Sub-Regional South East Asia Vaccine Procurement Practitioners Exchange Forum (VPPEF)

Meeting Report



12-13 September 2019 Yangon, Myanmar

Organized by:

UNICEF in partnership with the National Vaccine Institute of Thailand and the Learning Network for Countries in Transition (LNCT)







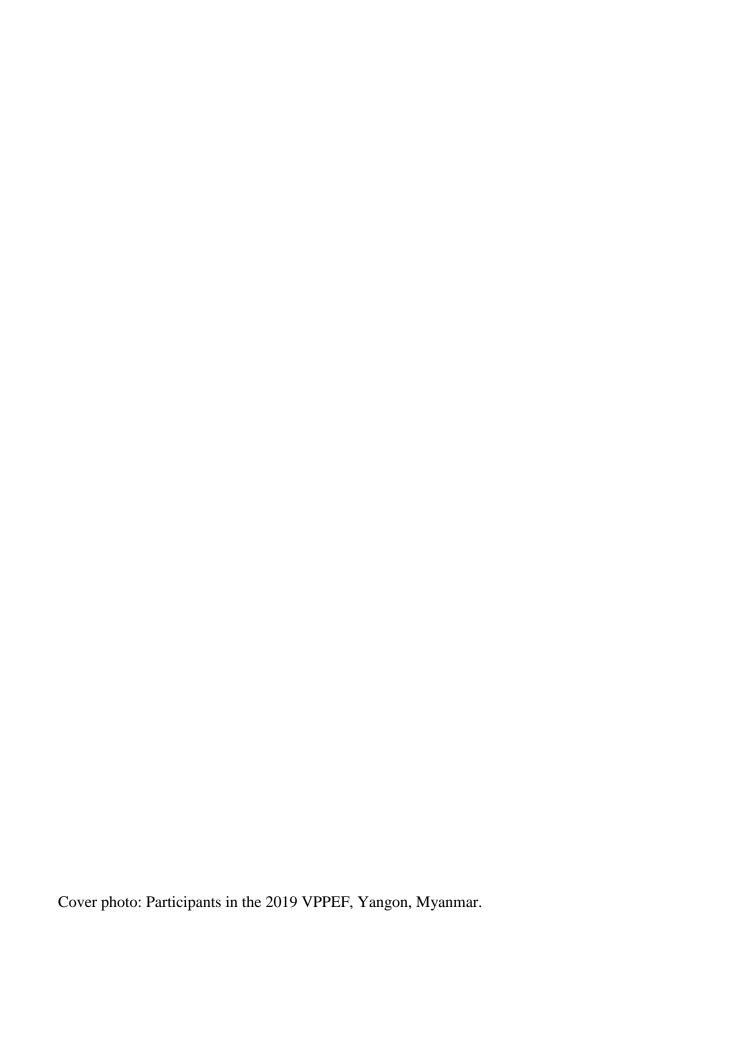


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Acronyms

AMC Advance Market Commitment

ASEAN Association of Southeast Asian Nations
AVSSR ASEAN Vaccine Security and Self-Reliance

bOPV bivalent oral polio vaccine
CAPs Country Action Plans
CO Country Office

DCVMN Developing Countries Vaccine Manufacturers Network EAPRO East Asia and Pacific Regional Office (of UNICEF)

EPI Expanded Program on Immunization

GBT Global Benchmarking Tool
GMP Good Manufacturing Practice
GRP Good Regulatory Practice
HPV Human papilloma virus
IPV Inactivated polio vaccine

IVD Immunization and Vaccine Development

JRF Joint Reporting Form

LNCT Learning Network for Countries in Transition

LTA Long-term agreement MA Market Authorization

MI4A Market Information for Access to Vaccines MCO Myanmar Country Office (of UNICEF)

NCL National Control Laboratory
NIP National Immunization Program

NVI National Institute of Vaccines Thailand

NRA National Regulatory Authority

PQ Pre-qualification/ pre-qualified (vaccine)

RO Regional Office

SAGE Strategic Advisory Group of Experts

SD UNICEF Supply Division

TTSPP Temperature Time Sensitive Pharmaceutical Products

UNICEF United Nations Children's Fund

V3P Vaccine Product, Price and Procurement

VII Vaccine Independence Initiative
VIC Vaccine Industry Consultations
VMI Vendor Managed Inventory

VPPEF Vaccine Procurement Practitioners Exchange Forum

VVM Vaccine vial monitor
WHO World Health Organization

Introduction

The objectives of the Vaccine Procurement Practitioners Exchange Forum (VPPEF or the Forum) are to provide a unique environment to build country vaccine buyers' procurement capacity and build a community of practice. The Forum included country representatives involved in vaccine procurement at various stages of Gavi support as well as self-financing and vaccine-producing countries.

This report summarizes key discussions and outcomes from this Sub-Regional Vaccine Procurement Workshop co-hosted by the Learning Network for Countries in Transition (LNCT) UNICEF Supply Division, and the National Vaccine Institute (Thailand). The theme of the event was on sustainable introduction of new vaccines to national immunization programs, with the addition of a focus on vaccine security to ensure the sustained, uninterrupted supply of affordable vaccines of assured quality.

The 2019 VPPEF was held at the Lotte Hotel in Yangon, Myanmar on 12- 13 September, 2019, buttressing the Asian Vaccine Conference (ASVAC). The forum had some 45 country participants from nine countries (Indonesia, Laos, Mongolia, Myanmar, Papua New Guinea, Philippines, Thailand, Vietnam and Timor-Leste) and 11 resource persons from partners including PATH, Clinton Health Access Initiative (CHAI), the World Health Organization (WHO), and Gavi. The meeting logistics and country participant mobilization was led by the UNICEF Myanmar country office with support from the UNICEF East Asia and Pacific Regional Office (EAPRO).

The 2019 VPPEF meeting had the following objectives:

- To build a community of practice on vaccine procurement at the sub-regional level to support the sharing and exchange of challenges, opportunities and best practices in securing supply of affordable, quality assured vaccine;
- For returning VPPEF country participants, to present on last year's country action plans: progress, achievements and challenges in implementation.

Session Proceedings

Session 1: Welcome and Introduction

Representatives from the three hosting organizations (UNICEF, NVI Thailand, and LNCT) welcomed the group. Nakorn Premsri from NVI Thailand noted that the forum was a good opportunity to convene in Asia and share good and better—not just the best—practices. Grace Chee from LNCT pointed out that the nine countries were all in different stages; some are procuring through UNICEF, others procuring independently, and some producing vaccines; most have a mix of these different modalities. This variety of stages will lead to a rich discussion. Aurelia Gasca of UNICEF Supply Division emphasized that this Forum was a chance to learn from each other. She emphasized that the resource persons were there to support the participants, and encouraged a level of informality to allow for asking questions and sharing experience.

Loic Sanchez (UNICEF Supply Division) walked the group through the agenda (see Annex 1) and provided a bit of context for the VPPEF. It is a country-led event, and participants should feel free to discuss topics openly. The representatives from LNCT, UNICEF, NVI, WHO, CHAI, PATH, and Gavi are all present to assist the country teams with their action plans for next year.

Aurelia briefly covered the "Rules of engagement" including requesting active participation, flagging if people were speaking too fast, and requesting that participants silence their phones.

Session 2: Country Key Challenges and Best Practices

The participants were asked to think about the 1-2 procurement-related challenges and opportunities their country faces, or issues they would like to learn about.

All country delegations expressed an interest in learning from others' best practices. Additionally, they identified the following expectations:

Indonesia	Learning about harmonizing regulation for supporting procurement.	
Lao PDR	Exploring if ASEAN (Association of Southeast Asian Nations) countries	
	can improve vaccine security through pooled procurement.	
Mongolia	As this is the first time the delegation has attended, they looked to develop	
	a network and joining any existing information sharing platform.	
Myanmar	Learning about integrating UNICEF procurement and local procurement.	
	Also guidance on sustainable financing for routine immunization.	
Papua New Guinea	Learning more on financing modalities for procurement.	
Philippines	Hearing ideas on logistics or supply chain solutions related to vaccines.	
Thailand	Looking for partners to collaborate with on vaccine security (including	
	procurement, stockpiling, and knowledge sharing) in the region through	
	AVSSR (ASEAN Vaccine Security and Self-Reliance).	
Timor-Leste	Seeking advice on how to approach procurement after Gavi support	
	phases out.	
Vietnam	Looking to learn how to locally manufacture Pentavalent and inactivated	
	polio vaccine (IPV).	

The session also included self-introductions from the country delegations, resource persons, and support staff (see Annex 2 for list of participants).

Session 3: Aligning Vaccine Decisions with Procurement and Supply

Nakorn Premsri of NVI Thailand moderated the session and provided a brief overview of the topic. Vaccine security is a balance between the supply and demand of vaccines. If there's an oversupply, the manufacturer may change to producing other products and prices increase. If there's a limited supply, there may not be enough vaccines during an outbreak.

Introducing a new vaccine to the Expanded Program on Immunization (EPI) can be a complicated process. Thailand begins with determining the disease burden, and then moves to economic valuation and the budgeting processes (which is also a negotiation with the Ministry of Finance and within Ministry of Health). Following the budget allocation, the process moves to the actual procurement of vaccines which must align with regulations and finally, once the vaccines are received, distribution through cold chain.

For vaccine security, an uninterrupted supply is needed. Some strategies for ensuring an adequate supply include regional pooled procurement; multiyear tender; Advanced Market Commitment (AMC), and stockpiling, among others.

Nakorn also covered the procurement cycle: define needs, select product, develop specifications, establish criteria, select procurement method, prepare for bidding and evaluation, solicit and receive offers, evaluate and adjudicate bids, select and award, create a contract, and monitor and report performance.

Clint Pecenka from PATH presented on health economics in the context of effective vaccine decision-making.

Effective vaccine decision-making helps ensure the following:

- Selection and design of interventions that meet public health needs.
- Use of effective, safe, high-quality products.
- Successful programmatic implementation.
- Long-term supply security.
- Affordable prices.
- Program sustainability.
- Optimal use of resources.

Health economics can be an input into decision-making by identifying the broader costs and consequences of a proposed intervention, beyond simply the commodity price. For example, one can look at the economics of the introduction of a new vaccine to determine the relative cost-effectiveness as compared to not introducing the vaccine. This type of analysis is well suited to inform decision-makers of the overall impact, in terms of health outcomes, cost effectiveness,

sustainability, and system costs, including cost-savings, when considering a change to their vaccine schedule.

Aurelia Gasca presented on linkages between policy decision-making and procurement. UNICEF Supply Division (SD) is the only UN agency with a mandate to procure vaccines. The division procures vaccines for over 100 countries and partners. The three pillars of vaccine security are accurate forecasting, available funding, and appropriate contracting. Vaccine security occurs when there is a sustained and uninterrupted supply of affordable vaccines of assured quality for every child.

Any national immunization program needs to link the programmatic aspects and procurement in some major categories, including demographics/ forecasting and planning, epidemiology/ procurement approach, regulatory/ import requirements, governance and oversight/ procurement principles.

UNICEF has a number of guiding procurement principles. They aim for a fair, competitive, and transparent procurement process. They also look to minimize cost and increase effectiveness and seek the best value for money. UNICEF Supply Division aims to use strategic procurement to achieve vaccine security. The team uses market intelligence, forecasting and planning, budgeting and financing mechanisms, and innovative contracting approaches to allow manufacturers to contribute to part of the tender. One tool UNICEF SD uses are Long-term Agreements (LTAs). These are good-faith framework agreements under which UNICEF awards contracts to multiple suppliers per product. Under an LTA, UNICEF will make a good-faith effort to procure a specified amount from specific suppliers, but they are non-binding agreements. They are based on the forecasted demand from countries for certain vaccines in certain presentations. UNICEF Supply Division communicates with country offices on countries' needs and provides them with price estimates when requests come through.

Tanapat Laowahutanon (from NVI Thailand) presented on strategic procurement of vaccine in support of Universal Health Care (UHC), focusing on Thailand. Thailand's procurement cycle involves four steps: 1) review product selection; 2) specify quality standards; 3) determine quantities needed; and 4) reconcile needs and funds.

In Thailand, vaccines in hospitals under the UHC scheme are procured by the National Health Security Office (NHSO) and the GPO (Government Pharmaceutical Organization). Following procurement, the vaccines are stockpiled in a central warehouse. To request a vaccine, a hospital or primary care center will send an electronic request to the Vendor Managed Inventory system, and the GPO will send the vaccine.

Under the Review Medicine Selection step, all vaccines to be procured must be listed on the Thai National List of Essential Medicines (NLEM). This list covers drugs needed for the protection of and treatment of health problems of Thai people at an essential level in an

economic and cost-effective manner. Items on this list must meet the burden of efficacy, safety, efficiency, and affordability.

Any new vaccine must pass an expert panel, and then is passed to a screening working group. From here, it might have to be sent to a Health Economic Working Group. If there is no need to involve the Health Economics Working Group, then it is sent to a subcommittee for NLEM, then once it has passed that (and affordability is confirmed), then it is eligible for vaccine procurement.

The NHSO has two ways of determining the quantity needed: previous consumption and based on the target population size. They use a web-based application called VMI (Vendor Managed Inventory) which is part of the GPO. Meeting the budget means balancing the quantities and unit prices. If the NHSO team is still not meeting the budget, they will either 1) reduce the quantity or 2) reduce the unit price. The quantity needed can be reduced through stockpile reduction, control of wastage rate, or undertaking a medical audit. To reduce the unit price, negotiation can occur with things like tax exemptions, or cost-plus-pricing formula.

To address procurement challenges, the NHSO seeks strategic partnerships to explore pooled procurement, assist in price negotiations, and ensure vaccine quality. To address vaccine security, NHSO is seeking multiyear contracts and engaging with local producers. When faced with vaccine shortages, NHSO is careful to report the shortage, and also looks to manage stockpiles at the hospital level.

The Question & Answer period covered the following topics:

- When asked about the Thailand procurement cycle timing, Tanapat responded that they have to send requests of quantities needed 8 months ahead of time. Then the procurement process takes 2-3 months. Nakorn added that the approval process for new vaccines takes much longer; some took 8 years to get approved as they had to pass through multiple committees. That said, most take 1-2 years for approval. Nakorn also commented that Thailand has not yet done multiyear procurements but aims to do so next year for the Expanded Program on Immunization (EPI) program. To overcome issues associated with a short shelf life for vaccines, Thailand will place a two-year order but the delivery will be staggered to keep the stock fresh.
- Tanapat also shared that for an outbreak response, there is faster procurement through the Department of Disease Control, whereas EPI goes through a normal procurement system.
- The Indonesia delegation asked Aurelia about UNICEF SD's flexibility to meet national regulations. Aurelia responded that all UNICEF SD vaccines are WHO pre-qualified (PQed), this is a condition of tender, and the list and prices are all available online. UNICEF SD relies on WHO to make sure that the quality aspects are ensured (prequalification status). However, if a country with a stringent National Regulatory Authority (NRA) requests the procurement, this is taken into consideration. The Indonesia team clarified that their issue involves Indonesian regulations that prohibit multi-year budgetary commitments, so they cannot send a letter of intent for an Advanced

Market Commitment. Is there anything UNICEF can do to assist overcoming this hurdle? Aurelia indicated she couldn't give an immediate answer, but could check with colleagues to see if there are any options such as having a waiver. Juliette Puret from Gavi explained that the idea behind AMC is to ensure demand to the producers by pooling countries, to get a guaranteed price. They need to ensure a long-term engagement, so not sure if this can be changed for one country (especially a big country like Indonesia). However, it is something to discuss as is the adaptability of the national regulation.

- The Indonesia delegation asked the Thailand delegation about their experience applying an AMC (Advance Market Commitment). Nakorn responded that they hadn't used it yet, and faced the same issue, that the country does the budget annually. He noted that this is a problem for many countries.
- The Myanmar delegation asked UNICEF about their process regarding multiple suppliers and meeting the requests of the country. Aurelia discussed the LTAs which are non-binding agreements; UNICEF promises to procure from specific suppliers. UNICEF uses the annual forecast to understand when the countries will need the vaccines, and in what presentation. Which supplier and what price is available on the UNICEF SD website.
- The Myanmar delegation asked the Thailand presenters details about the NHSO. Tanapat indicated that NHSO is an autonomous body.
- Stephane Guichard (WHO SEARO) pointed out that systematically many countries go to UNICEF for vaccine procurement, and then complain about price and overhead.
 Conversely, very few countries seem to meet suppliers directly. Everyone works in a silo, there is almost no collaboration. Countries are free to reach out to manufacturers and to issue a Request for Proposals.
- Grace Chee noted that, globally, NHSO is considered a very rigorous body. How does NHSO decide to introduce a new vaccine or antibiotic? Tanapat responded that it starts when the body sends a request to the expert bodies. From the time of the request, it might be 2 to 8 years (rotavirus took 8 years).
- Abu (UNICEF Regional Office) commented regarding Clint's presentation that for many countries, it's not possible to do detailed health economics studies. How can they access data? Can PATH provide support to make comparisons? Clint responded that yes, a literature review can help, there are databases that exist, and ideally countries can find a similar country in the region with a similar disease burden.
- Abu asked the Thailand delegation for a clarification of what was meant by a medical audit. Tanapat explained that an audit team goes to hospitals and primary care centers to see who actually received the vaccine, to test that the administration of the vaccine is in line with what's being reported.

Session 4: Day Wrap Up/ Key Takeaways

Loic summed up the first day, noting that the expectations and requests from participants covered a variety of topics, ranging from regulatory and market intelligence to collaboration and

information exchange. The facilitators and participants will keep sharing information and go back to the expectations and to ensure that all the points have been addressed accordingly. From the Thailand example, we learned the importance of forecasting and planning as well as the importance of data quality and how to improve data quality.

Session 5: Market Intelligence

Dashpagam Otgonbayar, Head of the Immunization Department in Mongolia presented on the situation in Mongolia. There are five national committees on immunization in Mongolia. They all have different sources of information and role in procurement. Mongolia has vaccine supply from UNICEF, local tendering, and, in the past, donations by Gavi. Currently, the government pays for all vaccines and immunizations.

Mongolia faces human resource challenges such as understaffing and high turnover. Additionally, the NRA is not fully functional and there is a lack of information of available products and prices beyond current suppliers. There is no routine, formal means of data collection and analysis of the vaccine market.

Luzviminda Garcia from the Department of Health began the presentation by discussing how the Philippines utilizes market intelligence. The Philippines team prepares and submits their vaccine forecast to UNICEF. To develop the forecast, they utilize the V3P (vaccine product price web platform), UNICEF Market Notes, and local market analysis. They also use the ViVa dashboard for stock analysis and consult with the local offices of WHO and UNICEF.

In the Philippines, the default mode is public bidding. If there is a failed bidding (i.e., no producer responds to the RFP), they request UNICEF support. If the cost is above a certain price, they need clearance.

For vaccine introduction, Philippines refers to WHO-SAGE (Strategic Advisory Group of Experts) guidance notes. After analyzing the disease burden it goes through various reviews. The Philippines has Universal Health Care, so they must apply a cost-effective analysis. Additionally, a Certificate of Product Registration is required by the Food and Drug Administration. Philippines uses a web-based Vaccination Supply Stocks Management to monitor vaccines and logistics stock inventory.

Some of the challenges that Philippines has faced include: bid failures (volume, delivery schedule, price); inadequate national storage capacity; challenges with distribution and warehousing; vaccine stockouts; and stockpiling not being part of planning and forecasting.

Stephane Guichard from WHO presented on vaccine market dynamics in the Southeast Asia Region. WHO sees this region as one with a strong voice that should be raised to vaccine manufacturers. It comprises about 35% of the global market by volume, but only 8% of the value.

Ninety five percent of the vaccines procured in the region include: bOPV, MMR/MR, and Pentavalent. The remaining percentage is comprised of BCG, DTP, Measles, HepB, TT, DT/Td, HPV, JE, PCV, Influenza and Rotavirus.

All countries completed Joint Reporting Form (JRF) enabling V3P and M14A analysis. Five of the countries are self-procuring (i.e., not using UNICEF to procure). Looking at HPV as an example, global supply is insufficient to meet demand. HPV self-procuring countries (Thailand and Indonesia) negotiated a median price 2.7 folds higher than UNICEF median price for HPV. However, Indonesia builds the shipping costs into the price, so it seems higher than UNICEF cost, but might not be when comparing point-to-point costs.

There is no link between Gavi support and access to WHO PQ vaccines. The PQed vaccines are available through UNICEF procurement or direct procurement.

There are a number of challenges and opportunities in the region. One challenge is that full market authorization for a new vaccine can take one year. Also, countries are struggling to comply with good distribution practices (GDP), good storage practices (GSP), and management of Temperature Time Sensitive Pharmaceutical Products.

Without proper vaccine demand forecast and market intelligence, manufacturers don't know how much to produce. Countries can exchange information with suppliers and explore the feasibility of pooled-procurement mechanisms for selected countries and vaccine in the region. Market authorization procedures should take into account WHO PQed products and implement expedited approvals in Gavi-supported countries and middle-income countries.

There are four steps into the pooled procurement approach (informed buying; coordinated informed buying; group contracting; central contracting). These all need transparency, political commitments across countries, expertise, financial support and agreed-upon procedures.

Question & Answer

Tony Nelson opened the Question and Answer portion with a comment that the introduction of new vaccines is the biggest anxiety for countries in the region. With vaccines like HPV and rotavirus, it takes many steps to get to market and then new vaccines have limited competition. He posed a question to the Mongolia delegation, if they would be able to recommend a new Indian vaccine if it were not licensed by NRA? Mongolia responded that per the Medical Devices Law, all vaccines should be registered and have market authorization. Tony further queried if they heard about a cheaper vaccine made in India, but the suppliers had not yet visited Mongolia, would DOH reach out to these suppliers? The Mongolia delegation indicated that would be up to the local companies who have authorization. Tony echoed Stephane's earlier point, that most countries rely on the manufacturers coming to them, rather than being proactive and exploring all available opportunities.

Stephane was asked about efforts towards regional procurement. He responded that manufacturers often find the requirements for market authorization to be burdensome. WHO has asked that manufacturers develop a list of general challenges, and perhaps they could give a presentation on these challenges at the next Developing Countries Vaccine Manufacturers Network (DCVMN) meeting. By the end of this year, WHO should have this list from the manufacturers, and then will work with countries to address these barriers.

Miloud (from LNCT) commented that the market authorization requirements were inhibiting countries from taking advantage of all the quality products on the market. For example,

requirements such as high registration fees, paying vaccines in local currency, going through local agents, having information in the local language, visiting production sites might make sense for medication but don't make full sense for vaccines. It's important for countries to introduce flexibility in their legislation and procedures to take into account the differences between vaccine and medicine products and markets.

The PNG delegation queried about vaccine pricing, noting that in some cases, the cost was cheaper through direct procurement and in some cases, cheaper through UNICEF. If vaccines are produced regionally, shouldn't that reduce shipping costs versus being sent from Europe? Loic clarified that SD doesn't necessarily seek the cheapest vaccine, they seek sustainability and assured quality. Stephane responded that for countries that procure "traditional" vaccines, there is a small difference between UNICEF's price and the direct price. Generally speaking the Southeast Asia region does well with traditional vaccines in direct procurement, while for new vaccines it's easier to go through UNICEF.

The Thailand delegation asked about the reasons for the global HPV vaccine shortage. Stephane responded that initially there were issues with the schedule of HPV vaccine. As that's gotten sorted out, there are new manufacturers coming online. However, countries still aren't meeting with manufacturers, and better dialogue is needed. Loic further commented that there should be more collaboration and information exchange at the regional level. Juliette noted that Gavi is happy to provide cost information (especially regarding HPV, rotavirus, and PCV). They can put the EPI manager in touch with the manufacturers. Market intelligence is not that easy to get, you may have to dig for information yourself.

Tony pointed out that smaller countries may have a harder time negotiating with a manufacturer, as they are purchasing less. Also, if a country has to publicly publish the price, the manufacturer might not agree to a low price. These are instances in which pooled procurement can be useful.

Clint mentioned that certain pricing agreements exist, but they may be hard to know from an individual country's perspective. However, UNICEF can tell you if your country falls under an agreement.

COUNTRY POSTERS

To facilitate the sharing of experiences across countries, prior to the workshop, each country team prepared a poster summarizing their vaccine procurement processes. Posters included the procurement mechanisms for routine vaccines; a vaccine procurement organogram; a summary of vaccine procurement in practice, including regulatory framework, sources of financing, sources of market information, recent vaccine introductions, and shortages and stockouts; as well as key procurement challenges and future plans. The posters were presented during a set-aside "gallery walk" session. Participants were asked to review other countries' posters during a coffee break and provide some comments when the group reconvened.

- Stephane commented that there were discrepancies between what countries were reporting in the JRF and what they are reporting in their posters. Grace commented that often discrepancies arise based on who is filling out the form and from where they get their data.
- Vietnam was asked why they are procuring both measles and measles rubella (MR) from the same manufacturer. The team responded that they followed the Ministry of Finance decision; in the future the two vaccines might be different prices. The Thailand delegation noted that they procure both, and one is used for outbreak responses.
- The Myanmar team stated that in the posters they didn't see other countries having trouble procuring the rabies vaccine and asked if others faced this issue. Philippines commented that they do procure rabies vaccine, but it's not part of the national procurement program so wasn't included in the poster.
- The Indonesia team pointed out an issue that had been raised before, which is that in Myanmar, their procured price was cheaper through UNICEF that direct with the manufacturer. But this is for delivery to the national entry point. How does Myanmar analyze the cost of distribution of the vaccines?

Loic reminded everyone of resources that UNICEF provides regarding price data. These resources can be found in Annex 4.

Session 6: Sourcing Quality-Assured Vaccines

Miloud moderated the session and began with an introduction. Vaccines and immunizations are a tool for mass protection; people won't accept any negative effect of vaccines. Risk aversion is very high. Because vaccines administration is working with healthy people, kids and mothers, it's important to procure vaccines of assured quality, without compromises.

Stephane Guichard presented on new developments and challenges on vaccine quality regulation, including progress and issues in the region. The WHO conducted a series of assessments of National Regulatory Agencies, using the Global Benchmarking Tool (GBT). The GBT assesses the functionality of regulatory agencies by performance maturity levels 1-4. For a country that is producing vaccines, it should be level 3 or above. In the region, Thailand, Indonesia, and India (all vaccine-producing countries) are all at maturity level 3.

Reliance can be part of Good Regulatory Practices, taking assessments done by others into account, while also retaining responsibility for your own decision. Reliance can be defined as: an act whereby a regulatory authority in one jurisdiction may take into account/give significant weight to work performed by another regulator or other trusted institution in reaching its own decision. Recognition can be defined as: the routine acceptance of the regulatory decision of another regulator or other trusted institution. Recognition indicates that evidence of conformity with the regulatory requirements of country A is sufficient to meet the regulatory requirements of country B. Examples of reliance are the International Generic Drugs Regulatory Programme and WHO collaborative registration. WHO pre-qualification (PQ) is an example of recognition.

There are a number of regulatory challenges facing the region:

- Country-specific requirements for licensing distributors e.g., office and staff, tender through local representative only.
- Annual maintenance fees to continue registration.
- Requirements for specifications e.g., markings, labelling color country-specific and safety studies before the product is introduced in the National Immunization Programs (NIPs).
- Expedited approval of WHO PQed vaccine is not used for Market Authorization resulting in duplicate testing and other quality control procedures despite the PQ status.
- An NRA with limited capacity requires registration of the product at least in two European countries before the product is registered.
- Sites visits of manufacturing facilities for Good Manufacturing Practices (GMP) is required for market authorization (MA) in most of the countries despite the PQ and it is paid by the manufacturers.
- Several countries also want product testing in their National Control Laboratory (NCL), which may result with increasing time for actual use from the moment the product is supplied to the country.

WHO is working to strength the capacity of NRAs in the Southeast Asia region with priority given to countries producing vaccines. Capacity development and technical support include: direct assistance, assistance through collaborative mechanisms, strategic support, and policy dialogue.

Gertrudis Tandy presented on Indonesia's approach to sourcing quality assured vaccines. New vaccine introduction decisions are made by the Ministry of Health. Regulations require that all routine vaccines (included under the National Immunization Programme) should be produced domestically, by a state-owned enterprise. All imported vaccines need to be registered with the NRA. Indonesia's current main challenge is that IPV produced in the country is not yet a WHO PQ vaccine, and there are limited supply options. Additionally, vaccines are encouraged to be certified halal in addition to their regular registration. This is still under debate for implementation.

Vaccine procurement involves many stakeholders (Ministry of Planning, Ministry of Health, Ministry of Finance, Parliament, Food and Drugs Control Agency etc.). All these actors mean the planning process takes a long time.

Indonesia has some "best practices". This includes E-purchasing which has increased accountability, transparency, and timeliness. All NIP vaccines procured have been registered by NRA, and require WHO PQ Standard certificates and vaccine vial monitor (VVMs) written in vaccine vials package as a vaccine specification. Health facilities have standard and functioning cold chain equipment.

Indonesia is in the process of developing a rotavirus vaccine. It is currently undergoing clinical trials and should be ready by 2021.

Kongxay Phouphenghack presented on Lao's experience. Vaccine procurement goes through a couple of chains (MoH and MoF, national assembly). The Lao population is quite small and the country has limited regulation capacity, so the country procures through UNICEF.

The main challenges facing Lao are: delays in procurement funding disbursement; uncertainty of government support on newly-introduced vaccines procurement; vaccine prices post Gavi transition is uncertain (PCV, HPV, RV); and that there are many steps for financial approval of funds.

Lao is looking to strengthen collaboration with other departments of MoH and MoF. They are also working with the private sector to mobilize funds for vaccine procurement. There is also interest in collaboration with ASEAN countries to plan for regional pool procurement. Lao is also seeking funding post-Gavi for immunization from multilateral and bilateral partners.

The best practices that Lao is currently undertaking include: having an immunization law that the government must dedicate funding to the NIP. Lao is also using ViVa and other electronic tools (such as M-supply) to manage vaccine supplies, forecasting and procurement through UNICEF or other vaccine suppliers.

Pramort Akarapanon from Thailand FDA shared Thailand's experience with sourcing quality assured vaccines. Thailand uses a "Good Reliance Practice", by borrowing from stringent regulatory authorities (e.g., from US, Japan, Canada) as well as the WHO guidelines and standards to guide its regulatory decisions. This is in an effort to reduce the duplication of work and speed market authorization.

New government requirements have become the challenges for the Thailand FDA. Once the FDA accepts application fees for a given product, it is committed to reducing the timeline for approval by 20%. However, the FDA is asked to do this with the same number of staff. The organization has started to implement the e-submission platform, but it has not been stable or reliable yet.

Question & Answer

Miloud opened the question & answer session by querying the country teams if their EPI vaccines are all registered/have Market Authorization. Indonesia, Mongolia, and Vietnam indicated theirs were. Myanmar commented that the vaccines might not be registered. PNG responded that all their vaccines are WHO PQ, but they don't have an NRA. Timor and Lao also do not have an NRA.

The length of time it takes to get registered (and then the validity) ranged among the countries. Mongolia fast-track only took 1 month, with the regular process taking 2-3 months and the validity is for two years. Myanmar registration is only 1-2 months. Thailand registration can take 8 months- 7 years, but then the validity is for life. Indonesia takes 2-3 months for registration, and then the validity is for 2 years. These varied responses demonstrate that a lot of work needs to be done to harmonize regulatory frameworks.

The Philippines team asked about assurance that vaccine stocks are safe if they are not PQed by WHO. Stephane responded that if they are not PQ, then they have to go through the Market Authorization, unless your country is collaborating with another NRA.

Indonesia shared some details on the halal certification of their vaccines. It's not the NRA doing this, it's a separate process involving the Indonesian Muslim Council (MUI). Currently, not all the EPI vaccines are halal, but Indonesia is working towards it. There is not a national regulation, but rather an insistence from the community. Stephane further commented that there is not necessarily a harmonized definition of halal among different countries.

Timor-Leste queried if Vaccine Independence Initiative (VII) mechanism might be possible for Lao. Aurelia explained that VII is a financing instrument through UNICEF. If a country has challenge of meeting finances to pay for vaccines, it can apply to this fund. Some countries can't pay until the goods arrive in the country. They can then reimburse the VII throughout the year. There's a ceiling as to how much a country can borrow. Once paid, they can request another installment. Abu commented that it's worked very well in the Pacific Islands as they have small populations, and it guarantees a continuous supply of vaccines.

Miloud concluded the session by emphasizing that vaccine quality is a must, there cannot be compromises. It's a shared responsibility. Manufacturers but also country NRAs and UN agencies such as WHO and UNICEF are working to provide high-quality vaccines.

Session 7: Country Working Groups

During this session, the participants worked in their country groups along with a facilitator. Those that had action plans worked to update them and identify remaining challenges. Those who did not have an action plan were asked to come up with 2-4 priority actions that can be implemented in the coming year. They were also asked to identify someone to present to other countries in the subsequent session. The facilitators were as follows:

Country	Facilitator
Indonesia	Beth
Lao	Abu and Elizabeth
Mongolia	Tony
Myanmar	Satish
Papua New Guinea	Juliette
Philippines	Aurelia
Thailand	Aniqa
Timor-Leste	Stephane

Vietnam	Miloud
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Many countries reported progress on many of the action points developed last year at the 2018 VPPEF. Some even managed to integrate the action points into their national work plan. Across the board, the facilitators noticed a significant improvement in registering progress on Action Points. This underscores the continuity of and progress made between the annual VPPEFs.

Session 8: Peer review

In Session 8, countries were grouped into threes as follows:

Group	Country
	Thailand
Group 1	Mongolia
	Myanmar
	Vietnam
Group 2	Philippines
	Timor-Leste
	Indonesia
Group 3	Lao PDR
	Papua New Guinea

Each country was given five minutes to present their action plan, including key challenges and priority actions to address those challenges. The other two country teams provided feedback and suggestions. The groups each selected one person to present a high-level overview across the three countries, identifying common priorities; learning and experience sharing; and key challenges. This summary was presented in plenary.

Group 1 countries are all in different stages of vaccine procurement. Thailand is a vaccine producer, Mongolia has transitioned from Gavi support and is fully self-financing, and Myanmar is currently in Gavi's preparatory transition stage. They all experience budget issues and resource limitations. Myanmar plans to be post- transition in 2023, but they need to increase the budget to replace Gavi financing. Mongolia managed to build the political will to mobilize these resources. Thailand also did this, and utilized intra-ministerial influencers to assist.

Data management was also a common concern, as was stringent procurement regulations. Mongolia still uses UNICEF procurement because it's cost effective and they can use UNICEF's market influence. The Myanmar government needs to work on the procurement systems.

Group 2 countries were also at different stages. For this group, the main challenges are:

- 1) Availability and sustainability of cold chain facilities (especially in Philippines and Timor-Leste).
- 2) Budget. The countries don't have enough staffing for capacity building or expansion of immunization.

- 3) Regulatory issues. Timor-Leste is in the process of establishing a regulatory team. In Philippines, there were issues with product registrations, which hampered delivery of vaccines.
- 4) Innovation and technology. Vietnam already has 12 vaccines produced locally and will add two more. They want to have these vaccines prequalified and exported to other countries. Vietnam has a platform for a nationwide vaccination system and want to use the data to better inform the process.

Group 3 consisted of a vaccine producer country (Indonesia) and two in the Gavi transition phase (Lao in 2023 and PNG in 2025).

The group identified the following key challenges:

- 1) Budget issues. PNG was looking at the advanced payment mechanism or while Indonesia was struggling with regulations related to procurement through UNICEF (PNG and Indonesia). The countries also were facing challenges with fund disbursement and sufficient funding.
- 2) Capacity for accurate forecasting and data management (all countries).
- 3) Lack of a national regulatory authority (Lao and PNG).

The countries are working on seeking exceptions to regulations. For example, PNG and Indonesia have laws that don't align with the UNICEF procurement process. They also are seeking to improve interagency coordination and forecasting and data management systems. Establishment and strengthening of the NRA is also a key activity.

The Thailand team offered some advice on this, pointing to three pillars: knowledge, political will, and people power (the beneficiaries). Universal health coverage underpins the Thai success, and the budget follows. The political will that created the universal health coverage will stay. Advocates for vaccines in Thailand also have the numbers on their side; the government pays less now or pays more for treatment and hospitalization later.

The participants then took five minutes to complete the online survey, the results of which are included in Annex 3.

Session 9: Wrap up and closing remarks

Nakorn provided some closing remarks, mentioning that the forum has been very informative, allowing everyone to share expertise. He reminded the group that they had covered vaccine decisionmaking and procurement, but also market intelligence and guidance on how to make strategic decisions on vaccines. The forum has also been very interactive, allowing for an exchange of ideas, experience, and knowledge. This last session was very useful for discussing the details of the country programs. Knowledge is very important, but knowing each other is also important. Please keep in touch and keep working together. After this forum, everyone has the opportunity to do some homework and take next steps. Finally, Nakorn, on behalf of NVI, thanked all the forum sponsors.

Grace summarized the key messages as follows:

- Some content areas that came out in the expectations session: how to improve financing and better manage procurement, and consideringooled procurement as a way to address some of these procurement issues.
- We heard from Thailand about their the rigorous process of procurement, considering global supply and market. Where there is good global supply, does it make sense to invest and replicate locally?
- On the topic of market intelligence, questions arose on where to get price information
 when no longer funded by Gavi. Stephane reminded us that all countries can source
 WHO PQ vaccines, unrelated to whether they receive Gavi funding or through UNICEF
 or not.
- There was a call for better regional collaboration to better negotiate with providers.
- We can never compromise on quality over price for vaccines. Within the region we can
 be assured of the quality of vaccines Indonesia, India, and Thailand are producing.
 Thailand's strong NRA relies on WHO PQ, saving a lot of work. Countries can rely
 where it's appropriate.
- Philippines asked about how to ensure quality. Even if there is Market Authorization, we need good surveillance and a quick response to any adverse effects.
- While this meeting made progress, many unaddressed questions remain and we need to continue dialogue. We should all take advantage of platforms provided to continue the exchange online.

Davika from the UNICEF Myanmar country office provided closing remarks. The event had precise agenda topics that were cross cutting for countries in the region. The Forum provided an opportunity for exchanges and information sharing as well as networking and hearing each other's experiences. This creates a common community for exchanging ideas that should be carried forward.

End of Program

Annexes

Annex 1: Agenda

EASTERN-ASIAN SUB-REGIONAL

Vaccine Procurement Practitioners Exchange Forum (VPPEF)

12 to 13 September 2019

Yangon, Myanmar

12 September

No.	Time	SESSION	CHAIR	FACILITATION	OBJECTIVE/ CONTENT	PRESENTER
				METHODOLOGY		
	1.00	Registration				UNICEF Country Office,
						Myanmar
1	1.30	Welcome and	N/A	Plenary	Welcome and keynotes from	Nakorn Premsri, Thailand
		Introduction			the presenters	National Vaccine
						Institute
						Aurelia Gasca, UNICEF
						SD
						Grace Chee
2	1.45	Countries key	Aurelia Gasca,	Open discussion	Each country delegation intro	duces their members and
		challenges and best	Loic Sanchez,		presents their expectations fo	r the event.
		practices	UNICEF SD			

3	2.45	Aligning Vaccine Decisions with Procurement and Supply	Nakorn Premsri, Thailand National Vaccine Institute	10min per presentation 20min panel discussion/ Q&As 5min wrap-up by the chair	Objective: show the importance of integrating supply considerations earlier into the policy decision making. This session will set the frame for the discussions on Day 2.	Aurelia Gasca, UNICEF SD Clint Pecenka, PATH (rotavirus) Tanapat Laowahutanon, NVI Thailand (JE, HPV)
4	4.00	Wrap-up of the day – key takeaways Aurelia Gasca, UNICEF SD				
•	Social event					

13 September

No.		SESSION	CHAIR	FACILITATION METHODOLOGY	OVERVIEW	PRESENTER	
5	9.00	Market Intelligence	Loic Sanchez, UNICEF SD	Presentations (countries, WHO) and Q&A with presenters	Available information to make confident procurement decision.	2 Country representatives (Mongolia and Philippines) Luzmila Stephane Guichard, WHO SEARO Tony Nelson, Chinese University of Hong Kong	
Break	10.20	Country Posters Gal	Country Posters Gallery Walk				
6	11.15	Sourcing quality assured vaccines	Miloud Kaddar, LNCT	Panel and then Q&A	How countries ensure access to vaccine of assured quality.	Stephane Guichard, WHO SEARO Pramote Akarapanon, Thai FDA Representatives from the Gov. of Indonesia and Lao	
Lunch	12.45						
7	1.30	Country working groups	Grace Chee, LNCT Loic Sanchez, UNICEF SD	Participants break into country delegation groups	Discussions on vaccine second challenges, good practices Outcome will be a country	and potential risks.	

Break	3.00					
8	3.15	Peer-review	Loic Sanchez, UNICEF SD	Participants break into three groups	Countries report back on challenges and mitigation plans	Country delegations
9	4.15	Wrap-up & closing remarks	UNICEF SD Nakorn Premsri, Thailand National Vaccine Institute Grace Chee, LNCT			

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Annex 3: Workshop Feedback¹

Did the Forum meet your country objectives and expectations?

Agree or Strongly Agree	97%
Neutral	3%

Length of the Forum

Appropriate length	82%
Too short	15%
Too long	3%

Were the presentations easy to follow, and the presenters clear?

Yes	94%
No	6%

How would you evaluate the level of information exchanged?

Just right	82%
Not enough	18%

Day I - Aligning vaccine decisions with procurement and supply

Most useful	39%
Useful	61%

Day II - Market Intelligence

	8
Most useful	58%
Useful	36%
Fairly useful	6%

Day II - Sourcing quality-assured vaccines

Most useful	48%
Useful	48%
Fairly useful	3%

Day II - Country team work

Most useful	45%
Useful	55%

UNICEF historically has held the VPPEF at the global level. In your opinion, would your country benefit more if it was held at the regional level (which is the case of the Yangon VPPEF)?

Global	12%
Global, held every other year	42%
Regional	45%

¹ Sometimes, due to rounding, the totals will not add up to 100%.

Do you foresee that the 2019 Yangon VPPEF will lead to further cross-country collaborations? Which areas?

Those who responded positively suggested the following areas for collaborations:

- Particularly in forecasting and establishing an NRA in our country.
- Participation in UNICEF VII.
- Vaccine procurement mechanisms and financing modalities
- Pooled procurement discussions (particularly within ASEAN); regional sourcing
- Vaccines prices and price negotiation
- Planning and technical capacity improvement
- Convergence and reliance in vaccine regulation
- Vaccine security
- Advocacy at the policy level
- Market intelligence

MARKET INTELLIGENCE

Make confident decision making in your vaccine sourcing processes

Yangon – Sub-regional VPPEF 2019

In an attempt to foster cross-country exchange of Market Intelligence to support countries formed decisions about their procurement of vaccines, please find below a non-exhaustive list of available online resources that were mentioned during this event.

GLOBAL MARKET TRENDS

Unicef Market Influencing Dashboard	Unicef publishes a Market Influencing dashboard that highlights critical determinants of a commodity's global market health. The dashboard summarizes UNICEF's global market assessment of 72 strategic essential lifesaving products for women, children, and young people, including vaccines, cold chain equipment (CCE), and safe injection equipment (SIE).	Link
WHO Global Vaccine	Description of the individual and global vaccine markets dynamics from a supply and demand perspective.	<u>Link</u>
PRODUCTS		
Gavi Detailed product profiles	Comprehensive information on Gavi-supported vaccines.	<u>Link</u>
Unicef Market Notes	Highlights on the current market trends in supply, demand, shortages, surplus, availability of the vaccines procured UNICEF.	<u>Link</u>
List of diseases and corresponding vaccines	A list of the currently available and pipeline vaccines and WHO policy recommendations, together with other key resources.	<u>Link</u>
PRICE		

PRICE

Factsheet on vaccine pricing for Gavi Fully Self-financing & Accelerated Transition	List of vaccine pricing, presentations and conditions for Gavi transitioning countries.	Link			
WHO Market Information for Access to Vaccines	Details of countries vaccine purchases consolidated with JRF data.	<u>Link</u>			
PAHO Vaccine price	Expanded program for immunization vaccine prices for the PAHO region.	<u>Link</u>			
QUALITY					
WHO Pre- Qualified Vaccines Database	Online repository of all WHO Pre-qualified vaccines with basic product attribute information	<u>Link</u>			
NITAG resource center	Overview of the NITAGs across the globe based on the 6 WHO criteria.	<u>Link</u>			
MANUFACTURERS					
WHO Prequalified vaccines per manufacturers	All WHO pre-qualified vaccines (and manufacturers) targeted against disease(s).	<u>Link</u>			
Access to Vaccines Index	The Index maps how vaccine companies are responding to global calls to increase immunization coverage. The index compares key characteristics of each company. The companies evaluated in the Index have diverse business models, reflected in their vaccine	<u>Link</u>			

COMMUNITY OF PRACTICE

<u>Link</u>

pipelines, portfolios, revenues and number of doses sold globally.

A platform dedicated to supporting countries as they transition away from Gavi support to full domestic financing of their national immunization programs.

VPPN

A network of senior-level practitioners from middle-income countries and Gavi transitioning countries to exchange and solve problems related to vaccine procurement,

GENERAL INFORMATION

Advocacy for List of online resources related to vaccine and immunization. **immunization**

Link
