Security: Regional Stockpile
- Human Resource Development
- Price Policy and Pooled Procurement
- Communication and Coordination Plan

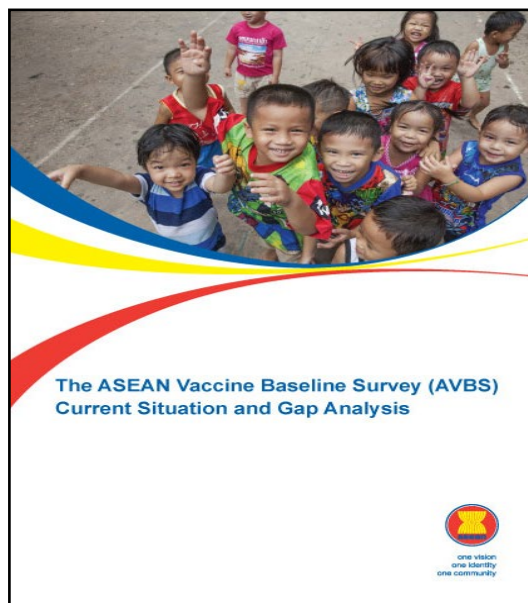


NVI Leads Activities for AVSSR

- ASEAN Vaccine Baseline Survey
- ASEAN Leaders Declaration on Vaccine Security & Self-Reliance
- Regional strategic and action plan



Status of the ASEAN Vaccine Security & Self-Reliance



AVBS 2017: Capacity of ASEAN Member States

- Vaccine R&D
- Local Vaccine Production
- National Regulatory Authority
- National Immunization Program

ASEAN Leaders' Declaration on ASEAN Vaccine Security and Self-Reliance (AVSSR)

1. **WE**, the Heads of State and Government of the Association of Southeast Asian Nations (ASEAN), namely Brunei Darussalam, the Kingdom of Cambodia, the Republic of Indonesia, the Lao People's Democratic Republic, Malaysia, the Republic of the Union of Myanmar, the Republic of the Philippines, the Republic of Singapore, the Kingdom of Thailand, and the Socialist Republic of Viet Nam, on the occasion of the 35th ASEAN Summit in Bangkok, Kingdom of Thailand, on November 2019:
2. **RESPECTING** independency and self-reliance of ASEAN Member States (AMS), as well as to the regional and global solidarity]
3. **RECALLING** the Global Vaccine Action Plan (GVAP) was endorsed by the 194 Member States of the World Health Assembly in May 2012 to achieve the Decade of Vaccines vision by delivering universal access to immunization. The GVAP mission is to improve health by extending by 2020 and beyond the full benefits of immunization to all people, regardless of where they are born, who they are or where they live;
4. **REAFFIRMING** our commitment to the ASEAN Post-2015 Health Development Agenda and the

ALD-AVSSR Endorsed at:

ASEAN Health Cluster 3: July 2019

Senior Officials Meeting on Health Development: August 2019

ASEAN Health Ministers: August 2019

Key Components of the ALD on AVSSR

- Strengthen **Collaboration and Cooperation** among ASEAN Member States to ensure Sustained, **Uninterrupted and Timely supply** of **Affordable Quality Vaccines** to Prevent, Control and Reduce the Burden of Vaccine Preventable Diseases in ASEAN Region
- Aims to achieve **Regional Vaccine Security**
- Build **Capacity** and **Share Best Practices**
- Develop, Implement and Monitor regional **Strategic and Action Plans** to achieve equitable access to safe affordable quality vaccines.
- Support the development of **Platforms to Operationalize Plans** to address key priority areas of shared regional concern





Next Steps of the AVSSR

1. Propose the ALD-AVSSR for endorsement at:
 - ASEAN Socio-Cultural Community Council
 - ASEAN Coordination Committee
 - **ASEAN Summit (November 2019)**
2. Develop the Strategic & Action Plan:
 - Communication & Coordination Plan
 - Price and Pooled Procurement Mechanism
 - Emergency Regional Stockpile
 - Human Resource Development Program
 - Implementation Body for the AVSSR (E.g. Advisory Committee, Working Group, Consortium)

Yangon, Myanmar
14 September 2019

Collaboration in vaccine procurement to achieve supply security

Session: ASEAN Vaccine Security and Self-Reliance

UNICEF

- Types of collaboration in procurement (Price sharing, Joint Tenders, Pooled Procurement)
- Challenges of collaboration for vaccine procurement for multiple countries
- Requirements / Prerequisites for pooled procurement and other collaborative mechanisms for procurement
- Benefits of pooled procurement in the region

Vaccine Security - UNICEF's Focus - For Every Child

Vaccine Security = sustained & uninterrupted supply of affordable vaccines of assured quality



Accurate forecasting



Available funding

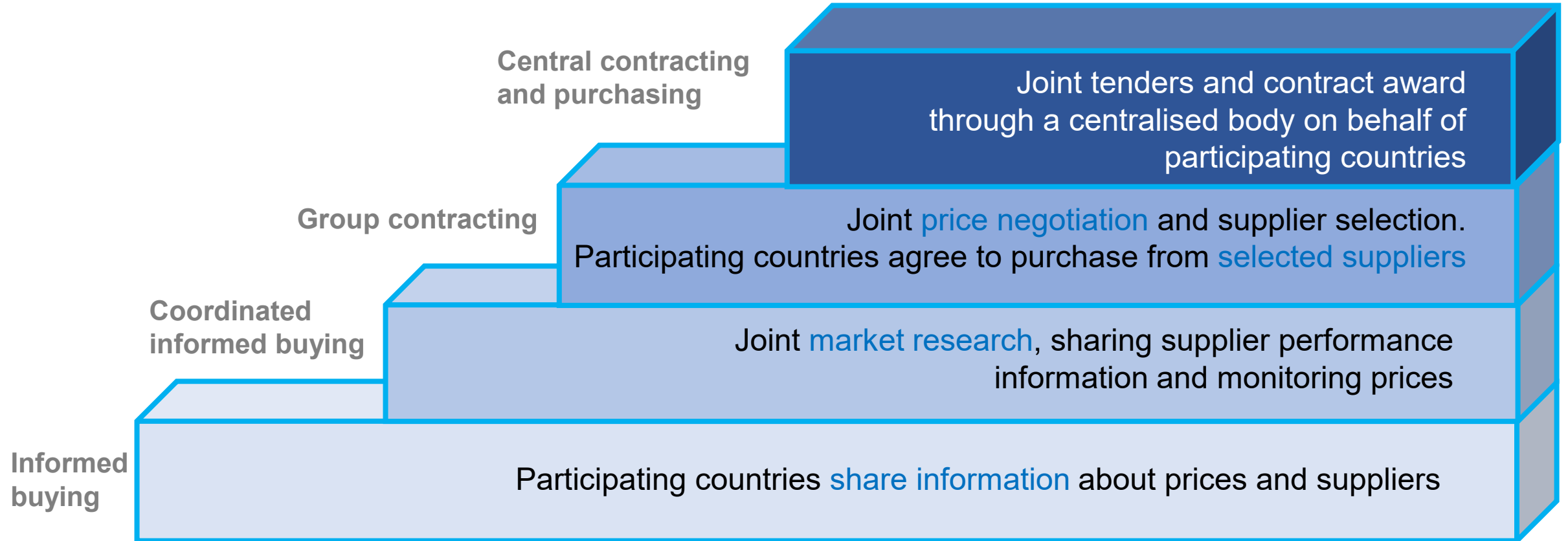


Appropriate contracting

UNICEF works for every child, everywhere!

UNICEF | for every child

Level of Collaboration in Procurement



Challenges of Collaboration for Vaccine Procurement for Multiple Countries



Regulatory requirements

Different **registration** and regulatory requirements



Legislation

Rigid procurement **laws** and legal environment



Product presentation

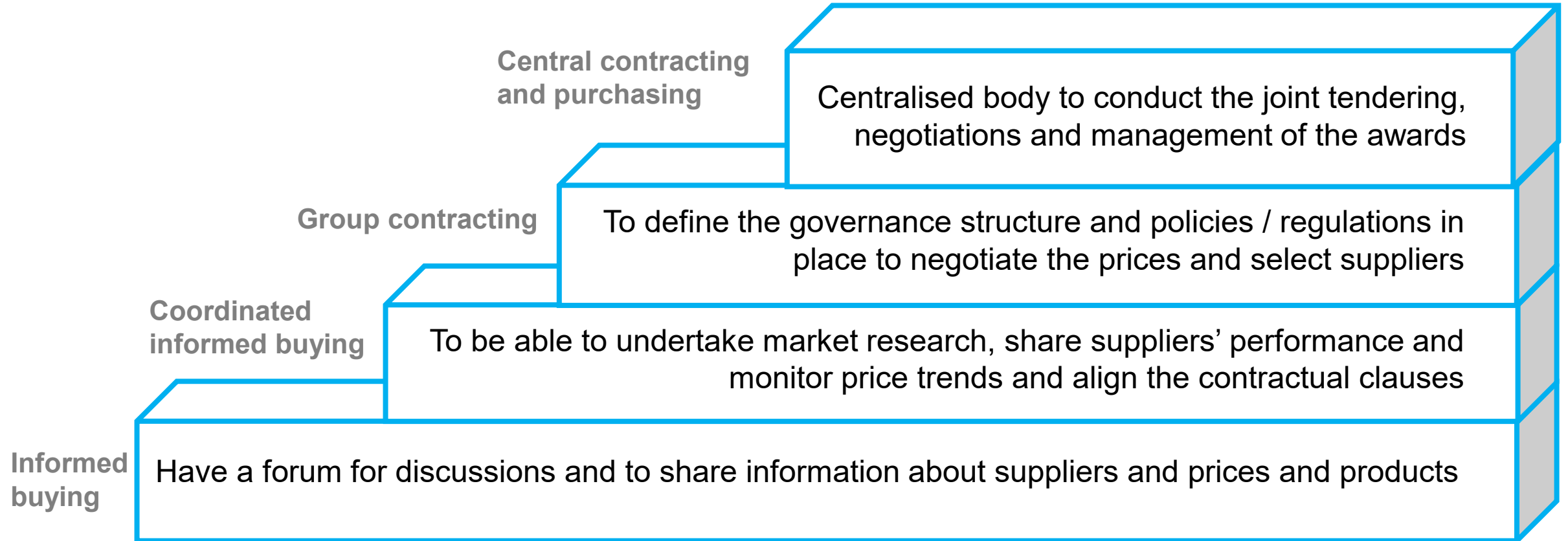
Different product **presentations** and immunisation programmatic requirements



Governance & Oversight

Different national **structures** and decision making process

Prerequisite of Collaboration in Procurement



Strategies to Address the Challenges



Coordination & solidarity

Define roles & responsibilities between countries



Market research and Demand projection

Long term comittment



Contractual Provisions & Supply chain

Special contractual clauses to allow for flexibility (opt-out)



Budget optimisation

Optimise financing streams and payment terms

Benefits for Collaboration on Vaccine Procurement

Vaccine Security → Sustained & uninterrupted supply of affordable vaccines of assured quality ✓



Affordable Price

Achieve affordable and sustainable prices for vaccines



Market Access

Increase purchase and negotiation power



Contracting

Increase efficiency in tendering and contracting



Increased market knowledge

Increase vaccine market knowledge & transparency



THANK YOU

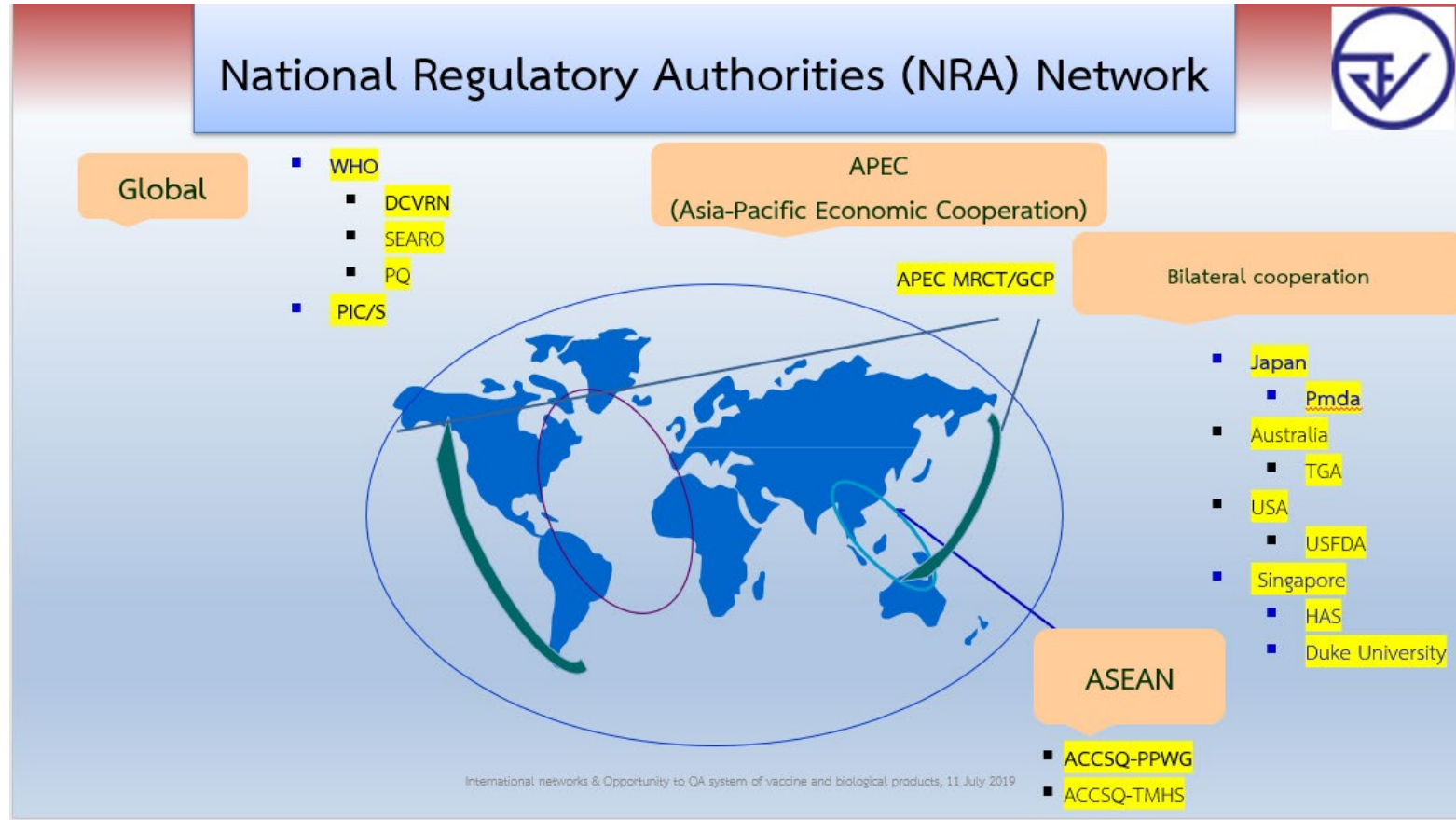
THE REGULATIONS AND COLLABORATION IN ASEAN

PRAMOTE AKARAPANON, MR

BUREAU OF DRUG CONTROL

FOOD AND DRUG ADMINISTRATION, THAILAND

National Regulatory Authorities (NRA) Network



National Regulatory Authorities (NRA) Network

	Regulatory Authorities (NRA)
<ul style="list-style-type: none"> • EU 	<ul style="list-style-type: none"> • European Medicines Agency (EMA)
<ul style="list-style-type: none"> • The Americas 	<ul style="list-style-type: none"> • The Pan American Network for Drug Regulatory Harmonization (PANDRH)
<ul style="list-style-type: none"> • The Caribbean Countries 	<ul style="list-style-type: none"> • The Caribbean Community (CARICOM)
<ul style="list-style-type: none"> • The Africa 	<ul style="list-style-type: none"> • East African Community (EAC) • Southern African Development Community (SADC)
<ul style="list-style-type: none"> • The Southeast Asian Countries 	<ul style="list-style-type: none"> • The Association of Southeast Asian Nations (ASEAN) <ul style="list-style-type: none"> - ACCSQ Pharmaceutical Product Working Group

Objectives & Outcomes (ASEAN)

	Topic
<ul style="list-style-type: none">Objectives	<ul style="list-style-type: none">The objective of the ACCSQ-PPWG is to develop harmonization schemes of pharmaceuticals' regulations of the ASEAN member countries to complement and facilitate the objective of ASEAN Free Trade Area (AFTA), particularly, the elimination of technical barriers to trade posed by these regulations, without compromising on drug quality, safety and efficacy.
<ul style="list-style-type: none">Outcomes	<ul style="list-style-type: none">Develop the ASEAN Common Technical Dossier (ACTD) and ASEAN Common Technical Requirement (ACTR) for the registration of pharmaceuticals for human use.
	<ul style="list-style-type: none">Develop several guidelines regarding the pharmaceutical product registration and variation

Regulatory collaboration

- The European regulatory system for medicines is good model for other countries or regions
 - Building trust and mutual reliance.
 - Work-sharing, avoid duplication and use resources efficiently.
 - Not only the Drug application but also the inspection and pharmacovigilance.

WAY FORWARD

- Explore the new area for the Collaboration in ASEAN
 - Vaccine pooled procurement: VACCINE SECURITY
 - Post marketing surveillance (Pharmacovigilance)

CHALLENGES

&

OPPORTUNITIES

CHALLENGES

- The Countries specific legal basis
 - Policy
 - Regulation.
- Technical barriers

OPPORTUNITIES

- Collaboration among ASEAN member states to develop the system for the vaccine security
 - The vaccine pooled procurement
 - The Vaccine price
 - The vaccine shortage
- Collaboration among ASEAN member states to develop the system for the Post marketing surveillance (Pharmacovigilance)

Thank you

ASEAN Vaccine Security and Self-Reliance (AVSSR): lesson learnt from Thailand

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Ms. Somruethai Supungul ⁽²⁾

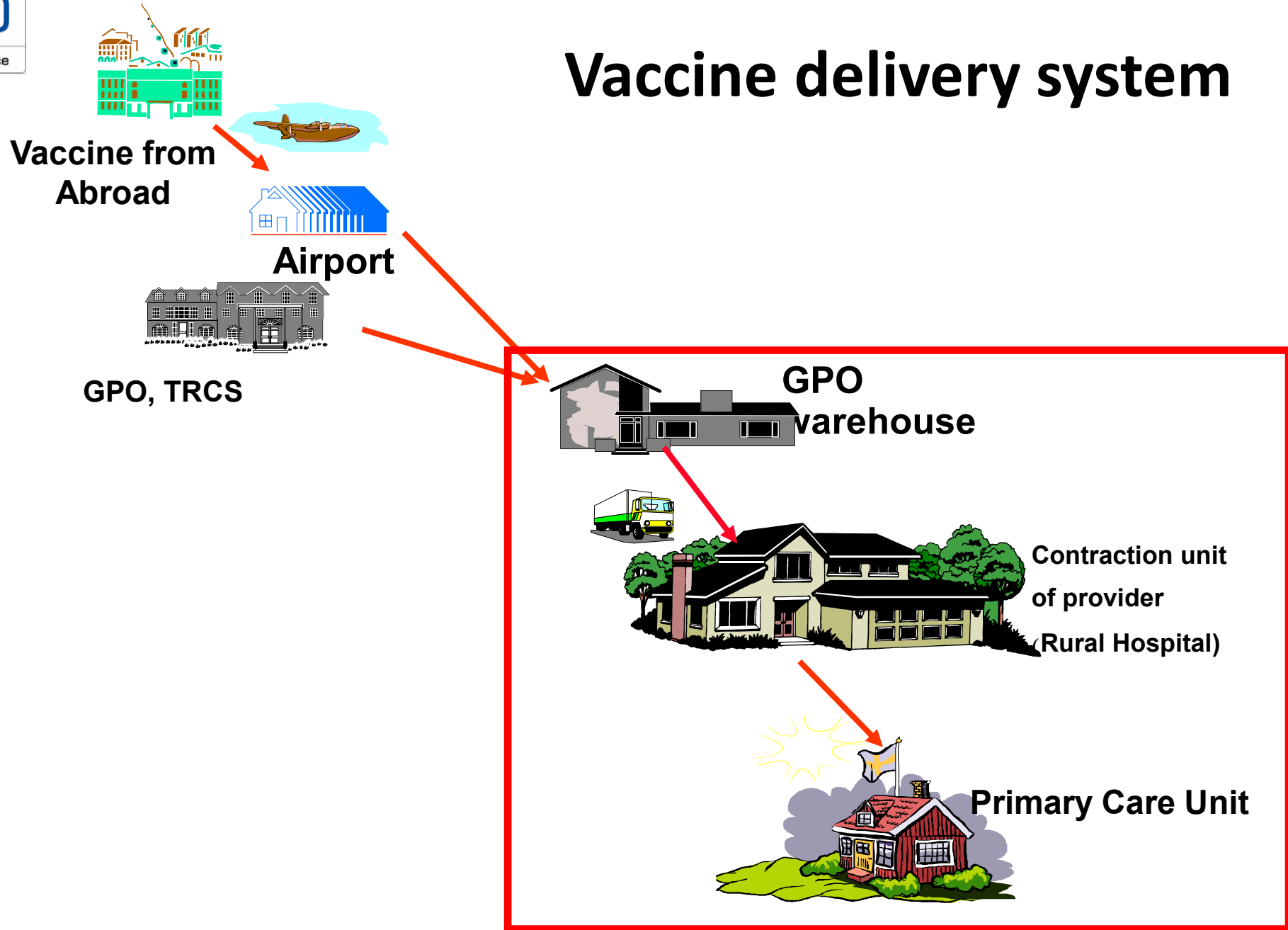
Mrs. Orathai Suwaranrak⁽²⁾

(1) Bureau of Primary care management, (2) Bureau of Medicines and Medical instrument Management

Topics

1. Vaccine security concept
 - 1) Accurate forecasting
 - 2) Available funding
 - 3) Appropriate contracting
2. Quality standards
3. Outputs
4. Challenges
5. NHSO perspective as the procurement agency of Thailand on pooled procurement

Vaccine delivery system



Vaccine Security is based on 3 pillars

Vaccine Security



Reference: https://www.unicef.org/supply/files/3._Overview_of_UNICEF_vaccine_procurement.pdf

Accurate forecasting

1. Estimation method⁽¹⁾:
 - 1) Estimates based upon target population
 - 2) Estimates based upon previous consumption
2. Reconcile these 2 methods
3. Confirm with suppliers

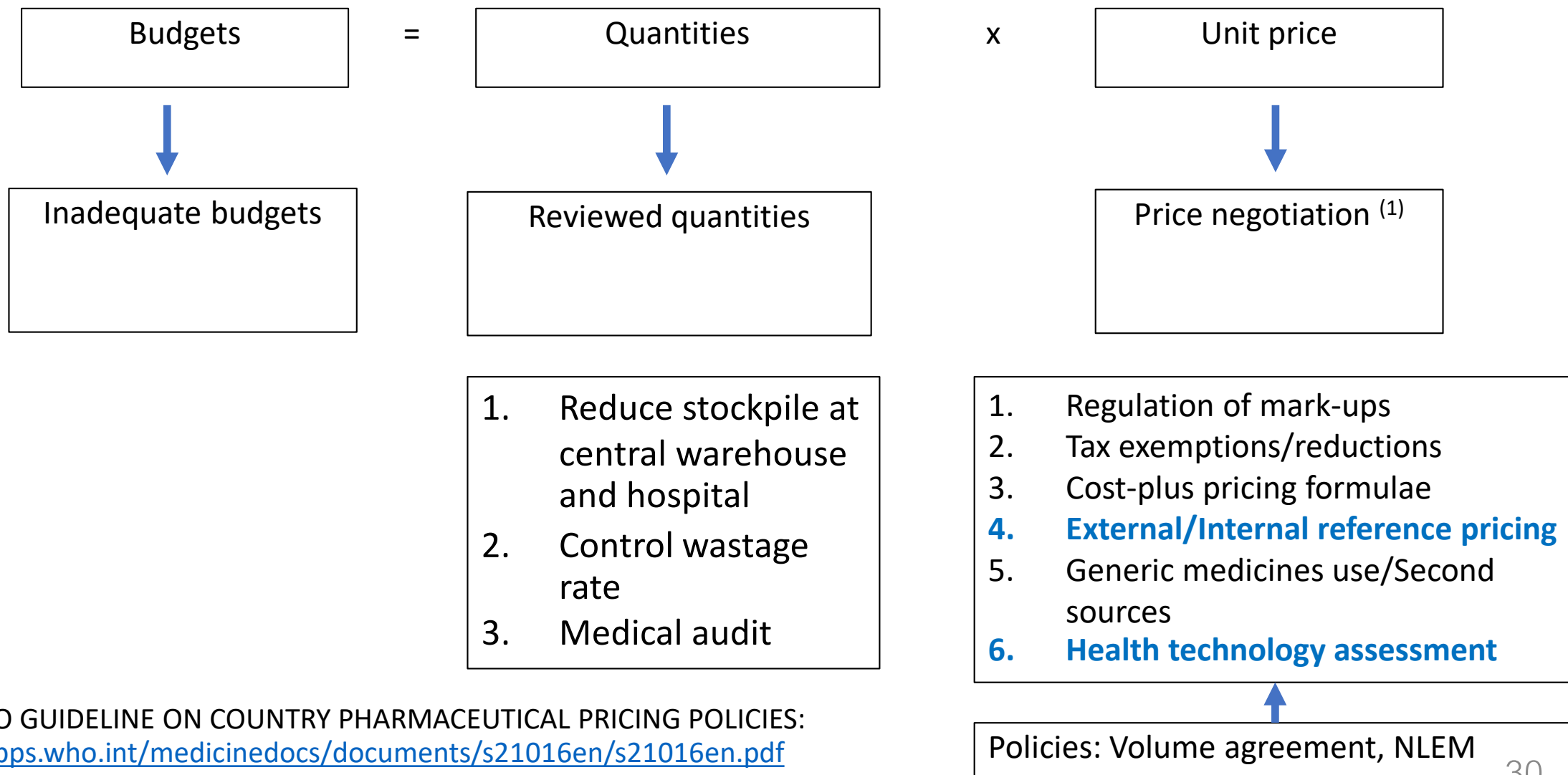
Reference: 1 Vaccine forecasting and needs estimation

https://www.who.int/immunization/programmes_systems/supply_chain/resources/tools/en/index3.html

Available funding

1. National Health Security Act B.E. 2545 (A.D. 2002)
 - determine sources of funds for services provision must come from the annual government budget and other incomes
2. National Health Security board separate funds for services provision in 4 part
 - 1) Prevention and Promotion: EPI vaccine, Flu vaccine
 - 2) Outpatient care
 - 3) Inpatient care
 - 4) Rehabilitation care

Available funding



(1)! WHO GUIDELINE ON COUNTRY PHARMACEUTICAL PRICING POLICIES:
<http://apps.who.int/medicinedocs/documents/s21016en/s21016en.pdf>

Comparison of estimated budget for vaccines procurement before and after negotiation by Subcommittee NLEM

Year	Vaccine lists	Before negotiation (million \$)	After negotiation (million \$)	% Reduce
2018	A,B	76.39	15.85	79.26

Appropriate contracting

- One year contracting
- Confirm quantities of vaccine needed with suppliers
- Send quantities of vaccine needed to suppliers 8 month earlier new fiscal year
- Vaccine shortage still exist

Challenges

- 1. Region strategic partnership to procure vaccine:**
 - 1) Pooled procurement
 - 2) Price negotiations
 - 3) Vaccine quality
- 2. Vaccine security**
 - 1) Multiyear contracts and pooled procurement should be established
 - 2) Local producers
- 3. Vaccine shortage management**
 - 1) Report vaccine shortage situation
 - 2) Establish a way to manage vaccine stockpiles during shortages at the hospital level

NHSO perspective as the procurement agency of Thailand on pooled procurement

Issues	factors
Feasibility	<ol style="list-style-type: none"><li data-bbox="468 496 2351 725">1. AEC Blueprint 2025 in C.7 (health care)<ul style="list-style-type: none"><li data-bbox="563 582 2351 725">• Enhanced Connectivity and Sectoral Cooperation: promote better health care (affordable and quality healthcare)<li data-bbox="468 751 2351 1053">2. Government Procurement and Supplies Management Act B.E. 2560<ul style="list-style-type: none"><li data-bbox="563 925 2351 1053">• The policy committee on Government Procurement and Supplies Management

NHSO perspective as the procurement agency of Thailand on pooled procurement

Issues	details
Mechanism	<ol style="list-style-type: none">1. To setup Pooled procurement framework in AEC<ul style="list-style-type: none">• committee and subcommittee, roles, vaccine specification, vaccine quantities need, etc.• Composition of committee: MOPH, NVI, Ministry of Foreign Affairs, Ministry of Commerce, Office of the Council of State , NGO and NHSO2. To consult details of Pooled procurement framework in AEC with the policy committee on Government Procurement and Supplies Management (Thai)3. To procure vaccine follow Pooled procurement framework in AEC

NHSO perspective as the procurement agency of Thailand on pooled procurement

Issues	details
Challenges	<ul style="list-style-type: none">• International cooperation to setup Pooled procurement framework in AEC need political commitment



Panel Discussion