



In Focus: A Progress toward Single ASEAN Pharmaceutical Market



The disrupted supply chain and the surge of Covid-19 pandemic have led to shortages of medical supplies and equipment. This highlighted the needs to strengthen supply-chain of pharmaceutical products to ensure a timely access of pharmaceutical products to ASEAN people. Policy reforms are necessary to address trade barriers in the trade of pharmaceutical products such as the registration procedures that could take few months to years and the different interpretations of the principle-based standards or regulation amongst different AMS. Particularly as research from Economic Research Institute for ASEAN and East Asia (ERIA) in 2021 showed that production of pharmaceuticals in ASEAN is highly internationalised and relies heavily on the Global Value Chain (GVC).

Recognising this need, the ASEAN Economic Ministers and ASEAN Health Ministers adopted the ASEAN Pharmaceutical Regulatory Policy (APRP) on 15 June 2022. The APRP aimed to (i) provide a basis for structuring regulatory systems for pharmaceutical products across ASEAN, (ii) support the measures adopted for removal and reduction of technical barriers to pharmaceutical products trade, (iii) strengthen cooperation among ASEAN National Regulatory Authorities to combat falsified pharmaceutical products and provide access to high quality, safe, and efficacious pharmaceutical products in ASEAN.

About the Bulletin

ASEAN for Business is a bulletin published by the Enterprise and Stakeholder Engagement Division of the ASEAN Secretariat.

This monthly bulletin provides quick updates on specific topics related to the ASEAN Economic Community (AEC) for businesses operating in the region.

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Scope of the ASEAN Pharmaceutical Regulatory Policy (APRP)



The development of the policies, approval, & recognition arrangements, harmonised regulatory requirements, & practices governmental institutions.



Human Pharmaceutical Products, placed on the AMS market, such as: vaccines, antidotes, and other critical or life-saving pharmaceuticals, including the non-marketed pharmaceutical products for emergency situations.



All activities related to the development, testing, manufacture and distribution of pharmaceutical products.

The APRP does not apply to:



Veterinary pharmaceuticals and other categories of health products such as medical devices, traditional medicines, health supplements, and cosmetics.

Principles of the ASEAN Pharmaceutical Regulatory Policy

(i) Integrated “Life-Cycle” Approach

APRP guides regulatory and control systems to supervise and evaluate all relevant aspects of pharmaceutical medicine development, including the pre-clinical and clinical testing, sourcing of materials, production, placement on the market and withdrawals, distribution, product related information, post-marketing oversight, use, and disposal.

(ii) Harmonised Standards and Good Practices

APRP encourages AMS to harmonise technical requirements, standards, practices, and guidelines to be aligned with the international standards, practices and guidelines for pharmaceutical products, including those developed by World Health Organization (WHO), Organisation for Economic Co-operation and Development (OECD), International Council for Harmonisation (ICH) and Pharmaceutical Inspection Convention

and Pharmaceutical Inspection Co-operation Scheme for Pharmaceutical Products (PIC/S).

(iii) Legislation for Pharmaceutical Regulation

APRP requires all AMS to ensure, to the furthest extent possible, that national pharmaceutical legislation is comprehensive, up to date, covers all necessary elements, and aligned with international and ASEAN Agreement whenever applicable.

(iv) Regulatory assessments, inspections, and testing

APRP guides AMS to grant marketing authorisation for pharmaceutical products that conform to the available ASEAN harmonised technical regulatory requirement, international standards, practices, and guidelines.

(v) Collaboration to increase effectiveness and efficiency

To increase efficiency and reduce duplication, APRP encourages ASEAN National Regulatory Authorities to establish an effective arrangement to closely collaborate with all relevant stakeholders.

(vi) Strengthening and Harmonisation of Regional and National Pharmaceutical Regulatory Systems

APRP advises AMS to allocate adequate resources to implement the APRP and to eliminate unnecessary regulatory and administrative barriers to intra-ASEAN pharmaceutical trade.

(vii) Transparency and Information Sharing

Finally, APRP also requests all AMS to effectively communicate policies, plans, and regulations with all stakeholders at national and regional levels in transparent manner.

Benefit for Business

Once implementation instruments are in place the harmonisation of the regulatory processes among AMS will:

- provide a strong incentive to pharmaceutical companies as it will standardise requirements and will allow them to launch their products in a number of markets simultaneously.
- significantly eliminates non-tariff barriers to pharmaceutical trade in ASEAN and further integrate ASEAN into one single pharmaceutical market
- increase investor’s confidence as market access becomes increasingly transparent and unified.

HIGHLIGHTS FROM THE 54th MEETING OF THE ASEAN ECONOMIC MINISTERS (AEM) AND RELATED MEETINGS

The 54th Meeting of the ASEAN Economic Ministers (AEM) and Related Meetings were held from 13-18 September 2022 to take stock of the progress in advancing and further strengthening the ASEAN Economic Community since the 53rd AEM Meeting in 2021. The meeting has noted updates and endorsed initiatives as highlighted below:

BUILDING BACK BETTER FROM THE COVID-19

The region has made remarkable progress from the reopening to recovery phases of the pandemic

In 2021, ASEAN recorded 3.4% economic growth. The momentum is expected to be sustained with an estimated growth of 5% in 2022 and 5.2% in 2023 supported by strong economic fundamentals.



ASEAN's merchandise trade reached USD 3,340.6 billion in 2021, a 25.2% increase from 2020.



Inflows of Foreign Direct Investment (FDI) in ASEAN reached USD 174.1 billion in 2021, a 42.3% increase from 2020.

ENHANCING ASEAN'S SUPPLY CHAIN RESILIENCE

The ongoing efforts to expand the list of goods under the Memorandum of Understanding (MoU) on the Implementation of Non-Tariff Measures on Essential Goods under the Ha Noi Plan of Action and its extension until Nov 2024.



More trade facilitation activities including in the areas of ASEAN Single Window (ASW), ASEAN Customs Transit System (ACTS), Non-Tariff Measures, the Mutual Recognition Arrangement (MRA) of Authorised Economic Operators.



The study on enhancing container processing procedures in a number of ASEAN Member States to improve ASEAN's logistic competitiveness.



FUTURE-PROOFING OF ASEAN'S TRADE AGREEMENTS

Finalisation of the Guiding Principles for the ASEAN Trade in Goods Agreement.



Preparation for the signing of the Protocol to Amend the ASEAN Movement of Natural Person Agreement in 2022.



Launch of the negotiations for the ASEAN Framework Agreement on Competition.



Transition to a two-annex negative list in accordance with the future Fifth Protocol to Amend the ASEAN Comprehensive Investment Agreement (ACIA).



HARNESSING ASEAN'S DIGITAL TRANSFORMATION

Agreement to expedite the study for the Digital Economy Framework Agreement (DEFA) with negotiations expected to commence as soon as possible.



MOVING TOWARDS A SUSTAINABLE ECONOMY

The Work Programme to support the implementation of the Framework for Circular Economy for the ASEAN Economic Community.



The Concept Note for ASEAN Strategy on Carbon Neutrality which provides an orderly, inclusive, and safe transition pathway that complements AMS' efforts under Paris Agreement.



LEVERAGING THE GLOBAL ASEAN

Progress in the upgrade negotiations for AANZFTA with a view to substantively conclude the agreement in 2022.



Activation of the ASEAN-India Trade in Goods Agreement (AITIGA) Joint Committee to review the AITIGA.



Finalisation of the Joint Feasibility Study Report to enhance the ASEAN-China Free Trade Agreement (ACFTA 3.0).



The Inaugural RCEP Ministers' Meeting, the first since the entry into force of the Agreement



The on-going ASEAN – Canada Free Trade Agreement negotiations.



Upcoming Events

8th ASEAN Economic Community Dialogue

Jakarta,
5
October 2022

9th ASEAN Coordinating Committee Working Group on Public Health Emergencies (ACCWGPHE) Meeting

Phnom Penh,
6
October 2022

28th ASEAN Transport Meeting

Bali,
14-17
October 2022

8th ASEAN Economic Community (AEC) Dialogue



8th ASEAN ECONOMIC COMMUNITY DIALOGUE

PROMOTING THE GROWTH OF DIGITAL START-UP ECOSYSTEM IN ASEAN

Wednesday, 5 October 2022
10:00 - 12:30pm (GMT+7)
Jakarta, Indonesia | Hybrid

Scan to register:



Mr. Soe Thein
Permanent Secretary
Ministry of Transport and
Communications, Republic
of the Union of Myanmar,
and Chair of ASEAN Digital
Senior Officials Meeting



H.E. Satvinder Singh
Deputy Secretary-General
of ASEAN for ASEAN
Economic Community



Bernardino Vega
Chair of ASEAN Business
Advisory Council Indonesia



Dr. Ming Tan
Founding Executive
Director, Tech For Good
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Paula Paw
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