



Regional Strategic and Action Plan for ASEAN Vaccine Security and Self-Reliance (AVSSR) 2021-2025

1. Background

The Regional Strategic and Action Plan for AVSSR 2021-2025 is based on the ASEAN Vaccine Baseline Survey (AVBS) (Annex 1), literature reviews, outputs of previous technical workshops in the past 5 years (Annex2) among AMSs and information from various stakeholders at international level. Through the inputs received from AHC 3 and SOMHD, this AVSSR Strategic and Action Plan was revised and endorsed by AHC 3 on 22 July 2020. It was finalised and endorsed by SOMHD on 20 October 2020. The outline of this document includes the following:

- Scope of the AVSSR and the Regional Strategic and Action Plan for AVSSR
- Analysis of the feasible potential areas of collaboration
- Proposed 5 strategies and expected outputs drawing from the analysis

2. Definition scope vision and key principles

2.1 Definitions

- “**Vaccine security**” has been defined as the “sustained, uninterrupted and timely supply of affordable vaccine of assured quality”
- “**Vaccine self-reliance**” refers to the ability of the country and/or region to optimally ensure sufficient vaccines for use in routine immunization and emergency situation, based on its own capacities and resources and without needing much help from outside.

2.2 Scope:

2.2.1 Vaccine and Biologicals (In the scope of Vaccine Preventable Diseases)

2.2.2 Timely and equitable access to affordable and quality-assured COVID-19 vaccine/s’ be the focus of the first phase for the urgent implementation of the Plan [Addressed by the Special SOMHD meeting on 22 July 2020]

2.3 Vision: Towards Realising Vaccine Security and Self-Reliance for All: Ensure healthy ASEAN through timely, equitable access to affordable and quality-assured vaccines

2.4 Key principles underpinning the collaboration

- Shared regional vision: collaboration model based on fundamental principles of ASEAN*
- Align with global and regional policies
- Building on existing mechanisms or platforms (not to reinvent the wheel)
- Human rights and equity: access to vaccines/biologicals and scientific progress as basic rights



- Information and Knowledge sharing: as regional public goods
- Future-oriented and sustainability: a vision based on expected future challenges opportunities and sustainability
- Accountability: a call to all stakeholders, particularly decision-makers, to deliver on ensuring access to vaccines

3. Potential collaboration areas

- Having reviewed literature, relevant global and regional policies and plans, outputs from technical workshops and consultation meeting among international partners,
 - 3.1..1 We can analyze the major challenges, feasibility of collaboration through vaccine development cycle as shown in Table 1**
 - 3.1..2 Using the analysis from Table 1, we re-categorize the areas of collaboration into 5 strategies as shown in Table 2**
** the essential information is shown in annex 1 and 2.

Glossary of Acronyms

Acronym	Explanation
ADB	Asian Development Bank
AEC	ASEAN Economics Community
AEVS	ASEAN Emergency Vaccine Stockpile
AMSs	ASEAN Member States
ASCC	ASEAN Socio-Cultural Community
ASEAN	Association of Southeast Asian Nations
AVPP	ASEAN Vaccine Pooled Procurement
AVRF	ASEAN Vaccine Research Fund
AVSSR	ASEAN Vaccine Security and Self-Reliance
BMGF	Bill & Melinda Gates Foundation
CDC	Centers for Disease Control and Prevention
CEPI	Coalition for Epidemic Preparedness Innovations
DCVMN	Developing Countries Vaccine Manufacturers Network
EPI	Expanded Programme on Immunization
EVM	Effective Vaccine Management
Gavi, the Vaccine Alliance	Global Alliance for Vaccines and Immunization
GPO	Government Pharmaceutical Organization
GSPOA	Global Strategy and Plan of Action on Public Health, Innovation and Intellectual Property
HRD	Human Resource Development
ISO	International Standard Organization
IOM	International Organization for Migration
IVI	International Vaccine Institute
MDGs	Millennium Development Goals
M&E	Monitoring and Evaluation
MOA	Memorandum of Agreement
MOU	Memorandum of Understanding
NCL	National Control Laboratory
NIP	National Immunization Programme
NITAG	National Immunization Technical Advisory Group
NRA	National Regulatory Authorities
NVI	National Vaccine Institute, Thailand
PAHO	Pan American Health Organization
PATH	Program for Appropriate Technology in Health
PDPs	Productive Development Partnerships
PMS	Post Marketing Surveillance
PPP	Public Private Partnership
PPWG	Pharmaceutical Product Working Group
R&D	Research and Development

SDGs	Sustainable Development Goals
SOPs	Standard Operating Procedures
TOR	Term of Reference
TRIPS	Trade-Related Aspects of Intellectual Property Rights
UHC	Universal Health Coverage
VPDs	Vaccine Preventable Diseases
VPPEF	Vaccine Procurement Practitioners Exchange Forum
VRC	Vaccine Research Center
WS	Workshop for Development of AVSSR Strategic and Action Plans 2018
WHA	World Health Assembly
WHO	World Health Organization
UNICEF SD	United Nations Children's Fund Supply Division



Table 1: The analysis of major challenges through vaccine development cycle and the feasibility of collaboration for the regional strategies

Category	Regional/global Challenges	Feasibility of collaboration	Specific/possible areas or actions for collaboration	potential partners
1. Research and development	1.1 Limited capacity of R&D in the region (need support in the new/appropriate technologies in resource-constraint settings to address public health needs to combat diseases in the region)	X not feasible <ul style="list-style-type: none"> It needs huge investment and AMSs have their own decision and reserve to collaborate in this area in previous WS. 	-	-
	1.2 The innovative model for R&D financing is essential for the success in the development of new affordable vaccines	√ feasible <ul style="list-style-type: none"> A global framework (Global Strategy and Plan of Action on Public Health, Innovation and Intellectual Property: GSPOA), adopted by WHA in May 2008, clearly identified and recommended to have an innovative model for R&D financing and to support R&D in neglected tropical diseases. 	These 2 issues need the movement at the global level. So AMSs can work together to identify key policy areas/agree on how to advance these issues to global/regional policy fora. R&D Issues to be proposed: <ul style="list-style-type: none"> ask for innovative financing model and support developing countries/support R&D on neglected diseases There are 2 ways to propose: (depending on the agreement or country's interest) Collectively move this issue at global/regional policy (on behalf of AMSs) Share national position on this issue at global/regional policy for a 	WHO, ASEAN, CEPI
	1.3 Lack of R&D in neglected vaccines			
	1.4 Multinational clinical research for vaccine is crucial for vaccine development and a network of the	√ feasible <ul style="list-style-type: none"> In our region, there are quite a number of highly capable clinical 	Multinational clinical research network	



	<p>national research centers should be strengthened to collaborate and exchange information. (This would be beneficial for developing country manufacturers to connect with the network to conduct multinational studies which can facilitate vaccine licensing.)</p>	<p>research centers/laboratory facilities which have been linked through some platforms and linked by multinational vaccine manufacturers.</p> <ul style="list-style-type: none"> ▪ If we can establish the clinical research network among AMSs, it could foster the clinical researches to support vaccine development in the region. 		
2.Production	<p>2.1 Half of the AMSs have vaccine production capacities but we need more advanced technologies for new vaccines in particular the neglected vaccines that address public health needs of the region.</p>	<p>X not feasible (to collaborate among AMSs)</p> <ul style="list-style-type: none"> ▪ It needs huge and long-term investment and AMSs have their own decision and reserve not to collaborate in this area in previous WS. <p>√ feasible (to get the support from partners)</p> <ul style="list-style-type: none"> ▪ DCVMN is a strong network with regular meeting. ▪ There are a number of global projects/platforms to support manufacturers in developing countries. (Global Action Plan on Influenza Vaccine, the Inactivated polio vaccine (IPV) project, South-South collaboration) 	<p>These 2 issues need the movement at global level. So AMSs can work together to identify key policy areas/agree on how to advance these issues to global/regional policy fora.</p> <p>Production Issues to be proposed: ask partners (WHO, other development partners) to support the capacity of vaccine manufacturers in developing countries.</p> <p>There are 2 ways to propose: (depending on the agreement or country's interest)</p> <ul style="list-style-type: none"> ▪ Collectively move this issue at global/regional policy for a (on behalf of AMSs) ▪ Share national position on this issue at global/regional policy fora 	-
3.QAQC	<p>3.1 the regulatory processes need harmonization to support vaccine security</p>	<p>Harmonization of Standards and Technical Requirements in ASEAN for pharmaceuticals has been in place and agreed among AMSs under the Pharmaceutical Product Working Group (PPWG), [e.g. ASEAN</p>	-	<p>PPWG, ASEAN, AMSs</p>



		Common Technical Requirements (ACTR) was officially adopted by AMSs on July 2012. This is one of the best practices for ASEAN collaboration.]		
4.Use	<ul style="list-style-type: none"> In this regional plan, we will focus on some specific areas of the immunization program e.g. Adverse Event Following Immunization (AEFI), immunization coverage, cold-chain and vaccine delivery system. Such specific areas would be a difficult issue that can't be tackled by a single country or a single organization. We will not duplicate the work which is the key responsibility of the international organizations but will build on the existing mechanism/platforms). 			
4.1National immunization program management	4.1.1 some areas of the immunization programs are not well-addressed. <ul style="list-style-type: none"> Massive migration among AMSs and border health Vaccine financing in the context of UHC/GAVI transition 	√ feasible <ul style="list-style-type: none"> Use and build on existing platform (for example WHO, GAVI, UNICEF, IOM) 	Proposed: Reviewing needs of AMSs regarding vaccine in the NIPs and expected areas for regional collaboration to improve and ensure the vaccine security among NIPs. Needs for vaccination delivery by international partners, e.g. IOM, UNICEF, may also be reviewed.	WHO, UNICEF, GAVI, IOM
4.2Vaccine procurement	4.2.1 Vaccine shortage, disruption of vaccine supply and vaccine price are main barriers for vaccine security in ASEAN and regional pooled procurement is one of the key strategies to tackle such hurdle	√ feasible <ul style="list-style-type: none"> AMSs proposed pooled-procurement as a key area for collaboration The feasibility needs to be studied and discussed e.g. analyze each AMS whole procurement processes, their regulations and interests (in particular the type of vaccines), models of pooled procurement 	<ul style="list-style-type: none"> Identify the steps/regulation/barr iers of each AMSs' procurement process Analyze the feasibility of regional pooled procurement/other models of pooled procurement/bargai ning (bilateral procurement) 	WHO, UNICEF, GAVI
4.3Stockpiling	4.3.1 During routine immunization or in emergency situation, the availability of some vaccines/biologicals is the challenge to achieve vaccine security. AMSs recognize that	√ feasible <ul style="list-style-type: none"> AMSs proposed stockpiling as key area for collaboration Some mechanism of stockpiling exists. It is possible to build on the existing mechanism starting with a 	<ul style="list-style-type: none"> Analyze the status/existing stockpiling mechanisms at global/regional/natio nal level 	AMSs, WHO (Bi-regional), UNICEF, GAVI



	stockpiling is one of the key strategies to achieve vaccine security	specific vaccine/ biological and plan for expansion in the next step.	<ul style="list-style-type: none"> Develop the model of stockpiling and mechanism for implementation 	
5.Capacity building	Capacity building is the most interested area to collaborate among AMSs	<p>√ feasible</p> <ul style="list-style-type: none"> Requested by AMSs A number of capacity building programs have been conducted by partners. 	<ul style="list-style-type: none"> ASEAN capacity building center on vaccine security Systematically review of the capacity building programs, rosters of experts Develop Vaccinology training course(s) in specific areas (topics as follows are for example only: procurement, cold chain and logistic/vaccine management, Technologies in Vaccine Research and Development, Vaccine design and preclinical development, Clinical development of vaccine, regulatory considerations for evaluation of vaccine, technology transfer programme, vaccine potency testing, etc.) 	AMSs (especially MOSTI of Malaysia through the Open Science platform), WHO, UNICEF, GAVI, CEPI



Table 2 the strategies, expected outputs, time line, partners and possible sources of budget and support

Program/project activities	Expected outputs	timeline	Potential partners	Possible sources of budget and support
Strategy 1	Advance AVSSR into global policy level			
	<p>Background</p> <p>Immunization has been an important global policy agenda for decades since the birth of NIPs around the world in 1977. It has made a number of significant progresses in reducing VPDs with the guidance from a series of global plans and strong support from development partners.</p> <p>At present, after the launch of GVAP (Global Vaccine Action Plan) in WHA 64, the lessons learned from GVAP were drawn to develop the next global plan namely “Immunization agenda 2030” which inspires immunization communities to achieve the immunization goal in 2030. From the comprehensive review, most of the global immunization plans always focused on the program implementation, the evidence-informed policy decision mechanism, new vaccine introduction, disease elimination/eradication, information and M&E system. Vaccine security in particular vaccine management/global vaccine production capacity have not been well-addressed in these plans while vaccine security itself is the main element that hampered the success of national immunization program.</p> <p>It is opportune time in 2020 and beyond that vaccine security and vaccine self-reliance shall be advocated consistently by AMSs as an essential element at global level in WHO’s Immunization agenda 2030 and other relevant global policies and strategies. This expected output could be achieved by the following actions:</p> <ul style="list-style-type: none"> ▪ ASEAN deliver regional one voice intervention to highlight vaccine security and vaccine self-reliance into immunization agenda 2030 and other relevant global plans and strategies. <p>Or</p>	WHA 74, May 2020	AMSs, WHO, GAVI, UNICEF	-



Program/project activities	Expected outputs	timeline	Potential partners	Possible sources of budget and support
	<ul style="list-style-type: none"> ▪ Each AMSs deliver intervention to highlight AVSSR into immunization agenda 2030 and other relevant global plans and strategies <p>And</p>			
	<ul style="list-style-type: none"> ▪ AMSs may wish to share their selected positions on some specific issues at global/regional policy fora, such as: <ul style="list-style-type: none"> ○ R&D delinkage ○ Foster the development of neglected vaccines (Public health needs in the region) ○ Strengthen vaccine production capacity in developing countries <p>Expected output</p> <ol style="list-style-type: none"> 1. ASEAN's vaccine security and vaccine self-reliance interventions/ activities under this Regional Strategic and Action Plan 2021-2025 will contribute to WHO's final "Immunization Agenda 2030: global strategy to leave no one behind" 		<p>AMSs, WHO, GAVI</p>	
Strategy 2	Support the effective procurement strategies and establish the regional stockpiling mechanism			
	<p><u>Vaccine procurement</u></p> <p>Vaccine procurement is a vital function of immunization programs, with important implications for total program cost as well as reliable supply of appropriate products.</p> <p>Vaccine procurement differs in important respects from procurement of other health commodities. First, since vaccines are given to healthy children, safety and product quality must be an exceptionally high priority in procurement decisions. Second, most vaccines have relatively few suppliers, which limits procurement options and in some cases gives suppliers considerable leverage. Third, lead times are typically long, from 8 to 24 months, so procurement decisions must be made well in advance to avoid stock-outs.</p>			



Program/project activities	Expected outputs	timeline	Potential partners	Possible sources of budget and support
	<p>Currently, ASEAN countries can procure vaccines directly from manufacturers or through UNICEF. Vaccine prices are affected by the volume of the order, the certainty of demand and of payment, and the duration of the supply contract, as well as by product characteristics and market competitiveness. On its own, country can influence some determinants of vaccine prices, but others are beyond their control. In this situation, there are many procurement strategies that would support countries to get good quality vaccines at affordable price and ensure uninterrupted supplies. These strategies are included regional pooled procurement, multiyear tender, advanced market commitment and central bargaining. So the procurement processes of each country should be reviewed and analyzed. Then the suitable procurement options for each country and the region can be identified and proceed.</p> <p>In the light of the development of the regional strategy, we should collectively work together to identify good procurement strategies to support countries in achieving vaccine security of the region.</p> <p>Expected outputs</p> <ol style="list-style-type: none"> 1. The comprehensive analysis of each AMS's procurement processes and challenges for various procurement strategies 2. The recommendations for innovative/effective procurement strategies in the region <p><u>Stockpiling</u></p> <p>Global or regional vaccine/biologicals stockpiles, in which vaccines/biologicals are reserved for use in emergencies or supply shortages, have effectively provided countries with the capacity for rapid response to emergency situations, such as outbreaks of diphtheria, yellow fever and measles.</p>			



Program/project activities	Expected outputs	timeline	Potential partners	Possible sources of budget and support
	<p>The high cost and insufficient supply of many vaccines, including oral cholera vaccine and pandemic influenza vaccine, have prompted discussion on expansion of the use of vaccine stockpiles to address a wider range of emerging and re-emerging diseases.</p> <p>However, the decision to establish and maintain a vaccine stockpile is complex and must take account of disease and vaccine characteristics, stockpile management, funding, and ethical concerns, such as equity. Past experience with global vaccine stockpiles provide valuable information about the processes for their establishment and maintenance.</p> <p>In this Regional plan, we shall explore existing literature and stockpile data to discuss lessons learned, factors determining success/failure of regional or g vaccine/biological stockpiles and to inform the development of future regional vaccine stockpiles in ASEAN.</p> <p>Expected outputs</p> <ol style="list-style-type: none"> 1. The review and analysis of stockpiling mechanisms at regional and global levels 2. The model/mechanism of stockpiling for ASEAN 3. The establishment of ASEAN stockpiling mechanism 			
Strategy 3	Establish or strengthen information sharing platforms to support AVSSR			
	<p>The demand for accurate data and their use in programme management and decision-making has increased as countries strive to meet the ambitious global immunization goals. These agreed upon goals require new, more precise and finer types of measurements than have often been used in many low- and middle- income countries. Improved information systems and data quality will also be critical to measuring progress in achieving the Sustainable Development Goals (SDGs) and Universal Health Coverage (UHC), such as improvements in equity of service delivery and in reaching under-served, marginalized, and migrant populations.</p>		<p>AMSs, WHO, UNICEF, GAVI</p>	



Program/project activities	Expected outputs	timeline	Potential partners	Possible sources of budget and support
	<p>Recent efforts by countries and immunization partners to improve immunization-related data have resulted in successes in a number of countries. However, poor quality and under use of data remain a persistent problem in many, affecting the ability of countries and partners to monitor progress against the global goals as well as to support optimal changes to immunization programmes.</p> <p>Apart from the information related to disease surveillance and program performance, there are a number of information sharing system/platforms which are essential for vaccine security, for example, vaccine price sharing, state of the art of vaccine R&D, vaccine product pipelines.</p> <p>In this Regional Strategic and Action Plan, we would like to strengthen/build on the existing information sharing platforms which will play an essential role in the decision making thereby ensuring success of vaccine security and self-reliance.</p> <p>Expected Outputs</p> <ol style="list-style-type: none"> 1. Review of the status of information systems that collect relevant data for vaccine security and self-reliance, the availability of modern information technologies, and their current and potential future role in supporting the collection, management, analysis and use of the data; 2. Identification of knowledge gaps and creation of prioritized research agenda around data quality and use. 3. Proposed list of information that could be shared as appropriate, contingent on legal and information confidentiality feasibility: <ul style="list-style-type: none"> ▪ R&D pipeline (State of the art) ▪ Pipelined vaccine product manufactured in ASEAN ▪ VPD surveillance/outbreaks ▪ Vaccine financing (in the context of UHC and GAVI transition) ▪ Vaccine price sharing ▪ Vaccine Lot Release rejection ▪ Vaccine regulatory guidelines 			



Program/project activities	Expected outputs	timeline	Potential partners	Possible sources of budget and support
	<ul style="list-style-type: none"> ▪ Vaccine schedule/program performance ▪ Best practices in each stage of the whole vaccine development cycle (i.e. R&D, production, regulation, and immunization) 			
Strategy 4	Strengthen capacity of the key stakeholders to achieve vaccine security in ASEAN			
	<p>Vaccine security is an interconnected, complex and extremely difficult issue. To reach its ultimate goal, we require the process by which stakeholders in vaccine development cycle (at individual, organizational and national levels) to obtain, improve, and retain the skills, knowledge, tools, equipment, and other resources needed to do their jobs competently. Such process defined as “capacity development” which allows individuals and organizations to perform at a greater capacity. (larger scale, larger audience, larger impact, etc.).</p> <p>In this regional strategy, we address capacity development as an essential element.</p> <p>Expected output</p> <ol style="list-style-type: none"> 1. Establishment or identification of the ASEAN training centers for capacity development in ASEAN* <p>List of other activities</p> <ol style="list-style-type: none"> 2. Roster of experts 3. List of capacity building program 4. Identify areas/needs for capacity building <ul style="list-style-type: none"> ○ Procurement ○ Cold chain and logistics/vaccine management ○ Sustainable financing in the context of UHC/GAVI transition ○ NITAG ○ Vaccine production ○ NRA/NCL 		AMSS, WHO, UNICEF, GAVI	



Program/project activities	Expected outputs	timeline	Potential partners	Possible sources of budget and support
	<p>Note: AMSs well acknowledged that there are trainings that are conducted by various organisations e.g. WHO on the regulation of vaccines and thus efforts should not be duplicated.</p>			
<p>Strategy 5</p>	<p>To establish monitoring and evaluation mechanism (including the communication and coordination) for the implementation of the plan</p>			
	<p>Monitoring and evaluation are critical for assessing the wide, diverse range of interventions being implemented to reach vaccine security and self-reliance. Furthermore, it is a tool for identifying and documenting successful programmes and approaches and tracking progress toward common indicators across related projects. Monitoring and evaluation forms the basis of strengthening understanding around the many multi-layered factors underlying vaccine security and self-reliance and the effectiveness of the response at the stakeholders at all levels.</p> <p>Monitoring and evaluation together provide the necessary data to guide strategic planning, to design and implement programmes and projects, and to allocate, and re-allocate resources in better ways.</p> <p>In addition, we incorporate communication and cooperation as an important component in the fifth strategy. The communication and coordination aims to be used as a tool for increasing understanding, perception, and awareness on the regional initiative of vaccine security and self-reliance among AMSs. Its objective is also to gain support from all relevant sectors concerned to work closer under the same vision, including increase access of target population to quality vaccines for better health</p> <p>Expected outputs</p> <ol style="list-style-type: none"> 1. The TOR, working mechanism and indicators to monitor and evaluate the Regional Strategic and Action Plan 2. Communication and coordination activities 			

ANNEX 1

The ASEAN Vaccine Baseline Survey (AVBS), 2017 was conducted by Thailand in collaboration with ASEAN Member States. It aims to describe the most current capacities, gaps / challenges in relation to the whole vaccine value chain. The AVBS is the first activity stipulated in the current ASEAN Health Cluster III (AHC3) Work Plan for 2016-2020. The second activity is to develop regional strategies and action plans to achieve AVSSR using AVBS as an input.

The “AVSSR Workshop 2018” was held during 28-30 March 2018 in Bangkok. The participants were vaccine experts and officials from all ASEAN member states (AMSs). In the workshop, the preliminary findings of the AVBS 2017, the accuracy of the verified data and collected new information from the participants has been shared and discussed. The results of the AVBS are collected from all sources until the end of March 2018 to ensure that the most recent ASEAN vaccine baseline information is well captured. Accordingly, the preliminary AVBS was then finalized immediately after the workshop and circulated to all key informants for more than 5 rounds for their consideration and endorsement.

On December 2018, AVBS full report was submitted to the Senior Officials’ Meeting on Health Development (SOMHD) and officially endorsed through an Ad referendum (Circulation of the report to SOMHD via email). Hardcopies were printed out by ASEAN Secretariat and presented to the 14th ASEAN Health Minister Meeting (AHMM), in Cambodia, during 29-30 August 2019, also published on ASEAN official website (see link: [https://asean.org › storage › 2017/02 › AVBS_Final_23082019](https://asean.org/storage/2017/02/AVBS_Final_23082019)).

Material and Method

The data used and presented in the AVBS full report were from multiple sources. These were collected through 4 main channels from **1) the AVBS 2017**¹, 2) Country expert interviews, 3) field visits to potential vaccine manufacturers in selected AMSs and 4) desk research from relevant previous surveys and internet-searchable sources. It must be noted that the relevant data from sources other than the AVBS 2017 were selectively used only to supplement the missing or unclear information from the AVBS 2017 survey template, which determines the core contents.

Data Analysis

SWOT analysis technique was used to indicate the current capacity and possibilities of the achieving regional vaccine security and self-reliance through firm collaboration in common areas among AMSs. The said-potential area of this study comprised 1) Research and Development (R&D) 2) Production 3) Regulatory system (QA/QC) and 4) National Immunization Programmes (NIPs).

¹**The AVBS 2017** collected primary data directly from AMSs through a self-administered Microsoft Excel® template which consist of 7 work sheets with 9 tables in accordance with the 4 designated areas of vaccine value chain i.e. vaccine research and development, production, regulation and immunization. The AVBS template is available at the following address: http://www.nvi.go.th/index.php/blog/2017/01/AVBS_2017. The template was distributed by the ASEAN Secretary Office (ASEC) to the Focal Points of Health Cluster 3 of each AMS on 17 July 2017, requesting that the duly completed templates be submitted back to the NVI by 30 September 2017 as an indicative deadline date.



Annex 1. The ASEAN Vaccine Baseline Survey (AVBS) 2017: The SWOT analysis

AREA OF COLLABORATION	STRENGTH	WEAKNESS	OPPORTUNITIES	THREATS
Research and Development	<ul style="list-style-type: none"> Some linkage platforms/network of vaccine researchers A number of highly capable vaccine R&D experts (especially in clinical trials) High capacity of some laboratories in the region Some existing funding support in R&D 	<ul style="list-style-type: none"> A few institutional capacities in the region Most of the researches are in lab scale and cannot be scale up. 	<ul style="list-style-type: none"> There are many international funding organizations e.g. Bill and Malinda Gates' Foundation, PATH, USAID etc. ASEAN and other tropical areas are one of the most popular clinical trial sites, due to enormous burden of diseases and capacity of many institutes to conduct clinical trials 	<ul style="list-style-type: none"> New vaccine R&D technologies requires more budget than the conventional technology R&D is the most time-consumed process and need technological advancement
Production	<ul style="list-style-type: none"> A number of pharmaceutical companies in the region can produce vaccines for NIPs High quality of vaccine production Strong political commitment and support for national vaccine production (domestic use) 	<ul style="list-style-type: none"> Oligopoly vaccine producers (Mostly in the developed countries with new technology vaccines) Some of vaccine manufacturers in the region have capacities in downstream production (filling and packaging), therefore they are partly relied on the multinational companies. Vaccine production capacity in the region cannot reach the regional demand (in the context that we assess the self-reliance capacity of the region) 	<ul style="list-style-type: none"> ASEAN share common areas of interest Technology transfer/knowledge sharing Large population, economy of scale and high Foreign Directed Investments Availability of vaccine production capacities in some countries 	<ul style="list-style-type: none"> High standard of vaccine quality requirement Access to new technology
Regulatory system	<ul style="list-style-type: none"> NRAs are proactive NRAs meet WHO-GMP compliance/PQ and PIC/S High QA/QC standard for global market 	<ul style="list-style-type: none"> Some countries are PIC/S member A few countries achieved WHO-PQ Some AMSs are lack of essential capacity to perform some NRA functions, giving that standard requirements are different between vaccine producing countries and non-vaccine producing countries 	<ul style="list-style-type: none"> Progress on the harmonization of the regulation the initiative of ASEAN harmonization scheme is composed of two important activities; 1) ASEAN common technical dossier (ACTD) and 2) ASEAN technical requirement (ACTR) 	<ul style="list-style-type: none"> Non-tariff barrier Regulatory requirements in some countries in the world i.e. 1) need to have vaccine manufacturer's representatives in distributing countries and vaccine prequalified by WHO 2) to have no less than 18 months of vaccine shelf life and 3) to have an agreement on tech-transfer on imported vaccines to local manufacturers
National Immunization Programmes	<ul style="list-style-type: none"> Common vaccine products for the NIPs (common essential vaccines) 	<ul style="list-style-type: none"> Some new vaccines have been considering for further introduction 	<ul style="list-style-type: none"> Shares the same WHO recommendations/guideline for all immunization programmes 	<ul style="list-style-type: none"> High price of new vaccines Massive migration



	<ul style="list-style-type: none"> Adequate supply of some NIPs vaccines e.g. BCG, OPV, DTP 	<p>to the NIPs by different AMSs such as HPV, PCV, JE and Rotavirus</p>		<ul style="list-style-type: none"> Outbreaks of VPD reemerged in many countries around the world Sustainability of the NIPS in particular the vaccine financing in the context of UHC and GAVI transition
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Annex 2. Chronological events of the previous technical workshops for developing an ASEAN Security and Self-Reliance, 2014-2018

WORKSHOP AMONG ASEAN COUNTRIES ON OPPORTUNITIES FOR REGIONAL VACCINE SECURITY (IN CLOSE COLLABORATION WITH WHO-COUNTRY OFFICE)				
Date Of The Event	Objective	Participant	Area Of Collaboration	Output
1-3 October 2014	<ol style="list-style-type: none"> To understand perspective of <u>vaccine security</u> among ASEAN countries. To <u>identify the needs of ASEAN countries</u> with regard to vaccine security, And to <u>identify the potential areas</u> for cooperation among countries. 	<ol style="list-style-type: none"> Technical experts (R&D, production, NRA/NCL, NIPS) from AMSs Senior experts from International Development partners i.e. WHO Thai vaccine experts from MoPH and relevant stakeholders <p>Total 78 participants</p>	<p>Four area of collaborations to enhance vaccine security in the region were proposed;</p> <ol style="list-style-type: none"> System development for vaccine security Human Resource Development (HRD) ASEAN Price Policy for Vaccine (APPV) Communication and Coordination 	<p>The follow-up workshop is requested. The proposal of the workshop will be proposed to;</p> <ol style="list-style-type: none"> the AEGCD in the 9th AEGCD Meeting in November 2014 the Senior Officials Meeting on Health Development (SOMHD) in 2015 ASEAN Health Minister Meeting (AHMM) in 2016
FOLLOW-UP WORKSHOP ON COLLABORATIVE MODELS FOR THE EFFECTIVE COMMUNICATION AND COORDINATION AMONG ASEAN COUNTRIES FOR REGIONAL VACCINE SECURITY				
Date Of the Event	Objective	Participant	Area Of Collaboration	Output
17-18 August 2015	<ol style="list-style-type: none"> To review and understand the existing models, programs or activities on communication and coordination related to the importance issue of vaccine security in ASEAN and worldwide To establish concrete strategies and action plan of the effective communication and coordination to enhance regional vaccine security and self-reliance 	<ol style="list-style-type: none"> Technical experts from AMSs who is responsible for vaccine research and development, production, regulation and national immunization Senior experts from International Development partners i.e. WHO-CO, WHO-HQ, WHO-SEAR, ASEC, UNICEF, IVAC Thai experts from MoPH, NVI and relevant sectors <p>Total 44 participants</p>	<p>Focused on the effective communication and coordination among AMSs</p>	<ol style="list-style-type: none"> A draft of the effective communication and coordination action plan was proposed The workshop participants also proposed to push this important issue to be included in the ASEAN-Post 2015 Health Development Agenda (ASEAN Health Cluster 3 Work Plans) through an official adoption from SOMHD and AHMM, respectively Key potential issues were proposed to be included in the AHC3 Work Plans 2016-2020 i.e. <ol style="list-style-type: none"> ASEAN Leaders' Declaration, Strategic and Action Plans on AVSSR and Communication and Coordination Action Plan (CCAP)



WORKSHOP ON DEVELOPMENT OF REGIONAL STRATEGIC AND ACTION PLANS FOR THE ASEAN VACCINE SECURITY AND SELF-RELIANCE (AVSSR)			
Objective	Participant	Area Of Collaboration	Output
1) Present, discuss, and verify the results of ongoing ASEAN Vaccine Baseline Survey (AVBS) 2) Develop a draft of regional strategic and action plans for the AVSSR	1) AMSs who are responsible for vaccine research and development, production, regulation and national immunization nominated by the national focal points 2) Senior experts from International Development partners i.e. WHO-CO, WHO-HQ, WHO-SEAR, ASEC, UNICEF, PAHO 3) Thai's expert from MoPH, NVI and relevant sectors Total 70 participants	1) Develop an effective management system for sustainable supply of quality vaccines 2) Support and networking on research, development, production, and regulation of regional essential vaccines. Only one measurement indicator proposed is the establishment of supportive mechanism for ASEAN targeted vaccine development and production 3) Enhance the existing collaboration, knowledge transfer, and financing for development of essential infrastructure and human resources for vaccine development and production 4) Formulate an appropriate platform for ensuring the implementation of the AVSSR strategic and action plans in the long run	1) A first draft of ASEAN Vaccine Baseline Survey (AVBS) 2) A first draft of Communication and Coordination Action Plan (CCAP) for advocating the implementation of the AVSSR 3) A first draft of the AVSSR strategic and action plans for 2018-2020 4) A first draft of concept paper on formulation of an appropriate platform for operationalizing the AVSSR strategic and action plans 5) A first draft of concept paper and ASEAN Leaders Declaration on the AVSSR