

5.1 Introduction to the ACTD

The **ASEAN Common Technical Document (ACTD)** is the regional application of the CTD idea that MRA102T teaches in its ICH form: a common organisation of the registration dossier across the ASEAN member states, so that one core dossier can be filed across the region with only the administrative part changing. The ACTD is organised in four parts. **Part I** carries the administrative data: application forms, labels, product information and country specific documents, the part that remains national. **Part II** is the quality part: drug substance and drug product data on the CTD Module 3 pattern. **Part III** is the non clinical part, and **Part IV** the clinical part, each with overviews and summaries styled on the ICH Modules 2, 4 and 5 but arranged in the ACTD's own order. Two practical consequences follow. Because the ACTD tracks the CTD rather than copying it section for section, a global dossier must be **remapped** into ACTD order for ASEAN filings, a documents exercise MRA102T's craft exists for; and because ASEAN registration remains national, the ACTD buys format convergence, not a single approval, each member state assessing and deciding for itself.

The ASEAN Common Technical Document (ACTD)



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Figure: The ACTD: Part I administrative, the part that stays national, and Parts II, III and IV carrying quality, non clinical and clinical content on the CTD pattern, remapped to ASEAN order (Unit 5, section 5.1).

5.2 China

China's system has been rebuilt within a decade into a stringent style authority centred on the **National Medical Products Administration (NMPA)**, with technical review by its **Center for Drug Evaluation (CDE)**. The reforms that matter to this branch: the 2015 overhaul that cleared a backlog and raised data integrity expectations; acceptance of foreign clinical data on stated conditions and China's entry into ICH in 2017, after which the CTD and the ICH guidelines became the working grammar of Chinese filings; the **marketing authorization holder system**, made general by the revised **Drug Administration Law 2019**, separating the holder from the manufacturer on the Japanese pattern; the revised Drug Registration Regulation of 2020 with its four expedited channels (breakthrough therapy, conditional approval, priority review, special approval); and a registration classification reform sorting chemical drug applications into innovative, improved and generic classes. Human genetic resources administration adds a China specific gate on clinical data and sample movements. For Indian industry, China is now less an emerging market in the Unit 4 sense than a stringent market with its own language, timelines and local presence requirements.

5.3 South Korea

South Korea's authority is the **Ministry of Food and Drug Safety (MFDS)**, renamed from the Korea FDA in 2013, with review supported by its National Institute of Food and Drug Safety Evaluation. Registration runs in CTD: new drug data packages are reviewed in full, with Korean bridging considerations where ethnic factors justify them, while generics proceed on bioequivalence against the Korean reference, within one of the world's most developed generic substitution cultures. Post approval, Korea operates re-examination periods for new drugs on the Japanese pattern and a risk based pharmacovigilance system with designated safety centres. Korea sits in this unit as ASEAN's northern comparator: an Asian stringent authority whose forms, language and local testing practices the regional filer must handle as distinctly as China's.

5.4 The ASEAN region: the five named countries

The syllabus names five ASEAN states, and the filer meets each through the ACTD dossier with national assessment. **Singapore**, through the **Health Sciences Authority (HSA)**, is the region's reliance model: new drug applications are routed through **full, abridged and verification routes** according to whether and where the product is already approved by HSA's reference agencies, the verification route being among the fastest stringent grade assessments in the world, and generics assessed on the abridged pattern.

Malaysia, through the **National Pharmaceutical Regulatory Agency (NPRA)** and the Drug Control Authority that registers, requires registration before import or sale, in ACTD, with five year registration validity and a local registration holder answerable in Malaysia. **Thailand**, through its Food and Drug Administration, registers on ASEAN harmonised requirements with Thai language labelling and a local licence holder. The **Philippines**, through its FDA (successor to the Bureau of Food and Drugs), registers under the FDA Act of 2009, with a certificate of product registration of defined validity and heavy practical reliance on certificates of pharmaceutical product from the country of origin, the Unit 4 passport at work. **Vietnam**, through the Drug Administration of Vietnam under its Pharmacy Law, registers with dossier requirements that have historically included clinical data expectations for defined categories and a local representative structure. The five together state the regional truth: one format, five sovereign decisions, speeds set by each state's reliance policy.

5.5 The CIS: Russia, Kazakhstan and Ukraine

The Commonwealth of Independent States markets are in a long transition from national Soviet successor systems to a regional one. The **Eurasian Economic Union (EAEU)** has built a common market for medicines with Union level rules: registration by the Union's mutual recognition and decentralised procedures, a single register of medicines, Union GMP, and expert organisations in each member state doing the assessment work. **Russia**, the Union's dominant market, moves registrations onto the EAEU track under its transition timetable, with the national law on circulation of medicines as the substrate, Russian language dossiers and labelling, and its own GMP inspection of foreign sites, an inspection Indian exporters know well. **Kazakhstan** participates in the same Union system through its national expert organisation, with national pricing and procurement layers over the Union registration. **Ukraine** stands outside the EAEU and has spent a decade converging on the EU instead: its system, administered by the Ministry of Health with the State Expert Center's assessment, works in CTD, recognises reliance on stringent approvals for defined categories, and has reformed repeatedly toward the European model. For the filer the CIS lesson is cartographic: know which of the two convergence projects, Eurasian or European, each market belongs to, because the dossier, language, inspection and register all follow that choice.

5.6 The GCC: Saudi Arabia and the UAE

The Gulf states combine strong national authorities with a regional inheritance. The **Gulf Central Committee for Drug Registration**, operating through the Gulf Health Council, historically ran a centralised registration whose certificates member states adopted; the centre of gravity has since moved to the national authorities, of which two dominate. **Saudi Arabia's Food and Drug Authority (SFDA)**, established 2003, is the region's stringent authority: registration in eCTD, full assessment with defined review tracks including priority review, Saudi specific requirements on pricing (a formal price certificate and the region's reference pricing habits), Arabic labelling, and a pharmacovigilance centre of regional standing; SFDA approvals are themselves used as reference approvals across the region. The **United Arab Emirates** regulates federally through the Ministry of Health and Prevention, with CTD based dossiers, local agent requirements, federal pricing, and the emirate level health authorities layering facility and practice regulation over the federal product registration. The **GCC prerequisites** an applicant assembles are thus: a dossier in the common format, evidence of status and GMP of the CoPP kind, pricing documentation, Arabic compliant labelling, and a local establishment answerable in market. Stability expectations deserve a working note: the Gulf's climatic zone requirements for long term stability data are the standing technical trap for dossiers assembled to temperate market defaults.

5.7 Cosmetics in Brazil, ASEAN, CIS and GCC

The cosmetics closing item gathers four regional models. **Brazil**, under **ANVISA**, sorts cosmetics into **Grade 1** products, whose basic properties need no detailed proof, handled by electronic **notification** with immediate effect, and **Grade 2** products, with specific indications and claims requiring proof, subject to **registration** with ANVISA assessment; labelling in Portuguese and local responsible company requirements complete the system, and Brazil is accordingly the unit's one true approval model for higher claim cosmetics. **ASEAN** harmonised cosmetics through the **ASEAN Cosmetic Directive**, which transplants the EU model into the region: a responsible company places the product on the market after **notification** to each member state's authority, holding a product information file with safety assessment for inspection, with ingredient annexes modelled on the EU lists. The **CIS and EAEU** regulate cosmetics under the Eurasian technical regulation **TR CU 009/2011** on the safety of perfumery and cosmetic products: conformity is declared or, for defined categories such as children's cosmetics, certified and state registered, with the EAC mark on the pack. The **GCC** applies the Gulf standard **GSO 1943** for cosmetic safety through national notification and registration practice, with Arabic labelling and prohibited ingredient lists aligned to the European annexes. Read across Units 1, 2 and 5, the world's cosmetics settle into a spectrum the student can now state: notification with accountability in the EU and ASEAN manner at one end, registration by risk grade in the Brazilian manner at the other, and ingredient control in the Australian manner off to the side.

Frequently Asked Questions

Q: How does an ANDA differ from an NDA if both end in a marketing approval? An NDA proves safety and effectiveness on the applicant's own full evidence. An ANDA proves sameness: the same active ingredient, form, strength and route as a Reference Listed Drug, pharmaceutical equivalence, the same labelling, and bioequivalence within the 80.00 to 125.00 percent acceptance range. The ANDA contains no clinical efficacy programme, which is why Hatch-Waxman made generics cheap enough to transform the market.

Q: What exactly does a Paragraph IV certification do? It asserts that a patent listed in the Orange Book is invalid, unenforceable or not infringed by the generic product. The applicant must notify the patent owner and the NDA holder; if they sue within 45 days, FDA approval is automatically stayed for up to 30 months while the court decides. The first applicant to win or settle through a Paragraph IV challenge earns 180 days

of generic marketing exclusivity.

Q: US DMF, EU ASMF and Japanese MF look alike. What is the practical difference? All three keep the substance maker's confidential data closed to the applicant while the authority reviews it in connection with an application. The EU ASMF is split into an Applicant's Part that the applicant does read and a Restricted Part it does not, and has an EU worksharing procedure. Japan registers the file and issues a registration certificate and number, and pairs the system with accreditation of the foreign manufacturer. The US DMF is closed in full and referenced by a Letter of Authorization.

Q: Which products must use the EU centralised procedure? Biotechnology derived medicines, orphan medicines, advanced therapy medicinal products and medicines for the specified major therapeutic areas must use it. Other new active substances and products representing significant innovation may choose it. The reward is a single Commission decision valid across the EU and EEA, on a CHMP opinion reached over 210 active assessment days plus clock stops.

Q: What is the difference between Type IB and Type II variations in the EU? A Type IB variation is a minor change that is neither Type IA nor Type II, worked on a tell, wait and do pattern: the holder notifies and may implement after 30 days if the authority does not object. A Type II variation is a major change that may significantly affect quality, safety or efficacy; it is fully assessed, ordinarily over 60 days, and may be implemented only after approval.

Q: Is notification of a cosmetic in the EU an approval? No. Under Regulation 1223/2009 the Responsible Person notifies the product on the Cosmetic Products Notification Portal before placing it on the market, but no authority approves it. Legality rests on the Responsible Person's duties: a safety assessment by a qualified assessor, a Product Information File held for the authorities, compliance with the ingredient annexes, and corrective action duties if the product proves unsafe.

Q: What did MoCRA change for cosmetics in the United States? The Modernization of Cosmetics Regulation Act 2022 kept the American rule of no premarket approval (colour additives excepted) but added the machinery around it: mandatory facility registration, product listing, safety substantiation, serious adverse event reporting within 15 business days, FDA records access, mandatory recall authority, and rule making for cosmetic GMP and fragrance allergen labelling.

Q: Japan has already approved a drug after full review. Why does it re-examine it years later? Because the Japanese system treats approval of a new drug as the start of a formal evidence period. The holder collects use results and safety data under the GPSP rules through the re-examination period, in principle eight years for a new active ingredient, intensified by early post-marketing phase vigilance in the first six months. At the end, PMDA and MHLW re-evaluate the product on the real world record and confirm, adjust or withdraw the approval.

Q: Does WHO prequalification allow a company to sell a medicine in a country? No. Prequalification is a listing relied on by purchasing agencies and national regulators; it confers no marketing right. Its power is reliance: a prequalified product from a prequalified site can be registered faster in many countries, including through collaborative registration procedures, and can be bought by UNICEF, the Global Fund and similar procurers.

Q: What is the difference between the ICH CTD and the ASEAN ACTD? The ACTD is ASEAN's regional adaptation of the CTD idea. Instead of the CTD's five modules it uses four parts: Part I administrative (the country specific part), Part II quality, Part III non clinical and Part IV clinical, arranged in ASEAN's own order. A global CTD dossier must be remapped into ACTD order for ASEAN filings, and the ACTD standardises format only; each ASEAN state still grants its own registration.

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