

2025 ASEAN DECLARATION OF COMMITMENT ON ASEAN DRUG SECURITY AND SELF-RELIANCE (ADSSR)

Adopted in Kuala Lumpur, Malaysia on 26 May 2025

WE, the Member of the Association of Southeast Asian Nations (ASEAN), namely Brunei Darussalam, the Kingdom of Cambodia, the Republic of Indonesia, the Lao People's Democratic Republic, Malaysia, the Republic of the Union of Myanmar, the Republic of the Philippines, the Republic of Singapore, the Kingdom of Thailand, and Socialist Republic of Viet Nam, stand in solidarity on the occasion of the 46th ASEAN Summit, on 26 May 2025;

RECALLING the achievement of progress since the adoption of the Regional Collaborative Strategy for ASEAN Drug Security and Self-Reliance (ADSSR) at the 15th ASEAN Health Ministers Meeting (AHMM) in May 2022;

REAFFIRMING the commitment of ASEAN on increasing access to safe, efficacious, affordable, quality vaccines and drugs through the operationalization of the ASEAN Leaders Declaration on ASEAN Vaccine Security and Self-Reliance (AVSSR) and the ASEAN Health Sector's priority on the drug security and self-reliance through the Framework of the Regional Collaborative Strategy for ADSSR, and in line with the Chairman's Statement of the 43rd ASEAN Summit 2023 para 103 on the possibility of establishing an ASEAN's capacities in Vaccines Therapeutic and Diagnostic Manufacturing and Research Development, ASEAN Health Sector priorities are contributing towards the implementation of the ASEAN Comprehensive Recovery Framework Broad Strategy 1 on Enhancing Health System. ADSSR is also aligned with the ALD on ASEAN as an Epicentrum of Growth at the 43rd ASEAN Summit 2023, ASEAN Pharmaceutical Regulatory Policy adopted by the AHMM and the ASEAN Economic Ministers Meeting (AEM) in June 2022;

RECALLING that ADSSR is designed based on the work programme listed by ASEAN and is one of the Strategic Plans by ASEAN in the ASEAN Post 2015 Health Development Agenda 2021-2025 under ASEAN Health Cluster 3 (AHC3);

NOTING that:

1. The challenges faced by the ASEAN Member States that are documented in the Situational Analysis and Feasibility of Regional Collaboration to improve Drug Security and Self-Reliance Report was noted by the 15th AHMM in May 2022;
2. Vital findings from situational analysis and feasibility study were utilised to develop the ADSSR Framework and enhance the approach to achieve ADSSR to increase access to safe, efficacious, affordable and quality medicines and to promote holistic health care across the region. The analysis highlights that the ASEAN region, with its growing population, represents a significant pharmaceutical market as a whole.

ACKNOWLEDGING that:

1. All ASEAN Member States have well established pharmaceutical legislations and regulatory authorities and most ASEAN Member States have sufficient capacity to perform national regulatory functions. It is also showed that some ASEAN Member States are involved in the production of pharmaceutical products and active pharmaceutical ingredients (API), and most ASEAN Member States are pharmaceutical exporters with a huge variation in export values.

2. Various methods are being employed by ASEAN Member States to improve medicines affordability. Most countries are using tenders and price negotiations as well as health technology assessment. Sharing information of medicines prices and pharmaceutical suppliers or manufacturers in ASEAN may benefit all ASEAN Member States. On the production, regulation, supply and distribution, procurement and pricing of pharmaceuticals; the analysis also provided a clear picture of the opportunities that may enable ASEAN Member States to work together to improve the access to medicines and self-reliance, such as cooperation in the development or trials of new medicines for diseases unique to the region and collaboration in the manufacturing of needed and prioritized medicines within the ASEAN Member States.

RECOGNISING the importance of aligning regulatory pathways among ASEAN Member States and enhancing collaboration in the procurement and supply of medicine to ensure an uninterrupted and timely supply, especially during public health emergencies, and the need to strengthen communication platforms and information-sharing mechanism among ASEAN Member States to ensure successful collaboration across all domains;

FURTHER NOTING that the key objective of ADSSR is for all ASEAN Member States to cooperate and collaborate within an agreed framework and strategies to improve accessibility and sustainability of drugs; particularly, essential, lifesaving, orphan and non-commercially viable medicines. This is aligned with the vision of the ASEAN Health Sector through the ASEAN Post 2015 Health Development Agenda 2021-2025 and primarily in the ASEAN Health Cluster 3 (AHC 3) Work Programme on Strengthening Health Systems and Access to Care and its health priority on pharmaceutical development. ADSSR also supplements the other priorities of the ASEAN Health Sector on the rational use of medicines, drug price transparency, vaccine security and self-reliance, combating substandard and falsified medicines, access to antidote, anti-toxin and anti-poison and addressing antimicrobial resistance.

REAFFIRMING the endorsement of the Framework for Regional Collaborative Strategy for ADSSR by AHC 3 on 15 September 2021 and by the Senior Official Meeting for Health Development (SOMHD) on 11 October 2021 as well as the subsequent adoption by the 15th AHMM in Bali, Indonesia on 11 to 15 May 2022, reflect the need for political will, leadership and meaningful partnerships with relevant national, regional and global stakeholders in order to address the healthcare needs of most vulnerable populations in ASEAN.

NOTING that the ADSSR Framework serves as a reference for ASEAN Member States and various stakeholders across the ASEAN region and globally to coordinate and contribute to this regional effort, encompassing collaborative efforts across three (3) important scopes:

- a. Access to essential medicines, non-commercially viable medicines (such as orphan medicines and antidotes), and high-cost medicines and biological products;
- b. Ensuring availability during public health emergencies and at all times; and
- c. Covering the entire process from production, registration, and procurement to distribution and supply chain management.

ASSERTING that ADSSR is a complementary measure to enhance respective efforts of ASEAN Member States to implement national legislations and priorities in order to address accessibility, affordability and sustainability concerns related to medicines, especially during emergency situations such as disasters, epidemics and pandemics.

RECOGNISING that, while remarkable efforts have been made to improve the accessibility of medicines in ASEAN Member States communities, especially during the COVID-19 pandemic, millions of people from low- and middle-income countries still lack access to safe, efficacious, quality-assured and affordable medicines. The lessons learned from COVID-19 present a window of opportunity to enhance the resilience of health systems and healthcare service delivery across ASEAN Member States, advancing towards improved universal health coverage (UHC).

WE HEREBY DECLARE our commitments to ASEAN Drug Security and Self-Reliance, and the Framework on Regional Collaboration for ADSSR to:

1. **CREATE** opportunities for ASEAN Member States to collaborate and cooperate at the regional level through the operationalization of the Framework for Regional Collaborative Strategy for ADSSR and establishment of feasible mechanisms and systems to improve regional drug security.
2. **STRENGTHEN** the continuum of medicine's life cycle from production, registration, procurement and distribution to ensure uninterrupted supply chain and availability of safe, efficacious and quality-assured medicines at all times. This may be achieved through an enhanced platform of communication and data sharing related to this priority to ensure successful collaboration across all domains.
 - a. Regulatory pathways alignment among ASEAN Member States and collaboration in the procurement and supply of pharmaceutical products*,¹ especially during public health emergencies. This will ensure uninterrupted and timely supply of pharmaceutical products* among the ASEAN Member States. Regulations and legislations should be in place to allow the use of unregistered products during public health emergencies in some countries.
 - b. Improvement in supply and distribution of medicines, especially for orphan and non-commercially viable medicines in ASEAN Member States. Fast-track mechanisms such as exemption of product/ medicine registration during public health emergency has been applied by a few countries while the others ensure that enough buffer stock of selected items are kept by the concession company to ensure continuous supply.
 - c. Cooperation on R&D for the development or trials of new medicines for diseases unique to the region and collaboration in the manufacturing of needed medicines that meet quality standards within ASEAN Member States are two feasible mechanisms to improve ASEAN's self-reliance to ensure the availability of essential medicines.
 - d. Potential collaboration on the development of a regional medicine pooled procurement system, considering possible regional limitations. This is essential to increase negotiation power and maximize cost-saving in all ASEAN countries especially with the

¹ *Pharmaceutical product:

a. Any substance or combination of substances presented for treating or preventing diseases in human beings or

b. Any substance or combination of substances which may be administered to human beings with a view to making a medical diagnosis or to restoring, correcting or modifying physiological function in human beings. Pharmaceutical products include, for example, chemical medicinal products, biological medicinal products (e.g. vaccines, /anti/toxins/biopharmaceuticals), including medicinal products derived from human blood or human plasma, advance therapy medicinal products (e.g. gene therapy medicinal products, cell therapy medicinal products), herbal medicinal products and radiopharmaceuticals. Each ASEAN Member State may define the scope of pharmaceutical products subject to its laws and regulations for pharmaceutical products in its territory respecting common principles.

help of existing information sharing platform such as Price Information Exchange for Medicines (PIEMEDS). Mutual understanding needs to be strengthened among ASEAN Member States and between the private and government sectors in every ASEAN Member States.

3. **PLEDGE** to ensure the involvement of all ASEAN Member States. This commitment will present opportunities and benefits from collaboration in grouped-production or grouped-purchasing of medicines from and for the ASEAN region, rather than sourcing from the non-member countries.
4. **COMMIT** to periodic strategic and operational monitoring and evaluation reviews at national and regional levels, to ensure progressive achievement and realization of ADSSR.
5. **TASK** the ASEAN Health Ministers to cooperate with ASEAN Ministers and other relevant sectoral bodies and other relevant stakeholders to implement this Declaration mobilise resources, monitor and report on progress, using all appropriate instruments based on national laws and policies.

ADOPTED at Kuala Lumpur, Malaysia, this Twenty Sixth Day of May in the Year Two Thousand and Twenty-Five, in a single original copy in the English language