Situational Analysis and Feasibility of Regional Collaboration to Improve ASEAN Drug Security and Self-Reliance (ADSSR)

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Situational Analysis and Feasibility of Regional Collaboration to Improve ASEAN Drug Security and Self-Reliance (ADSSR)

The ASEAN Secretariat
Jakarta

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FOREWORD

Access to essential drugs and medicines is a vital component of Universal Health Coverage. The availability of safe, effective, affordable and quality medicines is important in achieving equitable and accessible health services most especially in times of natural disasters and during public health emergencies such as in outbreaks, epidemics and pandemics. The undersupply of these medicines can crucially disrupt the delivery of quality healthcare and services to national, regional and global populations.

To ensure regional cooperation around the provision of safe, effective, affordable and quality medicines, the ASEAN Health Sector, through the ASEAN Health Cluster 3 (AHC 3) on Strengthening Health Systems and Access to Care, prioritized ASEAN Drug Security and Self- Reliance (ADSSR) in 2016. The project commenced with the collection of relevant ASEAN Member States (AMS) data towards policy development. Currently, this initiative is under AHC 3's Health Priority 17 on Pharmaceutical Development under the ASEAN Post-2015 Health Development Agenda from 2016-2020 and 2021-2025.

The publication on the Situational Analysis and Feasibility of Regional Collaboration to Improve ASEAN Drug Security and Self-reliance (ADSSR) provides a baseline on the pharmaceutical situation in AMS. Different methodologies were employed by lead country Malaysia to assess the determinant factors affecting the pharmaceutical situation across AMS and to analyse the feasibility of collaborating with stakeholders on the domains of pharmaceutical production, medicines registration and regulation, supply and distribution of medicines, and medicines procurement and pricing.

This priority further complements the regional priority on ADSSR and is of significant importance to the implementation of the ASEAN Comprehensive Recovery Framework under Broad Strategy 1 on Enhancing Health Systems.

I sincerely congratulate the ASEAN Health Sector, particularly AHC 3 and lead country Malaysia, for developing the Situational Analysis and Feasibility of Regional Collaboration to Improve ADSSR as the basis for developing the Regional Collaborative Strategy for ASEAN Drug Security and Self-reliance which was adopted by the 15th ASEAN Health Ministers Meeting in 2022 and in promoting evidence-based regional programme initiatives on ADSSR.

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PREFACE

Ensuring timely access to quality and affordable medicines is not only an important priority for Malaysia but for all countries in order to achieve universal health coverage. As a member of ASEAN, Malaysia is truly honoured to be mandated as the focal point to lead the Regional Collaborative Strategy on ASEAN Drug Security and Self-Reliance (ADSSR) project. This has given us the chance to contribute to the ASEAN community by providing an actual glimpse of the complex events and processes involved throughout the pharmaceutical drug life cycle in ASEAN Member State (AMS) countries.

The project kickstarted in 2018 with preparation of the concept note that was presented at the 3rd ASEAN Health Cluster 3: Strengthening Health System and Access to Care Meeting in Singapore. After all AMS agreed to the proposal, the Baseline Pharmaceutical Situational Analysis Survey was conducted by distribution of questionnaires to all pharmaceutical focal points of respective AMS. Despite various differences in pharmaceutical regulatory and legislation among the AMS, the collaborative effort is well received among AMS.

The data collection was concluded in December 2019 right before the COVID-19 pandemic. The following year was very challenging for all AMS as the pandemic did test our preparedness in ensuring adequate supply of medicines for our people. The importance of this regional collaboration became even more apparent during the pandemic.

We would like to thank everyone from the Pharmaceutical Services Programme, Ministry of Health Malaysia for their relentless efforts since the initial conceptual phase, tool development, data collection and analysis until the completion of this publication. We are extremely grateful to all AMS for meticulously checking every revisions of the manuscript before being endorsed by the ASEAN Health Cluster 3 (AHC 3) and the Senior Official Meeting of Health Development (SOMHD). Special thanks to Public Health Development Division, Ministry of Health Malaysia and ASEAN Secretariat for their consultation and constructive feedbacks.

We hope that this publication will serve as a stepping stone for future collective and collaborative works among the AMS in ensuring drug security and self-reliance. May our work be part of our continuous commitment to leaving no one behind.

Norhaliza Binti A Halim
Senior Director of Pharmaceutical Services Programme
Ministry of Health Malaysia

CHAPTER 1

Introduction

Countries in the ASEAN region persistently face several crucial challenges to ensure continuous access to medicines for the population. These include disruptions in the availability of some essential medicines including those needed to treat infectious diseases. These medicines are often claimed to be 'non-commercially viable' to manufacture, hence are not produced due to the low demand resulting to inaccessibility. As these medicines are essential for treatments, when supply is disrupted, the ASEAN Member States (AMS) have to look for alternative sources, usually forced to pay higher prices and sometimes have to accept products of poor quality. In the case of life-saving medicines and orphan medicines, due to the limited demand, the cost of these medicines could be very high and vary widely among AMS. This could also be the case for new life-saving patented medicines.

Fundamentally, ensuring access to essential medicines is a key objective of all health systems and is an integral component of the progress towards universal health coverage (UHC). Despite global and national efforts to improve access and affordability of medicines, millions of people, in particular from low- and middle-income countries, still remain without full access to quality-assured and affordable medicines. The ASEAN Post-2015 Health Development Agenda[1] is an initiative to achieve a healthy, caring and sustainable ASEAN community by clustering and goal setting health priorities into four clusters. The health clusters highlight different health priority issues which are promoting healthy lifestyle, responding to hazards and emerging threats, strengthening health system and access to care and ensuring food safety.

The ASEAN Health Cluster 3 (AHC 3) Work Plan for 2016-2020 on Strengthening Health Systems and Access to Care focuses on strengthening the regional capabilities, capacities and advocacy in health system development in order to increase the access to safe, affordable, quality and holistic health care. Malaysia was given the mandate as the lead country and focal point for the ASEAN Drug Security and Self-Reliance (ADSSR) project under the work plan. Another similar effort to ensure vaccine security in the region, known as ASEAN Vaccine Security and Self-Reliance (AVSSR), was assigned to Thailand as the lead country. The overall objective of ADSSR is for all AMS to work together to improve the access to medicines by improving the drug security and self-reliance in the region. The project was carried out from 2018 to 2020 and was divided into two stages which were the situational analysis and feasibility study, and the development of the framework for regional collaborative strategies to improve drug security and self-reliance. This document is mainly reporting on the findings from the baseline pharmaceutical situational analysis and feasibility study conducted among AMS.

CHAPTER 2

Method

Four key activities were conducted throughout the two-year project period, which were the preparation of the concept note, Baseline Pharmaceutical Situational Analysis Survey, supplementary information search and focus group discussion among the AMS representatives. The findings were used to develop the framework and draft action plans for the regional collaborative strategies to improve drug security and self-reliance in ASEAN.

2.1 PREPARATION OF THE CONCEPT NOTE

The concept note was a proposal presented by the representative from the Ministry of Health (MOH) Malaysia during the Third Meeting of ASEAN Health Cluster 3 on Strengthening Health System and Access to Care held in July 2018 in Singapore. The preliminary information was collected through literature and documents search. A series of internal discussions were also conducted to gather information on developing suitable methodology for the situational analysis study.

2.2 BASELINE PHARMACEUTICAL SITUATIONAL ANALYSIS SURVEY

Once the concept note was agreed by the AMS representatives during the ASEAN Health Cluster 3 Meeting, the questionnaire for the Baseline Pharmaceutical Situational Analysis Survey was developed by the ADSSR project team in MOH Malaysia. Reference was made to similar questionnaires published by the World Health Organization (WHO)[2,3]. The content validity of the questionnaire was assessed through a pilot study conducted in 2018. Based on the returned questionnaires and the comments received from the pilot study, the project team then revised and refined the questionnaire before distributing the finalised version to the ten (10) AMS via ASEAN Secretariat in November 2018. The data collection period was concluded in December 2019.

The Baseline Pharmaceutical Situational Analysis Survey is a self-administered questionnaire with six domains including:

i. Demographic and health information – to identify country demographic and health background, healthcare resources and national medicines policy.

ii. Legislation and regulation – to identify regulatory authority responsible for marketing authorization, licensing, inspection, quality control as well as sale and supply.

iii. Production and trade – to identify pharmaceutical manufacturing capacity and trade volume.

iv. Procurement and logistics – to identify procurement and supply system as well as pharmaceutical distribution and logistics.

v. Financing and pricing – to identify existing financial and pricing mechanisms practiced.

vi. Political commitment – to gather willingness and readiness to commit and implement any regional collaborative efforts agreed.

2.3 SUPPLEMENTARY INFORMATION SEARCH

Although the overall response rate for the Baseline Pharmaceutical Situational Analysis Survey was high (80% as of December 2019), not all the questions in every domain were fully answered. Hence, supplementary information search through desktop review was essential to complement the data collected. Information were gathered from reliable official sources such as official country website and journal publications. Supplementary information search was actively conducted and additional information was extracted between November 2019 to March 2020.

2.4 FOCUS GROUP DISCUSSION (SWOT ANALYSIS ON REGIONAL COLLABORATION)

The Technical Meeting on Regional Collaborative Strategy for ASEAN Drug Security and Self-Reliance (ADSSR) was conducted at The Everly Hotel, Putrajaya, Malaysia from 6 to 8 November 2019. The aims of this meeting were to present and discuss the preliminary findings of the situational analysis and to organise a focus group discussion (FGD) among the AMS representatives. The meeting was hosted by Malaysia, and well attended by the AMS with two delegates from Brunei Darussalam, Cambodia and Singapore; and Lao PDR with one delegate. The meeting was also attended by representatives from the ASEAN Secretariat and Director of National Vaccine Institute, Thailand.

During the meeting, the AMS representatives delivered short presentations of respective country pharmaceutical profiles, answering specific questions that were distributed before the meeting (Appendix 1). Prior to the FGD during the technical meeting, a presentation about drug security issues particularly in the region was shared by Dr. Socorro Escalante from the WHO Western Pacific Regional Office. She shared her knowledge on the challenges related to drug security and highlighted the ways to improve it. Her presentation on ASEAN Drug Security and Self Reliance can be found in Appendix 2.

The FGD was carried out in the form of strengths, weaknesses, opportunities and threats (SWOT) analysis. It is a strategic planning tool to evaluate internal and external upon a common vision or specific goal. This kind of analysis is a common method for an organization like ASEAN to assess its capacity to execute a plan or achieve an attainable goal. The themes discussed in the SWOT analysis were selected in concordance with domains of the Baseline Pharmaceutical Situational Analysis Survey that corresponded with the determinants of access to medicines.

At the end of the technical meeting, a framework for regional collaborative strategy for drug security and self-reliance among AMS was drafted based on the discussion and feedbacks gathered from the AMS representatives.

Figure 1. Delegates at the Technical Meeting on Regional Collaborative Strategy for ASEAN Drug Security and Self-Reliance

2.5 DOCUMENT REVIEW BY AMS

Write up on the findings from this situational analysis, desktop review and FGD were then reported in a document, which was subsequently disseminated and reviewed by the ten AMS. Several review sessions were done by AMS and from these sessions, additional information and input from every AMS country were incorporated into the document as part of the improvement of the document. This was done to ensure precise information gathered and also to achieve ad referendum among AMS.

CHAPTER 3

Findings

3.1 SITUATIONAL ANALYSIS SURVEY

In total, eight out of ten AMS responded to the Baseline Pharmaceutical Situational Analysis Survey within the data collection period. These include Brunei Darussalam, Cambodia, Indonesia, Lao PDR, Malaysia, Philippines, Singapore and Thailand. Viet Nam submitted the answered questionnaire in September 2020. Meanwhile, the attendance for technical meeting was only 50% with the absence of representatives from Indonesia, Myanmar, Philippines, Thailand and Viet Nam (Table 1). Data for Myanmar were obtained solely from desktop reviews.

Table 1. List of AMS that completed the ADSSR Baseline Pharmaceutical Situational Analysis Survey and attended the ADSSR Technical Meeting in November 2019

ASEAN Countries	Baseline Pharmaceutical ADSSR Technical Meeting Situational Analysis Survey	ADSSR Technical Meeting
Brunei Darussalam	√	√
Cambodia	√	√
Indonesia	√	Did not attend
Lao PDR	√	√
Malaysia	√	√
Myanmar	Not answered	Did not attend
Philippines	√	Did not attend
Singapore	√	√
Thailand	√	Did not attend
Viet Nam	√	Did not attend

3.1.1 Demographic and Health Information of ASEAN

The documented estimation on total ASEAN population in 2018 was 653.6 million. The top five ASEAN countries with the highest population were Indonesia, Philippines, Viet Nam, Thailand and Myanmar (Table 2). In contrast, the lowest population among AMS was recorded in Brunei Darussalam, Singapore and Lao PDR. Regionally, the total estimation of GDP per capita for ASEAN amounted to USD 129,511.3 in 2018[4].

Table 2. AMS population profile

Country	Health status						
	Population (2018)	GDP per capita (USD) (2018)	Life expectancy at birth (years) (2017)	Life expectancy at birth (males) (2017)	Life expectancy at birth (females) (2017)	IMR (per 1,000 live births) (2018)	MMR (per 100,000 live births) (2017)
Brunei Darussalam	442,400	31,436.9	77.0	76.3	78.3	9.5	62.0
Cambodia	16,005,373	1,526.9	69.7	67.1	71.3	24.0	160.0
Indonesia	267,663,435	3,893.0	71.0	69.2	73.5	21.2	313.0
Lao PDR	7,061,507	2,567.5	57.3	65.5	69.1	52.0	206.0
Malaysia	31,528,585	11,239.0	76.0	74.0	78.0	6.7	29.1
Myanmar	53,708,395	1,326.0	67.0	63.0	70.0	37.0	250.0
Philippines	106,651,922	3,102.7	71.0	67.0	75.0	23.0	121.0
Singapore	5,638,676	64,581.9	83.0	81.0	85.0	2.0	8.0
Thailand	69,428,524	7,273.6	77.0	73.0	80.0	8.0	37.0
Viet Nam	95,540,395	2,563.8	75.0	71.0	79.0	17.0	43.0

Abbreviation: GDP - Gross Domestic Product; IMR – Infant mortality rate; MMR – Maternal mortality rate
(Source: World Bank Open Data[4] and Baseline Pharmaceutical Situational Analysis Survey)

The average life expectancy at birth in ASEAN countries was 72.4 years with the highest in Singapore at 83 years while the lowest was Lao PDR at 57.3 years. Indonesia recorded the highest infant and maternal mortality rate at 21.2 cases per 1,000 live births and 313 cases per 100,000 live births respectively. Singapore had the best health status, based on infant mortality rate, by far among AMS countries with only two cases of infant mortality per 1,000 live births and eight cases of maternal mortality per 100,000 live births. Differences in life expectancy across countries might be attributed to the differences in income levels, living standards, lifestyles, education and accessibility of quality health services.

In terms of human resources capacity, Singapore had the highest number of physicians per 1,000 populations (2.3) followed by the Brunei Darussalam (1.8) and Malaysia (1.5) while the lowest was Cambodia with only 0.2 physicians per 1,000 people. On the other hand, the number of pharmacists per 1,000 populations was consistently low with the lowest in Indonesia with only 0.05 per 1,000 population to the highest was Malaysia with 0.34 per 1,000 population.

On average, AMS countries reported 1.7 beds per 1,000 population with Brunei Darussalam having the highest number of hospital beds (3.4 per 1,000 population) while Lao PDR reported the lowest numbers (0.8 per 1,000 population). The health system capacity and utilization of healthcare services are correlated with availability of the services providers. Lower utilization of healthcare services may suggest scarcity of resources including human resources and infrastructures.

3.1.2 Healthcare Financing Mechanisms in ASEAN

ASEAN countries, despite the geographical proximity, have a huge variety of health systems and health financing mechanisms depending on their history and available resources. Overall, AMS countries spent around 2.4% to 5.5% of their GDP on health. The health expenditure showed a significant variation across the AMS with the highest level of health spending per capita reported in Singapore (USD 2,619) and the lowest in the Myanmar (USD 58 per capita). The share of government spending on healthcare varied from as high as 94.8% in Brunei Darussalam to as low as 23.8% in Cambodia. Selected health expenditure indicators in 2017 were shown in Table 3.

Table 3. Health expenditure indicators of the ASEAN countries in year 2017

Country	CHE (in million USD)	CHE per Capita in USD	CHE as % GDP	GGHE as % CHE	Domestic HE as % of CHE	External HE as % CHE
Brunei Darussalam	288	671	2.37	94.82	100	-
Cambodia	1,314	82	5.92	23.8	84.9	15.1
Indonesia	30,352	115	2.99	48.37	99.5	0.5
Lao PDR	426	62	2.53	35.15	83.3	16.7
Malaysia	12,146	384	3.86	50.59	100	-
Myanmar	3,098	58	4.66	14.81	91.0	9.0
Philippines	13,944	133	4.45	31.91	97.4	2.6
Singapore	14,950	2,619	4.44	48.2	100	-
Thailand	17,055	247	3.75	76.13	100	-
Viet Nam	12,380	130	5.53	48.62	98.0	2.0

Abbreviation: CHE – Current Health Expenditure; GGHE – General Government Health Expenditure; HE – Health Expenditure
(Source: WHO Global Health Expenditure Database[5] (Accessed March 31, 2020))

All AMS had adopted some form of public-private mixed models in their healthcare systems but with different fund allocations by each sector for healthcare expenditure for each country. Healthcare delivered by public facilities in AMS countries are heavily financed by general revenues and taxation collected by the federal government while the private sector is funded through private health insurance and out of pocket (OOP) payments by the consumers.

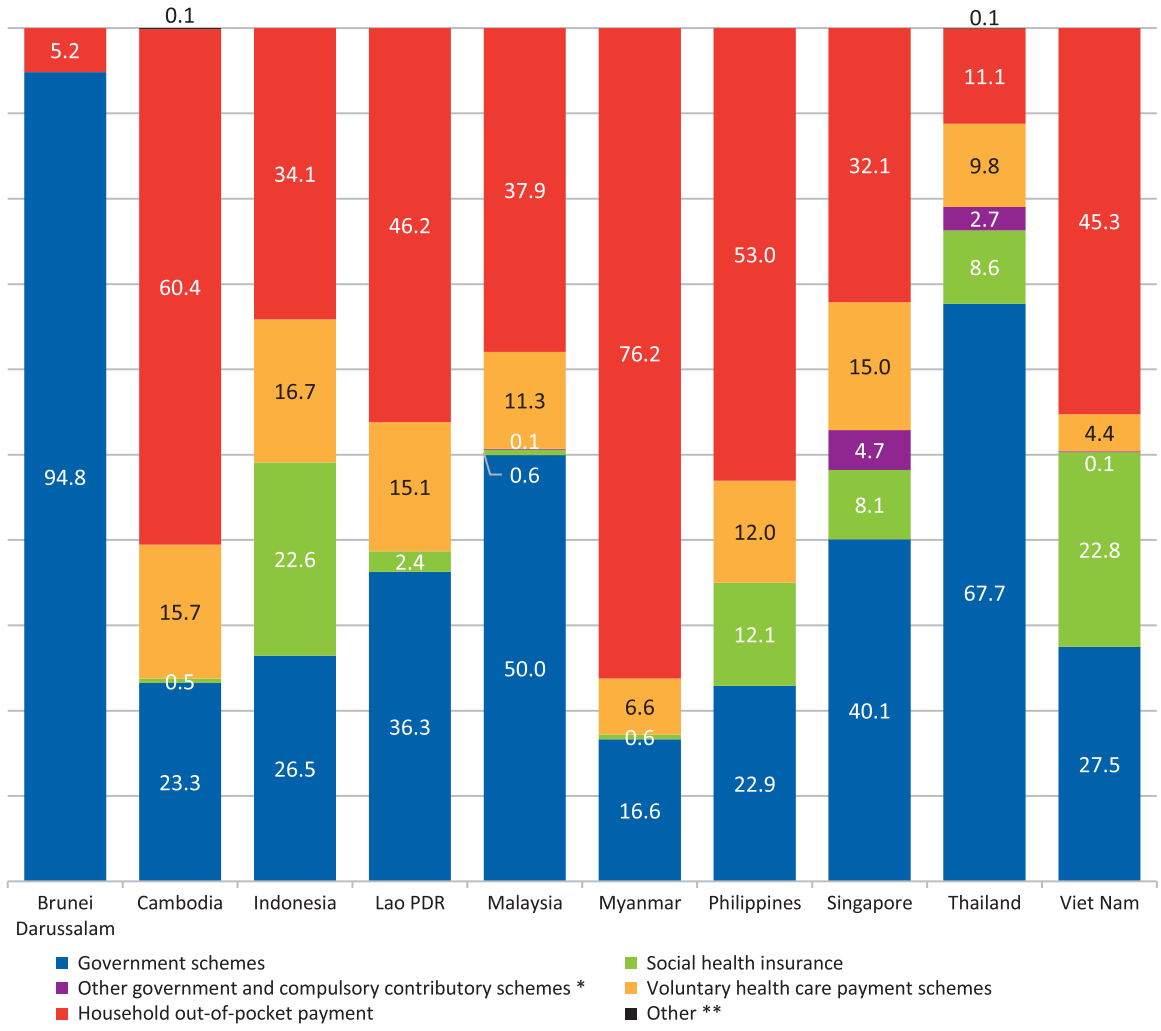
The contribution of public and private sources to financing the health system varied greatly across the AMS. High income and upper-middle income countries like Brunei Darussalam, Singapore, Malaysia, and Thailand generally had higher public share of health expenditure. In Brunei Darussalam where all citizens are covered by comprehensive public healthcare services, the source of revenues collection for their health care system is mainly coming for the natural resources like petroleum[6]. In Cambodia, Lao PDR and Myanmar, external funding such as bilateral and multilateral loans and grants to the government accounted for a significant portion of the total health expenditure.

Other than that, in Indonesia, Philippines and Viet Nam, social health insurance schemes contributed to a significant share of the health expenditure. Meanwhile, OOP spending accounted for a much greater proportion of health expenditure in lower-middle income countries such as in Cambodia (60.4%) and Myanmar (76.2%) compared to higher countries such as Thailand (11.1%) and Brunei Darussalam (5.2%). The composition of the health expenditure by health financing schemes in ASEAN countries were presented in Figure while the health financing systems were summarised in table 4.

Following the financial crisis in 1997-98, market forces have resulted in many ASEAN countries to strengthen their social protection mechanisms and essential health services[7]. Many innovative pro-poor financing schemes were implemented, such as the Universal Coverage (UC) Scheme, also known as 30-Baht Scheme, in Thailand and Health Equity Funds in Cambodia. In recent years, efforts have been further stepped up in the AMS countries to strengthen their health systems and expand population coverage towards achieving universal health coverage. For example, Indonesia, Philippines, Viet Nam and Lao PDR had expanded their population coverage to above 80% with tax-financed health insurance and social health insurance. Lao PDR, for example, through the implementation of the tax-based National Health Insurance (NHI) since 2016 and merging the existing fragmented health schemes in the country, was reported to achieve almost full population coverage by 2018.

In terms of scope of coverage, Brunei Darussalam, Indonesia, Malaysia, Singapore, Thailand and Viet Nam offer comprehensive health services to the population[6]. Among these countries, Brunei Darussalam and Malaysia provide comprehensive services through public healthcare facilities, ranging from preventive and primary healthcare to tertiary hospital care with free medication at public primary care facilities including medicines for malaria, tuberculosis, sexually transmitted disease (STD) and HIV/AIDS-related. They also subsidised at least one vaccine at public primary care facilities. In term of the depth of public healthcare coverage, both governments of Brunei Darussalam and Malaysia give a lot of subsidies to healthcare goods and services to the citizens with only minimal co-payment charges to the public. To date, all citizens of Brunei Darussalam and Malaysia only pay B$1 (USD 0.70) and MYR1 (USD 0.23) respectively for each visit to the outpatient department.

Figure 2. Composition (%) of the current health expenditure (CHE) by health financing schemes in ASEAN countries (2017)



Note:
** Thailand - compulsory private insurance schemes; Singapore and Malaysia - compulsory medical saving accounts (CMSA); Viet Nam - unspecified government schemes and compulsory contributory schemes;*
*** Other refers to non-resident schemes*
(Source: WHO Global Health Expenditure Database[5] (Accessed March 31, 2020)

Table 4. Summary of health financing systems in ASEAN countries

COUNTRY	BRUNEI DARUSSALAM[9,12,10]	CAMBODIA[9,12,10]	INDONESIA[13,14]	LAO PDR[9,15,16,17,8]	MALAYSIA[9,18,19,20]
Health system/ scheme	Publicly funded and provided health system	National Social Security Fund (NSSF), Health Equity Fund (HEF), service delivery grants, CBHI	Jaminan Kesehatan Nasional (JKN)	National Health Insurance (NHI)	Dichotomous health system (almost equal public and private mixed system)
Coverage	Universal access to public healthcare services	30% of population collectively (2017). NSSF covers civil servants and formally employed workers; HEF covers 16.2% of the total population or 80.9% of the poorest quintile (2017)	83% of population (2019)	Almost full population coverage (2018) with the integration of CBHI, HEF and a Free Maternal, Neonatal and Child Health (FMNCH) programme under NHI.*	Universal access to public healthcare services
Source of finance	General government revenue	General government revenue, donors' development assistance and household OOP are the major HF sources. Formally employed workers' scheme – premiums at 2.6% of the employee's salary, paid by employer; civil servants' scheme – premium at 1% of the salary and paid by the state	Central government budget and some local government budget; payroll contributions by employees and employers; premiums from community	General taxation, combined with contributions from workers in formal employment, household OOP and external sources	Public-general government revenue channelled predominantly through MOH; Private-mainly household OOP and PHI

COUNTRY	BRUNEI DARUSSALAM[9,12,10]	CAMBODIA[9,12,10]	INDONESIA[13,14]	LAO PDR[9,15,16,17,8]	MALAYSIA[9,18,19,20]
Purchasers/fund holders	MOH	NSSF – under the Ministry of Labor and Vocational Training; HEF – operated by MOH with claims and payment verification done by a semi- autonomous Payment Certification Agency	Badan Penyelenggara Janinan Sosial-Kesehatan (BPJS-K)	National Health Insurance Bureau (NHIB) under the MOH	Public - MOH Private - individual and PHI
Provider payment method	Line item budgeting with salaried healthcare workers	Line item from government budget, FFS, case-based payment, service delivery grant, performance-linked grants	Primary care – capitation; Hospital – INA-CBG (DRG); Providers claim for referral services and medicines according to National Formulary	OP – capitation; IP - case-based	Public - line item / global budgeting with salaried healthcare workers; Private - FFS
Benefits package	Essential healthcare to high cost / tertiary care	Not defined	Essential healthcare to high cost / tertiary care	Essential healthcare	Essential healthcare to high cost / tertiary care

**SASS (government employees and dependents), SSO (enterprise employees and dependents) and Police schemes was also being integrated to the NHI scheme starting 2019*

Table 4. Summary of health financing systems in ASEAN countries (continue)

COUNTRY	PHILIPPINES[9,13,22]	SINGAPORE[23,24]	THAILAND[13,25,26]			VIET NAM[9,13,27,28,29]
Health system/ scheme	National Health Insurance Program	Government means-tested subsidies + 3M System, namely MediShield Life (SHI), Medisave (national medical savings scheme), and Medifund (social safety net)	Universal Coverage (UC) Scheme	Civil Servant Medical Benefit Scheme (CSMBS)	Social Health Insurance (SHI) scheme	Social Health Insurance Scheme
Coverage	92% of population (2016)	Universal coverage	Overall - universal coverage. UC covers 75% of population	Government employees and dependents (9% of population)	Private-sector employees	87% of population (2018)
Source of finance	General government revenue – fully subsidise premium for the poor, DOH funds regional and apex hospitals, local government units fund primary and secondary care; Premium contributions by public and private employees and the informal sector	Government subsidies – general tax revenue; Medisave – saving 4-10.5% of monthly salary; MediShield - premium paid using Medisave; Medifund - government funded endowment fund	General tax through annual budget bill to National Health Security Office	General tax through annual budget bill	Premium – equal tripartite contributions from payroll tax paid by employers, employees, and the government	Government revenue – fully subsidized premium for the poor, partial subsidies for the informal; Payroll tax contribution by formal public and private employees and employers

COUNTRY	PHILIPPINES[9,13,22]	SINGAPORE[23,24]	THAILAND[13,25,26]			VIET NAM[9,13,27,28,29]
Purchasers/fund holders	Philippine Health Insurance Corporation (PhilHealth)	MOH, Central Provident Fund Board	National Health Security Office	Comptroller General Department, Ministry of Finance	Social Security Office, Ministry of Labour	Viet Nam Social Security
Provider payment method	Budget allocation to facilities; OP – FFS, moving towards capitation with fixed co-payment and case payment for selected procedures; IP – case-based payment; balance billing allowed for non-poor	Public sector institutions – DRG system, case payment; Private GPs – FFS	OP – capitation through contractual agreement with networks of primary healthcare and district hospitals; IP – DRG with global budget, fee schedule for specific high-cost procedures	OP – FFS directly reimbursed to hospitals; IP – DRG without global budget, with different bands of costs weighed in favour of tertiary care and teaching hospitals	OP – capitation; IP – DRG within global budget	Capitation – in over 60% of district hospitals, and some provincial hospitals and equivalent; DRG – hospitals; FFS – the rest
Benefits package	Essential healthcare	Essential healthcare to high cost/tertiary care	Essential healthcare to high cost/tertiary care	Essential healthcare to high cost/tertiary care	Essential healthcare to high cost/tertiary care	Essential healthcare to high cost/tertiary care

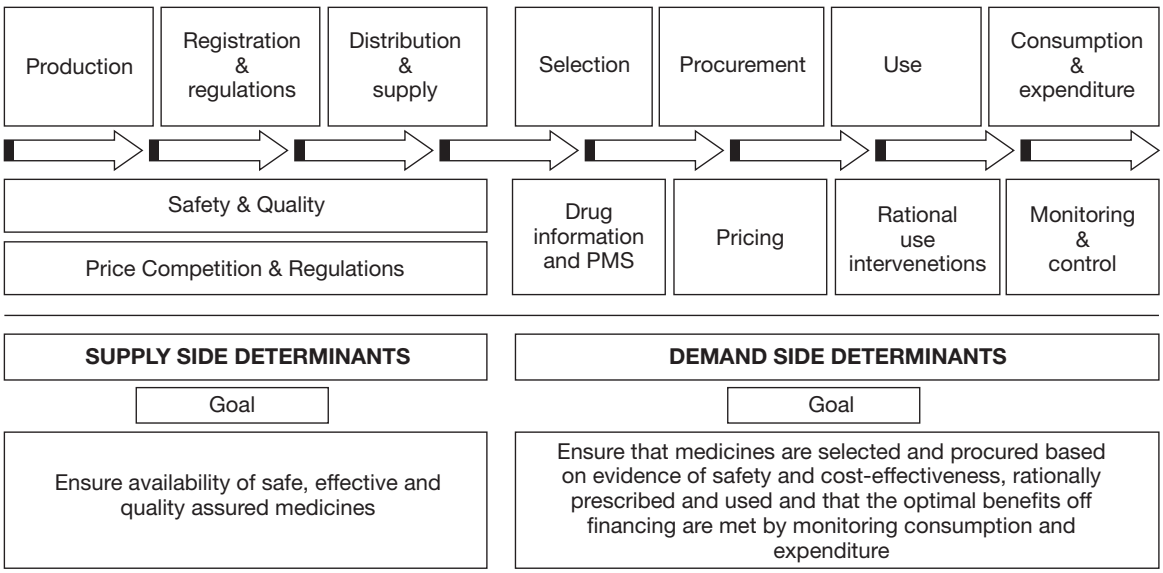
Abbreviation: CBHI – community-based health insurance; DOH – Department of Health (Philippines); DRG – diagnosis-related group; FFS – fee-for-service; HEF – Health Equity Fund; HF – health financing; IP – inpatient; MCH – maternal and child health; MOH – Ministry of Health; MoHS – Ministry of Health and Sports (Myanmar); NGO – non-governmental organization; NHI – national health insurance; NHIB – National Health Insurance Bureau; NSSF – National Social Security Fund; OOP – out of pocket; OP – outpatient; PHI – private health insurance; SHI – social health insurance

3.1.3 Pharmaceutical Product Life Cycle

Since each AMS has different health system, it is crucial to understand the current practice and challenges faced by each AMS in order to work together to achieve access and affordability to medicines. In specific, priority should be given to understanding the activities involved throughout the pharmaceutical product life cycle in each AMS such as registration and regulations, selection and procurement processes as well as distribution and supply chain.

Generally, the pharmaceutical product life cycle can be divided into two parts, which are the supply side determinants and the demand side determinants. The supply side determinants encompass a wide range of activities from drug research and development (R&D) up to the packaging and distribution of the final medicinal product. Activities carried out in this part of the product life cycle ensure the availability of safe, effective and quality assured medicines to the population. On the other hand, the demand side determinants involve processes such as drug selection, procurement as well as consumption and expenditure. Activities at this end ensure that medicinal products for use are selected, procured and used rationally on evidence of safety and cost-effectiveness to gain optimal benefits (Figure 3). Once a drug has been developed, the developer needs to apply to the national drug regulatory authority for registration and marketing authorisation in the country it intends to manufacture and distribute the drug.

Figure 3. Pharmaceutical products life cycle



Adopted from Dr. Socorro Escalante's presentation during the Technical Meeting on Regional Collaborative Strategy for ADSSR in Putrajaya, Malaysia.

Similar authorisation is also required for exporting purposes of the drug. The main role of the drug regulatory authority is to ensure that efficacy, safety and quality standards have been closely observed throughout the drug development as well as its manufacturing and safekeeping processes. This is to protect the health of the mass population in general. Once the output medicine is manufactured, it is now ready for distribution to various retail sources such as pharmacies, supermarkets in case of certain over-the-counter (OTC) drugs and hospitals. It can also be purchased by bulk procurement by a government or by an international agency. On the demand side, for bulk purchasing by a government especially, an authority is responsible for selecting the drug to be purchased by considering the therapeutic benefits offered as well as the economic benefits. Then only, the drug will be procured and its utilisation will be monitored to avoid any mishaps.

3.1.4 Pharmaceutical Regulation in ASEAN

As part of the quality assurance system at national level, medicines registration and marketing authorisation is one of the key criteria for the tendering and importation of medicines in most of the AMS. Overall, all countries do have regulation and legislation in place for pharmaceutical national regulatory system or authority. According to the survey, there are legal provisions in all AMS for marketing authorization of pharmaceuticals. In general, if a pharmaceutical company wishes to market their product in any of these countries, it has to follow the guidelines and rules obligated by the authority body.

Every AMS has the designated body that is responsible for medicines regulatory in their country (table 5). As example;

Table 5. Pharmaceutical regulatory authority and marketing authorization in ASEAN

Country	Legal provision for NRA	NRA	Legal provision for MA	Involvement in regional/ international harmonization initiatives	Publicly accessibility of the list of registered products	Requirement of WHO Certification Scheme certificate for MA
Brunei Darussalam	√	√	√	√	√	√
Cambodia	√	√	√	√	√	N/A
Indonesia	√	√	√	√	√	√
Lao PDR	N/A	N/A	N/A	N/A	N/A	N/A
Malaysia	√	√	√	√	√	√
Myanmar	N/A	N/A	N/A	N/A	N/A	N/A
Philippines	√	√	√	√	√	√
Singapore	√	√	√	√	√	X
Thailand	√	√	√	√	√	√
Viet Nam	√	√	√	√	√	X

Abbreviation: NRA – National Regulatory Authority; MA – marketing authorization; N/A – not answered
(Source: Baseline Pharmaceutical Situational Analysis Survey)

Table 6. Licensing of pharmaceuticals and regulatory inspection in ASEAN

Country	Licensing			Legal Inspection provision for inspection	Inspection				National guidelines/checklists for inspection				Exemption for GMP Inspection with WHO Pre-qualification
	Manufac-turer	Wholesale/ distributor	Importer/ exporter		Manufac-turer	Wholesale/ distributor	Importer/ exporter	Retail distributor/ pharmacies	Manufac-turer	Wholesale/ distributor	Importer/ exporter	Retail distributor/ pharmacies	
Brunei Darussalam	√	√	√	√	√	√	√	√	√	√	√	√	√
Cambodia	√	√	√	√	√	√	√	√	√	√	√	√	X
Indonesia	√	√	√	√	√	√	√	√	√	√	√	√	X
Lao PDR	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
Malaysia	√	√	√	√	√	√	√	√	√	√	√	√	X
Myanmar	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
Philippines	√	√	√	√	√	√	√	√	√	√	√	√	√
Singapore	√	√	√	√	√	√	√	√	√	√	√	√	X
Thailand	N/A	√	√	√	√	X	X	X	√	√	√	√	X
Viet Nam	√	√	√	√	√	√	√	√	√	√	√	√	N/A

Abbreviation: GMP – Good Manufacturing Practice; N/A – not answered
(Source: Baseline Pharmaceutical Situational Analysis Survey)

3.1.5 Pharmaceutical Production Capacity in ASEAN

Drug discovery is the process of developing new drugs. It involves both basic researches to identify new chemical entities and more advanced applied research from synthesising the new chemical entity into candidate drug until live animal and human clinical trials on that drug. However, (research and development) R&D in the pharmaceutical sector need not necessarily focus exclusively on new formulation. It could for instance also focus on combining existing formulation into a single dosage form, adaptation of existing formulation to local climate condition, identification of new modes of drug delivery or reverse engineering of an originator drug so that it could be off patent in the country seeking to manufacture its generic equivalent.

There are quite remarkable number of drug-related R&D activities conducted among the AMS. Based on this study, it was found that Indonesia, Singapore and Thailand had been focusing on new active substances discovery with Thailand, in particular, focusing on herbal substance (Table 7). In Indonesia alone, there are six R&D based Japanese pharmaceutical companies having their operations in the country, which include Astellas, Eisai, Meiji, Otsuka, Takeda and Tanabe and their presence dated back in the late 1960s. Eisai's top leading products including Aricept (donepezil) for Alzheimer's disease and Pariet (rabeprazole) for gastrointestinal disorders are locally packed in Bogor, Indonesia (although not manufactured)[39].

Table 7. Medicines production capability in ASEAN

Country	R&D of new active substances	Production of API	Production of finished pharmaceutical dosage forms	Repackaging of finished dosage forms
Brunei Darussalam	X	X	√	√
Cambodia	X	X	√	X
Indonesia	√	√	√	√
Lao PDR	N/A	N/A	N/A	N/A
Malaysia	X	√	√	√
Myanmar	N/A	N/A	N/A	N/A
Philippines	N/A	X **	√	√
Singapore	√	√	√	√
Thailand	√ *	√	√	√
Viet Nam	N/A	√	√	√

Note:
** herbal products;*
*** reported to depend heavily on the importation of API*
Abbreviation: API – active pharmaceutical ingredients; R&D – research and development;
N/A – not answered
(Source: Baseline Pharmaceutical Situational Analysis Survey)

According to World's Drug and Medicine Export 201840, ASEAN countries contributed approximately 1.74% of the total pharmaceutical products consumption globally with six out of ten AMS, i.e. Indonesia, Malaysia, Philippines, Singapore, Thailand and Viet Nam, were ranked among the top 100 world pharmaceutical exporters. Singapore ranked the highest among AMS at the 17th place with medication export of more than USD 5 billion, contributing to 1.4% of total global consumption (Table 8).

Table 8. The value of medicines exported by the AMS in 2018

Exporter from ASEAN	Rank	Medication exports (USD)	% of world total consumption
Singapore	17	5,191,976,000	1.4
Indonesia	43	440,736,000	0.1
Thailand	45	393,909,000	0.1
Malaysia	55	203,169,000	0.1
Viet Nam	66	109,601,000	0.03
Philippines	83	31,655,000	0.01
Cambodia	111	2,087,000	0.0001
Brunei Darussalam	124	851,000	0.00002
Myanmar	148	110,000	0.00003
Lao PDR	-	-	-

Source: World's Drug and Medicine Export 2018[40]

The production process of pharmaceutical products has three distinct phases which are primary, secondary and tertiary manufacturing. The primary manufacturing involves the production of active pharmaceutical ingredients (API), intermediates and excipients. Although all AMS except Brunei Darussalam, Cambodia and Philippines reported that they are capable of producing APIs in this study, APIs import are generally high among AMS countries. Indonesia, for example, imported 85-90% of its APIs[39]. Secondary production is when the raw materials are combined to produce pharmaceuticals formulation and all AMS reported that they have the capacity to perform secondary manufacturing. Finally, tertiary manufacturing involves the packaging of finished products or repackaging of bulk finished products. A manufacturing plant can import finished products from elsewhere and only handled repackaging of the finished products according to the market demand. Based on our findings, Cambodia is the only AMS country who does not perform any tertiary production in the region.

The above-mentioned manufacturing processes require close attention to ensure that top quality, safety and hygiene standards are maintained. Hence, adherence to the GMP and established standard operating procedures (SOP) is essential. Compromising any SOP and GMP could potentially pose dire health consequences to the end users. For example, the raw materials and ingredients must be kept in very specific conditions

with accurate temperature and humidity as well as and in containers with correct specifications. All machineries require constant cleaning and upkeep and certain areas dedicated for formulation must be in sterile condition. Hence, the personnel in-charge must be using specific personal protective equipment (PPE) while accessing the area. Once manufactured, the outputs require thorough testing to ensure that no impurities exist and that the dosage forms are consistent. Finished pharmaceutical products also need to be stored in specific settings. Most AMS countries exercise compulsory requirement for all pharmaceutical manufacturing facilities (both local and foreign players) to comply with GMP standards except Lao PDR (based on country presentation during the ADSSR Technical Meeting). The authority made GMP compliance compulsory only to foreign companies while industries owned by local citizens are expected to partially comply. Some AMS such as Indonesia, Malaysia, Singapore and Thailand even go an extra mile to obtain additional globally accepted compliance certification like the Pharmaceutical Inspection Co-operation Scheme (PIC/S)[41].

3.1.6 Drug Procurement and Distribution in ASEAN

The medicine demand determinants deal with several components of pharmaceutical management such as selection, procurement, storage, distribution and rational usage of medicines and supplies. Supply chain efficiency is a major determinant of the availability and affordability of quality medicines and supplies. The Essential Medicines List (EML) is a long-established approach to improve the access to medicines. The first edition of WHO's Model List of Essential Medicines was published in 1977. Since then, most countries have developed their own National Essential Medicines Lists (NEML) and regularly updating it. Countries either rely on the NEML, national medicines formulary or a national procurement list to ensure efficient procurement activities especially within the public sector and to promote rational use of medicines.

According to the survey, there are about 700 to 1,800 items listed in the procurement lists of AMS, and such lists are also being used as reference for public insurance reimbursement in certain AMS such as Cambodia, Indonesia, Philippines and Thailand. Drug procurement list for Malaysia, for example, is called the Ministry of Health (MOH) Medicines Formulary (also known as the Blue Book), and the MOH Medicines Formulary Review Panel is responsible for the selection of products into the list. Although the procurement list served as the basis for public drug procurement, most AMS do have some provisions for purchasing medicines that are not on the list. Purchasing of medicines outside of the list is normally due to emergency situations like pandemic. Another reason is when the drug is yet to be registered in a particular country but it is important and lifesaving for certain patients.

Public procurement of pharmaceuticals and medical supplies in most AMS are governed by national laws and regulations (Table 9 and Table 10). Based on our survey, the basis for Good Pharmaceutical Procurement Practice is well defined in procurement legislation, regulations and procedures of all AMS except Philippines and Viet Nam. Several agencies could be involved in the procurement of medicines and medical supplies in the AMS. The key ones are the funding agencies, procurement units from the Ministry or Department of Health and medical stores.

From the survey, only four countries (Brunei Darussalam, Indonesia, Malaysia and Singapore) had provided the top 20 most expensive products purchased by the public sector. It was noted that over half of the most expensive medicines purchased by these countries were oncology drugs. The major roles of central medical stores are storage and delivery. According to the survey, we found that there is a substantial level of automation implemented for logistics and inventory control by most of AMS countries.

Cost-effective procurement is a well-recognised challenge for small countries who have small markets and therefore less negotiation power. The challenge of 'small markets' can also apply to the entire product groups for which only small volumes are needed. These products are also often termed as non-commercially viable medicines. Antidotes are one example of such drugs, which are difficult to procure either because of global shortages or because of the small volumes needed at any one time. Public procurement agencies have been experiencing unfulfilled tenders for essential antidotes due to low prices and small volumes, resulting in facility stock-outs.

Thailand and Indonesia had participated the Initiative for Coordinated Antidotes Procurement in the South-East Asia Region (iCAPS) that was launched in 2018. This systematic and efficient procurement initiative of antidotes utilises Thailand's Ramathibodi Poison Centre as the regional hub to procure antidotes for a wide range of common poisonings, such as non-specific poisoning, heavy metal poisoning, cyanide poisoning, lead poisoning and methemoglobinemia. To date, there are eight items available in the procurement list of iCAPS[42]. It is also found in this study that another AMS country that had already participated in a pooled procurement effort is Philippines. Philippines joined the pooled procurement initiative to purchase certain drugs from United Nations (UN) agencies.

Table 9. Overview of the procurement and supply of medicines in the public sector in ASEAN

Country	Public procurement legislation	Good Procurement Practice	Centralized procurement*	Agency responsible for public medicines procurement				Agency responsible for public medicines procurement				National/ central medical store	Regional medical store
				Government/ MOH	NGO	Private distributor contracted by the government	Private distributor	Government/ MOH	NGO	Private distributor contracted by the government	Private distributor		
Brunei Darussalam	√	√	√	√	X	√	X	√	X	√	X	√	N/A
Cambodia	√	√	√	√	X	X	X	√	X	X	X	N/A	N/A
Indonesia	√	√	√[β]	√	√[#]	√	X	√	X	√	X	X	X
Lao PDR	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
Malaysia	√	√	X	√	X	√	√	√	X	√	√	X	√
Myanmar	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
Philippines	√	X	X	√	X	X	√	√	X	√	X	√	√
Singapore	X	√	√	X	X	√[α]	X	X	X	X	√	X	X
Thailand	√	√	√	√	X	X	√	√	X	√	X	N/A	N/A
Viet Nam	√	X	√	√	X	√	√	√	X	√	√	X	X

*Note: *centralized procurement at the national level for the regions or provinces; [#]GAVI: JE Vaccine, MR, IPV, ADS and Safety Box; [α]Private company- ALPS owned by the 3 Public Healthcare Clusters under MOH; [β]Medicines for national programmes (e.g. AIDS, TB, Malaria, Vaccine for basic immunization program, etc). Abbreviation: MOH - Ministry of Health; NGO – non-governmental organization; N/A – not answered.*
(Source: Baseline Pharmaceutical Situational Analysis Survey)

Table 10. Tender process for public sector procurement in ASEAN

Country	Type of tender process			Tender board/ committee overseeing public sector procurement	Separation of key functions of procurement office and tender committee
	Local & National competitive tender	International competitive tender	Negotiation/ direct purchasing		
Brunei Darussalam	√	X	X	√[α]	√
Cambodia	√	√	√	√	√
Indonesia	√	X	√	√[β]	√
Lao PDR	N/A	N/A	N/A	N/A	N/A
Malaysia	√	X	√	√	√
Myanmar	N/A	N/A	N/A	N/A	N/A
Philippines	√	√*	√[#]	√	√
Singapore	√	√	√	√	√
Thailand	√	X	√	√	√
Viet Nam	√	X	√	√	√

Note:
** only for selected essential medicines procured through UN agencies;*
[#] for single sourced and patented products;
[α] Main Tender Board, MOF/Mini Tender Board, MOH/Quotation Committee, MOH;
[β] Inspectorate General Audit Board of the Republic of Indonesia Financial and Development Supervisory Agency
Abbreviation: MOH – Ministry of Health; MOF – Ministry of Finance; N/A – not answered
(Source: Baseline Pharmaceutical Situational Analysis Survey)

3.1.7 Medicines Pricing Mechanisms in ASEAN

In the efforts to contain the rising cost of healthcare, many of the AMS have developed pricing strategies aimed to regulate or influence the prices of medicines financed by the public sector in particular. It was found from the survey that each country has a designated agency to set medicines prices in all AMS countries except Brunei Darussalam. The most commonly practiced strategies among the AMS are external reference pricing (ERP) and tendering and negotiation (Table 11). When using ERP, the government considers the price of a medicine in other countries as benchmark before establishing a price locally. On the other hand, tendering process involves the engagement between the government and manufacturers.

Manufacturers are requested to submit quotations for a particular contract in a competitive bidding process to allow further reduction of medicines prices. The negotiation process normally serves as a procurement strategy by the government in order to assist the suppliers and to decide on volume of pharmaceutical products awarded. All AMS countries exercised multiple pricing strategies simultaneously except for Brunei Darussalam which only uses ERP to influence medicines prices. All types of pharmaceutical products listed in the medicines formulary and the EML including originator, generic and biosimilars are covered under these pricing policies.

Another tool used to determine the value for money of a medicine is by performing health technology assessment (HTA). HTA often involves cost-effectiveness analysis (CEA) which is a tool used to compare the quality-adjusted life years gained against the drug cost between a new drug and an existing drug being used in the country. Indonesia, Malaysia, Philippines, Singapore and Thailand have formal HTA programmes to conduct pharmacoeconomic evaluation, while Brunei Darussalam, Cambodia, Lao PDR, Myanmar and Viet Nam are yet to have national HTA programme. Countries without HTA use informal mechanisms and related activities for the determination of value for money.

Despite the wide use of tendering and negotiation in determining medicines prices in the region, transparency in the process differs substantially across AMS countries. Brunei Darussalam and Malaysia offer some level of transparency on their pricing database but with limited access while Philippines offers open access to such database with a Drug Price Reference Index that provides the lowest net price for each medicine and publishes tender prices following the bidding process[43]. WHO had developed a sharing platform known as Price Information Exchange for Medicines (PIEMEDS) to be used by countries for sharing information on pharmaceutical pricing. Medicines price transparency can help to make medicines more affordable and purchasers could be more informed in the negotiation with suppliers. However, only Malaysia and Philippines had reported that efforts to utilise this pricing sharing platform has started in their respective countries.

Table 11. Key pricing mechanisms used by AMS

Country	Free pricing	Internal Reference Pricing	External Reference Pricing	Special Pricing Agreement	Health Technology Assessment	Cost Plus Pricing	Tendering & Negotiation
Brunei Darussalam	N/A	N/A	√	N/A	N/A	N/A	N/A
Cambodia	N/A	N/A	N/A	N/A	N/A	N/A	N/A
Indonesia	N/A	N/A	N/A	N/A	√	√	√
Lao PDR	N/A	N/A	N/A	N/A	N/A	N/A	√
Malaysia	√	√	√	√	√	N/A	√
Myanmar	N/A	N/A	N/A	N/A	N/A	N/A	N/A
Philippines	√	√	√	N/A	√	N/A	√
Singapore	√	√	N/A	N/A	√	N/A	√
Thailand	N/A	√	√	√	√	N/A	√
Viet Nam	√	√	√	N/A	N/A	√	√

Abbreviation: N/A – not applicable
(Source: Baseline Pharmaceutical Situational Analysis Survey and adopted from Verghese et al.[44])

3.1.8 Political Commitment

Most AMS reported having similar issues on the access to non-commercially viable medicines, orphan medicines and expensive patented medicines. Based on the responses obtained from the political commitment domain of the survey, several AMS expressed positive views on the concept of pooled procurement to improve the access to medicines

in the ASEAN region. Inevitably, the idea of pooled procurement had also raised concerns about difference in regulatory requirements, procurement responsibility, financial and procurement regulation, forecasting of needs and medicines distribution.

The responses from the country presentations during the technical meeting indicated that most AMS are willing to participate in regional collaborations. Majority of the AMS representatives who attended the technical meeting proposed collaboration in three areas, which were regulatory harmonization, sharing of suppliers' information and medicines price sharing. Through regional collaboration, the AMS expect more competitive medicines pricing and the improved availability of more medicines in their countries. Subsequently, further engagements with all AMS to find common grounds and pursue political commitment is necessary for regional collaboration.

3.2 SWOT ANALYSIS ON REGIONAL COLLABORATION

During the technical meeting held in November 2019 in Putrajaya, the determinants discussed above were further deliberated and the feasibility of regional collaboration for ADSSR were discussed using SWOT analysis. The four domains of SWOT analysis were Production, Medicines Registration and Regulation, Supply and Distribution of Medicines, and Medicines Procurement and Pricing.

The SWOT analysis identified many challenges faced by the AMS regarding the production, regulation, supply and distribution, and procurement and pricing of pharmaceuticals. Nevertheless, the analysis also provided a clear picture about the opportunities for the AMS to work together at the regional level to improve the access to medicines. For instance, AMS agreed that cooperation in R&D for the development or trials of new medicines for diseases unique to the region and collaboration in the manufacturing of needed medicines within the AMS are two feasible mechanisms to improve ASEAN's self-reliance to ensure the availability of important medicines. Better regulatory pathway harmonization among the AMS and collaboration in the procurement and supply of medicines, especially during public health emergencies, could also be considered by the AMS to ensure uninterrupted and timely supply of medicines. More importantly, platforms of communication and data sharing among AMS should be encouraged to ensure successful collaborations in all the domains.

3.2.1 Domain 1: Pharmaceutical Production

Based on the information collected from the SWOT analysis, one of the issues faced by the AMS was the supply of raw materials and API. Nevertheless, one significant strength of ASEAN countries was that there are good manufacturing facilities located in a few member states due to the support and encouragement for local production from their government. Competition to export their products is an identified threat for pharmaceutical manufacturing in AMS, but regional collaboration in pharmaceutical manufacturing will create opportunity for the local pharmaceutical manufacturers to explore the export market.

Table 12. SWOT analysis for pharmaceutical production in ASEAN

Strength	Weakness
Manufacturing - There are local and MNC manufacturing facilities - Country procurement policy encourage local production - Local manufacturer scheme for product supply by concessions company - Supportive pharmaceutical regulatory **R&D** - Existence of R&D facilities - Incentive by government (grant)	**Manufacturing** - Use imported API - Rely on local market - Mainly for export - Limited supply on raw materials - Limited number of demand and production **R&D** - Lack of expertise - Limited funding - Limited raw material
Opportunity	**Threats**
Manufacturing - Exploration in export market - Medicines pooled procurement among AMS **R&D** - Sharing training centre and opportunity among AMS - Increase government incentives	**Manufacturing** - Competition with export pharmaceutical products **R&D** - Less support from manufacturer

3.2.2 Domain 2: Medicines Registration and Regulation

Different authority and regulatory pathways among the AMS, especially on public health emergency system, is one of the challenges faced by the AMS in order to collaborate, for example, pooled procurement. Regulations and legislations, however, are in place to allow for the use of unregistered products during public health emergency in some countries. For example, Cambodia has the Fast Drug Approval mechanism, while Malaysia has Special Regulatory Pathway in allowing unregistered product to be use during emergency.

Table 13. SWOT analysis for Medicines Registration and Regulation in ASEAN

Strength	Weakness
- Various regulatory & legislation is in place within AMS to expedite the registration of products: • Malaysia has conditional registration for innovative medicine which allow registration at phase II clinical study • Brunei Darussalam and Malaysia are using Priority Review mechanism which involves giving priority to a product for registration • Malaysia implements rolling submission which allows market authorization holder to submit incomplete dossier to expedite registration - Various regulatory & legislation is in place within AMS allowing unregistered products to be used case of Public Health Emergency: • Cambodia have Fast Drug Approval mechanism in place during emergency • Malaysia have Special Regulatory Pathway in which DG can give special permits allowing unregistered product to be use	- Lack of regulatory and legislation coordination at regional level - Lack of regulatory system on Public Health emergency at regional level - Regulatory authority does not have established post-marketing surveillance (PMS) - Limited capacity in the coordination of PMS, e.g. product recall
Opportunity	**Threats**
- Formation of ASEAN coordination centre for Pharmaceutical - ASEAN Regional Post-marketing Surveillance - Initiating & sharing of investigation & findings - Improving accessibility & affordability for public	- International Trade Agreement - Use of government rights & compulsory license - Threat from innovator company - Data exclusivity issue - Patented drugs

3.2.3 Domain 3: Supply and Distribution of Medicines

The issues of availability of medicines especially for orphan and non-commercially viable drugs could be due to the lack of appropriate mechanisms in certain countries. Fast track mechanism such as the exemption of registration during emergency has been applied by a few countries while the others ensure that enough buffer stock of selected items are kept by the Concession Company to ensure continuous supply. The delayed access to stockpile, outbreak and uncontrolled disease are critical threats listed as well. Hence, the ability and capacity of local companies among the AMS to manufacture important pharmaceutical products is very important.

Table 14. SWOT analysis for pharmaceutical supply and distribution in ASEAN

Strength	Weakness
- Integrity in supply chain to ensure quality safe medicines - Efficient concession to ensure fast delivery - Fast track mechanism (exemption of registration during emergency) - Certain stockpile items are kept (buffer stock) by concession company to ensure continuous supply	- Less manufacturing capacity for certain stockpile - Lack of mechanism to ensure availability of medicines in the country - Lack of knowledge of regulations in other countries - Limited cooperation between stakeholders - Insufficient information to source out stockpile from other countries - Limited storage space for cold chain and non-cold chain items - Shortage of drugs when company discontinue when they have no economy of scales - Challenging transportation depending on geographical
Opportunity	**Threats**
- Identify the types of medicines for collaboration (stockpile) - Accurate forecasting and commitment of buy will attract manufacturers to produce - Opportunity for local companies to manufacture certain products - Apply good distribution practice - Availability of local companies to manufacture certain products - Conditional registration for critical drugs	- Delayed access to stockpile; further outbreak and uncontrolled disease - Sense of urgency among stakeholders might differ - Multiple health incidents occurring at the same time - Public health emergencies might differ among AMS countries

3.2.4 Domain 4: Medicines Procurement and Pricing

Collaborations, such as medicines pooled procurement, among the AMS is challenging due to different currencies and language barriers. On the other hand, existing information sharing platform like PIEMEDS will be very helpful for more informed medicines procurement and pricing. Before initiating any regional collaboration in medicines procurement, the mutual understanding needs to be strengthened among the AMS, and between the private and government sectors in every AMS.

Table 15. SWOT analysis for pharmaceutical procurement and pricing in ASEAN

Strength	Weakness
- Strengthening PIEMEDS for sharing information purpose on procurement & pricing - Implementation of electronic Procurement System in most AMS - Harmonization of National Essential Medicines List/National Formulary - Special approval for unregistered product or non-formulary	- Different currency & language - Substandard GMP compliance for local manufacturers - Manual procurement system for certain AMS - Quantification on tender procurement based on consumption data - No specific price assumption method - Price negotiation not happening once tender is awarded (Lao PDR)
Opportunity	**Threats**
- Increase quantum demand - Willingness to share price data - Regional SOP for drug negotiation protocol - Quantum sharing procurement approach (protecting the local player) - Collaboration to harmonize GMP manufacturing facilities - Cost saving	- Need mutual understanding to pursue between intra-agency governments - Difficult to do negotiation at regional level - Need to strengthen public private agreement

CHAPTER 4

Discussion

The ASEAN region has a growing population and it is considered a big pharmaceutical market as a whole. Overall, all AMS have well established pharmaceutical legislations and regulatory authorities. According to the information gathered, most AMS have sufficient capacity to perform national regulatory functions. Majority of the AMS medicine regulatory authorities are involved in the regional harmonization initiatives especially in terms of technical requirements, although the drug registration procedures vary considerably among the countries. The regulation, legislations, institutional framework and capacities to regulate the movement of quality assured medicines within the member countries are relatively diverse. There is also no system of mutual recognition of ASEAN member states on the decisions of medicines registration in place yet. Therefore, streamlining regulatory processes and procedure are important factors enabling regional collaborations.

This situational analysis showed that some countries are involved in the production of pharmaceutical products and API, and most countries are pharmaceutical exporters with a huge variation in their export values. As some countries are manufacturers and some are buyers, this creates opportunities for collaboration in grouped-production or group-purchasing of non-commercially viable products from and for the ASEAN region, rather than sourcing from the other regions.

In terms of medicines pricing, the survey found that various methods are employed by the AMS to improve medicines affordability. Most countries are using tenders and price negotiations as well as health technology assessment. In this respect, sharing information of medicines prices and pharmaceutical suppliers or manufacturers at the regional level may benefit all the AMS. Existing price sharing platforms such PIEMEDS can be explored to initiate collaboration to improve ADSSR.

The SWOT analysis identified many challenges faced by the AMS regarding the production, regulation, supply and distribution, and procurement and pricing of pharmaceuticals. Nevertheless, the analysis also provided a clear picture about the opportunities for the AMS to work together at the regional level to improve the access to medicines. For instance, AMS agreed that cooperation in R&D for the development or trials of new medicines for diseases unique to the region and collaboration in the manufacturing of needed medicines within the AMS are two feasible mechanisms to improve ASEAN's self-reliance to ensure the availability of important medicines. Better regulatory pathway harmonization among the AMS and collaboration in the procurement and supply of medicines, especially during public health emergencies, could also be considered by the AMS to ensure uninterrupted and timely supply of medicines. More importantly, platforms of communication and data sharing among AMS should be encouraged to ensure successful collaborations in all the domains.

In summary, the situational analysis and feasibility study provided the initial evidence to support the regional collaboration among the AMS to improve drug security and self-reliance within the region. Based on responses gathered from the AMS, this study suggested that information sharing should be considered as a significant step in the strategies and action plans for regional collaboration.

CHAPTER 5

Conclusion

The AMS share several challenges in ensuring the continuous access to medicines, such as the disruptions in the supply of some essential medicines and non-commercially viable medicines, and the high and varying prices of many life-saving, orphan medicines and patented medicines. The ADSSR Project was thus carried out with the aim to develop a framework for regional collaborative strategy and action plans among the AMS to improve drug security and self-reliance in the region. Survey of Baseline Pharmaceutical Situation and supplementary information search was carried out as situational analysis to examine the laws, regulations and policies pertaining to production, regulatory, distribution, procurement, pricing, medicines use practices, and the gaps and challenges in the ten AMS. SWOT analysis provided a clear picture about the opportunities and challenges for the AMS to work together at the regional level to improve the access to medicines. Findings reported that the regional collaboration to improve the drug security and self-reliance among AMS is feasible.

REFERENCES

1. ASEAN Secretariat. *ASEAN Post-2015 Health Development Agenda (2016- 2020)*. Jakarta: The ASEAN Secretariat; 2018.
2. Pascale Brudon, Jean-Daniel Rainhorn MRR. Indicators for monitoring national drug policies : a practical manual. 1999.
3. World Health Organization. WHO Operational package for assessing, monitoring and evaluating country pharmaceutical situations : guide for coordinators and data collectors. 2007:WHO/TCM/2007.2.
4. The World Bank. World Bank Open Data. https://data.worldbank.org/. Published 2020.
5. World Health Organization. Global Health Expenditure Database. https://apps.who.int/nha/database. Published 2020. Accessed March 31, 2020.
6. Myint CY, Pavlova M, Thein KNN, Groot W. A systematic review of the health- financing mechanisms in the association of southeast asian nations countries and the people's Republic of China: Lessons for the move towards universal health coverage. PLoS One. 2019. doi:10.1371/journal.pone.0217278.
7. Chongsuvivatwong V, Phua KH, Yap MT, et al. Health and health-care systems in southeast Asia: Diversity and transitions. *Lancet*. 2011. doi:10.1016/S0140-6736(10)61507-3.
8. International Labour Organization (ILO). Expansion of Lao PDR's National Health Insurance accelerates progress towards universal health coverage. https://www.ilo.org/asia/media-centre/articles/WCMS_735797/lang--en/index.htm.
9. Chu A, Kwon S, Cowley P. Health financing reforms for moving towards universal health coverage in the western pacific region. *Heal Syst Reform*. 2019;5(1):32-47.doi: 10.1080/23288604.2018.1544029.
10. Kolesar R, Pheakdey S, Jacobs B, Chan N, Yok S, Audibert M. Expanding Social Health Protection in Cambodia: An assessment of the current coverage potential and gaps, and social equity considerations. *Études Doc n°3,* CERDI. 2019. https://halshs.archives-ouvertes.fr/halshs-02018867/document.
11. Commonwealth Health Online. Health systems in Brunei Darussalam. http://www.commonwealthhealth.org/asia/brunei_darussalam/health_systems_in_brunei_darussalam/.
12. Health Policy Project. *Health Financing Profile: Cambodia.*; 2016. doi:10.1093/heapol/czs005.
13. RESYST (Resilient and Responsive Health Systems). Strategic Purchasing Factsheet. RESYST. https://resyst.lshtm.ac.uk/resources/strategic-purchasing-factsheet. Published 2014.

14. Shreeshant P, Dutta A, Fagan T, Megan G. *Financial Sustainability of Indonesia's Jaminan Kesehatan Nasional.*; 2019.

15. World Health Organization. Overview of Lao health system development 2009- 2017. 2018:vii, 87p.

16. Masaki, Emiko; Sorensen, Birte Holm; Nagpal, Somil; Komphasouk, Banthida; Thitsy, Sophavanh; Obst, Michael Andreas; Chamleunsab, Mayuly; Panyanouvong, Thiphaphone; Nanthalad, Khamhou; Vongsonephet T. Managing Transition: Reaching the Vulnerable while Pursuing Universal Health Coverage. 2017:143.

17. International Labour Organization (ILO). *Moving towards Universal Social Health Protection Lao People's Democratic Republic (PDR).*; 2018. https://www.social-protection.org/gimi/gess/RessourcePDF.action;jsessionid=EW5jAtt-QC0txLZpfGVAj6L47yuxhmWsnC5kAUlu-BaE3eh2ZFOW!-1463413688?id=55648.

18. Atun R, Berman P, Hsiao W, Myers E, Wei AY. Malaysia Health Systems Research Volume 1: Contextual Analysis of the Malaysian Health System, March 2016. 2016. doi:10.1108/IJHCQA-05-2013-0051.

19. Institute for Public Health Malaysia. *National Health & Morbidity Survey 2015.*; 2015.

20. Ministry of Health Malaysia. Malaysia National Health Accounts: Health Expenditure Report 1997-2018. 2019.

21. Teo HS, Cain JS. *Myanmar Health Financing System Assessment.*; 2018. doi:10.1596/31007.

22. Dayrit, Manuel; Lagrada L. Philippines Health System Review 2018. Health Syst Transit. 2018. doi:10.1007/3-540-44864-0_15.

23. Liu, C. and Haseltine W. International Health Care System Profiles: The Singaporean Health Care System. https://international.commonwealthfund.org/countries/singapore/.

24. Singapore's Healthcare Financing System. https://www.moh.gov.sg/docs/librariesprovider5/resources-statistics/educational-resources/3menglish_final.pdf.

25. Jongudomsuk P, Srithamrongsawat S, Patcharanarumol W, Limwattananon S, Pannarunothai S, Vapatanavong P et al. *The Kingdom of Thailand - Health System Review*. World Health Organization, Regional Office for the Western Pacific; 2015. doi:10.1007/s13398-014-0173-7.2.

26. Tangcharoensathien V, Witthayapipopsakul W, Panichkriangkrai W, Patcharanarumol W, Mills A. Health systems development in Thailand: a solid platform for successful implementation of universal health coverage. Lancet. 2018;391(10126):1205-1223. doi:10.1016/S0140-6736(18)30198-3.

27. World Health Organization. Health financing in Viet Nam. https://www.who.int/vietnam/health-topics/health-financing. Published 2020.

28. Mailfert, M.; Phe Goursat M. Expanding Social Health Protection : Towards Equitable Coverage in Viet Nam. 2020.

29. International Labour Organization (ILO). Viet Nam Health Insurance. https://www.social-protection.org/gimi/RessourcePDF.action;jsessionid=qtFfChQyx4HKdTU2aQ2F8cNn7PLo3aJvO_9JQIq2zI7xQfKPZhER!2015759462?id=54588.

30. Jay Cohen, Sophea Sin, Pichrotanak Bunthan T& G. Medicinal product regulation and product liability in Cambodia: overview | Practical Law. Thomson Reuters. https://uk.practicallaw.thomsonreuters.com/w-016-6538?transitionType=Default&contextData=(sc.Default)&firstPage=true&bhcp=1. Published 2019.

31. National Agency for Drug and Food Control (NADFC) Republic of Indonesia. *An Overview of The Drug Regulatory System in Indonesia*.

32. Andaman Medical. Drug Registration Updates in Indonesia. ANDAMAN MEDICAL. https://www.andamanmed.com/drug-registration-indonesia/. Published 2018.

33. National Pharmaceutical Regulatory Agency (NPRA). About the Drug Control Authority (DCA). https://www.npra.gov.my/index.php/en/about/drug-control-authority-dca/about-the-dca.html. Published 2020.

34. Eugenia Kolivos, Isaac Lin, Curd H. *A Comparative Overview of Distribution and Marketing of Drugs across Asia-Pacific.*; 2019. https://corrs.com.au/insights/a-comparative-overview-of-distribution-and-marketing-of-drugs-across-asia-pacific.

35. World Health Organization. *WHO Expert Committee on Specifications for Pharmaceutical Preparations.* Geneva; 2014. https://www.who.int/medicines/areas/quality_safety/quality_assurance/expert_committee/ISBN9789241209861-TRS986.pdf.

36. Drew & Napier LLC. Regulatory, Pricing and Reimbursement: Singapore. PharmaBoardroom. https://pharmaboardroom.com/legal-articles/regulatory-pricing-and-reimbursement-singapore/. Published 2019.

37. ASEAN Secretariat. ACCSQ Pharmaceutical Product Working Group. https://asean.org/?static_post=accsq-pharmaceutical-product-working-group. Published 2012.

38. Lätzel R. *Development of the ASEAN Pharmaceutical Harmonisation Scheme-An Example of Regional Integration-Wissenschaftliche Prüfungsarbeit Zur Erlangung Des Titels.*; 2007.

39. United Nations Conference on Trade and Development (UNCTAD). *Local Production of Pharmaceuticals and Related Technology Transfer in Developing Countries A Series of Case Studies by the UNCTAD Secretariat*.; 2011.

40. Workman D. Drugs and Medicine Exports by Country. http://www.worldstopexports.com/drugs-medicine-exports-country/. Published 2018.

41. Pharmaceutical Inspection Co-operation Scheme (PIC/S). Members. https://picscheme.org/en/members.

42. World Health Organization. Access to medical products in the South-East Asia Region 2019. 2019.

43. Department of Health Republic of Philippines. Drug Price Reference Index. https://dpri.doh.gov.ph/. Published 2019.

44. Verghese NR, Barrenetxea J, Bhargava Y, Agrawal S, Finkelstein EA. Government pharmaceutical pricing strategies in the Asia-Pacific region: an overview. *J Mark Access Heal Policy.* 2019. doi:10.1080/20016689.2019.1601060.

ANNEX

REGIONAL COLLABORATIVE STRATEGY FOR ASEAN DRUG SECURITY AND SELF-RELIANCE (ADSSR)

CHAPTER 1: INTRODUCTION

Universal health coverage (UHC) can only be achieved once access to safe, effective and quality medicines is made affordable. Unfortunately, many countries struggle to ensure continuous access of quality-assured and affordable medicines to their population and ASEAN region has not been spared. Disruptions in supply of the non-commercially viable essential medicines had forced ASEAN Member States (AMS) to pay higher prices and even have to accept poor quality medicinal products.

1.1 PHARMACEUTICAL BURDEN AMONG ASEAN

Total healthcare expenditure among ASEAN countries is expected to rise from USD 425 billion to USD 740 billion by 2025[1]. Among the contributing factors affecting the rising of healthcare costs are increased of ageing population increased prevalence of smoking and obesity in the region. This unprecedented increment of approximately USD 320 billion definitely requires immediate attention from all AMS. Hence, it becomes vital for the region to answer this pharmaceutical needs by ensuring a timely and affordable quality-assured medicines to the population.

1.2 TOWARDS A COORDINATED REGIONAL EFFORT TO ENSURE DRUG SECURITY & SELF-RELIANCE

The ASEAN Health Cluster 3 (AHC 3) Work Plan for 2016-2020 on Strengthening Health Systems and Access to Care focuses on strengthening the regional capabilities, capacities and advocacy in health system development in order to increase the access to safe, affordable, quality and holistic health care. This is part of the ASEAN Post-2015 Health Development Agenda to achieve a healthy, caring and sustainable ASEAN community. The Regional Collaborative Strategy for ADSSR is manifested in a framework developed based on the situational analysis and feasibility study, literature reviews and outputs from technical meeting conducted between 2018 until 2020. This framework has been revised and endorsed by AHC 3 on 15th September 2021 and followed by endorsement by Senior Official Meeting for Health Development (SOMHD) on 11th October 2021.

CHAPTER 2: FRAMEWORK FOR THE REGIONAL COLLABORATIVE STRATEGY FOR ADSSR

Drug security is defined as sustained supply as well as uninterrupted access to medicines used for health promotion, prevention, treatment, rehabilitation and palliative care purposes at all times and during public health emergency preparedness in assured quantity and quality. Drug self-reliance is the capability of a country or region to warrant a sustainable amount of drug supply in time of normal usage or emergency without relying too much help from others. Drug security and self-reliance is crucial throughout the drug's life cycle starting from the production, registration, procurement until distribution and supply chain to ensure availability of safe, effective and quality assured medicine.

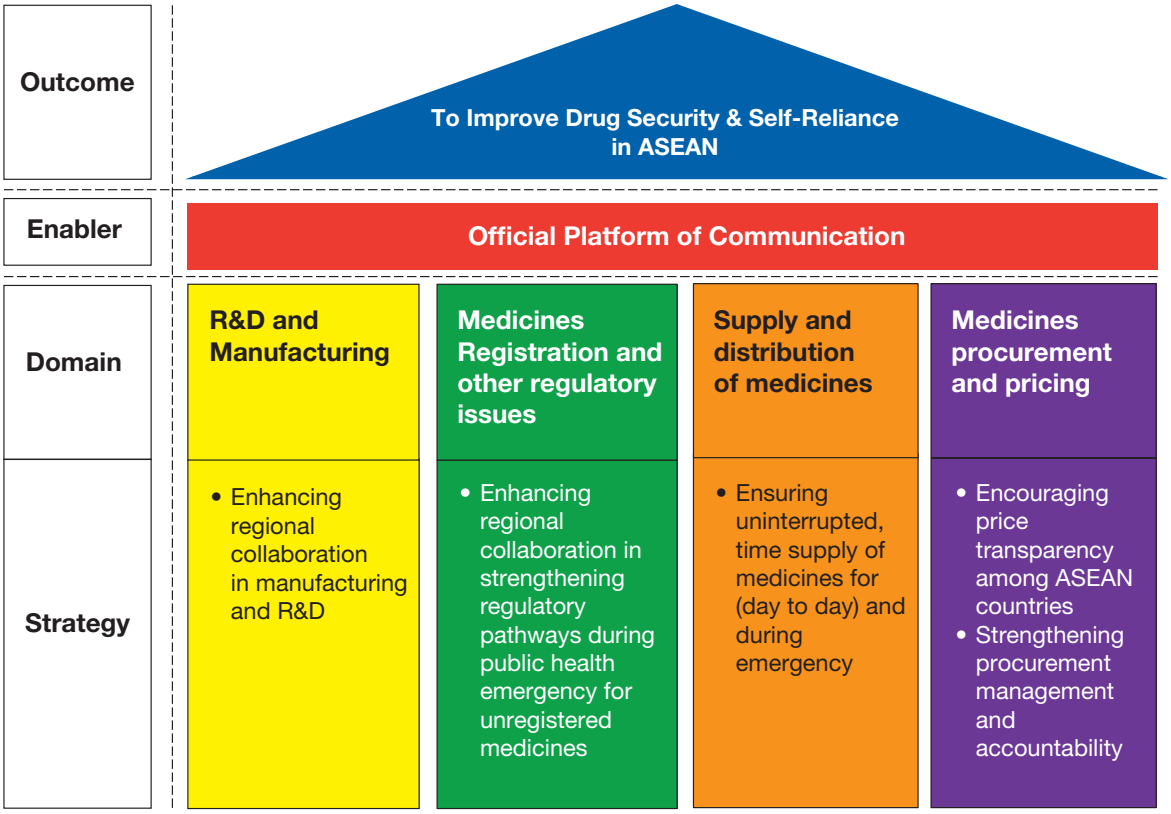
2.1 OBJECTIVES OF ADSSR FRAMEWORK

The ultimate aim of the ADSSR framework is to improve drug security and self-reliance in ASEAN region. It also serves as reference for various stakeholders across all the pillars to coordinate and contribute to this regional effort. This collaboration is hope to provide competitive medicines pricing and improve medicines availability in the region. The framework will encompass regional collaborative efforts across three important scopes in achieving drug security and self-reliance which are:

1. Access to essential medicines, non-commercially viable drugs (orphan drugs and antidotes), as well as high cost medicines and biological products.
2. Public Health Emergency Preparedness.
3. Regulatory Processes in the Pharmaceutical Life Cycle Management.

The framework as illustrated in Figure 1 offers a foundation for developing the strategies and action plans to achieve desired outcomes relating to drug security and self-reliance in the region which comprises of four domains: (1) R&D and manufacturing; (2) Medicines registration and other regulatory issues; (3) Supply and distribution of medicines; and (4) Medicines procurement and pricing. Above all, an official communication platform is needed for all AMS to effectively discuss and communicate on the four domains.

Figure 1. Framework for the Regional Collaborative Strategy for ADSSR



CHAPTER 3: STRATEGIES FOR THE REGIONAL COLLABORATIVE STRATEGY FOR ADSSR

A list of recommendations was devised for each of the domains. Above all, an effective cross countries communication is one of the most critical aspects in each strategy. The need for accurate and real-time data for decision making and management of healthcare is vital to ensure better health outcome of the population. Almost all activities involved throughout the pharmaceutical product life cycle such as regulatory guidelines, procurement and pricing require information input from all AMS to be shared together for better health outcome in ASEAN region. An official communication platform is the key enabler to ensure success of the Regional Collaborative Strategy of ADSSR. Overall, it is anticipated that sophisticated data exchange among the AMS will be instituted in the action plans. Hence, the proposed strategies included the development of platforms for the secure access and sharing of information among the AMS. Further elaboration of the strategies is displayed in Table 1.

3.1 DOMAIN 1: R&D AND MANUFACTURING

3.1.1 Strategy 1: Enhancing regional collaboration in manufacturing and R&D

Better regional collaboration among the AMS in terms of manufacturing and R&D is crucial. There is a need of good platform for communication among the AMS to share updates and promote the development of novel drug especially for tropical diseases and non-commercially available medicines among the AMS. This is important to make ASEAN self-sufficient to at least fulfil our own needs and demands. Technical meeting or working group should be formed to ensure that information related to the manufacturing capacities in AMS is up to date and transparent. For R&D, more incentive and funding for R&D will provide room for improvement in terms of training and acquiring consultation from the experts.

3.2 DOMAIN 2: MEDICINES REGISTRATION AND OTHER REGULATORY ISSUES

3.2.1 Strategy 2: Enhancing regional collaboration in strengthening regulatory pathways during public health emergency for unregistered medicines

Harmonization in the regulation and legislation of pharmaceutical among the AMS will help to improve the accessibility and affordability of pharmaceutical products in ASEAN. Therefore, the enhancement of regional collaboration to harmonize and align regulatory pathway among the AMS is one of the vital strategies in order to expedite the marketing authorization approval of unregistered medicines without compromising important factors like quality, safety and efficacy of medicines supply, especially during public health emergency. This is crucial in ensuring the availability of the medicines as well as to support the ASEAN Public Health Emergency Operation Centre (EOC) in a timely manner.

3.3 DOMAIN 3: SUPPLY AND DISTRIBUTION OF MEDICINES

3.3.1 Strategy 3: Ensuring uninterrupted, timely supply of medicines for day to day use and during emergency

Ensuring the uninterrupted supply of medicines is an important strategy to ensure the availability of medicines during normal or emergency time. Collaboration between the AMS in strengthening the procurement capability is needed to ensure the continuity of patient care and disease containment especially during outbreak and emergency. One of the ways to tackle this issue is by developing a platform for information sharing and to enhance the communication between AMS. In addition, AMS have to work together to address and identify the regional needs as well as ensuring an emergency stockpile. Also, group contracting for manufacturing of orphan medicines and non-commercially viable medicines could be initiated.

3.4 DOMAIN 4: MEDICINES PROCUREMENT AND PRICING

3.4.1 Strategy 4: Encouraging price transparency among ASEAN countries

AMS is encouraged to improve the price transparency. This can be initiated using existing price sharing platform such as PIEMEDS for medicines price and MI4A for vaccines price. The list for medicines with their price and supplier information shared will be based on the health needs of each AMS. This is substantial to ensure that every member can get the best price in negotiation process with the supplier or manufacturer.

3.4.2 Strategy 5: Strengthening procurement management and accountability

Strong procurement management and accountability is also critical to ensure the compliance to agreed procurement procedure in AMS. This initiative can be introduced in terms of forecasting quantity and price estimation in pooled procurement process. AMS should streamline the procurement pathway through standard guidelines and also to determine specific quantification model to estimate the volumes and prices of medicines.

Table 1. Strategies for the Regional Collaborative Strategy for ADSSR

Strategy	Objective	Initiative
Domain 1: R&D and Manufacturing		
Strategy 1: Enhancing regional collaboration in manufacturing and R&D	To formalise a platform of communication among ASEAN Member States (AMS), and to promote R&D especially in the development of drug for neglected tropical disease and targeted non-commercially viable medicines to be self-sufficient to fulfil ASEAN needs and demands.	**Initiative 1.1: Setting up a committee/technical working group** • To get list of medicines manufactured by each country (AMS) and production capacity • Harmonization and collaboration work on GMP **Initiative 1.2: Incentive and funding for R&D** • Training of researcher • Engage with experts with consultants • Centre for R&D (Drug development)
Domain 2: Medicines Registration and Other Regulatory Issues		
Strategy 2: Enhancing regional collaboration in strengthening regulatory pathways during public health emergency for unregistered medicines	To align regulatory pathway in order to expedite the marketing authorization approval without compromising quality, safety & efficacy of medicines during public health emergency, to ensure the availability of medicines needed during public health emergencies in a timely manner, and to support the ASEAN Public Health Emergency Operation Centre (EOC).	**Initiative 2.1: Establishing the Alternative Regulatory Pathway for Public Health Emergency** **Initiative 2.2: Enhancement of ASEAN Joint Assessment Procedure for Pharmaceutical Products** **Initiative 2.3: Enhancement of Post-Marketing Alert System (PMAS)**

Strategy	Objective	Initiative
Domain 3: Supply and Distribution of Medicines		
S***trategy 3:*** Ensuring uninterrupted, timely supply of medicines for day to day use and during emergency	To enhance collaboration between AMS countries to address medicines supply issues and strengthening procurement capabilities to ensure the continuity of care for patients and disease containment during outbreak and emergency, address the regional needs and identify emergency stockpile, and to ensure continuous supply.	**Initiative 3.1: Developing a platform for information sharing and enhance communication between AMS countries** **Initiative 3.2: Determining a common list of drugs which is applicable and agreed upon by all AMS countries** **Initiative 3.3: Group contracting for manufacturing orphan medicines and non-commercially viable medicines after establishing MOU among AMS**
Domain 4: Medicines Procurement and Pricing		
Strategy 4: Encouraging price transparency among ASEAN countries	To strengthen price information sharing that is currently available on public domain and expand to other countries to enhance negotiation power and to ensure the best price in negotiation process.	**Initiative 4.1: Obtaining the willingness or political will of each country to share price and supplier information of medicines on public domain or existing price-sharing platform** E.g.: • Thailand – vaccines price in MI4A, manufacturers information in DCVMN • Malaysia – medicines price in PIEMEDS, RRP in public domain • Philippines – medicines price in PIEMEDS • Indonesia- medicines and vaccines price in e-Catalogue **Initiative 4.2: Selecting the scope or list of medicines for price and supplier information sharing based on the health needs of each country**

Strategy	Objective	Initiative
Strategy 5: Strengthening procurement management and accountability	To strengthen procurement management in terms of forecasting quantity and price estimation that is essential in pooled procurement process and to ensure compliance to consented procurement procedures.	**Initiative 5.1: Developing guidelines for sustainable pooled procurement** **Initiative 5.2: Determining quantification model to estimate quantum demand and price**

CHAPTER 4: CONCLUSION AND WAY FORWARD

The framework of regional collaborative strategy for ADSSR has been revised and endorsed by AHC 3 on 15th September 2021 and followed by endorsement by SOMHD on 11th October 2021. This framework is aimed to be adopted by ASEAN Health Ministerial Meeting (AHMM) and ASEAN Leaders' Declaration (ALD) to ensure continuous commitment from all AMS in achieving drug security and self-reliance in the region. Next, the action plans shall be developed for the Regional Collaborative Strategy for ADSSR. The lead country or institution for each initiative or project under the strategy, the expected outputs and indicators, timelines and resources shall be further discussed and deliberated by the AMS. It was with great hope that the proposed strategies could help the AMS to improve the access to medicines and achieve better health outcome for the population.

REFERENCES

1. https://www.solidiance.com/insights/healing/white-papers/the-usd-320-billion-healthcare-challenge-in-asean

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