

Technical Specification – Pharmaceutical Development (HP 18)

Access to safe, effective, and affordable medicines and health products is a cornerstone of resilient and responsive health systems. Health Priority 18 (HP 18) on Pharmaceutical Development focuses on strengthening the pharmaceutical sector across ASEAN through improved regulatory systems, local production capacity, quality assurance mechanisms, and equitable access to essential medicines and vaccines. These efforts support not only national health goals but also regional preparedness and response to health emergencies.

Projects intending to contribute to HP 18 should demonstrate that they have taken into account the following general, global, regional and national considerations.

General

- Overarching themes:
 - Rationale use of medicines
 - Combating substandard and counterfeit medicines
 - Equitable access to affordable medicines, therapeutics, and biologics
 - Evidence improved on the benefits and uses of traditional and complementary medicines

Global

- Refer to the United Nations Human Rights, Office of the High Commissioner "[Access to medicines, vaccines, and other health products](#)" for activities and guidelines that promote equitable access
- Refer to the Global Initiative on Health and the Economy "[Driving Equitable Access to Health Products and Technologies](#)" for activities and guidelines that promote equitable access
- Refer to the WHO's [Access to Health Products and Medicines](#) for resources and standards to guide ideas to improve access
- Refer to the WHO's resources for [substandard and falsified medical products](#) to learn about the problem, challenges, and some approaches to help combat it
- Refer to the British Medical Journal article titled "[Interventions to combat or prevent drug counterfeiting: a systematic review](#)" to understand different approaches for combating counterfeiting
- Refer to the WHO's [Traditional, Complementary, and Integrative Medicine](#) for resources to help design activities to increase the evidence of use of alternative therapies
- Use the WHO's [global report on the use of traditional and complementary medicine](#) to identify activities that may improve equitable access to safe, quality and effective traditional and complementary medicine services that can potentially meet communities' needs and build sustainable and culturally sensitive primary health care.

- Refer to advanced regulatory agency listings of licensed medical products to determine the regulatory approval status of drugs, biologics, and vaccines. Examples include the [United States Food and Drug Administration agency](#), [European Medicines Agency](#), and the [UK Medicines and Healthcare Products Regulatory Agency](#).

Regional:

- Refer to the [AHC 3 Work plan for Cluster Priority 18 \(Pharmaceutical development\)](#)
- *"ASEAN Action Plan for combating substandard and falsified medicines"*
- Refer to the WHO document titled *"National policies for safety of medicines in the Asia Pacific region"* to understand policies of specific countries in the region to aid in developing activities
- Refer to WHO's guidance for [essential medicines](#) in South East Asia to guide intervention design
- Refer to the *"ASEAN Strategic Framework to Combat AMR (2019-2030)"* to align activities with its six strategic objectives.
- Use resources provided by the [South-East Asia Regulatory Network](#) to obtain current information and knowledge of medical product regulation and to participate in workshops and events.
- Reach out to WHO or FAO regional offices to learn of any relevant regional initiatives to complement or collaborate with.

National

- National regulations on approval of medical products including traditional and complementary medicines
- National guidelines on ensuring access to Universal Healthcare
- National regulations on counterfeit and substandard drugs
- National regulations for Good Manufacturing Practice for medical products
- National AMR stewardship policies and regulations
- Antibiotic prescription and use regulations issued by the National Regulatory Authority or Medicines Control Agency (human and animal use)