Market Access Barriers

An overview of key barriers to generic and biosimilar market entry in select EU trading partners

Author:

vulcanconsulting

Sponsored by:

medicines for europe
better access. better health.

Author:

Vulcan Consulting (drafted by Pascal König, Senior Account Manager, and Niamh Murphy, Account Executive)

Contributors:

International Affairs Committee of Medicines for Europe

OCTOBER 2024

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Foreword

Foreword by Adrian van den Hoven, Director General at Medicines for Europe

Generic medicines are a cornerstone of patient access to high-quality, safe, effective, and affordable treatments worldwide. In Europe, they account for 70% of all dispensed medicines, while in countries like the United States and India, this share surpasses 90%.

Biosimilar medicines have enabled Europe to save €50 billion between 2006 and 2023, including €10 billion in 2023 alone. These products offer a significant opportunity for both high-income and lower-income countries to dramatically expand access to vital biological therapies for patients.

The generic and biosimilar medicines sector, also actively engaged in continuous innovation through value-added medicines, represents a pillar of industrial excellence within the European Union. This is demonstrated by its workforce of 190,000 employees across over 400 manufacturing sites.

This study, requested by the International Affairs Committee (IAC) of Medicines for Europe, provides an overview of the main barriers to market entry faced by EU generic and biosimilar pharmaceutical companies operating in 11 key third-country markets.

The findings confirm the importance for the European Union's trade and external policies to continue addressing these barriers, which not only undermine the competitiveness of EU-based pharmaceutical companies but also restrict access to more affordable generic and biosimilar medicines.

In line with the Trade Strategy adopted by the European Commission in 2021, Medicines for Europe supports an open, fair and assertive trade policy. This policy should continue to recognise the global and extensive nature of pharmaceutical supply chains and to strengthen existing partnerships while forging new ones, and assertively address market access barriers and the enforcement of trade commitments.

This is also aligned with President-elect Ursula von der Leyen's political guidelines for the 2024-29 European Commission, which emphasise the importance of deepening trade relations with global partners and ambitiously enforcing existing trade agreements.

The findings also confirm that major trading partners are investing in pharmaceutical (bio-) manufacturing, underscoring the importance of the industrial policy work launched by the

European Union with the Critical Medicines Alliance, which should pave the way for a Critical Medicines Act.

Medicines for Europe hopes that this study will serve as a valuable resource for European Union decision-makers as they work to achieve these strategic objectives in the upcoming mandate, with the goals of fostering better and faster patient access to generic and biosimilar medicines in third countries and creating new growth opportunities for EU-based generic and biosimilar pharmaceutical companies.

Executive Summary

This report seeks to provide an overview of the main barriers to market entry experienced by EU generic and biosimilar pharmaceutical companies in key third-country markets. Together with the International Affairs Committee (IAC) of Medicines for Europe, 11 countries of varying socio-economic status, trade relationship with the European Union and geographic spread were chosen.

This report was primarily based on a comprehensive analysis of publicly available sources provided by Government Ministries and Agencies, the Word Trade Organisation, and the European Union, among others. Additionally, the research team examined a range of studies and research papers, with the United States government's National Library of Medicine, and specifically the Journal of Market Access and Health Policy, providing an extensive resource. Additional anonymised information derived from Medicines for Europe members was also used to complement the study with real-world experiences faced by companies active in those markets.

While there are a range of concrete barriers to trade in pharmaceuticals, the specific focus of the report is on:

- **Public Procurement rules:** Prioritisation of domestic suppliers in tenders, as seen in countries like Brazil, China and India, can limit foreign companies' access.
- **Regulatory Assessments**: Complex regulations and lack of harmonization with the EU, common in several jurisdictions, can cause delays and higher costs.
- **Local Manufacturing preferences**: Local content rules, such as those in Indonesia, can disadvantage foreign manufacturers by favouring domestic production.
- **Local rules on pricing and reimbursement:** Price controls and reimbursement policies significantly influence market access in most of the assessed countries.
- **Intellectual property rules:** Patent linkage systems and patent extensions, first introduced in the US and now used in various countries, delay the entry of generic and biosimilar medicines.

The above were selected on the basis that they form the primary non-tariff barriers to market entry experienced by companies.

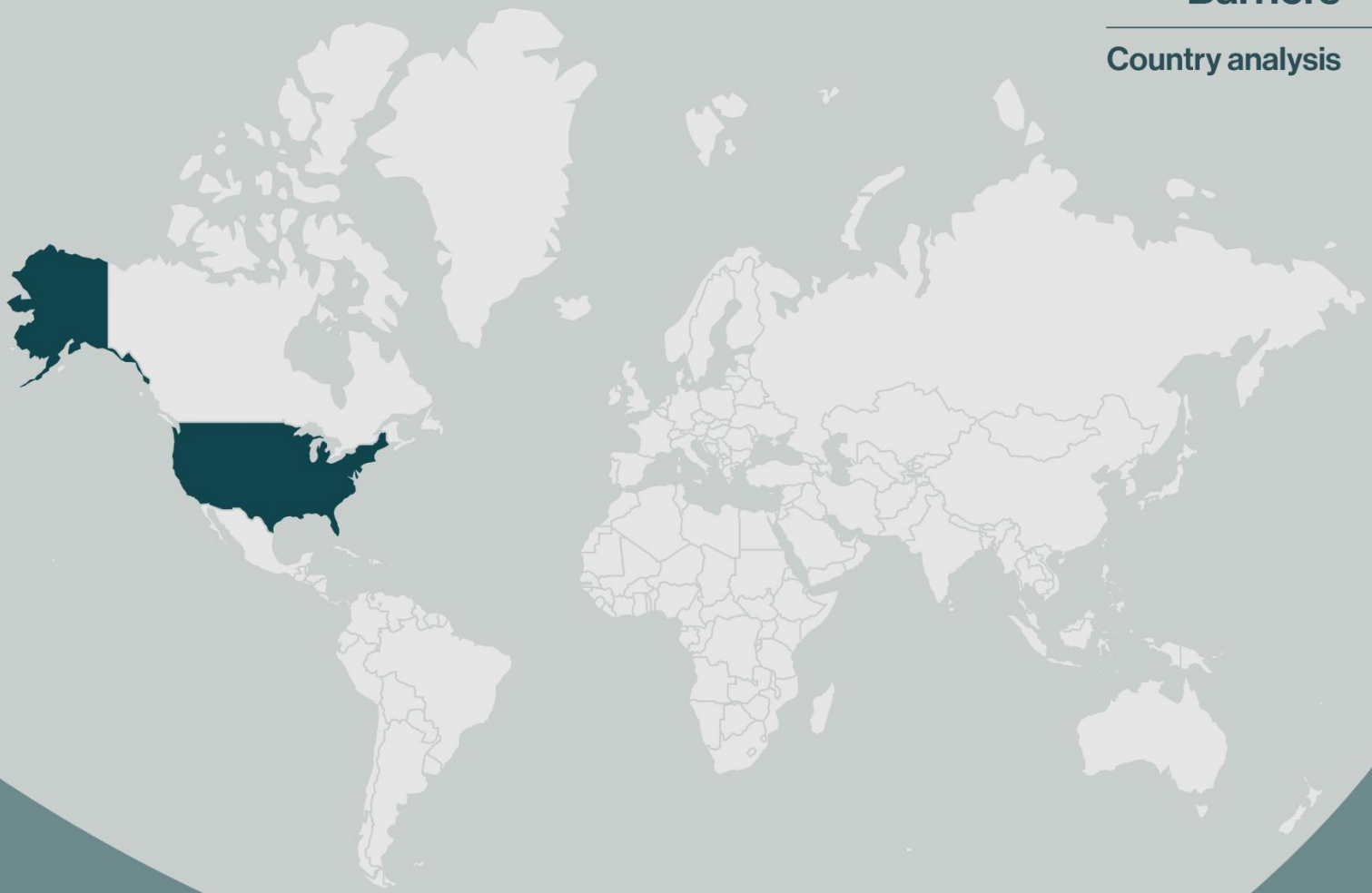
In addition, a comprehensive overview of the duties applied by the analysed countries on pharmaceutical products (HS code 30.XX) can be found in the annex.

The report has been developed in different stages since February 2024, with the sections on the United States of America, China, India, Indonesia, the Republic of Korea and Türkiye finalised by May. The remaining country analyses (Australia, Brazil, Japan, Kazakhstan and South Africa) were prepared by September.

Given the changing nature of legislation, the information provided in this report is as accurate as possible as of September 2024. In cases where a country has a regularly updated list of critical medicines or list of medicines qualifying for reimbursement, relevant links to the respective Government Agency website are provided. While all attempts were made to provide the most up-to-date and factual information, the authors are not able to guarantee the report's accuracy in its entirety.

Market Access Barriers

Country analysis



United States of America

Public Procurement rules	Regulatory Assessments	Local Manufacturing	Pricing and Reimbursement	Intellectual Property rules
No specific limitations on generic and biosimilar medicines; EU-based companies are excluded from bidding on all contracts targeting small US-based contractors.	EU-US MRA on GMPs in place, but lack of Single Development Programme for complex generic medicines.	No specific limitations; National objective to expand local manufacturing.	Fractured system based on State and Federal Programs; Private Insurance Plans.	Patent Linkage System; Patent Term Extension; Generic and biosimilar market entry often delayed by sophisticated patent thickets, litigation, and pay-for-delay tactics.

Introduction

While the United States of America[1] has long been a strong proponent of open, international trade, it continues to pursue a "Buy American" agenda to strengthen domestic industry. While none of the restrictions under the "Buy American Act of 1933" (BAA) currently apply to pharmaceutical products, including generic and biosimilar medicines, the "Buy American" approach remains relevant in ongoing policy discussions. As such, different initiatives such as President Trump's 2020 Executive Order to 'buy American' for certain essential medicines[2], or Senator Rick Scott's 2023 proposal for an "AMERICAN DRUGS ACT[3]" are recent examples for (limited) "Buy American" measures in the generic and biosimilar medicines sector.

In 2017, the Food and Drug Administration (FDA) announced the Drug Competition Action Plan[4] (DCAP) to remove barriers to the development and market entry of generic and biosimilar

[1] See: https://www.igbamedicines.org/doc/IGBATradePrinciples.pdf
[2] See: https://www.washingtonpost.com/business/2020/08/06/buy-american-trump-executive-order-drugs/
[3] https://www.rickscott.senate.gov/services/files/16B9C715-1373-4D37-91F0-0077723870D5
[4] For full information about the FDA Drug Competition Action Plan: https://www.fda.gov/drugs/guidance-compliance-regulatory-information/fda-drug-competition-action-plan

medicines in the more than $635 billion U.S. pharmaceutical market. According to IQVIA, in 2022, 87.2% of small molecule medicine prescriptions were dispensed as unbranded generic medicines with revenues from unbranded generic medicines continuing to decrease despite rising prescription rates.

Public procurement rules

Despite general domestic content requirements under the Buy American Act of 1933 (BAA)[5], pharmaceutical products, including generic and biosimilar pharmaceutical products are excluded from the BAA's scope. EU suppliers of generic and biosimilar medicines can access[6] the US procurement market under the provisions of the WTO Agreement on Government Procurement (GPA)[7].

The GPA is the only instrument in which the United States of America has taken binding commitments regarding the access of EU operators, suppliers and services to the US procurement market. The commitments cover Federal entities (Government Departments and Agencies), as well as the 37 States who have signed up to it, but not cities[8]. While certain exemptions exist with regard to aviation and mass transit and highway projects, there are no specific barriers towards the pharmaceutical industry.

In this context, it should be noted carefully that there are different procurement rules at the Federal and State level, with rules at the latter varying widely between the different States.

It is noteworthy, however, that EU-based companies are excluded from bidding on all contracts targeting small US-based contractors below the "US Simplified Acquisition Threshold" of US $250.000. To circumvent these restrictions, EU-based companies would have to establish, pay taxes and employ staff in the United States of America.

[5] See: https://www.govinfo.gov/content/pkg/USCODE-2009-title41/html/USCODE-2009-title41.htm
[6] Trade Barriers: Procurement: Buy American: https://trade.ec.europa.eu/access-to-markets/en/barriers/details?isSps=false&barrier_id=11190
[7] WTO: Agreement on Government Procurement: https://www.wto.org/english/tratop_e/gproc_e/gproc_e.htm
[8] For the full list of Federal entities and States see: https://e-gpa.wto.org/en/Annex/Details?Agreement=GPA113&Party=UnitedStates&AnnexNo=2&ContentCulture=en&AdvancedSearch=False

Regulatory Assessments

As a result, qualified persons operating in the EU do not need to batch test human medicines covered by the MRA, provided that they have verified that these controls have been carried out in the United States for products manufactured in and imported from the United States. The scope of the MRA includes (among others):

- marketed finished pharmaceuticals for human use in various pharmaceutical dosage forms such as tablets, capsules, ointments, and injectables,
- marketed biological products,
- intermediates,
- active pharmaceutical ingredients or bulk drug substance.

Currently, the MRA does not cover:

- vaccines for human use,
- plasma derived pharmaceuticals,
- investigational products (clinical trial material), specific to each agreement.

Completely excluded from the MRA are:

- Advanced Therapy Medicinal Products (ATMPs),
- human blood, human plasma, human tissues and organs.

The FDA and the EU have considered the issue of expanding the scope of the MRA to include vaccines and plasma-derived pharmaceuticals for human use, with a review due in July 2025.

However, regulatory cooperation on clinical trials would remove unnecessary bureaucratic burdens remaining to regulatory approval. As highlighted by Medicines for Europe and the Association for Accessible Medicines[9] ahead of 5th EU-U.S. Trade and Technology Council Ministerial meeting, the establishment of an EU-U.S. Single Development Programme for complex generic medicines would "avoid study duplications, cut development program inefficiencies, and better respond to patient needs, [while being] coherent with the use of foreign comparator products in clinical trials supporting biosimilar dossiers."

[9] See: https://www.medicinesforeurope.com/wp-content/uploads/2024/01/Joint-statement-AAM-MfE-EU-US-TTC5.pdf

Local Manufacturing Preferences

In the US, local manufacturing preferences can vary depending on factors such as industry, government policies, consumer preferences, and economic conditions. While global supply chains remain an important part of the manufacturing landscape, there is a renewed focus on local manufacturing in the United States of America driven by among others the Biden Administration's Inflation Reduction Act (IRA)[10]. While the IRA has gained notoriety in Europe with regard to its domestic manufacturing requirements for electric vehicles, it does not contain any such provisions for the pharmaceutical industry. It does, however, authorise the Secretary of the Department of Health and Human Services (HHS) to negotiate prices directly with participating manufacturers for certain high expenditure, qualifying single source Medicare medicines without generic or biosimilar competition.

It is notable that the White House seeks to improve the US's domestic market share, creating jobs and reducing supply chain risk in the pharmaceutical industry through its National Biotechnology and Biomanufacturing Initiative[11]. The initiative emphasizes a strengthening of domestic production of pharmaceuticals, from key starting materials (KSM) and active pharmaceutical ingredients (APIs) all the way through to finished dosage forms (FDFs).

Local rules on pricing and reimbursement

Given the fractured healthcare environment in the United States of America, local rules on pricing and reimbursement stand as the most significant non-tariff barrier affecting the market access of generic and biosimilar medicines. These rules, established at both State and Federal levels, profoundly influence the affordability, availability, and utilization of pharmaceutical products, thus shaping market dynamics and patient access.

(a) State Medicaid programs and drug formularies

Each State administers its own Medicaid program and has the authority to establish its own list of covered medications and their respective reimbursement rates (drug formulary). Formulary decisions are often influenced by considerations such as cost-effectiveness, therapeutic

[10] To read the IRA's full text: https://www.congress.gov/bill/117th-congress/house-bill/5376/text
[11] See: https://www.whitehouse.gov/briefing-room/statements-releases/2022/09/14/fact-sheet-the-united-states-announces-new-investments-and-resources-to-advance-president-bidens-national-biotechnology-and-biomanufacturing-initiative/

efficacy, and budgetary constraints, meaning that reimbursement rates under by Medicaid formularies[12] may vary significantly between States.

(b) Private insurance plans and Pharmacy Benefit Managers (PBMs)

These entities negotiate with pharmaceutical manufacturers to establish reimbursement rates and formulary placement for medicines covered by their plans. Generic and biosimilar medicines may face challenges in gaining favourable reimbursement and formulary placement, particularly if brand-name products are preferred or incentivized through rebates or other financial arrangements.

Additionally, some insurance plans may impose higher cost-sharing requirements for patients seeking generic or biosimilar alternatives, such as higher co-payments or co-insurance rates. Formulary exclusions or restrictive policies may also hinder market entry for generic and biosimilar manufacturers, creating barriers to competition and affordability within the private insurance market.

(c) Federal programs and pricing regulations

At the federal level, pricing and reimbursement rules are influenced by programs such as Medicare, in particular Part D, which provides healthcare coverage to elderly and disabled individuals.

While Medicare Part D generally covers generic and biosimilar medicines, pricing and reimbursement policies may impact their utilisation and market competitiveness. Regulatory initiatives aimed at reducing drug costs, such as the Medicare Drug Price Negotiation Act, may have implications for generic and biosimilar manufacturers, affecting their ability to compete in the market and provide affordable alternatives to patients.

Intellectual property rules

The Hatch-Waxman Act of 1984[13] established the growth of generic and biosimilar medicines in the United States of America by allowing for their simplified market access after the expiry of patent protections[14] and up to a maximum of 12 years of market exclusivity (only for biological

[12] See: https://www.cms.gov
[13] Drug Price Competition and Patent Term Restoration Act of 1984
[14] According to the United States Patent and Trademark Office (USPTO), patents grant the holder exclusive rights to manufacture, market, and sell the drug for a specified period, typically 20 years from the date of filing.

products). Under the Act, instead of repeating clinical trials, manufacturers of generic and biosimilar medicine must demonstrate bioequivalence.

While the Hatch-Waxman Act allows manufacturers of generic and biosimilar medicines to begin conducting bioequivalence tests and to apply for FDA approval prior to the expiration of patent protection and exclusivity extensions, a generic and biosimilar manufacturer must either wait for the expiration of any patents held by the original medicine before marketing its product, or it can certify (Paragraph IV certification) that its medicine does not infringe the patents, that the patents are invalid, or both.

Subsequently, the first generic and biosimilar manufacturer to file a substantially complete abbreviated new drug application and a successful Paragraph IV certification is awarded 180 days of exclusivity, during which time a second generic and biosimilar manufacturer cannot sell their medicine.

Yet, despite the provisions set out in the Hatch-Waxman Act, drug manufacturers employ a number of tactics to block or significantly delay the entry to market of biosimilar products. These include, among others:

- Litigation to challenge the generic manufacturers' certifications,
- Drug reformulation and modification,
- Acquisition of secondary patents (patent thickets),
- Engagement of "reverse-payment" or "pay-for-delay" settlements,
- Filing of so-called "citizen petitions".

Additionally, according to a study[15] for the National Institute for Health, anticompetitive antitrust behaviour has also been identified as a considerable obstacle to new market entries of generic and biosimilar manufacturers. This study was further expanded upon by the FDA in a letter[16] to the United States Patent and Trademark Office (USPTO), with then-Acting Commissioner Woodcock calling for increased inter-agency cooperation on the matter, stressing the issues of patent thickets, abuses of continuation patents, and evergreening.

As part of this cooperation, continue to fight abuses of the FDA's Orange Book patent linkage system to promote and protect competition in the generic medicine and biosimilar market. According to the Federal Trade Commission, improperly listed patents are considered an abuse of the regulatory system that creates an artificial barrier to entry and prevents lower cost drug

[15] Generic drugs in the United States: Policies to address pricing and competition (2019): https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6355356/
[16] See: https://www.fda.gov/media/152086/download?attachment

alternatives from entering the market, hindering competitive drug pricing and harming the consumer and healthcare system as a whole.

While it is notable that the US regulators are investigating this, similar developments are being observed in the European Union, with the European Union's competition department having investigated more than 70 cases between 2018 and 2022[17].In this context, however, it is noteworthy that the actions undertaken by EU competition authorities are primarily reactive, resulting in considerable delays to market access by generic and biosimilar medicines.

The US was the first country to introduce patent term extensions, already in 1984 with the Hatch-Waxman Act. Under this regime, the US allow for up to five years of Patent Term Restoration.[18]

Conclusion

Despite considerable political and public policy initiatives to remove market entry barriers, generic and biosimilar medicines access to the U.S. market remains complicated by regulatory and legal hurdles, particularly for non-U.S. manufacturers. While there are no obvious barriers preventing EU-manufactured generic and biosimilar medicines from accessing the U.S. domestic market, the lack of a single development programme for complex generic medicines, as well as extensive litigation practices to challenge, block or significantly delay the entry to market of generic and biosimilar products continue to be considerable challenges to EU manufacturers seeking to expand on the U.S. market. In the fragmented U.S. healthcare system, local pricing and reimbursement rules at both State and Federal levels are the most significant non-tariff barrier, impacting market access, affordability, availability, and utilisation of generic and biosimilar medicines.

[17] See: https://ec.europa.eu/commission/presscorner/detail/en/ip_24_413
[18] See: Small Business Assistance: Frequently Asked Questions on the Patent Term Restoration Program | FDA

Market Access Barriers

China

Public Procurement rules	Regulatory Assessments	Local Manufacturing	Pricing and Reimbursement	Intellectual Property rules
"Buy Chinese" requirements significantly limit access to public procurement.	No EU-China MRA; Concerns on GMP inspections; Lengthy registration process for imported medicines.	No explicit provisions, but priority list for RLP shows local manufacturing preference.	Must be listed on National Reimbursement Drug List; Generics 100% reimbursed.	Patent Linkage System; Patent Term Extension.

Introduction

China's domestic pharmaceutical industry has been continually growing over the past 10 years, making it the world's second largest biopharmaceutical manufacturer. Generic medicines account for more than 90% of the domestic market [19].

It should be noted that the European Commission's "Communication on addressing medicine shortages in the EU[20]" can be considered a response to the country's prevalence in global biopharmaceutical manufacturing and calls for concrete measures to reduce the bloc's dependency on Chinese imports of active pharmaceutical ingredients (APIs)[21].

[19] International Journal of Health Policy and Management (2023): Value-Based Generic Drug Evaluation Focus on Chinese Real-World Evidence - PMC
[20] European Commission Communication on addressing medicine shortages in the EU. https://commission.europa.eu/document/download/da376df1-c70e-48ba-8844-3024f25746b6_en?filename=Communication_medicines_shortages_EN_0.pdf
[21] Non-paper on Improving the security of medicines supply in Europe https://vandenbroucke.belgium.be/nl/non-paper-improving-security-medicines-supply-europe

Public procurement rules

China's public procurement rules are extensively shaped by the political priorities of the Chinese Communist Party, with the "Buy Chinese" principle leading the Government's public procurement rules. Despite Chinese companies enjoying broad access to EU public procurement, the European Commission has repeatedly raised the issue of EU companies' unfair treatment with its Chinese counterparts – to limited or no avail.

While the principle covers all sectors, with most market access problems reported in the medical devices sector, difficulties are also observed in accessing the public procurement market for products manufactured in China by foreign-invested joint ventures. Public procurement in China is governed by two sets of national laws, which restrict the access by non-Chinese entities:

(1) The 1999 Tendering and Bidding Law,
(2) The 2002 Government Procurement Law.

Within those frameworks, the 2002 Government Procurement Law (GPL), and specifically Article 10 - the "Buy Chinese Clause" – provides the legal foundation for limiting access of imported goods and services over Chinese-made products.

Under Article 10, government entities are required to procure goods subject to public procurement domestically. As has been observed by the European Commission's April 2024 investigation under its International Procurement Instrument[22], any products procured publicly fall under the scope of Article 10. Only under rare exceptions, specifically when the goods are unavailable in China or, if available, cannot be procured on reasonable commercial terms[23] or are for use outside China, may public entities procure goods and services from non-Chinese companies. However, despite a number of assurances and State Council documents[24], the definition of domestic goods and its interpretation remain unclear, thus creating legal uncertainty for foreign-invested entities operating joint ventures whether their goods and services qualify as domestic products. In practice, this legal ambiguity ensures that only wholly

[22] European Commission: Commission launches first investigation under EU International Procurement Instrument https://ec.europa.eu/commission/presscorner/detail/en/IP_24_2044
[23] The domestic equivalent must be at least 20 % more expensive.
[24] See: State Council Document No. 5 (2017), Article 16 of the Foreign Investment Law, and State Council Circular 39 (2019).

owned Chinese companies are able to successfully bid in public tenders, while foreign ones are only allowed under certain conditions[25].

Regulatory Assessments

Despite a high-level political commitment to strengthening cooperation and dialogue on health and innovation, there is currently no EU-China Mutual Recognition Agreement in place. However, since the signing of the 2010 EU-China "Consultation and Cooperation Mechanism[26]" between the European Commission's DG SANTE and the Chinese State Food and Drug Authority, regular consultations and specific interactions on pharmaceuticals take place.

Under this agreement, the EMA's activities[27] focus on assisting China in implementing EU-equivalent Good Manufacturing Practice (GMP) and Good Clinical Practice standards, with a long-term view to:

- facilitate the use of products and data coming from China, and
- achieve a global approach to the manufacture and supervision of medicines in the long term.

In this context, concerns have been raised regarding EU-GMP inspectorates having unofficially suspended inspections in the country due to legal uncertainty following China's April 2023 revision of its Counterespionage Law[28]. Under the revised law, there are significant concerns that inspectors could be detained in China under industrial espionage accusations.

The import of non-Chinese manufactured medication is governed by the Regulations for Implementation of the Drug Administration Law of the People's Republic of China, and in particular Chapter 5 on Control over Drugs[29]. All medicines intended for human use must receive

[25] See: ECIPE Policy Brief: China's Public Procurement Protectionism and Europe's Response: The Case of Medical Technology: https://ecipe.org/publications/chinas-public-procurement-protectionism/
[26] Consultation and Cooperation Mechanism between the Directorate-General for Health and Consumers of the European Commission and the State Food and Drug Administration of the People's Republic of China https://www.asktheeu.org/en/request/502/response/1828/attach/12/Memorandum%20of%20understanding%201.pdf.pdf
[27] See: https://www.ema.europa.eu/en/partners-networks/international-activities/bilateral-interactions-non-eu-regulators/china
[28] China tightens Counterespionage Law - Risk for Audits and Inspections? https://www.gmp-compliance.org/gmp-news/china-tightens-counterespionage-law-risk-for-audits-and-inspections
[29] See: Regulations for Implementation of the Drug Administration Law of the People's Republic of China: http://www.npc.gov.cn/zgrdw/englishnpc/Law/2007-12/14/content_1384270.htm

pre-market approval from the China Food and Drug Administration before being placed on the market.

According to the provisions of the Drug Administration Law, companies importing medication into China must undergo a 10-step application, evaluation and approval process, which in total can take between 265 and 773 days in length[30].

Local Manufacturing Preferences

Regarding generic and biosimilar medicines, it is also important to note that the NMPA manages a list of so-called reference listed drugs (RLP)[31], to which the relevant generic must demonstrate equivalence in both quality and therapeutic effects.

Additionally, China encourages the domestic development of high-quality generic and biosimilar medicines. In this context, it should be noted that China awards the first generic to successfully challenge a relevant patented medicine with 12-month market exclusivity via an innovative patent linkage system, as well as an Abbreviated New Drug Application process.

While there are no explicit local preferences in the application process for generics, the NMPA's order of priority for the choosing of relevant RLP displays a distinct preference for local products:

(1) Originator medicine approved in China,
(2) Medicine manufactured by the confirmed foreign originator pharmaceutical company in China or manufactured with technology transferred from overseas to China,
(3) Originator medicine not imported to China.

When the production of the originator medicine is discontinued, or the originator medicine is not appropriate to be an RLD, the generic medicine applicant may choose an internationally recognized alternative as the RLD. This includes products that have received marketing approval and RLD status in countries and regions with standardized management, such as the U.S., Japan, and the EU.

[30] For a breakdown of the process steps, see: https://www.lehmanlaw.com/resource-centre/faqs/health-sciences/what-is-the-standard-registration-procedure-for-importing-drugs-into-china.html
[31] See: https://baipharm.chemlinked.com/database/catalogue-reference-listed-drugs

Local rules on pricing and reimbursement

For launching a pharmaceutical product in China, registration on the National Reimbursement Drug List (NRDL) is required. The List is updated on an almost annual basis. Once on the list, the national basic medical insurance covers 50% to 70% of the cost of the medicines, on average, with generics enjoying full reimbursement.

The NRDL is separated into two classes:

- Class A: Generic medicines that are 100% reimbursed,
- Class B: premium medicines that are partially reimbursed (50%-90%)

It is notable that NRDL negotiations with industry occur on an almost annual basis. While not legally mandated, during these negotiations, companies regularly lower drug prices in order to secure a place on the NRDL. As such, according to a Study on "Access to innovative drugs and the National Reimbursement Drug List in China," public reimbursement in China continues to align more closely with the approaches most used in Europe.[32]

As of 1 January 2024, the 2023 NRDL is in effect, with a total of 3,088 medicines, including 126 new additions. The 126 new additions can be classified as:

- 21 medicines for tumour treatment
- 17 medicines for covid-19 treatment and anti-infection
- 15 medicines for diabetes, psychotropic drugs, and autoimmune diseases
- 15 medicines for rare diseases (among them, Avapritinib Tablets are also used for tumour treatment)
- 59 medicines for other therapeutic areas

Out of the 126 additions, a total of 121 underwent price negotiation, resulting in an average reduction of price by 61.7%. The remaining 5 medicines were directly selected for inclusion in the NRDL.

[32] Journal of Market Access: Access to innovative drugs and the National Reimbursement Drug List in China: Changing dynamics and future trends in pricing and reimbursement (2023): https://www.ncbi.nlm.nih.gov/pmc/articles/PMC10266112/

Intellectual property rules

The recently introduced patent linkage system and supplementary protection certificate are major barriers to timely market access for generic and biosimilar medicines.

While a review of the Drug Registration Regulation sought to address the substantial systematic concerns, China's patent linkage system would be considered "unlawful" under EU law[33] and forms a systematic barrier to market access by generics and biosimilars.

Conclusion

China is ranked as the world's second-largest biopharmaceutical manufacturer, primarily focusing on generic and biosimilar medicines. Government procurement policies are driven by the "Buy Chinese" principle and heavily favour domestic suppliers, despite Chinese access to EU procurement. Currently, there is no EU-China Mutual recognition Agreement, but a "Consultation and Cooperation Mechanism" is in place. China is found to prioritise local generic and biosimilars development which is evident in the NMPA'S preference for domestic products.

Launching a pharmaceutical product in China requires registration on the National Reimbursement Drug List (NRDL), while the import of non-Chinese manufactured medication is governed by the Drug Administration Law of the People's Republic of China. Intellectual Property Rules issue significant barriers to market access for generic and biosimilar medicines.

[33] European Commission: Pharmaceutical Sector Inquiry – Final Report (Page 315)(2009): https://competition-policy.ec.europa.eu/system/files/2022-05/pharmaceutical_sector_inquiry_staff_working_paper_part1.pdf

Market Access Barriers

India

Public Procurement rules	Regulatory Assessments	Local Manufacturing	Pricing and Reimbursement	Intellectual Property rules
"Preference to Make in India Order" puts 'non-local' suppliers in a less competitive position.	Limited EU-India cooperation on GMP and clinical trials; Medicines and international manufacturing site must be registered for import.	Ambition for local sourcing, identifying and securing of critical supplies in the pharmaceutical supply chain.	Price fixing based on market-based approach; Same treatment for Indian and non-Indian manufactured generics.	No limitations; Indian Patent Act provides for both pre-grant and post-grant opposition measures.

Introduction

India is a major exporter of pharmaceuticals – in particular of generic medicines - worldwide, with over 200 countries served. India supplies over 50% of Africa's requirement for generic medicines, 40% of the generic demand in the US and 25% of all medicines in the UK. Eight out of 20 global generic companies are from India. It is also notable that 65-70% of WHO vaccines are sourced from India[34].

On 17 June 2022, the European Union relaunched negotiations with India for a Free Trade Agreement and launched separate negotiations for an Investment Protection Agreement[35]. The negotiations aim to remove structural barriers to trade and open up services and public procurement markets to companies in both markets. Additionally, the negotiations on an investment protection agreement aim to provide investors from both sides with legal certainty and protection for non-discrimination, expropriation without compensation and unfair treatment of investors and their investments, while preserving the right to regulate.

Moreover, in February 2023, the EU and India launched a Trade and Technology Council (TTC)[36] to "deepen strategic engagement on trade and technology", with a dedicated Working Group for

[34] See: Pharmaceutical industry, Pharmaceutical Exports from India- IBEF
[35] For all negotiating proposals and reports, see: https://policy.trade.ec.europa.eu/eu-trade-relationships-country-and-region/countries-and-regions/india/eu-india-agreement/documents_en
[36] For the Terms of Reference, see: https://digital-strategy.ec.europa.eu/en/library/terms-reference-eu-india-trade-and-technology-council

trade, investment and resilient value chains. A first annual meeting of the TTC was held in May 2023[37].

The Government of India has implemented measures to boost domestic pharmaceutical manufacturing and reduce import dependencies through two Production Linked Incentive (PLI) schemes. The PLI scheme for Key Starting Materials (KSMs), Drug Intermediates (DIs), and Active Pharmaceutical Ingredients (APIs) and the PLI scheme for Pharmaceuticals. These support 48 projects and 55 selected applicants respectively.[38]

Public procurement rules

India's public procurement rules on pharmaceuticals are shaped by the Government's "Preference to Make in India Order" and its relevant implementing guidelines[39]. Subject to the provisions of this Order and to any specific instructions issued by the Nodal Ministry or in pursuance of this Order, staggered purchase preference shall be given to 'Class I local supplier', 'Class II local supplier', followed by non-local suppliers.

Under the rules, so-called 'non-local' suppliers are thus placed in a structurally less competitive position competing for Indian Government contracts than local suppliers. The main exception to the rule regards global tender enquiries, allowed for contracts exceeding INR 200 crore, unless prior approval from the competent authority is obtained. In these cases, 'non-local suppliers' are considered to be eligible to bid with 'Class-I local suppliers' and 'Class-II local suppliers', creating a level playing field.

Regulatory Assessments

Building on a cooperation agreement with India dating from 1994, the EU and India adopted a joint action plan for the India-EU strategic partnership in 2005, setting up a dedicated Working Group on Pharmaceuticals.

As part of this cooperation, the EMA supports India[40] in applying international standards, particularly for good manufacturing practice (GMP) and clinical trial activities, facilitates capacity building and regulatory contacts, and also facilitates discussions with the Indian

[37] At the first TTC, the EU and India agreed to deepen their common work on resilient value chains, work to resolve bilateral market access issues and exchange information on each other's mechanisms on foreign direct investment screening.
[38] For details on the selected projects and applicants, see: Schemes | Department of Pharmaceuticals
[39] See: https://pharmaceuticals.gov.in/policy/public-procurement-policy
[40] https://www.ema.europa.eu/en/partners-networks/international-activities/bilateral-interactions-non-eu-regulators/india

authorities regarding regulatory aspects related to ayurvedic medicine and its use in Europe, through its Committee for Herbal Medicinal Products.

Additionally, it is noteworthy that the import, manufacturing, sale, and distribution of pharmaceutical products, including APIs and finished formations is regulated by the Drugs and Cosmetics Act and the Drugs and Cosmetic Rules[41]. Under the Act, not only medicinal products themselves, but also the international manufacturing site needs to be registered for importation to India. If the drugs fall within the definition of a "New Drug" (Rule 122 E), the New Drug Approval is the pre-requisite for submission of an application for registration and/or importation of the product.

An application[42] for registration and importation must be made to India's Licensing Authority[43] under the Act by the Local Authorized Agent of the foreign manufacturer, having either an Indian manufacturing or sales license, or by an Indian entity having a wholesale license.

The Indian government also intends to overhaul its regulatory framework with a draft New Drugs, Medical Devices and Cosmetics Bill, proposed in 2022 and intended to replace the 1940 Drugs and Cosmetics Act. [44]

Local Manufacturing Preferences

For the purposes of the abovementioned public procurement preferences, the 30th December 2020 Ministry of Chemicals & Fertilizers Guidelines on the Procurement of Goods & Services in Pharmaceutical Formulations set the following minimum local content criteria: [45]

- Class-I local supplier: local content equal to or more than 80%.
- Class-II local supplier: local content more than 50% but less than 80%.
- Non-Local supplier: local content less than or equal to 50%.

[41] See: https://cdsco.gov.in/opencms/export/sites/CDSCO_WEB/Pdf-documents/acts_rules/2016DrugsandCosmeticsAct1940Rules1945.pdf
[42] For detailed guidance, see: https://cdsco.gov.in/opencms/export/sites/CDSCO_WEB/Pdf-documents/import-registration/Import_guidance_doc.pdf
[43] Drugs Controller General (I) at CDSCO, FDA Bhawan, Kotla Road, Near Bal Bhawan, New Delhi
[44] For an overview: Background Note on The Drugs, Medical Devices and Cosmetics Bill, 2023
[45] See: Guidelines for implementing the provisions of Public Procurement (Preference to Make in India) Order (PPO), 2017 - revision, related to procurement of Goods & Services in Pharmaceutical Formulations.pdf

National Pharmaceutical Strategy

In October 2023, the Indian Government launched its draft National Pharmaceutical Policy[46], designed to align with the Government's overarching "Vision Pharma 2047[47]" economic strategy. The Strategy seeks to make India a global leader in the manufacturing of innovative and quality pharmaceuticals and medical devices. Critically, among the key ambitions of the draft Policy is the promotion of local sourcing and the identifying and securing of critical supplies in the pharmaceutical supply chain.

The National Pharmaceutical Policy seeks to complement the Vision by strategically addressing the challenges faced by India's pharmaceutical industry and provide definitive policy interventions to enhance the collective ecosystem. For this, it focuses on 5 key pillars:

1. Global Pharmaceutical Leadership,
2. Promoting Self-Reliance,
3. Advancing Health Equity and accessibility,
4. Enhancing Regulatory Efficiency in the Indian Pharmaceutical Sector, and
5. Attracting investments.

Local rules on pricing and reimbursement

The National Pharmaceutical Pricing Authority[48] (NPPA), an independent body of experts in the Ministry of Chemicals and Fertilizers Department of Pharmaceuticals, is responsible for the fixation and revision of prices of scheduled formulations under the Drugs (Prices Control) Order (DPCO), as well as monitoring and enforcement of drug prices. NPPA also provides inputs to Government on pharmaceutical policy and issues related to the affordability, availability, and accessibility of medicines.

The NPPA fixes the ceiling price of formulation listed in Schedule I of the DPCO – the National List of Essential Medicines (NLEM). Under the market-based approach adopted in DPCO 2013, the ceiling price of a scheduled formulation is determined by working out the average of price to retailer (PTR) in respect of all branded-generic and generic versions of that particular formulation having a market share of one percent and above, and then adding a notional retailer margin of 16% to it. The same treatment is granted to both Indian and non-Indian manufactured generics. The maximum retail price (MRP) for that particular drug formulation must not exceed the notified ceiling price plus applicable taxes.

[46] See: https://pharmaceuticals.gov.in/sites/default/files/31.10.23%20Draft%20National%20Pharmaceuticals%20Policy.pdf
[47] See: https://darpg.gov.in/sites/default/files/final%20vision%20india2047..approved.pdf
[48] See: https://pharmaceuticals.gov.in/dpconppa

The NPPA fixes the retail price (RP) of medicine based on the Form-I application received from marketing authorisation holders (MAH). The notified RPs are applicable only to the applicant MAHs. Retail prices are fixed on the same method as applicable for fixation of ceiling price.

NPPA also fixed the retail prices of Fixed Dose Combinations (FDCs) of various anti-diabetic medicines that have become off-patent/on the verge of becoming off-patent, to ensure that the benefit of medicines becoming off-patent is passed on to the consumer.

Intellectual property rules

According to the European Commission, India's intellectual property rights environment often lacks stability and predictability. However, it is notable that opportunities to block or significantly delay the entry to market of generic and biosimilar products are more limited in India compared to other jurisdictions given the Indian Patent Act provides for both pre-grant and post-grant opposition measures[49]. Under the Act's opposition mechanism, third parties have at least six months from the publication date of the application to file a pre-grant opposition. Meanwhile, a post-grant opposition may be filed within one year of the patent granting decision.

It is for this resulting legal certainty for generic and biosimilar manufacturers, that the European Commission has sought to introduce a pre-grant opposition mechanism in its legislative proposal on the introduction of a Unitary SPC for medical products[50].

Conclusion

The EU and India are actively engaged in negotiations for both a Free Trade Agreement and Investment Protection Agreement, aimed at removing trade barriers and enhancing cooperation in services and public procurement. Additionally, the launch of a Trade and Technology Council (TTC) in 2023 signifies a joint effort to strengthen trade and investment.

India's procurement policies are shaped by the "Preference to make in India Order" and can create some challenges for non-local suppliers. India intends to to align with global best regulatory practices as the Indian Government seeks to make India a global leader in the manufacturing of innovative and quality pharmaceuticals. Regulation in India is covered by the National Pharmaceutical Pricing Authority and the Drugs and Cosmetics Act. In terms of

[49] For further information and ground for opposition, see: https://www.wipo.int/export/sites/www/scp/en/revocation_mechanisms/opposition/pdf/opposition_india.pdf
[50] For the full set of proposals, see: https://single-market-economy.ec.europa.eu/publications/proposals-regulations-supplementary-protection-certificates_en

intellectual property rights, while the European Commission has highlighted concerns regarding the stability and predictability of India's environment, the presence of pre-grant and post-grant opposition mechanisms guarantees more legal certainty for generic and biosimilar manufacturers.

Market Access Barriers

Indonesia

Public Procurement rules	Regulatory Assessments	Local Manufacturing	Pricing and Reimbursement	Intellectual Property rules
Procurement via a national "e-Katalog"; Must be on list of eligible products; Negotiated prices based on import transfer price + additional percentage.	No EU-Indonesia agreements; Ongoing discussions in context of FTA negotiations.	Local content requirements favouring domestic manufacturers.	Government fixed pricing structures for generic medicines.	No limitations.

Introduction

With the world's fourth-largest population, Indonesia is the largest pharmaceutical market in the Southeast Asia region, with the market growing by nearly 50% in 2021. Demand for pharmaceutical products in the country has grown steadily over the past decades as a result of improved access to public healthcare through the introduction of a Universal Health Coverage scheme. According to the WHO, Indonesia allocates 3% of GDP (2019) to health expenditure. As a result of improved access to public healthcare, life expectancy at birth (years) has improved by 4.14 years from 67.2 years in 2000 to 71.3 years in 2019[51].
According to the Indonesian Pharmacists Association, approximately 95% of pharmaceutical APIs are imported from other countries, with the level of foreign ownership of pharmaceutical companies having increased from 75% to 100% over the past decade. In Indonesia, generic medicines are used as much as 70% for patients with national health insurance, while patented drugs are used as much as 30% for patients without insurance[52].

For the Indonesian government, protection for pharmaceutical patents, while required under the WTO TRIPS Agreement, constitutes a serious public health issue given its budgetary restrictions[53]

[51] See: https://data.who.int/countries/360
[52] See: Rochmah TN, Ratnasari D, Robby HD. Comparison of economic loss between generic drug and patent drug in stock-out and stagnant condition at Surabaya Islamic Hospital, Indonesia. J Public Health Afri. 2019;10(s1):1169
[53] See: https://one.oecd.org/document/DAF/COMP/WD(2018)114/en/pdf

and public policy goal of providing affordable and low-barrier access to medicines through domestic developmental policy[54]. Under government rules, generic and biosimilar medicines[55] are classified into two groups - unbranded and branded.

Public procurement rules

Indonesia's pharmaceutical public procurement system lets local governments - including government-owned - shop online via an "e- Katalog". The system requires entities to seek maximum local content[56] in order to ensure domestic inputs or resources in industrial production, with goods that meet local manufacturing requirements receiving prioritized system access. In 2019, hospitals and clinics used the e-Katalog system to procure $2.7 billion worth of medicines and medical devices covered by Indonesia's national public health insurance system. The e-Katalog is managed by the Government Goods & Services Procurement Policy Agency (LKPP).

There are three main methods used to procure medicines and medical devices for hospitals and clinics in Indonesia under the national public health insurance system.

1. First, national public procurement tenders are used for products of similar specifications that can be supplied by multiple distributors.
2. Second, the national e-Katalog online procurement system is used by public and private hospitals and clinics to procure specialized medicines and medical devices for which there is only one supplier or very few suppliers.
3. Third, individual hospitals conduct procurement tenders, usually for more highly specialized products that would only be used at that hospital.

Only products that have current Indonesian regulatory approval and have been included in the Ministry of Health's list of eligible products are considered for enrolment in the e-Katalog. Prices are negotiated between LKPP staff and the local MAHs. For imported products, prices are negotiated based on the import transfer price plus an additional percentage to allow for local distribution costs, post-marketing surveillance costs, and a profit margin[57], including biosimilars, generics and branded off-patent products.

[54] Tomi Suryo Utomo: the pharmaceutical patent protection impact on Indonesia drugs price: https://media.neliti.com/media/publications/40693-ID-the-pharmaceutical-patent-protection-impact-on-indonesia-drugs-price.pdf
[55] A generic drug is defined as a copy of an ethical (prescription) drug formerly protected by patents that have now expired. Both unbranded generics and all branded generics are included. However, off-patent drugs that continue to be offered by the original manufacturer under the original name, and which form part of the 'generic eligible market, are not included.
[56] See: https://trade.ec.europa.eu/access-to-markets/en/barriers/details?barrier_id=11121&sps=false
[57] See: U.S. Department of Commerce, International Trade Administration https://www.trade.gov/market-intelligence/indonesia-medical-procurement-system

Regulatory Assessments

There are currently no third country agreements between the European Union and Indonesia governing confidentiality agreements or concerning the conformity assessment of regulated products. There are, however, ongoing discussions between the European Commission and Indonesia on pharmaceuticals in the context of the ongoing free trade agreement negotiations[58].

Local Manufacturing Preferences

Under Ministry of Industry Regulation No. 16/2020, medical products that have been certified by the Ministry of Industry as having high local content are prioritised over otherwise similar imported products in e-Katalog procurement[59].
The regulation provides for specific calculation methods of local content for pharmaceutical products based on their raw materials (50%), research and development (30%), manufacturing (15%), and packaging (5%)[60].

It is important to note that both the current and incoming governments are committed to enhancing pharmaceutical resilience by focusing on locally manufactured raw materials.

Local rules on pricing and reimbursement

Indonesia's 2023 "Health Omnibus Law" allows the central government to centrally regulate and control the prices of drugs and medical devices, including via "MoH Regulation 98 on Highest Retail Prices of Drugs". Without prejudice to country of origin, Regulation 98 stipulates the highest retail price (known as harga eceran tertinggi or HET) for generic, biosimilars and non-generic medicines from pharmacies to patients.

[58] For more information on the EU-Indonesia FTA negotiations, see: https://policy.trade.ec.europa.eu/eu-trade-relationships-country-and-region/countries-and-regions/indonesia/eu-indonesia-agreement_en

[60] For a full breakdown of requirements and the calculation method, see https://ssek.com/blog/new-local-content-regulation-for-pharmaceutical-products-in-indonesia/

However, it appears that the government only imposes fixed pricing structures under Regulation 98 for generic medicines[61], the prices of which must follow the fixed prices issued by the government through either of the following:

- MOH decrees (for generic drugs that are not sold in e-catalogues)
- The e-catalogue prices set out for the medicines (for generic medicines that are sold through the e-Katalog).

Intellectual property rules

Indonesia does not provide for patent term extensions, nor does it have a patent linkage system in place.

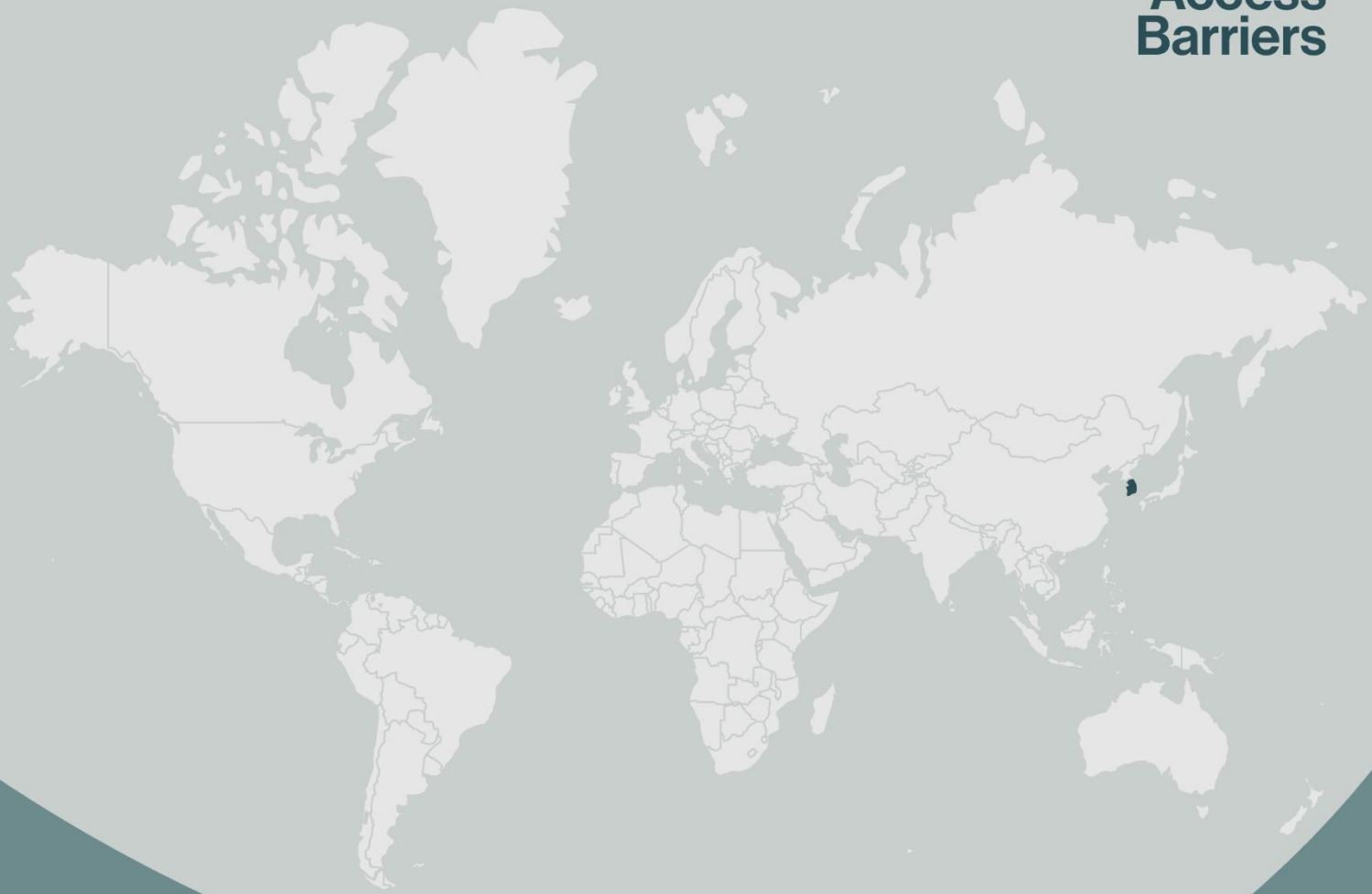
Conclusion

When considering both Active Pharmaceutical Ingredients (API) and Finished Dosage Forms (FDF) together, Indonesia has the largest pharmaceutical market in Southeast Asia, with generic medicines accounting for up to 70% of treatments covered by national health insurance. The public procurement system requires entities to seek maximum local content in order to promote domestic inputs or resources in industrial production. Products must have Indonesian regulatory approval and be included in the Ministry of Health's list of eligible products to be considered for enrolment in the e-Katalog.

Currently, there are no EU-Indonesia agreements governing confidentiality or concerning the conformity of regulated products, but discussions are ongoing within trade negotiations. Local content requirements favour domestic manufacturers. Indonesia's 2023 "Health Omnibus Law" allows the central government to centrally regulate and control the prices of drugs and medical devices, notably through "MoH Regulation 98 on Highest Retail Prices of Drugs".

[61] For further information, see: https://insightplus.bakermckenzie.com/bm/healthcare-life-sciences/indonesia-health-omnibus-law-series-key-updates-on-pharmaceutical-preparation-and-medical-device-provisions

Market Access Barriers



Republic of Korea

Public Procurement rules	Regulatory Assessments	Local Manufacturing	Pricing and Reimbursement	Intellectual Property rules
No specific limitations on generic and biosimilar medicines.	Regulatory cooperation under the FTA; Generics approved at regional level.	No explicit preferences; Promotion of domestic manufacturing.	Positive list system grants benefits selectively to products with excellent treatment and high economic value; Price of generic medicines determined by formula.	Patent Linkage System; Patent Term Extension.

Introduction

The Republic of Korea's pharmaceutical industry is a significant player in the Asian bio-pharmaceutical value chain. Valued at around 25.4 trillion Korean Won (KRW) as of 2021, pharmaceutical spending accounted for approximately 1.7% of Korea's GDP in 2022.

Based on the principle of "same ingredients and same strength, at the same price", in April 2012, Korea introduced a policy that mandated both the prices of generic and off-patent originator medicines to be set at 53.55% of the on-patent prices of the originator 1 year after entering the market to curb increasing medication expenses. This policy applies to products with three or more generic medicines with the exception of certain products and aims to lower overall medicine prices and eliminate the price gap between brand-name drugs and generic and biosimilar medicines[62].

[62] Kim D-S, Shin J, Chung J. Analysis of the Korean generic medicine market: Factors affecting the market share of generic medicines. Clin Transl Sci. 2022; 15:433–441. 10.1111/cts.13161 https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8841453/#:~:text=For%20oral%20drugs%2C%20the%20value,billion%20(18.8%25)%20in%202019

Thus, Korea does not have an incentive to use generic medicines because the out-of-pocket costs for patients remain the same as for brand-name medicines[63].

Public procurement rules

Since 2011, a comprehensive European Union – Republic of Korea Free Trade Agreement[64] is operational, with the Agreement also addressing non-tariff barriers in the pharmaceutical and medical devices sector through its provisions on IP rights and government public procurement.

Trade in pharmaceuticals is set out in a dedicated Annex (Annex 2-D) to the FTA, with access to Korea's public procurement market provided under both the Agreement and the Republic of Korea's ratification of Annex 4 of the WTO Agreement on Government Procurement (GPA).

Regulatory Assessments

Annex 2-D of the FTA includes provisions to foster regulatory cooperation on pharmaceuticals and medical devices.

Through these provisions, the EU and the Republic of Korea have agreed to take into account international provisions, practices and guidelines and to consider requests by either Party to accept conformity assessments of that Party when performed in accordance with the Good Laboratory Practices and Good Manufacturing Practices of pharmaceutical products and medical devices and when both Parties' corresponding practices are in accordance with international practices.
A Working Group on Pharmaceutical Products and Medical Devices, established under article 15.3 of the FTA, meets at least once a year to promote cooperation between the EU and the Republic of Korea.

Within the general pharmaceutical system, medicines have to be approved by the Ministry of Food and Drug Safety (MFDS) before they are made available on the market. MFDS.. An expedited review is applied to medicines that need prompt approval to treat serious, life-threatening

[63] Kim DS, Park S, A Focus Group Interview Study of Prescribers. Pharmacists, companies, and policy experts on the same price system to the same ingredient medicines. Korean J Health Econom Policy. 2018; 24:123.
[64] European Union: Free Trade Agreement between the European Union and its Member States and the Republic of Korea: https://eur-lex.europa.eu/resource.html?uri=cellar:a2fb2aa6-c85d-4223-9880-403cc5c1daa2.0022.02/DOC_3&format=PDF

diseases, such as AIDS and cancer. Generic medicines are reviewed by the Drug Evaluation Department and approved by regional FDAs. [65]

Additional bridging studies and local analytical comparability testing are required for biosimilar medicines developed for the EU market to enter the Republic of Korea [66], which increase R&D costs and delay market access.

Local rules on pricing and reimbursement

Under the existing FTA, EU-based exporters of pharmaceuticals and medical devices to Korea benefit from more transparent pricing decisions in the government public procurement process, within which Korean health authorities set the medicines' reimbursement prices at which drugs are reimbursed.

Under the provisions of the FTA, Korea:

- introduced detailed binding rules on transparency regarding decisions on reimbursement,
- stipulated the option of having such pricing decisions reviewed by a court,
- ensured the criteria on which the decisions on reimbursement and pricing are based shall be objective and clear, and
- set up a working group for regulatory co-operation. The EU and Korea should consider requests to accept each other's conformity assessments based on international practices.

Within the general pharmaceutical system, medicines have to be approved by the Ministry of Food and Drug Safety (MFDS) before they are made available on the market. New medicines that need a safety and efficacy review are examined by the MFDS, while generic medicines are approved by regional offices of the MFDS. An expedited review is applied to medicines that need prompt approval to treat serious, life-threatening diseases, such as AIDS and cancer.

Korea operates a positive list system, which grants benefits selectively to products with excellent treatment and high economic value[67]. The assessment for inclusion is undertaken by a Drug

[65] More details on the approval process are available here
[66] Ministry of Food and Drug Safety of the Republic of Korea, National Institute of Food and Drug Safety Evaluation, Biosimilar Product Evaluation Guideline, July 2022, available here
[67] However, essential medicines that are used for serious, life-threatening diseases without an alternative treatment method can be listed in the national drug formulary list, even if their cost-effectiveness has not been proven.

Benefit Coverage Assessment Committee (DBCAC) comprised of representatives of consumer and health professional groups and related experts to assess whether a new medicine will be listed in the national drug formulary list. While new medicines have to undergo price negotiations, the price of generic medicines is determined by a formula[68].

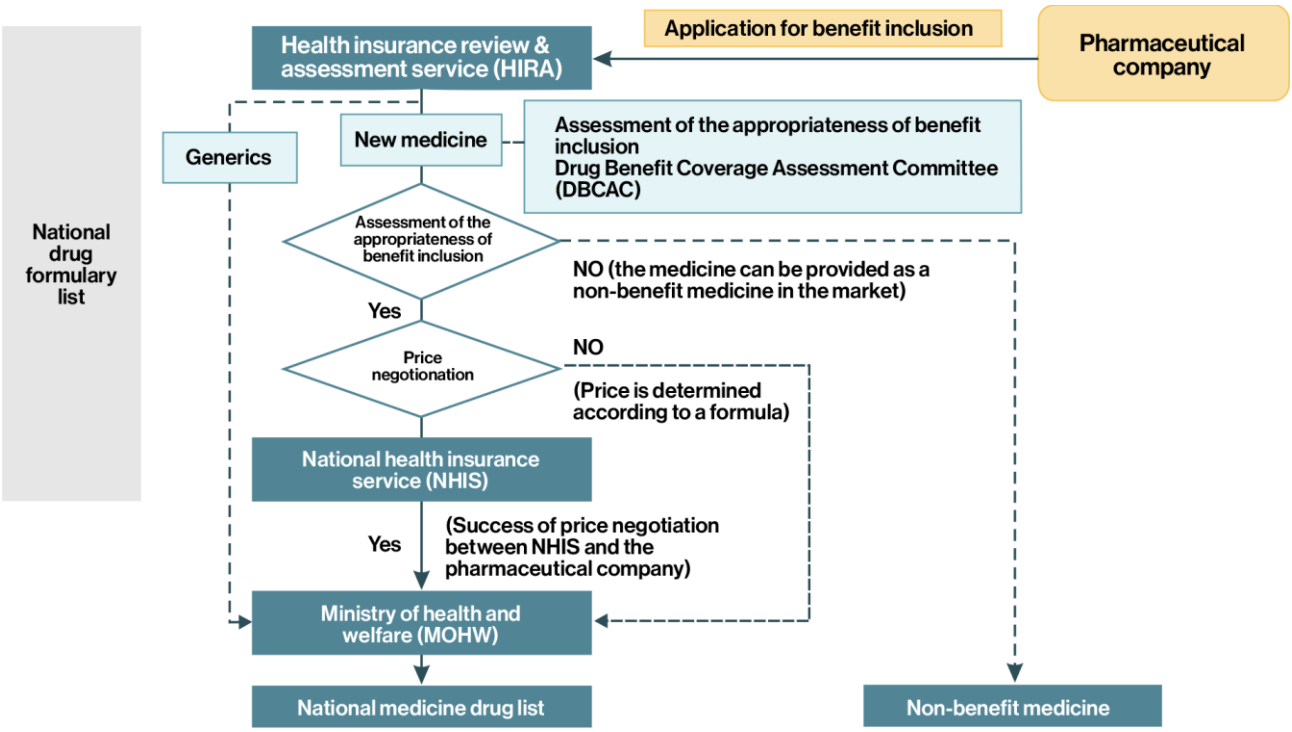


Figure 1: Republic of Korea - System for the approval, listing, and reimbursement © PPRI/WHO

Incentive system for generics

Under the Korean system, if a pharmacist intends to substitute a prescription medicine with another medicine, the pharmacist requires prior consent from the prescriber. However, if the pharmacist substitutes a medicine with another medicine with the same compound, dose, and formulation and with proven bio-equivalency, advance consent is not required, but only notification of the prescriber within a day.

This "generic substitution system" provides a considerable financial incentive for pharmacists to prescribe generic medicines, as they will obtain 30% of the price difference between the prescribed and the substituted medicines as an incentive.

[68] See WHO/Pharmaceutical Pricing and Reimbursement Information (PPRI): https://ppri.goeg.at/sites/ppri.goeg.at/files/inline-files/PPRI_Pharma_Profile_SouthKorea_final.pdf

Moreover, Korea operates an Incentive Program for Medicine Cost Saving to promote the use of generic medicines. Under this program, Korean medical institutions and pharmacies can receive an incentive when they reduce medicine costs by substituting with cheaper alternatives or purchasing medicines at lower prices. The total incentive amount to medical institutions is a sum of the incentive for purchasing medicines at lower prices and the incentive for the reduction of medicine use.

Local Manufacturing Preferences

While the Government of Korea actively promotes domestic manufacturing of pharmaceuticals, particularly in the generic and biosimilar sector, its healthcare system does not operate any explicit preferences for locally manufactured pharmaceuticals.

Intellectual property rules

As part of the implementation of its FTAs with the European Union and the United States of America, the Korean government introduced a patent term extension of up to 5 years, significantly delaying patient access to generic and biosimilar medicines.

Moreover, the patent linkage system in place in Korea translates into additional barriers for the generics and biosimilars industry, as access to market may be considerably delayed through extensive legal activities for being granted market approval[69]. Relevant patents in Korea are published in the Ministry of Food and Drug Safety's so-called K-Orange Book, with those listed subject to the patent linkage system.

Conclusion

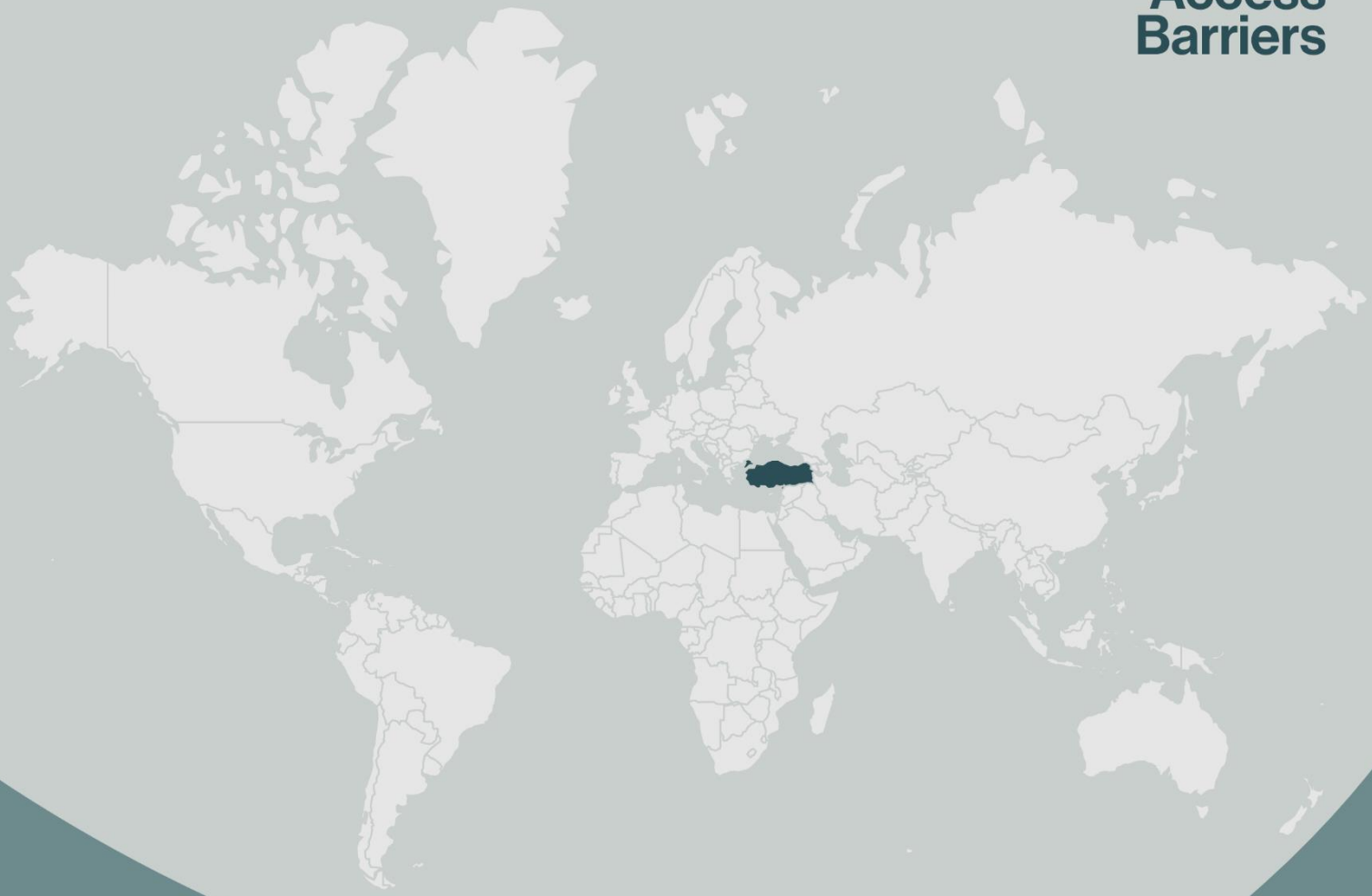
The Republic of Korea's pharmaceutical industry plays a significant role in the Asian bio-pharmaceutical value chain. The European Union-Republic of Korea Trade Agreement, in effect since 2011, includes provisions on intellectual property rights and government procurement, with a dedicated annex for pharmaceutical trade. EU exporters also benefit more from clearer pricing

[69] South Korea's patent linkage system would be considered "unlawful" under EU law in line with the European Commission's 2009 Pharmaceutical Sector Inquiry: https://competition-policy.ec.europa.eu/system/files/2022-05/pharmaceutical_sector_inquiry_staff_working_paper_part1.pdf

decisions in public procurement. Within the general pharma system, medicines must be approved by the Ministry of Food and Drug Safety before market availability.

Korea's system also requires pharmacist consent for generic substitution but offers a financial incentive for pharmacists to prescribe generic medicines. While the government does promote domestic pharmaceutical manufacturing, there are no explicit preferences for local products. A patent linkage system introduced in 2015 carries a complicated market approval for generic medicines under the US-Republic of Korea FTA. All relevant patents can be found in the Korean Ministry of Food and Drug Safety's so-called K-Orange Book.

Market Access Barriers



Türkiye

Public Procurement rules	Regulatory Assessments	Local Manufacturing	Pricing and Reimbursement	Intellectual Property rules
Each hospital operating its own procurement; Pricing main criteria for tender acceptance. No requirement to share information on procurement processes and their results.	No EU-Türkiye agreements; Türkiye does not accept EU GMP since 2010, resulting in delays and added costs.	The 2016 forced localisation rules have been reversed.	Reference Price System; Based on pricing structures in FR, SPA, IT, POR, GRE + prices of exporting country + serial release country. Final price = lowest price of any above.	No limitations.

Introduction

Public health indicators in Türkiye have improved significantly since 2002 due both to the changes in the healthcare system and improvements in socioeconomic indicators. Importantly, in 2003, the public healthcare system began a 10-year structural reform[70] from a segmented, low coverage and unequal benefits package scheme to a comprehensive, unified and same benefits package system for all residents. The change has contributed to improvements in availability and accessibility of health care services.

Under the reformed system, a primary emphasis has been placed on cost-containment strategies, with the system revolving around reference pricing, statutory discounts and cost-effectiveness assessments, as well as a global budget for pharmaceuticals.

[70] For further information about Türkiye's 2003 Health Transformation Programme, see: https://www.worldbank.org/en/results/2018/04/02/turkish-health-transformation-program-and-beyond

Public procurement rules

Under the Turkish system, hospitals carry out their own procurement procedures, with each hospital operating its own procurement commission. Pricing is the main criterion for accepting a tender, with the lowest-priced offer winning[71]. In predetermined competitions (by-invitation only procurements)[72], companies for consideration are directly contacted by the relevant commissions. It is notable that hospitals do not share information about their procurement processes and their results. Additionally, there are no pharmacoeconomic evaluations required and no HTAs.[73]

Regulatory Assessments

As an EU accession candidate country, there is a considerable amount of regulatory cooperation between Turkish and EU authorities. Chiefly among them is the "EU4 alignment on medicines regulation in the Western Balkans and Türkiye' project under the European Commission's Instrument for Pre-Accession Assistance Programme[74]. Planned activities under the project include Planned activities for beneficiaries which include Türkiye's participation as observer in selected EMA working groups and parties among others.

Despite the regulatory cooperation as part of Türkiye's accession programme, however, there are no formal regulatory exchanges or agreements. Although there have been calls from the originator industry for a possible mutual recognition agreement with Türkiye[75], there have been instances where Turkish companies passed initial GMP audits but failed follow-up audits two years later. Given the very low prices of pharmaceuticals in Türkiye, there are concerns about whether all locally produced products sold in the Turkish market fully comply with GMP standards.

It should also be noted that Türkiye does not accept EU Certificates of Good Manufacturing Practices (GMP) since March 2010[76]. In the absence of reciprocal agreement on the acceptance

[71] Pharmaceuticals are not mixed with other goods and services and are purchased alone. The frequency of the procurement process is determined entirely by the hospital itself.
[72] Cases where the good or service has some specific characteristics and not everyone can produce.
[73] See WHO/Pharmaceutical Pricing and Reimbursement Information (PPRI): https://ppri.goeg.at/sites/ppri.goeg.at/files/inline-files/Short_PPRI_Pharma_Profile%20Turkey%202017_consolidated_1.pdf
[74] The project started in January 2024 and covers activities until 2026.
[75] See: https://www.efpia.eu/media/578016/efpia-input-to-trade-policy-review-consultation-final.pdf
[76] Following a circular of the Turkish Ministry of Health (MoH) issued on 31 December 2009, manufacturers of pharmaceutical products exported to Türkiye must submit a GMP certificate issued by the Turkish MoH or the authority of another country with which Türkiye has reciprocal certification agreement.

of GMP certificates, EU manufacturers are obliged to submit a number of documents related to their manufacturing facilities and are subject to on-site inspections by the Turkish authorities.

This has led to a significant backlog of unprocessed requests[77], as well as considerable delays in the registration and marketing in Türkiye of new pharmaceutical products, including generic and biosimilar medicines, imported from the European Union.

Türkiye's defunct forced localisation rules

Following the Ministry of Health's 2016 plan to implement a domestic manufacturing policy (localisation policy) for certain pharmaceutical products, in April 2019, the EU launched WTO dispute settlement proceedings against Türkiye claiming that the localisation measure breaches the WTO rules and should be repealed.

Under the policy, all medicines placed on the domestic market, which can feasibly be produced in the country had to be produced domestically. Additionally, it also included provisions for a ban on the use of imported medicines. Under these provisions, local authorities retained the right to reject a medicine from reimbursement, often resulting in the given product being taken off the market or a MAH shifting its manufacturing to local suppliers[78]. Specifically, the practices constituted the requirement for foreign producers of pharmaceuticals to move their production to Türkiye for those pharmaceuticals to be eligible for reimbursement under its national social security schemes.

Following a 2019 challenge by the European Union[79] and a comprehensive Dispute Settlement process by the WTO, Türkiye reversed its policies of localisation and prioritisation of pharmaceutical products[80]. As a result, the issue has been resolved; however, ongoing monitoring is essential, and any violations should be promptly reported.

Local rules on pricing and reimbursement

Since 2004, the pricing of pharmaceuticals in Türkiye has been based on a reference price system. Under the system, the Social Security Institution (SSI), on behalf of the Ministry of Health, will consider pricing structures in France, Spain, Italy, Portugal, Greece, plus the prices of the

[77] For the official barrier registered with the European Commission, see: https://trade.ec.europa.eu/access-to-markets/en/barriers/details?barrier_id=14532&sps=false
[78] See: Made in Turkey: The localization policy and its effects https://www.gbreports.com/article/made-in-turkey
[79] See: https://trade.ec.europa.eu/access-to-markets/fr/barriers/details?barrier_id=10962&sps=false
[80] On 25 July 2022 the WTO's Arbitration Panel ruled in the EU's favour on all claims. https://www.wto.org/english/tratop_e/dispu_e/cases_e/ds583_e_testomar.htm

country from which they are imported, as well as those of the serial release country. The final reference price will be that of the lowest price charged in any of the reference countries.

Although the final reference price will be that of the lowest price charged in any of the reference countries, Türkiye is taking 60% of the previous year's average currency to define the Turkish Lira prices. As a result, if the cheapest product in the five reference countries is 100TL, the same product price becomes around 20-25 TL in Türkiye. Therefore, many companies do not launch their new innovative products and even retrieve some existing ones from the market.

Apart from the low gross price policy, there are high mandatory discount practices for products that want to get reimbursement. The SSI holds a quasi-monopoly role reference price system, allowing it to dictate mandatory discounts to companies. As a result of the low-price policy, some products cannot be found in the market due to their high cost. Due to reference price practices, Turkish prices may also negatively affect other countries. Products may not be provided on the market in Türkiye to prevent prices in different countries from decreasing.

Intellectual property rules

Under the Government's cost containment policy, it is a government objective to promote the access to market of generic and biosimilar medicines.

Türkiye does not provide for patent term extensions, nor does it have a patent linkage system in place.

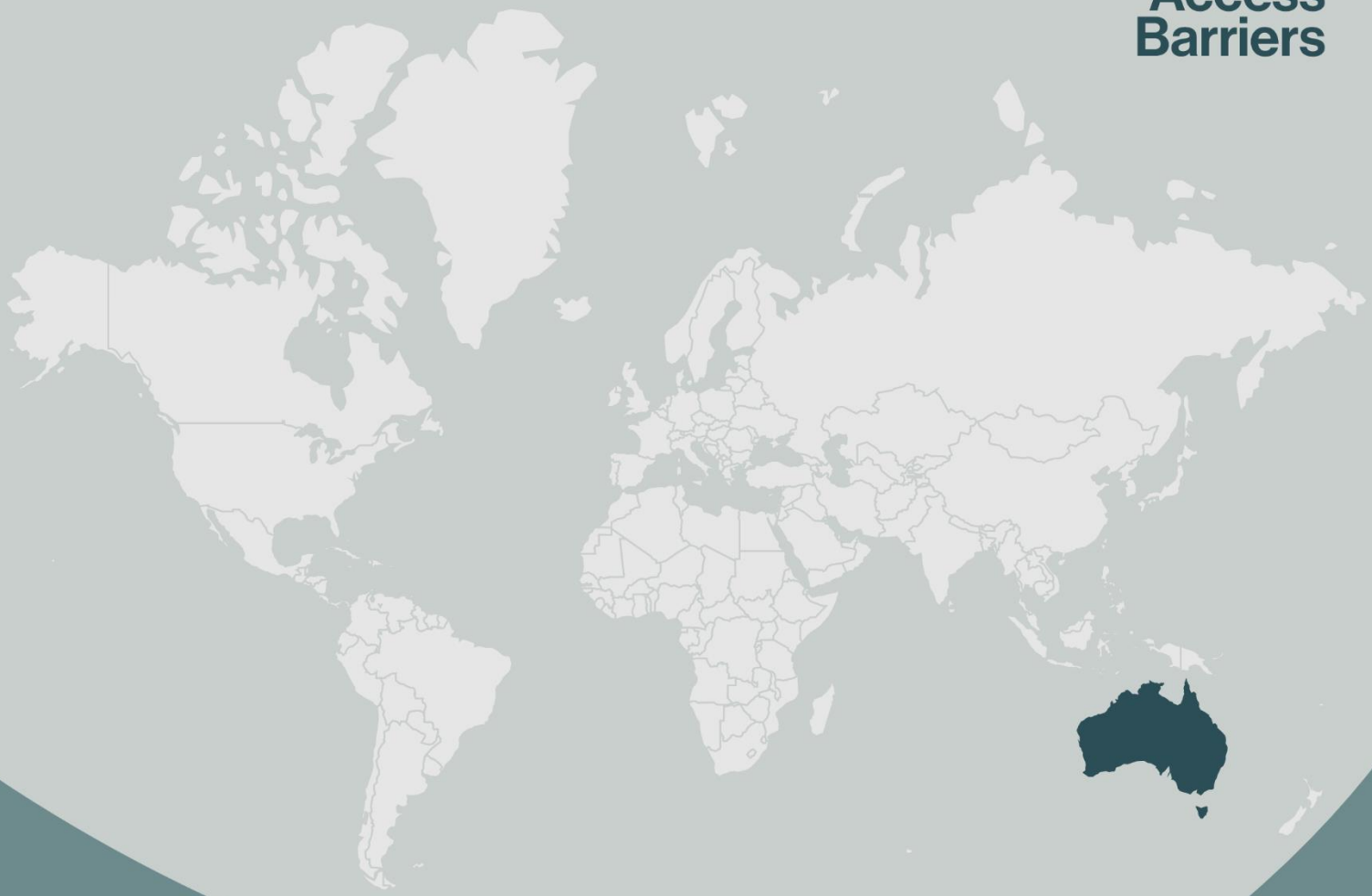
To promote timelier access to generic and biosimilar medicines, the 6-year baseline Regulatory Data Protection period in Türkiye starts from the date of the first marketing authorisation in the EU, as opposed to the first marketing authorisation in Türkiye.

Conclusion

The evolution of Türkiye's healthcare system over the past two decades reflects a complex interplay of reforms, regulatory adjustments, and external pressures. This transition from a fragmented, inequitable healthcare system to a unified, comprehensive system, focusing on cost containment, and the promotion of generic pharmaceuticals, underscores a commitment to enhancing healthcare affordability and sustainability.

Although Türkiye reversed its problematic policies of localisation and prioritisation of pharmaceutical products as a result of the WTO challenge, ongoing monitoring is essential. The reluctance to accept EU GMP Certificates has resulted in barriers, delaying the entry of pharmaceutical products into the market. Moreover, the reference pricing system, while intended, to control costs, may inadvertently limit patient access to certain medications and impact pricing dynamics beyond Türkiye's borders.

Market Access Barriers



Australia

Public Procurement rules	Regulatory Assessments	Local Manufacturing	Pricing and Reimbursement	Intellectual Property rules
No specific limitations on generics and biosimilars; Tendering primarily at State and Territories level; Public Procurement part of EU-Australia FTA negotiations.	MRA on GMP for human medicines in place, but administrative burdens persist.	No specific limitations National ambition to expand local manufacturing.	Funding of medicines through the national Pharmaceutical Benefits Scheme (PBS).	Pre-grant opposition framework; Patent Term Extension.

Introduction

Australia's public healthcare system consists of a complex mix of service providers and organisations at the federal, state and territory level, with all levels of government sharing responsibility for funding, operating, managing and regulating the country's healthcare system. The private for-profit and not-for-profit sectors also play a role in operating public and private hospitals, pharmacies and medical practices, as well as providing private health insurance products.

The federal government is responsible for aspects such as the development of national health policy, the funding of medical services through Medicare – the country's universal healthcare programme - and medicines through the Pharmaceutical Benefits Scheme (PBS), health and medical research, as well as the regulation of medicines and medical devices. Meanwhile, state and territory governments retain responsibility for state-level aspects including the funding and management of public hospitals.

Medicare pays rebates for medical services and procedures provided by private practitioners in the community such as GPs and other medical practitioners, and Medicare ensures Australians

have access to free or low-cost hospital services for public patients in public hospitals and a range of prescription pharmaceuticals subsidised under the PBS. Medicare is funded by the Australian Government through taxation revenue, including a Medicare Levy[81] and a Medicare Levy Surcharge[82]. People who do not qualify for Medicare are either subject to full fees for health services or take out private health insurance.

Public procurement rules

There are approximately 5,800 community pharmacies, 700 public hospitals and 700 private hospitals across Australia, the majority of which have a hospital pharmacy department, or subcontract medication supply and pharmacy services to external pharmacy providers. Public hospitals in every jurisdiction except New South Wales (NSW) and the Capital Territory (ACT)[83] can supply PBS-subsidised medicines across various PBS schedules for patients discharging from hospital, outpatients, and patients receiving care in day-treatment facilities.

Meanwhile, medicines for inpatients at public hospitals are not subsidised through the PBS, meaning that the hospital bears the associated costs through a fixed and/or capped annual medicines budget for medicines expenditure. Thus, when inpatients in public hospitals require the use of high-cost medicines, hospitals may have additional clinical, formulary and budget considerations, creating an incentive to prescribe generic medicines.

Most Australian states and territories have state-wide bodies, who tender for medicines under a state-wide contract. In the majority of states, public hospitals then have an obligation to purchase under the terms of the state-wide contract.

- Contracts typically have a lifetime of 4-6 years.
- The size and scale of procurement for large hospitals can contract lifespans.
- There is more limited tendering in the private hospital system.

According to the Australian Competition Authority (ACCC), there is usually no reluctance amongst hospital pharmacies to switch to generic alternatives, particularly at the state level. It is notable that, most public hospital pharmacies would only stock one brand of a particular drug. Unlike community pharmacies, hospitals patients do not generally have a choice between an originator or generic drug but receive whichever the hospital will have bought through tendering.

[81] The Medicare levy is 2% of taxable income.
[82] The Medicare Levy surcharge ranges between 1%, 1.25% and 1.5% depending on taxable income.
[83] NSW and ACT public hospitals are only able to access PBS-subsidized medicines listed under the s100 Highly Specialised Drugs (HSDs) Program.

According to the ACCC, overall, it is uncommon for an originator to secure long-term contracts once generics enter for high-cost medicines, as the originators are unlikely to be competitive with generic medicines during the tendering process[84].

Negotiations on opening Australia's public procurement market to EU-based companies are ongoing in the context of the EU-Australia Free Trade Agreement.

Regulatory Assessments

The provisions of the 2008 EU-Australian Partnership Framework[85], the basis for current bilateral trade and economic relations, aim to reduce technical barriers and improve trade in services and investment.

Additionally, an EU-Australia Mutual Recognition Agreement (MRA) on GMP for human medicines has been in place since 1999, as well as a confidentiality arrangement between the European Medicines Agency, the European Commission and Australia's Therapeutic Goods Administration since 2012[86].

Under the existing MRA, a two-way alert system on the exchange of certificates of GMP compliance for manufacturers and batch certificates is in operation. The Agreement covers all products manufactured in the territories of the EU and Australia except advanced therapy medicinal products (ATMPs).

As of 1 July 2022, the National Health Amendment (Enhancing the Pharmaceutical Benefits Scheme) Act 2021 gives effect to reforms in the Strategic Agreement[87] with Medicines Australia and the Generic and Biosimilar Medicines Association.

Amongst other things, the amendments to statutory price reductions ensure that First New Brand statutory price reductions automatically apply to existing pharmaceutical items. As a result, new price agreements are not required. An updated list of First New Brand Price Reductions is published monthly by the PBS[88].

[84] See: https://www.accc.gov.au/system/files/public-registers/documents/File%20note%20of%20meeting%20with%20The%20Society%20of%20Hospital%20Pharmacists%20of%20Australia%20-%2016.02.22%20-%20PR%20-%20AA1000592%20Juno%20%26%20Ors.pdf
[85] For further information, see: https://www.eeas.europa.eu/sites/default/files/partnership_framework2009eu_en.pdf
[86] For further information, see : https://www.ema.europa.eu/en/partners-networks/international-activities/bilateral-interactions-non-eu-regulators/australia
[87] For the text of the Strategic Agreement, please see: https://www.pbs.gov.au/info/general/medicines-industry-strategic-agreement
[88] To download the latest version of the First New Brand Price Reductions (in excel): https://www.pbs.gov.au/info/industry/pricing/pbs-items/first-new-brand-price-reductions

As part of the reforms under the National Health Amendment (Enhancing the Pharmaceutical Benefits Scheme) Act 2021, the Therapeutic Goods Administration (TGA) also gained powers to reduce regulatory barriers for generic prescription medicines registration and streamline the application process easier by making regulatory requirements clearer and more transparent.

In 2021, the Strategic Agreements with the Medicines Industry, introduced a new Medicines Supply Security Guarantee to bolster medicine supply and insulate patients, pharmacists, and prescribers from the impact of the increasing number of global medicines shortages by implementing mandatory stock levels for certain critical high-volume medicines.

Local Manufacturing Preferences

While the Australian government set out a comprehensive Medicine-Medical Product Manufacturing roadmap in 2011[89] aimed at increasing domestic manufacturing of pharmaceuticals and medical products are one of the priority sectors of the 2020 Modern Manufacturing Initiative[90], there are no specific local manufacturing requirements or preferences in place – indeed local and non-local manufacturers are required to undergo the same release for supply regulatory processes[91].

Local rules on pricing and reimbursement

Pharmaceutical Benefits Scheme

The Australian Government subsidises the cost of many medicines through the Pharmaceutical Benefits Scheme (PBS), a key component of the country's National Medicines Policy (NMP). The PBS is established under Part VII of the National Health Act 1953. Expenditure on the PBS is uncapped and can therefore increase as new medicines are added and demand grows.

According to a model by Australia's Parliamentary Budget Office, the Australian Government's payments for the PBS are expected to rise from $13 billion to $21 billion.

[89] For further information, see: https://gabionline.net/policies-legislation/Australia-launches-new-medicines-road-map-and-substitution-policy
[90] For further information, see: Modern Manufacturing Initiative and National Manufacturing Priorities announced | Department of Industry Science and Resources
[91] Therapeutic Goods Administration, Manufacturer RFS responsibilities: https://www.tga.gov.au/resources/resource/guidance/release-supply-medicines/manufacturer-rfs-responsibilities

Medicines that are subsidised under the PBS are listed on the Schedule of Pharmaceutical Benefits, which is revised monthly through technical amendments via a National Health Legislation Amendment Instrument[92]. Through the PBS, the Australian government can use its power to determine which pharmaceuticals will be eligible for PBS listing and pricing negotiations[93].

Intellectual property rules

Australia operates a pre-grant opposition system for standard patent applications[94] under Chapter 5, Section 59 of the Australian Patents Act 1990, allowing any person to oppose the granting of a patent within three months of acceptance of the application being advertised in Australia's Official Journal of Patents. This represents a very important safeguard in the patent granting system against any enforcement of patents that unduly delay generic medicines market launch, since it brings forward the invalidation of illegitimate patents without impact on patients, healthcare systems and competition from the generic industry.

Despite Australia's pre-grant opposition system, national intellectual property law provides for a patent term extension with the possibility of obtaining an extension up to 5 years, proving a considerable barrier to launch and market entry of generic and biosimilar medicines in Australia [95].

Conclusion

The 2008 EU-Australian Partnership Framework, and the existing EU-Australia Mutual Recognition Agreement (MRA) on Good Manufacturing Practices (GMP) for human medicines, already facilitate cooperation between Australia and the EU in the pharmaceutical sector. Furthermore, recent reforms under the National Health Amendment (Enhancing the Pharmaceutical Benefits Scheme) Act 2021 streamline the registration process for generic medicines, enhance price reduction mechanisms, and ensure medicine supply security.

[92] For the latest version, see: https://www.legislation.gov.au/F2012L01982/latest/versions
[93] For further information, see: https://www.aph.gov.au/Parliamentary_Business/Committees/Senate/Former_Committees/freetrade/report/final/ch04
[94] For further details of Australia's pre-grant opposition system, see: https://www.wipo.int/export/sites/www/scp/en/meetings/session_17/opposition/australia.pdf
[95] Generic and Biosimilar Medicines Association of Australia: https://www.gbma.com.au/generic-facts/gbma-fact-sheet/intellectual-property/

Additionally, negotiations are ongoing to open Australia's public procurement market to EU-based companies as part of the EU-Australia Free Trade Agreement, aimed at further enhancing trade and investment. Australia's intellectual property system, despite having a pre-grant opposition mechanism, provides for a patent term extension which can, pose barriers to the market entry of generic and biosimilar medicines.

Market Access Barriers

South Africa

Public Procurement rules	Regulatory Assessments	Local Manufacturing	Pricing and Reimbursement	Intellectual Property rules
Guided by National Drug Policy, managed by Affordable Medicines Directorate; Explicit focus on cost-effectiveness; Dedicated Essential Drugs List.	No EU-South Africa agreements; Limited recognition of EU regulatory submissions, but no positive impact on review times.	No specific limitations, although South Africa seeks to expand local manufacturing in the medium term.	Fixed pricing structures for all medicines; Generics favoured for reimbursement via financial incentives.	No limitations.

Introduction

South Africa represents a crucial segment of the pharmaceutical industry in Africa, with a market valued at ZAR 67 billion in May 2024 by local IQVIA MAT data[96]. From this, the generics market in South Africa represented a value of ZAR 24 billion. In 2023, pharmaceutical spending in South Africa accounted for about 1.8% of its GDP, demonstrating the substantial investment the nation places in its healthcare system, particularly in the pharmaceutical sector. This reflects the commitment of South Africa to providing accessible and affordable healthcare to its citizens.

In recent years, South Africa[97] has proposed policies aimed at controlling the increasing costs of medications and encouraging the use of generic and biosimilar medicines. However, these policies have not been enforced to date by the National Department of Health. Currently, as long as a new entrant to the market is lower in price than the existing competition, no fixed discount requirements are imposed. Based on market experience, a first-to-market generic brand may enter the market at a price 60% lower than the innovator drug.

[96] For further information see: https://www.iqvia.com/-/media/iqvia/pdfs/mea/240709_iqvia_mea-pharmaceutical-market-quarterly-report_q1-2024.pdf

[97] Department of Health Strategic Plan 2020/21 – 2024/25: https://www.health.gov.za/wp-content/uploads/2020/11/depthealthstrategicplanfinal2020-21to2024-25-1.pdf

However, the usual range is closer to 15% to 25% lower than the innovator's price. Subsequent generic medicines generally enter the market at approximately 5% to 10% lower than the most cost-effective alternative available. These prices are periodically reviewed and adjusted to ensure competitiveness and alignment with current market conditions.

Public procurement rules

The South African Department of Health oversees the procurement of generic medicines, ensuring the availability of affordable and essential medicines through a combination of policies and regulations. The National Drug Policy, within the Affordable Medicines Directorate[98], guides this process by emphasizing the use of generic names and selecting cost-effective medicines, supported by the regularly updated Essential Drugs List[99]. The public procurement framework mandates transparency, competitiveness, and equity, focusing on value for money, fairness, and accessibility[100].

The Department manages tenders for medicine supply, adhering strictly to National Treasury guidelines, with bids evaluated on cost-effectiveness. While not mandatory for foreign companies, compliance with Broad-Based Black Economic Empowerment (B-BBEE) regulations can improve the chances of winning tenders. Partnering with local businesses or establishing local operations can help in meeting these requirements. Specific tenders, such as those for the supply of pharmaceuticals, are detailed in the department's procurement notices and guidelines[101].

Regulatory Assessments

In South Africa, the regulatory assessment of generic drugs is governed by the South African Health Products Regulatory Authority (SAHPRA)[102]. The approval process starts with the submission of an application, when the pharmaceutical company must submit a comprehensive application dossier to SAHPRA.

[98] Department of Health, Essential Drugs Programme: https://www.health.gov.za/nhi-hpp-edp/
[99] Department of Health, Essential Medicines List: https://www.health.gov.za/nhi-edp-stgs-eml/
[100] For the full Public Procurement Bill, see: https://www.treasury.gov.za/public comments/DPPB2023/Public Procurement Bill - to OCSLA F.pdf
[101] For further information, see: https://www.health.gov.za/tenders/
[102] For further information, see: https://www.sahpra.org.za/

It should be noted that there is no bilateral relation between the SAHPRA, the European Medicines Agency and the European Commission on pharmaceutical manufacturing[103]. However, SAHPRA officially recognizes reliance for regulatory submissions from the following countries' authorities: EMA CP, EMA DCP, UK MHRA, JPN MHLW, Swissmedic, AUS TGA, Health Canada, and US FDA. Despite this recognition, the review times for dossiers submitted with reliance on these authorities have not been shorter compared to those without such reliance.

Incentive system for generic medicines

The National Drug Policy and the Essential Drugs List provide comprehensive guidelines for healthcare providers, encouraging the prescription of generic medicines as first-line treatments where appropriate[104].

Under these programs, public hospitals and clinics are encouraged to procure and dispense generic medicines through government procurement policies that favour cost-effective options. This approach is supported by the government's pricing regulations, which set maximum prices for medicines to make them more affordable.

The government has published a framework for a national health insurance system[105] based on the same principles, where the reimbursement policies favour the use of generics, providing financial incentives for prescribing and dispensing these medications; however, it is not yet in effect, with full implementation projected to take 10-15 years[106].

Local Manufacturing Preferences

Despite high import costs and late access to innovative pharmaceuticals, South Africa does not operate any local manufacturing requirements to facilitate entering the market so far. However, SAHPRA has published guidelines[107] for comment in 2024 that will offer local manufacturers (whether for bulk production, packaging, or a combination) a 'preferential' submission review at the regulator. These changes are proposed to be implemented at the start of 2025.

[103] The only exception to this is the EU's support for the expansion of Aspen's manufacturing capacity to locally produce COVID-19 vaccines in South Africa.
[104] For further information on the Standard Treatment Guidelines and the Essential Medicines List, see: https://knowledgehub.health.gov.za/content/standard-treatment-guidelines-and-essential-medicines-list
[105] For further information on South Africa's nation health insurance system, see: https://www.parliament.gov.za/project-event-details/54
[106] South Africa Department of Health, National Health Insurance: https://www.health.gov.za/nhi/
[107] For further information, see: https://www.sahpra.org.za/document/gwp-guideline-for-the-importers-and-distributors-of-scheduled-substances/

Intellectual property rules

South Africa does not provide for patent term extensions, nor does it have a patent linkage system in place.

Conclusion

The South African generic medicines sector offers a dynamic environment underpinned by the government's robust policies to control medication costs and encourage the uptake of generic medicines.

Additionally, the Department of Health's transparent and competitive procurement processes ensure fair access to the market. While there are no local manufacturing requirements, incentive programs by the government support local manufacturing.

Market Access Barriers

Japan

Public Procurement rules	Regulatory Assessments	Local Manufacturing	Pricing and Reimbursement	Intellectual Property rules
Governed by EU-Japan Economic Partnership Agreement; Covers central and sub-central government entities, , as well as other entities, including the Welfare and Medical Services Agency.	EU-Japan MRA on GMPs.	No specific limitations, National objective to expand local manufacturing of generic medicines via pro-generic price intervention.	Price fixing by national authority based on market-based approach – generic price set at up to 50% of originator medicine. Specific market and policy intervention to promote use of generics.	Patent Linkage System; Patent Term Extension.

Introduction

Japan is one of the largest pharmaceutical markets globally, valued at approximately $87.23 billion in 2023, with expectations to grow to $91.94 billion by 2029. In 2021, Japan's pharmaceutical spending accounted for approximately 2% of its GDP[108], indicating the significant investment the country places in its healthcare system, particularly in pharmaceuticals, and reflecting the commitment to providing high-quality healthcare to its population.

Over the past years, Japan has implemented various policies to control rising medication expenses and promote the use of generic and biosimilar medicines, which include setting prices of generic drugs at a significant discount compared to their branded counterparts shortly after entering the market[109]. The typical price for generic medicines is set at around 50% or less of the original brand-name drug's price when they first enter the market. This pricing is reviewed and adjusted periodically to ensure it remains competitive and reflective of market conditions. As a

[108] Pharmaceutical spending | OECD

[109] For further information, see: https://www.imarcgroup.com/japan-pharmaceutical-market

result, the generic medicines market size in Japan reached approximately $11.5 billion in 2023 and is projected to grow to $21.4 billion by 2032, exhibiting a compound annual growth rate of 6.9%[110].

Public procurement rules

The 2019 EU-Japan Economic Partnership Agreement (EPA) [111] governs the access of EU companies to Japan's public procurement market. Under the EPA, this access must be based on principles of transparency and non-discrimination. In line with the WTO Agreement on Government Procurement (GPA), the EPA covers government procurement conducted by central government entities, sub-central government entities, including 47 prefectures and 20 designated cities, as well as other entities, including the Welfare and Medical Services Agency[112].

Additionally, the EPA covers public procurement conducted by core cities, 89 local independent administrative agencies (supervised by local governments) as well as 6 additional independent administrative agencies, including the Pharmaceutical and Medical Devices Agency[113] .

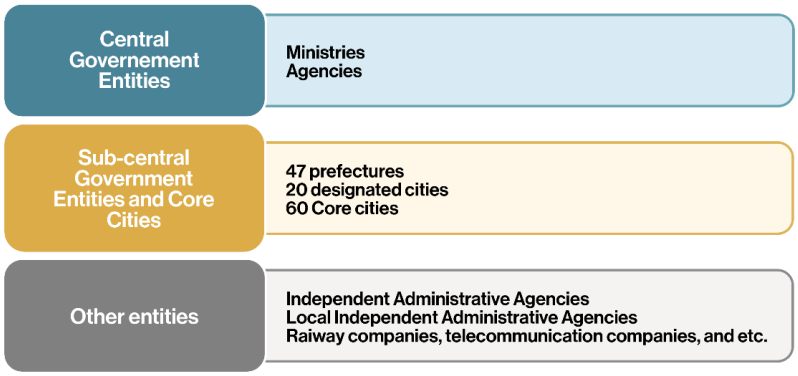


Figure 2: Sub-central government entities and other entities covered by the EU-Japan EPA.

Incentive system for generic medicines

Japanese government policies increasingly support the use of generic medicines, providing a favourable environment for market entry[114]. In a similar approach to France, in Japan's National

[110] https://www.imarcgroup.com/japan-generic-drug-market
[111] https://policy.trade.ec.europa.eu/eu-trade-relationships-country-and-region/countries-and-regions/japan/eu-japan-agreement_en
[112] For the full list of entities covered see: https://www.mofa.go.jp/mofaj/ecm/it/page24_000219.html
[113] Guide for EU Suppliers on Government Procurement in Japan (September 2020), European Commission: https://trade.ec.europa.eu/access-to-markets/en/country-assets/tradoc_159028.pdf
[114] Japan Health Policy Now (2019). For further information, see: http://japanhpn.org/wp-content/uploads/2019/10/Section6_JHPN_ENG.pdf

Health Insurance System (NHIS), when physicians prescribe medical drugs, it is a common rule to use the generic name of the active ingredient. However, a physician can choose to put his signature on his prescription to specifically request the pharmacist to dispense the original drug and not to change to generic drugs.

Pharmacies, unless there are specific instructions from the physician, are encouraged to dispense generic medicines upon briefing to the patient and getting prior consent. Incentives are set to make sure pharmacies will proactively choose to dispense generic medicines.

Within the NHIS, it is a common practice that the reimbursement price of generic medicines is set significantly lower than that of the original drug, generally at 50% or less. Furthermore, reimbursement prices are determined by taking actual market prices into consideration. Therefore, if several generic drugs which contain the same API exist in the market and price competition occurs in the market, a cheaper reimbursement price will be set reflecting those circumstances. This pricing is reviewed and adjusted on an annual basis to ensure it remains competitive and reflective of market conditions.

During those price reviews, undertaken in June and December, prices of both branded and generic drugs offered via the NHIS reimbursement are adjusted based on market dynamics and prices. If generic or biosimilar drugs are to be included in the NHIS list for the first time, the norm is to set its price at 50% of the originator product[115].

After initial inclusion in the NHIS list, prices will be gradually reduced at each annual drug price revision which target all listed products in the NHIS list, according to the changes in the actual market dynamics. In cases where several generic medicines exist, a policy is implemented for setting one price per each price range, in line with the following guidelines:

- Generic medicines whose price is estimated to be less than 30% of the highest price are included in the list at a single price (weighted average),
- Generic medicines whose price is estimated to be 30% or higher but less than 50% of the highest price are included in the list at a single price (weighted average),
- Generic medicines whose price is estimated to be 50% or higher of the highest price are included in the list at a single price (weighted average).

[115] Two exceptions to the norm exist: 1) The price of internal medicine is set at 40% of the price of the original drug if the number of items proposed for inclusion in the NHI list exceeds 10 items; and 2) price of biosimilar is to be set at 70% of the original drug.

Regulatory Assessments

A Mutual Recognition Agreement (MRA) on human medicines between the European Union[116] and Japan has been in operation since 29 May 2004. An update, extending the MRA's scope to sterile and biological products and active pharmaceutical ingredients entered into force in July 2018[117]. The MRA covers all covered products manufactured in the EU or Japan and includes provisions for an exchange of certificates of GMP compliance for manufacturers through the EudraGMDP database and batch certificates[118].

Local Manufacturing Preferences

While Japan does not explicitly favour local products in public procurement, the government's policies ensure a competitive environment that supports domestic manufacturers. This includes price reviews and adjustments to keep generic medicines competitively priced against branded drugs. As a result, the number of generic medicine companies based in Japan has increased in recent years, with a significant portion being small-scale manufacturers.

Intellectual property rules

Japan operates a patent linkage system and allows for a patent term extension of up to 5 years. This extension applies to patents covering active ingredients, medicinal uses, and methods of manufacturing medicines, significantly delaying access to generic and biosimilar medicines for patients. It is notable, that Japan's patent linkage system would be considered "unlawful" under EU law[119] and forms a systematic market access barrier to generics and biosimilar medicines.
Japan has also implemented an early resolution mechanism that forces patent disputes before any launch of a generic medicine. While intended to enable generic manufacturers to challenge the validity of patents or to declare non-infringement, providing a clearer pathway for generic

[116] For further information, see: https://www.ema.europa.eu/en/human-regulatory-overview/research-development/compliance-research-development/good-manufacturing-practice/mutual-recognition-agreements-mra#japan-12963
[117] For full information on the EMA's bilateral relation see, https://www.ema.europa.eu/en/partners-networks/international-activities/bilateral-interactions-non-eu-regulators/japan
[118] See: Japan Pharmaceutical and Medical Devices Agency: https://www.pmda.go.jp/english/review-services/gmp-qms-gctp/0001.html
[119] European Commission: Pharmaceutical Sector Inquiry – Final Report (Page 315)(2009): https://competition-policy.ec.europa.eu/system/files/2022-05/pharmaceutical_sector_inquiry_staff_working_paper_part1.pdf

medicines to enter the market once patent protections expire, this form of patent linkage system is not legislated and is based upon an operating rule set by the health authority, and its operation criteria is not clear, and then *de facto* represents an unnecessary patent linkage barrier for any generic medicine launch in Japan.

Conclusion

Japan's market for generic medicines has significantly evolved, underpinned by robust government policies aimed at reducing healthcare costs and increasing the accessibility of medications. The EU-Japan Economic Partnership Agreement further enhances market access by ensuring non-discrimination and promoting regulatory cooperation, allowing European generic manufacturers to compete on an equal footing with domestic firms. Despite the complexities of Japan's patent linkage system and the competitive landscape, the growing demand for affordable medications driven by an aging population presents significant opportunities for generic manufacturers.

Market Access Barriers

Brazil

Public Procurement rules	Regulatory Assessments	Local Manufacturing	Pricing and Reimbursement	Intellectual Property rules
Brazil is not a signatory of the WTO GPA.	EU-Brazil confidentiality agreement since 2021; Dedicated "Brazilian Generics Law".	Preferences for domestic manufacturers in public procurement.	Government imposes maximum price ceilings.	No limitations.

Introduction

The Brazilian pharmaceutical market is the third largest in the Americas region, following the U.S. and Canada, and has the largest generic medicine sector among Latin American countries, representing almost 28%[120] of the country's pharmaceutical sales. Brazil's pharmaceutical manufacturing landscape has grown considerably and is well-placed to serve other emerging South American markets.

Brazil's public healthcare system consists of a complex mix of service providers and organisations at the federal, state and territory level, with all levels of government sharing responsibility for funding, operating, managing and regulating the country's healthcare system.

Some of the most important international pharmaceutical companies operate manufacturing sites in Brazil, with approximately 66% of companies with domestic manufacturing sites also being domestically owned[121]. Despite the country's large geographic and economic size, U.S. FDA and EMA-approved sites are mostly present in Brazil's eastern states such as Rio de Janeiro, Sao Paulo, Minas Gerais and Paraná.

[120] Full paper available here: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6612747/#:~:text=Generic%20substitution%20in%20Brazil&text=Among%20Latin%20American%20countries%2C%20Brazil,number%20of%20conflicts%20and%20challenges.
[121] Full article here: https://www.pharmaceutical-technology.com/analyst-comment/brazil-pharma-manufacturing/

One important point regarding the Brazilian scenario is the Innovation Law and Partnerships Legislation that allows public agreements with the local public laboratories and offers exclusivity on the direct sale to the Ministry of Health for a certain period (Ordinances GM/MS nº 4.472 e nº 4.473, both enacted on 20/6/2024).

The "Brazilian Generics Law"[122] regulates the entry of generic medicines into the market. Generics may only be registered after the submission of bioequivalence and pharmaceutical equivalence tests[123]. According to the Brazilian Association of Generic Drugs Industries (PróGenéricos), the sector expands by more than 10% annually.

Public procurement rules

On 1 April 2021, Brazil passed its New Public Procurement Law (Law No 14,133/2021) [124], revoking Law No 8,666/1993, which had been in place for almost 28 years. This new law outlines the principles and rules for public procurement, including steps and requirements for awarding contracts and guidelines for government and private contracted parties. The old law remains in force only for contracts initially governed by it. From now on, we are referring to Law No 14,333/2021 as the Brazilian Public Procurement Law (PPL).

Pursuant to the Brazilian Federal Constitution, public procurement rules apply to all government-controlled entities, including public agencies, government funds, public foundations, and government-owned companies at federal, state, and local levels. These entities shall comply with public procurement procedures to engage in contracts for acquiring goods, works, and services, as well as for selling assets. These procurement rules are provided by three main statutes, as indicated below. Apart from eventual form of inspiration, there is no connection between Brazilian official procurement rules and those rules provided by any supra-national body (such as WTO GPA, EU, UNCITRAL).

Depending on the scope of the public procurement process or who is the government contracting authority, other laws may apply, such as the following:

[122] Brazilian Generics Law (9787/99)
[123] More information here: https://www.iam-media.com/article/20-years-of-the-brazilian-generics-law
[124] For the full text see: L14133

Law No 8,987/1995	Provides general rules for concessions of the right to provide public services, such as sanitation, energy, toll roads, and airport infrastructure.
Law No 10,520/2002	Provides rules for an alternative type of procurement process used for the acquisition of common goods and services that the government regularly contracts out.
Law No 11,079/2004	Legal framework for public-private partnerships (PPPs), where the government engages with private parties to provide public services or render services to the government, requiring high investments and long-term amortization.
Law No 12,462/2011	Originally created for special public procurement rules for infrastructure projects for the 2014 FIFA World Cup and 2016 Olympic Games, now applied to various national projects including health, security, and innovation.
Law No 13,303/2016 and Decree No 8,945/2016	Legal framework for government-owned companies, providing specific procurement rules for public companies, mixed-capital companies, and their subsidiaries, allowing strategic partnerships without prior public bidding.
New PDP Ordinance	Regulates the Partnership Program for Productive Development (PDP), guiding national investments in innovation and production through technological transfers of strategic products to reduce the vulnerability of the SUS and expand access to health.
National List of Essential Medicines (RENAME)	Guides the use of medicines and supplies in the SUS, presenting the medicines offered at all levels of care and providing transparency in access to the network's medicines, supporting the Rational Use of Medicines.

Foreign companies must be legally established in Brazil or represented by a Brazilian entity to participate in national tendering processes.

Depending on the product or service, the Brazilian public sector may be the largest buyer in the country. According to the European Commission, prejudicial government public procurement policies may pose a substantial barrier to EU exporters.

It should also be noted that Brazil is not a signatory of the WTO's Agreement on Government Procurement (GPA). Although an accession had been negotiated, Brazil officially withdrew its request in November 2023, arguing that a membership would "impose severe limits on the use of the government's purchasing power as an instrument to induce the country's economic and social development, particularly in areas such as public health, technology, and innovation"[125].

Regulatory Assessments

Since 2021, the European Commission, European Medicines Agency (EMA) and the Brazilian Health Regulatory Agency (ANVISA) have a confidentiality arrangement[126] in place, allowing the exchange of confidential information as part of their regulatory and scientific processes. The arrangement allows, among others, for the exchange of information on applications for scientific advice, marketing authorisation and post-authorisation variations; GMP inspections; as well as GCP inspections for specific products and GCP inspection reports available to EMA or the European Commission

Foreign companies must have a partner company legally established in Brazil that must take on legal responsibility for marketing authorisation, distribution and post-marketing surveillance within Brazil. The General Management of Drugs and Biological Products (GGMED)[127] are tasked with coordinating, supervising, controlling and evaluating the activities related to the registration and post-registration of APIs, drugs, biological products and clinical research in medicines involving humans.

[125] For the full statement see: https://www.gov.br/mre/en/contact-us/press-area/press-releases/brazil-withdraws-offer-to-accede-to-the-wto-government-procurement-agreement
[126] For further information and the full scope see: https://www.ema.europa.eu/en/partners-networks/international-activities/bilateral-interactions-non-eu-regulators/brazil
[127] Full overview of the registration process of generic drugs in Brazil: https://www.gov.br/anvisa/pt-br/english/regulation-of-products/drugs

Local Manufacturing Preferences

Decree 11.890/24 [128], regulating article 26 of the new Public Procurement Law (Law 14.133/24) grants a 10% preference margin in favour of the price of all nationally manufactured products and services compared to the foreign ones.
In addition, the Decree established an additional 10% preference margin for manufactured goods and services "resulting from technological development and innovation carried out in the country".
The cumulative preference margins cannot exceed 20%.
This applies to products manufactured and services under specific conditions with the justification of achieving economic growth, national technological innovation and employment. The conditions relate to national manufactured products and services that meet the Brazilian technical standards or involve specific R&D activities performed in Brazil by the tenderers.

Local rules on pricing and reimbursement

Brazil's model for drug price controls consists of Government-established price ceilings by CMED (Camara de Regulação do Mercado de Medicamentos). Under this system, no reimbursement of drug prices in the public system exists as it offers its services, products, and treatments without charge to citizens. In addition, there is a co-payment model under the „Farmacia Popular" government program, where citizens pay a portion of the cost for certain medications, but this does not qualify as a traditional reimbursement.

In contrast, the ANS (National Supplementary Health Agency), responsible for supplementary health assistance, regulates sectoral operators, including their relationships with providers and consumers and ensures the beneficiary's right to reimbursement for services and medicines in Brazil, but does not establish values or fixed percentages. Reimbursement is calculated according to the amount paid by the operator to professionals accredited by the agreement.

[128] For the full text see: Portal da Câmara dos Deputados

Intellectual property rules

In 2021, Brazil ended the ANVISA's participation in examining patent applications, significantly speeding up the process. Brazil grants patents for a duration of 20 years from the filing date. The previous system allowed for up to 10 years of extension for pharmaceuticals. This system had resulted in several medicinal products having extremely long patent protection, even exceeding or approaching 30 years in certain cases.

However, a 2021 decision by Brazil's Supreme Court declared the provision of a 10-year patent term from the granting date unconstitutional, due to examination delays. As a result, no automatic extensions for pharmaceuticals are currently in place. The current framework, providing a 20-year patent protection from the date of filing, ensures a better balance between rewarding innovation and allowing generic and biosimilar competition to improve patient access and reduce the burdens on healthcare systems[129].

Conclusion

Brazil's pharmaceutical market is a highly significant player in the Americas region, being a role model for other countries, and offers good opportunities due to its growing generic medicine sector, with sales extending beyond Brazil to Latin America and African countries. Recent regulatory improvements, cooperation with the EU and the abolition of automatic patent extensions have streamlined processes and enhanced market access. However, public procurement rules include provisions favouring nationally manufactured products.

[129] For further information, see: https://progenericos.org.br/src/uploads/2022/12/manifesto_adi_5529_4.pdf

Market Access Barriers

Country analysis

Kazakhstan

Public Procurement rules	Regulatory Assessments	Local Manufacturing	Pricing and Reimbursement	Intellectual Property rules
No specific limitations on generics and biosimilars; Governed by EU- Kazakhstan Enhanced Partnership and Cooperation Agreement.	Regulatory cooperation on GMP certificates, technical standards; Dispute resolution mechanism.	National policy to expand local manufacturing, including through purchase preferences towards domestic producers.	Price controls with periodic revision.	Pre-grant opposition framework; Patent Term Extension.

Introduction

Kazakhstan represents a significant segment of the pharmaceutical industry in Central Asia, with a market valued at US$426.23 million in 2023. In parallel, health care expenditure in Kazakhstan accounted for about 1.8% of its GDP[130] in 2023. Kazakhstan's pharmaceutical market is witnessing a surge in demand for innovative medicines, driven by the government's focus on healthcare development.

A significant trend in Kazakhstan's pharmaceutical market is the growing demand for generic pharmaceuticals, driven by their affordability compared to branded drugs. The generic drug market in Kazakhstan was valued at approximately KZT 100 billion in 2023. Projections indicate that this market is expected to expand to KZT 200 billion by 2032.

[130] For further information, see: https://www.worldbank.org/en/country/kazakhstan/overview

Public procurement rules

The 2020 EU- Kazakhstan Enhanced Partnership and Cooperation Agreement (EPCA)[131] provides EU-based companies with improved access to Kazakhstan's public procurement market.

The procurement system is centralized in Kazakhstan, primarily managed through the Electronic Government Procurement (e-GP) platform. The Kazakh Ministry of Finance oversees procurement policies and compliance, while the State Audit Committee audits and monitors the proper use of public funds, ensuring accountability and integrity in the procurement process. Additionally, the state-owned SK-Pharmacy LLP[132] was established to centralize and streamline the procurement, storage, and distribution of medical supplies, ensuring that healthcare facilities across the country have consistent access to necessary medicines and medical products.

Regulatory Assessments

The EPCA provides a comprehensive framework for trade and economic relations between the EU and Kazakhstan. Under the EPCA, the EU and Kazakhstan have agreed to cooperate on the recognition of GMP certificates, which simplifies the approval process for EU-made pharmaceuticals entering the Kazakh market[133]. Under the Agreement, EU companies also benefit from mutual recognition of technical standards, and a dispute resolution mechanism.

Local Manufacturing Preferences

The Kazakh government expects to increase the share of local pharmaceutical production to 50% by 2030[134], with a particular focus on generics and biosimilars. Domestic medicines currently account for 18% of the value of the market and 38% of the volume. In order to attract foreign investors in local manufacturing, the government provides incentives such as tax reliefs and

[131] For further information on the EPCA, see: https://policy.trade.ec.europa.eu/eu-trade-relationships-country-and-region/countries-and-regions/kazakhstan_en
[132] For full information on SK-Pharmacy LLP, see: https://sk-pharmacy.kz/
[133] https://www.eeas.europa.eu/kazakhstan/european-union-and-kazakhstan_en?s=222
[134] The Kazakh government initially scheduled to increase its domestic production to 50% by 2025. In early 2024, the target date was delayed to 2030. https://sk-pharmacy.kz/eng/cooperation/podderzhka_otech_proizvoditele/dolgosrochnye_dogovora

exemptions[135]. Furthermore, the government has established special economic zones where businesses can benefit from customs incentives such as 0% import customs duties and exemptions from foreign labour force quotas.

In 2011 Kazakhstan signed so called off-take agreements with pharmaceutical manufacturers who decided to invest into local manufacturing infrastructure under the condition of upgrade of manufacturing standards to GMP. 10 years of exclusivity purchase of domestically produced medicines by SFK was the offset in the above agreements. All medicines purchased within the contracts had to be localised and produced under GMP standards. Around 800 medicines were contracted across 2011-2019 and around 65% of these medicines are already commercialised.

Local rules on pricing and reimbursement

The public health system operates full price controls (i.e., regulation of ex-factory, wholesale and pharmacy retail prices) on medicines, with them being subsidized through the countries' "Guaranteed Free Health Package". The system, based on external reference countries, is governed by the Order of the Minister of Healthcare No. KR DSM-247/2020[136], which has been subsequently amended. Currently, the Kazakh Ministry of Health undertakes annual price revisions, but these are expected to be shorted to 6-month intervals in the future.

Intellectual property rules

In Kazakhstan, patents are granted for up to 20 years from the filing date, with a possible extension of up to 5 years for pharmaceuticals. Kazakhstan has a pre-grant opposition framework that allows interested parties to challenge the validity of a patent application before it is granted, helping to prevent the issuance of patents that might unduly delay the entry of generic medicines into the market[137].

Section 3 of the EU-Kazakhstan Enhanced Partnership and Cooperation Agreement regulates the enforcement of intellectual property rights, covering various types of IP, including measures to

[135] Examples are a 100% reduction in corporate income tax, zero-rate land tax, and property tax exemptions, as well as VAT exemptions for importing raw materials under investment contracts.
[136] See: https://cis-legislation.com/document.fwx?rgn=129148. It should be noted that the Order which repealed the previous "Rules for regulating prices for medicines", dated April 19, 2019 (last amendments dated June 17, 2020) has already undergone several amendments, the last of which is dated July 3, 2023.
[137] For further information on the patent system, see: https://qazpatent.kz/en/

ensure fair and effective legal processes and remedies. Furthermore, in line with article 94 of the EU-Kazakhstan Enhanced Partnership and Cooperation Agreement, Kazakhstan provides 6 years of data exclusivity from the granting of the first marketing authorisation of the medicinal product in any country that is Party to the Agreement (i.e. either an EU Member State or Kazakhstan). The validity of this interpretation was confirmed by at least three decisions of the Supreme Court of Kazakhstan in 2023 and 2024[138].

Conclusion

Kazakhstan's pharmaceutical market is experiencing significant growth, driven by increasing demand for both innovative and generic medicines, supported by government policies promoting healthcare development and local production. The government aims to increase the share of domestically produced pharmaceuticals to 50% by 2030, offering incentives like tax reliefs and special economic zones to attract foreign investment. The country also provides for a pre-grant opposition framework.

[138] Decision No. 6001-22-00-6an/2177 (2) of 16 March 2023, Decision No. 6001-22-00-6an/2329 of 25 April 2023 and Decision No. 6001-23-00-6an/1616 of 4 April 2024

About Medicines for Europe

Medicines for Europe represents the generic, biosimilar and value-added medicines industries across Europe. Its vision is to provide sustainable access to high quality medicines for Europe, based on 5 important pillars: patients, quality, value, sustainability and partnership. Its members directly employ 190,000 people at over 400 manufacturing and 126 R&D sites in Europe.

Medicines for Europe member companies across Europe are both increasing access to medicines and driving improved health outcomes. They play a key role in creating sustainable European healthcare systems by continuing to provide high quality, effective generic medicines, whilst also innovating to create new biosimilar medicines and bringing to market value added medicines, which deliver better health outcomes, greater efficiency and/or improved safety in the hospital setting for patients.

For more information, please follow us at www.medicinesforeurope.com and on LinkedIn and X at @medicinesforEU.

About Vulcan Consulting

Founded in 2016 by our CEO, Lucinda Creighton, a former Minister for European Affairs, Vulcan Consulting is a leading government and regulatory affairs firm.

We specialise in providing clients in the healthcare, pharmaceutical and MedTech industries with strategic advice to understand and navigate the political landscape across the European Union. We bring decades of experience to bear as a key thought leadership partner for our clients.

Understanding our clients and their needs is at the core of what Vulcan does. Delivering effective, practical advice requires genuine insight into our clients' objectives and culture. We develop an in-depth understanding of their issues, exploring potential scenarios and defining the best strategic approach in order to capitalise on opportunities and mitigate risks.

Vulcan helps clients achieve their public policy objectives by bringing a suite of analytical, innovative and forward-looking approaches to strategic planning. For our multinational clients without an extensive government affairs function on the ground in Ireland, we routinely monitor and gather intelligence on developments of interest to allow them to make decisions from an informed position.

Annex 1: Summary overview

United States of America

Public Procurement rules	Regulatory Assessments	Local Manufacturing	Pricing and Reimbursement	Intellectual Property rules
No specific limitations on generic and biosimilar medicines; EU-based companies are excluded from bidding on all contracts targeting small US-based contractors.	EU-US MRA on GMPs in place, but lack of a Single Development Programme for complex generic medicines.	No specific limitations, National objective to expand local manufacturing.	Fractured system based on State and Federal Programs; Private Insurance Plans.	Patent Linkage System; Patent Term Extension. Generic and biosimilar market entry often delayed by sophisticated patent thickets, litigation, and pay-for-delay tactics.

China

"Buy Chinese" requirements significantly limit access to public procurement.	No EU-China MRA; Concerns on GMP restrictions; Lengthy registration process for imported medicines.	No explicit provisions, but priority list for RLP shows local manufacturing preference.	Must be listed on National Reimbursement Drug List; Generics 100% reimbursed.	Patent Linkage System; Patent Term Extension.

India

"Preference to Make in India Order" puts 'non-local' suppliers in a less competitive position.	Limited EU-India cooperation on GMP and clinical trials; Medicines and international manufacturing site must be registered for import.	Ambition for local sourcing, identifying and securing of critical supplies in the pharmaceutical supply chain	Price fixing based on market-based approach; Same treatment for Indian and non-Indian manufactured generics.	No limitations; Indian Patent Act provides for both pre-grant and post-grant opposition measures

Indonesia

Procurement via a national "e-Katalog"; Must be on list of eligible products; Negotiated prices based on import transfer price + percentage.	No EU-Indonesia agreements; Ongoing discussions in context of FTA negotiations.	Local content requirements favouring domestic manufacturers.	Government fixed pricing structures for generic medicines.	No limitations.

Republic of Korea

No specific limitations on generics and biosimilars.	Regulatory cooperation under the FTA; Generics reviewed at regional level.	No explicit preferences; Promotion of domestic manufacturing.	Positive list system grants benefits selectively to products with excellent treatment and high economic value Price of generic medicines determined by formula.	Patent Linkage System; Patent Term Extension.

Türkiye

Each hospital operating its own procurement; Pricing main criteria for tender acceptance. No requirement to share information on procurement processes and their results.	No EU-Türkiye agreements; Türkiye does not accept EU GMP since 2010, resulting in delays and added costs.	The 2016 forced localisation rules have been reversed.	Reference Price System; Based on pricing structures in FR, SPA, IT, POR, GRE + prices of exporting country + serial release country. Final price = lowest price of any above.	No limitations.

Australia

No specific limitations on generics and biosimilars; Tendering primarily at State and Territories level; Public Procurement part of EU-Australia FTA negotiations.	MRA on GMP for human medicines in place, but administrative burdens persist.	No specific limitations National ambition to expand local manufacturing.	Funding of medicines through the national Pharmaceutical Benefits Scheme (PBS).	Pre-grant opposition framework; Patent Term Extension.

South Africa

Guided by National Drug Policy, managed by Affordable Medicines Directorate; Explicit focus on cost-effectiveness; Dedicated national Essential Drugs List.	No EU-South Africa agreements; Limited recognition of EU regulatory submissions, but no positive impact on review times.	No specific limitations, although South Africa seeks to expand local manufacturing in the medium term.	Fixed pricing structures for all medicines; Generics favoured for reimbursement via financial incentives.	No limitations.

Japan

Governed by EU-Japan Economic Partnership Agreement; Covers central and sub-central government entities, as well as other entities, including the Welfare and Medical Services Agency.	EU-Japan MRA on GMPs.	No specific limitations, National objective to expand local manufacturing of generic medicines via pro-generic price intervention.	Price fixing by national authority based on market-based approach – generic price set at up to 50% of originator medicine. Specific market and policy intervention to promote use of generics.	Patent Linkage System; Patent Term Extension.

Brazil

Brazil is not a signatory of the WTO GPA.	EU-Brazil confidentiality agreement since 2021; Dedicated "Brazilian Generics Law".	Preferences for domestic manufacturers in public procurement.	Government imposes maximum price ceilings.	No limitations.

Kazakhstan

No specific limitations on generics and biosimilars; Governed by EU- Kazakhstan Enhanced Partnership and Cooperation Agreement.	Regulatory cooperation on GMP certificates, technical standards; Dispute resolution mechanism.	National policy to expand local manufacturing.	Price controls with periodic revisions.	Pre-grant opposition framework; Patent Term Extension.

Annex 2: Overview of duties applied

While this report predominantly assesses non-tariff barriers to market access to generic and biosimilar medicines, duties remain a significant obstacle to accessing third-country markets. In addition to non-tariff barriers, the level of import duties applied is generally proportionate to a country's objective of safeguarding its domestic manufacturing industry and openness to global trade in goods.

Below is a comprehensive overview[139] of the duties applied by the assessed countries on pharmaceutical products (HS 30.XX) imported from the European Union.

	USA	CN[1]	IN[1]	ID[2]	KR[3]	TR[4]	AU[1]	BR[1]	JP[5]	KZ[1]	ZA[6]
Glands and other organs for organo-therapeutic uses, dried, whether or not powdered; extracts of glands or other organs or of their secretions for organo-therapeutic uses; heparin and its salts; other human or animal substances prepared for therapeutic or prophylactic uses, not elsewhere specified or included											
30.01.20		3%									
30.01.20.10			10%					5.4%			
30.01.20.20			10%								
30.01.20.30			10%								
30.01.20.90			10%					5.4%			
30.01.90.10		3%	10%					7.2%			
30.01.90.90		3%									
30.01.90.31								3.6%			
30.01.90.39								3.6%			

[139] As per the European Commission's Access2Markets Database; Up to date as of 9 August.
[1] Based on MFN; [2] EU-Indonesia FTA; [3] EU-Republic of Korea FTA; [4] Member of the EU Customs Union; [5] EU-Japan FTA; [6] EU-South Africa FTA.

	USA	CN[1]	IN[1]	ID[2]	KR[3]	TR[4]	AU[1]	BR[1]	JP[5]	KZ[1]	ZA[6]
30.01.90.91			10%								
30.01.90.99			10%								
Human blood; animal blood prepared for therapeutic, prophylactic or diagnostic uses; antisera, other blood fractions and immunological products, whether or not modified or obtained by means of biotechnological processes; vaccines, toxins, cultures of micro-organisms (excluding yeasts) and similar products; cell cultures, whether or not modified											
30.02.10		3%									
30.02.12											
30.02.12.10			10%								
30.02.12.11								7.2%			
30.02.12.12 - 16								3.6%			
30.02.12.20			10%								
30.02.12.30			10%								
30.02.12.34								7.2%			
30.02.12.36								3.6%			
30.02.12.40			10%								
30.02.12.90			10%								
30.02.13 - 15			10%								
30.02.15.10.41							5%				
30.02.15.90											
30.02.20		3%									

Market Access Barriers

An overview of key barriers to generic and biosimilar market entry in select EU trading partners

	USA	CN[1]	IN[1]	ID[2]	KR[3]	TR[4]	AU[1]	BR[1]	JP[5]	KZ[1]	ZA[6]
30.02.30		3%									
30.02.41											
30.02.41.10			10%	5%							
30.02.41.17								3.6%			
30.02.41.20			10%								
30.02.41.28								3.6%			
30.02.41.90				5%							
30.02.42			10%	5%							
30.02.42.10 - 80								3.6%			
30.02.42.90											
30.02.49			10%								
30.02.49.10			10%					3.6%			
30.02.49.20			10%					3.6%			
30.02.49.90			10%								
30.02.49.91								3.6%			
30.02.49.92								3.6%			
30.02.49.94								7.2%			
30.02.49.99								7.2%			
30.02.51			10%					3.6%			
30.02.59			10%					7.2%			

	USA	CN[1]	IN[1]	ID[2]	KR[3]	TR[4]	AU[1]	BR[1]	JP[5]	KZ[1]	ZA[6]
30.02.90								7.2%			
30.02.90.10		3%	10%								
30.02.90.20		3%	10%								
30.02.90.30		3%									
30.02.90.40		3%									
30.02.90.90		3%	10%								
Medicaments (excluding goods of heading 3002, 3005 or 3006) consisting of two or more constituents which have been mixed together for therapeutic or prophylactic uses, not put up in measured doses or in forms or packings for retail sale											
30.03.10			10%								
30.03.10.10				5%							
30.03.10.11		6%						12.6%			
30.03.10.12		6%						7.2%			
30.03.10.13		6%						12.6%			
30.03.10.14								7.2%			
30.03.10.19		6%						7.2%			
30.03.10.20				5%				7.2%			
30.03.10.90		6%		5%							
30.03.20		6%	10%	5%							
30.03.20.11								7.2%			
30.03.20.19								7.2%			

	USA	CN[1]	IN[1]	ID[2]	KR[3]	TR[4]	AU[1]	BR[1]	JP[5]	KZ[1]	ZA[6]
30.03.20.21								12.6%			
30.03.20.29								7.2%			
30.03.20.31								7.2%			
30.03.20.32								7.2%			
30.03.20.39								7.2%			
30.03.20.41								12.6%			
30.03.20.49								7.2%			
30.03.20.51								12.6%			
30.03.20.52								12.6%			
30.03.20.59								7.2%			
30.03.20.61								12.6%			
30.03.20.69								7.2%			
30.03.20.71								7.2%			
30.03.20.79								7.2%			
30.03.20.92								7.2%			
30.03.20.99								7.2%			
30.03.31		5%	10%					12.6%			
30.03.39		6%	10%	5%							
30.03.39.12								12.6%			
30.03.39.13								12.6%			

	USA	CN[1]	IN[1]	ID[2]	KR[3]	TR[4]	AU[1]	BR[1]	JP[5]	KZ[1]	ZA[6]
30.03.39.14								7.2%			
30.03.39.15								7.2%			
30.03.39.22								12.6%			
30.03.39.23								12.6%			
30.03.39.29								7.2%			
30.03.39.31 – 37								12.6%			
30.03.39.39								7.2%			
30.03.39.81								10.8%			
30.03.39.82								10.8%			
30.03.39.92								12.6%			
30.03.39.94								12.6%			
30.03.39.99								7.2%			
30.03.40.10		5%									
30.03.40.90		5%									
30.03.41 – 43			10%	5%				7.2%			
30.03.49			10%	5%							
30.03.49.20								12.6%			
30.03.49.30								7.2%			
30.03.49.40								12.6%			
30.03.49.90								7.2%			

Market Access Barriers

An overview of key barriers to generic and biosimilar market entry in select EU trading partners

	USA	CN[1]	IN[1]	ID[2]	KR[3]	TR[4]	AU[1]	BR[1]	JP[5]	KZ[1]	ZA[6]
30.03.60			10%	5%				7.2%			
30.03.90				5%							
30.03.90.10		6%	10%								
30.03.90.11								7.2%			
30.03.90.12 - 14								12.6%			
30.03.90.15 - 19								7.2%			
30.03.90.20		5%	10%								
30.03.90.29								7.2%			
30.03.90.30			10%								
30.03.90.31 - 34								12.6%			
30.03.90.37								12.6%			
30.03.90.39								7.2%			
30.03.90.41 - 47								12.6%			
30.03.90.49								7.2%			
30.03.90.51 - 57								12.6%			
30.03.90.59								7.2%			
30.03.90.61 - 67								12.6%			
30.03.90.69								7.2%			
30.03.90.71 - 77								12.6%			
30.03.90.79								7.2%			

	USA	CN[1]	IN[1]	ID[2]	KR[3]	TR[4]	AU[1]	BR[1]	JP[5]	KZ[1]	ZA[6]
30.03.90.81 - 87								7.2%			
30.03.90.89								7.2%			
30.03.90.90		5%	10%					12.6%			
30.03.90.91								7.2%			
30.03.90.92								12.6%			
30.03.90.93								12.6%			
30.03.90.94								7.2%			
30.03.90.96								12.6%			
30.03.90.97								12.6%			
30.03.90.99								7.2%			
Medicaments (excluding goods of heading 3002, 3005 or 3006) consisting of mixed or unmixed products for therapeutic or prophylactic uses, put up in measured doses (including those in the form of transdermal administration systems) or in forms or packings for retail sale											
30.04.10			10%								
30.04.10.10		6%									
30.04.10.11								12.6%			
30.04.10.12		6%						7.2%			
30.04.10.13		6%						12.6%			
30.04.10.14								12.6%			
30.04.10.15				5%				12.6%			

	USA	CN[1]	IN[1]	ID[2]	KR[3]	TR[4]	AU[1]	BR[1]	JP[5]	KZ[1]	ZA[6]
30.04.10.16				5%							
30.04.10.19		6%		5%				7.2%			
30.04.10.20				5%				7.2%			
30.04.10.21								12.6%			
30.04.10.29								7.2%			
30.04.10.31								7.2%			
30.04.10.32								7.2%			
30.04.10.39								7.2%			
30.04.10.41								12.6%			
30.04.10.49								7.2%			
30.04.10.51								12.6%			
30.04.10.52								12.6%			
30.04.10.59								7.2%			
30.04.10.61								12.6%			
30.04.10.69								7.2%			
30.04.10.71								7.2%			
30.04.10.79								7.2			
30.04.10.90		6%									
30.04.10.92								7.2%			
30.04.10.99								7.2%			

Market Access Barriers

An overview of key barriers to generic and biosimilar market entry in select EU trading partners

	USA	CN[1]	IN[1]	ID[2]	KR[3]	TR[4]	AU[1]	BR[1]	JP[5]	KZ[1]	ZA[6]
30.04.20		6%	10%								
30.04.20.10				5%							
30.04.20.11								7.2%			
30.04.20.19								7.2%			
30.04.20.31				5%							
30.04.20.39				5%							
30.04.20.71				5%							
30.04.20.79				5%							
30.04.20.91				5%							
30.04.20.99				5%							
30.04.31								12.6%			
30.04.31.10		5%	10%								
30.04.31.90		5%	10%								
30.04.32		5%	10%								
30.04.32.10				5%				12.6%			
30.04.32.20								12.6%			
30.04.32.40				5%							
30.04.32.90				5%				7.2%			
30.04.39		5%	10%	5%							
30.04.39.12								12.6%			

	USA	CN[1]	IN[1]	ID[2]	KR[3]	TR[4]	AU[1]	BR[1]	JP[5]	KZ[1]	ZA[6]
30.04.39.13								7.2%			
30.04.39.14								7.2%			
30.04.39.15								7.2%			
30.04.39.22								12.6%			
30.04.39.23								12.6%			
30.04.39.29								7.2%			
30.04.39.31 - 37								12.6%			
30.04.39.39								7.2%			
30.04.39.81								10.8%			
30.04.39.82								10.8%			
30.04.39.92								12.6%			
30.04.39.94								12.6%			
30.04.39.99								7.2%			
30.04.40.10		5%									
30.04.40.90		5%									
30.04.41			10%	5%				7.2%			
30.04.42			10%	5%				7.2%			
30.04.43			10%	5%				7.2%			
30.04.49			10%								
30.04.49.11				5%							

	USA	CN[1]	IN[1]	ID[2]	KR[3]	TR[4]	AU[1]	BR[1]	JP[5]	KZ[1]	ZA[6]
30.04.49.19				5%							
30.04.49.20								12.6%			
30.04.49.30								7.2%			
30.04.49.40								12.6%			
30.04.49.51				5%							
30.04.49.59				5%							
30.04.49.60				5%							
30.04.49.70				5%							
30.04.49.80				5%							
30.04.49.90				5%				7.2%			
30.04.50		6%	10%								
30.04.50.10				5%				7.2%			
30.04.50.20								12.6%			
30.04.50.21				5%							
30.04.50.29				5%							
30.04.50.30								12.6%			
30.04.50.40								12.6%			
30.04.50.50								7.2%			
30.04.50.60								7.2%			
30.04.50.90								7.2%			

	USA	CN[1]	IN[1]	ID[2]	KR[3]	TR[4]	AU[1]	BR[1]	JP[5]	KZ[1]	ZA[6]
30.04.50.91				5%							
30.04.50.99				5%							
30.04.60			10%					7.2%			
30.04.60.10				5%							
30.04.60.20				5%							
30.04.60.90				5%							
30.04.90				5%							
30.04.90.10		6%	10%	5%							
30.04.90.19								7.2%			
30.04.90.20		4%	10%	5%							
30.04.90.21 – 26								12.6%			
30.04.90.29								7.2%			
30.04.90.30			10%	5%							
30.04.90.31 – 37								12.6%			
30.04.90.39								7.2%			
30.04.90.40			10%								
30.04.90.41 – 47				5%				12.6%			
30.04.90.49				5%				7.2%			
30.04.90.50		3%	10%								
30.04.90.51				5%				12.6%			

	USA	CN[1]	IN[1]	ID[2]	KR[3]	TR[4]	AU[1]	BR[1]	JP[5]	KZ[1]	ZA[6]
30.04.90.52								7.2%			
30.04.90.53 – 55				5%				12.6%			
30.04.90.57								12.6%			
30.04.90.59				5%				7.2%			
30.04.90.60		4%	10%								
30.04.90.61								12.6%			
30.04.90.62				5%				12.6%			
30.04.90.63								12.6%			
30.04.90.64 – 65				5%				12.6%			
30.04.90.66 – 67								12.6%			
30.04.90.69				5%				7.2%			
30.04.90.70			10%								
30.04.90.71				5%				7.2%			
30.04.90.72				5%				12.6%			
30.04.90.73 – 77								12.6%			
30.04.90.79				5%				7.2%			
30.04.90.80			10%								
30.04.90.90		4%	10%								
30.04.90.91				5%				7.2%			
30.04.90.92 – 93				5%				12.6%			

	USA	CN[1]	IN[1]	ID[2]	KR[3]	TR[4]	AU[1]	BR[1]	JP[5]	KZ[1]	ZA[6]
30.04.90.94				5%				7.2%			
30.04.90.95				5%							
30.04.90.96				5%				12.6%			
30.04.90.97								12.6%			
30.04.90.98				5%							
30.04.90.99				5%				7.2%			
Wadding, gauze, bandages and similar articles (for example, dressings, adhesive plasters, poultices), impregnated or coated with pharmaceutical substances or put up in forms or packings for retail sale for medical, surgical, dental or veterinary purposes											
30.05.10.00.05							5%			5%	
30.05.10.10		5%	10%	5%				10.8%			
30.05.10.20			10%					10.8%			
30.05.10.30								10.8%			
30.05.10.90		5%	10%	5%				10.8%			
30.05.90											
30.05.90.10.02		5%	10%	5%			5%			5%	
30.05.90.19								10.8%			
30.05.90.20			10%	5%				10.8%			
30.05.90.30			10%								
30.05.90.31										5%	
30.05.90.40			10%								

	USA	CN[1]	IN[1]	ID[2]	KR[3]	TR[4]	AU[1]	BR[1]	JP[5]	KZ[1]	ZA[6]
30.05.90.50			10%							5%	
30.05.90.60			10%								
30.05.90.70			10%								
30.05.90.90		5%	10%	5%				10.8%			
30.05.90.90.06							5%				
30.05.90.99										5%	
Pharmaceutical Goods as specified in Note 4 to this chapter											
30.06.10		5%									
30.06.10.10			10%								
30.06.10.11.01							5%				
30.06.10.12.02							5%				
30.06.10.14.04							5%				
30.06.10.19.06							5%				
30.06.10.20			10%								
30.06.10.21.07							5%				
30.06.10.29.09							5%				
30.06.10.30.01										8%	
30.06.10.30.09										6.5%	
30.06.10.90								10.8%			
30.06.20		3%	10%								

Market Access Barriers

An overview of key barriers to generic and biosimilar market entry in select EU trading partners

	USA	CN[1]	IN[1]	ID[2]	KR[3]	TR[4]	AU[1]	BR[1]	JP[5]	KZ[1]	ZA[6]
30.06.30		4%	10%								
30.06.30.19								10.8%			
30.06.30.20				5%							
30.06.30.29								10.8%			
30.06.40		5%	10%								
30.06.40.00.10							5%				
30.06.40.11								10.8%			
30.06.40.20				5%							
30.06.50		5%	10%					10.8%			
30.06.60								10.8%			
30.06.70	5%	6.5%	10%	5%				12.6%		5%	
30.06.70.00.28							5%				
30.06.91	4.2%	10%	10%	5%							
30.06.91.10								5.4%			
30.06.91.90								16.2%			
30.06.92		5%	10%					12.6%			
30.06.92.10				15%							
30.06.92.10.02							5%				
30.06.92.20.03							5%				
30.06.92.90				15%							

	USA	CN[1]	IN[1]	ID[2]	KR[3]	TR[4]	AU[1]	BR[1]	JP[5]	KZ[1]	ZA[6]
30.06.92.90.05							5%				
30.06.93			10%	5%				7.2%			
30.06.93.10											
30.06.93.20	40¢/kg + 10.4%										
30.06.93.50	6.4%										
30.06.93.60	0.2¢/liter										
30.06.93.80	5%										
30.06.93.90	5%										

vulcanconsulting

Dublin & Brussels
Email: info@vulcanconsulting.eu
Tel: +353 1 960 2270
+32 (0) 2 791 75 76