

# RATIONAL USE OF MEDICINES IN THE ASEAN REGION



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one identity  
one community





# **RATIONAL USE OF MEDICINES IN THE ASEAN REGION**

The ASEAN Secretariat  
Jakarta

The Association of Southeast Asian Nations (ASEAN) was established on 8 August 1967. The Member States are Brunei Darussalam, Cambodia, Indonesia, Lao PDR, Malaysia, Myanmar, Philippines, Singapore, Thailand and Viet Nam. The ASEAN Secretariat is based in Jakarta, Indonesia.

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## MESSAGE



The ASEAN Socio-Cultural Community (ASCC) is committed to improving the quality of life of its peoples through cooperative activities that are people-oriented, people-centred, environmentally-friendly in order to promote sustainable development. ASEAN Member States (AMS) have been making sustained efforts to ensure that ASEAN touches the everyday lives of its peoples who continue to participate in and fully benefit from the potential of regional integration and community building. This could only happen if the ASEAN peoples are productive and healthy. Hence, the region is committed to protecting its peoples from the impact of all health-related hazards and emerging threats. One of the efforts being made is the promotion of Rational Use of Medicine in ASEAN.

As defined by the World Health Organization (WHO), RUM requires that “patients receive medications appropriate to their clinical needs, in doses that meet their own individual requirements, for an adequate period of time, and at the lowest cost to them and their community”. However, irrational use of medicines is a major global problem including in ASEAN. It is a significant obstacle to ASEAN’s access to adequate, effective and affordable health care.

The RUM in the ASEAN Region publication is a collaborative study of the World Health Organization Western Pacific Region (WPRO) and the ASEAN Working Group on Pharmaceutical Development (AWGPD) under the leadership of the Philippines Department of Health-National Center for Pharmaceutical Access and Management (DOH-NCPAM). This study sought to assess the current situation on RUM and identifies the consistencies and gaps in each AMS.

I sincerely hope that this publication could lead to greater regional health security and contribute to future economic benefits to AMS in terms of savings from additional health care costs due to irrational use of medicines.

A handwritten signature in black ink, which appears to be 'L. Minh'.

**Le Luong Minh**  
Secretary-General of ASEAN

## ACKNOWLEDGEMENTS

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## ACRONYMS AND ABBREVIATIONS

AMR	Antimicrobial Resistance
AMS	ASEAN Member States
ASEAN	Association of Southeast Asian Nations
BRN	Brunei Darussalam
DTC	Drugs and Therapeutics Committee
EML	Essential Medicines List
KHM	Cambodia
IDN	Indonesia
INN	International Nonproprietary Name
LAO	Lao PDR
MYS	Malaysia
MMR	Myanmar
MoH	Ministry of Health
ORS	Oral Rehydration Solution
PHL	Philippines
PSCP	Pharmaceutical Sector Country Profile Questionnaire
RUM	Rational Use of Medicines
SEARO	South-East Regional Office
SGP	Singapore
STGs	Standard Treatment Guidelines
THA	Thailand
VNM	Viet Nam
WHA	World Health Assembly
WHO	World Health Organization
WPRO	Western Pacific Regional Office

# EXECUTIVE SUMMARY

Rational Use of Medicines (RUM) was identified as a priority agenda under the ASEAN work plan on pharmaceutical development 2011-2015. This focus on RUM comes at a time when health systems in the ASEAN region face increasing challenges for high-quality health care because of ageing populations, emerging communicable and non-communicable diseases, increasing population incomes and health literacy and demands for new medicines and other health technologies.

This *ASEAN RUM Study* is one of the subcomponents of the Work Plan of the *ASEAN Working Group on Pharmaceutical Development (AWGPD)*. The AWGPD is tasked to assess the impact of pharmaceuticals on public health and improving access to quality medicines and health care services.<sup>1</sup>

In this study, it was revealed that ASEAN Member States (AMS) were consistent in the establishment of national EMLs, the selection of medicines for the EMLs through a formal committee, and the processes used (i.e., explicitly documented criteria) in this selection. They were also consistent in the establishment of legal provisions on the licensing and prescribing practices of prescribers and the mandatory use of INNs in the public health sector.

Several inconsistencies among AMS however were identified through the rapid assessment. The identified inconsistencies or gaps pertain to the following policies and practices relevant to RUM:

- Availability of national EMLs to the general public
- Availability of national EMLs in public health facilities
- Bases for inclusion of medicines in national EMLs
- Operational processes of formal EML committees
- Development, alignment, and availability of STGs
- Other national structures/initiatives to promote the rational use of medicines
- Regulations on dispensing by prescribers and pharmaceutical personnel
- Use of INN in the private sector
- Establishment of DTCs in hospitals
- Code of conduct for doctors, nurses, and pharmacists
- Inclusion of RUM components in training curricula
- Mandatory continuing education on pharmaceutical issues
- Information gap in prescribing practices in public health facilities
- Policy on generic substitution
- Dispensing without prescriptions
- Prescribing practices of non-physicians at the primary care level

RUM needs to be in the policy framework of the ASEAN Member States to contribute to the overall goal of improving health and quality health care across the ASEAN. Political will is necessary to implement multiple interventions directed at different stakeholders including prescribers, medicine dispensers as well as patients and consumers. Better use of medicines anchored on well-supported national programmes will not only lead to greater health security amongst AMS but also future economic benefits in terms of savings from reduced out-of-pocket spending and prevention of extra health care costs arising from the harm to patients and health care systems by the irrational use of medicines.



## BACKGROUND

The Initiative for ASEAN Integration is aimed at narrowing the development gap through the establishment of an ASEAN community that is founded on regional cooperation and social and economic integration. The ASEAN Blueprints on Political Security, Socio-Cultural Community, and Economic Community developed in 2009 laid out the necessary actions to be taken to successfully establish an ASEAN Community by 2015.<sup>1</sup>

Rational Use of Medicines (RUM) was identified as a priority agenda under the ASEAN work plan on pharmaceutical development 2011-2015. Specifically, RUM was an identified action under the strategic objectives of “ensuring access to adequate and affordable healthcare, medical services and medicine, and promoting healthy lifestyles for the peoples of ASEAN” (Strategic Objective No. 22) (ASEAN, 2009).<sup>1</sup> This focus on RUM comes at a time when health systems in the ASEAN region face increasing challenges for high-quality health care because of ageing populations, emerging communicable and non-communicable diseases, increasing population incomes and health literacy and demands for new medicines and other health technologies.

This *ASEAN RUM Study* is one of the subcomponents of the Work Plan of the *ASEAN Working Group on Pharmaceutical Development (AWGPD)*. The AWGPD is tasked to assess the impact of pharmaceuticals on public health and improving access to quality medicines and healthcare services.

### ***The concept of rational use of medicines (RUM)***

As defined by the World Health Organization (WHO), the rational use of medicines requires that “*patients receive medications appropriate to their clinical needs, in doses that meet their own individual requirements, for an adequate period of time, and at the lowest cost to them and their community (WHO, 1985)*”.<sup>2</sup>

The irrational use of medicines has been identified as a major global public health concern. It involves any situation wherein there is overuse, underuse, or misuse of medicines in the healthcare system. Such examples of irrational use of medicines include the use of too many medicines by an individual (also termed “polypharmacy”); inappropriate use of antimicrobials for non-bacterial infections; overuse of injections instead of more appropriate oral formulations; prescribing medicines not in accordance with clinical/standard treatment guidelines; inappropriate self-medication (more often of prescription-only medicines); and non-adherence of patients to dosing regimens.<sup>2-4</sup>

The “WHO estimates that more than half of all medicines are prescribed, dispensed or sold inappropriately, and that half of all patients fail to take them correctly (WHO, 2010)”.<sup>4</sup>

## ***Impacts of irrational use of medicines***

Irrational use has serious, costly and potentially fatal consequences to individual patients and health systems. At the patient level, irrational use can lead to wasteful out-of-pocket spending on medicines, adverse drug events, suboptimal treatment, hospitalizations and premature mortality. At the health system level, irrational use can cause tremendous amounts of wastage in national health budgets, poor outcomes of care and the loss of credibility of health care providers to patients because of failure of treatment. Irrational use of medicines can also threaten national and global health security with the dramatic spread of antimicrobial resistance as the most significant consequence increasingly threatening the health of populations with uncontrollable infections whereas the development of new cures remains far in the horizon.<sup>2-4</sup>

## ***Existing global and regional initiatives on RUM***

The movement toward the rational use of medicines began in 1977 with the WHO introducing the bold concept of the ‘essential medicines list’ —a core list of drugs deemed important to meet priority public health needs selected based on the criteria of safety, efficacy and cost-effectiveness.<sup>4-5</sup>

In 1985, rational use of medicines was formally defined and adopted during the *Nairobi Conference of Experts on the Rational Use of Drugs* in Kenya.<sup>6</sup> Since then, many initiatives have been taken to ensure the integration of RUM in national policies and major resolutions at the World Health Assembly (WHA) adopted by WHO Member States. RUM currently underlies the WHO Medicines Strategy (WHA54.11)<sup>7</sup> and is a key feature of recent WHA resolutions —access to essential medicines (WHA67.22)<sup>8</sup>; promoting the rational use of medicines (WHA60.16)<sup>9</sup>; containment of antimicrobial resistance (WHA58.27, WHA67.39)<sup>10,11</sup>, and; regulations on the promotion of medicines (WHA52.19).<sup>12</sup>

The core components and interventions of RUM as defined by WHO are summarized and contained in *Box 1* which are similarly the topics for review in this survey<sup>2</sup>:

### **Box 1. Core interventions and strategies on the rational use of medicines**

1. *Establishment of a multidisciplinary national body to coordinate policies on medicine use*
2. *Use of clinical guidelines*
3. *Development and use of national essential medicines list*
4. *Establishment of drug and therapeutics committees in districts and hospitals*
5. *Inclusion of problem-based pharmacotherapy training in undergraduate curricula*
6. *Continuing in-service medical education as a licensure requirement*
7. *Supervision, audit and feedback*
8. *Use of independent information on medicines*
9. *Public education about medicines*
10. *Avoidance of perverse financial incentives*
11. *Use of appropriate and enforced regulation*
12. *Sufficient government expenditure to ensure availability of medicines and staff*

## **Current situation on RUM in the ASEAN**

At the ASEAN, some Member States have published national medicines policies where an action framework on RUM is already in place with variable strategies either aimed at the public sector alone or both at the public and private sectors (e.g. Malaysia, Philippines, Thailand).<sup>13-16</sup> Further, AMS may also undertake regional initiatives through their affiliation with respective WHO Regional Offices. For example, the WHO SEARO Regional Committee has already adopted a regional strategy for the prevention and containment of antimicrobial resistance following a resolution issued in 2010 (SEA/RC63/R4).<sup>17-18</sup> Meanwhile, countries in the Western Pacific Region (WPRO) such as the Philippines have long established national surveillance systems on drug resistance since the 1980's and have renewed their commitment for improved regional coordination and collaboration since 2011 as a consequence of the revived global focus on AMR.<sup>19</sup>

ASEAN Member States have widely differing healthcare systems as well as diverse legal, political and regulatory contexts which may elucidate the variations in policies and practices to promote RUM (See *Table 1*). Nonetheless, concerted regional action is needed as the irrational use of medicines is a significant obstacle to the ASEAN's achievement of ensuring access to adequate, affordable and quality health care. Irrational use also poses significant public health threats not only within individual Member States but across the region and globally as well (e.g. AMR). This rapid assessment is the first regional situational analysis of RUM in the ASEAN that aims to understand consistencies and gaps in RUM practices and develop recommendations for action in the Region.

**Table 1. Pharmaceutical situation in ASEAN Member States**

	BRN	KHM	IDN	LAO	MYS	MMR	PHL	SGP	THA	VNM
Population (2013) <sup>1</sup>	417,784	15,135,169	249,865,631	6,769,727	29,716,965	53,259,018	98,393,574	5,399,200	67,010,502	89,708,900
GDP per capita <sup>2</sup> (current US\$) (2013)	38,563	1,008	3,475	1,646	10,514	1,144 <sup>3</sup> (2011)	2,765	55,182	5,779	1,911
Health expenditure, total (% of GDP) (2012) <sup>4</sup>	2.3	5.4	3.0	2.9	3.9	1.8	4.6	4.7	3.9	6.6
Pharmaceutical sales, % of Health Expenditure (2011) <sup>5</sup>	16.50	24.10	27.40	10.90	15.30	-	34.50	6.90	33.10	31.80
Size of the pharmaceutical market (Pharmaceutical sales, US\$ BN (2011) <sup>5</sup> )	0.063	0.177	6.044	0.037	1.814	-	2.911	0.716	4.407	2.425
Pharmaceutical sales, US\$ per capita (2011) <sup>5</sup>	155	12	25	6	63	-	31	138	64	27
Pharmaceutical expenditure per capita in USD (2009) <sup>6</sup>	337	19	18	21	55	16	47	369	144	104
Public expenditure on pharmaceuticals per capita USD (2006) <sup>6</sup>	132.0	1.3	0.7	0.2	12.1	0.1	2.1	45.5	42.5	2.8
Financing mechanism for pharmaceuticals	*Medical care free of charge	Public (14%) <sup>7</sup> Private (86%)	NA	80% (Private) <sup>8</sup> 20% (Public)	*Public health system provide medicines free of charge for particular conditions <sup>9</sup>	NA	12% (public) <sup>10</sup> 88% (private)	NA	90% (public) <sup>11</sup> 10% (private)	NA

<sup>1</sup> The World Bank. (2014). Data: 2012 Population (Total). Retrieved July 2014, from The World Bank Group: <http://data.worldbank.org/indicator/SP.POP.TOTL>

<sup>2</sup> The World Bank. (2014). Data: GDP per capita (current US\$). Retrieved June 2014, from The World Bank Group: <http://data.worldbank.org/indicator/NY.GDP.PCAP.CD/countries>

<sup>3</sup> United Nation Statistics Division. (2014). Cambodia. Retrieved June 2014, from UNdata A world of information: <http://data.un.org/CountryProfile.aspx?crName=Cambodia>

<sup>4</sup> The World Bank. (2014). Data: Health expenditure total (% of GDP). Retrieved June 2014, from The World Bank Group: <http://data.worldbank.org/indicator/SH.XPD.TOTL.ZS/countries>

<sup>5</sup> International Federation of Pharmaceutical Manufacturers and Associations. (2012). The Pharmaceutical Industry and Global Health: Facts and Figures 2012. Geneva, Switzerland: IFPMA.

<sup>6</sup> WHO Global Health Expenditure Database; OECD Health Data 2012

<sup>7</sup> Ministry of Health Cambodia. (2011). 2011 Pharmaceutical Country Profile for Cambodia.

<sup>8</sup> Management Sciences for Health. (2012). Chapter 11: Pharmaceutical Financing Strategies. Available from: <http://www.msh.org/sites/msh.org/files/mds3-ch11-financing-strategies-mar2012.pdf>

<sup>9</sup> Malaysia Pharmaceutical Country Profile.

<sup>10</sup> Department of Health Philippines. (2011). 2011 Pharmaceutical Country Profile for the Philippines.

<sup>11</sup> World Health Organization (WHO). (2011). The World Medicines Situation Report. Data retrieved from: [http://www.who.int/entity/medicines/areas/policy/world\\_medicines\\_situation/Delivered\\_database\\_use\\_articleSep2011.xls](http://www.who.int/entity/medicines/areas/policy/world_medicines_situation/Delivered_database_use_articleSep2011.xls)



# STUDY OBJECTIVES AND METHODS

## **Study Objectives**

This study aims to provide an understanding of current policies and practices on the rational use of medicines across ASEAN Member States (AMS) by addressing the following specific objectives:

1. To establish baseline data on RUM practices among AMS.
2. To identify consistencies in RUM practices among AMS that may be incorporated into a unified regional RUM policy.
3. To identify gaps in RUM practices among AMS that may be addressed by a unified RUM policy.
4. To recommend policy options in promoting RUM across the region.

## **Methods**

### **Study design**

This is descriptive study using a cross-sectional design summarizing individual country data on different core interventions and strategies of RUM as defined by the WHO. We used a pre-validated questionnaire adapted from the *Pharmaceutical Sector Country Profile Questionnaire* (PSCP) developed by the WHO and the Global Fund in 2011 used to obtain general information on structures, processes and outcomes relevant to the national pharmaceutical situations of individual Member States. We also conducted a review of official databases on medicines (i.e. WHO Country Profiles, IMS Health, World Bank) and official country documents such as national medicines policies and country reports available in the public domain.

### **Overview of the rapid assessment questionnaire**

The RUM questionnaire was derived from Section 8 (or “Selection and Rational Use”) of the PSCP questionnaire, which covers 3 areas important in ensuring the rational use of medicines, namely (1) national structures; (2) prescribing practices; and (3) dispensing practices.

The RUM questionnaire was circulated among AMS focal points in January 2013 to obtain comments and ensure that the tool is appropriate to the ASEAN setting. The questionnaire was finalized in March 2013.

The RUM questionnaire consists of 58 questions (42 of which are core questions and 16 of which are supplementary questions). For AMS, the questionnaire was also modified to include a question on why respondents considered the irrational use of medicines as a problem in their respective countries (Question 1.1.23S).

## **Data collection**

The survey was conducted over a period of 3 months from March 2013 to May 2013. The RUM questionnaire was disseminated to focal points of all 10 ASEAN Member States through email (i.e. Ministry of Health, Food and Drug Administration) in coordination with the ASEAN Secretariat. Submission of completed questionnaires was also done electronically. Responses from participating AMS were validated with their respective pharmaceutical country profiles. The initial draft of the report was also presented during the *Third Rational Use of Antimicrobial Agents Workshop* held in Subang Jaya, Malaysia in June 2013 and the *29<sup>th</sup> ASEAN Working Group for Pharmaceutical Development Meeting* held in Cambodia in May 2014 where country representatives also validated the data.

## **Data analysis**

Data from the accomplished questionnaires of individual Member States were collated and extracted and then entered into a database using Microsoft Excel 2010 spreadsheet. Categorical data (i.e., yes or no questions) were analyzed and presented as frequencies, whereas numerical and qualitative responses were reported as enumerated by country respondents. Tables and bar graphs were constructed for the core and supplementary questionnaire items to compare the responses of AMS and also identify consistencies and gaps in the implementation of national programmes on RUM.

## RESULTS

A total of 10 ASEAN Member States participated in the rapid assessment, namely Brunei Darussalam, Cambodia, Indonesia, Lao PDR, Malaysia, Myanmar, Philippines, Singapore, Thailand and Viet Nam.

### ***The problem on the irrational use of medicines in the ASEAN***

All AMS acknowledged that the irrational use of medicines was a major problem in their countries. It was perceived as a problem because it contributed to poor health outcomes (6 of 10 AMS) and increased expenses (at the individual, institutional, and societal levels). Other reasons pointing to the irrational use of medicines as a major problem were the resulting wastage, hazards to consumers' health, drug resistance, and possible abuses of the system. It was also pointed out that the irrational use of medicines occurs at all levels of health care and that the problem reflects the lack of understanding of RUM among patients and consumers (See Table 2).

**Table 2. The problem of irrational use of medicines among ASEAN Member States**

Country	Country Response
<i>Brunei Darussalam</i>	Irrational use of medicines leads to poor patient treatment outcomes, wastage and possible abuse of the system.
<i>Cambodia</i>	No response.
<i>Indonesia</i>	Irrational use of medicines still occurs at every level of health facilities.
<i>Lao PDR</i>	Irrational use is a bad practice and has a negative impact on patient health outcomes. In the case of irrational use of antibiotics, it will cause ineffective treatment, treatment failure or drug resistance.
<i>Malaysia</i>	A National Survey on the Use of Medicines (NSUM) by Malaysian Consumers in 2012 showed that 56.5% fully understand the proper use of their medicines.
<i>Myanmar</i>	It leads to wastage of scarce resources and widespread health hazards.
<i>Philippines</i>	Aside from increasing out-of-pocket payment for the patients, irrational medicines use contribute to poor health outcomes.
<i>Singapore</i>	In Singapore, medicines are regulated as general sales medicines, Pharmacy Only Medicines and Prescription Only Medicines, based on their risk profile and indications. As healthcare facilities are readily accessible in Singapore, the majority of our population is able to obtain appropriate medical treatment and advice. To date, there is no data to assess the degree and nature of inappropriate use of medicines in the different healthcare sectors in Singapore. For the public health institutions, there is no evidence of serious irrational use.

Country	Country Response
<i>Thailand</i>	Irrational use of medicines is a major problem in Thailand for a long time now and this is one of the major factors that contribute to high drug expenditures. Thailand's drug expenditure as percentage of health expenditure is 35% while in developed countries it is between 10-20%. During the World Health Assembly in 2006, it was mentioned that estimated rate for the irrational use of medicines in government settings is not less than 50%, so a big amount of drug expenditures will be saved after implementing Rational use of medicines policy. The policy makers realized the importance of RUM so the National Medicines Policy emphasizes this and appointed a national committee to promote the rational use of medicines. This year (2013), Rational use of medicines is one of the strategies of Ministry of Public health service plan.
<i>Viet Nam</i>	Irrational use of medicines leads to (1) increased healthcare cost on the part of the patients and the society; (2) prolonged hospitalization; and (3) increased mortality.

Question: "Why is irrational use of medicines considered as a major problem in the country?"

## National Structures

### Essential Medicines Lists

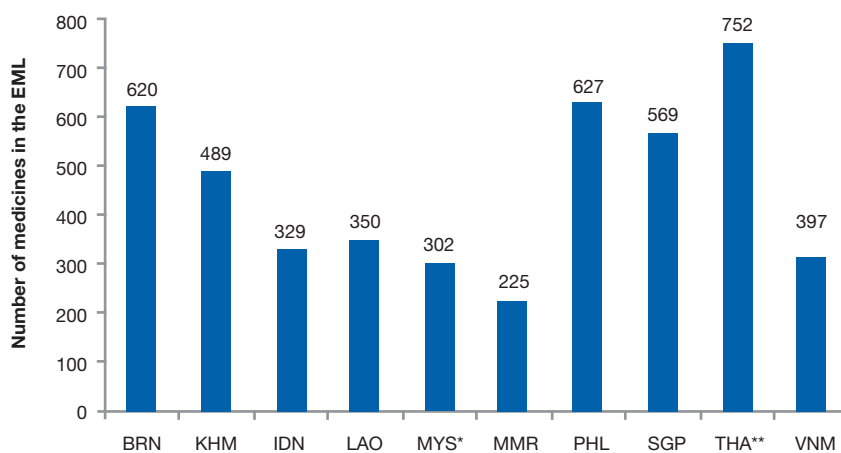
All participating AMS have National Essential Medicines Lists (EML) which are publicly available. Brunei Darussalam's EML is referred to as the National Standard Drug List and is circulated internally within its Ministry of Health. The List is shared however upon request by those external to the Ministry including the private health sector. AMS such as Thailand and the Philippines have made their Lists available on the Web. Except for Brunei Darussalam, Singapore, and Lao PDR, the EMLs of AMS are also available through the World Health Organization's website.

Six (6) AMS reported on the availability of EMLs in public health facilities. The Philippines, Brunei Darussalam, Cambodia, Indonesia, Singapore and Lao PDR reported 100% availability. Malaysia and Thailand reported the lack of data on availability. Thailand however reported that their EML is used as the basis for reimbursement under the Civil Service Medical Benefit Scheme and Universal Health Coverage Scheme. Myanmar similarly alluded to the availability of the EML in all public health facilities in reporting that their EML was distributed in all public health facilities up to the township level.

Eight (8) out of 10 AMS had recently updated EMLs, with their most recent versions published in 2012 or 2013. EMLs contained from 225 to more than 800 medicines, with Myanmar's EML having the least number of medicines and Thailand's EML having the most. The median number of medicines in an AMS' EML is 350 (See Figure 1). Thailand and Myanmar's EMLs do not include medicine formulations specifically for children. Majority of AMS have developed their own National Medicines Formulary, with Lao PDR reporting that the WHO Model Formulary (2007) was used in developing their own formulary. Only Brunei Darussalam does not have a National Medicines Formulary. In Malaysia the existing MOH Formulary is

comprised of essential and supplementary medicines. The formulary is revised thrice a year and since 2013, the MOH Malaysia has actively intensified several activities towards the development of the National Medicines Formulary. This involves the participation of many stakeholders in the public and private sectors.

**Figure 1. Number of medicines listed in the national essential medicines lists of ASEAN Member States**



\*As of 2014, Malaysia has a total of 320 medicines in the EML.

\*\*Thailand has 676 modern medicines and 76 herbal medicines.

The selection of medicines for inclusion in national EMLs is done by a formal committee (or equivalent structure) in all AMS. Thailand in particular has a subcommittee that is responsible for this selection. To be considered for membership in national EML committees, 6 AMS require that conflicts of interest be declared. Brunei Darussalam, Myanmar, Cambodia and Lao PDR do not require their national EML committee members to make such declarations. Majority of AMS had written processes for selecting medicines for inclusion in their EMLs. Only Myanmar and Cambodia had no such written processes. For AMS with such processes, explicitly documented criteria are used as the basis for the selection of medicines (See Table 3).

**Table 3. Implementation of Essential Medicines List among ASEAN Member States**

Strategy/ Interventions	BRN	KHM	IDN	LAO	MYS	MMR	PHL	SGP	THA	VNM
National Essential Medicines List (EML) exists.	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
There is a written process for selecting medicines on the EML	✓	x	✓	✓	✓	x	✓	✓	✓	✓
The EML is publicly available	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
There is a mechanism to align the EML with the Standard Treatment Guidelines (STGs)	✓	✓	✓	x	x	✓	✓	x	✓	✓
The EML includes formulations specific for children	✓	✓	✓	✓	✓	x	✓	✓	x	✓
There are explicitly documented criteria for the selection of medicines in the EML	✓	x	✓	✓	✓	x	✓	✓	✓	✓
There is a formal committee or other equivalent structure for the selection of products on the National EML	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
Conflict of interest declarations are required from members of national EML committee	x	x	✓	x	✓	x	✓	✓	✓	✓

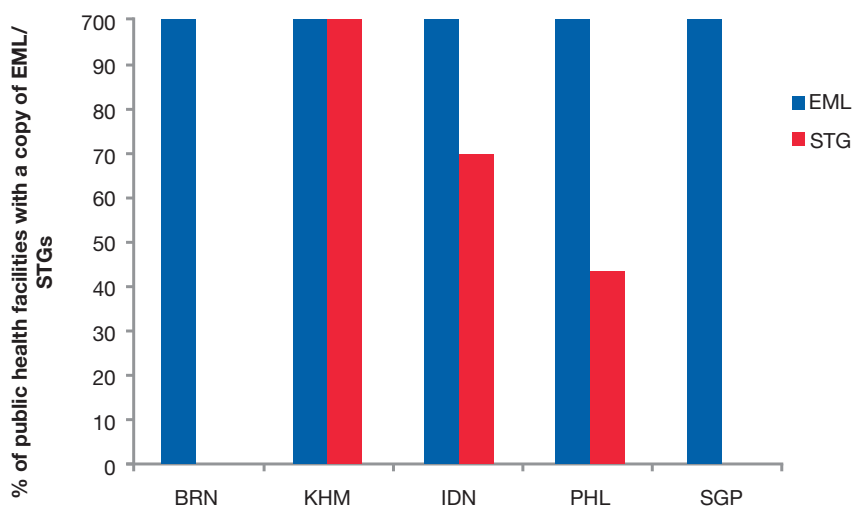
### Standard Treatment Guidelines

Majority of the participating AMS have mechanisms in place to align their EMLs with Standard Treatment Guidelines (STGs). Malaysia, Singapore and Lao PDR indicated that they do not have such mechanisms in place, while Myanmar provided no response. Currently Malaysia has developed two (2) STGs, i.e., National Antibiotic Guideline and Chemotherapy protocol. The medicines under these guidelines are required to be listed in the MOH Drug Formulary, but not necessarily in the EML.

Almost all Ministries of Health (MoH) of the AMS produce or endorse National STGs for the most common illnesses, except the MoH of Singapore. Indonesia, Cambodia, and Lao PDR reported that their STGs are currently being developed or updated. AMS that did have these treatment guidelines had guidelines for care at the primary level. Only the Philippines and Myanmar that had no treatment guidelines specific to secondary (or hospital) care, while only Lao PDR and Viet Nam that were without guidelines for pediatric illnesses. The Philippines' Department of Health has developed national STGs on leprosy (1998), sexually transmitted infections (2003), rabies (2007), tuberculosis (2008), capillariasis (2009), and dengue (2012).

Four (4) of the participating AMS reported on the level of availability of STGs. The Philippines reported the lowest known availability at 42.90%, followed by Indonesia at 70%, while Cambodia and Lao PDR reported 100% availability. On the other hand, no information was available for Malaysia, Thailand, Singapore and Brunei Darussalam (See Figure 2). Myanmar again alluded to the availability of national STGS in reporting that the guidelines have been distributed at the medical officer, health assistant, and voluntary health worker levels. Malaysia, on the other hand, noted that the STGs developed by the Health Technology Assessment Unit of the MOH are uploaded in their official website.

**Figure 2. Percent availability of essential medicines lists (EML) and standard treatment guidelines (STG) in public health facilities**



*Malaysia, Myanmar, Thailand and Viet Nam have no available data.  
Brunei Darussalam and Singapore have no data on the availability of STGs in public health facilities.*

**Table 4. Existence of Standard Treatment Guidelines among ASEAN Member States**

Strategy/ Intervention	BRN	KHM	IDN	LAO	MYS	MMR	PHL	SGP	THA	VNM
National Standard Treatment Guidelines (STGs) for most common illnesses are produced/ endorsed by the MoH	✓	✓	✓	✓	✗	✓	✓	✗	✓	✓
STGs specific to primary care exist	✓	✓	✓	✓	✗	✓	✓	✗	✓	✓
STGs specific to Secondary care (hospitals) exist	✓	✓	✓	✓	✗	✗	✗	✗	✓	✓
STGs specific to Paediatric conditions exist	✓	✓	✓	✗	✗	✓	✓	✗	✓	✗

### Other National Initiatives

AMS also reported on other national initiatives and structures that promote the rational use of medicines, and these are initiatives related to policy, research and surveillance, and communication and advocacy.

A number of AMS have adopted their own national strategies to contain the problem of antimicrobial resistance. These include Indonesia, Malaysia, Thailand, Brunei Darussalam, and Viet Nam. Malaysia was the earliest to adopt such a strategy in 2007, followed by Indonesia, Thailand, and Viet Nam. Thailand's strategy is elucidated on in its National Drug Policy and Strategy 2012-2016. The Philippines strategy has been very recently signed by the President of the Philippines as an Administrative Order mandating the creation of an interagency committee on AMR to formulate and implement a national action plan.

Initiatives have also gone beyond the policy level, in fact 6 AMS have either a national program or committee that monitors and promotes the rational use of medicines. Malaysia was again the first to accomplish this through its National Medicines Policy. In 2009, Thailand formed its Rational Use of Medicine sub-committee, while Myanmar accomplished this through its essential medicines project.

Other mechanisms also exist to advocate for the rational use of medicines. Six (6) AMS (namely Indonesia, Malaysia, Philippines, Thailand, Singapore and Cambodia) have funded national intersectoral task forces to coordinate the promotion of appropriate use of antimicrobials and prevention of spread of infections. In Thailand, the Antimicrobial Working Group of the Rational Use of Medicines Subcommittee has been appointed with these tasks (See Table 5). The Indonesian and Malaysian MoH have also collaborated with non-governmental organizations and community leaders to empower the public on the quality use of medicines. Brunei Darussalam, Philippines, Singapore and Lao PDR reported that such collaborations have yet to occur (See Table 6).



**Table 5. Containment efforts against Antimicrobial Resistance among ASEAN Member States**

Strategy/ Intervention	BRN	KHM	IDN	LAO	MYS	MMR	PHL	SGP	THA	VNM
A written National strategy exists to contain antimicrobial resistance.	✓	✗	✓	✗	✓	✗	✗	✗	✓	✓
A funded national intersectoral task force exists to coordinate the promotion of appropriate use of antimicrobials and prevention of spread of infection.	✗	✓	✓	✗	✓	✗	✗	✓	✓	✗
A national reference laboratory/or any other institution has responsibility for coordinating epidemiological surveillance of antimicrobial resistance	✓	✓	✓	✗	✓	✓	✓	✓	✓	✓

In terms of research initiatives undertaken, 5 participating AMS have conducted a survey on the rational use of medicines in the previous 2 years. Singapore, Thailand, Cambodia, and Viet Nam did not conduct such a survey, while Myanmar has no answer. In addition, only Lao PDR does not have a national laboratory (or any other institution) that is responsible for coordinating epidemiological surveillance of antimicrobial resistance.

Five (5) AMS have national medicines information centers, which are either publicly- or independently-funded, that provide information on medicines to prescribers, dispensers, and consumers. Malaysia's National Drug Information Center was established in 2007. Singapore, Thailand, Myanmar, Cambodia, and Lao PDR reported that they had no such centers. In addition, only Indonesia and Malaysia reported that they have established a dedicated website for consumer education and protection. The Philippines, Singapore, Brunei Darussalam, and Lao PDR do not have similar portals. The remaining participant AMS had no responses.

Majority of participating AMS have conducted public education campaigns on rational medicine use in the previous 2 years. Only Singapore and Myanmar have yet to do so. A few countries have also conducted projects and campaigns at schools (for all levels) to educate students on the rational use of medicines (e.g., Indonesia, Malaysia and Brunei Darussalam) (See Table 6).

**Table 6. Strategies and interventions on RUM education and advocacy among ASEAN Member States**

Strategy/ Intervention	BRN	KHM	IDN	LAO	MYS	MMR	PHL	SGP	THA	VNM
A public or independently funded national medicines information center provides information on medicines to prescribers, dispensers and consumers	✓	✗	✓	✗	✓	✗	✓	✗	✗	✓
Public education campaigns on rational medicine use topics have been conducted in the previous two years	✓	✓	✓	✓	✓	✗	✓	✗	✓	✓
A survey on rational medicine use has been conducted in the previous two years	✓	✗	✓	✓	✓	NA	✓	✗	✗	✗
A national programme or committee (involving government, civil society, and professional bodies) exists to monitor and promote rational use of medicines	✗	✓	✓	✓	✓	✓	✗	✗	✓	✗
Project in collaboration with nongovernmental organizations and community leader to empower public on quality use of medicines exists.	✓	NA	✓	✗	✓	NA	✗	✗	NA	NA
Project and campaign conducted in all school levels to educate students on the quality use of medicines exist.	✓	NA	✓	✗	✓	NA	✗	✗	NA	✗

Strategy/ Intervention	BRN	KHM	IDN	LAO	MYS	MMR	PHL	SGP	THA	VNM
Establishment of a dedicated portal (website) on consumer education and protection.	x	NA	✓	x	✓	NA	x	x	NA	NA

NA - no response

## Prescribing practices

### Policy and Regulation

In all participating AMS, legal provisions exist to govern the licensing and prescribing practices of prescribers. Likewise, essentially the same is true for the restriction of dispensing by prescribers, except in Malaysia, Singapore and Brunei Darussalam. Such legal provisions have been in place since 1982, as in the case of Thailand and its Medical Professional Act of 1982. Legal provisions for licensing and prescribing practices of prescribers were established in 2004 for Indonesia, 1984 in Brunei Darussalam and 2002 in Lao PDR. While legal provisions to restrict dispensing by prescribers were established in 2009 for Indonesia and 2003 in Lao PDR. One specific example is the prescribing of pharmaceutical substances by their International Non-proprietary Names (INN). In this case, it is mandatory in the public sectors of the majority of AMS, except for Lao PDR. Viet Nam is the only AMS that mandates this in the private sector as well. Finally, in all AMS prescribers in the private sector also dispense medicines.

Regulations on the need to establish Drug and Therapeutics Committees (DTCs) in hospitals also exist for majority of the participating AMS, except for Singapore, Brunei Darussalam and Myanmar. And for AMS with these regulations, more than half of their general and referral hospitals and regions/provinces have DTCs. In Lao PDR however, it is unknown if more than half of the referral hospitals have such committees. Furthermore, more than half of referral hospitals in Brunei Darussalam and more than half of general and referral hospitals and regions/provinces in Singapore actually have DTCs in spite of the lack of regulations requiring the organization or development of DTCs.

Professional codes of conduct exist that govern the professional behavior of doctors and nurses. Majority of participating AMS (7 of 10) have codes of conduct for doctors, with more than half of the AMS (7 of 10) have codes for nurses. Myanmar and Lao PDR have no established codes of conduct for both doctors and nurses.

**Table 7. Legal provisions on prescribing among ASEAN Member States**

Strategy/ Intervention	BRN	KHM	IDN	LAO	MYS	MMR	PHL	SGP	THA	VNM
Legal provisions exist to govern the licensing and prescribing practices of prescriber	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
Legal provisions exist to restrict dispensing by prescribers	x	✓	✓	✓	x	✓	✓	x	✓	✓
Prescribers in the private sector dispense medicines	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
Regulations require hospitals to organize/develop Drug and Therapeutics Committees (DTCs)	x	✓	✓	✓	✓	x	✓	x	✓	✓

### Education and Training

Medical training curriculum components relevant to the rational use of medicines are varied among the participating AMS. The concept of EML is least commonly included in the core curriculum of medical students (5 of 10 AMS), followed by the use of standard treatment guidelines (6 of 10 AMS), pharmacovigilance (8 of 10), and problem-based pharmacotherapy (9 of 10). In addition, only Indonesia, Myanmar, and Lao PDR reported that all components were found in their core medical training curriculum. Only Brunei Darussalam reported that none of the components were included, while the other AMS lacked 1 or 2 of the relevant components (See Table 8).

**Table 8. Components of core medical training among ASEAN Member States**

Strategy/ Intervention	BRN	KHM	IDN	LAO	MYS	MMR	PHL	SGP	THA	VNM
Concept of EML	x	x	✓	✓	x	✓	x	x	✓	✓
Use of STGs	x	x	✓	✓	x	✓	✓	x	✓	✓
Pharmacovigilance	x	✓	✓	✓	✓	✓	✓	✓	x	✓
Problem based pharmacotherapy	x	✓	✓	✓	✓	✓	✓	✓	✓	✓

Mandatory continuing education that includes pharmaceutical issues is not commonly required in AMS. Only Viet Nam requires such continuing education for all relevant health personnel – physicians, nurses, and paramedical staff. Malaysia, Brunei Darussalam, Myanmar, and Cambodia do not require any continue education on pharmaceutical issues at

all. Furthermore, for physicians, this is only required in 5 of 10 participating AMS (Indonesia, Singapore, Philippines, Lao PDR, and Viet Nam). For nurses, this is only required in 4 AMS (Philippines, Singapore, Thailand, and Viet Nam). Finally, only Viet Nam requires such continuing education for paramedical staff.

### **Practices in Public Health Facilities**

There are a number of information gaps in this area, with some AMS only able to provide partial reporting. In Indonesia, an annual survey is conducted by the Directorate General of Pharmaceutical and Medical Devices Development on the prescribing patterns in the treatment of respiratory tract infections, unspecified diarrhea, and myalgia. Thailand on the other hand was unable to provide information on prescribing practices as few research has been done (the results of which cannot be generalized to the entire country). Although Singapore was not able provide data, it was noted that most medicines are prescribed using generic names in the public sector and there is a future plan to conduct drug utilization research.

Six (6) of 10 participating AMS reported on the average number of medicines that are prescribed per patient contact in public health facilities. Two (2) medicines are most frequently prescribed (range 2.00 – 3.51). Singapore, Thailand, Myanmar, and Viet Nam were unable to provide information on this. Five (5) of 10 AMS also reported that 85 – 100% of these medicines are in fact dispensed to patients (lowest – Philippines, highest – Malaysia, Brunei Darussalam, Lao PDR). Indonesia, Singapore, Thailand, Myanmar, and Viet Nam were unable to report on this. Finally, 82 – 100% of medicines were reported to be adequately labelled in public health facilities (lowest – Lao PDR, highest – Malaysia, Singapore and Brunei Darussalam). In Singapore, the labelling of medicines in public sector is computerized. Thailand, Myanmar and Viet Nam were unable to provide information on adequate labelling.

Six (6) of 10 AMS reported on the proportion of medicines prescribed in out-patient public health facilities that are found in the national EML. Seventy-eight percent (78%) to 100% of these medicines are listed in national EMLs (lowest – Indonesia and Lao PDR, highest – Brunei Darussalam). Six (6) of 10 participating AMS also reported on the proportion of medicines prescribed by INN, which ranged from 55 – 100% (lowest – Malaysia, highest Brunei Darussalam). Brunei Darussalam noted that its reporting of 100% for medicines prescribed by INN in outpatient public health facilities is an assumption since all public health facilities are expected to implement the Brunei Darussalam Health Information Management System which only uses INNs.

Only 4 of 10 participating AMS reported on the proportion of patients that received antibiotics and injections. In Indonesia, Philippines, Cambodia, and Lao PDR, 48% to 63% of patients that consulted in out-patient public health facilities received antibiotics (lowest – Indonesia, highest – Philippines). In Indonesia, the Philippines, and Lao PDR, 5 – 30% of these patients received injections (lowest – Cambodia at 0%, highest – Lao PDR). Singapore, Thailand and Myanmar were unable to provide figures due to the unavailability of data, while Malaysia, Brunei Darussalam, and Viet Nam did not respond to the survey question. Only 3 AMS reported on the proportion of children with diarrhea treated with Oral Rehydration Solution (ORS), while Indonesia, Malaysia, Singapore and Thailand had no available data to provide.

Myanmar, Cambodia and Viet Nam failed to answer the survey question. Sixty percent (60%) to 100% of children with diarrhea are treated with ORS (lowest – Philippines, highest – Brunei Darussalam).

**Table 9. Comparison of RUM practices of public health facilities among ASEAN Member States**

Strategy/ Intervention	BRN	KHM	IDN	LAO	MYS	MMR	PHL	SGP	THA	VNM
Average number of medicines prescribed per patient contact in public health facilities (mean)	2	2.5	3.51	2	3	No data	2	No data	No data	No data
% of medicines prescribed in outpatient public health care facilities that are in the national EML (mean)	100%	99%	78%	78%	No data	No data	93.10%	85%	No data	No data
% of medicines in outpatient public health care facilities that are prescribed by INN name (mean)	100%	99%	87.13%	72%	55.00%	No data	86.80%	No data	No data	No data
% of patients in outpatient public health care facilities receiving antibiotics (mean)	No data	55%	48%	53%	No data	No data	63.30%	No data	No data	No data

Strategy/ Intervention	BRN	KHM	IDN	LAO	MYS	MMR	PHL	SGP	THA	VNM
% of patients in outpatient public health care facilities receiving injections (mean)	No data	0%	5.43%	30%	No data	No data	10.00%	No data	No data	No data
% of prescribed drugs dispensed to patients (mean)	100%	93%	No data	100%	100%	No data	84.80%	No data	No data	No data
% of medicines adequately labelled in public health facilities (mean)	100%	95%	90%	82%	100%	No data	97.10%	100%	No data	No data

## Dispensing practices

### Policy and Regulation

Among participating AMS, only Lao PDR has no existing laws that govern dispensing practices of pharmaceutical personnel (n.b. Viet Nam provided no response to this question). Furthermore, more than half of participating AMS (6 of 10) had a professional association code of conduct to govern the professional behaviour of pharmacists (e.g., Indonesia, Malaysia, Philippines, Singapore, Cambodia and Brunei Darussalam). Again, Viet Nam provided no response to this particular question.

### Education and Training

Indonesia, Philippines, Singapore, Thailand and Vietnam reported that their basic pharmacist training curriculum includes all components relevant to the rational use of medicines, namely, the concept of EML, use of STGs, drug information, clinical pharmacology, and medicines supply management. Use of STGs was the most frequently excluded component (e.g., in Malaysia, Cambodia, and Viet Nam), while all AMS included drug information in their training curriculum. Clinical pharmacology was not included in the training curricula of Myanmar and Lao PDR, while only Myanmar did not have medicines supply management included. Brunei Darussalam currently has no established pharmacy school.

Mandatory continuing education that includes the rational use of medicines is required for pharmacists in half of participating AMS (5 of 10), particularly in Indonesia, Malaysia, Lao PDR, Singapore and Viet Nam.

**Table 10. Components of basic pharmacist training curriculum**

Strategy/ Intervention	BRN*	KHM	IDN	LAO	MYS	MMR	PHL	SGP	THA	VNM
Concept of EML	-	x	✓	✓	✓	✓	✓	✓	✓	✓
Use of STGs	-	x	✓	✓	x	✓	✓	✓	✓	✓
Drug Information	-	✓	✓	✓	✓	✓	✓	✓	✓	✓
Clinical pharmacology	-	✓	✓	x	✓	x	✓	✓	✓	✓
Medicines supply management	-	✓	✓	✓	✓	x	✓	✓	✓	✓

\*Brunei Darussalam has no pharmacy school

### Generic Substitution

In 7 of 10 participating AMS, generic substitution at the point of dispensing is allowed in public sector facilities. This, on the other hand, is not allowed in Myanmar and Thailand. Viet Nam was the sole non-respondent for this question. Only 4 of 10 participating AMS (e.g., Indonesia, Philippines, Singapore, and Lao PDR) was generic substitution in private sector facilities allowed. In Singapore, generic substitution in the private sector is carried out with prescriber's agreement.

**Table 11. Generic substitution policies among ASEAN Member States**

Strategy/ Intervention	BRN	KHM	IDN	LAO	MYS	MMR	PHL	SGP	THA	VNM
Generic substitution at the point of dispensing in public sector facilities is allowed	✓	✓	✓	✓	✓	x	✓	✓	x	NA
Generic substitution at the point of dispensing in private sector facilities is allowed	x	x	✓	✓	x	x	✓	✓	x	NA

NA - no response

### Dispensing Practices without Prescriptions

In majority of participating AMS (7 of 10), antibiotics are sometimes sold over-the-counter without any prescription and even though this may be contrary to regulations. It is unknown



whether this practice occurs or not in Malaysia. In Brunei Darussalam and Singapore, such practices were reported not to occur. Similarly, more than half (6 of 10) AMS also reported that medicines for injection were sometimes sold over-the-counter without a prescription (e.g., Thailand, Singapore, Myanmar, Cambodia, Lao PDR, and Viet Nam). Singapore noted that not all injectable preparations are regulated as Prescription Only Medicines like the insulin preparations which are regulated as Pharmacy Only Medicines and as such can be purchased from pharmacies under the supervision of a pharmacist.

### Prescribing Practices of Non-Physicians at the Primary Care Level

Prescribing of prescription-only medicine by non-physician staff occurs at the primary care level in the public health sector of some AMS, even though this may be contrary to existing regulations on prescribing. This practice occurs in Cambodia, Indonesia, Malaysia, Thailand, Brunei Darussalam, and Lao PDR, but was not reported to occur in the Philippines, Singapore, and Myanmar. The latter country noted however that it is unknown whether the practice occurs among nurses. Indonesia pointed out that such practices occur because of a lack of medical doctors at public primary health care facilities located in remote areas. While in Cambodia, it was reported in the Pharmaceutical Country Profile that the distribution of qualified prescribers is uneven and inadequate in numbers, therefore trained nurses are permitted to prescribe where there is deemed necessary.

**Table 12. Healthcare practitioners who prescribe prescription-only medicines at the primary care level in the public sector**

Strategy/ Intervention	BRN	KHM	IDN	LAO	MYS	MMR	PHL	SGP	THA	VNM
Nurses	✓	✓	✓	✓	✓	U	✗	✗	✓	NA
Pharmacists	NA	✗	✗	✓	✗	✗	✗	✗	✓	NA
Paramedics	✗	✗	✓	✓	✓	✗	✗	✗	✓	NA
Personnel with less than one month training	✗	✗	✗	✗	✗	✗	✗	✗	U	NA

*U - unknown*

There are a few AMS wherein prescribing by non-physician staff is allowed. In Brunei Darussalam for instance, nurse practitioners are allowed to prescribe for minor ailments and from a limited medicines list. While in Thailand, nurse practitioners, pharmacists, and paramedics (with a prescribed minimum years of training) are allowed to prescribe prescription-only medicine under the supervision of a doctor, hospital director, or director of the contracting unit of primary care. Nurses most frequently prescribe (6 of 10), followed by paramedics (4 of 10) and pharmacists (2 of 10).

## DISCUSSION AND RECOMMENDATIONS

There are a number of consistencies in RUM practices among participating AMS in terms of national structures that are currently in place and in terms of prescribing practices. All AMS have an existing national EML and whose listed medicines are selected by formal committees following explicitly documented criteria. Furthermore, there are existing legal provisions on licensing and prescribing practices of prescribers in all participating AMS. The use of INNs is also mandated in the public sector. Finally, the private sectors in all AMS also dispense medicines. These consistencies may already be included in a unified RUM policy for the ASEAN so as to ensure continued implementation of such policies and practices.

However, there are considerable variations in other RUM practices among AMS which could be considered gaps, and for which a unified RUM policy could be used to bridge such gaps. Such variations pertain to the method and extent of availability of national EMLs, their content and accompanying documents, and processes of evaluation of medicines for inclusion. The following are the issues that may need to be resolved or decided on by the ASEAN for elaboration in a unified RUM policy:

**Availability of national EMLs to the general public** – Though many EMLs are available to the public, the manner by which these are made available is varied. There are EMLs that are available on the Web, while others that require a formal request. The ASEAN needs to decide on its commitment to making the national EMLs available to the general public.

**Availability of national EMLs in public health facilities** – There are a number of ways that this has been done by a few AMS (e.g., basis for reimbursement by government and physical distribution of EMLs in health facilities), although the extent to which these accurately reflect “actual” availability in health facilities may be questionable. Therefore, a closer examination of the supply and demand side factors may be necessary to adequately address this issue.

**Criteria for inclusion of medicines in national EMLs** – There are significant variations in the number of medicines in national EMLs and in the inclusion of pediatric formulations in the lists. It is the prerogative of individual AMS to decide on medicines that are most suitable for their own country settings. Therefore, the actual content of national EMLs may not be the issue, but rather the processes for inclusion or exclusion of medicines. The development of a National Formulary to accompany or supplement the EML may also be considered for all AMS. It may be worthy to look at existing processes and methods of evidence review to support the development of EML. The rigor of analysis may vary across countries and other factors such as cost, resource use, local epidemiology and health system organization may contribute to the decisions of national committees. WHO may support AMS in training national committees on evidence based selection or cross country learning may be explored drawing from the best practices of AMS with more advanced methods of analysis. It was also revealed in the study that traditional medicines play a major part in health systems across the ASEAN such as Thailand where 76 out of 752 medicines in the EML are herbal medicines. Building evidence for the use and promotion of traditional medicines can be a future area of collaboration among AMS.

**Operational processes of formal EML committees** – Operational processes of committees that decide on medicines for inclusion in EMLs may have a profound impact on the quality of the EMLs. Though all AMS have processes for selection of medicines, not all have written processes. In addition, the recommended frequency by which such EMLs are updated need to be determined and decided upon by the ASEAN. Lastly, declaration of conflicts of interest of individuals applying or in consideration for membership to national EML committees may also be determined through a unified RUM policy.

**Development, alignment, and availability of STGs** – STGs are an important means by which AMS can ensure the rational use of medicines; however, their development, alignment with national EMLs, and availability differ substantially among AMS. There are differences in the development of STGs for common illnesses encountered at the primary care level, secondary care level, and for pediatric care. Existing STGs are also not necessarily aligned with EMLs, i.e., recommended medicines within an STG may not necessarily be limited to only those in EMLs. Finally, as with national EMLs, the actual availability of STGs to practitioners may need to be determined.

**Other national structures/initiatives to promote the rational use of medicines** – There are number of initiatives that are undertaken to varying degrees in AMS that promote RUM, and may be considered for inclusion in a policy mandating their implementation. These include the following:

- Policy on Antimicrobial Resistance (AMR)
- National Program or Committee on RUM
- National Intersectoral Task Force on AMR
- Collaboration with Non-Government Organizations (NGOs) and community leaders
- Periodic conduct of RUM survey
- National Laboratory/Institution for AMR Surveillance
- National Medicines Information Center
- Dedicated website for consumer education and protection
- Public education campaigns on RUM
- Projects/campaigns at schools to educate students on RUM

In considering which initiatives to be universally undertaken by the ASEAN, thoughtful consideration must be made to ensure that AMS have the capacity to implement such initiatives.

**Regulations on dispensing by prescribers and pharmaceutical personnel** – Though there are legal provisions on the licensing and prescribing practices of prescribers, similar legal provisions on dispensing by both prescribers and pharmaceutical personnel do not exist in all AMS. The point of dispensing is critical in ensuring the rational use of medicines in so far as this is the point at which individuals are finally handed medicines. A lack of regulations on dispensing may result in an indiscriminate dispensing of medicines and lead to the irrational use of medicines.

**Use of INN in the private sector** – The use of INNs is not mandated in the private sector, as it is in the public sector, of all AMS. Mandating the use of INNs however may require further consultation with prescribers to ensure that such mandate is not perceived as a restriction, but, rather, as a means of promoting RUM as part of a broader framework on quality health care.

**Establishment of DTCs in hospitals** – DTCs in hospitals are needed to establish and maintain hospitals' formularies, but more importantly to implement medicines use policies that are aimed at ensuring the safety, appropriateness, and cost-effectiveness of medicines given to patients. The presence of such DTCs, however, in general and referral hospitals and in all regions/provinces in an AMS is varied.

**Code of conduct for doctors, nurses, and pharmacists** – Not all AMS have codes of conduct for doctors, nurses, and pharmacists that are relevant to their prescribing or dispensing practices. Such codes of conduct could significantly improve such practices in favour of the rational use of medicines. Again, however, the revision or development of such codes may need to be done in consultation/collaboration with these professionals to ensure their buy-in and support.

**Inclusion of RUM components in training curricula** – Promoting the rational use of medicines among prescribers (specifically physicians) and dispensers is important not only to encourage their rational prescribing or dispensing of medicines but also to encourage them to counsel their patients/clients about the hazards of irrational use of medicines. Among AMS that have included RUM components in their training curricula for prescribers and dispensers, there are differences in the specific components included. Again, consideration must be made of the capacity of AMS to include all components in their training curricula.

**Mandatory continuing education on pharmaceutical issues** – Continuing education on pharmaceutical issues is not mandated for all prescribers and dispensers in AMS. Educating on RUM should not be limited to training at university as there is still a need to reinforce the value of rationally prescribing and dispensing medicines afterwards.

**Information gap in prescribing practices in public health facilities** – Though most participating AMS were able to provide information on prescribing practices in public health facilities, few were able to provide information obtained through studies. Self-reporting of such practices may need to be validated with independent research so as to more accurately determine prescribing practices in public health facilities.

**Policy on generic substitution** – Generic substitution is more commonly allowed in public than in private health facilities in AMS. Because of the mandated use of INNs in public health facilities, it is no surprise that generic substitution is also allowed in these institutions. In addition, in certain AMS, this substitution is allowed even without an explicit policy; however, such practices may need to be mandated through a policy and specifically in private health facilities (where the use of INNs is less likely to be mandated).

**Dispensing without prescriptions** – Dispensing prescription-only medicines without prescriptions (e.g., antibiotics and medicines for injection) is detrimental in general to the health system. It encourages the irrational use of medicines by the general public because they have unlimited access to any medicine. The indiscriminate dispensing of antibiotics contributes to the emergence and persisting problem of antimicrobial resistance, while the indiscriminate dispensing of injections may result in fatal adverse drug reactions.

**Prescribing practices of non-physicians at the primary care level** – Prescribing by non-physicians occurs at the primary care level in some AMS. In certain cases, such prescribing is allowed provided that it occurs under the supervision of physicians. In Indonesia, these practices occur in instances where there are no available physicians. It may be worthwhile to determine if this is also the case in other AMS and if such practices may be allowed in setting without physicians.

### ***Strengths and limitations of the study***

This assessment is the first study conducted among AMS providing an overview of existing policies, practices and national strategies on the rational use of medicines. In assessing the regional situation, we used a set of key indicators from a well-accepted and standardized tool developed by the WHO with some revisions to fit the ASEAN context. While the indicators are limited to broad policies on prescription and dispensing practices and the specific use of antibiotics, injections and diarrheal medications, the study can fill the gap in knowledge on quality use of medicines across the ASEAN and be used as baseline information to help AMS in improving their national programmes and identify priority areas of action like the rapidly emerging problem on antimicrobial resistance. AMS may want to complement findings of this study with further investigations relevant to the use of medicines specific to other disease and therapeutic categories according to their own country needs.

This study was not also designed to examine the factors that contribute to the inconsistencies in the implementation of key interventions to promote RUM in the ASEAN. Therefore, a more in-depth study is recommended to look at the possible influences within countries (i.e. economic, social, cultural, legal, regulatory, and political) which may explain the current challenges in successfully implementing RUM policies in specific settings. Examining these factors may help AMS in tailoring and instituting multi-faceted interventions directed at healthcare workers and patients in the community and health care facilities.

## CONCLUSION

The present report provides substantial evidence that improving the rational use of medicines is a major challenge that must be addressed by individual health systems and by ASEAN Member States through a coordinated approach as a Region. Almost all Member States recognized irrational use of medicines as a serious problem causing significant morbidity and mortality, the depletion of national health resources and the emergence of global public health threats such as antimicrobial resistance.

Several basic policies on are consistently being implemented across the ASEAN as evidenced by well-established essential medicines lists and having legal provisions on the prescribing and dispensing of medicines by health care providers. Some countries in the ASEAN have prioritized RUM in their national policies to solidify efforts on RUM amongst health providers in both the public and private sectors (e.g., Malaysia, Philippines, Thailand). These good practices need to be sustained and scaled up at the national level. Governments can lead by crafting RUM policies appropriate to their country settings. Regulatory and educational efforts on RUM should be targeted not only at public health facilities but also the private and informal sectors as medicines are prescribed, dispensed and used outside of the public health care system in many AMS. Clearly defined organizational structures and institutional mechanisms within health care systems must also be identified and supported to ensure monitoring and coordination of activities among all the stakeholders involved in RUM.

Yet despite successful initiatives to improve the use of medicines, there is also evidence of widespread irrational use of medicines. Across the ASEAN, there is suboptimal and varied implementation of known effective strategies to promote RUM as recommended by the WHO. The over-the-counter availability of antibiotics and injections without any prescription in more than half of the countries is an alarming problem that shows weak regulatory oversight and the lack of provider and consumer knowledge on RUM. Antibiotic misuse is a particularly serious issue that needs concerted action of AMS in terms of identifying effective strategies that could be implemented as part of national programmes and the roadmap of action by the ASEAN.

There is also fragmented information on RUM initiatives and no documentation and sharing of country best practices. Common RUM indicators to analyze and compare country situations must be agreed upon amongst AMS probably drawing from a subset of WHO set of indicators used in this study. These indicators may serve as tools to regularly monitor progress at the country and regional levels and help individual AMS in refining national policies to improve the use of medicines.

In conclusion, RUM needs to be in the policy framework of the ASEAN Member states to contribute to the overall goal of improving health and quality health care across the ASEAN. Political will is necessary to implement multiple interventions directed at different stakeholders including prescribers, medicine dispensers as well as patients and consumers. Better use of medicines anchored on well-supported national programmes will not only lead to greater

health security amongst AMS but also future economic benefits in terms of savings from reduced out-of pocket spending and prevention of extra health care costs arising from the harm to patients and health care systems by the irrational use of medicines.

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