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ASEAN Pharmaceutical Regulatory Framework (APRF)

Introduction

The ASEAN Pharmaceutical Regulatory Policy (APRP) was adopted by the Ministerial Bodies responsible for health and economy to provide ASEAN Member States a common reference to further develop the pharmaceutical sector with enhanced availability of safe, efficacious and quality pharmaceuticals. As ASEAN integrates the pharmaceutical sector, the APRP provides the basis for collaboration between national regulatory authorities for pharmaceuticals and establishes a common purpose across the relevant ASEAN Sectoral Ministerial Bodies and their subsidiary bodies. This will facilitate the development of a sustainable and robust regulatory framework for pharmaceuticals within the ASEAN region.

The ASEAN Pharmaceutical Regulatory Framework (APRF) is aimed at providing a coherent and integrated approach and will link the initiatives in this sector in a legal framework, towards closing gaps and ensuring quality, safety and efficacy across the lifecycle of pharmaceuticals. The APRF will build upon the existing commitments and initiatives in order to provide a structure and the legal and organisational instruments to realise the targets as set for the sector.

ASEAN Member States will implement the APRF through progressive actions upon adoption of the legally binding APRF Agreement. The implementation will be enabled through the development of an implementation plan and mechanism established through consultation coordinated by the Member States' representatives to the ASEAN Pharmaceutical Product Working Group (PPWG) and ASEAN Health Cluster 3 (AHC3) and with other relevant stakeholders. The consultations will include the development and establishment of an implementing legal instrument (APRF Agreement). The consultations will include considerations for the governance of the APRF and its structure, composition and operations. It is intended that the APRP provides the underlying principles for the realisation and operation of the APRF. This Framework will link National Regulatory and Health Authorities and other related institutions in ASEAN to establish an arrangement that enables close cooperation and collaboration to achieve the common agreed objectives for the Framework.

Fundamentals, Objectives and Operations of the ASEAN Regulatory Pharmaceutical Framework

ASEAN Pharmaceutical Regulatory Framework

The APRF builds upon the Member States' existing commitments in order to provide a structure and the instruments to realise the integration of the pharmaceuticals market in the region, high level of protection of public health and a comprehensive

collaboration between National Regulatory Authorities of Member States while ensuring enhanced product quality, safety and efficacy.

The APRF is envisioned to be an ASEAN regulatory system of governance, legislative, institutional, organizational and procedural measures and standards to achieve the ASEAN pharmaceutical regulatory objectives of:

- An integrated ASEAN market of pharmaceuticals; and
- Assured availability of quality, safe and efficacious pharmaceuticals in ASEAN.

The APRF will be made operational through a collaborative arrangement of ASEAN National Regulatory Authorities and Health Authorities as defined in the APRF Agreement.

The arrangement will take into consideration all existing relevant initiatives of the PPWG and AHC3 including mutual recognition arrangements (MRAs), harmonisation of technical requirements and other cooperation and collaboration initiatives. It is intended that this arrangement facilitates the realisation of the principles of the APRP including the pooling of resources, sharing of information, regulatory cooperation and development of recognition arrangements.

Additional communication procedures and platforms, including databases, shall be developed to ensure effective sharing of regulatory information within the collaborative arrangement. Sharing and handling of commercially sensitive and proprietary information shall be enabled by the appropriate confidentiality agreements when necessary and by implementing adequate protective measures.

The management of the APRF will be overseen by a coordinating committee to ensure that the operational functions are implemented and administered in a coordinated manner with common procedures wherever these are required.

The APRF will be implemented through the APRF Agreement, which will comprise a governing mechanism, rights and obligations of Member States and the operating rules for activities related to pharmaceutical regulation, with roles assigned to relevant ASEAN bodies.

Scope of the ASEAN Pharmaceutical Regulatory Framework Agreement

The APRF Agreement will encompass principles, legal arrangements, requirements, processes and a coordinating mechanism for the implementation of the APRF. The APRF Agreement will include provisions ensuring quality, safety, efficacy and control of pharmaceuticals in ASEAN through an integrated “life-cycle” approach which considers all relevant aspects of development (including preclinical and clinical testing), sourcing of materials, production, placement on the market and market withdrawals, distribution, product-related information, post-marketing oversight (including market surveillance and pharmacovigilance), use and disposal.

The APRF Agreement will not apply to veterinary pharmaceuticals and to other categories of health products such as medical devices, traditional medicines, health supplements and cosmetics, which are subject to other ASEAN Agreements. It does not apply to regulation of pricing of pharmaceutical products.

The APRF Agreement will not prevent an individual ASEAN Member State and its health authority to adopt specific measures in emergency and special situations identified by and relevant to such Member State.

Objectives of the ASEAN Pharmaceutical Regulatory Framework Agreement

The APRF Agreement is intended to:

- Provide a basis and framework to ASEAN Member States and their National Regulatory Authorities to facilitate the development of harmonised strategies that enhance national regulatory systems and expedite market integration initiatives;
- Facilitate the implementation of existing measures and the adoption of additional measures for removal or reduction of technical barriers to intra ASEAN trade in pharmaceutical products by Member States in order to develop an integrated ASEAN market of pharmaceuticals and to enhance ASEAN Member States' pharmaceuticals security and self-reliance;
- Ensure timely access to high quality, safe and efficacious pharmaceutical products and their availability through transparent and accountable procedures in order to support healthcare systems in ASEAN and protect public health;
- Enhance efficiency and effectiveness of regulatory practices in ASEAN by strengthening collaboration among ASEAN National Regulatory Authorities in regulation of pharmaceutical products, including vaccines, antidotes and other critical or life-saving pharmaceuticals based on harmonised regulatory and technical standards, practices and guidelines; and
- Strengthen cooperation among ASEAN National Regulatory Authorities in combating pharmaceutical products and pharmaceutical operators non-compliant with relevant legislation and regulatory requirements.

Outline of the instruments within the APRF Agreement

The APRF Agreement will be developed to define the general obligations and rights of Members States for the implementation and operation of the APRF. The APRF Agreement will include provisions for systematic and coordinated development of supplementary legal instruments and other supporting instruments as required for the harmonization and implementation of specific measures within the scope of the APRF. The adoption of this strategy will ensure consistency and homogeneity of approaches across ASEAN to facilitate the achievement of the objectives of the APRF. Thus, it will ensure the alignment of regulatory initiatives with the principles of the APRP,

strengthening of the institutional landscape and coordination between all parties involved.

The APRF Agreement will include:

- Provisions for the governance of the Framework;
- Provisions for the development and maintenance of a collaborative arrangement of ASEAN National Regulatory Authorities and Health Authorities coordinated by the PPWG and the AHC3 in their respective areas of competence. This will include common rules, structures, legal instruments and operating procedures;
- Provisions to ensure that Member States' pharmaceutical regulatory systems and their components are capable to address in a coordinated manner all aspects of the pharmaceutical life-cycle, that adequate resources are allocated and that all the components of the system function effectively and efficiently in line with established ASEAN policies and practices as well as other relevant international or ASEAN common requirements for pharmaceuticals;
- Provisions for national regulatory bodies to participate in initiatives established to attain the APRF's targets in compliance with common principles and procedures. In this regard, ASEAN Member states with advanced pharmaceutical regulatory systems would be encouraged to provide technical assistance on a bilateral or multilateral level; and
- Provisions to develop and implement binding arrangements, which are set out such that when compliance of national pharmaceutical regulatory systems or their components with principles of the APRF is achieved, within a defined scope, then national regulatory systems or their components are considered as equivalent.

The APRF Agreement will enable specific requirements for all relevant aspects of the life cycle of pharmaceutical products to be defined in the dedicated supplementary legal instruments (protocols). These instruments would be a constituent part of the APRF Agreement.

Upon realisation of the APRF, mutual recognition or equivalence arrangements with other countries, regions or relevant international bodies like the World Health Organisation may be considered using established mechanisms and procedures in ASEAN to facilitate ASEAN economic integration and improve availability and access to needed medicines.

Arrangements for the development of the APRF Agreement

The APRP and APRF documents will provide the basis for the development of the APRF Agreement, which will be a legal document defining for ASEAN cooperation in pharmaceutical regulation and trade.

The PPWG and AHC3, as subsidiary bodies under ASEAN Economic Ministers and ASEAN Health Ministers, will undertake the development of the legal instruments for implementation of the APRF. The APRF Agreement, as the umbrella legal instrument, will be developed through the establishment of a Task Force comprising representatives nominated by the Member States. The roles of Task Force will be specified in a terms of reference.

The APRF Agreement will include a provision for the establishment of a coordinating committee with the assigned responsibility of coordinating the implementation of the APRF Agreement and its associated implementing instruments. The coordinating committee will be established and collectively governed by ASEAN Member States. The coordinating committee will provide guidance on the development and implementation of initiatives through common and coordinated approaches. The roles of the coordinating committee will be specified in a terms of reference to be developed by the APRF Task Force.
