

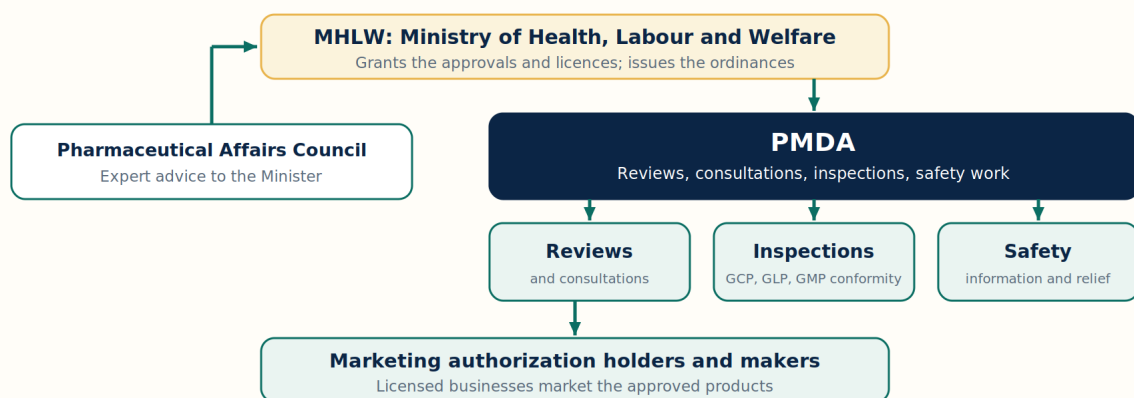
Unit 3: Japan

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3.1 The PMDA and the Japanese division of labour

Japan splits the two questions that the FDA answers together. The **Ministry of Health, Labour and Welfare (MHLW)** holds the legal authority: it grants the approvals and licenses, issues the ordinances, and takes the final decisions, advised by its council machinery, the Pharmaceutical Affairs and Food Sanitation Council. The **Pharmaceuticals and Medical Devices Agency (PMDA)**, established in 2004 as an incorporated administrative agency, does the work: it conducts the scientific **reviews** of new drugs, devices and regenerative products, offers the **consultations** through which development programmes are agreed, runs the **reliability and GCP inspections** behind the reviews, operates the safety information and adverse event systems, and administers the relief services that compensate victims of adverse drug reactions and infections. The model is deliberate: PMDA reviews and recommends, MHLW approves, and the applicant's practical life is lived with PMDA, whose consultation system, much more formal and heavily used than its Western counterparts, is where Japanese development programmes are really shaped. Japanese language, formats and data expectations make Japan the advanced market most often entered with local regulatory counsel and, frequently, a Japanese partner.

Japan: MHLW decides, the PMDA reviews



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Figure: The division of labour: MHLW grants approvals and licenses on the advice of its council, while the PMDA conducts reviews, consultations, inspections and safety work, and manufacturers and marketing authorization holders operate under licence (Unit 3, section 3.1).

3.2 Pharmaceutical laws and regulations

The governing statute is the **Act on Securing Quality, Efficacy and Safety of Products Including Pharmaceuticals and Medical Devices**, universally shortened to the **Pharmaceuticals and Medical Devices Act (PMD Act)**, the 2013 renaming, effective 2014, of the former Pharmaceutical Affairs Act, the renaming itself reflecting the statute's extension to the regenerative medicine products it now expressly governs. Below the Act sit the ministerial instruments that carry the working law: the ordinances on manufacturing control and quality control (the GQP ordinance), on post marketing safety control (the GVP ordinance), and on the conduct of post marketing studies (the GPSP ordinance), with GMP issued as a ministerial ordinance, and vigilance and quality duties thereby split between two named control systems, a

quality system (GQP) and a vigilance system (GVP), each with its own responsible officers inside the marketing authorization holder. Licensing runs on two tracks, and the distinction matters: a **marketing authorization holder licence** (in three categories, by product class) authorises the business of marketing, while each product requires its own **marketing approval** and each manufacturing site its own manufacturing licence with GMP conformity inspection. Japan thus separates, more explicitly than the US or EU, the licence to be in the business, the approval of the product, and the conformity of the plant.

3.3 Types of registration applications

Applications for marketing approval are filed by category, the Japanese application being classified by what is new about the product, and the category fixes the data package and the consultation path. The principal classes are: drugs with **new active ingredients**; drugs with new combinations; drugs with new routes of administration; drugs with new indications; drugs with new dosage forms or new dosages; and **generic drugs**, filed by reference to the approved originator with bioequivalence at their centre. Around this classification the modern Japanese system has built its acceleration and access instruments: the **SAKIGAKE designation** (from 2015) for pioneering products intended for serious conditions, with priority consultation, pre evaluation and priority review and a concierge style PMDA shepherding; the **conditional early approval** system for drugs for serious diseases where confirmatory trials are impracticable, approved on early data with post marketing obligations; priority review and orphan drug designation (for conditions affecting fewer than 50,000 patients in Japan, with research support and a re-examination premium). As elsewhere, classification is the first professional act: the same product is a different application, with a different dossier, fee and clock, according to which class it honestly falls in.

3.4 The Master File system in Japan

Japan's counterpart of the DMF and ASMF is the **Master File (MF)** system for drug substances, intermediates, excipients and packaging materials, operated by the PMDA since 2005 under the amended statute. The maker registers the confidential manufacturing and quality information with PMDA and receives an **MF registration certificate** bearing the registration number; an approval applicant then cites that number in its application, and PMDA reviews the closed material in connection with the application without the applicant seeing it, the same triangular confidentiality as the US system. Two features are distinctively Japanese. Registration is a **public administrative act**: the register of files and their holders is maintained by PMDA, so the existence and ownership of a file is a matter of record even though its content is closed. And the system is paired with the accreditation of foreign manufacturers: a non Japanese site making a substance or product for the Japanese market must be **accredited** by MHLW, without which its material cannot feed an approval, accreditation and MF registration together forming the foreign supplier's entry paperwork.

3.5 The Japanese drug approval process

The approval process builds on consultation. Sponsors meet PMDA in formal consultations (on clinical trial design, on dossier strategy, and pre application) whose recorded conclusions are treated as commitments on both sides; the clinical trials run under Japanese GCP with the notification machinery MRA103T described. The application for marketing approval is filed with PMDA, which conducts the scientific review and the **GCP, GLP and data reliability inspections**, and may conduct GMP conformity inspection of the named sites. The review report passes to MHLW, where the expert committees of the Pharmaceutical Affairs and Food Sanitation Council deliberate, and the Minister grants the approval. Standard review is conventionally described at about **12 months** of PMDA review for a new drug, with priority review products at about **9 months**, excluding the applicant's answer time on inquiries, on the clock stop pattern familiar from the EU. National Health Insurance price listing follows approval, a step Japanese planning treats as

part of one two stage launch.

3.6 Manufacturing, packaging and labeling in Japan

The manufacturing side of the Japanese system is the MAH system of section 3.2 at work: the marketing authorization holder answers for the product's quality and safety, operating the **GQP** quality system that controls its manufacturers, domestic and foreign, accredited and inspected for GMP conformity on the approval cycle and in periodic conformity inspections thereafter. **Packaging and labeling** show a characteristic Japanese form: the **package insert**, the approved professional text, moved to electronic provision as the default under the revised law, with the printed insert in transition; container and carton labelling carry the statutory statements in Japanese, including the MAH's name and address, the manufacturing number and the expiry, and patient facing information sheets are standard practice for prescription products.

3.7 Post marketing surveillance in Japan

Japan operates the most formalised post marketing evidence machinery of the three advanced systems, built on two instruments. The **re-examination system** attaches to new drugs at approval: a re-examination period is set (for a new active ingredient, in principle **eight years**), during which the holder must collect and analyse use results and safety data under the GPSP ordinance, and at its end the product is literally re-examined: MHLW and PMDA re-evaluate efficacy and safety on the accumulated record, and the approval stands confirmed, adjusted or, in principle, withdrawn. Running beside it is **Early Post-marketing Phase Vigilance**, an intensive first **six months** after launch in which the holder proactively works the hospital and pharmacy channel for safety information and reports findings on a tight schedule. Adverse reaction reporting, periodic safety reporting on the international pattern, and PMDA's medical information database network (MID-NET), giving access to real world electronic medical record and claims data for safety studies, complete the picture. Approval in Japan is provisional in a way it is not in Washington or Amsterdam, and the market itself is enrolled as the second, obligatory phase of the evidence programme.

Japan post marketing: vigilance early, re-examination last



Figure: The two instruments: early post-marketing phase vigilance in the first six months, continuing surveillance through the period, and the formal re-examination, in principle at eight years for a new active ingredient, that closes the cycle (Unit 3, section 3.7).

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