



# DRIVING COMPREHENSIVE HEALTHCARE POLICY IN ASEAN



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## Executive Summary

As ASEAN continues to develop economically, and the population of the region continues to grow, the provision of affordable and universal healthcare becomes more important.

The challenge facing all governments in the ASEAN region is to ensure that healthcare is readily available to the entire population, even those in the most remote locations, at an affordable price and within manageable budgets.

Despite the general perception that ASEAN has a youthful population, many countries in the region are facing a rapidly ageing demographic between now and 2050. With ageing populations - and shifting demographics from rural to increasingly urban and middle-class societies - come new healthcare challenges. Populations will require different sorts of healthcare services, delivered in a different way. This presents both cost and organisational challenges for Governments and healthcare authorities across the region. New partnerships and collaborations will be needed to meet the growing demand for services and changing needs of patients. **Member companies from the EU-ASEAN Business Council stand ready to collaborate and partner on the solutions outlined in this paper.**

WE BELIEVE THAT THE MASSIVE RISE IN HEALTHCARE DEMAND POSES ONE OF THE GREATEST CHALLENGES THE ASEAN NATIONS HAS EVER FACED, YET THEREIN LIES ALSO IMMENSE OPPORTUNITY. IF POLICY MAKERS AND BUSINESSES MAKE THE RIGHT CHOICES TODAY, GREAT VALUE AND A HEALTHY FUTURE CAN BE SECURED FOR PATIENTS, GOVERNMENTS AND SHAREHOLDERS ALIKE

ASEAN Healthcare Challenge & Opportunity  
Solidiance, 2018

This paper makes recommendations in three areas: Regulatory Affairs, Public Health Policies and, Trade and Access. The recommendations are aimed at helping the governments of Southeast Asia deliver improved and cost-effective healthcare for their citizens.

## Table of Recommendations

Issue	Objectives	Recommendations
<b>Trade and Market Access Issues</b>	Market Access	<p>The EU-ABC recommends that ASEAN governments create a level playing field for foreign companies consistent with WTO and Bilateral Investment Protection Treaties.</p> <p>The EU-ABC recommends that there be a liberalisation of foreign ownership rules to encourage more companies to enter the market, which will drive innovation, quality standards and increase overall investment in the region.</p> <p>The EU-ABC recommends the adoption of an ASEAN wide common regional licensing and regulatory standards that would allow companies to streamline their licensing process and allow them to bring their products and services to market faster.</p>
	Halal Standards & the Provision of Healthcare	The EU-ABC recommends that governments in Southeast Asia should not make Halal Certification mandatory for medicines and healthcare products.
	Private Sector Consultation	The EU-ABC recommends more industry consultations or regular dialogues to ensure transparency, involvements, and to enhance sustainable access to medicines with health authorities across the ASEAN region.
<b>Regulatory Affairs</b>	Regulatory Affairs	<p>The EU-ABC recommends that harmonised regulatory standards be adopted across the ASEAN region.</p> <p>The EU-ABC recommends that there is an increase in the capacity of regulators so as to allow for faster decision-making process and to allow for deeper engagement with stakeholders.</p>
	Harmonised approaches to approvals and testing for faster healthcare access	The EU-ABC recommends ensuring consistency in the implementation of ASEAN regulatory harmonisation across member countries to continuously reduce country specific requirements and different interpretations.
	Rx-to-OTC Switch	<p>The EU-ABC recommends that a dedicated ASEAN OTC/non-prescription regulation framework working group be established under the auspices of PPWG and that it will develop and be responsible for the construction of a well-defined non-prescription regulation framework.</p> <p>The EU-ABC recommends that Rx to OTC Switch should be formally included in the work of the PPWG with the broad aim of formally designating more medicines to be non-prescription medicines across the ASEAN region.</p> <p>The EU-ABC recommends that the reclassification framework for Rx-to-OTC switching should be established across ASEAN with clear and consistent criteria, evidence based and focusing on safety and self-treatment of products with process transparency and industry dialogues during the reclassification procedure to provide scientific expertise in benefit to evaluation purpose.</p>
	Effective Regulatory Data Protection	The EU-ABC supports legislation development to provide effective and adequate protection of regulatory data submitted for the market approval of new products and switching products against unfair commercial use in

		alignment with WTO TRIPS agreement Article 39.3 on data protection.
	Protection and Enforcement of Pharmaceutical Patent Rights	The EU-ABC recommends that consideration be given to a balancing mechanism in a market authorisation system to ensure adequate and effective protection of patent rights for the innovator holders, while allowing generic products to be marketed as soon as the innovator patent expires.
		The EU-ABC urges governments to ensure enforcement and any revisions of patent laws towards this international alignment especially on patentability criteria, patent registration procedure, compulsory licensing.
		The EU-ABC recommends eliminating provisions that would impose new patent disclosure requirements regarding the source and origin of genetic resources.
		The EU-ABC recommends that the patent registration procedure should be streamlined to ensure effectiveness in examination and approval based on international guidance.
	Traditional and Herbal Medicines	The EU-ABC encourages that the Regulatory Framework on Traditional Medicine be signed and adopted in order to bringing greater certainty to this sector.
	Vitamins, Food and Mineral Supplements	The EU-ABC encourages that the Regulatory Framework on Health Supplements be signed and adopted.
<b>Health Policies</b>	Digital Health Initiatives	The EU-ABC recommends that rules and policies relating to digital health initiatives be developed and adopted at a regional level rather than at the national level.
		The EU-ABC also recommends that ASEAN continues to take steps to lower barriers for digital healthcare products and services while developing a common regulatory framework that the countries of ASEAN can adopt.
	Medical Nutrition	The EU-ABC recommends that ASEAN to put more emphasis on the adoption of nutritional therapy to complement the existing healthcare mechanisms in the region, and also to synergise with significant investment, e.g. into R&D by food companies in the region leveraging the value of nutrition for an ageing population or non-communicable chronic diseases.
	Other Health Aids	The EU-ABC recommends that ASEAN countries adopt a harmonised approach to other health aids that provided benefits to patients.
	Public-Private Healthcare Initiatives	The EU-ABC recommends that ASEAN governments develop a regional wide set of regulations regarding Public-Private Partnerships for social infrastructure, especially relating to the healthcare industry and to engage with the private sector in developing public private health initiatives in order to deliver better health services to patients.
		The EU-ABC recommends that the ASEAN government explore the alternative option to enhance sustainable healthcare financing which include innovative reimbursement models, new financing models, as well as alternative funding sources apart from the healthcare budgeting.

	Sustainable Healthcare Financing through Universal Health Coverage and Access to Health Insurance	<p>The EU-ABC therefore recommends that ASEAN Finance Ministries look at a range of possible tax incentives to foster the growth of the insurance sector.</p> <p>The EU-ABC recommends that the ASEAN Member states collaborate with the private sector to develop a robust, sustainable health funding system that works for patients and other stakeholders.</p>
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## Healthcare in ASEAN

The ASEAN Economic Community Blueprint 2025 (AEC Blueprint 2025) states that Healthcare is one of five priority sectors for the ASEAN region. ASEAN says that it wants to see a strong healthcare industry with “better healthcare facilities, products and services” providing both “affordable and quality healthcare” for the region. As part of the AEC Blueprint 2025, ASEAN set out seven strategic measures for the industry, namely<sup>1</sup>:

- Continued opening up of private healthcare markets and Public-Private Partnership (PPP) investments in the provision of universal healthcare in the region;
- Harmonisation of standards and conformance in healthcare products and services, such as common technical documents required for registration processes and nutrition labelling;
- Promotion of sectors with high-growth potential such as health tourism and e-healthcare services, which will not have a negative impact in the healthcare system of each ASEAN Member State;
- Promotion of strong health insurance systems in the region;
- Further facilitate the mobility of healthcare professionals in the region;
- Enhance further the development of an ASEAN regulatory framework on traditional medicines and health supplements, through setting of appropriate guidelines or frameworks; and,
- Continue to develop and issue new healthcare product directives to further facilitate trade in healthcare products in the region.

The EU-ASEAN Business Council (EU-ABC), in general, supports each of these strategic goals and hopes to be able to work with relevant ASEAN bodies and national governments to assist in their achievement. Taken together they should help to ensure better provision of, and access to, healthcare throughout the ASEAN region. However, we note that there is much that needs to be done to improve on the provision of affordable and quality healthcare in the region, and there will be a need for governments, regulators, trade and industry groupings, and the private sector to work better and more intelligently together on holistic solutions to achieve these goals.

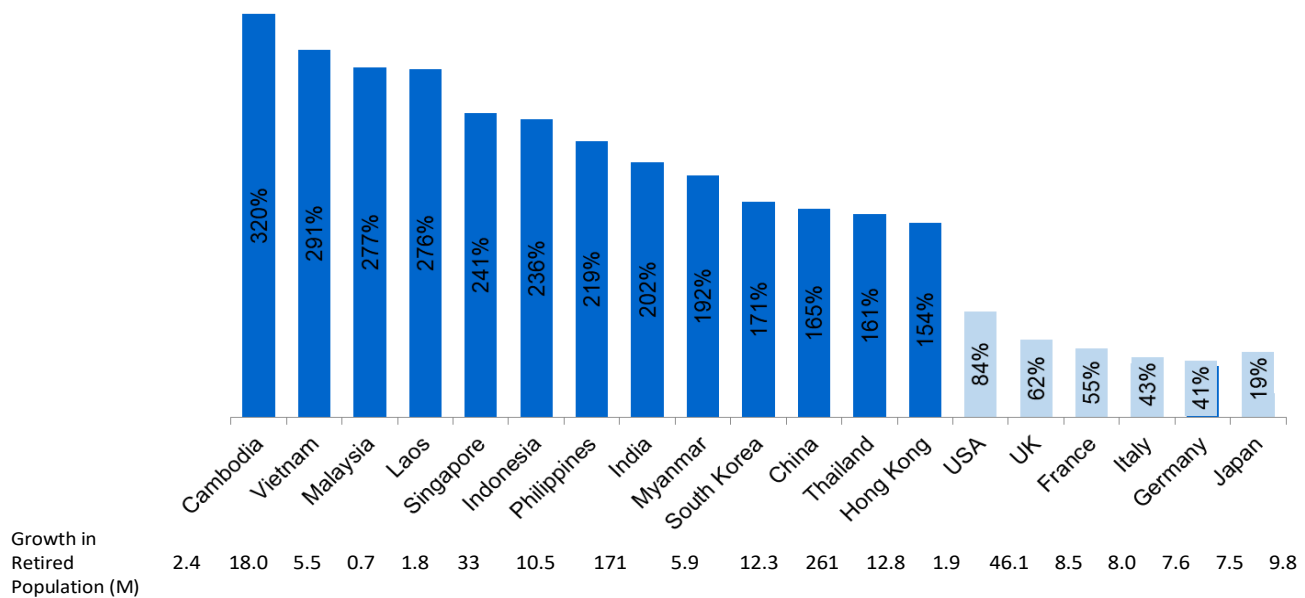
The challenge facing the ASEAN region is to ensure that healthcare is both readily available to all of the population of the region, even those in the most remote locations, at an affordable price. As Figure 1 below shows, despite the general perception that ASEAN has a youthful population, many countries in the region are facing a rapidly ageing demographic between now and 2050. This will naturally mean an increasing need for the provision of healthcare across the region. With ambitious Universal Healthcare Coverage objectives in some ASEAN countries such as Vietnam, Indonesia and the Philippines, increasing expenditure on the provision of health services should be expected and planned for.

One of the major policy questions for the ASEAN Member States is the extent to which they can afford to boost expenditure levels whilst also directing scarce government funds to other development requirements. In particular, governments want to avoid having to reduce healthcare coverage due to a lack of funds. As shown in Figure 2, compared to many developed countries, expenditure levels on healthcare, as a percentage of GDP, are relatively low across ASEAN. Ageing and growing populations mean that a new paradigm in

<sup>1</sup>AEC Blueprint 2025, Section C.7, paragraphs 60 and 61.

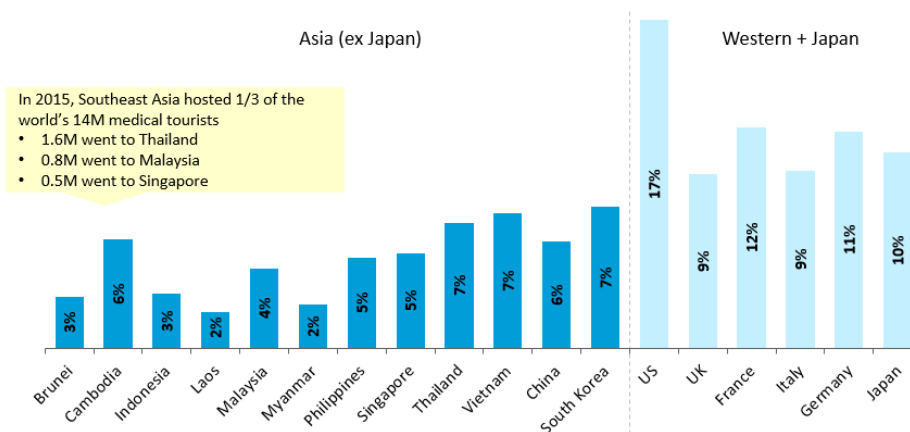
healthcare is required, one centred on value-based healthcare, looking at health outcomes of treatment relative to cost “driven by the widespread recognition that historical trends in costs of healthcare are unsustainable in developed economies and are what emerging economies can ill-afford to replicate”.<sup>2</sup>

**Figure 1 - Growth in retired population (65+) 2015 – 2050**



Source: United Nations, Department of Economic and Social Affairs, Population Division (2015).

**Figure 2 – Total healthcare spending as a % of GDP**



Source: World Health Organization Global Health Expenditure database

<sup>2</sup> “Succeeding in a value-based environment: new business models to thrive in the future of healthcare”, The Economist Intelligence Unit, 2013



## Key Issues

### Market Access and Trade Issues

#### ***Market Access***

As the demand for healthcare in the ASEAN region continues to grow, companies are still challenged by market access issues which vary across the ASEAN region. These issues impact companies' abilities to provide access to medicines, medical care and other healthcare related services, resulting as the barriers of patients access to the appropriate treatments as needed.

The EU-ABC believes that improving market access will allow companies to increase their presence in this region thus leading to more competition, increasing access to innovative products and better services, all of which benefit both patients and governments.

For many companies, entering the ASEAN market still poses a challenge as there continues to be restrictions on their ability to freely enter the region. Unfortunately, these restrictions have a greater impact on MSME's who lack the necessary resources to track and comply with various regulations that countries have introduced.

While many national governments have introduced policies designed to attract foreign investment and companies to attract capital, the same governments continue maintain control over foreign companies in many industries. In most countries, there remain significant restrictions on foreign ownership rules and requirements for joint ventures. These ownership rule restrictions may limit a company's willingness to enter the market. In addition, for some countries in the ASEAN region, there continues to remain a complex and long licensing regime for the creation of new companies.

Another example of a regulatory challenge includes localisation requirements in countries such as Vietnam, which specifically mandate pharmaceutical companies to choose local national logistics services companies over experienced multi-national companies. The bases for these requirements are often unclear but lead to safety concerns due to service quality challenges faced by these less-experienced agencies. The net result is that these localisation requirements often result in medicines and devices costing more, or becoming less readily available, to the people who need them.

In addition, the recent requirement for Certificate of Pharmaceutical Product (CPP) to include information on active pharmaceutical ingredients that are not aligned with international acceptance standard of WHO CPP guidance adds an administrative burden to CPP-issuing health authorities and industry.

The general market environment also has an impact on developing innovation and attracting the investment. This is particularly true where policies related to pricing and reimbursement of pharmaceutical products are concerned. Recent developments in these areas include the Maximum Drug Retail Price Program (MDRP) in Philippines, price control for retail channels in Malaysia and private hospital price control and establishment of a median price policy in Thailand. However, it is important to ensure that any price control framework supports the principles of clarity, transparency, consistency of enforcement and inclusiveness including private company consultation. It is our view that such policies should make use of international reference pricing or external reference pricing (IRP or ERP) in order to take into account different levels of economic development, capabilities of health systems, burden of diseases as well as other factors.


 A graphic with a blue and white geometric background. The text is in blue and orange.
 

**DEFINITION OF MARKET ACCESS: BRINGING OF PRODUCTS OR SOLUTIONS TO THE RIGHT PATIENT AT THE RIGHT PRICE POINTS IN A TIMELY MANNER THROUGH THE EFFICIENT ENABLEMENT OF REGISTRATIONS, REIMBURSEMENT, LISTING, TRAINING AND SUPPLY.**

Mandatory price cuts for pharmaceuticals do not necessarily support governments in their objectives of providing universal health coverage and can also create negative impacts for patients. The use of price controls can be counterproductive as it can discourage investors from operating in a market or from introducing new medicines. Thus, governments should consider alternative and more sustainable solutions rather than short-term price cuts. The EU-ABC would be willing to collaborate with governments to support improved budget management, whilst ensuring continued access to medicines for the benefit of patients.

Referring to reimbursement policies, the procedures for reimbursement listing evaluation should also consider the value of innovation to therapeutic outcomes including real world evidence (RWE) and clinical needs, rather than simply focussing on cost savings. Governments should explore alternative access models for innovative medicines to support budget management and predictability in order to ensure the benefit of timely access and treatment choice of the patients.

To improve market access for healthcare related products and services, the EU-ABC recommends:

- 1. That ASEAN governments create a level playing field for foreign companies consistent with WTO and Bilateral Investment Protection Treaties.**
- 2. The liberalisation of foreign ownership rules to encourage more companies to enter the market, which will drive innovation, quality standards and increase overall investment in the region.**
- 3. The adoption of an ASEAN-wide common regional licensing and regulatory standards that would allow companies to streamline their licensing process and allow them to bring their products and services to market faster.**
- 4. The establishment of transparent procedures in pricing and reimbursement with industry inclusiveness and consultation would be important to ensure the market environment for investment.**
- 5. That national governments should consider the value of innovation to therapeutic outcomes including real world evidence (RWE) and clinical needs.**
- 6. That alternative access models for innovative medicines be explored to support budget management and increase budget predictability and therefore enhance patient access.**

### **Halal Standards & the Provision of Healthcare**

The EU-ABC recognises that the issue of Halal certification is a sensitive subject for many in the ASEAN region, however the potential introduction of Halal certification for some medical products and medicines does raise the risk of limiting access to medicines since they might become either unavailable or technically inappropriate for many citizens across the region. The EU-ABC fully understands and accepts that people are entitled to protection and freedom of worship, each according to his/her own religion or belief. However, for the sake of public health, it is necessary in this particular context to distinguish between pharmaceuticals (medicines and vaccines) and food, beverages and cosmetics as well as consumer goods where the certification of halal is concerned.

Most drugs are not intended to be consumed upon the free choice of consumers. Medicines, especially prescription drugs, are prescribed to patients by doctors who have the necessary competence and expertise to choose medicines appropriately and in the best interests of the patients' health. Categorising certain pharmaceutical products as non-halal could potentially run contrary to public health objectives and possibly hinder a patient's access to optimal health treatment and disease prevention (vaccines) if doing so could lead either the doctor or patient to decline use of a particular medicine.

Halal certification for biotechnology products, such as vaccines, risks to inspire a growing reluctance among patients requiring treatments. This will lead to under-application of certain vaccines, due to either spiritual observance or doubts about its safety, which will have the unintended consequence of harming public health. Under-vaccination has severe health ramifications at national and international levels as diseases can cross international and community borders just as easily and as frequently as the people who carry them. In the perspective of public health, the safety of pharmaceutical products, not its halal status, is the core issue that

must be guaranteed by the state. For the patients' interest, halal certification could also prolong the time taken for patients to get access to medicine which may harm patients' safety.

EU-ABC would like to reiterate that halal certification should not be made as any mandatory criteria during the marketing authorisation or pharmaceutical procurement process. The same rigorous criteria used by regulatory authorities in the evaluation aspects of quality, safety and efficacy when assessing and approving pharmaceuticals for marketing authorisation should also be the same criteria in procurement in ensuring access to the product by the public.

**The EU-ABC therefore recommends that governments in Southeast Asia should not make Halal Certification mandatory for medicines and healthcare products.**

### ***Private Sector Consultation***

Having adequate and sustainable healthcare financing is one key enabling factor to ensure a greater chance of success in innovation development, due to the market environment. It is important that the government has appropriate and adequate sources of funding since increasing chronic diseases and life expectancies associated with an ageing population tends to drive overall healthcare expenditures up.

This will also ensure sustainable access to healthcare and innovative medicines in the public hospital channel, preserving doctor's choice for treatment outcomes and quality for patients, which require public and private efforts to provide alternative and collaborative solutions in the long term. This should be developed through a multi-stakeholder approach, aiming for sustainable long-term solutions rather than short-term measures, which may result in limiting access to medicines impacting patients and choices of treatments.

In terms of the healthcare industry, it is crucial that both the Pharmaceutical Products Working Group (PPWG) and the Product Working Group for Traditional Medicines and Health Supplements (TMHSPWG) involve the private sector in their work to increase transparency and understanding, as well as to ensure that the latest information is made available to the working groups to assist them with their work.

**EU-ABC recommends more industry consultations or regular dialogues to ensure transparency, involvement, and to enhance sustainable access to medicines with health authorities across the ASEAN region.**

### **Regulatory Affairs**

The regulatory environment plays a major role in patient access to innovative medicines as well as business access in market entry. EU-ABC members are dedicated in ensuring that they are aware of and taking steps to comply with relevant laws, policies, and regulations across ASEAN. The improvement in regulatory environment, in predictability, transparently and international alignment, could enhance the incentive for business to expand more investment in ASEAN region as well as, significantly, benefit ASEAN patients for opportunity of access to better treatment choices.

While our members are committed to compliance, the regulatory requirements across the ASEAN region are fragmented and often country-specific, resulting in our members having to reconfigure their submissions for each country. This regulatory fragmentation acts a restriction to entry to the ASEAN region with companies choosing to enter on specific markets that have clear and efficient regulations.

Another barrier that companies face is many of the regulators in the region have limited capacity for making licensing decision quickly, resulting in long and unpredictable delays for companies in bringing their healthcare products and services to market. The regulator's capacity is limited by the number of staff, the rapidly changing environment in the healthcare industry and lack of resources to conduct their activities in a timely manner.

Finally, there is still a limited number of platforms where regulators and regulatory professionals from companies can meet in a neutral setting to discuss and solve in-depth regulatory issues.

**The EU-ABC recommends that harmonised regulatory standards be adopted across the ASEAN region.**

**The EU-ABC also recommends an increase in regulatory capacity to accelerate approval processes for bringing new products and services to market and deepen engagement with stakeholders.**

**Harmonised approaches to approvals and testing for faster healthcare access**

One of the key objectives of the ASEAN Economic Community is to achieve a “single market and production base”<sup>3</sup>, an overall vision that the AEC Blueprint 2025 supports. To achieve this, ASEAN needs to ensure a harmonised approach to standards and approvals across multiple sectors, including in the healthcare sector. For the healthcare sector, the AEC Blueprint 2025 states that a strategic measure for the region to achieve is the “further harmonisation of standards and conformance in healthcare products and services, such as common technical documents required for registration purposes and nutrition labelling”<sup>4</sup>. This is a welcomed commitment, but progress towards this goal has been slow to date and, arguably, the objective should be to go further.

Some core principles that need to be considered in developing a regional wide framework for regulatory harmonisation include:

- Increased knowledge sharing between regulatory bodies across ASEAN to enhance good regulatory practice;
- Development of regulatory requirements in alignment with international guidance and practices.
- The streamlining of regulatory processes using risk-based evaluations or simplified registration in particular for “over-the-counter” products (OTCs), based on international regulatory practice and scientific standards;
- Ensure consistency in the implementation of ASEAN Common Technical Document (ACTD) / Variation Guidelines to ensure harmonised implementation across countries to avoid occurrence of country specific requirements and differing interpretations;
- Encourage industry and regulator collaboration to speed up consumer/patient access to innovative products, especially by optimising drug registration process that harmonises regulatory requirements with international guidelines (ICH, WHO) and regional practices;
- Increase regulatory efficiency, encourage regulatory authority collaboration or mutual recognition and reduce costs to the ASEAN authorities – to reduce application backlogs and allow for better use of limited resources via the enablement of work sharing amongst the authorities in ASEAN and putting in place consistent regulatory processes across the region.
- Increase institutional expertise within ASEAN health authorities.

Adopting these steps will help benefit regulatory efficiency as would having a strong commitment from competent regulatory bodies to having regular discussions on implementation focus with the private sector.

The Pharmaceutical Products Working Group (PPWG) under the ASEAN Consultative Committee on Standards and Quality (ACCSQ) is the lead ASEAN body working on this issue. Whilst it is recognised and accepted that technical experts will need to agree on specific standards, higher level political and official involvement

## ASEAN COMMON TECHNICAL DOSSIER

ASEAN COMMON TECHNICAL DOSSIER (ACTD) IS A GUIDELINE OF THE AGREED UPON COMMON FORMAT FOR THE PREPARATION OF A WELL-STRUCTURED COMMON TECHNICAL DOSSIER (CTD) APPLICATIONS THAT WILL BE SUBMITTED TO ASEAN REGULATORY AUTHORITIES FOR THE REGISTRATION OF PHARMACEUTICALS FOR HUMAN USE.

<sup>3</sup> See ASEAN Economic Community Blueprint 2015, Section II, Paragraph 6, published 2007

<sup>4</sup> See Section C.7, paragraph 61, sub-paragraph ii of the AEC Blueprint 2025.

will be necessary, especially as some domestic regulatory and legislative changes may be required. **The EU-ABC would welcome a commitment to be consulted by the PPWG on its work.**

The PPWG under the ACCSQ has made some significant strides in putting in place frameworks that should help remove some of the technical barriers to trade of pharmaceuticals across Southeast Asia. The establishment of an ASEAN Common Technical Dossier created a common format and structure for applications for drug marketing authorisations in all 10 ASEAN Member States – though it is only a guideline that “demonstrates an appropriate write up format” for applications, rather than an agreed methodology for approvals or an acceptance that approvals in one regime will automatically lead to approvals in another ASEAN Member State<sup>5</sup>. The PPWG has also established the ASEAN Common Technical Requirements (ACTR) which is a guide that sets out for applicants the common expectations of pharmaceutical regulatory authorities within ASEAN when deciding on marketing authorisation.

**The EU-ABC recommends that to ensure consistency in the implementation of ASEAN regulatory harmonisation across the ASEAN Member States, there should be continuous efforts to reduce country specific requirements and different interpretations.**

### ***Rx-to-OTC Switch***

Part of the aim of the healthcare initiatives under the AEC Blueprint 2025 is to make healthcare more accessible to more people across the region. Despite the natural geographical and infrastructural constraints, and high costs of providing universal healthcare coverage, one area which would allow for increased access to medicines would be to make more pharmaceutical products non-prescription available “over-the-counter” (OTC) as opposed to only being available via prescriptions (Rx) from doctors and physicians.

This would bring benefits not only to patients and healthcare professionals, but also to governments by shifting healthcare resources to other critical healthcare priorities and empowering consumers to treat self-diagnosed and minor illnesses without prescription. Current research shows that significant funds (both direct and indirect) can be saved as a result of wider availability of self-care medicines.<sup>6</sup> While there is limited information available on the ASEAN region, it is estimated that an Rx to OTC switching would provide US\$102 billion in value to the US healthcare system annually.<sup>7</sup> The potential financial savings for Rx to OTC switching in the ASEAN region should, therefore, be equally significant.

There are many types of OTC medicines, many of which have been available globally for a long time and have long track records of safety and efficacy. Examples of such medicines include painkillers for mild to moderate conditions, cough and general cold treatments, drugs for the treatment of minor skin conditions and rashes etc. Others have been more recent additions to the OTC arena, and include medicines for the treatments of conditions such as acid indigestion, cold sores, hay fever and other mild allergic conditions. In many developed countries and regions (e.g. Australia, Europe, New Zealand) there is a graduation in the availability of OTC products, with a split between those readily available and on general sale in convenience stores, those available in self-selection area in drug stores, and those that are available “behind the counter” where there is a need for a pharmacist to provide assistance and guidance to the end consumer.

Some initiatives for a switch from Rx-to-OTC are being undertaken within ASEAN and between ASEAN and certain of its partners – such moves are welcomed. Currently there is an unclear pathway for the Rx to OTC switch in the region and what switches have been allowed have been very limited. However, it is our understanding that the topic of Rx-to-OTC switch is not formally part of the discussion scope of the PPWG.

**It is the EU-ABC’s recommendation that a dedicated ASEAN OTC/non-prescription regulation framework working group be established under the auspices of PPWG and that it will develop and be responsible for the construction of a well-defined non-prescription regulation framework.**

<sup>5</sup> ASEAN Common Technical Dossier for the Registration of Pharmaceuticals for Human Use, p. 3.

<sup>6</sup> The Value of Self-Medication: Summary of existing evidence, Joshua Noone and Christine Blanchette, 2017

<sup>7</sup> Consumer Healthcare Products Association. The value of OTC medicine to the United States [internet]. CHPA; January 2012.

**It is also the EU-ABC's recommendation that the issue of Rx-to-OTC be formally included in the work of the PPWG with the broad aim of formally designating more medicines to be non-prescription medicines for the benefit of patient access across the ASEAN region.**

**In addition, it is recommended that the reclassification framework for Rx-to-OTC switching should be established across ASEAN with clear and consistent criteria, evidence based and risk-benefit based assessments in and focusing on safety and self-medication of products with process transparency and industry dialogues during the reclassification procedure to provide scientific expertise in benefit to evaluation purpose.**

### **Effective Regulatory Data Protection**

The effective implementation and enforcement of data protection provisions or data exclusivity are essential for innovation and development in pharmaceutical sector as this requires substantial financial investment for drug discovery, development, and regulatory approval of innovative medicinal products as well as regulatory data generation to fulfil regulatory requirements and compliances. Therefore, the protection against unfair commercial use of other parties to rely on the data, which have been generated and submitted in the purpose of market authorisation approval of innovative medicinal products, should be considered appropriately.

To date, a regulatory data protection regime has not been established in Indonesia, the Philippines, and Thailand, and enforcement of such regimes is uneven in other countries. And for those countries which the regulatory data protection system has been established including in Vietnam, it would still be required to ensure the effectiveness in implementation to ensure a predictable environment in enhancement of innovation and investment.

**PRESCRIPTION TO NON-PRESCRIPTION SWITCHES HOLD PROMISE FOR GOVERNMENTS BY HELPING TO EASE PRESSURES ON THE FORMAL HEALTHCARE SYSTEM, AS CONSUMERS TREAT MORE OF THEIR EVERYDAY HEALTH CONDITIONS WITHOUT THE COSTS ASSOCIATED WITH THE FORMAL SYSTEM**

**World Self Medication Industry 2009 Report "SWITCH: Prescription to non-prescription medicines switch" Executive Summary, p.3**

Regulatory data protection is not an extension of the patent right or patent term and is not a form of market exclusivity, but provides a limited duration of time to protect the submitted regulatory information and test data of the rightful owner effectively from unfair commercial use by others that rely on the same information.

For innovative medicines, the protection period starts from the new drug registration approval date and is applicable only once for any new drug and only in the case of new active ingredients. It does not prevent the introduction of generic versions of the innovative drug during the data exclusivity period, if the market approval of the generic version does not use or rely upon the innovator's test data.

For Rx-to-OTC switches, additional studies and research post-authorisation of a switch must be undertaken to ensure ongoing consumer safety, so the additional regulatory data protection would generally be applied to incentivise the innovator for additional studies in support of switching evaluation.

**The EU-ABC supports legislation development to provide effective and adequate protection of regulatory data submitted for the market approval of new products and switching products against unfair commercial use in alignment with WTO TRIPS agreement Article 39.3 on data protection.**

### ***Protection and Enforcement of Pharmaceutical Patent Rights***

Based on the current legal system across ASEAN, aside from Singapore, registration of generic products is allowed while the innovator product is still under valid patent protection. Though the marketing of generic products is subject to the condition that it will only be legal upon patent expiry of the original invention, it is the case that the generic products are marketed prior to the patent expiration, whether intentionally or unintentionally. This impacts the sustainability investment of both innovating and generic companies, incurring more cost and time efforts in the event of patent infringements, benefiting none of the parties.

**The EU-ABC recommends that consideration be given to a balancing mechanism in a market authorisation system to ensure adequate and effective protection of patent rights for the innovators, while allowing generic products to be marketed as soon as the innovator patent expires.**

This balancing mechanism would be developed by establishing a system where the generic companies would be informed of the patent status of the medicine to be registered with authorities and that the marketing condition will not be applied until the expiration of the patent. This is to create an effective enforcement system in order to prevent patent infringement that may cause unnecessary business conduct costs as such.

Intellectual Property Protection should be aligned with international obligations to promote innovation and investment for future development of innovative medicines. The EU-ABC would like to urge governments to ensure enforcement and any revisions of patent laws towards this international alignment especially on patentability criteria, patent registration procedure, and compulsory licensing.

On patentability criteria, the incremental innovation will be valuable for the research and development of innovative medicines to improve treatment and health outcomes which should not be discriminated. We would also like to recommend eliminating provisions that would impose new patent disclosure requirements regarding the source and origin of genetic resources. Such requirements would introduce uncertainties into the patent system that inhibits innovation in relevant technologies and undermines the potential of benefit-sharing.

On patent registration procedure, timely patent registration will assure investments towards innovation. Respectively, predictable timeframe in patent approval without unnecessary delay would be important. The patent registration procedure should be streamlined to ensure effectiveness in examination and approval based on international guidance. The government should ensure that the patent opposition system is aligned with this principle to attract the investment towards innovation in the countries.

### ***Traditional and Herbal Medicines***

The AEC process presents an opportunity for ASEAN to put in place common technical requirements, standards and guiding principles across Southeast Asia to encourage better individual health and trade in health products across ASEAN. Such harmonised standards exist in the area of traditional and herbal medicines in other regions, such as in the European Union.<sup>8</sup>

**PATENTS ARE ENGINES OF GROWTH AND ARE CRITICAL TO THE VITALITY OF THE INDUSTRY. THEY CREATE THE INCENTIVE FOR COMPANIES TO MAINTAIN THEIR INVESTMENTS TO FIND NEW AND BETTER CURES FOR GLOBAL HEALTH ISSUES, AND TO IMPROVE THE HEALTH OF PEOPLE AROUND THE WORLD.**

*Loc Xuan Le, Tilleke, 2014*

<sup>8</sup> Directive 2004/24/EC of the European Parliament and of the Council in regards traditional herbal medicinal products, March 2004

Presently within the region, there are differing requirements for testing of herbal medicines, both in terms of the tests required and the standards employed which makes trade within the region challenging and, in some cases, prohibitive.

**TRADITIONAL MEDICINE HAS EXPANDED ITS FOOTPRINT FROM ITS TRADITIONAL TRADE STABLE (MEDICINE HALLS, LOCAL VILLAGE DOCTORS) INTO MODERN TRADE CHANNELS (SUPERMARKETS, PHARMACIES AND CONVENIENCE STORES).**

MATT ZAFRA, OLIVER WYMAN

By way of example, the Thai Food & Drug Administration (FDA) requires special microbial testing for Clostridia. It is the only country in the region to do so. Such tests are cost-intensive but are also largely redundant since nearly all herbal drugs are affected by harmless Clostridia species.

There are also different requirements for testing heavy metals in the region. Some countries accept the European approach of testing on mercury, lead and cadmium in herbal medicines. Others, such as Thailand, require testing the herbal drug and finished products for additional contaminants like arsenic.

The EU-ABC notes and welcomes the ongoing dialogue between ASEAN Member States on common guiding principles with respect to the standards for traditional and herbal medicines. However, after drafting an agreement for the Regulatory Framework for Traditional Medicines in 2017, the agreement has not yet been signed.<sup>9</sup> As part of the ratification process of the Regulatory Framework above, specific changes will need to be incorporated into national laws within a five-year transition period. **The EU-ABC encourages that the**

**Regulatory Framework on Traditional Medicine to be signed and adopted in order to bringing greater certainty to this sector.**

Adopting internationally accepted standards on traditional and herbal medicines would enable an increase in trade between ASEAN and the rest of the world, thus allowing ASEAN producers to compete globally and expand their operations. Common standards would also allow broader availability across ASEAN, thus increasing access and reducing costs for the end-consumer/patient.

### ***Vitamins, Food and Mineral Supplements***

Similar to traditional and herbal medicines, there have been some ongoing discussions in the region on adopting common technical requirements, standards and guiding principles in the area of food, vitamin and mineral supplements. It is important that these discussions are completed, and regulations implemented consistently across ASEAN to gain the true value of a "single market and production base". As with traditional and herbal medicines, at the moment the various health authorities across Southeast Asia are insisting on country-specific requirements that make trade within the region challenging and, in some cases, prohibitive.

Harmonised standards exist in the area of food, vitamin and mineral supplements in other trading regions such as the European Union<sup>10</sup>. They are also within the scope of the harmonised regulation of CODEX Alimentarius, which was ratified via the WTO Agreement on Sanitary and Phytosanitary Measures. Harmonised standards based on internationally accepted standards would allow ASEAN producers to compete more effectively internationally.

Like the Regulatory Framework on Traditional Medicines noted above, in 2017 the ASEAN member states appear to have reached an agreement on the common guiding principles with respect to the health supplements standards, but no regulatory framework has yet been signed.<sup>11</sup> **The EU-ABC encourages that the Regulatory Framework on Health Supplements to be signed and adopted.**

<sup>9</sup> Proposed ASEAN Agreement of Traditional Medicines, 2015

<sup>10</sup> Directive 2002/46/EC of the European Parliament and of the Council of 10 June 2002 on the approximation of the laws of the Member States relating to food supplements.

<sup>11</sup> ASEAN Agreement on Health Supplements, November 2015



Whilst the EU-ABC welcomes the inclusion of food supplements in the scope of regulatory harmonisation in ASEAN, it is a concern that further delay of this adoption of the Regulatory Framework on Health Supplements will result in ASEAN member countries taking different approaches to certain topics which will add to complexity, costs and potentially a lack of access for end users.

## Health Policies

### ***Self-Care: Improved Individual Healthcare at More Sustainable Costs***

As noted in this document, a challenge for ASEAN member states is the lack of financial sustainability in their healthcare systems due to numerous factors such as aging populations and rising incidences of chronic diseases. In addressing the healthcare sustainability challenges, a self-care concept can contribute to that aspect.

Self-care is a method of promoting better understanding, health literacy, prevention and health care within domestic and community surroundings. The goal of self-care is to reduce the reliance and need to seek advice and treatment from healthcare professionals, thus removing pressure on often scarce and expensive resources from having to treat minor ailments and complaints, allowing medical practitioners to focus on more critical conditions.

Self-medication is a critical component of self-care and a well-functioning health-care system as it is undoubtedly the primary resource for first-line treatment in any health-care system, as espoused by the World Health Organization. It is a treatment of common health problems with medicines especially designed and labelled for use without medical supervision and approved as safe and effective for such use.

Self-care can also result in financial savings that are beneficial to the patient, the healthcare system, and the broader economy. These savings come as a result of lower direct spending (less clinic and doctor visits, less direct payments for prescriptions) and indirect positive externalities (increased productivity of patients, doctors able to focus on higher need cases).

If applied and implemented properly, self-care also promote the benefits of increasing health literacy, thus reducing the instances of infections and diseases though educating communities on the needs for improved hygiene and preventative measures to halt the progress of diseases such as malaria or dengue fever (e.g. through increased use of mosquito nets; removing stagnant water etc.).

**SELF CARE COMPRISES THE ACTIONS THAT INDIVIDUALS TAKE FOR THEMSELVES, ON BEHALF OF AND WITH OTHERS, TO DEVELOP, PROTECT, MAINTAIN AND IMPROVE THEIR HEALTH, WELLBEING OR WELLNESS.**

**[PAGB, A Self Care White Paper: Supporting the delivery of the NHS Long Term Plan.](#)**

However, self-care should not be seen in isolation. It is not a cure-all for the provision of universal healthcare coverage. It needs to be seen and used alongside other measures, such as increased Rx-to-OTC switching which would make more medicines generally available without the need for patients to consult healthcare professionals.

Nevertheless, self-care does have the ability to provide significant efficiencies in the delivery of healthcare across ASEAN and contribute to a sustainable healthcare system. As populations age, and as urbanisation continues apace in the region, new healthcare risks and pressures will emerge. Empowering people to begin their healthcare journey with self-care by first taking better care of themselves will relieve some pressure from the healthcare system, allowing scarce and expensive resources to be better focused on more critical needs.

Self-care itself comes in many forms which when taken together will reduce costs for the state and enhance peoples' lives. Providing education on the development of healthy lifestyle choices (e.g. increased exercise and healthier diets) will increase understanding and promotion of the maintenance of good health. Self-care should also include increased knowledge for the general populace on the effective use of medicines and

healthcare interventions, including the use of self-diagnosis through the availability of proper information and self-care learning tools (perhaps through applications on smartphones) and then self-treatment through the responsible use of OTC medicines for the treatment of minor ailments.

WORLDWIDE DIGITAL HEALTH MARKET  
TO HIT \$504.4 BILLION BY 2025.

Global Market Insights Inc. 2019

**The EU-ABC recommends that ASEAN develop a regional policy blueprint to promote greater self-care across the region.**

Such a blueprint could include the following elements:

- A regional definition and framework for self-care to inform and guide self-care research and policy reforms;
- Guide the population of the region to help themselves through promoting greater self-care literacy using digital tools and applications;
- Entrench self-care into overall health and education policies through changes to school curricula and greater investments in health promotion and disease prevention campaigns;
- Increased institutional knowledge and leadership capacity to promote self-care, especially in the less developed and remote or isolated parts of the region;
- Greater encouragement for healthcare professionals to promote and facilitate self-care;
- Development of closer collaboration between the public and private sectors to promote self-care.

### ***Digital Health Initiatives***

Digital health is the use of electronics technology to help improve individuals' health and wellness. Digital health can cover everything from electronic records to wearable devices, from artificial intelligence to sensors, and as a means for educating the broader population about healthy behaviours. Digital health initiatives are just as diverse with companies focused on preventing disease, helping patients monitor and manage chronic conditions, lowering the cost of healthcare provision, and tailoring medicine to individual needs.<sup>12</sup>

When the high mobile penetration rates, improving internet infrastructure and increasing number of mobile users in the ASEAN region are combined with the rapid developments in healthcare technology, digital health initiatives represent a method for supplementing the delivery of health care services across a wide geographic region. Digital initiatives would allow for informed patients to be dealt with more efficiently, and apps that help patients manage their conditions from home could ease the strain on healthcare resources.

Finally, digital health initiatives would help ASEAN countries to meet their goals of working with the industry to provide better healthcare facilities, products and services, and affordable and quality healthcare as laid out in the AEC Blueprint 2025.

The introduction of digital health technologies and initiatives has also meant new challenges for public policy makers. Perhaps most difficult for governments is that many of these new challenges are not in the healthcare sector but in the technology and innovation sectors. As more services are delivered and information regarding patients are stored electronically, the issues of cybersecurity, privacy and data governance as related to patients and the health industry must be designed to protect individuals' information, allowing for interoperability between various systems and devices, and to help maintain trust in the system.

A second major challenge for the new and growing sector is the divergence of regulations covering digital health services, products and initiatives. While some divergence is expected as different countries move at various speeds, if ASEAN countries can develop a common regional regulatory system for digital health, then it will have an opportunity to gain greater benefits of these new technologies on behalf of the population.

Digital health represents a new and potentially transformative way of delivering healthcare if the correct policies are in place. The EU-ABC is committed to working with ASEAN and national governments in

<sup>12</sup> "What is digital health?", Jo Best. ZDNet.com, February 2019.

supporting them in developing their policies for digital health. While the specific technical recommendation relating to cybersecurity, privacy and data governance are outside the scope of this paper, **the EU-ABC recommends that the relevant rules and policies be developed and adopted at a regional level rather than at the national level.**

**The EU-ABC also recommends that ASEAN continues to take steps to lower barriers for digital healthcare products and services while developing a common regulatory framework that the countries of ASEAN can adopt.**

### ***Medical Nutrition***

Health and social care systems that are put in place to meet the regional goals should as much as possible be aimed at improving patient outcome whilst providing economic benefits. In this regard, **the EU-ABC recommends ASEAN to put more emphasis on the adoption of nutritional therapy to complement the existing healthcare mechanisms in the region, and also to synergise with significant investment, e.g. into R&D by food companies in the region by leveraging the value of nutrition for an ageing population or non-communicable chronic diseases.**

Nutrition intervention in the management of disease-related malnutrition has consistently been shown to be significantly benefiting both for patients and healthcare systems. In developing a regional healthcare framework, it would benefit the region if ASEAN could also include the development of a clearly defined regulatory framework for medical nutrition (in alignment with CODEX standards) to ensure appropriate and accessible solutions for healthcare professionals and patients who, due to disease or medical condition, are unable to meet their nutritional needs through normal diet, who have distinctive nutritional requirements secondary to disease or medical condition, or whose nutritional status and health can be improved by employing medical nutrition.

There is a growing body of evidence from individual studies and meta-analyses demonstrating the benefits of oral nutritional intervention with medical nutrition in improving nutritional status, reducing adverse health outcomes, and reducing the economic burden of malnutrition on society.

Evidence-based national, international and professional guidelines for oral nutritional intervention with medical nutrition in general and specific patient populations are also widely available. However, the implementation of good nutritional practices remains ad-hoc, and poor awareness of the value of nutritional care, and especially medical nutrition, is prevalent. In combination with pressure on finite healthcare budgets which threatens funding for nutritional care, this will lead to poorer health outcomes and higher healthcare costs in the long run.

### ***Other Health Aids***

Other products, such as sun creams, can also be considered as healthcare products as they help to prevent certain diseases and medical conditions (eg. Skin cancer) and thus encourage better individual health and wellness. For items such as sun creams, SPF limits, UVA and UVB guidance, and ingredient acceptability are areas where some form of harmonised approach in ASEAN would bring about benefits to both consumers and producers.

**The EU-ABC recommends that ASEAN countries adopt a harmonised approach to other health aids that provide benefits to patients.**

### ***Public-Private Healthcare Initiatives***

As more countries in the region move towards providing Universal Health Coverage and face expanding healthcare costs, one option that governments in the region are using to guarantee that their citizens are receiving quality medical care is public-private partnership agreements. A public-private partnership (PPP) is a specialised method employed by governments for the delivery of public goods and infrastructure services. PPPs have been widely used by ASEAN member countries since the early 1980s and are to be distinguished

from conventional procurement methods such as design and construction contracts.<sup>13</sup> In the healthcare space, PPPs have been used to deliver clinical services themselves.

ASEAN has acknowledged the importance of PPPs in their 2014 Principles of Public Private Partnership Framework, which recognises that private participation can enhance existing public capacity in providing social infrastructures such as health care.<sup>14</sup> Public-private healthcare initiatives represent an opportunity for governments and private industries to cooperate to provide broader, available and more efficient health care systems to the citizens. Moreover, successful public-private healthcare initiatives like those mentioned in the side bar show that ASEAN countries are already taking advantage of these opportunities.

Despite the acknowledgment that PPPs can lower costs and provide broader healthcare services than those currently available, governments in the ASEAN region appear to be reluctant to engage with the private sector to develop PPPs. National government appear to view that PPPs should be limited to infrastructure building rather than service delivery. By limiting PPPs to infrastructure development only, patients and governments may see higher costs and/or less choice in the provision of health services. Some countries such as Vietnam are starting to move in the right direction by continuing to update PPP regulations in their country while working towards more modern and sustainable PPP frameworks.

In order to be successful, PPPs require clear regulatory direction and certainty. Currently, despite the ASEAN's Principles of PPP Framework, there is often a lack of regulatory direction for PPPs in general and specifically for Public-Private Health Care Initiatives at the national level, which makes companies uncertain about the viability of these projects.

**The EU-ABC recommends that ASEAN governments develop a region-wide set of regulations regarding Public-Private Partnerships for social infrastructure, especially related to the healthcare industry and to engage with the private sector in developing public-private health initiatives in order to deliver better health services to patients.**

**Sustainable Healthcare Financing through Universal Health Coverage and Access to Health Insurance**

Adequate and sustainable healthcare financing is a critical enabling factor to enhance sustainable access to healthcare in order to ensure healthy populations contributing to healthy economic development of the

**PUBLIC-PRIVATE PARTNERSHIPS COULD HAVE THE GREATEST IMPACT. THE CONTRIBUTION OF THE PRIVATE SECTOR CAN BE WIDE-RANGING. IT CAN NOT ONLY RAISE MUCH-NEEDED CAPITAL, BUT ALSO SUPPORT CAPACITY BUILDING FOR DELIVERY OF HIGH-QUALITY HEALTHCARE.**

**Deborah Gildea, Head of Novartis Social Business Asia, 2018**

countries. It is important that the governments manage to have appropriate and adequate sources of funding since increasing chronic diseases and life expectancies associated with an aging population tend to drive overall healthcare expenditures up. This will require public and private efforts to provide alternative and collaborative solutions as a multi-stakeholder approach, aiming for sustainable long-term solutions rather than short-term measures that could result in reduced access for patients.

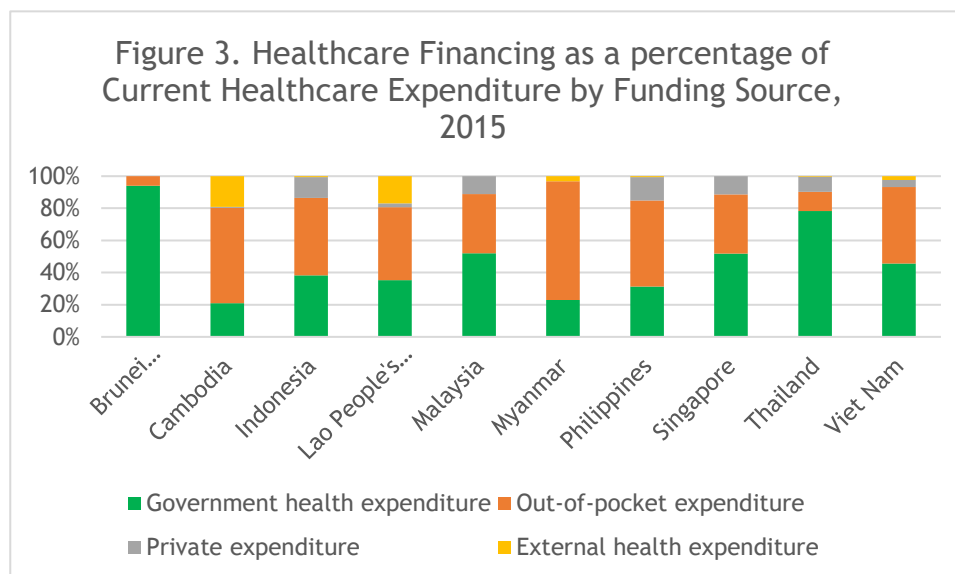
Many ASEAN countries have been moving towards some form of universal health coverage, especially Thailand, Indonesia and, the latest, Philippines. The challenges in sustainable healthcare financing would be not only to ensure adequate financing but also access to innovative medicines in order to meet high medical needs of patients associated with increasing trends of non-communicable chronic diseases including cardiovascular and cancerous diseases.

<sup>13</sup> ASEAN Public Private Partnership Guidelines, Economic Research Institute for ASEAN and East Asia, 2014

<sup>14</sup> ASEAN Principles for PPP Frameworks, ASEAN Secretariat, November 2014

The EU-ABC members have also experienced similar challenges in the other government agencies including in the European countries, and **we recommend that the ASEAN governments explore the alternative options to enhance sustainable healthcare financing which include innovative reimbursement models, new financing models, as well as alternative funding sources apart from the healthcare budgeting and improvement of resource inefficiency.** This could support the sustainable system development to enhance patient access for pharmaceuticals and medical devices and government budget management which EU-ABC would also like to collaborate and share experiences of some solutions from other countries for sustainable system development.

While some ASEAN member countries are working towards a universal health coverage, these countries still face common barriers in achieving this policy goal, including financial constraints due to low levels of government funding. This lack of funding has resulted in individuals in the ASEAN region personally paying higher medical related expenses.



At the moment, citizens in the ASEAN region pay from a low 5% out-of-pocket expenses as a percentage of health expenditure in Brunei to a high of 74% in Myanmar.<sup>15</sup> Across the region, the average ASEAN individual pays 40% out health expenditures out of their own pockets.

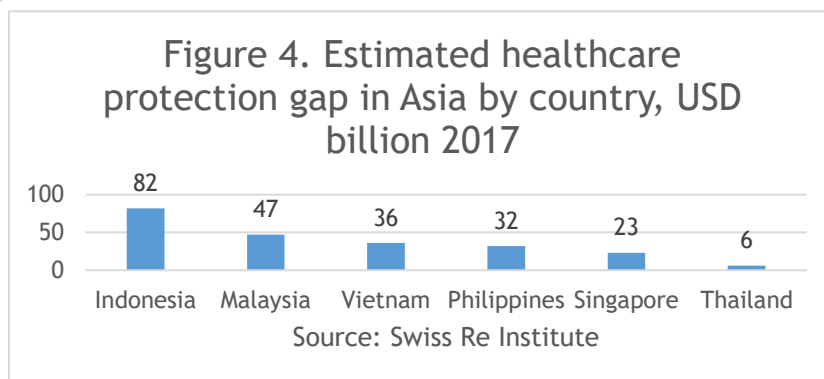
Conversely, private health insurance generally funds a low percentage of total health expenditure, e.g. Vietnam (1%), Singapore (2%) and Indonesia (3%), in contrast with Hong Kong (8%), Australia (9%) and US (34%).<sup>16</sup> The lack of private health insurance to a large extent leads to high out-of-pocket expenditure noted above.

As the ASEAN middle class grows, there is a rising desire for healthcare services, which can be efficiently funded by private health insurance. Private health insurance providers have the relevant expertise and are motivated to manage health cost in collaboration with healthcare providers. Of concern to public policy makers is that the health protection gap is significant and concerning in Southeast Asia. The health protection gap is defined as the sum of financial stress arising from unforeseen, direct out-of-pocket medical expenses and the unaffordable portion that households avoided.<sup>17</sup>

<sup>15</sup> Global Health Expenditure Database, World Health Organization

<sup>16</sup> Ibid

<sup>17</sup> "Asia's health protection gap: insights for building greater resilience", SwissRE, January 2019



According to the most recent research by Swiss Re, Southeast Asia's health protection gap amounts to 10% of the average household income at just under USD 2,000 per household with the average size of the health protection gap as a share of household income is estimated to be highest in Vietnam and Malaysia.<sup>18</sup>

While households face a health protection gap, the rising costs in healthcare provision poses a material threat to the sustainability of the healthcare system for governments. As reflected in the large healthcare protection gap, healthcare is underfunded in ASEAN. The challenge for national governments is that healthcare costs per capita has been rising faster than GDP per capita, putting a growing financial burden on the countries' ability to sustain these expenditures. With an aging population and an increasing demand for healthcare services, it is expected that national governments in the region will continue to face a financial burden on public budget without a viable healthcare funding system in place.

Insurance providers and private health insurance can play a key role in helping to fund the delivery of healthcare services across the ASEAN region. At the moment, the low uptake of private health insurance in the region means that healthcare funding is not optimal for governments or patients.

As laid out in the EU-ABC's 2019 paper titled *Advancing Insurance: Digital Growth & Sustainable Development*, one method for encouraging the uptake of private health insurance is to introduce tax incentives for the purchase of insurance policies. Many ASEAN markets have some incentive for the purchase of life or medical insurance, either by individuals or by companies.

Personal income tax relief is available to individuals in some countries, including Malaysia, Singapore and Thailand in ASEAN, but is not widespread. Countries which provide individual income tax relief for the purchase of life insurance policies have a higher penetration rate than those which do not. While there is a lack of data available on medical insurance in the ASEAN region, it is likely that similar tax relief on health insurance will lead to higher penetration rates and greater coverage for individuals.

**The EU-ABC therefore recommends that ASEAN Finance Ministries look at a range of possible tax incentives to foster the growth of the insurance sector.**

**We also recommend ASEAN member states to collaborate with the private sector to develop a robust, sustainable health funding system that works for patients and other stakeholders.**

<sup>18</sup> "The health protection gap in Asia: a modelled exposure of USD 1.8 trillion", SwissRe, October 2018

## About the EU-ASEAN Business Council

The EU-ASEAN Business Council (EU-ABC) is the primary and sole voice for European business within the ASEAN region.

It is formally recognised by the European Commission and the is an accredited entity under Annex 2 of the ASEAN Charter. Independent of both bodies, the Council has been established to help promote the interests of European businesses operating within ASEAN and to advocate for changes in policies and regulations which would help promote trade and investment between Europe and the ASEAN region. As such, the Council works on a sectorial and cross-industry basis to help improve the investment and trading conditions for European businesses in the ASEAN region through influencing policy and decision makers throughout the region and in the EU, as well as acting as a platform for the exchange of information and ideas amongst its members and regional players within the ASEAN region.

The EU-ABC conducts its activities through a series of advocacy groups focused on particular industry sectors and cross-industry issues. These groups, usually chaired by a Multi-National Corporation, draw on the views of the entire membership of the EU-ABC as well as the relevant committees from our European Chamber of Commerce membership, allowing the EU-ABC to reflect the views and concerns of European business in general. Groups cover, amongst other areas, Insurance, Automotive, Agri-Food & FMCG, IPR & Illicit Trade, Market Access & Non-Tariff Barriers to Trade, and Financial Integration.

### Executive Board

The EU-ABC is overseen by an elected Executive Board consisting of corporate leaders representing a range of important industry sectors and representatives of the European Chambers of Commerce in Southeast Asia. The Executive Board is led by its Chairman Mr Donald Kanak.

### Membership

The EU-ABC's membership consists of large European Multi-National Corporations and the nine European Chambers of Commerce from around Southeast Asia. As such, the EU-ABC represents a diverse range of European industries cutting across almost every commercial sphere from car manufacturing through to financial services and including Fast Moving Consumer Goods and high-end electronics and communications. Our members share a common aim to enhance trade, commerce and investment between Europe and ASEAN.



To find out more about the benefits of Membership and how to join the EU-ASEAN Business Council please either visit [www.eu-asean.eu](http://www.eu-asean.eu) or write to [info@eu-asean.eu](mailto:info@eu-asean.eu).

