

Unit 4: Emerging Markets and the World Health Organization

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4.1 Emerging markets: what the term means in regulatory work

In regulatory usage an **emerging market** is a market whose regulatory system is developing toward the stringent model: laws and agencies exist, dossiers are required, but assessment depth, inspection capacity and post marketing systems vary, and reliance on the decisions of stringent authorities and of WHO is a structural feature rather than an embarrassment. The regulated versus semi-regulated contrast of the subject's scope is best read as a spectrum. At one end stand the stringent regulatory authorities of Units 1 to 3, whose approvals others rely on. In the middle stand capable middle authorities, Brazil's ANVISA, India's CDSCO, China's NMPA and South Africa's SAHPRA among them, which conduct full assessments while also operating reliance routes. At the other end stand smaller authorities whose registration is expressly built on a reference approval plus a Certificate of Pharmaceutical Product, with national control exercised mainly at importation and in the market. The professional habits this spectrum demands are the unit's substance: map each market's reliance logic, keep one core dossier adaptable to each national format, and never assume a requirement met for one capital is met for the next.

4.2 Regional committees and harmonization bodies across the globe

The space between national systems is organised by regional bodies, and the syllabus names the six the practitioner meets most. **ASEAN**, the Association of Southeast Asian Nations, harmonises through its pharmaceutical product working group, producing the ASEAN Common Technical Document of Unit 5 and the cosmetics directive. **APEC**, Asia Pacific Economic Cooperation, works through its Regulatory Harmonization Steering Committee on convergence, training and reliance across the Pacific economies. The **EAC**, East African Community, runs a Medicines Regulatory Harmonization programme with joint assessments and a shared medicines register among its partner states. The **GCC**, the Gulf Cooperation Council, built centralised registration through its health council machinery alongside the strong national authorities of Unit 5. **PANDRH**, the Pan American Network for Drug Regulatory Harmonization, is the PAHO sponsored network through which the Americas converge. **SADC**, the Southern African Development Community, operates collaborative registration through the ZaZiBoNa initiative of joint assessments among participating states. None of these bodies grants a marketing authorization in its own name (the GCC's central registration historically came closest): their products are common documents, joint assessments, shared inspections and model laws, which national authorities then apply, harmonization by convergence rather than by the EU's transfer of sovereignty.

Regional harmonization committees across the globe



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Figure: The six committees across the globe: ASEAN and APEC in Asia Pacific, EAC and SADC in Africa, the GCC in the Gulf, and PANDRH in the Americas, each converging national systems without replacing them (Unit 4, section 4.2).

4.3 WHO GMP

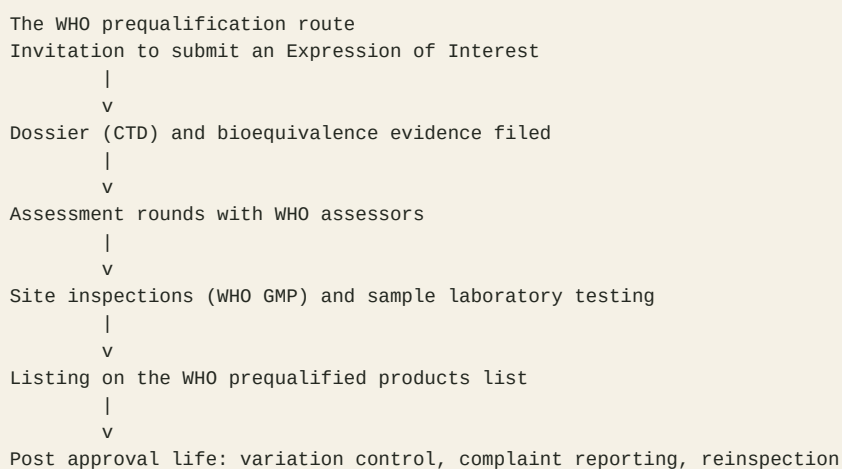
The World Health Organization's good manufacturing practice texts are the floor on which the emerging market world builds. The **WHO GMP main principles** for pharmaceutical products, published in the WHO Technical Report Series and revised over the decades, state the complete system: quality management, sanitation and hygiene, qualification and validation, complaints and recalls, contract production, self inspection and personnel, the same architecture as MRA101T's national texts, from which most national GMP codes in the developing world descend directly. Supplementary WHO GMP texts cover sterile manufacture, biological products, water systems and air conditioning, and the inspection guidelines used by the prequalification programme. Above the texts sits the **WHO Certification Scheme on the Quality of Pharmaceutical Products Moving in International Commerce**, the machinery of section 4.6: WHO GMP is what the Certificate of Pharmaceutical Product certifies compliance with, and the exporting state's authority attests, by issuing the certificate, that the plant is inspected against those standards. An Indian manufacturer therefore meets WHO GMP twice: as Schedule M's intellectual ancestor at home, and as the standard its export certificates assert abroad.

4.4 WHO prequalification: the programme and its purpose

The **WHO Prequalification Programme**, run by the Prequalification Team (PQT) within WHO's regulation department, was created so that the great purchasing agencies of global health, UNICEF, the Global Fund, UNITAID and their peers, could buy assured quality medicines, vaccines and diagnostics for diseases of the developing world without each running its own assessment industry. Prequalification is **not a marketing authorization** and confers no right to sell anywhere; it is a listing, on WHO's published lists, that a defined product from a defined site meets WHO's quality, safety and efficacy expectations, on which procurers and national regulators rely. Its scope follows the donor funded disease programmes: HIV, tuberculosis, malaria, hepatitis, reproductive health, and expanding areas. The pathway begins with a published **invitation to submit an Expression of Interest** for defined products; only products within an open invitation are assessed. For a generic, the dossier in CTD format, bioequivalence evidence to WHO's comparator standards, manufacturing data and samples support assessment; an innovator product already approved by a stringent authority takes an abridged course, and products assessed through collaborative registration with national regulators shorten the national registrations that follow.

4.5 The prequalification procedure and post approval requirements

The procedure has four working parts. **Dossier assessment:** WHO assessors, drawn from a global roster including stringent authority experts, evaluate the quality, bioequivalence and, where applicable, clinical data, in rounds of questions and responses. **Site inspection:** WHO inspectors, ordinarily with the national authority's inspectors invited, inspect the finished product and active substance sites against WHO GMP, and the bioequivalence facility against WHO GCP and GLP expectations. **Laboratory testing:** samples are tested in WHO contracted laboratories against the specifications. And **listing:** satisfactory completion places the product on the prequalified list with its site and specification identified. Listing brings standing obligations, the post approval requirements of the syllabus: **variations** to the prequalified product must be notified or approved by WHO on a grading pattern analogous to the US and EU ladders; complaints, quality defects and recalls are reported to WHO; the product and site are subject to **reinspection** on a risk based cycle; and failure to maintain the conditions leads to suspension or delisting, with procurers informed, a commercial sanction sharper than most fines. The programme thus behaves after listing exactly as a regulator behaves after approval, which is why national authorities are willing to rely on it.



4.6 The Certificate of Pharmaceutical Product: the passport document

The **Certificate of Pharmaceutical Product (CoPP, also CPP)** is the single most travelled document in this subject. Under the WHO Certification Scheme, the competent authority of the **exporting** country issues, at the exporter's request and in the WHO recommended format, a certificate addressed to the importing country stating: whether the product is authorized for marketing in the exporting country, and if not, why not; whether the manufacturing site is subject to regular inspection and complies with **WHO GMP**; and the approved product information. The importing authority relies on it as independent, government to government assurance of status and standards, in place of repeating the exporter's own claims. India's CDSCO and state authorities issue CoPPs in this format for Indian exports, and India's own import registration asks foreign authorities for the mirror document. Two practical rules complete the standard picture: the certificate speaks as at its issue date and importing states set validity expectations, so fresh certificates are a routine export department task; and the certificate certifies the product and site as authorized and inspected in the exporting country, which is why a product made solely for export and not marketed at home attracts the explaining question the format expressly provides for.

4.7 Country specific notes: the syllabus's named CoPP markets

The syllabus names the markets whose CoPP and registration practice the student should hold concretely. **South Africa:** registration with the **South African Health Products Regulatory Authority (SAHPRA)**, successor to the Medicines Control Council, a full assessment authority that works in CTD, uses the CoPP as supporting evidence of status, and participates in the ZaZiBoNa collaborative work of section 4.2. **Egypt:**

registration with the **Egyptian Drug Authority**, with the CoPP and legalised documentation prominent in the file and pricing a formal part of registration. **Algeria and Morocco**: francophone systems of the Maghreb, strong reliance on the CoPP and on reference market approvals, with local agent and legalisation requirements typical of the region. **Nigeria**: registration with **NAFDAC**, the National Agency for Food and Drug Administration and Control, of fixed validity period, supported by the CoPP and by NAFDAC's own inspections of foreign sites. **Kenya**: registration with the **Pharmacy and Poisons Board**, CTD based and CoPP supported, within the EAC harmonization movement. **Botswana**: registration with the **Botswana Medicines Regulatory Authority (BoMRA)**, a young authority expressly building reliance routes into its practice. The pattern across the seven is the unit in miniature: one core dossier, one passport document, seven national variations of evidence, agent, language and legalisation.

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