ECONOMIC LAWS PRACTICE
ADVOCATES & SOLICITORS

MARKET ACCESS BARRIERS IN THE PHARMACEUTICAL SECTOR IN INDIA'S KEY EXPORT DESTINATIONS

A study by Economic Laws Practice in collaboration with Pharmexcil and Indian Pharmaceutical Alliance

CONTENT

ACKNOWLEDGEMENT

The Indian Pharmaceutical Alliance (IPA) would like to acknowledge the Member Companies who committed their time to provide insights on Indian pharma's journey and international trade up until now and helped generate ideas on triggering accelerated growth in key export destinations. We thank the Department of Commerce and Pharmexcil for their guidance and contribution as our knowledge partners.

Finally, the IPA also acknowledges its Executive Council for their continuous support and guidance throughout this effort. None of this would have been possible without their timely involvement and commitment.

PREFACE

India has played a prominent role in responding to global health crises in the past. From making the treatment for HIV accessible to the entire world, to the quick mobilization of its resources to combat the COVID-19 pandemic, the Indian pharmaceutical industry's success story is not unknown to the world.

Currently, India is home to the 3rd largest pharmaceutical industry, in the world in terms of volume,[1] comprising over-the-counter medications, bulk drugs, biosimilars and biologics.[2] The industry has grown at a rate of almost 10%[3] over the past decade and includes a network of 3,000 drug companies and over 10,000 manufacturing units.[4] It is known globally for its generic medicines and affordable vaccines.[5]

From being a net importer of medical products in the 1970s[6] to becoming the largest supplier of generic medicines globally[7], India's journey as the pharmacy of the world has been remarkable. Indian drugs are exported to more than 200 countries[8], with generic drugs accounting for 20% of India's global exports of medical goods.[9] Low cost of production and quality research and development gives India a competitive advantage in the global market.[10] The Indian government also promotes the pharmaceutical sector through various policy interventions.[11]

Even though the exports of pharmaceutical products have witnessed a year-on-year growth[12], Indian exporters continue to face various hurdles in the form of trade barriers in global markets. These barriers, whether in the form of procedural delays or substantive regulations impacting the level playing field for imported pharmaceuticals have a limiting effect on the growth of the Indian pharmaceutical industry which in turn harms the patients. In order to eliminate such trade barriers and gain more market access for Indian exports, the Indian government is in the process of negotiating free trade agreements with its key trade partners. For example, the India-UAE **Comprehensive Economic Partnership Agreement** ("**CEPA**") has made the product approval process easier for Indian pharmaceutical products by granting a market approval to those pharmaceutical products which have been approved by certain third countries. This resulted in India's pharmaceutical exports increasing by 52% in the first two months of the CEPA coming into effect.[13] The Indian government is likely to enter into several other ambitious trade deals in the coming few years.

This report examines the regulatory environment of some of India's key trading partners, with a view to identify existing and potential trade barriers in these markets. The report has been prepared based on a review of key laws and regulations of destination countries as available in public domain, other secondary sources, and stakeholder consultations. Existing and potential trade barriers analyzed in this report include: tariffs, procedural and registration requirements, labelling and packaging laws, price controls, trade remedial measures, domestic subsidies, restrictions on government procurement and investment barriers. The scope of the study is limited to products classified under Chapter 30 of the Harmonized System.

The report has relied on information available in the public domain as on October 30, 2022.

1. Department of Pharmaceuticals, "Annual Report 2021-22" available at < https://rb.gy/hzkb9x> last accessed November 24, 2022.
2. Department of Pharmaceuticals, "Annual Report 2021-22" available at < https://rb.gy/hzkb9x > last accessed November 24, 2022.
3. Department of Pharmaceuticals, "Annual Report 2021-22" available at < https://rb.gy/hzkb9x > last accessed November 24, 2022.
4. India Brand Equity Foundation, "Indian Pharmaceutical Industry" (Last updated October 2022) available at < https://rb.gy/of65i2 > last accessed November 24, 2022.
5. India Brand Equity Foundation, "Indian Pharmaceutical Industry" (Last updated October 2022) available at < https://rb.gy/of65i2 > last accessed November 24, 2022.
6. Dr Ratna Devi, "Growing role of Indian Pharma in global response to AIDS" (January 7, 2016) PharmaBiz available at < https://rb.gy/gb0ifk> last accessed November 24, 2022.
7. India Brand Equity Foundation, "Indian Pharmaceutical Industry" (Last updated October 2022) available at < https://rb.gy/of65i2 > last accessed November 24, 2022.
8. India Brand Equity Foundation, "Indian Pharmaceutical Industry" (Last updated October 2022) available at https://rb.gy/of65i2 > last accessed November 24, 2022.
9. India Brand Equity Foundation, "Indian Pharmaceutical Industry" (Last updated October 2022) available at < https://rb.gy/of65i2 > last accessed November 24, 2022.
10. India Brand Equity Foundation, "Indian Pharmaceutical Industry" (Last updated October 2022) available at < https://rb.gy/of65i2 > last accessed November 24, 2022.
11. India Brand Equity Foundation, "Indian Pharmaceutical Industry" (Last updated October 2022) available at < https://rb.gy/of65i2 > last accessed November 24, 2022.
12. Department of Pharmaceuticals, "Annual Report 2021-22" available at https://rb.gy/hzkb9x > last accessed November 24, 2022.
13. Dilasha Seth, "India's trade gap with UAE widens as oil imports rise" (August 10, 2022) The Mint available at < https://rb.gy/6rlkwh > last accessed November 25, 2022.

AUSTRALIA

EXECUTIVE SUMMARY

INTRODUCTION

- The Australian pharmaceutical market was valued at about **USD 25.2 billion** in 2020. As with most developed nations, a growing geriatric population and the rise in chronic diseases are key factors driving such growth.
- Australia received 1.84% of India's total pharmaceutical exports in FY 2021-22. India's exports of pharmaceuticals stood at **USD 357.80 billion** for the same period, a small uptick from USD 316.89 million in FY 2020-2021.

ISSUES AND RECOMMENDATIONS

Tariff and Customs Barriers

- The Customs Tariff Act, 1995 is the principal legislation governing tariffs. The Australian Border Force is both the law enforcement agency and the customs service. If the value of goods exported to Australia exceeds AUD 1000, they are subject to the payment of customs duty and other charges.
- As per new tax laws, 'taxable importations' must be subjected to 10% **Goods and Services Tax** ("**GST**") calculated on their value. In general, pharmaceuticals are taxable, but cases where goods have been imported by individuals for personal use are exempt in some cases.
- India recently concluded the India-Australia **Economic Cooperation and Trade Agreement** ("**ECTA" or "India-Australia ECTA**"), where Australia has committed the entirety of Pharmaceuticals (Chapter 30) as duty-free upon entry into force. Hence, tariff barriers do not appear to be a concern for Indian exporters to Australia.

Registration requirements

- All therapeutic goods must be registered, and an entry must be made in the **Australian Register for Therapeutic Goods** ("**ARTG**") before they are legally imported into the country. The India-Australia ECTA has an annex on pharmaceuticals which states that both parties shall utilize, as appropriate, reports from regulatory authorities of the other party's therapeutic goods regulator. However, the Therapeutic Goods Act 1989 already has a few provisions envisaging a similar arrangement. Therefore, it is unclear how the commitments of the ECTA improve upon existing market access. The Indian government may engage with the Australian government to introduce deeper commitments in the upcoming Comprehensive Economic Partnership Agreement with Australia such that complete mutual recognition registration in the regulatory authority of either party is used as a basis for granting registration to medicines. Should this not be acceptable to the Australian government, then registration based on third-country reference regulatory authorities may be considered.
- Furthermore, registration requires the payment of several sets of fees and charges. From an exporter's point of view, a 'sponsor' in Australia must also be set up. The 'sponsor' would be responsible for importing the goods and applying and maintaining the ARTG entry. The fees and charges associated with registration are very high. These costs make it hard for any Indian firm to consider doing business in Australia. The timelines for registration are also longer than the general timelines in India. The Indian government, therefore, may engage with Australia to address challenges with respect to high transactional costs and time associated with such registration.

Good Manufacturing Practices

- Sponsors must obtain clearance for **Good Manufacturing Practices** ("**GMP**") for overseas manufacturers of their registered or listed products. India does not presently have a Mutually Recognized Agreement ("**MRA**") covering GMP compliance with Australia. India has agreed to some provisions in the recent ECTA, but they are broad and are not equivalent to an MRA. Therefore, it is still unclear which pathway of GMP clearance will apply in these cases. The Indian government may consider harmonizing its GMP compliances to endeavour for mutual recognition with respect to GMP compliances. If this is not accepted by the Australian government, then it may alternatively suggest recognition based on reference regulatory authorities.

Packaging and Labelling Requirements

- There are 2 basic instruments pertaining to packing medicinal products, (i) Code of Practice for Tamper-Evident Packaging of Therapeutic Goods and (ii) Therapeutic Goods Order 95 – Child-resistant packaging requirements for medicines ("**TGO**"). India does not have a similar legislative instrument. Consequently, there is an additional cost of compliance that the exporters must bear. Under Australia's new labelling rules comprising TGO 91 and 92, active ingredients need to be more prominently labelled. These rules are divergent from India's Drugs and Cosmetics Rules 1945, so there may be a higher cost burden in exporting to Australia. Indian companies may consider whether this poses an additional burden.

Price Controls

- Australia's primary direct benefit scheme in healthcare is the **Pharmaceutical Benefit Scheme** ("**PBS**"), under which the Australian government directly subsidises the cost of medicine for most medical conditions. However, under its agreements with the USA, Australia has given access to American firms in the selecting, listing and pricing processes under the PBS, along with an avenue for alternative review. India should try to formulate a similar arrangement with Australia.

Trade Remedies

- The Anti-Dumping Commission is the trade remedial authority of Australia. Some Indian subsidy programs have been countervailed in the past. Although, nothing has been levied against the pharmaceutical sector. Hence, this is not a significant barrier for exporters to Australia at the moment. However, it would be advisable to reaffirm that countervailing measures should be limited to excess remissions only and not extend to the full amount of assistance provided and that parties be notified in advance of any expected initiation of investigations as a part of **free trade agreement** ("**FTA**") negotiations.

Intellectual Property Protection

- IP Australia is the agency that administers intellectual property rights and legislation in Australia. Patents are governed under the Patents Act 1990. Protection can be extended up to 25 years for "pharmaceutical substances". There are infringement exceptions in place if the purpose for infringement is registration in the ARTG or is connected with obtaining similar regulatory approval under a law of a foreign country or a part of a foreign country.
- The procedure of getting approval and registering medicines is time-consuming. Additionally, initiating this process after the expiry of patent protection provides undue benefits to the patent holder. The lack of a formal notifying procedure about such applications to the patent holder creates uncertainties. As a result, patent holders can defend their rights only when the infringing product is available in the market.
- TGA has started releasing details of such medicines that are under evaluation. Relevant organisations could assist in the dissemination of this information in a timely manner to all stakeholders.
- Separately, like most other developed countries, Australia has provisions in place regarding patent term extensions and data exclusivity. The duration of these is limited to 5 years as opposed to other countries such as the USA, where this is much longer. The Indian government may hence advocate for such period to not be extended any further so as to allow timely entry of generic products on the market.

Broad Subsidies

- The **Medical Research Future Fund** ("**MRFF**") is an ongoing research fund set up by the Australian government. The Australian government uses some of the net interest from this investment to pay for medical research initiatives. If Indian pharmaceutical companies want to avail the benefits of the fund, then they can partner with an existing MRFF-eligible organisation as a participating institution in order to apply for funds.

Restrictions on Government Procurement

- The Commonwealth Procurement Rules set out the rules that officials must comply with when they procure goods and services and indicate good practice. An exception has been provided that allows entities to directly engage a **Small and Medium Enterprise** ("**SME**") for procurements valued up to USD 200,000, including GST providing that value for money can be demonstrated. However, bilateral consensus between India and Australia remains to be achieved in the context of Government Procurement, evidenced by the absence of any text on the same in the recently concluded India-Australia ECTA.

Investment Barriers

- Even though Australia does not have any specific restriction on investment in the pharmaceutical sector, investors are required to apply to the Foreign Investment Review Board for the acquisition of a 'substantial interest' in an Australian business valued above a certain threshold. There were concerns that the Australian government was using 'national security' as a crutch to stonewall investment proposals. Recent legislative changes have made this action more transparent.

COUNTRY SNAPSHOT

Sr. No.	Parameter	Description
1.	Region	Oceania
2.	Country	Australia
3.	Capital	Canberra
4.	Population	26,284,000 (2023 est.)
5.	Population growth rate (%)	1.25% (2022 est.)
6.	GDP (PPP)	USD 1620 billion (2022 est.)[14]
7.	GDP – real growth rate (%)	3.80% (2022 est.)[15]
8.	GDP – per capita (PPP)	USD 66,410 (2022 est.)[16]
9.	Exchange rates	0.69 per USD (February 2023)
10.	Population below the poverty line	13.4% (2022)
11.	Disease Profile	The top 10 causes of the total number of deaths in 2019 for all ages combined were Ischemic Heart Disease, Stroke, Alzheimer's disease, Lung Cancer, COPD, Colorectal Cancer, Chronic Kidney Disease, Prostate Cancer, Lower Respiratory Infection, and Diabetes[17]
12.	Life Expectancy	83(2022)[18]
13.	Current Health Expenditure per capita	USD 7926.46 (2022)[19]
14.	OOP Health Expenditure as % of health expenditure	15.98% (2019)[20]
15.	Age structure (%) (2020 est.)	**0–14 years**: 18.72%
		15–24 years: 12.89%
		25–54 years: 41.15%
		55–64 years: 11.35%
		65 years and over: 15.88%

Sources: CIA World Fact Book updated to April 27, 2022, ; International Monetary Fund World Economic Outlook , Anti-Poverty Week Australia and US Federal Reserve.

14. International Monetary Fund, "GDP, current prices" available at <https://rb.gy/gfjhej> last accessed February 24, 2023.
15. International Monetary Fund, "Real GDP growth", available at <https://rb.gy/jcxwni> last accessed February 24 2023.
16. International Monetary Fund, "GDP per capita, current prices" available at <https://rb.gy/mumvqr>, last accessed February 24, 2023.
17. Institute for Health Metrics and Evaluation, "Australia" available at < https://rb.gy/xghrbf> last accessed November 23, 2022.
18. The World Bank, "Life expectancy at birth, total (years) – Australia" available at < https://rb.gy/cm0kc6> last accessed February 20, 2023.
19. Australian Institute of Health and Welfare, "Health Expenditure", available at <https://rb.gy/j4z5fy> last accessed February 20, 2023.
20. The World Bank, "Out-of-pocket expenditure (% of current health expenditure)" available at <https://rb.gy/z452e9> last accessed February 20, 2023.

A. MARKET OVERVIEW

The Australian pharmaceutical market was estimated to have a value of **USD 25,250 million in 2020**. It is projected to increase to **USD 28,750 million by 2026** at a 2.1% compounded annual growth rate.[21] Like most developed nations, a growing geriatric population, along with the rise in chronic diseases, are key factors driving such growth.[22]

In FY 2021-22, India's exports of pharmaceutical products to Australia (Chapter 30) stand at USD 357.80 million for FY 2021-2022,[23] which accounts for 1.84% of India's total pharmaceutical exports.[24] Details of pharmaceutical exports disaggregated at the Heading-level have been provided below:

Overview of Pharmaceutical Exports from India to Australia

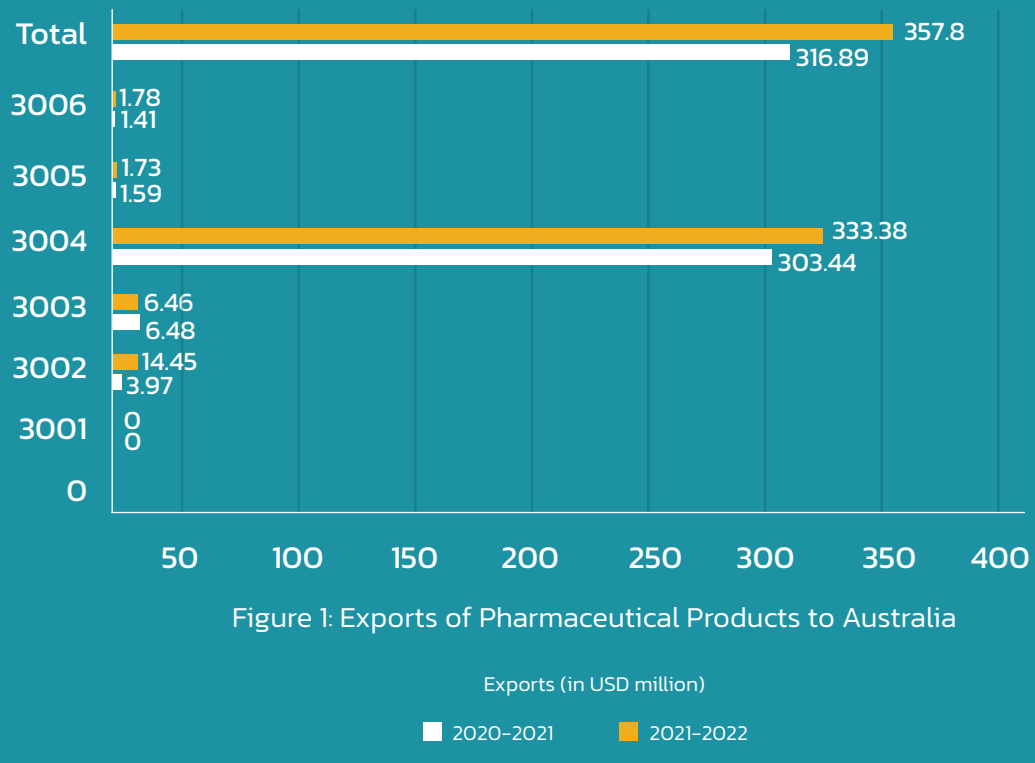


Figure 1: Exports of Pharmaceutical Products to Australia

21. Mordor Intelligence, "Australia Pharmaceuticals Market Growth, Trends, Covid-19 Impact, and Forecasts (2022 – 2027)" available at < https://rb.gy/wz1byt> last accessed November 23, 2022.\
22. Mordor Intelligence, "Australia Pharmaceuticals Market Growth, Trends, Covid-19 Impact, and Forecasts (2022 – 2027)" available at < https://rb.gy/wz1byt> last accessed November 23, 2022.
23. Export-Import Data Bank Version 7.1, Department of Commerce, Government of India available at <https://rb.gy/41jtxg> last accessed on November 23, 2022.
24. Export-Import Data Bank Version 7.1, Department of Commerce, Government of India available at <https://rb.gy/41jtxg> last accessed on November 23, 2022.

Table 1: Exports of Pharmaceutical Products to Australia (in USD million)

Heading	Description	2020-2021	2021-2022
3001	Glands and other organs for therapeutic uses, dried, whether or not powdered; extracts of glands	0	0
3002	Human, animal blood for medicinal use; Manufactured Immunological products w/n Biotech processes. Vaccines, Human, Animal blood for medicinal use; manufactured immunological products w/n biotech processes, vaccines etc.	3.97	14.45
3003	Medicaments (Excluding goods of headings no. 3002, 3005, or 3006), consisting of 2 or more constituents mixed together for human medicine. Not for retail sale	6.48	6.46
3004	Medicaments (Excluding items of 3002, 3005, 3006) for therapeutic/ prophylactic uses in measured doses or in packaging for retail sale	303.44	333.4
3005	Wadding, gauze, bandages and similar articles (for example, dressings, adhesive plasters, poultices), impregnated	1.59	1.73
3006	Miscellaneous pharmaceutical goods	1.41	1.78
	Total	**316.89**	**357.80**

Source: Directorate General of Commercial Intelligence and Statistics ("DGCI&S")

In Pharmexcil's estimation, close to 18 Indian companies hold market authorisations for the Australian market and 47 companies export formulations to Australia through arrangements with local 'sponsors'.[25] Approximately 90% of the prescriptions generated are estimated to be covered by the state-run PBS.[26] The high utilization of the PBS Scheme is another factor due to which generic medicines are not as popular in Australia.[27]

25. Pharmaceutical Export Promotion Council of India, "Regulatory & Market Profile of Australia" available at <https://rb.gy/3y8cmz> last accessed November 23, 2022
26. Pharmaceutical Export Promotion Council of India, "Regulatory & Market Profile of Australia" available at <https://rb.gy/3y8cmz> last accessed November 23, 2022
27. Pharmaceutical Export Promotion Council of India, "Regulatory & Market Profile of Australia" available at <https://rb.gy/3y8cmz> last accessed November 23, 2022.

B. REGULATORY ENVIRONMENT

The primary legislation governing the pharmaceutical industry in Australia is the Therapeutic Goods Act 1989[28], which sets out the legal requirements for the import, export, manufacture, and supply of "therapeutic goods"[29] in Australia. The primary regulator is the **Therapeutic Goods Administration** ("**TGA**").

Other relevant laws and regulations include the Therapeutic Goods Regulations 1990[30], which prescribes the procedure for listing and registering therapeutic goods; the Therapeutic Goods (Charges) Act 1989[31]; and Therapeutic Goods (Charges) Regulations 2018[32] , which prescribes various fees applicable to registered therapeutic goods in Australia, and the Patents Act 1990.[33]

SUGGESTIONS

In light of the recently concluded ECTA, tariff barriers do not appear to be a significant concern for Indian exporters of pharmaceuticals to Australia.

28. Therapeutic Goods Act, 1989
29. Under section 3 of the Therapeutic Goods Act, 1989, therapeutic goods have been generally defined as goods having "therapeutic use" i.e.:
"(a) preventing, diagnosing, curing or alleviating a disease, ailment, defect or injury in persons; or
(b) influencing, inhibiting or modifying a physiological process in persons; or
(c) testing the susceptibility of persons to a disease or ailment; or
(d) influencing, controlling or preventing conception in persons; or
(e) testing for pregnancy in persons; or
(f) the replacement or modification of parts of the anatomy in persons."
30. Therapeutic Goods Regulations, 1990
31. Therapeutic Goods (Charges) Act, 1989
32. Therapeutic Goods (Charges) Regulations, 2018
33. Patents Act, 1990

TARIFF & CUSTOMS BARRIERS

The Australian Border Force serves as both the border law enforcement agency and customs service.[34] The Customs Tariff Act 1995[35] is the principal legislation for the imposition of customs duty on goods imported into Australia. If the value of goods exported to Australia is more than AUD 1000, then the goods are subject to the following[36] :

Customs duty

Taxes and other charges, including an import processing charge[37]

In addition to the above, A New Tax System (Goods and Services Tax) Act 1999[38] provides that "taxable importations" must be subjected to 10% GST calculated on the value of the taxable importation. In general, drugs and medicinal preparations imported by a business entity are taxable.[39] However, goods imported by individuals for personal end use may be exempt in some cases.[40]

India has recently concluded the India-Australia ECTA. Consequently, tariffs faced by Indian exporters will be reflected in the tariff commitment schedule instead of **Most Favored Nation** ("**MFN**") duty rates. Out of 60 lines under the Pharmaceuticals Chapter (Chapter 30) where Australia has given commitments under its tariff schedule, only 19 tariff lines were previously subject to a basic customs duty (i.e., base rate of 5%), and the remaining 41 tariff lines attracted nil basic customs duty. Category A in Australia's Tariff Commitment Schedule infers complete tariff elimination upon entry into force.[41] After the ECTA comes into force, the entire Pharmaceuticals Chapter (Chapter 30) shall be duty-free, as all the tariff lines under this chapter are designated as Category A.

34. Australian Border Force, "Who We Are, Australian Border Force" available at < https://rb.gy/5bqqrc> last accessed November 23, 2022.
35. Customs Tariff Act, 1995
36. Customs Tariff Act, 1995
37. See Australian Border Force, "Cost of Importing Goods, Australian Border Force" available at <https://rb.gy/bcfyuw> last accessed November 23, 2022.
38. A New Tax System (Goods and Services Tax) Act 1999
39. A New Tax System (Goods and Services Tax) Act 1999
40. A New Tax System (Goods and Services Tax) Act 1999
41. 'Australia-India ECTA Annex 2A (Tariff Commitments), available at <https://rb.gy/erzsy4> last accessed November 23, 2022.

NON-TARIFF BARRIERS

A. REGISTRATION REQUIREMENTS

Under the Therapeutic Goods Act 1989, therapeutic goods comprise a broad range of items, such as bandages, pregnancy testing kits, herbal remedies, tissue grafts., etc. They generally fall under 3 main categories[42]:

Medicines

The category includes medicines prescribed via prescriptions from licensed medical professionals, over-the-counter medicines, and any medicine distributed free of cost via social welfare schemes such as paracetamol and echinacea.

Biologicals

Section 32A of the Act describes biologicals as things that are made from or contain human cells or tissues, such as human stem cells or skin.

Medical devices

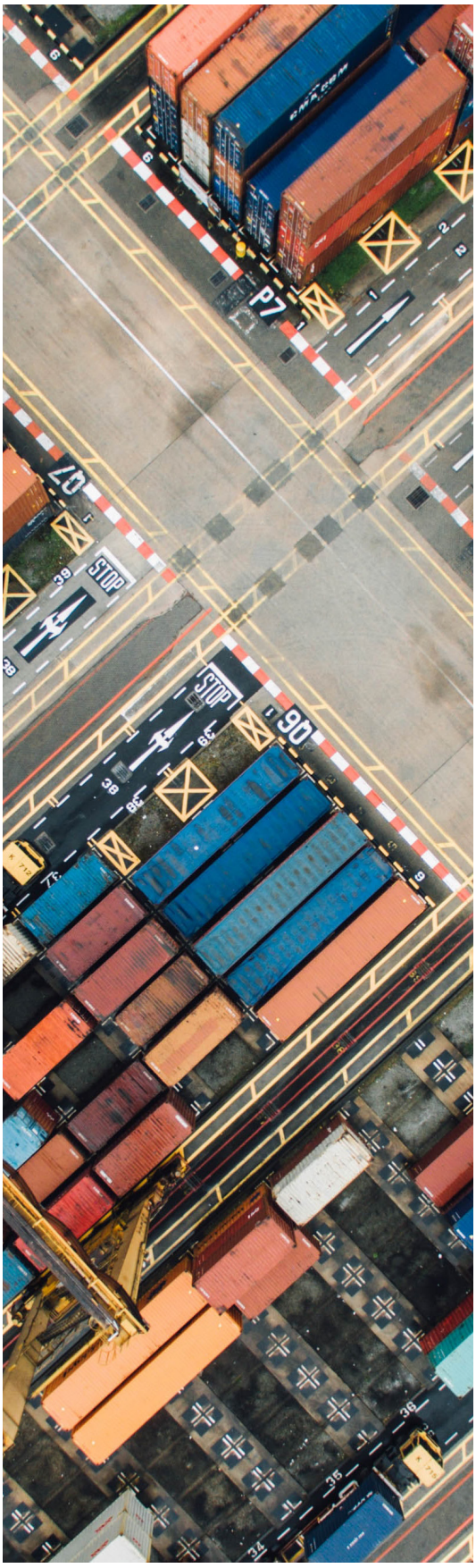
This category refers to instruments, implants and appliances, such as pacemakers and sterile bandages.

Other therapeutic goods (OTGs)

It includes residuary items like tampons and disinfectants.

42. Department of Health Therapeutic Goods Administration, "What are 'therapeutic goods?'' available at <https://rb.gy/v0lgqf> last accessed November 23, 2022.

- According to the Therapeutic Goods Act 1989, all therapeutic goods must be entered into the Australian Register of Therapeutic Goods before they are legally imported into Australia. Certain therapeutic goods are exempt from registration. The details of goods that are exempted from registration are provided in Schedule 5 of Therapeutic Goods Regulations 1990.[43] Goods are added to the ARTG once TGA has (a) assessed **higher-risk** therapeutic goods as meeting the requirements for quality, safety and (where appropriate) efficacy and/or performance or (b) validated **lower-risk** medicine, biological or medical device applications.[44]
- Under the ECTA,[45] Indian and Australian governments have agreed that the relevant "Therapeutic Goods Regulator"[46] of each party shall utilise, as appropriate, reports from regulatory authorities recognized by that Party's Therapeutic Goods Regulator as that party considers comparable for the purposes of pre-market evaluation, quality assessment, etc. of the products manufactured in the territory of the other party.
- However, evidence relating to manufacturing standards received from a relevant overseas authority is already acceptable under the Therapeutic Goods Act 1989. Therefore, it is unclear how the provisions of the ECTA contribute towards improving the already existing framework for the utilisation of foreign regulatory data. Further, the said provision is not subject to dispute settlement, thereby impacting the enforceability of obligations contained therein.



43. Therapeutic Goods Regulations, 1990
44. Department of Health Therapeutic Goods Administration, "Overview of supplying therapeutic goods in Australia" available at <https://rb.gy/es4yy3> last accessed on November 23, 2022.
45. Australia-India Comprehensive Economic Cooperation Agreement (AI-CECA) available at <https://rb.gy/vaxapz> last accessed November 23, 2022.
46. Australia-India Comprehensive Economic Cooperation Agreement (AI-CECA), Annex 7A (Pharmaceuticals) available at <https://rb.gy/vaxapz> last accessed November 23, 2022.

Indian Pharmaceutical Companies have significant approvals from the U.S. and the EU authorities.[47] The same is evident from the following data–

Authority	Name of Regulatory Agency	Nos.
USA	No. of Sites (Bulk drugs + Formulations) Registered with the US Food and Drug Administration (as of June 2021)	725
	Total No of Drug Master Files (Type II Active) Filed by Indian companies (as on September 30, 2019).	4500
	Abbreviated New Drug Applications Market Authorisations Granted to manufacturing units based in India of Indian companies (As on Dec 2020)	4346
	Formulation companies with US FDA approvals	68
EUROPE	Number of Certification of Suitability ("CEPs") received (as of May 2021)	1821
	Number of companies with CEPs as on May 2021	179
	No. of Sites Registered with EU GMP	542
	Number of CEPs with the Irish Medicines Board	300
	Number of companies registered in the Irish Medicines Board	19
	Number of Authorisations with Sweden Medical Product Agency ("MPA")	209
	Number of companies having Marketing Authorization ("MA's") with Sweden MPA	14
World Health Organization ("WHO") GMP	WHO GMP Certified Plants (as per Drug Controller General of India)	2050 (approx..)

Source: Annual Report 2020-21 of Pharmaceuticals Export Promotion Council of India[48]

47. Pharmaceutical Export Promotion Council of India, "17th Annual Report, 2020-21" available at <https://rb.gy/edorjt> last accessed November 23, 2022.
48. Pharmaceutical Export Promotion Council of India, "17th Annual Report, 2020-21" available at <https://rb.gy/edorjt> last accessed November 23, 2022.

i. Costs

There are a series of fees that needs to be paid at various steps of registration. The details of fees are provided in Schedules 9 and 9A of the Therapeutic Goods Regulations 1990. However, certain key components are provided below:

Purpose	Range of fees[49]
Provisional determinations for medicine	AUD 4,750 to AUD 22,500
Scientific advice about aspects of quality, safety or efficacy of medicine	AUD 8,660
Application for registration of a medicine in relation to which a provisional determination is already in force	AUD 30,100 to AUD 50,400
Evaluation fee for an application for registration of a medicine in relation to which a provisional determination is already in force	AUD 173,500 to AUD 263,000
Application fee for a medicine to be included as registered goods that are provisionally registered	AUD 30,000
Evaluation fee for an application for a medicine to be included as registered goods that are provisionally registered	AUD 126,500
Fee for varying an entry in the Register (not including evaluation of data)	AUD 440- AUD 1,760
Application for inclusion of Class 1 biological in the Register	AUD 1,140 for each application
Application for inclusion of Class 2, Class 3 or Class 4 biological	AUD 1,140 for each application

49. See Therapeutic Goods Regulations 1990, Schedule 9 and 9A for the exact details of the fees.

Further, the "Sponsor",[50] i.e., the person who is importing the therapeutic goods into Australia, is responsible for applying for and maintaining the ARTG entry.[51] To do the same, the Sponsor must pay annual charges as prescribed under the Therapeutic Goods (Charges) Regulations 2018.[52] Certain key components of various charges are provided below:

Purpose	Charges Range[53]
Annual charges for the registration or listing of biologicals medicines other than goods produced for export	AUD 1,170
Annual charges for the registration or listing of biologicals items other than medicines provided these produced for export	AUD 890
Annual charge for the inclusion of a biological in the Register under Part 3-2A of the Therapeutic Goods Act for a Class 1 biological	AUD 700
Annual charge for inclusion of a biological in the Register under Part 3-2A of the Therapeutic Goods Act for a Class 2, Class 3 or Class 4 biological	AUD 6,960
Annual charges for the registration or listing of goods that are not biologics	AUD 3,470 to AUD 4,260[54]
Annual charges for provisionally registered medicines for goods that are a biologic	AUD 16,900
Annual charges for provisionally registered medicines for goods that are not a biologic	AUD 13,800

These charges are quite exorbitant and could restrict market access for Indian pharmaceutical companies.

SUGGESTIONS

The requirement of a local sponsor can be expensive, adding to the already high charges for various aspects of registration with the TGA. This may affect the ease of doing business for Indian pharmaceutical companies. India may engage with the Australian government with respect to eliminating this requirement or alternatively, negotiating a reduction of the costs associated therewith.

49. According to the Therapeutic Goods Act 1989, a sponsor, in relation to therapeutic goods, means:
"(a) a person who exports, or arranges the exportation of, the goods from Australia; or
(b) a person who imports, or arranges the importation of, the goods into Australia; or
(c) a person who, in Australia, manufactures the goods, or arranges for another person to manufacture the goods."
50. This implies that domestic firms must comply with the "sponsor" provision as well.
51. Australian Government Department of Health Therapeutic Goods Administration, "Importing therapeutic goods" available at <https://www.tga.gov.au/importing-therapeutic-goods> last accessed November 23, 2022.
52. Therapeutic Goods (Charges) Regulations 2018, Regulation 7.
53. See Therapeutic Goods (Charges) Regulations 2018, Regulations 7, 8 and 9 for the exact details of the charges.
54. See Therapeutic Goods (Charges) Regulations 2018, Regulation 8 for the exact details of the charges.

ii. Timelines

- The registration process may take around 330 days (11 months).[55] In India, the **Central Drugs Control Organization** ("**CDSCO**") takes around 180 days to provide regulatory clearance for any new drugs or biologicals.[56] Therefore, getting regulatory clearance in Australia is a time-consuming process.
- The TGA contains a provision for Priority Review where the expected timeframe of registration is 150 days[57]. However, a set of criteria[58] must be met for a product to be allowed through this provision.
  - The medicine must either be a new prescription medicine or a new indication medicine.
  - Provide a justification of the life-threatening or seriously debilitating nature of the condition that necessitates priority approval.
  - Comparison against registered therapeutic goods for diagnosis, prevention or treatment. This involves proving that no alternative is registered on the ARTG, and if they do, the new medicine will have much higher efficacy or safety over those goods.
  - There should be justification that there is substantial evidence that the medicine is a major therapeutic advance based on the magnitude of improvement and other patient outcome indicators.
- Separately, the provisional approval pathway enables medicines to come on the market much earlier than the current framework. The provisional registration period for medicines that are approved will be 2 years. If required, the Sponsor may apply for up to 2 extensions of up to 2 years each to extend the provisional registration period to a maximum of 6 years, subject to approval by the TGA.[59] The criterion for provisional approvals is largely similar to priority reviews aside from one instance. For approval under the provisional approval pathway, a clinical study plan is required. This plan lays out how the Sponsor will achieve submission of confirmatory efficacy and safety data required for full registration.[60]

SUGGESTIONS

The utilization of data and approvals from reference regulatory authorities as a means to expedite the drug approval process may be suggested. This is because existing exceptions to the timeline are difficult to avail of due to the various conditions associated therewith.

55. Australian Government Department of Health, "Prescription medicines registration process" available at <https://rb.gy/ukecg1> last accessed November 23, 2022.
56. Morulaa Health Tech, "CDSCO Timelines" available at <https://rb.gy/ekp24>llast accessed November 23, 2022.
57. Therapeutic Goods Administration, "Priority review pathway: prescription medicines" available at <https://rb.gy/icfsyj> last accessed November 23, 2022.
58. Therapeutic Goods Administration, "Priority review pathway: prescription medicines" available at <https://rb.gy/icfsyj> last accessed November 23, 2022.
59. Therapeutic Goods Administration, "Priority review pathway: prescription medicines" available at <https://rb.gy/icfsyj> last accessed November 23, 2022.
60. Therapeutic Goods Administration, "Priority review pathway: prescription medicines" available at <https://rb.gy/icfsyj> last accessed November 23, 2022.

iii. Good Manufacturing Practices

Sponsors are required to obtain GMP clearance for overseas manufacturers of their registered or listed products in accordance with the Therapeutic Goods Act 1989.[61]

There are 3 ways in which a GMP clearance can be obtained in Australia:

01 **A Mutual Recognition Agreement ("MRA") Desktop Assessment:**
A desktop assessment may be conducted for manufacturers based out of countries with which Australia has entered into mutual recognition agreements.[62]

02 **A Compliance Verification ("CV") Desktop Assessment:**
A CV desktop assessment can be conducted for manufacturers who have been inspected by a regulatory authority that has an agreement or arrangement with the TGA.

03 **An on-site inspection by the TGA[63] :**
If no acceptable evidence from a recognized regulatory authority is currently available, the TGA shall conduct an on-site inspection. Notably, COVID-19 has delayed the timelines involved in obtaining site clearances through this process.

In the case of India, the ECTA provides that each party's Therapeutic Goods Regulator may utilise, as appropriate, GMP reports from regulatory authorities recognized by that party's Therapeutic Goods Regulator as a comparable regulator in relation to the quality assessment of manufacturing facilities in the territory of the other Party, subject to its laws and regulations, as amended from time to time.[64]

This may reduce the requirement for, or duration of, in-country inspections in the territory of the other Party. However, the provision is worded broadly and does not go as far as a typical MRA would. Moreover, the provision leaves a margin of discretion to the respective regulators, and it is unclear how this provision will be implemented in the future, i.e., which pathway of GMP clearance will apply in such cases.[65]

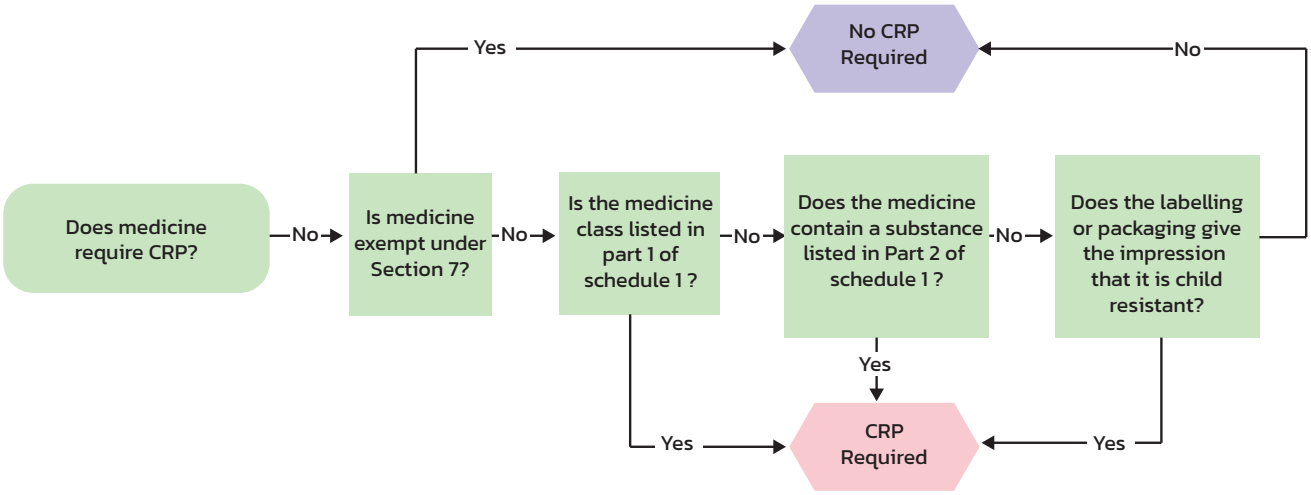
SUGGESTIONS

The usage of existing foreign review data in the drug review process could be utilized as a ground to advocate for greater recognition and weightage to be given to the data of Indian regulatory authorities in such drug review process. At the same time, the need to ensure greater transparency as to how such data is utilized by the authorities may be emphasized during negotiations.

61. Therapeutic Goods Act, 1989, Sections 25(1) (g), 26(1) (g) and 26A (3)
62. For example, the government of Australia has signed a mutual recognition agreement with the European Union: Australian Government Department of Industry, Science, Energy and Resources, "Reducing technical barriers to trade" available at <https://rb.gy/fmissj> last accessed November 23, 2022.
63. Therapeutic Goods Administration, "GMP clearance guidance, Version 18.3" available at <https://rb.gy/ups0wd> last accessed November 23, 2022.
64. Australia-India Comprehensive Economic Cooperation Agreement (AI-CECA), Annex 7A (Pharmaceuticals) available at <https://rb.gy/vaxapz> last accessed November 23, 2022.
65. Australia-India Comprehensive Economic Cooperation Agreement (AI-CECA), Annex 7A (Pharmaceuticals) available at <https://rb.gy/vaxapz> last accessed November 23, 2022

B. PACKAGING REQUIREMENTS

- The 2 important codes which dictate the packaging requirements in the pharmaceutical industry are: (i) The Code of practice for Tamper-Evident Packaging of Therapeutic Goods[66] and (ii) Child-Resistant Packaging Requirements for Medicines – Guidance on TGO 95.[67]
- **Tamper evident packaging** ("**TEP**") means packaging that has an indicator to provide visible or audible evidence to consumers that tampering may have occurred with the product. The code is not mandatory, but it has been established as a condition for membership in some relevant industry associations in Australia.[68] Tamper-evident packaging does not preclude the need for child-resistant packaging where the law requires such packaging.[69]
- The Australian government has implemented the Therapeutic Goods Order No. 95 – Child-Resistant Packaging Requirements for Medicines 2017[70], which makes it mandatory for medicines mentioned in Schedule 1 of the order to be packed in child-resistant packing. Child-resistant packing is designed to make it difficult for young children to gain access to the contents of the package. However, such packaging is not unduly difficult for adults to use properly. Since India does not have any such requirements, there is an additional cost of compliance that has to be borne by the exporters to Australia. The flow chart to determine if the medicine requires child-resistant packing is extracted below –



66. Department of Health, "Code of practice for tamper-evident packaging of therapeutic goods" available at <https://rb.gy/p2bhwx> last accessed November 23, 2022.
67. Department of Health, "Child-resistant packaging requirements for medicines – Guidance on TGO 95" available at <https://rb.gy/ovsrvt> last accessed November 23, 2022
68. Department of Health, "Code of practice for tamper-evident packaging of therapeutic goods" available at <https://rb.gy/p2bhwx> last accessed November 23, 2022.
69. Department of Health, "Code of practice for tamper-evident packaging of therapeutic goods" available at <https://rb.gy/p2bhwx> last accessed November 23, 2022.
70. Therapeutic goods Administration, "Labelling & packaging" available at <https://rb.gy/skm4ea> last accessed November 23, 2022.

C. LABELLING REQUIREMENTS

- The Australian government, on August 31, 2016[71], introduced revised labelling requirements for Australian Medicines. There were 2 orders that were issued, i.e., (i) Therapeutic Goods Order No. 91 – Standard for labels of prescription and related medicines[72] and (ii) Therapeutic Goods Order No. 92 – Standard for labels of non-prescription medicines[73] read with its amendments.[74]
- Under the new labelling rules, details about the active ingredients present in the drug need to be more prominently placed. Companies are advised to print active ingredients below or next to the product name on the front of the medicine pack.[75] Active ingredients need to be specified along with their quantity and proportion. Further few distinctive amendments for non-prescription medicines that were introduced are as under[76] –
  - Most of the over-the-counter medicines will need to be labelled with **critical health information** ("**CHI**"), which will enable the user to determine the purpose of the medicines to ensure the safe use of medicines. Section 6 of TGO 92 defines which of the information required under Sub-Section 8(1) is considered CHI[77] . CHI comprises the names of all active ingredients in the medicine and their quantity in proportion. It also includes the intended purpose of the medicine, relevant warning statements, directions for use, and any associated statements related to specific substances that may have to be declared (According to Schedule 1 of the order)
  - A list of various substances that are not active ingredients but are required to be declared was introduced under the new labelling rules,[78] many of these substances are included because they are allergens.
  - Contact details of the Sponsor or distributor need to be specified on the label too.
- Australian medicines that do not comply with the labelling standards specified in the aforesaid 2 orders cannot be released for supply without the prior consent of TGA. In specific circumstances, the TGA may consider giving consent under Section 14 of the Therapeutic Goods Act 1989 for individual products.[79]
- All these requirements are not prescribed under Indian Drug Rules, 1945. Thus, Indian pharmaceutical companies will have to redesign the labels for the products they are planning to sell in the Australian market. Further, in addition to aforesaid requirements, Order No. 91 and 92 also specify the font size, placement of text, space for labels, the colour of text, warning statements, etc.[80] The new labels will have to be according to this specification which will confer a higher cost burden on Indian firms.

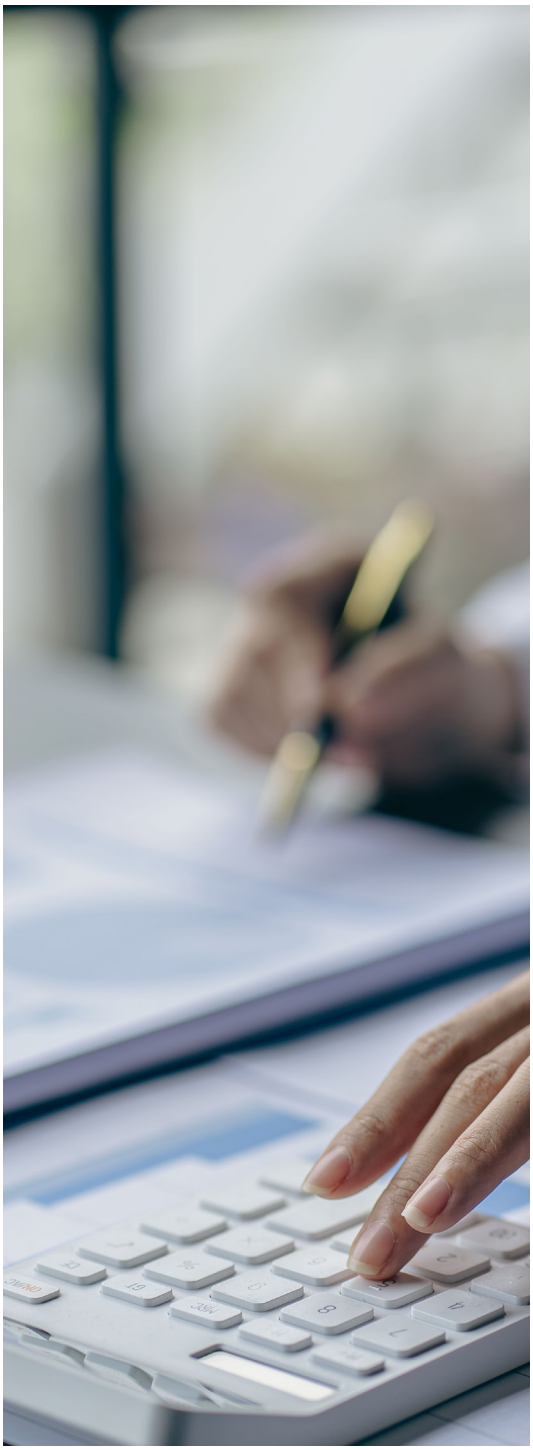
SUGGESTIONS

While we understand that labelling requirements may pose a trade barrier, we do not anticipate a significant business impact on large corporations as a result of these requirements. Such requirements are fairly standard across the world and are unlikely to impact multinational pharmaceutical companies. However, this may be a cause for concern for the MSME sector. India may consider undertaking harmonization efforts with respect to packaging and labelling with the Australian government in the long term.

71. Therapeutic goods Administration, "Labelling & packaging" available at <https://rb.gy/skm4ea> last accessed November 23, 2022
72. Therapeutic Goods Order No. 91 – Standard for labels of prescription and related medicines 2018.
73. Therapeutic Goods Order No. 92 – Standard for labels of non-prescription medicines 2017.
74. Therapeutic goods Administration, "Labelling requirements: information for sponsors" available at <https://rb.gy/Ojwi7t> last accessed November 23, 2022.
75. Therapeutic goods Administration, "Australia's medicine labels are becoming clearer" available at <https://rb.gy/stwt6i> last accessed November 23, 2022.
76. Therapeutic goods Administration, "Australia's medicine labels are becoming clearer" available at <https://rb.gy/stwt6i> last accessed November 23, 2022.
77. Therapeutic goods Administration, "Medicine Labels: Guidance on TGO 91 and TGO 92" available at <https://rb.gy/uhcd3b> last accessed November 23, 2022.
78. Department of Health, "Allergies and medicines" available at <https://rb.gy/2d2wui> last accessed November 23, 2022.
79. Australia-India Comprehensive Economic Cooperation Agreement (AI-CECA), Annex 7A (Pharmaceuticals) available at <https://rb.gy/vaxapz> last accessed November 23, 2022.
80. Therapeutic Goods Order No. 91 – Standard for labels of prescription and related medicines 2018, cl 7, 8 and 9, and Therapeutic Goods Order No. 92 – Standard for labels of non-prescription medicines 2017.

D. PRICE CONTROLS

- The Australian government has introduced the PBS[81]. PBS is part of the Australian government's broader National Medicines Policy, under which the government subsidises the cost of medicine for most medical conditions[82]. The list of medicines that are available at the subsidised rate is available online.[83]
- The scheme has been prescribed under the National Health Act 1953[84]. Under Section 101 of the National Health Act, 1953, **Pharmaceutical Benefits Advisory Committee** ("**PBAC**") has been established as an independent statutory body. PBAC is responsible for assessing the price proposed by a company for listing its medicines under PBS, and they also have the power to deny the inclusion of medicine on the list if the producer declines to reduce the price.[85]
- Given the obvious influence that PBS approval would have on the overall demand for any drug, a producer must ideally ensure that their drug is registered with the program. Under the 2005 Free Trade Agreement signed between Australia and the United States of America, Australia has provided certain concessions to US companies with respect to the PBS scheme[86] . These concessions allow for greater participation of American firms throughout the selecting, listing and pricing process under the PBS. In the India-Australia **Comprehensive Economic Partnership Agreement** ("**CEPA**"), India may adopt a similar approach and gain larger access to PBS. At the same time, access to the PBS scheme would provide greater transparency and would assist generic manufacturers in ensuring that price reductions are not unjustified.



SUGGESTIONS

In the long term, India must endeavour to gain access to the alternate resolution provision and the listing, pricing & selection processes of the PBS through its FTA mechanism.

81. Parliament of Australia, "The Pharmaceutical Benefits Scheme – an Overview" available at <https://rb.gy/hckbtn> last accessed November 23, 2022.
82. Department of Health, "About the PBS" available at <https://rb.gy/gonf9q> last accessed November 23, 2022.
83. Department of Health, "A-Z medicine listing – Viewing by Drug (View by Brand)" available at <https://rb.gy/bpwnj1> last accessed November 23, 2022.
84. The National Health Act 1953.
85. OECD, "Value in Pharmaceutical Pricing Country Profile: Australia" available at <https://rb.gy/r868vl> last accessed November 23, 2022.
86. Department of Foreign Affairs and Trade, "Letter dated 18 May 2004 by the Minister of Trade, Australia to United States Trade Representatives" available at <https://rb.gy/ngqqkb> last accessed November 23, 2022.

TRADE REMEDIAL MEASURES

The Anti-Dumping Commission is the trade remedial authority of Australia. There has been no specific anti-dumping or countervailing investigation into any medicine or biological goods.[87] However, the following Indian subsidy programs have been countervailed by the Australian Anti-dumping Commission in the past: [88]

Interest-free loan

While there are no countervailing duties with respect to the above programs imposed on the pharmaceutical sector, it may be possible that India's direct and indirect incentive programs, like the **Product Linked Incentives** ("**PLI**") scheme, are challenged by the Australian domestic industry in the future.

SUGGESTIONS

With respect to the trade remedial chapter of the FTA, it may be useful to reaffirm that countervailing measures, if any, should be limited to excess remissions only and not extend to the full amount of assistance provided. Additionally, the Indian government should request that provisions mandating prior notification before proceeding to initiate a trade remedial investigation be incorporated in the future CEPA. Similar provisions exist in some of India's existing FTAs, such as the India-Korea CEPA for example.

87. See Australian Government Department of Industry, Science, Energy and Resources, "Anti-Dumping Commission current cases and the electronic public record" available at <https://rb.gy/iqa8uq> last accessed November 23, 2022; Australian Government Department of Industry, Science, Energy and Resources, "Anti-Dumping Commission archived cases and the electronic public record" available at <https://rb.gy/iqa8uq> last accessed November 23, 2022.
88. Australian Government Department of Industry, Innovation and Science, "Final Report NO. 370" available at <https://rb.gy/2bzqi2> last accessed November 23, 2022.

INTELLECTUAL PROPERTY PROTECTION

A. INFRINGEMENT EXEMPTION[89]

- IP Australia is the Australian government agency that administers **intellectual property** ("**IP**") rights and legislation, including patent registrations.[90] Patents are governed under the Patents Act 1990[91], and protection is granted for a term of 20 years from the date of filing,[92] however, patent protection can be extended up to 25 years[93] for "pharmaceutical substances[94]".[95]
- The Patent Act 1990 provides certain exemptions for the exploitation of protected pharmaceutical products. The rights of a patent holder are not infringed if the exploitation is solely for:
  - Purposes connected with obtaining inclusion in the Australian Register of Therapeutic Goods of goods that:
    - » Are intended for therapeutic use; and
    - » Are not medical devices as defined in the Therapeutic Goods Act 1989; or
  - Purposes connected with obtaining similar regulatory approval under a law of a foreign country or of a part of a foreign country.
- This exception has been provided to strike a balance between generic manufacturers and patent holders.[96] The procedure of getting approval and registering the medicines under the Therapeutic Goods Act takes substantial time and initiating this process after the expiry of patent protection by default would have provided undue benefits to the patent holder. So, to remedy the aforesaid situation an exception has been carved out.
- Even though this exception aims at striking a balance, the lack of a formal notifying procedure about such applications to the patent holder creates uncertainties for the patent holder.[97] The patent holders are unaware of any potential patent-infringing product that might have been approved by TGA.

89. Patents Act, 1990, Section 119A.
90. Australian Government Australian Trade and Investment Commission, "Australian Intellectual Property laws" available at <https://rb.gy/8eydqa> last accessed November 23, 2022.
91. Patents Act, 1990.
92. Patents Act, 1990, Part 2, Section 67.
93. Patents Act 1990, Part 3, Section 77.
94. Pharmaceutical substance has been defined under the Patent Act 1990 as –
pharmaceutical substance means a substance (including a mixture or compound of substances) for therapeutic use whose application (or one of whose applications) involves:
(a) a chemical interaction, or physico chemical interaction, with a human physiological system; or
(b) action on an infectious agent, or on a toxin or other poison, in a human body;
but does not include a substance that is solely for use in in vitro diagnosis or in vitro testing.
95. IP Australia, "Types of Patents" available at <https://rb.gy/zibdkx> last accessed November 23, 2022.
96. IP Australia, "Regulatory use exemption from patent infringement for non-pharmaceutical patents" available at <https://rb.gy/5clsbr> last accessed November 23, 2022.
97. Pharmaceutical Research and Manufacturers of America, "Pharmaceutical Research and Manufacturers of America (PhRMA) Special 301 Submission 2022" available at <https://rb.gy/8tgksq> last accessed November 23, 2022.

- Further, due to the lack of proper redressal measures, the patent holders can defend their rights only once the infringing product is available in the market.[98] However, for generic medicine producers, this lacuna creates easier market access. To address these issues, TGA, since January 2021, has started publishing the details of prescription medicines that are under evaluation.[99] However, the interest of patent holders could not be protected completely due to the lack of a proper redressal mechanism. In the short term, India could work on proper representation to the TGA regarding any procedural bottlenecks. In the long term, a provision similar to the US–Australia FTA's commitments relating to alternate avenues of redressal that American firms have in the context of PBS could be formulated and discussed in the next review of the India–Australia ECTA.[100]

SUGGESTIONS

Timely dissemination of the list of prescription medicines "under evaluation" through the relevant bodies here would allow patent holders to protect their interests. Disclosures on drugs "under evaluation", as this information would be available to all potential generic companies too, may lead to increased generic competition/increased generic entries, as evident in other jurisdictions with similar provisions. India should emphasize that such disclosures be made by the Australian government.

B. PATENT TERM EXTENSIONS

Patent extensions for up to 5 years are available to make up for the delays in granting regulatory approval to account for the delays that can occur when obtaining regulatory approval for pharmaceuticals.

SUGGESTIONS

In general, the duration of patent extensions is shorter in Australia than in countries such as Canada and the United States. The Indian government should maintain the position that this period should not be extended further.

98. Pharmaceutical Research and Manufacturers of America, "Pharmaceutical Research and Manufacturers of America (PhRMA) Special 301 Submission 2022" available at <https://rb.gy/8tgksq> last accessed November 23, 2022.
99. Pharmaceutical Research and Manufacturers of America, "Pharmaceutical Research and Manufacturers of America (PhRMA) Special 301 Submission 2022" available at <https://rb.gy/yj0ig5> last accessed November 23, 2022.
100. Australia–US FTA, PBS Side Letter, Annex 2-C Pharmaceuticals available at <https://rb.gy/ngqqkb> last accessed November 23, 2022.

C. DATA EXCLUSIVITY

- Under the Therapeutic Goods Act 1989, data exclusivity for confidential information about the active component of a therapeutic good is granted 5 years of exclusivity from the date of regulatory approval of the medicine by the TGA.[101] During such 5-year timeframe, generic producers cannot rely on or reference such data in the process of seeking regulatory approval.[102] Crucially, the only information that is not available in the public domain is protected. Thus, products based on a previously registered component, combinations, or indications thereof or new dosages, are not granted exclusivity. This may prevent undue extension of data exclusivity based on minor modifications to the active component.
- Unlike Canada, in Australia, a third party may nevertheless be able to seek regulatory approval during the data exclusivity period but cannot rely on any confidential information provided to the TGA by the first applicant. Instead, they must prepare their own package of data and information.[103] Pragmatically, it may therefore be difficult to obtain generic approval without relying on any confidential information relating to the reference product. However, should any such confidential data be published during the exclusivity period (for example, public clinical trial data), the same will no longer be protected, and the generic industry may be able to rely on such information as a part of its data package while seeking approval.[104]

SUGGESTIONS

In general, the duration of patent extensions is shorter in Australia than in countries such as Canada and the United States. The Indian government should maintain the position that this period should not be extended further.

101. Therapeutic Goods Legislation Amendment Act, 1998, Section 25A(2); Therapeutics Goods Act, 1989, Section 25A.
102. Wrays IP, "An Update on Data Exclusivity Protection in Australia" available at <https://rb.gy/tf55hf> last accessed November 23, 2022.
103. Wrays IP, "An Update on Data Exclusivity Protection in Australia" available at <https://rb.gy/tf55hf> last accessed November 23, 2022.
104. Wrays IP, "An Update on Data Exclusivity Protection in Australia" available at <https://rb.gy/tf55hf> last accessed November 23, 2022.

BROAD SUBSIDIES

A. MEDICAL RESEARCH FUTURE FUND (MRF)

- MRFF is an ongoing research fund set up by the Australian government in 2015. Every year, the government uses some of the net interest from this investment to pay for medical research initiatives. In July 2020, the fund grew to AUD 20 billion.[105]
- As per the Medical Research Future Fund Act 2015,[106] only limited organisations can become an **MRFF Eligible Organization** ("**MRFF EO**"). Organisations need to apply to **National Health and Medical Research Council** ("**NHMRC**") to become an MRFF EO. However, the Act of 2015 lays down few parameters for MRF EO, due to which only the following types of organisations can apply to become MRFF EOs[107] :
  - Medical research institutes, i.e., bodies that conduct medical research as a primary purpose and which are also registered with the Australian Charities and Not-for-Profits Commission
  - Universities, i.e., Australian universities listed in either Table A or Table B of the Higher Education Support Act, 2003
  - Corporate Commonwealth entities, i.e., Commonwealth entities that are corporate bodies
  - Corporations, i.e., Australian public companies, Australian private companies, and other incorporated entities.[108]
- However, if Indian pharmaceutical companies want to avail the benefits of the fund, then they can partner with an existing MRFF EO as a Participating Institution in order to apply for funds. If the application is successful, then the Indian pharmaceutical companies will receive MRFF funding via the approved MRFF EO.

SUGGESTIONS

Indian companies do have ingress into the scheme. Hence, the scheme does not represent a significant barrier for exporters at the moment. However, the Indian government may consider liaising with the Australian government on how best Indian companies can benefit from this scheme.

105. Department of Health, "About the MRFF" available at <https://rb.gy/wp2lmw> last accessed November 23, 2022.
106. Medical Research Future Fund Act, 2015.
107. NHMRC, "MRFF Eligible Organizations" available at <https://rb.gy/aaxqmt> last accessed November 23, 2022.
108. Department of Health, "Medical Research Future Fund" available at <https://rb.gy/be25o4> last accessed November 23, 2022.

RESTRICTIONS ON GOVERNMENT PROCUREMENT

- The Australian government, on December 14, 2020, notified the[109] **Commonwealth Procurement Rules** ("**CPRs**"), which are the basic rule set for all procurements by the Australian government and govern the way in which entities undertake their own processes.[110] CPRs were passed under Section 105B (1) of the **Public Governance, Performance and Accountability Act 2013**[111] ("**PGPA Act**"). CPRs set out the rules that officials must comply with when they procure goods and services and indicate good practice. The CPRs have been designed to provide officials with flexibility in developing and implementing procurement processes that reflect their relevant entity's needs. CPRs defines criteria for procurement, and major considerations that an official has to follow are listed as under:
  - Value for money
  - Encouraging competition
  - Efficient, effective, economical and ethical procurement
  - Accountability and transparency
  - Procurement risk
  - Procurement method
- An exemption has been provided that allows entities to directly engage a small and medium enterprise for procurements valued up to AUD 200,000 (including GST), providing value for money can be demonstrated.[112]
- However, bilateral consensus between India and Australia remains to be achieved in the context of government procurement, evidenced by the absence of any text on government procurement in the recently concluded India-Australia ECTA. In the long term, a chapter on government procurement could be formulated during the next review of the India-Australia ECTA.

SUGGESTIONS

India may engage with Australia on government procurement with a renewed focus during the next review of its FTA.

109. Commonwealth Procurement Rules.
110. Notification of Domestic Legislation Relevant to The Agreement on Government Procurement, Notification from Australia, GPA/LEGIS/AUS/1 (18 December 2020).
111. Public Governance, Performance and Accountability Act, 2013.
112. Department of Finance, "Commonwealth Procurement Rules Appendix A" available at <https://rb.gy/xkyeui> last accessed November 23, 2022.

INVESTMENT BARRIERS RELEVANT TO THE PHARMACEUTICAL SECTOR

- Foreign direct investment into Australia is regulated by the Foreign Acquisitions and Takeovers Act 1975[113], as amended, and associated regulations and is screened by the **Foreign Investment Review Board**[114] (“**FIRB**”), a division of Australia’s Treasury.
- Even though Australia does not have any specific restriction on investment in the pharmaceutical sector, foreign investors are required to apply to FIRB for acquisitions of a “substantial interest” in an Australian business valued above a set threshold. Decisions are based on the “national interest” test, which includes national security concerns.
- It was observed in “Trade Policy Review: Australia 2020-Concluding remarks by the Chairperson”[115] that the screening and evaluation of investment proposals by the Australian government against national interest criteria had been increasingly straightened without any proper transparency. Further, contentions were made by the European Union that the Australian government had applied wide grounds for the testing of foreign investment that went past national security, which in turn had put the investors from the EU at a disadvantageous position.[116] To rectify the aforesaid issues, amendments were made to the Foreign Acquisitions and Takeovers Act 1975, which came into effect from January 1, 2021, vide which independent concepts of a “notifiable[117] national security” action and a “reviewable national security” action were introduced., there is better clarity on the ambit of national security.

SUGGESTIONS

Given the recent amendments, this may not be a significant barrier to Indian exporters.

113. Foreign Acquisitions and Takeovers Act, 1975.
114. Foreign Investment Review Board, “Foreign Investment Review Board” available at <https://firb.gov.au/> last accessed November 23, 2022.
115. World Trade Organization, “Concluding remarks by the Chairperson, Trade Policy Review Australia” available at <https://rb.gy/yqoasg> last accessed November 23, 2022.
116. Trade Policy Review, Australia, Minutes of the Meeting, WT/TPR/M/396 (27 May 2020).
117. Clifford Chance, “The Evolving Concept of National Security” available at <https://rb.gy/ry9raa> last accessed November 23, 2022.

CANADA

EXECUTIVE SUMMARY

INTRODUCTION

- Canada is the 9th largest market for pharmaceuticals in the world. India's exports to Canada are valued at **USD 354.8 million.** They constitute about 1.82% of India's total pharmaceutical exports to the world and 80% of Canada's import basket consists largely of formulations.
- Canada's pharmaceutical market is largely dominated by patented medicines. This may be the result of smaller price differences between patented and generic drugs and stringent intellectual property protection. As a result, per capita spending on medicine in Canada is amongst the highest in the world.

ISSUES AND RECOMMENDATIONS

Tariff and Customs Barriers

Most products falling under Chapter 30 are subject to zero duties. The only product groups that are subject to duties are placebos and certain lubricants. Hence, tariff barriers do not appear to be a significant concern for exporters.

Drug registration requirements

- The drug review process in Canada involves the issuance of a '**Notice of Compliance**' ("**NOC**") and a '**Drug Identification Number**' ("**DIN**"). The NOC permits the sponsor to market the drug in Canada and indicates the drug's official approval.
- There is no definitive timeline for completion of the drug review process. Additionally, the costs for registration are high, particularly in the case of innovative drugs. India may endeavour moving towards a mutual recognition agreement by harmonizing its regulatory requirements with international practice. In the interim, the Indian government may propose that pharmaceutical goods which are recognized by regulatory authorities of certain other countries[118] are also recognized by Canada. This approach has been taken in the India – UAE Comprehensive Economic Partnership Agreement as well which will effectively reduce transactional costs.
- Lastly, India may also suggest applying lower fees to approvals that are based on mutual recognition or on recognition from a reference regulatory authority.

118. Such regulatory authorities of other countries are termed 'Reference regulatory authorities'.

Generic Drug Review process

- For a generic drug to be considered equivalent to the patented drug in Canada, the generic drug must contain an 'identical amount of identical medicinal ingredients' as the patented drug. There are legislative changes proposed to widen the scope of such equivalence, but these are yet to be codified into law. Given India's strength in the production of generics, it is important for the Indian government to emphasize the need to broaden the scope of pharmaceutical equivalence.
- Unlike the USA which grants a 180-day market exclusivity to a first generic drugs[119] company in certain cases, Canada does not grant any exclusivity period for marketing generic drugs. However, Canada does have a provision which rewards the generic drugs company for the expense and risk of challenging patents. Therefore, the Indian government may also emphasize the need for such exclusivity to incentivize the generic industry.

Expedited Drug Review Process

- Canadian law provides for expedited drug review process in exceptional cases such as review of drugs for life threatening diseases. However, the criteria applied to trigger expedited review are not clear. The Indian government may discuss the possibility of extending the scope of coverage of expedited approvals to other categories of drugs and may seek greater clarity on the criteria and processes involved.

Good Manufacturing Practices/GMP

- Drugs sold in Canada are required to have requisite GMP certification to obtain a 'drug establishment license'.[112] In order to reduce the compliance burden and costs faced by Indian companies, the Indian government may seek either (i) recognition of GMP certification by Canada based on Indian GMP; or (ii) recognition of GMP certification issued by a third country such as the European Union. To make the process of GMP certification easier and simpler, remote verification may also be allowed.
- Health Canada has a guidance document in place for evaluating GMP practices for other countries to grant mutual recognition. The guidance document sets a high threshold for mutual recognition; however, it may be useful to examine the flexibilities these guidance documents provide when India's proposition for a Mutual Recognition Agreement is put forward.

Labelling Requirements

- Canada's labelling requirements involve bilingual labelling in French and English. This dimension is completely absent in the Indian market. Similarly, there are different labelling requirements for different type of drugs which may add to the compliance costs.
- Based on stakeholders' feedback, we understand that these requirements do not cast significant burden on large Indian pharmaceutical companies. However, this may be a cause for concern for the MSME sector, as these requirements may drive up costs.

119. In the USA, a first maker of any generic drug that challenges an existing patent is entitled for a 180-days period of exclusivity during which no other generic for the same patented drug can be marketed.
120. A Drug Establishment License is required for any company that fabricates, packages, labels, distributes, imports, wholesales, and/or tests drugs.

Intellectual Property Rights

- Canada accords 'innovative drugs' with market exclusivity for 8 years. As mentioned previously, there is no exclusivity for the first generic manufacturer. As a part of Canada-European Union Comprehensive Economic and Trade Agreement, new pharmaceutical products are granted additional exclusivity through the protection of an eligible patent. As a result, the actual exclusivity period for products from the European Union would increase from 8 to 10 years through the operation of a 'patent linkage system'. These provisions form part of Canada's free trade agreement obligations, so it is unlikely that these would be altered in the near future. However, India may still flag the issue as causing inordinate delays in generic drug approvals.
- There is a lack of a formal patent opposition framework in Canada. India has established formal procedures for pre and post grant opposition. During negotiations, India should not make any commitment relating to altering its patent opposition system.
- The Canadian Supreme Court has interpreted Canadian patents to have extraterritorial application. i.e., the Saccharin Doctrine. The Saccharin Doctrine broadly states that if a drug is produced with a patented intermediate, such drug would infringe the patent for the intermediate when the final product is imported and sold in Canada. The Saccharin Doctrine includes both products and processes. The Indian government should strongly put forth the position that patent protection should be limited to the Canadian territory during negotiations.
- India and Canada have a similar stance on compulsory licensing, especially on life-saving medicine such as the COVID-19 vaccines. However, India is keen on expanding the scope of such waivers to diagnostics and therapeutics and may liaise with the Canadian government on its position regarding such waivers.

Price Controls

- Prices for patented medicines in Canada are regulated under the Patented Medicine Prices Review Board. The **pan-Canadian Pharmaceutical Alliance** ("**pCPA**") negotiates prices for drugs supplied to their public health programs with provincial governments. Such negotiations culminate in a letter of intent. Manufacturers negotiate individual product licensing agreements with each province on the basis of these letters of intent. As a result, pricing across provinces in Canada is not uniform. Additionally, public drug plans are not mandated to list drugs that have gone through negotiations with the pCPA. This has been flagged as introducing the possibility of additional criteria or limitations for each province.
- The pCPA and the Canadian Generic Pharmaceutical Association have agreed to significantly reduce the prices of generic medicines. Moreover, amendments to the Patented Medicine Prices Review Board's pricing regulations have been introduced to further reduce the cost of medicines.
- Since the regulations introduced by the Canadian government at the central level are unlikely to change, the focus should be on the provincial level, where pricing flexibilities can be capitalized on. Pricing oral solid products at 25% of the brand reference price for when there are 3 or more generic products on the Canadian market does not take into account high manufacturing cost or low selling price. The Indian Government may consider asserting the need for the relaxation of the fixed price policy.

Trade Remedies

- Presently, there are no trade remedial measures in force. However, as a part of free trade agreement negotiations, the Indian government may emphasize that countervailing measures should be limited to excess remissions only and not extend to the full amount of assistance provided. It may also be stressed that the parties are notified in advance of any expected initiation of investigations.

Investment Barriers

- There are certain caps on investments from countries that are members of the WTO and are not state-owned enterprises. However, higher caps exist for investors that are from countries that are party to certain designated trade agreements with Canada. Similar provisions for Indian investors may be contemplated during negotiations for a free trade agreement.

COUNTRY SNAPSHOT

Sr. No.	Parameter	Description
1.	Region	North America
2.	Country	Canada
3.	Capital	Ottawa
4.	Population	39,315,000 (2023 est.)
5.	Population growth rate (%)	0.85% (2023 est.)
6.	GDP (PPP)	USD 2,240 billion (2022 est.)[121]
7.	GDP – real growth (%)	3.3% (2022 est.)[122]
8.	GDP - per capita (PPP)	USD 56,790 (2022 est.)[123]
9.	Exchange rates	1 Canadian Dollar = 0. 74 US Dollar (February 2023)
10.	Population below the poverty line	96.4% (2023 est.)
11.	Disease Profile	The top 10 causes of the total number of deaths in 2019 for all ages were Ischemic Heart Disease, Lung Cancer, Stroke, Alzheimer's Disease, COPD, Colorectal Cancer, Lower Respiratory Defect, Chronic Kidney Disease, Diabetes, and Falls[124]
12.	Life Expectancy	82[125] (2020)
13.	Current Health Expenditure per capita	USD 5048.37[126] (2019)
14.	OOP Health Expenditure as % of health expenditure	14.91%[127] (2019)
15.	Age structure (%) (2020 est.)	**0-14 years** - 15.99% (male 3,094,008/female 2,931,953)
		15-24 years - 1.14% (male 2,167,013/female 2,032,064)
		25-54 years - 39.81% (male 7,527,554/female 7,478,737)
		55-64 years - 14.08% (male 2,624,474/female 2,682,858)
		65 years and above - 18.98% (male 3,274,298/female 3,881,126)

Source: World Fact Book 2022, International Monetary Fund World Economic Outlook and World Bank Data

121. IMF, "GDP current prices", available at <https://rb.gy/gfjhej> last accessed February 24, 2023.
122. IMF, "Real GDP growth", available at <https://rb.gy/jcxwni> last accessed February 24, 2023.
123. IMF, "GDP per capital, current prices", available at <https://rb.gy/mumvqr> last accessed February 24, 2023
124. Institute for Health Metrics and Evaluation, "Canada" available at <https://rb.gy/ozyrgp> last accessed November 23, 2022.
125. The World Bank, "Life expectancy at birth, total (years) – Canada" available at <https://rb.gy/hyqsjt> last accessed November 23, 2022.
126. The World Bank, "Current health expenditure per capita (current USD) – Canada" available at <https://rb.gy/5rbggo> last accessed November 23, 2022.
127. The World Bank, "Out-of-pocket expenditure (% of current health expenditure) – Canada" available at <https://rb.gy/szbgyh> last accessed November 23, 2022.

INTRODUCTION

A. MARKET OVERVIEW

Canada is presently the 9th largest market for pharmaceuticals in the world in terms of value. The Canadian pharmaceutical market has grown at an average compounded annual growth rate of 5.1% since 2015.[128] Patented pharmaceutical products account for 81.3% of Canadian sales by value and with the remaining constituting generic products.[129] Notably, patented pharmaceutical products constitute 27.1% of prescriptions by quantity.

According to data from the Directorate General of Commercial Intelligence and Statistics, Department of Commerce, India's exports of pharmaceutical products (Chapter 30) to Canada stand at USD 354.84 million for FY 2021-2022.[130] Exports to Canada constitute about 1.82% of India's total pharmaceutical exports to the world. According to Pharmexcil data, formulations commanded more than 80 per cent of total exports from India and grew by 34.79% during the last year.

Details of India's pharmaceutical exports to Canada disaggregated at the Heading-level are provided below.

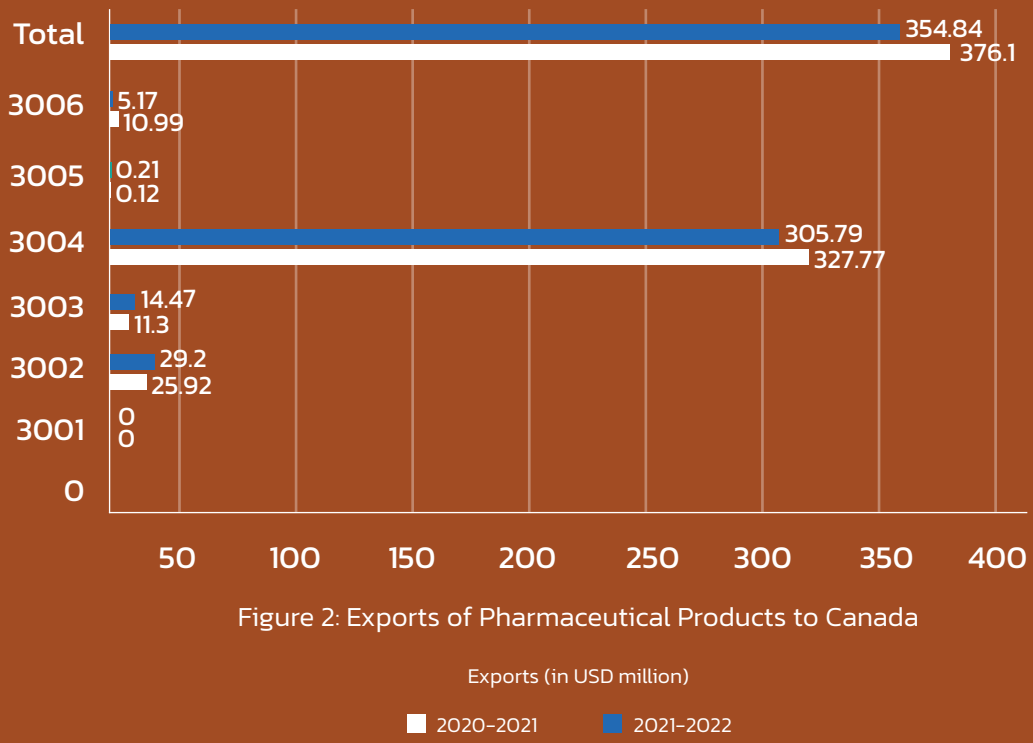


Figure 2: Exports of Pharmaceutical Products to Canada

128. Government of Canada, "Pharmaceutical Industry Profile" available at <https://rb.gy/yjtzff> last accessed November 23, 2022.
129. Government of Canada, "Pharmaceutical Industry Profile" available at <https://rb.gy/yjtzff> last accessed November 23, 2022.
130. Export-Import Data Bank Version 7.1, Department of Commerce, Government of India available at <https://rb.gy/41jtxg> last accessed on November 23, 2022.

Table 2: Exports of Pharmaceutical Products to Canada (in USD Million)

Heading	Description	2020-2021	2021-2022
3001	Glands and other organs for therapeutic uses, dried, whether or not powdered; extracts of glands	0	0
3002	Human, animal blood for medicinal use; Manufactured Immunological products w/n Biotech processes. Vaccines, Human, Animal blood for medicinal use; manufactured immunological products w/n biotech processes, vaccines etc.	25.92	29.2
3003	Medicaments (Excluding goods of headings no. 3002, 3005, and 3006), consisting of 2 or more constituents mixed together for human medicine. Not for retail sale	11.3	14.47
3004	Medicaments (Excluding items of 3002, 3005, 3006) for therapeutic/ prophylactic uses in measured doses or in packaging for retail sale	327.77	305.79
3005	Wadding, gauze, bandages and similar articles (for example, dressings, adhesive plasters, poultices), impregnated	0.12	0.21
3006	Miscellaneous pharmaceutical goods	10.99	5.17
	Total	**376.1**	**354.84**

Source: Directorate General of Commercial Intelligence and Statistics

Patented medicines largely dominate the Canadian pharmaceutical market due to a variety of reasons. As elaborated upon in subsequent sections of this chapter, these reasons include the existence of smaller price differences between patented and generic drugs, stringent intellectual property protection for patented drugs, and the lack of uniform pricing for generic drugs across provincial markets, among others. Per capita spending on medicines in Canada is amongst the highest in the world, despite the existence of price controls. Notably, the Canadian government has made efforts to reduce the costs of medicines and increase availability of generics in the recent past.

B. REGULATORY ENVIRONMENT

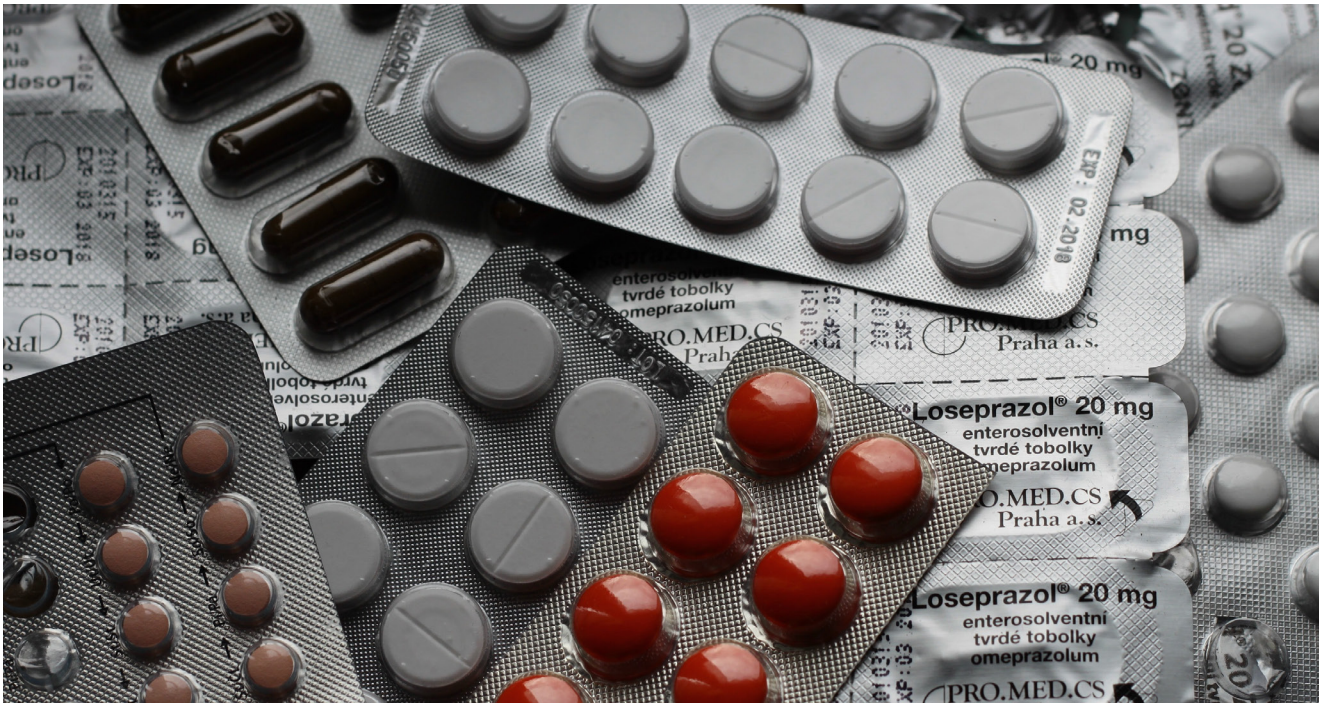
Canada is a highly regulated market, and pharmaceutical products are primarily regulated through the following legislations:

Foods and Drugs Act, 1985[131] read with the Food and Drugs Regulations.[132]

Patent Act, 1985[133] read with The Patent Rules, 1996

The Controlled Drugs and Substances Act[134] read with its associated regulations.[135]

- Typically, laws and regulations are supplemented through 'Guidance documents' issued by relevant governmental authorities.[136] Such 'Guidance documents' throw light on the processes of complying with relevant acts and regulations. These documents also assist the staff of Health Canada in their implementation. These documents are not binding in nature and allow for certain flexibilities in approach. Health Canada, the primary regulatory authority for the health sector in Canada, has also issued various 'Guidance documents' with respect to laws governing the pharmaceutical and health sectors.
- Health Canada is responsible for a range of activities including reviewing drug submissions for market authorization, monitoring drugs for safety in Canada and enforcing compliance across the industry.



131. Food and Drugs Act, RSC 1985, c F-27.
132. Food and Drug Regulations, CRC, c 870.
133. Patent Act, RSC 1985, c P-4.
134. Controlled Drugs and Substances Act, SC 1996, c 19.
135. Controlled Drugs and Substances Act (Police Enforcement) Regulations, SOR/97-234.
136. Government of Canada, "Guidelines" available at <https://rb.gy/8esdey> last accessed November 23, 2022.

A. OVERVIEW

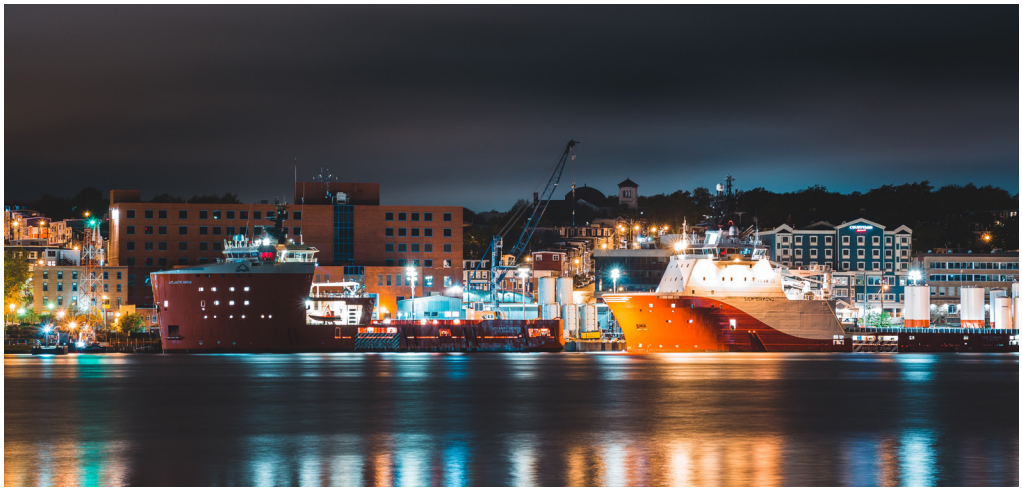
- The Canadian Customs Tariff is governed by the Customs Act and Customs Tariff Act and is administered by the Canada Border Services Agency.[137]
- Most products falling under Chapter 30 of Canadian Customs Tariff are subject to Nil duties, barring certain products. Varieties of placebos and certain blinded (or double-blinded) clinical trial kits and certain lubricants.[138] The tariffs applicable on such products are as follows:

Sr. No.	Tariff Line	MFN Tariff Rate
1.	3006.93.10 00 - - -Syrup based	6 %
2.	3006.93.20 00 - - -Sugar based	9.5 %
3.	3006.93.30 00 - - -Other food based	10.5%
4.	3006.93.40 00 - - -Non-alcoholic beverages based	11%
5.	3006.70 -Gel preparations designed to be used in human or veterinary medicine as a lubricant for parts of the body for surgical operations or physical examinations or as a coupling agent between the body and medical instruments -3006.70.90 00 - Others	6.5 %

Source: Canada Border Services Agency

SUGGESTIONS

In light of the above, tariff barriers do not appear to be a significant concern for Indian exporters of pharmaceuticals to Canada. Therefore, tariff commitments may not be a key factor in future FTA negotiations with Canada as far as the pharmaceutical sector is concerned.



137. Canada Border Services Agency, "Canada Border Services Agency" available at <https://rb.gy/ztmgng> last accessed November 23, 2022.
138. Canada Border Services Agency, "Customs Tariff – Schedule: Chapter 30 Pharmaceutical Products" available at <https://rb.gy/vak4bl> last accessed November 23, 2022.

Given the impact on human life and health, the pharmaceutical sector in Canada, much like the rest of the world, is subject to a variety of registration requirements, technical regulations, standards, and conformity assessment procedures.

A. MARKET AUTHORIZATION

Drug review process

- Drugs[139] are authorized for sale in Canada only upon clearing the drug review process conducted by the **Health Products and Food Branch** ("**HPFB**") of Health Canada. The drug review process is set out in brief below:
  - A 'New Drug Submission' must be filed with HPFB containing information and data about the drug's safety, effectiveness, and quality as well as results of studies conducted regarding the same. The submission also includes details regarding production, packaging, labelling details, therapeutic claims, and side effects.
  - HPFB reviews the submissions and evaluates the data submitted.
  - The drug is issued a NOC and a DIN if it is found that the benefits of the drug outweigh the risks and that the risks can be mitigated. An NOC permits the sponsor to market the drug in Canada and indicates the drug's official approval in Canada.
  - Certain biologic drugs (i.e., produced from living organisms or contain components of living organisms) may also be subject to testing of samples before and after authorization to sell in Canada has been issued. This is done through a 'Lot Release Process'.[140]

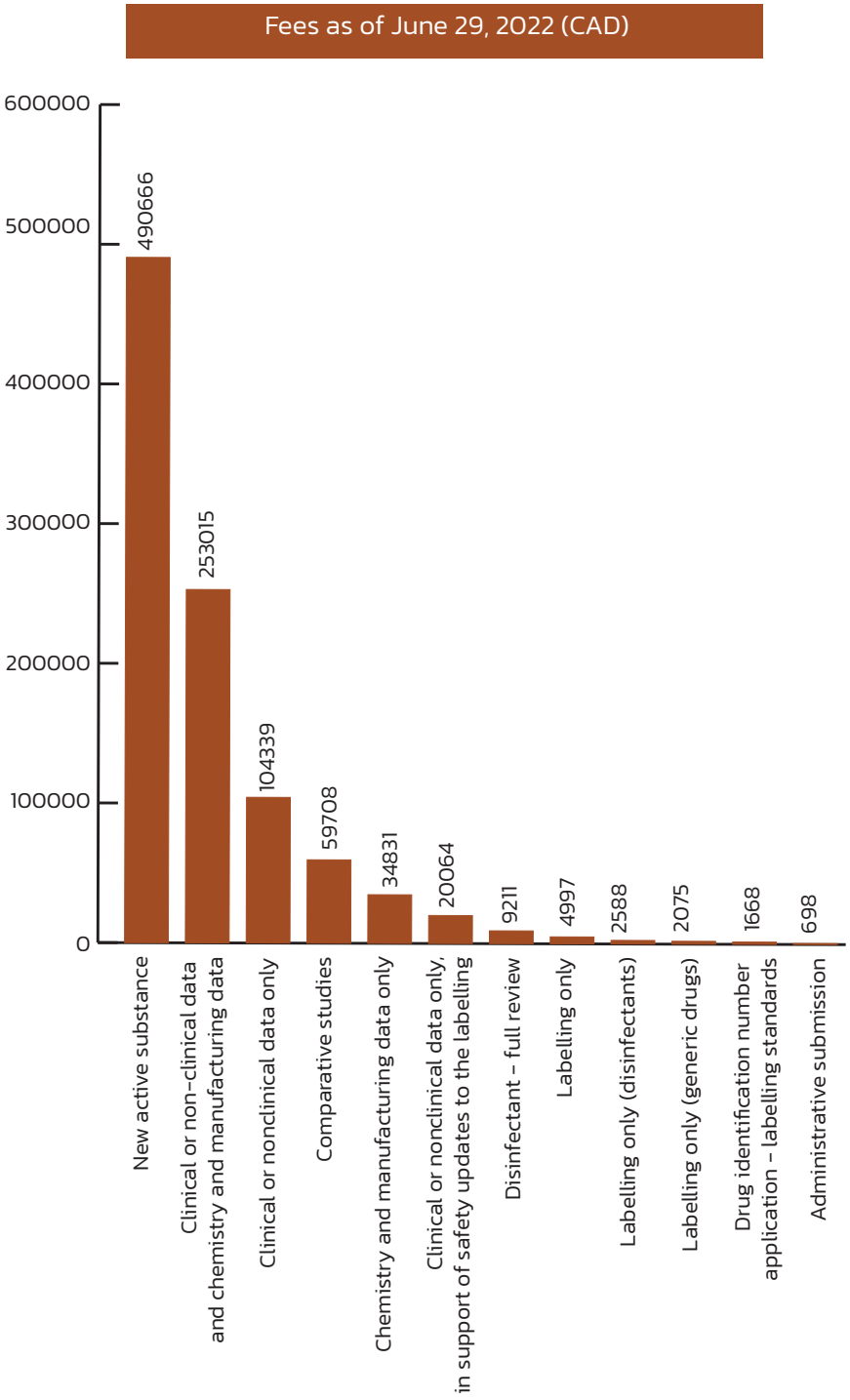
Timelines for review

Importantly, there is no fixed timeframe to complete the above drug review process.[141] However, secondary sources estimate that a total of at least 355 review days may be required for a sponsor to obtain a final decision from HPFB.[142] In contrast, the drug review process in India takes about half the time i.e., 180 days to conclude.[143] Some sources also estimate that the drug review procedure could extend to a period of 2 years in Canada.[144] Such delays may serve as a hindrance to Indian pharmaceutical companies seeking entry into the Canadian market.

139. According to the Food and Drugs Act, RSC 1985, c F-27, s 2, a drug is defined as follows:"drug includes any substance or mixture of substances manufactured, sold or represented for use in:
a) the diagnosis, treatment, mitigation or prevention of a disease, disorder, abnormal physical state, or its symptoms, in human beings or animals;
b) restoring, correcting or modifying organic functions in human beings or animals; or
c) disinfection in premises in which food is manufactured, prepared or kept."
140. Food and Drug Regulations, CRC, c 870, s C.04.015:
"On written request from the Director, every fabricator, packager/ labeller, tester, distributor referred to in paragraph C.01A.003(b) and importer of a drug shall submit protocols of tests together with samples of any lot of the drug before it is sold, and no person shall sell any lot of that drug if the protocol or sample fails to meet the requirements of these Regulations C.01A.003 b) a distributor of a drug for which that distributor holds the drug identification number."
141. Government of Canada, "How Drugs are Reviewed in Canada" available at <https://rb.gy/r6xipo> last accessed November 23, 2022. The website of Health Canada states that:
"HPFB has set internationally competitive performance targets for its conduct of reviews. The length of time for review depends on the product being submitted and the size and quality of the submission, and is influenced by HPFB's workload and human resources."
142. SPharm, "FAQ – The Drug Regulatory and Approval Process in Canada" available at <https://rb.gy/7uf09d> last accessed November 23, 2022.
143. Morulaa HealthTech "CDSCO Timelines" available at <https://rb.gy/ekp24l> last accessed November 23, 2022.
144. SPharm, "Drug regulatory and approval process in Canada Infographic" available at <https://rb.gy/etly6r> last accessed November 23, 2022.

Costs of review

The costs for such drug submissions can be prohibitive. According to Health Canada, fees are levied in proportion to the type and complexity of the regulatory activity. For instance, where a new substance is involved, fees can go as high as CAD 490,666.[145] A summary of the kinds of fees payable to Health Canada relating to the drug submission process is set out in the table below:



Source: Health Canada

145. Government of Canada, "Fees for Health Canada" available at <https://rb.gy/2yzbys> last accessed November 23, 2022.

SUGGESTIONS

- The regulatory requirements of Health Canada for establishing and operating a pharmaceutical company are stringent. Administrative delays at the federal and provincial level result in longer timelines and high costs of new drug approvals in Canada.
- India may endeavour moving towards a mutual recognition agreement by harmonizing its regulatory requirements with international practice. In the meanwhile, the Indian Government may propose that pharmaceutical goods which are recognized by regulatory authorities of certain other countries also be recognized by Canada.
- This approach has been taken in the India – UAE Comprehensive Economic Partnership Agreement as well. This may reduce the time taken for approvals. This is particularly important for complex pharmaceutical products. We understand that the European Medicines Agency is a regulatory authority that is likely to be accepted by the Canadian government for the purposes of recognition.
- India may also propose the commercialization of products which have already been approved in regulated markets such as the USA, the United Kingdom and the European Union. This would encourage Indian companies to form base in Canada, incentivizing investment and employment opportunities in Canada.
- Lastly, India may also suggest applying lower fees to such types of approvals that are based on recognition from a reference regulatory authority.

Drug Review Process for Generic Medicines

- A drug manufacturer may receive a **Notice of Compliance** ("**NOC**") to market a generic version of a drug product previously authorized by Health Canada (i.e., an innovator drug).
- Presently the scope for such generic drugs is limited. As per Section C.08.001.1 of the Food and Drug Regulations, for a generic drug to be considered equivalent to the patented drug, the generic drug must contain an 'identical amount of identical medicinal ingredients' as the patented drug. This is in contrast to other countries such as the U.S. and the EU that have a much wider ambit for generic products to demonstrate equivalence.[146]
- In this regard, the Canadian government has proposed amendments to the Food and Drug Regulations to allow for greater flexibility for generics. The process began in 2017 and Health Canada invited further comments on the proposed changes from stakeholders in 2019. The proposed changes are expected to be published in the Canada Gazette, in the fall[147] of 2022.[148]
- The amendments aim to change the requirement of an 'identical medicinal ingredient' to an 'identical therapeutically active component'. If the amendment to the legislation is accepted, a hydrate, solvate or salt of a Canadian reference product would also be eligible to qualify as a generic drug for approval.[149] However, it remains to be seen whether the proposed amendments will actually translate into law, given the rapid U-turn taken by Canadian authorities with respect to recently proposed amendments to Canada's Patented Medicines Regulations (as discussed later in this report) at the behest of the pharmaceutical lobbies in Canada.[150] Hence, the Indian government may need to closely follow up with the Canadian government regarding this issue in negotiations.
- Drug submissions related to generic drugs are called **Abbreviated New Drug Submissions** ("**ANDS**") and contain the following information:
  - Ingredients and specifications
  - Manufacturing process
  - Testing during manufacture
  - Testing prior to distribution and sale
  - Test results demonstrating bioequivalence to the brand name drug.
- As per the official reports, in 3 out of 5 years, it has taken longer to approve a generic product than it has to approve a new drug.[151] However, an analysis of the recent performance reports reveals that the timeframe for approval of generic drugs has improved. Nonetheless, the need for faster approval of generics is an issue that the Indian government may wish to highlight during negotiations.

146. Such regulatory authorities of other countries are termed 'Reference regulatory authorities'
147. Fall in Canada is typically the months of September, October and November
148. Government of Canada, "Forward Regulatory Plan 2022-2024: Regulations amending the Food and Drug Regulations (Improving Access to Generic Drugs)" available at <https://rb.gy/ouazv3> last accessed November 23, 2022.
149. European Medicine Agency, "Generic and Hybrid Medicines" available at <https://rb.gy/opqqqd> last accessed November 23, 2022.
150. Daphne Lainson and Nancy Pei, "Slam Dunk! New Basket Of Countries For PMPRB Reporting Remain, Controversial Amendments To Patented Medicines Regulations Dropped" (April 29, 2022) Mondaq available at <https://rb.gy/ftofuv> last accessed November 23, 2022.
151. Joel Lexchin, "Market Exclusivity Time for Top Selling Originator Drugs in Canada: A Cohort Study" (2017) 20(8) Value in Health 1139.

SUGGESTIONS

- The Indian government should emphasize the need to broaden the scope of bioequivalence for generic products in Canada.
- Commitments in this regard may be sought. Furthermore, it may be relevant to bring to the Canadian government's notice the significant time taken for generic approvals and request expedited approvals where such product has established bioequivalence in other jurisdictions and request expediting the same.
- Market exclusivity for a period of 180 days (such as in the USA) for the first generic producer may also be suggested as a means to incentivize generic producers.

Exceptions to the standard Drug Review Process

Priority Review Process

- An expedited 'priority review process' is in place for drug products for life-threatening or severely debilitating conditions, such as cancer, AIDS, or Parkinson's Disease, for which few effective therapies are on the market.[152] Such applications are processed with a shortened review target of 180 calendar days.[153]
- In the past, scholars have reported that it is unclear how Health Canada applies its criteria for a priority review. It is understood that in defining whether a condition is 'serious', Health Canada exercises certain discretion.[154] It is also reported that Health Canada does not reconsider its decisions regarding the qualification of drugs for a priority review.

Notice of Compliance with conditions

Under this process, expedited approval is granted to a manufacturer to market and sell a drug in Canada with the condition that the manufacturer executes additional studies to confirm the drug's benefit and safety.[155] The process covers drugs that offer treatment for conditions wherein no drug exists in Canada or offer an improved benefit/risk profile over existing therapies.[156] The approximate period for approval under this process is 200 days.[157]

Special Access Program

The HPFB also runs the 'Special Access Program', which allows doctors to access drugs which are currently unavailable or unapproved in Canada. The drug is only released after HPFB has determined that the need for such drug is legitimate and is prescribed by a qualified physician. Again, Health Canada enjoys discretion when it comes to administering this program.[158]

152. Health Canada, "Guide to the exceptional importation and sale of drugs in response to drug shortages (GUI-0148)" available at <https://rb.gy/6rpa4w> last accessed November 23, 2022.
153. Health Canada, "Guidance for Industry – Priority Review of Drug Submissions" available at <https://rb.gy/ruvfsx> last accessed November 23, 2022.
154. Joel Lexchin, "Health Canada's use of its priority review process for new drugs: a cohort study" (2015) 5 BMJ Open available at < https://rb.gy/19da7q> last accessed November 23, 2022.
155. Joel Lexchin, "Health Canada's use of its priority review process for new drugs: a cohort study" (2015) 5 BMJ Open available at < https://rb.gy/owvped/> last accessed November 23, 2022.
156. Joel Lexchin, "Health Canada's use of its priority review process for new drugs: a cohort study" (2015) 5 BMJ Open available at <https://rb.gy/19da7q> last accessed November 23, 2022.
157. Joel Lexchin, "Health Canada's use of its priority review process for new drugs: a cohort study" (2015) 5 BMJ Open available at <https://rb.gy/19da7q> last accessed November 23, 2022.
158. Health Canada, "Health Canada's special access programs: Overview" available at <https://rb.gy/dxqkzu> last accessed November 23, 2022.

Exception for shortages

With effect from March 2, 2022, Health Canada may temporarily allow the exceptional importation and sale of a foreign-authorized drug in order to mitigate shortages.[159] This is done by way of by adding it to the 'List of Drugs for Exceptional Importation and Sale incorporated into the Food and Drug Regulations'.[160] No Indian pharmaceuticals are presently on this list.

SUGGESTIONS

While there are several possibilities for expedited review, greater transparency and clarity on the practical application of such expedited review procedures by Health Canada and their potential to apply to drugs sold by Indian exporters would be helpful. India may seek clarity through negotiations.

Use of Foreign Reviews in the approval process

- An interesting aspect of the drug review process in Canada is that Health Canada also takes into consideration foreign reviews, if any, of such pharmaceutical products as a factor in its review of new drug submissions. Health Canada has issued a Guidance document titled Draft Guidance Document: The Use of Foreign Reviews by Health Canada[161] containing the procedures to follow when including a foreign review in applications.
- According to this, Health Canada may utilize foreign reviews as part of its evaluation of drug submissions, to variable degrees. However, the guidance document makes clear that a market authorization holder cannot be required to file a foreign review, nor can Health Canada unilaterally decide to delay the Canadian review until a foreign review is available. The guidance encourages applicants to provide such foreign review data, where it is already available.
- Despite such guidance however, the degree to which foreign reviews inform the decision making of Health Canada remains unclear.[162] Health Canada officials enjoy discretion in determining the appropriate method to be utilized to examine a foreign review. One of such methods also includes the possibility of basing their decision entirely on a 'critical assessment' of the foreign review.[163] Other factors may include the degree of similarity between the foreign and Canadian regulatory frameworks, the degree of similarity between the product reviewed and the product proposed for the Canadian market, the existence of any Canadian-specific considerations for the proposed product (e.g. disease prevalence, clinical practices, reference products) and the level of detail of the foreign review.[164]
- Given these factors, Indian companies that have regulatory approval in countries such as the USA that have largely similar regulatory frameworks may be at an advantage in consideration of their applications. However, at the same time smaller companies, without such approvals or reviews may not fare as well as it is unclear as to the extent to which such foreign reviews will influence the decision of Health Canada.

159. Health Canada, "List of drugs for exceptional importation and sale" available at <https://rb.gy/ya4dzj> last accessed November 23, 2022; Also see Sections C.01.014.8 and C.10.004 to C.10.011 of the Food and Drug Regulations
160. Health Canada, "List of drugs for exceptional importation and sale" available at <https://rb.gy/sresic> last accessed November 23, 2022.
161. Health Canada, "Draft Guidance Document: The Use of Foreign Reviews by Health Canada and revisions to the Use of Foreign Reviews pilot project" available at <https://rb.gy/qwhfna> last accessed November 23, 2022.
162. Health Canada, "Method 1, 2.3 Methods for the Use of Foreign Reviews, Draft Guidance Document: The Use of Foreign Reviews by Health Canada and revisions to the Use of Foreign Reviews pilot project" available at <https://rb.gy/qwhfna> last accessed November 23, 2022.
163. Health Canada, "Method 1, 2.3 Methods for the Use of Foreign Reviews, Draft Guidance Document: The Use of Foreign Reviews by Health Canada and revisions to the Use of Foreign Reviews pilot project" available at <https://rb.gy/qwhfna> last accessed November 23, 2022.
164. Health Canada, "Method 1, 2.3 Methods for the Use of Foreign Reviews, Draft Guidance Document: The Use of Foreign Reviews by Health Canada and revisions to the Use of Foreign Reviews pilot project" available at <https://rb.gy/qwhfna> last accessed November 23, 2022.

B. GOOD MANUFACTURING PRACTICES

- Part 2, Division C of the Food and Drug Regulations contain various requirements relating to Good Manufacturing Practices. No distributor or importer is permitted to sell a drug unless it in accordance with the various requirements relating to GMP.[165]
- Health Canada has also issued a Guidance Document on Good Manufacturing Practices Guide for Drug Products. Health Canada utilizes this document as a guidance while inspecting establishments to assess their Good Manufacturing Practices compliance with the Food and Drugs Act and Food and Drugs Regulations. A Canadian importer procuring pharmaceutical products manufactured abroad, must add such foreign building to its existing drug establishment license through an application and demonstrate compliance of such building with GMP.[166] Further, Health Canada assigns a 'new evidence required by date' (i.e., the date by which fresh evidence of GMP compliance is required) for such sites using a risk-based approach. Such date is often 4 years from the date of inspection and can be shortened if Health Canada considers such sites as higher risk based on various factors, again demonstrating the broad discretionary power possessed by Health Canada.
- Canada is party to several MRAs covering GMP Compliance Programmes. The **Regulatory Operations Enforcement Branch** ("**ROEB**") of Health Canada is the regulatory authority responsible for these MRAs. Canada presently has MRAs with the European Union, Australia, Switzerland, and the United Kingdom.[167] Notably, Canada does not have an MRA in place with the USA, despite the similarities in regulatory procedures between the two.[168] Canada is also an observer to the International Conference on Harmonization and where possible, applies their standards. There is presently no MRA with India.
- Moreover, Health Canada has issued a detailed guidance document for evaluating GMP practices to grant mutual recognition.[169] The document identifies components of another countries' GMP compliance programs that must be examined before granting mutual recognition. The document also ranks such components in order of importance, from Critical to Important and the entire checklist must be utilized for the assessment/evaluation of the GMP regulatory compliance programme in question. Thus, should India aspire to enter into an MRA with Canada, the high threshold set by the Health Canada authorities must be met. It may be useful to examine the inherent flexibilities such 'guidance documents' imply in such cases to put forward India's proposition for an MRA.
- As per the information available on Health Canada's website as of June 2022, and in light of COVID-19, Health Canada has resumed foreign onsite GMP inspections in the following situations:
  - Where it's critical to do so in light of the COVID-19 pandemic
  - To prevent a shortage of a medically necessary drug
- Further, where 'feasible', Health Canada is also considering conducting foreign inspections remotely. The contours of such remote inspections have not been defined and it appears that decision making is taking place on a case-by-case basis. Details of such inspections, if any, have not been made available.

165. Food and Drug Regulations, Section C.02.003
166. Health Canada, "How to demonstrate foreign building compliance with drug good manufacturing practices (GUI-0080)" available at <https://rb.gy/lfxzyl> last accessed November 23, 2022.
167. Health Canada, "Mutual Recognition Agreements" available at <https://rb.gy/4iwwxo> last accessed November 23, 2022.
168. Maryse Mercier, "Are we close to a Mutual Recognition Agreement with the USA?" (February 4, 2020) <https://rb.gy/grekhx> last accessed November 23, 2022.
169. Health Canada, "Mutual Recognition Agreement Evaluation Guide of Good Manufacturing Practices Compliance Programs" available at <https://rb.gy/nj8etq> last accessed November 23, 2022.

- Some of the factors considered by Health Canada while determining the risk of a foreign site include whether other trusted regulatory authorities are planning to inspect the foreign building and sharing of inspection reports between such authorities.
- In the absence of GMP evidence, importers may submit a 'foreign building assessment request' which will be reviewed on a case-by-case basis.[170] Such review would take longer than the general timelines outlined in the Guidance Document titled How to demonstrate foreign building compliance with drug good manufacturing practices (GUI-0080).[171]
- Thus, it appears that a wide ambit of discretion is available to Health Canada regarding conduct of foreign GMP inspections. Such discretion may create uncertainty for exporters with respect to timelines for the conduct of regular inspections and whether a remote inspection will be allowed in a particular case. While this is temporary given the COVID-19 pandemic, the general lack of an MRA with India exacerbates delays for Indian exporters.
- India should advocate for an MRA with respect to GMP clearance with Canada based on clearance granted in India. If such MRA is not acceptable to Canada, alternative, Indian companies could benefit if an expedited procedure for GMP approval based on existing approval in other third-party regulatory authorities could be introduced in Canada.

SUGGESTIONS

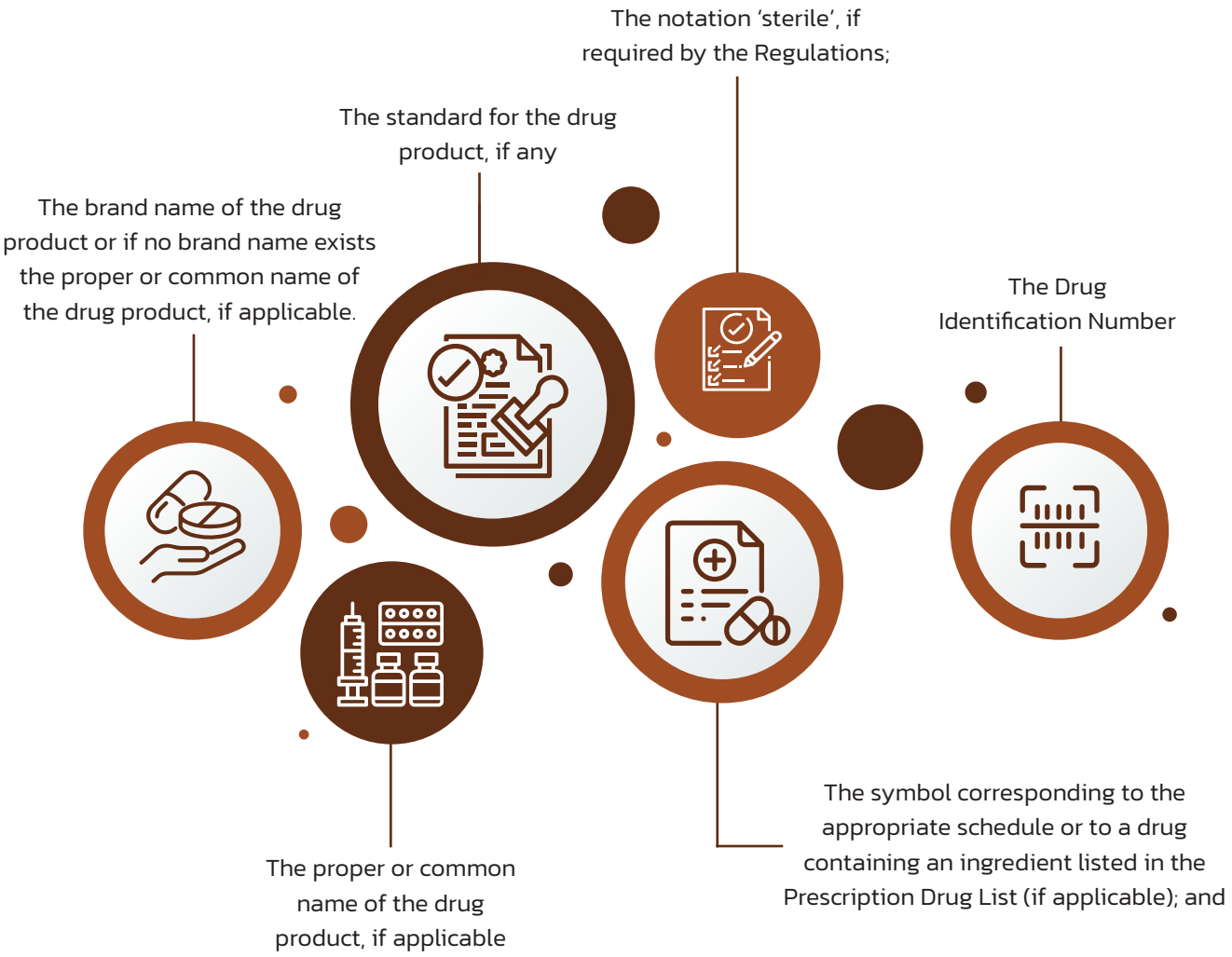
India should endeavour to harmonize its GMP compliances with international standards in order to conclude a mutual recognition agreement with Canada. In the absence of such MRA, the need for site inspections for the purposes of GMP compliance may be highlighted as unnecessary in cases where Indian drug manufacturers have received GMP recognition in a third-party reference country.

170. Health Canada, "Good manufacturing practices and COVID-19" available at <https://rb.gy/fkww43> last accessed November 23, 2022.
171. Health Canada, "How to demonstrate foreign building compliance with drug good manufacturing practices (GUI-0080)" available at <https://rb.gy/ovtwq7> last accessed November 23, 2022.

C. LABELLING REQUIREMENTS

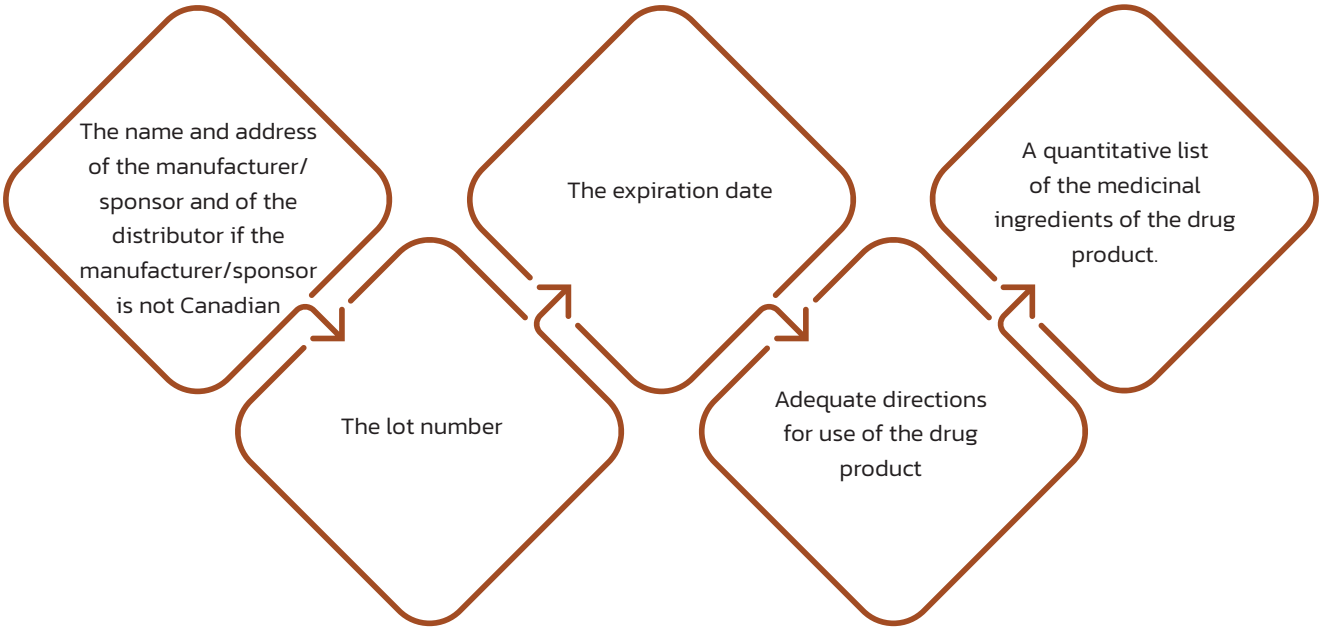
01 Labelling requirements for drugs are set out in Sections 3, 9, and 10 of the Food and Drugs Act and related provisions of the Food and Drug Regulations. Additional requirements for specified substances are contained in the Controlled Drugs and Substances Act, and its related Regulations including the Narcotic Control Regulations, Parts G and J of the Food and Drug Regulations and the Benzodiazepines and Other Targeted Substances Regulations.

02 Pursuant to Sections C.01.004 and C.01.005 of the Food and Drug Regulations, the principal display panel[172] of an inner and outer label must normally show the following information:



172. The principal display panel (that is (i.e.) main panel) is the main product display surface visible to the user under normal or customary conditions of display or use.

03 Pursuant to Section C.01.004 of the Food and Drug Regulations, the following information must normally be displayed on any panel of the inner and outer labels:



04 The following information is to be displayed on any panel of the outer label

The net amount of the drug product in the container in terms of weight, measure or number (for example (e.g.) number of tablets); and

A quantitative list of all preservatives in parenteral preparations and of all mercurial preservatives in any drug product containing mercury or a salt or derivative thereof as a preservative.

For prescription pharmaceutical products and those products administered or obtained through a health professional, Section C.01.004.01(1) requires that every label of a drug for human use in dosage form shall display a telephone number, email address, website address, postal address or any other information that enables communication with a contact person in Canada; and a statement to the effect that any injury to a person's health that is suspected of being associated with the use of the drug may be reported to the contact person.

05 There are some divergences in India's and Canada's labelling requirements. While they may appear simple on a tertiary level, they necessitate additional capacity building and a fresh set of labels. These requirements require setting up a line that prints different labels and ensuring that the correct label is affixed for the appropriate destination country. Therefore, these requirements are likely to result in an increase in cost.

06 In Canada, various information and tables are supposed to be printed in both English and French. For example, information regarding adequate directions for use of the drug; a quantitative list of the drug's medicinal ingredients by their proper names or, if they have no proper names, by their common names; the drug's non-medicinal ingredients listed in alphabetical order or in descending order of predominance by their proportion in the drug, preceded by words that clearly distinguish them from the medicinal ingredients; and various contact details about a representative of the organization selling the drug.[173] The requirement for publication in French may constitute an additional cost for Indian exporters.

07 In the Canadian context, symbology in labelling is also different. The symbol 'Pr' must be affixed on the top left corner of the label in the case of a prescription drug. In India, if it contains a substance specified in Schedule H it must be labelled with the symbol Rx and conspicuously displayed on the left top corner of the label and be also labelled with the following words: 'Schedule H drug – Warning: To be sold by retail on the prescription of a Registered Medical Practitioner only'.[174]

08 In Canada, the  Symbol consisting of a diamond shape outline in which an uppercase letter C is centred in a clear manner and a conspicuous colour and size, is designated as a controlled drug. The symbol "N" in a colour contrasting with the rest of the label or in type not less than half the size of any letters used thereon if the product is defined as a Narcotic. In the context of Indian regulation, the designator is 'NRx'. While it appears to be a simple change, it would require 2 different sets of labels to be printed.[175]

09 In India, some drugs have a reference to 'I.P' on their label, which refers to Indian Pharmacopoeia. IP prescribes standards for identity, purity and strength of drugs. Whereas, in the case of Canada, 'C.S.D' or 'Canadian Standard Drug' must be printed on the label.[176]

173. Food and Drug Regulations; Drugs and Cosmetics Rules, 1945.
174. Food and Drug Regulations; Drugs and Cosmetics Rules, 1945.
175. Food and Drug Regulations; Drugs and Cosmetics Rules, 1945.
176. Food and Drug Regulations; Drugs and Cosmetics Rules, 1945.

S.No	Particulars of difference in laws	India	Canada
1	Language	English	English and French
2	Symbology for Prescription Drug	'Pr' must be affixed on the top left corner of the label in the case of a prescription drug	It must be labelled with the symbol "Rx" on the left top corner of the label
3	Symbology for Controlled Drug	Labelling with:	Additional label: 'Schedule H drug – Warning: To be sold by retail on the prescription of a Registered Medical Practitioner only'
4	Symbology for Narcotic	The symbol 'N' in a colour contrasting with the rest of the label or in type not less than half the size of any letters used thereon	Labelling with: 'NRx'.
5	Standard	'C.S.D' (Canwadian Standard Drug)	'I.P' (Indian Pharmacopoeia)

09

Concluding, while individually these changes may not seem so onerous, they would represent a significant undertaking on the part of the firm to export pharmaceuticals to Canada.

INTELLECTUAL PROPERTY RIGHTS

The primary legislations relevant to pharmaceutical patents are the Patent Act, 1985[177] and the Patent Rules, 1996. The patent on a drug is valid for 20 years from the date of filing.

A. DATA EXCLUSIVITY OF INNOVATIVE DRUGS

- There may be certain pharmaceutical products which utilize new chemical entities, the origination of which involves considerable effort. With such products, tests or other data which determines the safety and effectiveness of a pharmaceutical product are also granted patent protection under the **USA–Mexico–Canada Agreement**[178] ("**USMCA**") and the Agreement on Trade-Related Aspects of Intellectual Property Rights[179] ("**TRIPS**").
- Under Canadian law, an innovative drug contains a medicinal ingredient not previously approved in a drug in Canada. Such medicinal ingredient cannot be a variation of a previously approved medicinal ingredient such as a salt, ester, enantiomer, solvate or polymorph, the origination of which involved considerable effort.[180]
- As an incentive to innovators, all drug products containing a new chemical entity are provided an 8 years of market exclusivity as per Section C.08.004.1 of the Food and Drug Regulations.[181] A further 6-month extension is provided for drugs aimed at the paediatric population.
- Consequently, a subsequent-entry manufacturer is not allowed to file a submission for a generic drug for the first 6 years of the 8 years.
- A biosimilar drug or generic drug does not qualify as an 'innovator drug' and therefore cannot itself benefit from the data protection or other regulatory exclusivity against other subsequent products. There is also no market exclusivity for the first approved generic drug or biologic drug against subsequent drugs. In contrast, the first approved generic in the USA is also eligible for exclusivity. However, such exclusivity is limited to a period of 180 days. [182]

177. Patent Act, RSC 1985, c P-4.
178. USA-Mexico-Canada Agreement, Article 1711.
179. Agreement on Trade-Related Aspects of Intellectual Property Rights, Article 39.
180. Health Canada, "Guidance Document: Data Protection under C.08.004.1 of the Food and Drug Regulations" available at <https://rb.gy/tuzkbm> last accessed November 23, 2022.
181. SPharm, "Frequently Asked Questions - Drug Regulatory & Approval Process in Canada" available at <https://rb.gy/c2out0> last accessed November 23, 2022; See also, Health Canada, "Guidance Document: Data Protection under C.08.004.1 of the Food and Drug Regulations" available at <https://rb.gy/tuzkbm> last accessed November 23, 2022.
182. U.S. Food and Drug Administration, "Small Business Assistance: 180 Day Generic Drug Exclusivity" available at <https://rb.gy/tdhddg /> last accessed November 23, 2022.

- On paper, the period of exclusivity granted in Canada is largely in line with and in some cases shorter than other highly regulated markets such as the EU and USA. For example, in the USA, market exclusivity for new drugs is 12.4 to 12.5 years.[183] However, a 2017 study reported that market exclusivity time may be longer for top selling originator drugs in Canada. Consequently, such drugs remain on the market for long periods without competition.[184] Another study conducted in 2021 which covered a total of 121 drugs found that the mean time for market exclusivity until patent expiration was 8.08 years. Additionally, the mean time from patent expiration until generic drug marketing was 1.53 years. This results in a mean difference of 9.61 years between the start of brand name and generic drug marketing.[185]

SUGGESTIONS

As the data exclusivity provisions form part of Canada's FTA obligations, it is unlikely that the Canadian government would be willing to introduce any changes thereto. However, the Indian government may nevertheless consider reiterating the need to shorten generic drug approvals in light of the delay caused by such market exclusivity provisions.

B. PATENT OPPOSITION

There does not exist any formal patent opposition procedure in Canada. In contrast, India maintains formal procedures for pre and post grant opposition which can be filed on various grounds. Under Section 34.1 of the Patent Act, any third party in Canada can file prior art with **Canadian Intellectual Property Office** ("**CIPO**"), explaining why they believe a claimed invention is not new or inventive. This is taken into consideration when the application is examined. Further, post-grant, a patent may be subject to re-examination upon the request of a third party. Such re-examination proceeding is confined to issues arising from any prior art supplied by the requesting party. The lack of detailed pre and post grant opposition may be viewed as a restriction on competition by generic manufacturers.

SUGGESTIONS

India should refrain from making any commitments with respect to altering its patent opposition system.

183. Henry G Grabowski and others, "Evolving Brand-Name and Generic Drug Competition May Warrant A Revision Of The Hatch-Waxman Act" (2011) 30(11) Health Affairs 2157.
184. Joel Lexchin, 'Market Exclusivity Time for Top Selling Originator Drugs in Canada: A Cohort Study' (2017) 20(8) Value in Health 1139.
185. Joel Lexchin, 'Time to Marketing of Generic Drugs After Patent Expiration in Canada' (2021) 4(3) Jama Network Open available at <https://rb.gy/3ufsy5> last accessed November 23, 2022.

C. PATENT TERM EXTENSION

- Further, as a part of its obligations under the **Canada-European Union Comprehensive Economic and Trade Agreement** ("**CETA**"), Canada provides up to 2 years of sui generis protection for new pharmaceutical products protected by an eligible patent, from the expiry of the patent.[186]
- The Certificate of Supplementary Protection regime came into force on September 21, 2017, through amendments to the Patent Act and the introduction of the Certificate of Supplementary Protection Regulations. This is executed through a system for supplementary certificates of protection that aim to make up for the time lost in obtaining market approval.
- Further, Health Canada does not grant an NOC, which is necessary to sell and distribute pharmaceutical products in Canada, until such 2-year extension period expires. In such cases, market exclusivity is extended from 8 to 10 years.
- This system may also place additional requirements prior to marketing approval, including requiring the subsequent drug manufacturer to establish that it is not infringing an existing patent, by filing appropriate paperwork and informing the originator of the patent who in turn can initiate a case of infringement.

SUGGESTIONS

As the patent extension provisions form part of Canada's FTA obligations, it is unlikely that the Canadian Government would be willing to introduce any changes thereto. However, the Indian government may nevertheless consider reiterating the need to shorten generic drug approvals in light of the delay caused by such patent linkage system.

D. EXTRATERRITORIALITY OF PATENTS

The case of Pfizer Canada Inc et al v The Minister of Health et al [2007 FC 898] is a landmark judgement which ruled on the extraterritoriality of Canadian patents. In the case, Ranbaxy produced a certain drug in India. The said drug was manufactured using an intermediate that was patented in Canada. It was found that by producing a drug with a patented intermediate, Ranbaxy infringed the patent for the intermediate when the final product was imported and sold in Canada.[187] Known as the Saccharin Doctrine, this rule is prevalent in many jurisdictions but has been limited to processes. The Canadian Supreme Court has expanded the scope of such doctrine to include products, thereby acting as a hindrance to innovation and competition.

186. Health Canada, "Guidance Document - Certificates of Supplementary Protection" available at <https://rb.gy/sbeqxk> last accessed November 23, 2022.
187. Heather Gardiner, "How to avoid the bitter taste of infringement litigation" (March 26, 2012) Canadian Lawyer available at <https://rb.gy/dhftbh> last accessed November 23, 2022.

E. COMPULSORY LICENSING

- Compulsory licensing is permitted under the Patent Act. Recent amendments to the Patent Act under Canada's COVID-19 Emergency Response Act have strengthened the Federal Government's ability to address vaccine shortages through the use of compulsory licenses. Specifically, the amendments are aimed at allowing the Federal Government to permit the "construct[ion], use, and [sale of] a patented invention to the extent necessary to respond to a public health emergency that is a matter of national concern". The Government is required to provide notice and pay royalties to the patent holder. However, the government has no further obligations to negotiate with patent holders.
- This is in line with India's position as well as the recent WTO decision on intellectual property waivers for COVID-19 vaccines. However, India is keen on expanding the scope of such waivers to diagnostics and therapeutics as well and this may be a key point of negotiation should the talks at the WTO eventually exclude these goods from the waiver.

SUGGESTIONS

The Indian government should strongly put forth the position that the scope of patent protection should be national and not extend into India. Language to this effect may be proposed in the draft FTA.

PRICE CONTROLS

The prices of pharmaceuticals in Canada have been reported as among the highest in the world[188] , despite the existence of price controls.

At the Federal level, the **Patented Medicine Prices Review Board** ("**PMPRB**") sets the maximum prices of patented medicines under the Patent Act. At the provincial level, prices of certain medicines listed as part of government 'drug benefit programmes' (i.e., programs that cover the cost of listed drugs for eligible recipients) are subject to negotiated price controls.[189] The pCPA, an organization comprised of the provincial, territorial and federal governments, negotiates prices for medicines with pharmaceutical manufacturers on behalf of such governments for items covered by their public drug benefit programmes.

188. Patented Medicine Prices Review Board, "Annual Report 2020" available at <https://rb.gy/wnychy> last accessed November 23, 2022.
189. Government of Canada, "Provincial and Territorial Public Drug Benefit Programs" available at <https://rb.gy/ubo6s7> last accessed November 23 ,2022.

A. FEDERAL PRICE CONTROLS

- The PMPRB operates under Sections 79 to 103 of the Patent Act. The PMPRB has jurisdiction for any medicine to which a patent 'pertains'. The PMPRB may hold public hearings and stakeholder engagements to determine whether the price of a patented medicine is excessive, and if so, order price reductions.[190] Specifically, the PMPRB bases its decision on whether the prices charged in Canada are at par with the prices in 7 identified reference countries, i.e., France, Italy, Sweden, Switzerland, Germany, the UK and the US. The PMPRB regulates manufacturer's prices and does not regulate retail sales.[191]
- Significant amendments[192] to the existing Patented Medicines Regulations were proposed in 2019 and their enforcement was delayed several times since. The new regulations were to result in significant price reductions for existing and new patented drugs. They also required manufacturers to prove that the otherwise confidential prices charged in Canada were justified.[193] They also introduced additional regulatory factors for consideration by the PMRB while determining whether the price of a drug was excessive, expanded the list of reference countries and introduced reduced reporting requirements for medicines deemed low risk for excessive pricing.[194] The proposed amendments have been subject to litigation before various forums. On June 29, 2020, the Federal Court struct down provisions relating to the manner in which prices and revenues are reported to the PMRB.[195] Subsequently, on February 18, 2022, the Court of Appeal of Quebec struck down provisions which would have required price and revenue reporting to take into account confidential rebates and those introducing new price regulatory factors and reporting requirements.[196]
- While these decisions are subject to appeal to higher judicial forums, the Canadian government in April 2022 decided that it will not be proceeding with the amendments related to new price regulatory factors, or with the requirements to file information relating to confidential pricing data.[197] However, it will proceed with the limited amendments which widen the basket of comparator countries and the reduced reporting requirements for medicines that are at a low risk of excessive pricing are being enforced.[198] With effect from July 1, 2022, the list of reference countries has been amended to replace high price countries such as USA and Sweden by lower price countries such as Australia, Belgium, Japan, Netherlands, Norway and South Korea. This may result in a reduction in prices. Additionally, the reduced reporting requirements are applicable to patented generic medicines as well.[199]

SUGGESTIONS

We understand that the regulations introduced by the Canadian government are unlikely to change. The focus should be on the provincial level, where pricing flexibilities can be capitalized on.

191. Government of Canada, "Regulatory Process – Patented Medicine Prices Review Board" available at <https://rb.gy/gzojke> last accessed November 23, 2022.
192. Government of Canada, "Frequently Asked Questions, Patented Medicine Prices Review Board" available at <https://rb.gy/5x2ygw> last accessed November 23, 2022.
193. Regulations Amending the Patented Medicines Regulations (Additional Factors and Information Reporting Requirements), SOR/2019-298.
194. Regulations Amending the Patented Medicines Regulations (Additional Factors and Information Reporting Requirements), SOR/2019-298.
195. Innovative Medicines Canada v. The Attorney General (Canada) 200 FC 725
196. Merck Canada Inc v. Procureur général du Canada 2022 QCCA 240
197. Daphne Lainson and Nancy Pei, "Slam Dunk! New Basket Of Countries For PMPRB Reporting Remain, Controversial Amendments To Patented Medicines Regulations Dropped" (April 29, 2022) Mondaq available at <https://rb.gy/ftofuv> last accessed November 23, 2022..
198. Daphne Lainson and Nancy Pei, "Slam Dunk! New Basket Of Countries For PMPRB Reporting Remain, Controversial Amendments To Patented Medicines Regulations Dropped" (April 29, 2022) Mondaq available at <https://rb.gy/ftofuv> last accessed November 23, 2022..
199. Health Canada, "Statement from Minister of Health on the Coming-into-Force of the Regulations Amending the Patented Medicines Regulations" available at <https://rb.gy/9pgzde> last accessed November 23, 2022.

B. PROVINCIAL CONTROLS

- There are no price controls akin to those set by the PMRB at the provincial level. However, provincial governments regulate the prices of selected drugs appearing on a provincial 'formulary list', under their public drug benefit plans. [200] These plans are not harmonized across provinces and a variety of different private and public drug plans for reimbursement exist across Canada. Prices of drugs under such plans are negotiated by the pCPA.[201]
- It has been reported that in April 2018, the pCPA was successful in reducing the prices by 25-40% of nearly 70 of the most commonly prescribed drugs.[202] However, there exist concerns about the lack of transparency in the pCPA's processes and governance.[203] Further, public drug plans are not mandated to list drugs that have gone through negotiations with the pCPA. Such negotiations culminate only in a letter of intent on the basis of which, manufacturers must negotiate individual product licensing agreements with each province. This has been flagged as introducing the possibility of additional criteria or limitations for each province.
- In addition, the pCPA in agreement with the Canadian Generic Pharmaceutical Association had also agreed to reduce prices of Canada's 70 top-selling generic drugs by 25% to 40% to between 10% or 18% of the brand-name price starting in 2018.[204] There is a tiered pricing framework in place as follows:

Table 4: Tiered pricing framework for generic medicines

Tier	% of Brand Reference Pricing
Tier 1: Where there is only 1 manufacturer of a generic product in the Canadian market	Priced at 75% of brand reference price if product listing agreement (PLA) or pricing agreement for brand exists in any jurisdiction (i.e., province) Priced at 85% of brand reference price if PLA or pricing agreement for brand product does not exist
Tier 2: Established when there are 2 generics on the Canadian market.	Priced at 50% of brand reference price
3 Tier 3: Established when there are 3 or more generic products on the Canadian market.	Priced at 25% of brand reference price for oral solids and at 35% for all dosage forms other than oral solids (e.g., liquids, patches, injectables, inhalers, etc.)

Source: pCPA

SUGGESTIONS

Pricing oral solid products at 25% of the brand reference price for when there are 3 or more generic products on the Canadian market does not take into account high manufacturing cost or low selling price. The Indian Government may consider asserting the need for the relaxation of the fixed price policy.

200. Dara Jospé, Jean Raphaël Champagne, Marie Lafleur, "Regulatory Pricing and Reimbursement" (August 11, 2022) PharmaBoardroom available at <https://rb.gy/jtvbww> last accessed November 23, 2022.
201. Dara Jospé, Jean Raphaël Champagne, Marie Lafleur, "Regulatory Pricing and Reimbursement" (August 11, 2022) PharmaBoardroom available at <https://rb.gy/jtvbww> last accessed November 23, 2022.
202. Kelsey Rolfe, "Health Canada moving to simplify generic drug approval process" (17 April 2019) Benefits Canada available at <https://rb.gy/w2hmfs> last accessed November 23, 2022.
203. Nigel Rawson, "Pan-Canadian Pharmaceutical Alliance Lacks Transparency and Accountability: Nigel Rawson for Inside Policy" (8 February 2019) Macdonald-Laurier Institute available at <https://rb.gy/ajoleh> last accessed November 23, 2022.
204. PDCI Market Access, "Reminder: New prices for generics under pCPA/CGPA agreement become effective April 1st, 2018" available at <https://rb.gy/z0srop> last accessed November 23, 2022.

TRADE REMEDIAL MEASURES

The primary legislation governing the application of trade remedial measures in Canada is the Special Import Measures Act. The Canadian International Trade Tribunal is the investigating authority.

As on the date of this report, there are presently no trade remedial measures specific to the pharmaceutical sector in force in Canada against India.

However, certain subsidy schemes granted by the Indian government that may also be utilized by the pharmaceutical sector have been previously countervailed in Canada (albeit in the context of non-pharmaceutical products). These are:

01 **Duty Drawback** ("**DDB**")

02 **Export Promotion Capital Goods Scheme** ("**EPCG**")

03 **Merchandise Export from India Scheme** ("**MEIS**") / Scheme for **Remission of Duties and Taxes on Exported Products** ("**RoDTEP**")

04 Interest Equalization Scheme on Pre and Post Shipment Rupee Export Credit

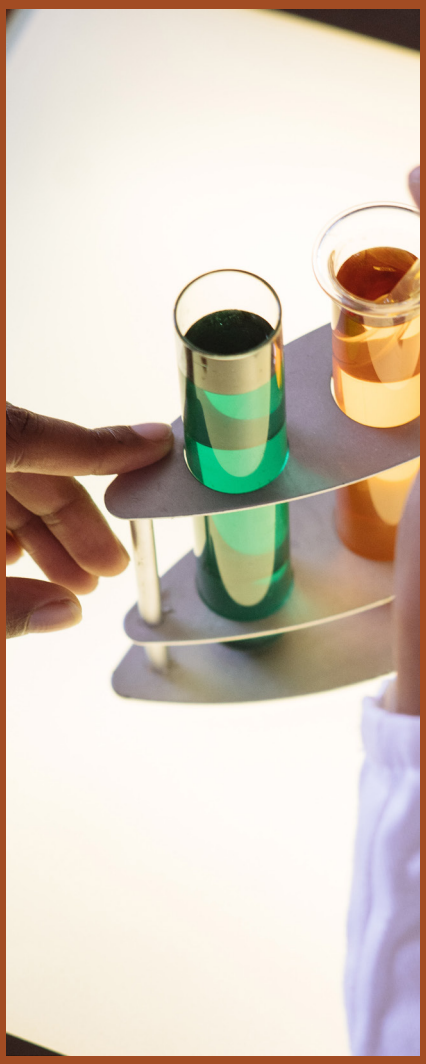
05 Advance Authorization

SUGGESTIONS

With respect to the trade remedial chapter of the FTA, it may be useful to re-affirm that countervailing measures, if any, should be limited to excess remissions only and not extend to the full amount of assistance provided. Additionally, the Indian government should request that provisions requiring Canada to provide a reasonable opportunity for consultations before proceeding to initiate a trade remedial investigation be incorporated in the future CEPA. Similar provisions exist in some of India's existing FTAs, such as the India-Korea CEPA for example.

BROAD SUBSIDIES

As per Canada's latest notification to the WTO Committee on Subsidies and Countervailing Measures under Article XVI:1 of the General Agreement on Tariff and Trade, 1994 and Article 25 of the Agreement on Subsidies and Countervailing Measures dated June 30, 2021[205] , is being circulated at the request of the delegation of Canada, there are presently no subsidies specific to the pharmaceutical sector being granted by the Canadian government.



Previously in the financial years 2018/19 and 2019/20, the provincial government of Québec had introduced a 'BioMed Propulsion Program' to provide financial support to Québec businesses with strong growth potential in the life sciences sector (including biotechnology and medical technology) and to help them market their research results. Assistance was provided in the form of an equity loan with a minimum and maximum threshold of USD 2.5 million and USD 10 million for medical technology businesses.

205. World Trade Organization, Committee on Subsides and Countervailing Measures, "Subsidies New and Full Notification Pursuant To Article XVI:1 Of The GATT 1994 And Article 25 Of The Agreement On Subsidies And Countervailing Measures" (8 July 2021) G/SCM/N/372/CAN

GOVERNMENT PROCUREMENT

The Advisory Council on the Implementation of National Pharmacare recommends that Canada implement universal, single-payer, public pharmacare to ensure better drug access for all.

The Advisory Council has also recommended the establishment of a 'Canadian drug agency', responsible for developing a national list of prescription drugs (i.e., a formulary). This will begin with an initial list of essential medicines followed by a comprehensive formulary, to be in place no later than
January 1, 2027.

Such an agency will serve as a strong negotiating forum which generic companies may find challenging to navigate.

However, we understand that a bill has been introduced in the National Assembly of Quebec which provides that "public bodies must, when tendering or awarding a contract not subject to an agreement, favour procurement of Québec goods, services or construction work from enterprises in the region concerned by such procurement."[206] Even though the bill has no legal effect at present, the growing preference of local goods over imported goods is a cause of concern which must be flagged.

206. Bill No. 12, National Assembly of Quebec, Second Session, Forty Second Legislature

INVESTMENT BARRIERS

The Investment Canada Act, 1985 is the primary legislation regulating foreign investment in Canada. Foreign investors must notify the Canadian government when acquiring a controlling interest in an existing Canadian business or starting a new business. Investors with investments below certain thresholds have the option to delay reporting for up to 30 days after implementation. Generally, investments above those thresholds are assessed based on whether they are of 'net benefit' to Canada and must wait for affirmative approval before implementation. The present threshold is USD 1 billion Canadian Dollars for investors that are from countries that are Members of the WTO and that are not state-owned enterprises ("**SOEs**") and USD 1.5 billion Canadian Dollars for investors that are not SOEs from countries that are party to certain designated trade agreements with Canada. Hence entering into a trade agreement with Canada would benefit smaller scale investors due to the higher threshold applicable to investments from trade agreement partners.

This may be a challenge for Indian pharmaceutical companies wishing to set up businesses in Canada.

SUGGESTIONS

Entering into an FTA would enable Indian companies to take advantage of the higher threshold applicable to FTA partners. The Indian government should emphasize the grant of this higher threshold to India upon signing of an FTA.

ISRAEL

EXECUTIVE SUMMARY

INTRODUCTION

- The trade relationship between India and Israel has grown over the years. According to the Department of Commerce, Government of India, India's pharmaceutical exports (Chapter 30) to Israel in FY 2021-2022 stood at **USD 16.06 million**.
- The pharmaceutical Industry in Israel is regulated under a comprehensive legislative framework and is supervised by the Ministry of Health and various subordinate bodies.

ISSUES AND RECOMMENDATIONS

Tariff and Customs Barriers

- Israel has 68 tariff lines under Chapter 30 (Pharmaceutical Products) of its Customs Tariff, according to tariff data taken from the WTO Tariff Analysis database at Harmonized System 8-digit level for 2021.
- Band-Aids, tetanus immunologicals, dental cement, and bone reconstruction cements appear to be the main product categories that have duties imposed. Every other category is subject to nil duties. Hence, there do not appear to be any major tariff barriers at the moment.

Registration & Marketing Authorization

- Every pharmaceutical product must be registered in the 'Israel Drug Register', and marketing approval must be granted for the first batch of the product that is marketed in Israel. Foreign companies must also appoint an authorized representative in Israel to register their products.
- For imported products, the same must have approval in certain reference countries in order to be approved in Israel, through a 'Certificate of Pharmaceutical Product' issued by such recognized country.
- Registration must be completed in 270 days under law. However, in practice, this often extends to 360 days. The time period is shorter if the product has already been registered or approved by other recognized regulatory bodies. Since approval in certain third countries is a prerequisite for registration in Israel, it may create an additional burden on smaller Indian manufacturers that are not registered in such countries. However, the practice of fast tracking of registrations based on existing approval by the FDA, EMA and Swissmedic may be advantageous to producers already approved by these authorities and may be explored further in negotiations. India may suggest taking this a step further by entering into a mutual recognition agreement based on recognition by these third country regulatory authorities.
- Some exceptions exist where registration is not required such as imports and manufacturing of pharmaceutical products for personal use of a specific patient, compassionate use, or for a specific pharmacy in small batches.
- The fast tracking of registrations based on existing approvals may be advantageous to Indian firms already approved by these authorities and spill over benefits from the same may be explored further in negotiations. India may suggest taking this a step further by entering into a mutual recognition agreement based on recognition by third country regulatory authorities.

Packaging & Labelling Requirements

- The packaging for pharmaceutical products requires certain information on a mandatory basis such as trade/generic name, specification of the 'Active Pharmaceutical Ingredient' ("**API**") used, among several others. However, certain aspects such as the name of the pharmaceutical, an instruction to review consumer information on the packaging, and the API must be listed in 4 languages i.e., Hebrew, Arabic, English and Russian. This may be onerous for certain segments of exporters, particularly Medium, Small and Micro Enterprises ("**MSME**").

Mutual Recognition Agreements

- Israel has 2 mutual recognition agreements in place with the European Union regarding 'Good Laboratory Practices' and acceptance of conformity assessment with a sectoral annex on 'Good Manufacturing Practice' or GMP in pharmaceuticals.
- A mutual recognition agreement for GMP certification on the basis of a third country reference may be considered as a proposal during negotiations in order to expedite clearances for Indian exporters.

Intellectual Property Protection

- Under Israeli Patent Law, patent protection is granted to all inventors for a period of twenty years. Israel grants patent term extensions for a limited period of time. Israel's intellectual property laws in general appear to be less stringent than other countries such as the European Union and the United States of America.

Price Controls

- The Ministry of Health publishes a price list for prescription drugs. The maximum prices of innovative & biosimilar drugs are equal to the average of the lowest 3 quoted wholesale prices among certain reference countries. For generic drugs or innovative drugs with generic alternatives, the prices are fixed at the price-level on the determining day of the previous year. Further appraisal requires government approval.

Government Procurement Programs/Incentives

- Israel recently released a "tax order" broadening the scope of Israel's Intellectual Property preferential tax regime also known as the Innovation Box Regime. The scope of this program includes products approved by the health regulators of the USA and the EU. These products under the Innovation Box Regime have numerous IP based tax benefits, and as a result, may be an incentive to set up manufacturing in Israel. Indian exporters and producers of pharmaceuticals may wish to consider whether programs like the innovation box regime constitute significant incentive to undertake manufacturing operations in Israel. The Indian Government should seek clarity from the Israeli Government as to how such schemes may benefit Indian exporters.

Trade Remedial Measures

- The investigating authorities in Israel have only rarely carried out trade remedial investigations, and none of them have involved pharmaceuticals. Additionally, as of the publication date of this report, India was not the subject of any investigations. Hence, trade remedial measures do not appear to constitute a significant market access barrier.

Restrictions on Government Procurement

- Israel is party to the Government Procurement Agreement ("**GPA**") of the World Trade Organization. Foreign suppliers that have won tenders are required to engage in an offset procurement in Israel. The offset requirements for countries that are a party to the GPA are at 20% of the value of the contract and 35% for procurements excluded from GPA coverage. After 15 years following the new GPA's implementation, Israel aims to completely eliminate such offset requirements. As India is not a signatory to the GPA, it's offset thresholds would be higher. This may be taken up in the course of bilateral negotiations.
- Israel has adopted closed tendering processes which means that it difficult to access by the foreign companies. There is also no centralized government portal for the advertisement of tenders. Appropriate dissemination of tender information may be discussed.

Investment Barriers

- Israel does not have any specific legislation for investment measures. There are a few authorities that are responsible for the promotion of foreign investment. There does not appear to be any significant barrier for India with respect to investment.

COUNTRY SNAPSHOT

Sr. No.	Parameter	Description
1.	Region	Middle East
2.	Country	Israel
3.	Capital	Jerusalem
4.	Population	8,914,885 (2022 est.)
5.	Population growth rate (%)	1. 44% (2022 est.)
6.	GDP (PPP)	USD 496.84 billion (2022 est.)[207]
7.	GDP – real growth rate (%)	6.1% (2022 est.)[208]
8.	GDP – per capita (PPP)	USD 55,360 (2022 est.)[209]
9.	Exchange rates	Israeli Shekel (ILS) 3.29 per USD (February 2021)
10.	Population below the poverty line	23% (July 2020)
11.	Disease Profile	Top 10 causes of total number of deaths in 2019, all ages combined, were Ischemic Heart Disease, Stroke, Alzheimer's disease, Chronic Kidney disease, Diabetes, Lung Cancer, Colorectal Cancer, Lower Respiratory Infect, COPD, Breast Cancer[210]
12.	Life Expectancy	83 (2020)[211]
13.	Current Health Expenditure per capita	USD 3456.39 (2019)[212]
14	OOP Health Expenditure as % of Health Expenditure	20.98% (2019)[213]
15.	Age structure (%) (2020 est.)	**0–14 years**: 26.76%
		15–24 years: 15.67%
		25–54 years: 37.2%
		55–64 years: 8.4%
		65 years and over: 11.96%

Sources: CIA World Fact Book updated to May 10, 2022[214] ; International Monetary Fund World Economic Outlook[215] ; The Jerusalem Post[216]

207. IMF, "GDP current prices" available at <https://rb.gy/vhs34g>, last accessed February 24, 2023.
208. IMF, "Real GDP growth", available at <https://rb.gy/jcxwni> last accessed February 24, 2023.
209. IMF, "GDP per capita, current prices", available at < https://rb.gy/mumvqr> last accessed February 24, 2023.
210. Institute for Health Metrics and Evaluation, "Israel" available at <https://rb.gy/kqpiej> last accessed November 23, 202.
211. World Bank, "Life expectancy at birth, total (years) – Israel" available at <https://rb.gy/neo2ye> last accessed November 23 ,2022.
212. World Bank, "Current health expenditure per capita (current US$) – Israel" available at <https://rb.gy/lr3jte> last accessed November 23, 2022.
213. The World Bank, "Out-of-pocket expenditure (% of current health expenditure)" available at <https://rb.gy/ihdoo5> last accessed November 23, 2022.
214. The World Factbook 2022, "Israel" Central Intelligence Agency, Federal Government of the United States (November 14, 2022) available at <https://rb.gy/ginhz9> last accessed November 23, 2022.
215. World Economic Outlook (October 2022) – GDP, current prices" available at <https://rb.gy/lzriu5> last accessed February 23, 2022
216. Maariv Online, "About two million Israelis live below the poverty line – report" (22 January 2021) The Jerusalem Post <https://rb.gy/tlnocq> last accessed November 23, 2022.

A. MARKET OVERVIEW

India is Israel's 7th largest trading partner worldwide and its 3rd largest trading partner in Asia. Bilateral trade between both countries largely covers diamonds and chemicals but in recent years this has expanded to cover other areas such as communication system, high tech products, electronic machinery, medical equipment etc.[217]

According to data from the DGCI&S,[218] India's pharmaceutical exports to Israel in FY 2021-2022 stood at USD 16.06 million, a sharp fall from USD 38.47 million USD in FY 2020-2021. Disaggregated data at Heading-level is as follows:

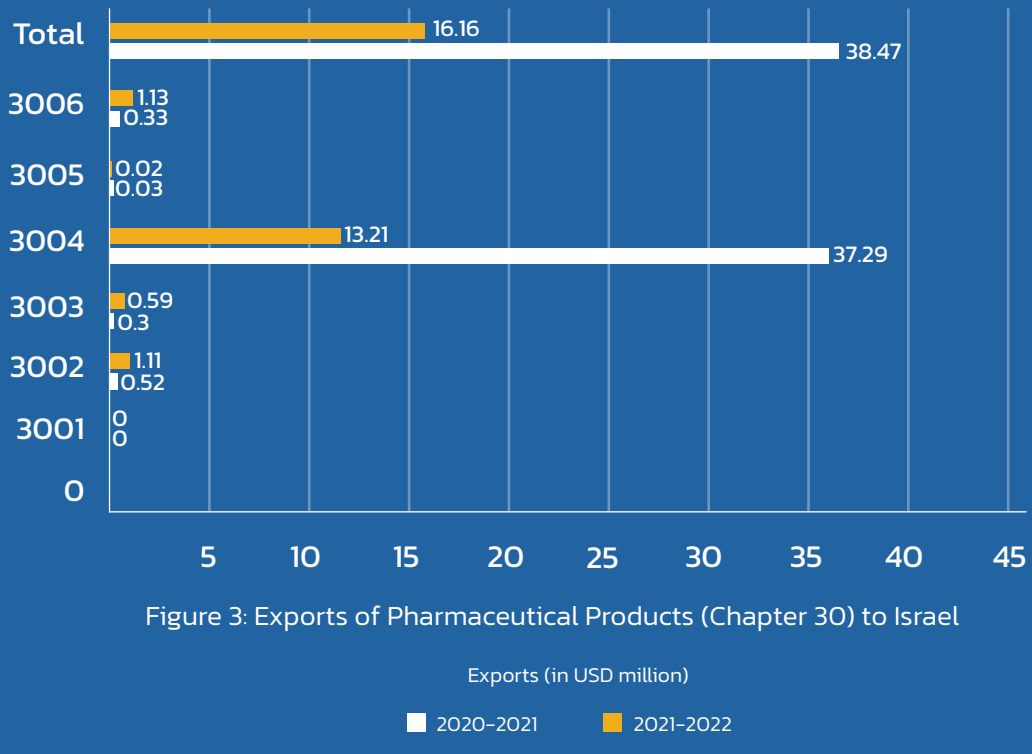


Figure 3: Exports of Pharmaceutical Products (Chapter 30) to Israel

Source: DGCI&S

INTRODUCTION

217. Embassy of India, Tel Aviv, Israel, "India-Israel Economic and Commercial Relations" available at <https://rb.gy/ebznc6> last accessed November 23, 2022.
218. Export-Import Data Bank Version 7.1, Department of Commerce, Government of India available at <https://rb.gy/41jtxg> last accessed on November 23, 2022.

Table 3: Exports of Pharmaceutical Products to Israel (in USD Million)

Heading	Description	2020-2021	2021-2022
3001	Glands and other organs for therapeutic uses, dried, whether or not powdered; extracts of glands	0	0
3002	Human, animal blood for medicinal use; Manufactured Immunological products w/n Biotech processes. Vaccines, Human, Animal blood for medicinal use; manufactured immunological products w/n biotech processes, vaccines etc.	0.52	1.11
3003	Medicaments (Excluding goods of headings no. 3002, 3005, or 3006), consisting of 2 or more constituents mixed together for human medicine. Not for retail sale	0.3	0.59
3004	Medicaments (Excluding items of 3002, 3005, 3006) for therapeutic/prophylactic uses in measured doses or in packaging for retail sale	37.29	13.21
3005	Wadding, gauze, bandages, and similar articles (for example, dressings, adhesive plasters, poultices), impregnated	0.03	0.02
3006	Miscellaneous pharmaceutical goods	0.33	1.13
	Total	**38.47**	**16.06**

Source: DGCI&S

- India and Israel have signed an "Agreement on Cooperation in the fields of Health and Medicine" on December 21, 2020, which will facilitate sharing of expertise and information on a host of topics including "regulation of pharmaceuticals, medical devices, and cosmetics FT. This will allow for easier access to information and greater transparency with respect to Israel's regulatory laws and processes for Indian exporters.
- There are 4 "sick funds" in Israel, which provide healthcare under the Israeli national healthcare system. Citizens must join one of such funds.

219. Embassy of India, Tel Aviv, Israel, "India-Israel Economic and Commercial Relations" available at <https://rb.gy/ebznc6> last accessed November 23, 2022.

B. REGULATORY ENVIRONMENT

The field of pharmaceuticals is regulated under a broad legislative framework. The primary regulatory authority is the Ministry of Health. The primary legislation is the Pharmacists Ordinance (New Version) 1981 which regulates the manufacture, marketing, prescription, importation, and registration of medicinal products.[220]

The following agencies of the Ministry of Health are relevant:

The **Institute for Standardisation and Control of Pharmaceuticals** ("**ISCP**"), responsible for ensuring the quality of pharmaceutical goods that are marketed in Israel.[221]

The Medicines Registration Department, responsible for the registration of medicines in Israel along with updating the contents of the drug registry.[222]

The Import of Pharmaceuticals and Drugs Department, responsible for granting approvals for the import of pharmaceutical products into Israel.[223]

The Pharmaceutical Monitoring Section responsible for approvals for labelling and packaging of medicines.[224]

The Pharmacovigilance and Drug Information Department, responsible for ensuring the safety of the drug treatment in Israel.[225]

220. Liad Whatstein and Oren Weiner, "Medicinal product regulation and product liability in Israel: overview" Thomson Reuters, Practical Law available at <https://rb.gy/mbqyby> last accessed November 23, 2022.
221. Ministry of Health, "The Institute for Standardization and Control of Pharmaceuticals" available at <https://rb.gy/p6kcbd> last accessed November 23, 2022.
222. Ministry of Health, "Medical Preparations Registration Department" available at <https://rb.gy/rvdxdd> last accessed November 23, 2022.
223. Ministry of Health, "Import of Pharmaceuticals and Drugs Department" available at <https://rb.gy/w0e9dp> last accessed November 23, 2022.
224. Ministry of Health, "Pharmaceutical Monitoring Section" available at <https://rb.gy/pvmwx0> last accessed November 23 ,2022.
225. Ministry of Health, "Pharmacovigilance and Drug Information Department" available at <https://rb.gy/yfapzr> last accessed November 23, 2022.

Israel's Customs Directorate oversees foreign trade management in Israel by performing activities such as the collection of importation taxes; enforcement of import export laws, simplification of trade processes; leading coordination work between ministries, custom agents, Israeli ports, etc.[226] The tariff and custom regulatory framework comprises of a number of legislations, the major ones of which are mentioned below:

A. IMPORT LICENSING

- The Free Import Order 5774-2014 (**Order**)[227] published by the Ministry of Economy and Industry contains mandatory technical requirements for customs clearance, including import licensing for certain listed products.[228] Schedule 1 of the Order defines the goods that are subject to an import licensing requirement along with the competent authority that issues such license.[229] Schedule 1 does not specify any product under Chapter 30.[230]
- Schedule 2 provides a list of products that primarily require an "import approval" (such as meeting of mandatory standards).[231] Certain products under Chapter 30 are listed in the schedule which require approvals from the Pharmaceutical Division of the Ministry of Health, prior to their importation.[232] The Order specifies that the Pharmaceutical Department is to issue its decision to the applicant for an import license, certificate or permit, within 21 working days from the date of application.[233]

SUGGESTIONS

The Free Import Order provides clarity on the applicable import requirements for various products including those to which import licensing requirements apply. The website of the Ministry of Economy and Industry notes that "some of the requirements enacted by certain laws and orders have yet to be included in the Order.

Therefore, there may be a license requirement for import pursuant a certain law which does not appear in the Free Import Order." Further, the latest version of the Order is only available in the Hebrew language. While there are presently no import licensing requirements on pharmaceuticals, it may be relevant to discuss transparency and proper dissemination of information with the Israeli government.

226. Israel Tax Authority, "Israel Customs Directorate Vision" available at <https://rb.gy/6ukgxu> last accessed November 23, 2022.
227. Import Licensing Procedures, World Trade Organization, "Free Import Order 5774-2014" available at <https://rb.gy/rpfthu> last accessed November 23, 2022. The Order is issued under Section 2 of the Import and Export Ordinance 5739-1979.
228. Federation of Israeli Chamber of Commerce, "Legality of the Import" available at <https://rb.gy/xsrvki> last accessed November 23, 2022.
229. Ministry of Economy and Industry, "Importer Guide" available at <https://rb.gy/nqaycx> last accessed November 23, 2022.
230. Import Licensing Procedures, World Trade Organization, "Free Import Order 2014 - 1st and 2nd Schedules" available at <https://rb.gy/ewc837> last accessed November 23, 2022.
231. Ministry of Economy and Industry, "Importer Guide" available at <https://rb.gy/nqaycx> last accessed November 23, 2022.
232. Import Licensing Procedures, World Trade Organization, "Free Import Order 2014 - 1st and 2nd Schedules" available at <https://rb.gy/ewc837> last accessed November 23, 2022.
233. Import Licensing Procedures, World Trade Organization, "Free Import Order, 2014" available at <https://rb.gy/mqhtgo> last accessed November 23, 2022. The latest version of the order as amended, is available on the website of Ministry of Economy and Industry only in Hebrew language.

B. TARIFF RATES & BARRIERS

- The Customs Tariff and Purchase Tax Order specifies the basic tariff rates applicable to products as per their **Harmonized System** ("**HS**") codes.[234]
- According to tariff data extracted from the WTO Tariff Analysis database[235] at the HS 8-digit level for 2021, Israel has 68 tariff lines under Chapter 30 (Pharmaceutical Products) of its Customs Tariff. Out of these 68 lines, 23 lines have non-zero duties ranging from 6-12%. Out of these 23 lines, 17 lines have been accorded with the description of "Others", which is a catchall designation for products under the subheading that does not have a description that fits in with any existing definition. The remaining 6 goods that are subject to duty are:

Tariff Line	Description	Duty (%)
30021510	--- Human tetanus immunoglobulin in measured doses in packaging of the kind put up for retail sale	8
30051020	---Which have undergone a process of impregnation or coating by pharmaceutical materials regarding which the director general of the ministry of health or the director general of the ministry of agriculture has approved that they are not of the kind produced in Israel nor are they substitutes for the kinds produced in Israel	2
30051040	---Stretchable or elastic band-aids	12
30059011	---Which have undergone a process of impregnation or coating by pharmaceutical materials regarding which the director general of the ministry of health or the director general of the ministry of agriculture has approved that they are not of the kind produced in Israel nor are they substitutes for the kinds produced in Israel	2
30059020	---Stretchable or elastic band-aids	12
30064000	- Dental cements and other dental fillings; bone reconstruction cements	6

- The primary product groups that seem have duty levied are Band-Aids, tetanus immunologicals, dental cement and bone reconstruction cements. However, they would not gravely affect our exporters as most exports to Israel occur under Heading 3004, that does not have any duty levied on any of its tariff lines.
- Separately, the "MASLUL" system in Israel is a system that enables all importers, exporters, and custom agents to submit and track their online application forms for licenses and approvals from the competent authorities.[236] Notably, at the present stage, the system includes approvals and licenses from the Ministry of Economy and Industry, Ministry of Health, the Standard Institution of Israel, and testing laboratories etc.[237]

SUGGESTIONS

Tariffs for most line items under chapter 30 are nil, however, during the course of trade negotiations, concessional tariff access may be proposed for the tariff lines such as Band-Aids which attract high duty, if these products are of interest to Indian pharma industry.

234. Israel Tax Authority, State of Israel, "Customs tariff and purchase tax" available at <https://rb.gy/mprhne> last accessed November 23, 2022. The website publishes the customs tariff and exemption tax order on goods with amendments from time to time. The Customs Ordinance of 1957 regulates customs administration, control, documentation, warehousing, valuation, payments of duties, drawback, and legal procedures. Customs Tariff and Exemption Tariff Order on Goods 2017 is also relevant.
235. World Trade Organization, "WTO Tariff analysis online database" <https://rb.gy/zy5cdt> last accessed November 23, 2022.
236. Israel Tax Authority, "The "MASLUL" system – a "Status System for Licenses and Approvals for Importers" between the customs and competent authorities" available at <https://rb.gy/rgeoet> last accessed November 23, 2022.
237. Israel Tax Authority, "The "MASLUL" system – a "Status System for Licenses and Approvals for Importers" between the customs and competent authorities" available at <https://rb.gy/rgeoet> last accessed November 23, 2022.

NON-TARIFF BARRIERS

A. REGISTRATION & MARKETING AUTHORISATION

Drugs sold in Israel must comply with the following procedures:

01

Registration of the medicinal product in the Israel Drug Register. [238]

02

Grant of marketing approval for the first batch of the product that is marketed in Israel for the first time.[239]

Foreign companies that are interested in exporting will first have to appoint a local distributor or legal representative in Israel to register their products.[240] One of the conditions for obtaining authorization to enter the Israeli market is that the registration of the medicinal product must be under the name of an Israeli resident, or a corporation registered in Israel.[241]

With respect to marketing approval, for imported pharmaceutical products, the products must be authorized in a recognized country (US, Canada, a pre-2004 EU country, Switzerland, Norway, Iceland, Australia, New Zealand and Japan).[242] Additionally, the application must be filed with a Certificate of Pharmaceutical Product ("**CoPP**") as issued by a recognized country no sooner than 2 years before the date of application.[243] The CoPP must indicate that the pharmaceutical product is authorized for marketing in the recognized country, but does not necessitate that the product actually be on the market therein. If a CoPP is not available, then applications for new drugs can be preliminarily filed with an FDA letter of approval or a positive opinion from the European Medicines Agency. Generic applications can be filed without a CoPP, but a CoPP must be provided within 10 months of filing and the agent will not be registered without a CoPP.

238. According to the Pharmacists' Regulations (Preparations) 1986, a medicine shall be registered in the National Drugs Registry only after its safety, efficacy and quality have been proved. See Zohar Yahalom and Segev Shani, "Registration of pharmaceuticals in Israel and its exemptions" [2004] 23(2) Med Law 379.
239. Thomson Reuters Practical Law, "Medicinal product regulation and product liability in Israel: overview" available at <https://rb.gy/xwlx2c> last accessed 28 July 2022.
240. Export.gov, "Healthcare Resource Guide: Israel" available at <https://2016.export.gov/industry/health/healthcareresourceguide/eg_main_108590.asp> last accessed November 23, 2022; See also, Yael Baratz, "Commercialisation of Healthcare in Israel: Overview" Thomson Reuters Practical Law available at <https://rb.gy/sisy4d> last accessed November 23, 2022.
241. Thomson Reuters Practical Law, "Medicinal product regulation and product liability in Israel: overview" available at <https://rb.gy/xwlx2c> last accessed 28 July 2022.
242. Thomson Reuters Practical Law, "Medicinal product regulation and product liability in Israel: overview" available at <https://rb.gy/xwlx2c> last accessed 28 July 2022.
243. Thomson Reuters Practical Law, "Medicinal product regulation and product liability in Israel: overview" available at <https://rb.gy/xwlx2c> last accessed 28 July 2022.

The law requires that the registration process of a new medicinal product must be completed within 270 days. However, in practice, the whole registration process for pharmaceutical products generally takes up to 360 days.[244] A shorter period of 180 days is applied for medicinal products which are already registered or have received a positive opinion from the US Food & Drugs Administration, European Medical Agency, or **Swiss Agency for Therapeutic Products** ("**Swissmedic**").[245] Further, small molecule generics are subject to a shorter period of 70 days for registration.[246]

SUGGESTIONS

The fact that approval in certain third countries is a pre-requisite for registration in Israel may create an additional burden on smaller Indian manufacturers that are not registered in such countries. However, the practice of fast tracking of registrations based on existing approval by the FDA, EMA and Swissmedic may be advantageous to producers already approved by these authorities and may be explored further in negotiations. India may suggest taking this a step further by entering into a mutual recognition agreement based on recognition by these third country regulatory authorities.

244. Export.gov, "Healthcare Resource Guide: Israel" available at <https://rb.gy/zutofd> last accessed November 23, 2022.
245. Export.gov, "Healthcare Resource Guide: Israel" available at <https://rb.gy/zutofd> last accessed November 23, 2022.
246. Thomson Reuters Practical Law, "Medicinal product regulation and product liability in Israel: overview" available at <https://rb.gy/xwlx2> last accessed 28 July 2022.

B. PACKAGING & LABELLING REQUIREMENTS

- The Pharmaceutical Monitoring Section is responsible for the approval of labels and packages for medicinal products.[247] Packaging & Labelling requirements of medicinal products are governed under various legislations[248] :
- The following requirements with respect to the packaging of medicinal products must be met[249] :
  - Trade name of the product and the generic name of the product (and where there is no generic name, the chemical name).[250]
  - Name and address of the registration holder of the product, or of the authorisation holder to import the product, as appropriate, and if the product is imported, the name and address of the importer. [251]:
  - Specifications of the API and the quantities per unit dose of the product, in their generic name, and where there is no generic name, the chemical name.[252]:
  - Date of manufacture of the product, batch number and expiration date.[253]:
  - A leaflet, stating the directions for use of the product, the active ingredients and their quantities, the inactive ingredients, the properties of the product and its contraindications. [254]:
  - The package of every medicinal product marketed to a patient in Israel must be marked with a barcode. [255]:
  - The name of the pharmaceutical, an instruction to review the consumer information package prior to use, and the active ingredient(s) must be given in 4 languages i.e., in Hebrew, Arabic, English and Russian.[256]
  - The objective of the pharmaceutical's use, warning labels, and any other information required by the Ministry of Health in Hebrew only[257]

SUGGESTIONS

While we understand that labelling requirements may pose a trade barrier, we do not anticipate a significant business impact on large corporations as a result of these requirements. Such requirements are fairly standard across the world and are unlikely to impact multinational pharmaceutical companies. However, this may be a cause for concern for the MSME sector. India may consider undertaking harmonization efforts with respect to packaging and labelling with the Israel government in the long term.

247. Ministry of Health, "Pharmaceutical Division" available at <https://rb.gy/nz2g89> last accessed November 23, 2022.
248. These include the Pharmacist Ordinance 5741-1981, Pharmacist Regulations (Preparations) 1986, Pharmacists Regulations (Sale of a product not in a pharmacy or not by a pharmacist), 2004; and MOH Procedures issued time to time. See, Thomson Reuters Practical Law, "Medicinal product regulation and product liability in Israel: overview" available at <https://rb.gy/xwlx2c> last accessed 28 July 2022.
249. Recently, the Pharmaceutical Division of Israel's Ministry of Health has announced a new procedure named "Procedure for Packaging Labelling of Medical Preparations (PRA-043/03)" replacing the earlier procedure of July 2007 (later amended in 2012). The procedure is governed by Regulation 20 of the "Pharmacists Regulations (Preparations) 5746-1986" and Regulation 13 of the "Pharmacists Regulations (Sale of an over-the-counter preparation not in a pharmacy or not by a pharmacist) 5765-2004". These Regulations are only available in Hebrew language. The Israel WTO-TBT Enquiry point notes that "the purpose of the procedure is to clarify the requirements of Regulation 20 and Regulation 13 and to ensure that all packaging requirements shall appear on the preparation packaging, listed in the Preparations Register, in order to provide patients with the essential information regarding the preparation and assist in providing safe and effective drug treatment. It collects all existing requirements into a unified list that contains also references to similar international requirements. See TBT/N/ISR/1161 (14 August 2020).
250. See TBT/N/ISR/1161 (14 August 2020).
251. See TBT/N/ISR/1161 (14 August 2020).
252. See TBT/N/ISR/1161 (14 August 2020).
253. See TBT/N/ISR/1161 (14 August 2020).
254. See TBT/N/ISR/1161 (14 August 2020).
255. See TBT/N/ISR/1161 (14 August 2020).
256. Pharmacists Ordinance (Amendment No. 17) Law, 5770-2010; See, Library of Congress, "Israel: Labelling of Pharmaceuticals" available at <https://rb.gy/qa8glh> last accessed November 23, 2022.
257. Pharmacists Ordinance (Amendment No. 17) Law, 5770-2010; See, Library of Congress, "Israel: Labelling of Pharmaceuticals" available at <https://rb.gy/njccns> last accessed November 23, 2022.

C. GOOD MANUFACTURING PRACTICES

- Israel has entered into 2 mutual recognition agreements with the EU with respect to good laboratory practices[258] and on the **acceptance of conformity assessment** ("**ACAA**") with a sectoral annex on good manufacturing practice in pharmaceuticals.[259]
- Under the agreement, Israel and the EU recognize "official batch releases"[260] carried out by each other's authorities. Furthermore, this is a specific type of MRA primarily based on the alignment of Israel's legislative system and infrastructure with those of the EU.

SUGGESTIONS

Mutual recognition of GMP clearances by reference to third country clearances such as the EU (with whom Israel already has an MRA) may be proposed to enable Indian exporters to obtain GMP clearance quicker.

258. Anabela Correia de Brito, Céline Kauffmann, and Jacques Pelkmans, "The contribution of mutual recognition to international regulatory co-operation" (2016) OECD available at <https://rb.gy/aei0t2> last accessed November 23, 2022.
259. The ACAA covers
    a. human chemical and biological pharmaceuticals
    b. human immunologicals
    c. radiopharmaceuticals
    d. vitamins, minerals, and herbal medicines if classified as medicinal products
    e. intermediate products and bulk pharmaceuticals
    f. active pharmaceutical ingredients
    g. excipients
    h. veterinary chemical pharmaceuticals
    i. premixes and preparation of veterinary medicated feedstuff
    j. veterinary biologicals except immunologicals

    See European Medicines Agency, "Human regulatory – Mutual recognition agreements (MRA)" available at <https://rb.gy/6b2llq> accessed 28 June 2022 and 'EU trade relations with Israel. Facts, figures, and latest developments' (Trade, European Commission) <https://rb.gy/usi4ck> last accessed November 23, 2022.
260. Official batch releases are defined under the ACAA as "Official Control Authority Batch Release (OCABR): Requirement by a Party, as referred to and regulated by pharmaceutical legislation and guidelines of the EU, the Council of Europe and Israel, that an Official Medicines Control Laboratory determines the conformity of a batch with the approved specifications as laid down in the marketing authorisation before the competent authority of the Party will allow that batch to be marketed. The examination includes testing on a schedule as defined in the guidelines referred to above."

INTELLECTUAL PROPERTY PROTECTION

A. LEGISLATIVE FRAMEWORK

The governing law for patent protection in Israel is the Patent Law 5727-1967[261], which has been amended several times.[262] The **Israel Patent Office** ("**ILPO**") is the body that controls and governs the patent registration procedure.

B. SCOPE OF PROTECTION

- Under the Israeli law patent protection is granted to inventors from all countries for a term of 20 years.[263]
- There exist restrictions on grant of certain kinds of patents. For example, patents are not granted on any method of therapeutic treatment on the human body. However, the following types of "therapeutic treatment on the human body" are protected[264] :
  - Products or compositions used for the treatment of the human body.
  - Purpose-limited product or composition claims (formerly, Swiss-type claims). Such claims provide adequate protection and are also recognized for primary, secondary and any subsequent medical indications of an active ingredient.
  - Diagnostic or detection methods.
  - Cosmetic (non-therapeutic) treatment.

261. Patents Law 5727-1967.
262. Other legislations governing Patents include the Patent Regulations (Office Practice, Rules of Procedure, Documents and Fees), 5728-1968; the Patent Regulations (Extension of Protection – Procedures for Order Application, for Opposition to an order and for Application for Revocation), 5758-1998; and the Patent Regulations (Application of the Patent Cooperation Treaty), 5756-1996
263. 'Patents' (Dr Shlomo Cohen & Co) <https://rb.gy/lpecak> accessed 28 June 2022.
264. Thomson Reuters Practical Law, "Medicinal product regulation and product liability in Israel: overview" available at <https://rb.gy/xwlx2c> last accessed 28 July 2022.

C. APPLICATION PROCEDURE

- Patent applications are filed with the ILPO for the purpose of registration. Israel is a strict examining country. The ILPO relies on the examination results, particularly for prior art citations, of parallel applications in the leading examination jurisdictions (Europe and the US).[265] In this context, it is important to note that the applicant claiming priority in its patent application submitted in Israel, must submit the application within 12 months after the previous application was submitted.[266] In addition, the ILPO conducts an independent prior art search and examines the application on various other grounds (for example, unity of invention, sufficient support for the claimed invention, and so on).[267]
- The Annual Report published by the ILPO in the year 2020 specifies that after a patent application is filed, it usually takes a few years i.e., 24 to 35 months until the examination commences.[268] The examination period thereafter, ranges between 12 to 20 months approximately, depending on the field of invention (approximately 18 months in case of pharma).[269] The examination time includes the time taken from the first examination till the final decision of acceptance or refusal or abandonment is given. The average time taken from the filing of application till the end of examination is 42 months.[270] However, this time period does not take into account the time for conducting opposition proceedings.[271]
- Pre-grant opposition is allowed by the ILPO wherein the application can be opposed within a time period of 3 months which is non-extendable.[272] The pre-grant opposition procedure is similar to a procedure for litigation in courts and may last for 2-3 years or even longer in some cases.[273]

SUGGESTIONS

The pre-grant opposition period may provide generic manufacturers with an avenue to oppose patents in Israel. However, the time period for such opposition is limited. Hence, India may consider whether it is useful to discuss the possibility of expanding this period with the Israeli Government.

D. PATENT TERM EXTENSION

Patent term extensions are granted in Israel to make up for the lost time due to delayed market approvals.[274] Patent term extensions are granted by reference to the extension period granted for a corresponding patent in a reference country.[275] Such period must be shorter than or equal to the shortest period granted in such reference country.[276] The reference countries are USA, UK, France, Germany, Spain, and Italy.[277]

265. Patents Law 5727-1967, Section 10.
266. Patents Law 5727-1967, Section 10.
267. Patents Law 5727-1967, Section 17.
268. State of Israel, "Israeli Patent Office 2020 Annual Report" available at <https://rb.gy/hmij9e> last accessed November 23, 2022.
269. State of Israel, "Israeli Patent Office 2020 Annual Report" available at <https://rb.gy/hmij9e> last accessed November 23, 2022.
270. State of Israel, "Israeli Patent Office 2020 Annual Report" available at <https://rb.gy/hmij9e> last accessed November 23, 2022.
271. State of Israel, "Israeli Patent Office 2020 Annual Report" available at <https://rb.gy/hmij9e> last accessed November 23, 2022.
272. Patents Law 5727-1967, Section 30.
273. Thomson Reuters Practical Law, "Medicinal product regulation and product liability in Israel: overview" available at <https://rb.gy/xwlx2c> last accessed 28 July 2022.
274. World Trade Organization, "Trade Policy Review: Israel 2018" available at <https://rb.gy/4vwavg> last accessed November 23, 2022.
275. World Trade Organization, "Trade Policy Review: Israel 2018" available at <https://rb.gy/4vwavg> last accessed November 23, 2022.
276. World Trade Organization, "Trade Policy Review: Israel 2018" available at <https://rb.gy/4vwavg> last accessed November 23, 2022.
277. World Trade Organization, "Trade Policy Review: Israel 2018" available at <https://rb.gy/4vwavg> last accessed November 23, 2022.

E. MARKET EXCLUSIVITY

- Pharmaceuticals containing a new chemical entity may be granted a 6-and-a-half-year period of marketing exclusivity of up to 6.5 years from the first registration in a recognized countries (i.e., US, EU, etc.).[278]
- During such period generic companies can still file applications based on bioequivalence, but marketing approval will only be granted after the end of the marketing exclusivity period.

SUGGESTIONS

Israel's IP laws in general seem to be less stringent than other countries such as the EU and USA, which may benefit generic players. Hence, the Indian may consider avoiding discussions on improvements in Israel's IP laws.

278. Lexology, "Snapshot: Medicine and Medical Device Pricing in Israel" available at <https://rb.gy/3miknt> last accessed 28 July 2022.

PRICE CONTROLS

The Ministry of Health is the competent authority for the purpose of pricing of medicines in Israel.[279] Israel sets maximum prices of all listed drugs whether these are covered by reimbursement programs or not.[280]

The maximum prices of innovative & biosimilar drugs are equal to the average of the lowest 3 quoted wholesale prices among the following countries i.e., UK, Germany, the Netherlands, France, Belgium, Spain, and Hungary. For Generic drugs or Innovative drugs with generic alternatives, the prices are fixed at the price-level on the determining day of the previous year (01.07.2018) and if a company wants to set a higher price for a particular product, it must be approved by the Ministry of Health.[281]

Most generic products sold in Israel are purchased by health funds. This purchasing power enables them to purchase generic products at a price below the maximum prices set by the Ministry of Health. Accordingly, pharmaceutical manufacturers usually negotiate prices with the Ministry of Health. Since parallel imports are allowed under Regulation 29 of the Pharmacists (Preparations) Regulations 1986, imported generic products are generally cheaper. [282]

Citizens may participate under the National Health Insurance Law of 1995, in one of 4 official health insurance programs. The list of medicines covered under such programs does not appear to be very wide.[283]

279. The prices of prescription drugs are determined under the Supervision of Prices of Goods and Services Act 5756-1996, the Order for the Supervision of Prices of Goods and Services (Maximum Prices for Prescription Preparations) 5761-2001 and the Order for the Supervision of Prices of Goods and Services (Application of the Act to Preparations) 5761-2001, See WHO Collaborating Centre for Pharmaceutical Pricing and Reimbursement Policies, Pharmaceutical pricing and reimbursement information, "Pharmaceutical Pricing and Reimbursement Policies in the In-and Out Patient Sector" available at <https://rb.gy/sawapx> accessed November 23, 2022; See also, Ministry of Health "Budgets and Tariffs" available at <https://www.health.gov.il/English/Topics/finance/Pages/default.aspx> last accessed November 23, 2022.
280. Listed drugs include Prescription drugs, over the counter drugs (OTC) and General Sale List drugs (GSL), whether the drug is reimbursed or not.
281. WHO Collaborating Centre for Pharmaceutical Pricing and Reimbursement Policies, Pharmaceutical pricing and reimbursement information, "Pharmaceutical Pricing and Reimbursement Policies in the In-and Outpatient Sector" available at <https://rb.gy/sawapx> accessed November 23, 2022.
282. Thomson Reuters Practical Law, "Medicinal product regulation and product liability in Israel: overview" available at <https://rb.gy/xwlx2c> last accessed 28 July 2022.
283. WHO Collaborating Centre for Pharmaceutical Pricing and Reimbursement Policies, Pharmaceutical pricing and reimbursement information, "Pharmaceutical Pricing and Reimbursement Policies in the In-and Outpatient Sector" available at <https://rb.gy/sawapx> accessed November 23, 2022.

GOVERNMENT PROGRAMS/ INCENTIVES

The **Israel Innovation Authority** ("**IIA**") is the implementing body of Israel's government policies for encouraging and supporting industrial **research and development** ("**R&D**") with the purpose of enhancing Israel's new export products and cross-border commerce.[284]

A. EXPANSION OF THE ISRAELI INNOVATION BOX REGIME

- Israel has a highly concentrated R&D landscape with more than 200 industrial multinationals engaged in doing R&D in Israel.[285] On July 1, 2019, released a Tax Order broadening the scope of Israel's Intellectual Property preferential tax regime also known as the Innovation Box Regime.[286] Earlier to the expansion of this regime, pharmaceutical companies could avail IP based tax incentives only with respect to the patented products. However, now the scope of the program has been expanded to also include products, whether patented or not, but approved by the health regulators in Israel or in other countries like U.S.A (United States Food and Drug Administration, FDA) and the European Union (European Conformité Européenne (CE) Marking).[287] These registered regulated products qualifying as IP pertain to medicinal products for human and animal use as provided under the Israeli Pharmaceutical Ordinance.
- This order in effect amended the Innovation Box Regime of 2017 which conferred benefits in the form of a reduced corporate income tax rate of 6% on certain IP based income and on capital gains from the future sales of the IP.[288] The withholding tax on dividends would also be subjected to a reduced rate of 4% for the qualifying companies.[289]

SUGGESTIONS

Indian exporters and producers of pharmaceuticals may wish to consider whether programs like the innovation box regime constitute significant incentive to undertake manufacturing operations in Israel. The Indian Government should seek clarity from the Israeli Government as to how such schemes may benefit Indian exporters.

284. The Israel Innovation Authority, "The Israel Innovation Authority" available at <https://rb.gy/ezurrb> last accessed November 23, 2022.
285. FDI Intelligence, "Israel hopes Innovation Box will bring R&D investment" available at <https://rb.gy/sjpp0a> last accessed November 23, 2022.
286. Ernst and Young, "New Israeli Innovation Box Regime: An update and review of key features" available at <https://rb.gy/vf26gq> last accessed November 23, 2022.
287. Ernst and Young Tax News Update, "Israel expands its Innovation Box Regime to pharmaceutical companies" (10 July 2019) available at <https://rb.gy/fegbxl> last accessed November 23, 2022.
288. Ernst and Young Tax News Update, "Israel expands its Innovation Box Regime to pharmaceutical companies" (10 July 2019) available at <https://rb.gy/fegbxl> last accessed November 23, 2022.
289. Invest in Israel, Ministry of Economy and Industry, "Israel's Innovation Box – An Unprecedented Opportunity for Multinational Companies" available at <https://rb.gy/neg1na> last accessed November 23, 2022.

TRADE REMEDIES

- The Commissioner of Trade Levies is the investigating authority for the purposes of Anti-dumping, Anti-subsidy, and Safeguard measures under Israeli law. [290]
- There are very few trade-remedial investigations that have been conducted by the Investigating authorities in Israel out of which none concern pharmaceuticals.[291] Also, no investigation has been conducted against India as on the date of this report.

SUGGESTIONS

Considering there are no trade remedial investigations launched by Israel concerning pharmaceuticals, this dimension does not represent a significant barrier for Indian exporters.

290. The domestic legislation in Israel for undertaking trade remedial measures is the Trade Levies and Safeguard Measures Law, 5751-1991, See Trade Levies and Defense Measures Law, 1991.
291. Ministry of Economy and Industry, "Policies and procedures – Decisions" available at <https://rb.gy/roc5se> last accessed November 23, 2022.

RESTRICTIONS ON GOVERNMENT PROCUREMENT

Israel is party to the Government Procurement Agreement (GPA) of the World Trade Organization. The Israeli law governing the conditions and procedure of procurement is the Mandatory Tenders Law of 1992. In case of a conflict between GPA and the domestic law, commitments under GPA will prevail.[292]Presently, Israel has invoked the developing country status under the GPA which allows it to enter into certain kind of offset arrangements. The offset requirements that are covered under the GPA is at 20% of the value of the contract and 35% for procurements excluded from GPA coverage.[293]

The offset requirement can be satisfied by the foreign supplier by subcontracting to local companies, mandatory procurement of domestic Israeli goods and services, investment, and cooperation in R&D, transferring know-how etc.[294] Israel aims to phase out its offset regime for procurements that are covered by GPA which are currently at the 20% offset level. It further aims to entirely eliminate the offsets after 15 years from the entry into force of the revised GPA.[295]

There is no centralized government platform for the advertising of government procurement. Israel's usage of a closed tendering process means that foreign companies will not always be aware of major tenders.[296]

SUGGESTIONS

India is not a party to the GPA and hence is automatically subject to a higher value addition threshold. This may be a factor relevant to negotiations with Israel to negotiate a lower threshold under a potential FTA. Further, Further, emphasis may be placed on appropriate dissemination of information regarding tenders.

292. Mandatory Tenders Law 5752-1992, Article 5(A)(b): "Regulations under this Law shall apply to the extent that they do not conflict with an undertaking of the State in an international agreement" such as the GPA.
293. World Trade Organization, "Trade Policy Review: Israel 2018" available at <https://rb.gy/m0ne0u> last accessed November 23, 2022.
294. World Trade Organization, "Trade Policy Review: Israel 2018" available at <https://rb.gy/4vwavg> last accessed November 23, 2022.
295. World Trade Organization, "Trade Policy Review: Israel 2018" available at <https://rb.gy/4vwavg> last accessed November 23, 2022.
296. International Trade Administration, United States of America, "Israel - Selling to the Public Sector" available at <https://rb.gy/l0eakk> last accessed November 23, 2022.

INVESTMENT BARRIERS

The Foreign Investment and Industrial Cooperation Authority is responsible for "foreign investment promotion and reciprocity" in Israel.[297] Israel does not have a specific law on foreign investment.[298] Furthermore, the Foreign Investment Promotion Authority – Invest in Israel is the body responsible for handling foreign direct investment in Israel functioning as the investment promotion arm for foreign investors.[299]

The Law for the Encouragement of Capital Investment provides investment incentives to both foreign and domestic investments. Such incentives can be in the form of "grants, tax incentives (rebate on profit tax), research and development support, wage financing, and training support."[300] Another investment promotion strategy of Israel is providing additional incentives to "approved" investors in the form of additional tax benefits administered by the Investment Promotion Centre. Israel emphasizes the focus of foreign investment opportunities towards industrial, tourism, and agricultural projects and special emphasis is put on high-tech companies and R&D activities.[301]

According to Israel's latest communication to the WTO in 2021 regarding implementation of Article 6.2 pertaining to the notification of publications in which Trade Related Investment Measures ("**TRIMS**") may be found, it has informed that Israel has "no trade-related investment measures in force."[302]

SUGGESTIONS

There does not appear to be any significant barrier for Indian exporters at the moment in this context. Indian exporters may consider whether incentives provided by the Israeli government would be considerable motivation to invest in Israel.

297. Ministry of Economy and Industry, "The Foreign Investment and Industrial Cooperation Authority" available at <https://rb.gy/2irxlu> last accessed November 23, 2022.
298. World Trade Organization, "Trade Policy Review: Israel 2018" available at <https://rb.gy/4vwavg> last accessed November 23, 2022.
299. World Trade Organization, "Trade Policy Review: Israel 2018" available at <https://rb.gy/4vwavg> last accessed November 23, 2022.
300. Ministry of Economy and Industry, "The Foreign Investment and Industrial Cooperation Authority" available at <https://rb.gy/2irxlu> last accessed November 23, 2022.
301. Ministry of Economy and Industry, "The Foreign Investment and Industrial Cooperation Authority" available at <https://rb.gy/2irxlu> last accessed November 23, 2022.
302. G/TRIMS/N/2/Rev.31 (11 October 2021).

UAE

EXECUTIVE SUMMARY

INTRODUCTION

- **United Arab Emirates**' ("**UAE**") pharmaceutical market was estimated to be worth USD 3.5 billion in 2020 and is expected to increase to USD 4.7 billion in 2025. India's exports of pharmaceutical products were at USD 196.1 million in the FY 2021-22.
- Under the recently concluded India-United Arab Emirates Comprehensive Economic Partnership Agreement or India-UAE CEPA, India has been offered a duty elimination on over 97% of its tariff lines, which corresponds to 99% of India's exports to the UAE in terms of value over the last decade. The CEPA also contains a separate Annexure for bilateral cooperation on pharmaceutical products.

KEY FINDINGS AND RECOMMENDATIONS

Tariff and Customs Barriers

As a member of the Gulf Cooperation Council ("**GCC**"), UAE has adopted the GCC Common Customs Law and its implementation rules. According to the GCC Customs Tariff, pharmaceutical products have a duty rate of 0%. In the context of the India-UAE CEPA, pharmaceutical products under Chapter 30 have been accorded a 0% duty rate. Tariffs do not appear to be a significant barrier for Indian exporters.

Marketing Authorization

- Marketing authorizations must be issued by the Ministry of Health and Prevention ("**MOHAP**"). Authorizations issued in foreign jurisdictions are not valid. In the case of a new medical product[303] or new use[304] or a new method of administration[305] , the marketing authorization can be issued by the MOHAP pursuant to an assessment that such product/use/method has met the assessment of research information[306] that stipulates efficacy and safety requirements. Generics can also be authorized, subject to equivalency to the original product, if its legal protection has expired, and for which a marketing authorization has been issued previously. The rules, conditions, and procedures for obtaining marketing authorization were expected to be provided by a new ministerial resolution. However, no such ministerial resolution in English is accessible in the public domain. Greater clarity on the process of application for seeking marketing authorization would be helpful. India may suggest that detailed guidance be issued on the process of applying for marketing authorization.
- With regard to the timeframe and fees for applying/securing a market authorization, the Federal Law No. 8 of 2019 on Medical Products, Pharmacy Profession and Pharmaceutical Establishments or Federal Law 2019 provides no guidance. However, Annex 5A of the CEPA provides that authorization must be provided to pharmaceutical products within 90 days if approval for such pharmaceutical products has been granted by some reference countries. In respect of all the other pharmaceutical products, which have not been approved by certain reference countries and for which inspection is required, the process must be concluded in 270 days. The CEPA prescribes the same for pharmaceutical products defined under the CEPA. India may request for clarification on the timeframe for granting marketing authorization for pharmaceutical products not falling under the CEPA.

Registration for Sales of Pharmaceutical Products

- Holders of market authorization have to register the product with MOHAP. The CEPA provides for the establishment of fast-track procedures for products that have existing approval from the regulatory authorities of certain reference countries. Also, in such cases, UAE does not need to carry out full assessment or inspections of manufacturing sites if the same has been approved by these reference countries. However, the fees for application and registration seem to be on the higher side. India may suggest applying lower fees for securing a registration certificate. India may also request for modalities for seeking fast-track approval, if any.

Labelling Requirements

- These requirements are given under Article 33 of the Federal Law 2019. Labelling requirements do not appear to place any onerous burdens on manufacturers.

303. New medical product is defined as "A Medical Product which contains a new Active Substance, for which no Medical Product containing the same substance has previously received a Marketing Authorisation in the State, and for which the products containing the Active Substance have been on the international market for less than two years."
304. New use is defined as "New Use: The usage which is recently added to the list of uses previously authorised for the Medical Product, which has been previously authorised to be marketed in the State, provided that such New Use results from effects separate from the Main Effects of its previous uses."
305. New method of use is defined as "A new method for the administration of the Medical Product which has not received a previous Marketing Authorisation in the State in order to obtain the Main Effects of the Product."
306. Research information is defined as "Research Information: Any information obtained from chemistry, Manufacturing, and controls data, and from preclinical and clinical researches, to support the safety, efficacy and quality of a New Medical Product, in order to obtain the Marketing Authorisation."

Good manufacturing practices

- The Federal Law 2019 requires mandatory Good Manufacturing Practices compliance issued by the relevant ministry of the UAE. The CEPA requires UAE to accept pharmaceutical products manufactured in India's territory provided that these products are approved by certain third-country regulatory authorities. However, CEPA allows UAE to conduct an inspection of manufacturing facilities (that are approved by third-country regulatory authorities) when there is evidence of quality defects identified in post-market surveillance, or any specific evidence of serious concern in relation to the product quality or consumer safety. This may not be a significant barrier to Indian exporters.

Intellectual Property- Patent

- The criteria for granting a patent under the Federal Law No. 11 of 2021 or Federal Law 2021 is that the new invention must be contrived from a creative idea or creative enhancement, forms an inventive step, and is capable of industrial application. Patent protection is granted for 20 years. Pre-grant and post-grant opposition to patents has been provided under Federal Law 2021. Given that no details on how the process of opposition to granting of patent/patent will function, the grounds on which the pre-grant or post-grant opposition can be made, and the periods within which such grievances will be entertained or addressed have been provided, India may consider requesting further guidance.

Intellectual Property- Data Exclusivity

- The data exclusivity period is set to 8 years from the date of marketing approval inside the UAE for innovative pharmaceutical products which contain active pharmaceutical ingredient for which no other pharmaceutical product has obtained a marketing license in the UAE. However, generic and biosimilar companies can apply for marketing approval within the last 2 years of the data exclusivity period. In general, the duration of exclusivity is shorter in UAE than in countries such as the United States. The Indian government should maintain the position that this period should not be extended further.

Trade Remedial measures

- There are no trade remedial measures in force against India. No countervailing duty investigation or duty imposition has been carried out by the UAE against India in the last 5 years. Hence, trade remedial measures do not represent a significant barrier for Indian exporters.

Price Controls

- The Higher Committee for Drug Policies or Committee under the MOHAP determines the prices of medical products. According to the Federal Law 2019 read with the Ministerial Resolution 140 of 2013 or Pricing Resolution and the Pricing Guidelines 2018 or Pricing Guidelines, the Committee will determine the CIF price of the pharmaceutical product and on the basis of this price306F , the agent or distributor of the pharmaceutical product (supplying pharmaceutical product to private hospitals and pharmacies), and the private hospital or pharmacy (selling the pharmaceutical product to the consumer) are each allocated a fixed margin of the CIF price. Further, with regard to generic products, a differentiated pricing mechanism is set forth for the imported generic drug versus the generic locally manufactured in the UAE.
- Indian exporters are subject to heavy price controls. By expecting prices of imported generic drugs to be as per the prices in the country of origin, despite the concerned exporter incurring higher costs associated with manufacturing the drugs as per UAE's standards (or standards of such other relatively more stringent authorities such as USFDA, EMA, etc.), the margins of the exporters may be impacted. Further, based on the discussions with the stakeholders, we understand that in the UAE, there is a system of providing complete reimbursement and therefore, the patients may not necessarily be attracted to purchase low-priced imported generic drugs. The Indian government may consider discussing the implications of the UAE pricing regulations with the Indian industry.

Government Procurement

- The UAE is not a signatory to the Government Procurement Agreement under the World Trade Organization. The CEPA includes a chapter on government procurement, which covers procurement by UAE's MOHAP. The Chapter contains provisions upholding principles of non-discrimination and national treatment, which will benefit Indian firms. The CEPA also provides for the preferential treatment of the Micro, Medium and Small Enterprises of both countries, provided that the eligibility criteria are transparent. Given the bilateral consensus on government procurement under the CEPA, this may not be a significant barrier to Indian exporters.

Investment Barriers relevant to the Pharmaceutical Sector

- Federal Decree 26 allows foreign investors to establish a presence without a local partner and allows 100% ownership of UAE companies in almost all sectors, including healthcare. In the free zones of the UAE, foreign companies can own 100% ownership rights, and have access to duty exceptions, cheap energy, and access to other administrative and support services. Also, there is no mandatory local content requirement. The recent CEPA states that both parties will be entering into a new bilateral investment agreement in the near future, which will replace the current treaty. Given the recent steps taken by both countries in furtherance to promoting trade and investment, this may not be a significant barrier to Indian exporters.

COUNTRY SNAPSHOT

Sr. No.	Parameter	Description
1.	Region	Middle East
2.	Country	United Arab Emirates[308]
3.	Capital	Abu Dhabi
4.	Population	10,000,000 (2023 est.)
5.	Population growth rate (%)	0.80% (2023 est.)
6.	Real (PPP)	USD 814.73 billion (2022 est.)[309]
7.	GDP – real growth rate (%)	5.1% (2022 est.)[310]
8.	GDP – per capita (PPP)	USD 47,790 (2022 est.)[311]
9.	Exchange rates	1 UAE Dirham = 0.27 USD (February 2023)
10.	Population below the poverty line	19.5% (2003 est.)
11.	Disease Profile	The causes of most deaths, all ages combined, are ischemic heart disease, stroke, chronic kidney disease, diabetes, chronic obstructive pulmonary disease, hypertensive heart disease, and pancreatic cancer[312]
12.	Life Expectancy	79[313]
13.	Current Health Expenditure per capita	USD 1,842.69 (2019)[314]
14	OOP Health Expenditure as % of health expenditure	12.51% (2019)[315]
15.	Age structure (%) (2023 est.)	**0–14 years**: 14.94%
		15–24 years: 12.36%
		25–54 years: 64.15%
		55–64 years: 6.59%
		65 years and over: 1.96%

Sources: CIA World Fact Book updated to May 10, 2022 , International Monetary Fund World Economic Outlook updated to October 2022

308. UAE is a federation of seven emirates (Abu Dhabi, Dubai, Sharjah, Ajman, Umm Al-Qaiwain, Fujairah, and Ras Al-Khaimah).
309. IMF, "GDP, current prices, available at <https://rb.gy/vhs34g> last accessed February 24, 2023.
310. IMF, "Real GDP growth" available at <https://rb.gy/jcxwni> last accessed February 24, 2023.
311. IMF, GDP per capita, current prices available <https://rb.gy/mumvqr> last accessed February 24, 2023.
312. Institute for Health Metrics and Evaluation, "United Arab Emirates" available at <https://rb.gy/ywnsgh> last accessed February 20, 2023.
313. World Bank, "Life expectancy at birth, total (years) – UAE" available at <https://rb.gy/egn2ps> last accessed February 20, 2023.
314. World Bank, "Current health expenditure per capita (current US$) – UAE" available at <https://rb.gy/lr3jte> last accessed November 23, 2022.
315. World Bank, "Out-of-pocket expenditure (% of current health expenditure) – UAE" available at <https://rb.gy/ihdoo5> last accessed February 20, 2023.

INTRODUCTION

UAE's pharmaceutical market was estimated at USD 3.5 billion in the year 2020[316] and is expected to hit USD 4.7 billion in 2025[317]. India's exports of pharmaceutical products to the UAE were at USD 196.1 million in the FY 2021-22[318]

A break-up of the types of pharmaceutical exports from India to UAE[319] is as follows:

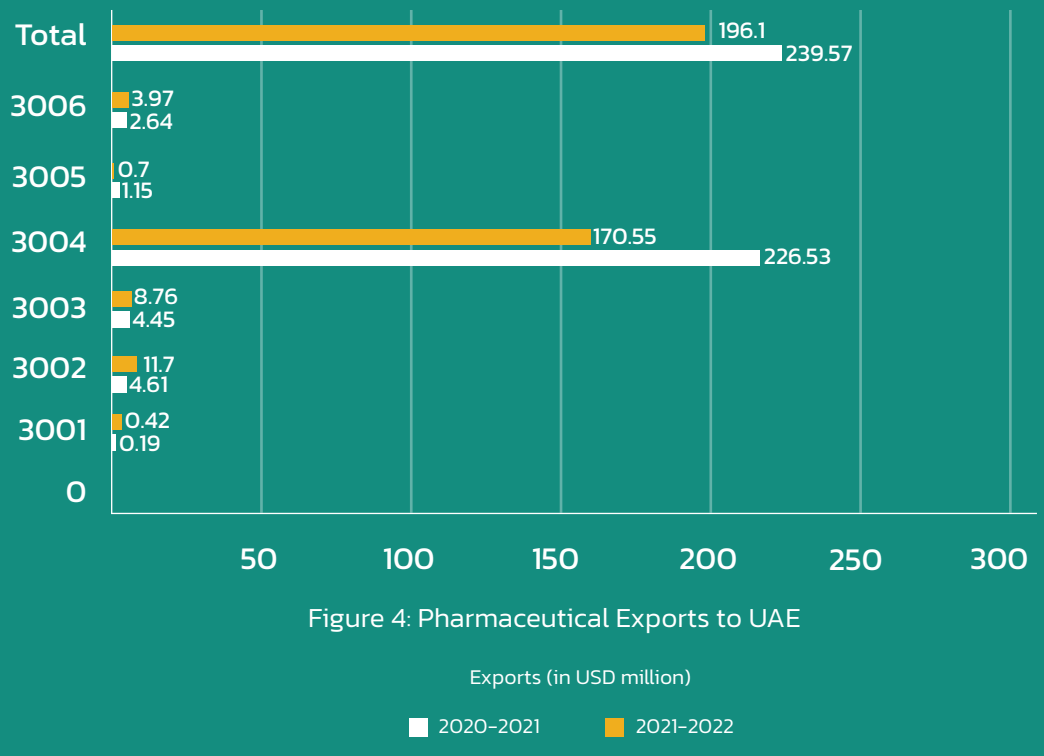


Figure 4: Pharmaceutical Exports to UAE

Source: DGCI&S

316. Himani Chandna, "How Trade Pact With UAE Will Boost Presence of Made-in-India Medicines in the Middle East" (February 25, 2022) News18 available at <https://rb.gy/tjsrqr> last accessed November 23, 2022.
317. Aarti Nagraj, "UAE Pharmaceutical Market to be valued at $44.7bn by 2025 as it boosts local manufacturing" (February 23, 2022) The National available at <https://rb.gy/m6orzu> last accessed November 23, 2022.
318. Trading Stats, "India Exports of pharmaceutical products to United Arab Emirates" available at <https://rb.gy/fkveek> last accessed November 23, 2022.
319. Export-Import Data Bank Version 7.1, Department of Commerce, Government of India available at <https://rb.gy/41jtxg> last accessed on November 23, 2022.

Table 4: Pharmaceutical Exports to the UAE

Heading	Description	2020-2021	2021-2022
3001	Glands, other Organs; Extracts of Glands or Other Organs	0.19	0.42
3002	Human or Animal Blood, Antisera and Other Blood Fractions, Vaccines, Toxins	4.61	11.7
3003	Medicaments	4.45	8.76
3004	Medicaments (Put up in Packings for Retail Sale)	226.53	170.55
3005	Wadding, Gauze, Bandages and Similar Articles	1.15	0.7
3006	Misc. Pharmaceutical Goods	2.64	3.97
	Total	**239.57**	**196.1**

- After formally launching negotiations in September 2021, India, and UAE signed the CEPA on February 18, 2022.[320] The same has come into force on May 1, 2022.[321] The CEPA is set to witness tariff reductions and market access relaxations across a wide range of goods and services. India has been offered a duty elimination on over 97% of its tariff lines, which corresponds to 99% of India's exports to the UAE in terms of value over the last decade.[322] The breakthrough achievement of CEPA in the realm of the pharmaceutical sector is the inclusion of a separate Annexure for Bilateral Cooperation on Pharmaceutical Products ("**Annexure**").[323]
- India's pharmaceutical exports to UAE have witnessed a compound annual growth rate of 25 percent during the last 5 years ending FY 2022.[324] Indian exports of pharmaceutical products are expected to only increase due to regulatory relaxations provided in the Annexure.[325]

320. Ministry of External Affairs, "List of documents launched/signed during the India-UAE Virtual Summit" (February 18, 2022) available at <https://rb.gy/xgpun4> last accessed November 23, 2022.
321. Customs Notification No. 22/2022-Customs dated April 30, 2022.
322. Ministry of Commerce and Industry, "India – UAE Economic Partnership Agreement to open up new markets for Indian goods and services" (February 20, 2022) available at <https://rb.gy/epnqml> last accessed November 23, 2022.
323. India-UAE CEPA, Annex 5A.
324. Export-Import Data Bank Version 7.1, Department of Commerce, Government of India available at <https://rb.gy/41jtxg> last accessed November 23, 2022.
325. Ramesh Shankar, "India-UAE CEPA: an opportunity for drug exporters" (March 23, 2022) Pharmabiz available at <https://rb.gy/bgmhow> last accessed November 23, 2022.

A. REGULATORY FRAMEWORK

- The law governing the import, manufacture, sale, and distribution of pharmaceuticals in the UAE is Federal Law 2019. [326]
- The primary aim of the Federal Law 2019 is to consolidate and modernize the legal framework for the purpose of placing medical and health products in the UAE market. The Federal Law 2019 deals with several areas including pricing, product registration, and status of marketing authorization applicant/ holder, import, export, distribution, warehousing, licensing requirements, product availability measures, clinical trials, and generics among others.[327]

A non-exhaustive list of other laws governing pharmaceuticals in the UAE is as follows:

Federal Law No. 14 of 1995 governing the imports of narcotic drugs and psychotropic substances.

Federal Law No. 17 of 2002 (Patent Law) and Ministry of Health Resolution No. 404 of 2000 (Patent Resolution) governing the registration of patents in pharmaceuticals.

Ministerial Decision No. 28 of 2018 (Orphan Drugs Registration) regulates the registration and pricing of innovative and orphan drugs

- The regulatory framework concerning pharmaceuticals in the UAE is overseen by the MOHAP. The MOHAP also formulates national medical and healthcare policies in the UAE and also oversees the healthcare market throughout the Northern Emirates. In addition, the healthcare systems of Abu Dhabi, Dubai, and Sharjah are specifically regulated by the **Health Authority Abu Dhabi** ("**HAAD**"), **Dubai Health Authority** ("**DHA**"), and the Sharjah Health Authority respectively. The other emirates i.e., Ajman, Ras Al Khaimah, Umm Al Quwain, and Fujairah, also have their healthcare departments, which are in turn governed by the MOHAP.[328]

326. The Federal Law 2019 entered into force on 30 January 2020, replacing Law No. 4 of 1983 on the Pharmacy Professional and Pharmaceutical Establishments and Law No. 20 of 1995 on the Drugs and Products.
327. Federal Law no. 8 on Medical Products, Profession of Pharmacy and Pharmaceutical Institutions.
328. Melissa Murray, Ayab Abdin and Surabhi Singhi, 'Medicinal product regulation and product liability in United Arab Emirates: overview' available at <https://rb.gy/8yhyfw> last accessed 11 July 2022.

TARIFF & CUSTOMS BARRIERS

GCC members apply common customs procedures and tariffs for imports from non-member states.[329] UAE being a member of the GCC has adopted the customs law as applied by the GCC.[330]

According to the Unified Customs Tariff for GCC States 2022[331], the duty rate is at 0% for all the products falling under Chapter 30.[332] Further, under the CEPA, UAE has agreed to provide immediate access to Indian pharmaceuticals products falling under chapter 30 and entering India at 0% duty rate.

SUGGESTIONS

In light of the above, tariff barriers do not appear to be a significant concern for Indian exporters of pharmaceuticals to the UAE, and tariff commitments as far as pharmaceuticals are concerned may no longer be a key factor for any negotiations with UAE.

329. World Trade Organization, "Trade Policy Review: UAE 2022" available at <https://rb.gy/hwonqx> last accessed November 23, 2022.
330. World Trade Organization, "Trade Policy Review: UAE 2022" available at <https://rb.gy/hwonqx> last accessed November 23, 2022: UAE implemented the GCC Common Customs Law and its Implementation Rules and Explanatory Note including the Unified Customs Tariff for GCC States 2022 through Federal Decree No. 85 of 2007 on the Common Customs Law for the Arab States of the Gulf.
331. Federal Authority for Identity, Citizenship, Customs and Port Security, "The Unified Customs Tariff for GCC States 2022" available at <https://rb.gy/pmlmnn> last accessed November 23, 2022.
332. World Trade Organization, "Trade Policy Review: UAE 2022" available at <https://rb.gy/hwonqx> last accessed November 23, 2022.

TECHNICAL BARRIERS TO TRADE

Given the impact on human life and health, the pharmaceutical sector in UAE, much like the rest of the world, is subject to a variety of technical regulations, standards, and conformity assessment procedures.

A. MARKETING AUTHORIZATION

- Market authorizations provided in foreign jurisdictions are not recognized, and cannot be used, in the UAE.[333] The Federal Law 2019 stipulates that a medical product[334] cannot be traded in the UAE unless a marketing authorization or an exclusive marketing authorization for the same is granted by the MOHAP.[335]
- The Federal Law 2019 particularly stipulates when a marketing authorization can be provided, for instance, in the case of a new medical product or new use or generic pharmaceuticals products.
  - With regard to a new medical product or new use or a new method of administration, the marketing authorization can be issued by the MOHAP pursuant to an assessment that the product has met the research information, thereby proving its efficacy, safety, and compliance with the approved quality specifications or marketing authorizations issued to the product by the countries of reference[336] , provided that the applicant has the marketing right, according to the intellectual property and trademark rules.[337]
  - As far as the marketing authorization for a generic pharmaceutical product[338] is concerned, the same may be granted if the said product is pharmaceutically equivalent and bioequivalent to another pharmaceutical product whose legal protection has expired, and for which a marketing authorization has been issued previously.[339]

333. Akshatha Achar, "Regulatory, Pricing and Reimbursement Overview: UAE" PharmaBoardroom available at <https://rb.gy/k5icjr> last accessed November 23, 2022.
334. Under the Federal Law 2019 a Medical Product is defined as "Every Medicinal Product or Medical Device or Healthcare Product." Further, the term Medicinal Product is defined as:
"Any product which consists of a substance or combination of effective substances, which achieves the principle purpose action in or on human beings or the animal, through biological effect, and which is manufactured or sold or offered to be used in the following cases:
1.Diagnosis, treatment, healing, alleviation, or prevention of a disease
2.Restoring, renewing, modifying, or correcting the physiological functions."
335. Article 3, Federal Law 2019.
336. Country of reference is defined as "Country of Reference: The country whose Marketing Authorisation of the Medical Product is relied upon to grant the Marketing Authorisation of such product in the State."
337. 'Article 4, Federal Law 2019.
338. Pharmaceutical Product is defined as "A Medical Product which is manufactured in a certain Pharmaceutical Form, for specific human or veterinary uses."; Generic Pharmaceutical Product is defined as "The Pharmaceutical Product which is equivalent to another Pharmaceutical Product, having the same qualitative and quantitative composition in Active Substances, and the same Pharmaceutical Form as the said product, and whose bioequivalent is demonstrated."
339. 'Article 6, Federal Law 2019.

- The applicant seeking such market authorizations must commit to the following:[340]
- Appointing one or more qualified persons[341] residing in UAE according to a resolution from the Minister.
  - Providing a medical warehouse to carry out the import, storage, distribution, and wholesale of marketing approved products.
  - Monitoring the flow of medical products through distribution channels.
  - Providing the necessary capabilities and systems to comply with the requirements to obtain marketing authorization for the medical product.
  - Monitoring the performance of the licensed medical product and receiving reports from pharmaceutical facilities about its effectiveness, safety, usage, and quality.
  - Informing the MOHAP and the concerned authority within 15 days of the date of knowledge of any unexpected/serious side effects or adverse effects reported or monitored during trading or local or international clinical research conducted.
  - Monitoring procedures of medical product withdrawal.
  - Monitoring product patent and manufacture right protection.
- Further details with respect to rules, conditions, and procedures for obtaining a marketing authorization were expected to be provided by a new ministerial resolution.[342] However, no such ministerial resolution in English is accessible in the public domain.[343]

Timeframe and fees

- The Federal Law 2019 does not clarify what is the timeframe to complete the marketing authorization process. It is also not clear what are the fees levied for each application and if there is any difference in fees levied for medical products, new medical products, or generic pharmaceutical products.
- However, Annex 5 to CEPA[344], provides that marketing authorization must be provided within 90 days for pharmaceutical products (as defined under the CEPA) which have been approved by the relevant regulatory authorities of Australia, Canada, the European Union, Japan, the USA, or the United Kingdom. In respect of all the other pharmaceutical products, which have not been approved by the relevant regulatory authorities from the aforementioned countries and for which inspection is required, the marketing authorization is required to be granted within 270 days from the application. Pharmaceutical products under the CEPA have been defined to include **finished pharmaceutical products** ("**FPPs**"), and certain marketed biological products for human use.

SUGGESTIONS

Greater clarity on the process of application for seeking marketing authorization would be helpful. India may suggest that detailed guidance be issued on the process of applying for marketing authorization.

Given that a timeframe of 90 days and 270 days (as applicable) has been prescribed for granting the marketing authorization for pharmaceutical products defined under the CEPA, India may request for clarification on the timeframe for granting marketing authorization for the other products.

340. 'Article 7, Federal Law 2019.
341. Article 1, Federal Law 2019: "Qualified Person: The person who is scientifically and technically qualified and licensed to engage in practice a specified activity within the field of the Profession of Pharmacy or profession of medicine, according to the provisions of the present Law and its Implementing Regulation."
342. Baker McKinzie, "Client Alert" (February 2020) available at <https://rb.gy/8fxzjm> last accessed November 23, 2022; See Article 3, Federal Law 2019.
343. Ministry of Health & Prevention, "Legal References" available at <https://rb.gy/mwyk9n> last accessed November 23, 2022.
344. India-UAE CEPA, Annex 5A.

B. REGISTRATION FOR SALES OF PHARMACEUTICAL PRODUCTS

- The holder of marketing authorization is required to register the pharmaceutical products prior to their sale before the MOHAP. However, prior to registering the products, the holder of marketing authorization is required to register itself before the MOHAP. The process for securing the registration of pharmaceutical products is set out below.[345]
  - An application for registration must be submitted in electronic form.
  - Payment must be completed in order to meet all conditions and required fees.
  - The competent technical committees will deliberate the registration of products, pursuant to which a recommendation will be submitted to the competent ministerial committee.
  - The committee's decisions are provided to the companies via the e-system.
  - The company should complete the requirements and submit them through the electronic service.
  - The relevant technical and ministerial committees will re-deliberate the registration of products that have been deferred in advance as soon as companies complete the requirements.
  - Pursuant to the approval, the certificates of registration of products are issued. Such registration certificates are valid for a period of 5 years effective the date of committee approval.

Timeframe

- The timeframe for securing the registration certificate is 45 days.[346] While a timeframe of 90 days has been prescribed for issuing market authorization for pharmaceutical products defined under the CEPA, no such timeframe has been prescribed, in general, for securing marketing authorization under Federal Law 2019 for all other kinds of pharmaceutical products. A short time period of 45 days for securing the registration certificate seems to provide some respite to companies intending to sell pharmaceutical products.
- In addition, the CEPA requires the UAE to consider establishing "fast-track" procedures for pharmaceutical products having approvals from at least one of the regulatory authorities/ reference countries namely Australia, Canada, European Union, Japan, United States of America, or the United Kingdom.[347] In furtherance of the same, UAE does not need to carry out a full assessment or inspect the applicant's manufacturing sites for the products already approved by reference countries included in pharmaceutical products under consideration for 'fast-track' procedure, except in the case of specialized products.

345. Ministry of Health & Prevention, "Registration of Pharmaceutical Product for General Sale" available at <https://rb.gy/a1gd6s> last accessed November 23, 2022.
346. Ministry of Health & Prevention, "Registration of Pharmaceutical Product for General Sale" available at < https://rb.gy/a1gd6s > last accessed November 23, 2022.
347. India-UAE CEPA, Annex 5A.

Fees

However, the costs for securing the said certificate are high. According to the MOHAP, an application fee of AED 100 and a fee of 5,000 AED towards registration of pharmaceutical products for general sale has been prescribed.[348]

SUGGESTIONS

- India may request for modalities for seeking fast-track approval, if any.
- In addition, India may suggest applying lower fees for securing a registration certificate.

C. LABELLING REQUIREMENTS

- Labelling requirements for medical products are set out in Article 33 of the Federal Law 2019. For a medical product to be traded or marketed, the data and information provided on the inner and outer label along with that on the Product Information Leaflet should be similar to the information and data mentioned in the relevant marketing authorization Annex[349] .
- The information on the label, for instance, should include name of the medication or pharmaceutical preparation, registration number, components of the medication, and their amounts, expiry date, name of the factory where the medication was produced, directions/methods to use the medication, and warnings including the potential side effects.[350]
- Further, the outer packaging of all healthcare products[351] must bear the phrase that: "This product is not intended for diagnosis, treatment, healing or prevention of any disease"[352].

SUGGESTIONS

While we understand that labelling requirements may pose a trade barrier, we do not anticipate significant business impact on large corporations as a result of these requirements.

Such requirements are fairly standard across the world and are unlikely to impact multinational pharmaceutical companies. However, this may be a cause for concern for the MSME sector.

348. Ministry of Health & Prevention, "Registration of Pharmaceutical Product for General Sale" available at <https://rb.gy/a1gd6s > last accessed November 23, 2022.
349. Federal Law no. 8 of 2019 on Medical Products, Profession of Pharmacy and Pharmaceutical Institutions, Article 33.
350. Melissa Murray, Ayab Abdin and Surabhi Singhi, 'Medicinal product regulation and product liability in United Arab Emirates: overview' available at <https://rb.gy/8yhyfw> last accessed 11 July 2022.
351. Healthcare Product is defined as any Medical Product which is used to protect the general health of the human being, and which is not intended for the diagnosis, treatment, healing or prevention of a disease, and whose purchase does not require a Medical Prescription or a direct medical monitoring when used.
352. Federal Law no. 8 of 2019 on Medical Products, Profession of Pharmacy and Pharmaceutical Institutions, Article 34.

GOOD MANUFACTURING PRACTICES

- The Federal Law 2019 requires manufacturers/entities to comply with good manufacturing practices/manual issued by the relevant ministry of the UAE. For instance, it requires the entities for whose interest a clinical trial is conducted to comply with certain good clinical practice manual, pharmaceutical laboratories, and licensed research centre to adhere to good laboratory practices, and manufacturers to comply with good manufacturing controls approved by the Ministry.
- Further, the CEPA, which provides for a separate annex on pharmaceutical products, requires UAE to accept Pharmaceutical Products manufactured in the other Party's territory provided that these products are approved by the regulatory authorities of Australia, Canada, the European Union, Japan, the United States of America, or the United Kingdom without the need for prior inspection. It also allows UAE to conduct its own inspection of the manufacturing facilities approved by the said regulatory authorities. However, inspecting the manufacturing facilities is an exception from the normal practice and shall be based on quality defects identified in post-market surveillance, or any specific evidence of serious concern in relation to the product quality or consumer safety.[353]

SUGGESTIONS

- India and UAE have agreed to accepting the pharmaceutical products (defined under the CEPA) that are approved by certain regulatory authorities.
- The inspection of manufacturing facilities by UAE is conducted based on quality defects identified in post-market surveillance, or any specific evidence of serious concern in relation to the product quality or consumer safety.
- This may not be a significant barrier to Indian exporters.

353. India-UAE CEPA, Annex 5A.

INTELLECTUAL PROPERTY

A. PATENT PROTECTION

- The primary legislation relevant to pharmaceutical patents in the UAE is the Federal Law 2021[354] which is aimed at reforming UAE law and bring it in line with international standards.[355]
- The competent authority for the purpose of registration of patents is the Ministry of Economy, whereby the applications can be filed online through the Ministry's website.[356] The Federal Law 2021 also provides the possibility to file an urgent application upon payment of certain fees.
- The criteria for granting a patent under the Federal Law 2021 is that the new invention must be contrived from a creative idea or creative enhancement, forms an inventive step, and is capable of industrial application.[357] The novelty requirement, in other words, if the invention has not been disclosed to the public prior to the filing date, is also assessed. In this behalf, a grace period has been provided under the Federal Law 2021, whereby, if the disclosures occur within 12 months prior to the filing, it will not break the novelty requirement. [358]
- Patent protection is granted for a period of 20 years from the date of the original filing.[359] The patent protection, however, does not apply, inter alia, to the combination of 2 or more medicines for the purpose of medical treatment by a licensed pharmacist.[360] The Federal Law 2021 also provides for the issuance of utility certificate for a period of 10 years.[361] Such a utility certificate is granted to an inventive step that is insufficient to qualify for patent eligibility.[362]
- Pre-grant and post-grant opposition to patent has been provided under Federal Law 2021.[363] It requires the formation of a grievance committee, whereby third parties looking to oppose the granting of a patent or after the patent is granted, can do so by paying a prescribed fee. However, no details have been provided about how the process of opposition will function, the grounds on which the pre-grant or post-grant opposition can be made, and the periods within which such grievances will be entertained or addressed.[364]

SUGGESTIONS

India may consider requesting further guidance on how the process of opposition to granting of patent/patent will function, the grounds on which the pre-grant or post-grant opposition can be made, and the periods within which such grievances will be entertained or addressed.

354. Federal Law 2021 On the Regulation and Protection of Industrial Property Rights; See also, World Trade Organization, "Trade Policy Review: UAE 2022" available at <https://rb.gy/hwonqx> last accessed November 23, 2022.
355. Federal Law No. 11 of 2021 repealed the Federal Law No. 17 of 2002 on Regulating and Protecting Industrial Property for Patents, Designs, and Industrial Drawings, as amended by Federal Law No. 31 of 2006.
356. United Arab Emirates, "Ministry of Economy" available at <https://rb.gy/wezuzc> last accessed November 23, 2022.
357. Federal Law 2021, Article 5.
358. Federal Law 2021, Article 5.
359. Federal Law 2021, Article 18.
360. Federal Law 2021, Article 22.
361. Federal Law 2021, Article 18.
362. Federal Law 2021, Article 6.
363. Federal Law 2021, Article 74.
364. Bird and Bird LLP, "New UAE patent legislation – shift towards US system?" (November 29, 2021) Lexology available at <https://rb.gy/d5dnos> last accessed November 23, 2022.

B. EXCLUSIVITY- DECREE 321

- UAE has issued the Ministerial Decree 321 of 2020 which regulates the use of data and information related to innovative pharmaceutical products registered inside the UAE.
- According to this Decree, the data exclusivity period is set to 8 years from the date of marketing approval inside the UAE for innovative pharmaceutical products which contain active pharmaceutical ingredient for which no other pharmaceutical product has obtained a marketing license in the UAE. However, generic and biosimilar companies can apply for marketing approval within the last 2 years of the data exclusivity period. While making this application, such generic and biosimilar companies.
- The Decree provides some room for MoHAP to grant marketing license to generic or biosimilar companies, despite the data exclusivity period, for public health or other reasons which are decided on a case-by-case basis.[365]
- The period of exclusivity granted in UAE is largely in line with and in some cases shorter than other highly regulated markets such as the EU and USA. For example, in the United States, market exclusivity for new drugs is 12.4 to 12.5 years.[366]

SUGGESTIONS

In general, the duration of exclusivity is shorter in UAE than in countries such as the United States. The Indian government should maintain the position that this period should not be extended further.

365. Lisa L. Mueller, "Change in Data Exclusivity for Pharmaceutical Products in the United Arab Emirates" BRICS & Beyond available at <https://rb.gy/wh8hca> last accessed November 23, 2022
366. Henry G Grabowski and others, "Evolving Brand-Name and Generic Drug Competition May Warrant a Revision of The Hatch-Waxman Act" (2011) 30(11) Health Affairs 2157.

TRADE REMEDIAL MEASURES

The primary legislation governing the application of trade remedial measures in UAE is Federal Law No. 1 of 2017 on anti-dumping, countervailing, and safeguard measures, read with its Implementation Rules.[367]

As on the date of this report, there are presently no trade remedial measures specific to the pharmaceutical sector in force in UAE against India. Only anti-dumping measure currently in force against India is on imports of ceramic tiles.[368] Further, there has been no countervailing duty investigation or imposed by UAE against India in the last 5 years.[369]

SUGGESTIONS

Considering there are no trade remedial investigations launched by UAE concerning pharmaceuticals, this dimension does not represent a significant barrier for Indian exporters.

367. World Trade Organization, "Notification of Laws and Regulations under Articles 18.5, 32.6, and 12.6 of the Agreements: UAE 2018" available at <https://rb.gy/yjgl5t> last accessed November 23, 2022.
368. World Trade Organization, "Notification of Laws and Regulations under Articles 18.5, 32.6, and 12.6 of the Agreements: UAE 2018" available at <https://rb.gy/yjgl5t> last accessed November 23, 2022.
369. 'World Trade Organization, "Trade Policy Review: UAE 2022" available at <https://rb.gy/hwonqx> last accessed November 23, 2022.

PRICE CONTROLS

- Federal Law 2019 read with the Pricing Resolution[370] and the Pricing Guidelines[371] set forth the modalities for controlling prices for pharmaceutical products.[372]
- The Federal Law 2019, as part of the marketing authorization procedure, mandates the establishment of a price for pharmaceutical products.[373] It also provides that the pharmaceutical product subject to price control cannot be sold at higher prices and shall not be subject to any price discounts.[374]
- The Higher Committee for Drug Policies ("**Committee**") established under the MoHAP will, among other things, determine the prices of pharmaceutical products in UAE as per the Pricing Resolution and the Pricing Guidelines.[375] A few examples are provided below.

Sale of pharmaceutical products by agents/distributors and hospitals/pharmacies

As per the Pricing Resolution, the Committee sets the prices for the sale of pharmaceutical products including prescription drugs and over-the-counter drugs sold by agents/distributors to hospitals/pharmacies and hospitals/pharmacies to a customer in the following manner.[376] First, the Committee will determine the CIF price of the pharmaceutical products. Second, on the basis of this CIF price[377], the agent or distributor of the pharmaceutical product, and the pharmacy or private hospital are each allocated a fixed profit margin of the CIF price as given in the table below:

Particulars	Profit Margin (%) of CIF Price (AED 0-250)	Profit Margin (%) of CIF Price (AED 250-500)	Profit Margin (%) of CIF Price (More than AED 500)
Distributor / Agent	15%	15%	15%
Pharmacy / Private Hospital	28%	28%	20%

Thus, in effect the actual price of the pharmaceutical product as payable by the end consumer is the sum total of the CIF price, the agent's margin and the pharmacy's margin.

370. Until the implementing regulations/decisions/rules/instructions to the Federal Law 2019 are issued, the implementing regulations under the repealed laws of 1983 and 1995 will remain in effect. Given that no implementing regulation to the Federal Law is available in the public domain, it appears that the regulations under the repealed laws are applicable for the purposes of price control. WTO Trade Policy Review Report indeed makes a reference to the Ministerial Resolution 140 of 2013 along with the Federal Law 2019; See World Trade Organization, "Trade Policy Review: UAE 2022" available at <https://rb.gy/hwonqx> last accessed November 23, 2022.
371. Pricing Guidelines (Version 1 of 2018), Public Health Policy & Licensing Sector, Drug Department.
372. Baker McKinzie, "Client Alert" (February 2020) available at <https://rb.gy/8fxzjm> last accessed November 23, 2022.
373. World Trade Organization, "Trade Policy Review: UAE 2022" available at <https://rb.gy/hwonqx> last accessed November 23, 2022.
374. World Trade Organization, "Trade Policy Review: UAE 2022" available at <https://rb.gy/hwonqx> last accessed November 23, 2022.
375. Article 29, Federal Law no. 8 on Medical Products, Profession of Pharmacy and Pharmaceutical Institutions
376. Clyde & Co., "Healthcare newsletter: Pharmaceutical edition" available at <https://rb.gy/hhvygr> last accessed November 23, 2022.
377. CIF (cost, insurance, and freight) generally means all of the costs incurred to get the relevant product from the place of origin to the named port of destination.

The scope of Pricing Resolution is limited to the supply of pharmaceutical products to the private sector vis., private hospitals, and pharmacies. When it comes to the supply of pharmaceutical products by the drug companies directly to the government authorities, the Pricing Resolution does not apply, and such prices are then determined on the basis of commercial arrangements entered into between the concerned drug company and the government authority.[378]

Sale of generic drugs

- The Pricing Guidelines prescribe differentiated pricing mechanism for generic drugs imported into the UAE and that manufactured and sold in the UAE.
- In the case of imported generic drugs, the lesser of the following prices must be adopted for the first generic drug:[379]
  - Calculating 60% of CIF approved for the innovator
  - Ex-factory price in the country of origin with an addition of 20%
  - CIF price proposed by the company
  - The median CIF price approved for the drug in the list of reference countries[380] including Austria, Bahrain, Belgium, Canada, Denmark, Finland, France, Germany Ireland, Italy, Kuwait, the Netherlands, Norway, Saudi Arabia, Spain, Sweden, Switzerland, and the United Kingdom.
- The same pricing mechanism is adopted for determining the prices for the second and third imported generic drugs except for "calculating 50% of CIF approved for the innovator" in the case of second generic drug and "calculating 40% of CIF approved for the innovator" for the third generic drug.
- On the other hand, in the case of locally manufactured generic drugs, the following pricing mechanism is adopted.[381]
  - Fully locally manufactured generic drug: Priced at 70% of innovative product price
  - Partially locally manufactured generic drug:
    - » First generic drug: Priced at 60% of innovative product price
    - » Second and subsequent generic drug: Priced with 60% of innovative product price
- Evidently, pharmaceutical product prices are heavily regulated in the UAE and remain under direct government supervision. This appears to have been done to keep the prices of medicines affordable for the consumers and to guard against anti-competitive prices by the pharmaceutical companies.
- However, since the UAE has a system of providing complete reimbursement to patients against the purchase of drugs, there is no incentive for them to purchase low-priced imported generic drugs, thereby reducing any incentives for Indian manufacturers to register their drugs.

378. Clyde & Co., "Healthcare newsletter: Pharmaceutical edition" available at <https://rb.gy/nrcpdh>last accessed November 23, 2022.
379. Pricing Guidelines (Version 1 of 2018), Public Health Policy & Licensing Sector, Drug Department, Article 7.
380. The list of reference countries is based on discussions with stakeholders.
381. Pricing Guidelines (Version 1 of 2018), Public Health Policy & Licensing Sector, Drug Department, Article 7.

SUGGESTIONS

Indian exporters are subject to price controls. By expecting prices of imported generic drugs to be as per the prices in the country of origin, despite the concerned exporter incurring higher costs associated with manufacturing the drugs as per UAE standards, the margins of the exporters may be impacted. Further, based on the discussions with the stakeholders, we understand that in the UAE, there is a system of providing complete reimbursement and therefore, the patients may not necessarily be attracted to purchase low-priced imported generic drugs. The Indian government may consider discussing the implications of the UK pricing regulations with the Indian industry.

GOVERNMENT PROCUREMENT

The UAE is not a signatory to the GPA.[382] However, government procurement is regulated both at the federal and the emirate level in UAE.

The principal legislation governing government procurement at federal level is the Cabinet Resolution No. 4 of 2019 on Procurement Regulations and Storehouse Management at the Federal Government.[383] The aim of this regulation is to provide for a unified procurement procedures for federal entities, reduce costs, ensure an effective procurement system, and align with International best practices.[384] However, the purchases of drugs are excluded from the ambit of this regulation.[385]

The CEPA has included for the first time a separate chapter on government procurement and includes within its ambit procurement by the UAE's MoHAP.[386] Both the countries have bilateral consensus that the concerned procuring entities shall uphold principles of non-discrimination and national treatment.[387]

Given the interest of both the countries in protecting their respective **Micro, Small and Medium Enterprises** ("**MSMEs**") sector, the CEPA provides for preferential treatment for the countries respective MSMEs, provided that the eligibility criteria be transparent.[388] Thus, both parties have reserved the right to apply a preferential procurement policy for its MSMEs in accordance with its laws and regulations.

SUGGESTIONS

Given the bilateral consensus on government procurement under the CEPA, this may not be a significant barrier to Indian exporters.

382. World Trade Organization, "Trade Policy Review: UAE 2022" available at <https://rb.gy/hwonqx> last accessed November 23, 2022.
383. World Trade Organization, "Trade Policy Review: UAE 2022" available at <https://rb.gy/6bsn2r> last accessed November 23, 2022.
384. World Trade Organization, "Trade Policy Review: UAE 2022" available at <https://rb.gy/hwonqx> last accessed November 23, 2022.
385. 'Article 2 of Cabinet Resolution No. (4) of 2019; World Trade Organization, "Trade Policy Review: UAE 2022" available at <https://rb.gy/hwonqx> last accessed November 23, 2022.
386. India-UAE CEPA, Annex 10B.
387. India-UAE CEPA, Article 10.5.
388. India-UAE CEPA, Article 10.22.

INVESTMENT BARRIERS RELEVANT TO THE PHARMACEUTICAL SECTOR

The primary legislations governing the foreign investment regime in UAE are the Federal **Commercial Companies Law** ("**CCL law**")[389], the Commercial Agencies Law, and the Federal Industry Law. Federal Decree-Law No. 26 of 2020 amending the CCL Law was promulgated on September 27, 2020.[390]

Prior to amendments in the CCL law, a foreign investor wishing to establish an onshore company in UAE, they were required to have a local partner with 51% of the share capital among others. Pursuant to the issuance of Federal Decree-Law No. 26 of 2020[391] , this requirement was relaxed. Thus, the Federal Decree 26 now allows foreign investors to establish without a local partner and can own up to 100% of the UAE companies in almost all the economic sectors including healthcare, except a few strategic sectors such as security, defence, and activities that have a military nature; banks, exchange houses, finance companies, insurance activities, and money printing; telecommunications; pilgrimage (Hajj) and Umrah services; Qur'an memorization centres; and services related to fisheries.[392]

As far as the Federal Industry Law is concerned, currently an exercise is ongoing to allow 100% foreign ownership of industrial projects, in line with the amendments made to the CCL law.[393]

Further, in the investments in free zones of UAE, foreign companies are not only allowed to have 100% ownership rights but can also take the benefit of numerous benefits such as exemption from customs duties and commercial levies, easy access to transport infrastructure, provision of energy at cheap rates, and other administrative and support services etc.[394]

Notably, while UAE does not mandate a local content requirement, it encourages both the Emirati and foreign investors to do the same in order to contribute to the development of the economy.[395] This, according to the WTO Trade Policy Report, is done through government procurement programmes, by granting preferences in tenders to companies that utilize local content and employ Emirati nationals, among other criteria.[396] However, this will be addressed by CEPA as both the countries have bilateral consensus to uphold non-discrimination and national treatment.

289. Federal Law No. 2 of 2015 on Commercial Companies
290. World Trade Organization, "Trade Policy Review: UAE 2022" available at <https://rb.gy/hwonqx> last accessed November 23, 2022.
291. Federal Decree-Law No. 26 of 2020.
292. Cabinet issued Resolution No. 55 of 2021 setting out a list of activities having a strategic impact. These activities are security, defence, and activities that have a military nature; banks, exchange houses, finance companies, insurance activities, and money printing; telecommunications; pilgrimage (Hajj) and Umrah services; Qur'an memorization centres; and services related to fisheries.
293. World Trade Organization, "Trade Policy Review: UAE 2022" available at <https://rb.gy/hwonqx> last accessed November 23, 2022.
294. World Trade Organization, "Trade Policy Review: UAE 2022" available at <https://www.wto.org/english/tratop_e/tpr_e/s423_e.pdf> last accessed November 23, 2022.
295. World Trade Organization, "Trade Policy Review: UAE 2022" available at <https://rb.gy/hwonqx> last accessed November 23, 2022.
296. World Trade Organization, "Trade Policy Review: UAE 2022" available at <https://rb.gy/hwonqx> last accessed November 23, 2022.

India and UAE have a bilateral investment treaty in force, that encourage strategic global partnerships.[397] At the same time, under the CEPA, a chapter on investment has been included. The same recognizes that the countries have agreed to enter into a new bilateral investment agreement replacing the current treat in force. The CEPA also affirms the countries desire to promote an attractive investment climate and expand trade in products and services. In furtherance to the same, a technical council will be established whose objectives inter alia would include promoting and enhancing investment and trade cooperation and facilitation between parties, monitor investment and trade relations to identify opportunities for expanding investment and trade, hold consultations on specific investment and trade matters of interest, identify and work toward the removal of impediments and facilitate investment and trade flows among others.

SUGGESTIONS

Given the recent steps taken by both the countries in furtherance to promoting trade and investment, this may not be a significant barrier to Indian exporters.

397. Investment Policy Hub, UNCTAD, "India – United Arab Emirates BIT (2013)" available at <https://rb.gy/hh0nsi> last accessed November 23, 2022.

UNITED KINGDOM

EXECUTIVE SUMMARY

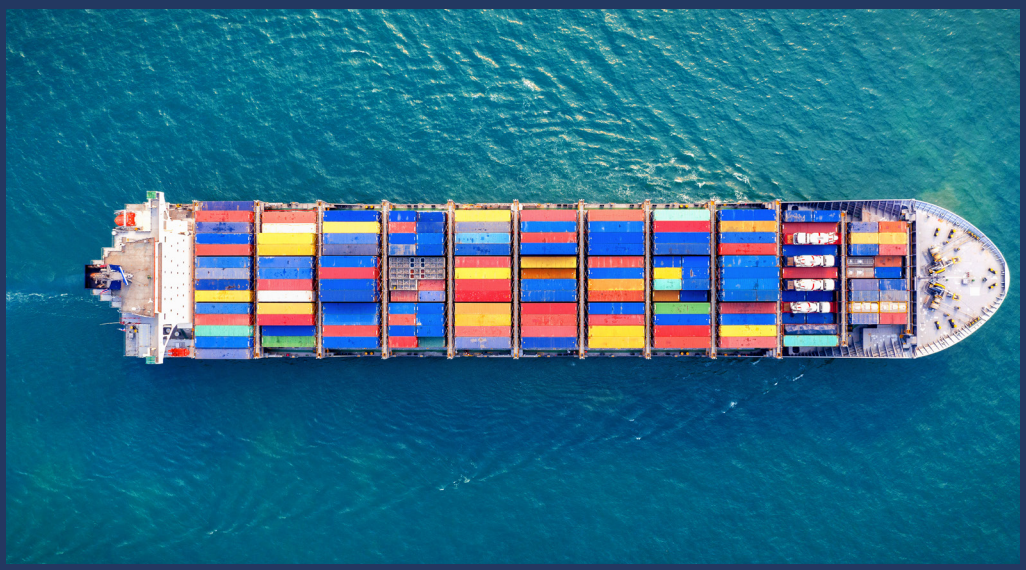
INTRODUCTION

- In 2021-22, the **United Kingdom** ("**United Kingdom**" or "**UK**") was the second largest importer of pharmaceutical products from India. It constitutes about 3.17%[398] of India's total pharmaceutical exports to the world, valued at **USD 615 million.**[399]
- The UK's pharmaceutical market is largely dominated by generic medicines. The use of generic medicines in the UK doubled between 2005 and 2017 to reach 75% of total prescriptions.[400] According to the Organization for Economic Co-operation and Development Health Statistics 2021, about 85% of the pharmaceutical products sold in the UK were generic drugs. It is the highest among European countries.[401] This growth has been driven by the UK government's increased focus on reducing overall healthcare costs.[402]
- Clearly, the UK is an important target market considering India's price advantage because of lower labor costs[403] and manufacturing capacity for generic drug production.

KEY FINDINGS AND RECOMMENDATIONS

Customs and Tariff Barriers

The pharmaceutical products falling under Chapter 30 are subject to Nil duties in the UK. There are also no tariff rate quotas on these products in the UK. Hence, tariff barriers do not appear to be a significant concern for Indian exporters.



398. Export-Import Data Bank Version 7.1, Department of Commerce, Government of India available at <https://rb.gy/41jtxg> last accessed on November 23, 2022.
399. Export-Import Data Bank Version 7.1, Department of Commerce, Government of India available at <https://rb.gy/41jtxg> last accessed on November 23, 2022.
400. Oxera, "The supply of generic medicines in the UK" available at <https://rb.gy/gp5ofs> last accessed November 23, 2022.
401. OECD iLibrary, "Health at a Glance 2021: OECD Indicators" available at <https://rb.gy/j0hnhm> last accessed November 23, 2022.
402. OECD iLibrary, "Health at a Glance 2021: OECD Indicators" available at <https://rb.gy/j0hnhm> last accessed November 23, 2022.
403. Strategic Investment Research Unit, National Investment Promotion and Facilitation Agency, "India: Pharmacy to the World" (July 31, 2020) available at <https://rb.gy/da7uqg> last accessed August 29, 2022.

Authorization Requirements

- The authorizations and licenses for selling or importing pharmaceutical products are issued by the Medicines and Healthcare Products Agency under the Human Medicines Regulations 2012. The process of obtaining relevant clearance to sell the drugs is a costly and time-consuming process.
- Based on discussions with stakeholders, a full-fledged mutual recognition agreement is highly unlikely to be agreed upon between the Indian government and the UK government, given the vastly differing standards of good manufacturing practices being followed in India. Therefore, India should move towards harmonizing its good manufacturing practices and other compliances with global standards, which will then allow India to bargain for a mutually recognized agreement with the UK government in the future. In the interim, India may suggest mutual recognition based on a third country reference regulatory authorities' approval.

Pricing Mechanism

- Certain policies/regulations directly or indirectly affect the pricing of drug sales made to the National Health Service. Also, the Health Service Medical Supplies (Costs) Act 2017 empowers the Secretary of State to control the prices of generic drugs. However, the Health Service Medical Supplies (Costs) Act 2017 is intended to be used where due to a lack of competition in the market, companies charge unreasonably high prices for generic drugs (and not in every case of sales of generic drugs).
- The Indian government may consider discussing the impact of price control policies/regulations in the UK with the industry.

Packaging and Labelling Requirements

- The packaging and labelling requirements are enlisted in the Human Medicines Regulations 2012. The requirements are standard and do not appear to place any excessive burden on manufacturers.

Intellectual Property Rights

- The process of securing a patent is a time-consuming process. However, once granted, patent protection is accorded for 20 years. Thereafter, a 'Supplementary Protection Certificate' is available for 5 years which comes into force when the patent expires – this affords similar protection to the active ingredient that is under patent protection. The duration of patent extensions is shorter in the UK than in countries such as Canada and the United States. The Indian government should maintain the position that this period should not be extended further.
- Separately, the Indian generic companies cannot do a 'Day One' launch in the UK during the SPC term. It is recommended that the Indian Government discusses the possibility of exports of drug products being allowed into the UK from India immediately after the patent term expiry to allow for a 'Day One' launch. If the UK Government provides an SPC waiver to Indian companies, these companies would be able sell the product on 'Day One' of the SPC expiry. This would be advantageous since it would help Indian generic companies to enter the market on time and it would ease the burden on the supply chain.
- Further, a pre-grant opposition/observation system is in place whereby the application for a patent can be opposed once it is published and before the patent is granted. The opposition system may provide generic manufacturers with an avenue to oppose patents in the UK. The Indian government may, however, consider discussing whether the UK patent system/patent opposition system is a concern for Indian manufacturers.
- Furthermore, the UK also provides market exclusivity for a period of 8 years and generic companies can apply for authorization to sell a drug after 8 years of the originator receiving the authorization. It takes up to 10 to 11 years for generic companies to receive authorization. Once the generic companies receive the authorization, it has to wait until the expiry of the patent or 'Supplementary Protection Certificate' (if available) and/or the market exclusivity given to the originator. The duration of exclusivity is shorter in the UK than in countries such as the US. The Indian government should maintain the position that this period should not be extended further.

Labelling Requirements

- The packaging and labelling requirements are enlisted in the HMR. The requirements are standard and do not appear to place any excessive burden on manufacturers.

Intellectual Property Rights

- The process of securing a patent is a time-consuming process. However, once granted, patent protection is accorded for 20 years. Thereafter, a **supplementary protection certificate** ("**SPC**") is available for 5 years which comes into force when the patent expires – this affords similar protection to the active ingredient that is under patent protection. The duration of patent extensions is shorter in the UK than in countries such as Canada and the United States. The Indian Government should maintain the position that this period should not be extended further. In addition, the Indian Government may consider discussing if the SPC system is a concern with Indian manufacturers.
- Further, a pre-grant opposition/observation system is in place whereby the application for a patent can be opposed once it is published and before the patent is granted. The opposition system may provide generic manufacturers with an avenue to oppose patents in the UK. The Indian Government may, however, consider discussing whether the UK patent system/patent opposition system is a concern for Indian manufacturers.
- Furthermore, the UK also provides market exclusivity for a period of 8 years and generic companies can apply for authorization to sell a drug after 8 years of the originator receiving the authorization. It takes up to 10 to 11 years for generic companies to receive authorization. Once the generic companies receive the authorization, it has to wait for until the expiry of the patent or SPC (if available) and/or the market exclusivity given to the originator. The duration of exclusivity is shorter in the UK than in countries such as the US. The Indian Government should maintain the position that this period should not be extended further.

Trade Remedies

- At the moment, there are no trade remedial measures in force against pharmaceutical products imported from India. However, certain Indian programs have been countervailed. If any Indian pharmaceutical company has availed the benefit of any of the schemes that have been countervailed, then the exports of those companies may be subjected to countervailing duty in the UK only if there is a domestic industry in the UK that complains to the UK trade-remedial authority.
- Further, it would be advisable to reaffirm that countervailing measures should be limited to excess remissions only and not extend to the full amount of assistance provided and that parties be notified in advance of any expected initiation of investigations, as a part of free trade agreement negotiations.
- Additionally, the Indian government should request that provisions requiring the UK to provide a reasonable opportunity for consultations before proceeding to initiate a trade remedial investigation be incorporated in the future free trade agreements.

Broad Subsidies

- The UK government launched a GBP 20 million fund under the Medicines and Diagnostics Manufacturing Transformation Fund. Private sector manufacturers involved in the manufacturing of human medicines, medical diagnostics, and medical technology, upon meeting certain mandatory criteria, can apply for and avail of the fund. The Indian government may consider discussing with the industry if they applied for and/or availed of the fund and if so, have they faced any constraints throughout the process. The Indian government may also consider discussing any concerns the industry may have about this policy.

Government Procurement

- As a result of the UK joining the Government Procurement Agreement, the government procurement suppliers will continue to have access to the majority of the UK's public procurement contracts while UK suppliers will continue to have access to global public procurement opportunities.
- Given almost the entirety of the pharmaceutical market is controlled by the UK government, it is critical that India is not discriminated in government procurement contracts, and therefore, it must protect its interest in the potential free trade agreement with the UK for easier access to the UK market.

Investment Barriers to Trade

- The National Security and Investment Act recently enacted by the UK empowers the UK government to make orders in connection with national security risks arising from the acquisition of control over certain types of entities and assets. The National Security and Investment Act introduces requirements for 17 core sectors like data infrastructure, energy, defense, transport, etc. and the pharmaceutical sector does not seem to form a part of it. Thus, there seems to be no specific restrictions on foreign investment in the UK in the pharmaceuticals sector.

COUNTRY SNAPSHOT

Sr. No.	Parameter	Description
1.	Region	Western Europe
2.	Country	United Kingdom
3.	Capital	London
4.	Population	67,844,000 (2023 est.)
5.	Population growth rate (%)	0.53% (2022 est.)
6.	GDP (PPP)	USD 3,780 (2022 est.)[404]
7.	GDP – real growth rate (%)	3.6% (2022 est.)[405]
8.	GDP – per capita (PPP)	USD 47,320 (2022 est.)[406]
9.	Exchange rates	1.2848 per USD (April 2020)
10.	Population below the poverty line	20% (2020/21 est.)[407]
11.	Disease profile	The top 10 causes of the total number of deaths in 2019, all ages combined were ischemic heart disease, stroke, COPD, lung cancer, lower respiratory infection, Alzheimer's disease, colorectal cancer, prostate cancer, breast cancer, and pancreatic cancer[408]
12.	Life expectancy	83 (2022)[409]
13.	Current Health Expenditure per capita	USD 4312.89 (2019)[410]
14	OOP Health Expenditure as % of health expenditure	17.07% (2019)[411]
15.	Age structure (%) (2023 est.)	**0–14 years**: 17.63%
		15–24 years: 11.49%
		25–54 years: 39.67%
		55–64 years: 12.73%
		65 years and over: 18.48%

Source: CIA World Fact Book updated to April 27, 2022[412] . International Monetary Fund World Economic Outlook updated to October 2022.[413] For exchange rates, please refer to Foreign Exchange Rates[414]

404. IMF, "GDP, current prices", available at <https://rb.gy/vhs34g>, last accessed February 24, 2023.
405. IMF, "Real GDP growth", available at <https://rb.gy/jcxwni> last accessed February 24, 2023.
406. IMF, "GDP per capita, current prices" available at <https://rb.gy/mumvqr> last accessed February 24,2023.
407. House of Commons Library, "Poverty in the UK: Statistics" available at <https://rb.gy/ctgsxl> last accessed February 20, 2023.
408. Institute for Health Metrics and Evaluation, "United Kingdom" available at <https://rb.gy/is4naa> last accessed February 20, 2023.
409. UK Government, "Mortality Insights from GAD – July 2022" available at <https://rb.gy/z5aj8d> last accessed February 23, 2023.
410. The World Bank, "Current health expenditure per capita (current USD) – United Kingdom" available at <https://rb.gy/xuuweq> last accessed February 20, 2022.
411. The World Bank, "Out-of-pocket expenditure (% of current health expenditure) – United Kingdom" available at <https://rb.gy/gcvccw> last accessed February 20, 2022.
412. The World Fact Book, 2022, "United Kingdom – Europe" available at <https://rb.gy/2qmcnx> last accessed August 29, 2022.
413. "World Economic Outlook (October 2022) - GDP, current prices" available at <https://rb.gy/lzriu5> last accessed February 23, 2022
414. The Board of Governors of the Federal Reserve System, "Foreign Exchange Rates – H.10" available at <https://rb.gy/4wqa4s> last accessed August 29, 2022.

A. MARKET OVERVIEW

According to the **Directorate General of Commercial Intelligence and Statistics** ("**DGCI&S**"), Department of Commerce,[415] India's pharmaceutical exports (under Chapter 30) to the UK stood at USD 614.61 million in FY 2021-2022 and USD 618.34 million in FY 2020-2021.

Details of India's pharmaceutical exports to the UK disaggregated at the HS 4-digit level are provided below.

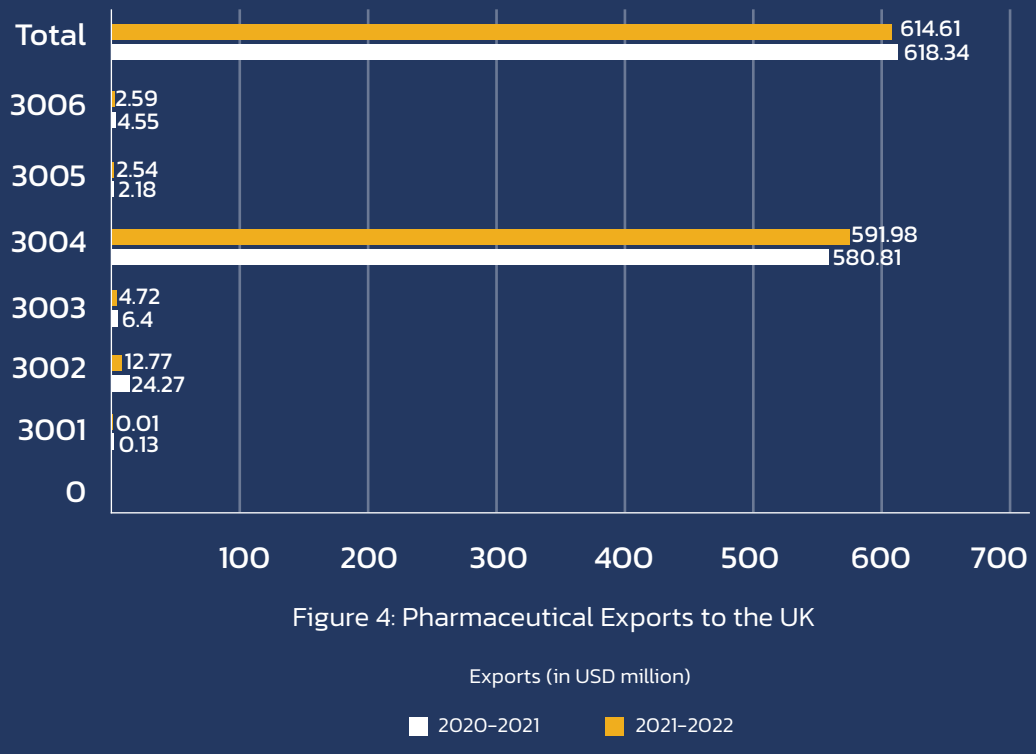


Figure 4: Pharmaceutical Exports to the UK

Source: DGCI&S

415. Export-Import Data Bank Version 7.1, Department of Commerce, Government of India available at <https://rb.gy/41jtxg> last accessed November 23, 2022.

Table 5: Exports of Pharmaceutical Products to UK

Heading	Description	Exports in FY 2020-2021 (in Million USD)	Exports in FY 2021-2022 (in Million USD)
3001	Glands and other organs for therapeutic uses, dried, whether or not powdered; extracts of glands	0.13	0.01
3002	Human, animal blood for medicinal use; Manufactured Immunological products w/n Biotech processes. Vaccines, Human, Animal blood for medicinal use; manufactured immunological products w/n biotech processes, vaccines etc.	24.27	12.77
3003	Medicaments (Excluding goods of headings no. 3002, 3005, or 3006), consisting of 2 or more constituents mixed together for human medicine. Not for retail sale	6.4	4.72
3004	Medicaments (Excluding items of 3002, 3005, 3006) for therapeutic/prophylactic uses in measured doses or in packaging for retail sale	580.81	591.98
3005	Wadding, gauze, bandages, and similar articles (for example, dressings, adhesive plasters, poultices), impregnated	2.18	2.54
3006	Miscellaneous pharmaceutical goods	4.55	2.59
	Total	**618.34**	**614.61**

Source: Directorate General of Commercial Intelligence and Statistics

According to the Organization for Economic Co-operation and Development (**OECD**) Health Statistics 2021, about 85% of the pharmaceutical products sold in the UK were generic drugs. It is the highest among European countries.[416] Clearly, the UK is an important target market considering India's price advantage because of lower labor costs[417] and manufacturing capacity for generic drug production.

416. OECD iLibrary, "Health at a Glance 2021: OECD Indicators" available at <https://rb.gy/j0hnhm> last accessed August 29, 2022.
417. Strategic Investment Research Unit, National Investment Promotion and Facilitation Agency, "India: Pharmacy to the World" (July 31, 2020) available at <https://rb.gy/da7uqg> last accessed August 29, 2022.

B. REGULATORY ENVIRONMENT

The MHRA[418], an executive agency of the **Department of Health and Social Care** ("**DHSC**"), is responsible for regulating medicines, medical devices, and blood components for transfusion in the UK.

The **Human Medicines Regulations 2012** ("**HMR**")[419] is the key legislation concerning "medicinal products"[420] for human use within the UK.[421] It sets out a comprehensive regime for the authorization, manufacture, import, distribution, sale, and supply of medicinal products, their labelling, advertising, and pharmacovigilance.[422]

418. Government of the United Kingdom, "Medicines, Medical Devices: About Us" available at <https://rb.gy/evp3ta> last accessed August 29, 2022.
419. The Human Medicines Regulations 2012.
420. The Human Medicines Regulations 2012, Regulation 2: "Medicinal product means "...(a) any substance or combination of substances presented as having properties of preventing or treating disease in human beings; or (b) any substance or combination of substances that may be used by or administered to human beings with a view to— (i) restoring, correcting or modifying a physiological function by exerting a pharmacological, immunological or metabolic action, or (ii) making a medical diagnosis.""
421. John Leadley, William Jones, Julia Gillert, "Promoting Medical Products Globally, Handbook of Pharma and MedTech Compliance: United Kingdom" Baker McKenzie available at <https://rb.gy/qazmjn> last accessed August 29, 2022.
422. Department of Health, National Institute of Health "Legislation covering medicines" <https://rb.gy/zq7x6b> last accessed August 29, 2022.

TARIFF & CUSTOMS BARRIERS

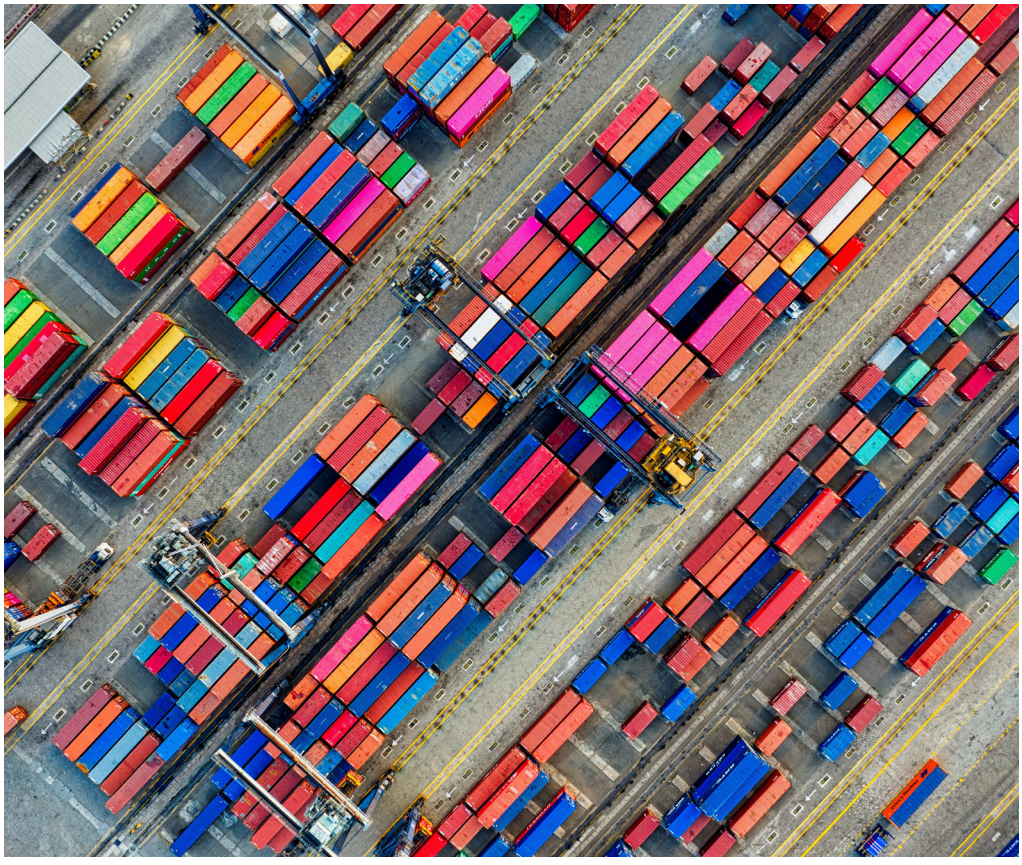
A. OVERVIEW

The UK, in May 2020, announced its Most Favoured Nation tax regime ("**UK Global Tariff**"), replacing the EU Common Customs Tariff.[423] The UK Global Tariff has doubled the number of products that are tariff-free compared to the EU Common Customs Tariff.[424]

According to the UK Global Tariff[425], the imports of all the products falling under Chapter 30 are subject to a nil rate of duty. There are no tariff-rate quotas on imports of pharmaceutical products as well under the UK Tariff Rate Quotas 2022.[426]

SUGGESTIONS

In light of the above, tariff barriers do not appear to be a significant concern for Indian exporters of pharmaceuticals to the UK. However, India should urge the UK to make tariff commitments of 0% basic customs duty and tariff-rate quota on imports of all pharmaceutical products under the potential free trade agreement between India and the UK.



423. United States Trade Representative, "2022 National Trade Estimate Report on Foreign Trade Barriers" available at <https://rb.gy/squeso> last accessed August 29, 2022.
424. United States Trade Representative, "2022 National Trade Estimate Report on Foreign Trade Barriers" available at <https://rb.gy/squeso> last accessed August 29, 2022.
425. Government of the United Kingdom, "Reference Document for the Customs Tariff (Establishment) (EU Exit) Regulations 2020 and the Tariff of the United Kingdom, version 1.10, dated 10 July 2022" available at <https://rb.gy/hthfee> last accessed August 29, 2022.
426. Government of the United Kingdom, "UK Tariff Rate Quotas 2022" available at <https://rb.gy/hthfee> last accessed August 29, 2022.

TECHNICAL BARRIERS TO TRADE

A. AUTHORIZATION REQUIREMENTS

- Medicinal products[427] are authorized for sale, supply or offer to sell or supply in UK only upon receiving a market authorization[428], a certificate of registration[429], a traditional herbal registration[430], an Article 126a authorization,[431] or wholesale dealers license[432], as may be applicable.
- However, in order to secure any of the above authorizations/certifications (except the wholesaler dealers license), an applicant must be established in the European Union.[433]
- Additionally, companies are authorized to import into the UK upon receiving a manufacturers license.

427. The Human Medicines Regulations 2012, Regulation 2: Medicinal product means:
"(a) any substance or combination of substances presented as having properties of preventing or treating disease in human beings; or
(b) any substance or combination of substances that may be used by or administered to human beings with a view to —
(i) restoring, correcting, or modifying a physiological function by exerting a pharmacological, immunological, or metabolic action, or
(ii) making a medical diagnosis."
428. The Human Medicines Regulations 2012, Regulation 46 read with Part 5.
429. The Human Medicines Regulations 2012, Regulation 46 read with Part 6.
430. The Human Medicines Regulations 2012, Regulation 46 read with Part 7.
431. The Human Medicines Regulations 2012, Regulation 46 read with Part 8.
432. The Human Medicines Regulations 2012, Regulation 46 read with Part 3.
433. The Human Medicines Regulations 2012, Regulation 46 read with Part 5 to 8.

i. Wholesale Dealers License

- A wholesale dealers license, in general, does not authorize the selling or supplying of medicinal products, or possession of the medicinal product for the purposes of selling or supplying, unless a marketing authorization, Article 126a authorization, certificate of registration, or traditional herbal registration is in force in respect of the product.[434] However, if the sale, or supply, or offer to sell or supply is of a special medicinal product, a wholesale dealers license will suffice.[435]
  - A medicinal product may qualify as a special medicinal product if:[436]
  - The medicinal product is supplied in response to an unsolicited order.
  - The medicinal product is manufactured and assembled as per the specifications of the doctor, dentist, nurse independent prescriber, pharmacist independent prescriber or supplementary prescriber.
  - The medicinal product is for use by a special needs patient.
  - The medicinal product is supplied – to a doctor, dentist, nurse independent prescriber, pharmacist independent prescriber, or supplementary prescriber; or for use under the supervision of a pharmacist in a registered pharmacy, a hospital, or a health centre.
  - No advertisement relating to the medicinal product is published by any person. The manufacture and assembly of the medicinal product are carried out under such supervision, and adequate precautions are taken.
- The companies that are interested in selling or supplying special medicinal products can obtain a wholesale dealers license.[437]
- The law requires that a wholesale dealers license be granted or refused within 90 days beginning after the day on which the application is received by the licensing authority.[438] Once a license is granted, the wholesale dealers have to comply with good distribution practices (among other obligations).
- The standard application fee for securing the wholesale dealers license is GBP 1,803, plus GBP 1,936 inspection fees. An annual fee of GBP 288 is also applicable to maintain the license.[439]

434. The Human Medicines Regulations 2012, Regulation 46 read with Regulation 18 (6).
435. The Human Medicines Regulations 2012, Regulation 46 read with Regulation 18 read with Regulation 43(6).
436. Special medicinal product means a product within the meaning of regulation 167 or any equivalent legislation in an EEA State other than the United Kingdom; - The Human Medicines Regulations 2012, Regulation 8.
437. The Human Medicines Regulations 2012, Regulation 46 read with Regulation 18.
438. The Human Medicines Regulations 2012, Regulation 46 read with Regulation 23.
439. Statutory guidance Current MHRA fees (September 2022) available at <https://rb.gy/duxgiu> last accessed September 17, 2022.

ii. Manufacturers License

- A person with a manufacturer's license in the UK can import medicinal products into UK from a foreign country. Foreign companies can also sell products to such persons with a manufacturer's license in the UK.[440]
- The manufacturer license holder is required to appoint a qualified person, who in case of imports of medicinal products from a foreign country will conduct all the necessary tests to ensure the quality of the medicinal products.[441] More specifically, if the medicinal product is imported from a non-**European Economic Area** ("**EEA**") state, irrespective of whether they are manufactured in the EEA state, the qualified person has to ensure that each batch of medicinal products has undergone, inter alia, the following[442] :
  - A full qualitative analysis
  - A quantitative analysis of all the active substances and
  - All other tests or check necessary to ensure the quality of medicinal products according to the requirements of the marketing authorization, Article 126a authorization, certificate of registration, or traditional herbal registration relating to those products.
- If the medicinal products are imported from a country with Mutual Recognition Agreement, the qualified person is not required to conduct a retesting of the products prior to releasing the products into the market.[443] UK accepts batch testing conducted on products in non-EEA countries like Australia, Canada, Israel, Japan, New Zealand, Switzerland, and the USA based on a Mutual Recognition Agreement with these countries.
- If batch testing were to be conducted, as per the discussion with the stakeholders, the process to complete the testing would take about 2 to 3 weeks and a cost of GBP 800 per batch will need to be incurred by the concerned foreign company, whose product is to be imported into the UK.

SUGGESTIONS

Based on discussions with stakeholders, a full-fledged mutual recognition agreement is highly unlikely to be agreed upon between the Indian government and the UK government, given the vastly differing standards of GMP being followed in India.

Therefore, India should move towards harmonizing its GMP and other compliances with global standards, which will then allow India to bargain for MRA with the UK government in the future. This will help Indian pharmaceutical products reach the UK market faster, and reduce working capital/ batch testing costs, thereby making Indian products more competitive.

440. The Human Medicines Regulations 2012, Regulation 46 read with Regulation 17.
441. Government of the United Kingdom, "Guidance – Apply for manufacturer or wholesaler of medicines licences" available at <https://rb.gy/qycfeq> last accessed September 17, 2022.
442. The Human Medicines Regulations 2012, Para 12 of Schedule 7.
443. Government of the United Kingdom, "Guidance – Apply for manufacturer or wholesaler of medicines licences" available at <https://rb.gy/qycfeq> last accessed September 17, 2022; and The Human Medicines Regulations 2012, Para 14 of Schedule 7.

B. RESTRICTIVE PRICING MECHANISM

- As per secondary sources, the sale of pharmaceutical products is not subject to direct price controls but is priced by the manufacturers.[444] However, a number of factors including government and **National Health Service** ("**NHS**") policies, commercial arrangements between the drug companies and the NHS, and competition affect drug pricing in the UK.[445] Further, the UK introduced the Medical Supplies Act to address instances of excessive and unfair pricing of generic medicines.[446]
- The NHS funds the majority of medicines prescribed to patients in the UK[447] and it is considered the market for pharmaceutical companies. The private healthcare market is therefore very minuscule compared to the NHS. According to secondary sources, such centralized buying power gives the NHS the upper hand to a great extent in pricing negotiations and discounts based on volume sales. In addition, the following schemes/regulations are set to create direct or indirect restrictions on the pricing or drive price competition of medicines in the UK.
  - Reimbursement framework[448]
  - The branded medicines supplied to NHS are subject to price control schemes:
    - **Voluntary Scheme for Branded Medicines Pricing and Access** ("**Voluntary Scheme**")
    - Statutory Scheme
  - Medical Supplies Act
- Reimbursement framework: The NHS issues drug tariffs[449] i.e., the basic price for drugs listed under Part VIII[450] Drug Tariff. NHS pays this price to a pharmacy upon receiving the relevant drug from the pharmacy. Given that the pharmacies are aware of the drug tariff for a relevant drug, it creates an incentive for the pharmacy to secure a drug with the lowest price from the market in order to be able to sell the same to NHS at a higher margin.[451] This creates competition between the suppliers to provide the relevant drugs for the lowest price.[452]
- Voluntary Scheme: The Voluntary Scheme is an arrangement agreement between the **Association of the British Pharmaceutical Industry** ("**ABPI**") and the Department of Health and is applicable to all branded medicines, irrespective of whether they are patent protected or not.[453] Under this scheme, the price of a new product must be approved by the Department of Health.[454] Further, the supplier of the drugs may not increase the list price of the said drugs without the prior approval of the Department of Health. However, in order to avoid stifling of innovation, the supplier is allowed to increase the list price of the concerned drugs (that contain new active substances) launched in the UK within 36 months from granting of market authorization. This is further subject to providing significant discounts to NHS.[455]

444. NHS Support Federation, "Billions are spent by the NHS on drugs every year, but how does it work?" (March 31, 2021) The Lowdown available at <https://rb.gy/7kgg5c> last accessed August 29, 2022.
445. Grant Castle, Brian Kelly & Raj Gathani, "Global Legal Insights: Pricing & Reimbursement 2020, United Kingdom" Global Legal Group available at <https://rb.gy/vaidxo> last accessed August 29, 2022.
446. National Audit Office, "Investigation into NHS spending on generic medicines in primary care, Department of Health and Social Care" available at <https://rb.gy/hdi6lk> last accessed September 17, 2022.
447. Grant Castle, Brian Kelly & Raj Gathani, "Global Legal Insights: Pricing & Reimbursement 2020, United Kingdom" Global Legal Group available at <https://rb.gy/vaidxo> last accessed August 29, 2022.
448. Oxera, "The supply of generic medicines in the UK" available at <https://rb.gy/gp5ofs> last accessed November 23, 2022.
449. Drug Tariff, available at <https://rb.gy/alvnr4> last accessed September 17, 2022.
450. Part VIII of Drug Tariff, available at <https://rb.gy/lwsaqj>, last accessed September 17, 2022.
451. Oxera, "The supply of generic medicines in the UK" available at <https://rb.gy/gp5ofs> last accessed November 23, 2022.
452. Oxera, "The supply of generic medicines in the UK" available at <https://rb.gy/gp5ofs> last accessed November 23, 2022.
453. Oxera, "The supply of generic medicines in the UK" available at <https://rb.gy/gp5ofs> last accessed November 23, 2022.
454. Oxera, "The supply of generic medicines in the UK" available at <https://rb.gy/gp5ofs> last accessed November 23, 2022.
455. Grant Castle, Brian Kelly & Raj Gathani, "Global Legal Insights: Pricing & Reimbursement 2020, United Kingdom" Global Legal Group available at <https://rb.gy/vaidxo> last accessed August 29, 2022.

- Statutory Scheme: The manufacturers/suppliers of the branded medicines that do not participate in the Voluntary Scheme, are by default subject to the Statutory Scheme.[456] Under the Statutory Scheme, the price increase requires the approval of the Secretary of State, who takes into account several factors including the following while providing its approval:
  - The clinical need for the product;
  - The cost of therapeutically equivalent or comparable products (including in other European Economic Area countries);
  - If the product contains a new active substance; and
  - Estimated profits and other financial parameters, etc
- Medical Supplies Act: Since 2016, the Competition and Markets Authority, i.e., the competition regulator in the UK, issued statements/infringement decisions[457] concerning certain generic medicine companies involved in excessive and unfair pricing.
- In order to tackle such excessive and unfair pricing, the Medical Supplies Act was introduced. Thus, while the prices of generic drugs are normally controlled by market forces, the Medical Supplies Act gives the power to the Secretary of State to require companies to reduce the price of generic medicine or impose other controls on that company's unbranded generic medicines. According to the factsheet to the Medical Supplies, it seems that these powers are intended to be used where due to a lack of competition in the market, companies charge unreasonably high prices for unbranded generic medicines (and not in all cases of generic medicines).[458]

SUGGESTIONS

In light of the above, certain schemes/regulations are set to create direct or indirect restrictions on the pricing or drive price competition of medicines in the UK.

Also, the Medical Supplies Act seems to aim to address only unfair and excessive pricing of generic medicines. The Indian government may consider discussing the impact of price control policies/ regulations in the UK with the industry.

456. National Health Service Act 2006, Sections 262–264.
457. National Audit Office,"Investigation into NHS spending on generic medicines in primary care, Department of Health and Social Care" available at <https://rb.gy/hdi6lk> last accessed September 17, 2022: "These include cases where companies had allegedly de-branded a medicine, making it generic and no longer subject to price regulation, and then used their market dominance to increase prices unfairly. The Competition and Markets Authority told us that it also has a number of active cases which involve suspected anti-competitive behaviour by pharmaceutical companies, relating to generic medicines."
458. Government of the United Kingdom, "Guidance - Apply for manufacturer or wholesaler of medicines licences" available at <https://rb.gy/qycfeq> last accessed September 17, 2022.

C. PACKING AND LABELLING REQUIREMENTS

- The HMR prescribes detailed labelling and packaging requirements for medicinal products.
- For instance, the labelling must contain all the information required under Schedule 24 of the HMR. Certain information which is considered critical for the safe use of the medicinal product is as follows:
  - Name of the medicine
  - Expression of strength (where relevant)
  - Route of administration
  - Posology
  - Warnings
- At the time of applying for market authorization, the applicant is required to submit one or more mock-ups of the outer packaging and immediate packaging proposed for the product; and a draft package leaflet to the concerned licensing authority.[459]
- Further, there is a mandate to express the name of a medicinal product in Braille format on the outer packaging of the product or on the immediate packaging of the product.[460]
- In addition, the containers of regulated medicines[461] are required to be child-resistant and opaque or dark-tinted.[462] Containers that are not reclosable will be considered child-resistant if they comply with the requirement of British Standard EN 14375:2003 published by the British Standards Institution on April 18, 2005 and containers that are reclosable need to comply with the requirement of British Standard EN ISO 8317:2004 published by the British Standards Institution on May 11, 2005.[463] These containers can also be in line with any equivalent or higher technical specification for non-reclosable/ reclosable child-resistant packaging that is recognized for use in the European Economic Area.[464]
- Also, specific instructions have been provided for packaging and labelling of paracetamol, a few of which are provided below:
  - Medicinal products, which are meant for children under age 12 and are in solid form and contain aspirin or paracetamol are required to be of white color and all the other colors are prohibited.[465]
  - In the leaflets for the medicines containing paracetamol a warning that too much paracetamol can cause delayed, serious liver damage needs to be provided.[466]
  - A warning that "Do not take more medicine than the label tells you to. If you do not get better, talk to your doctor", needs to be provided adjacent to either the directions for use or the recommended dosage.[467] In addition, an instruction specifying "Do not take anything else containing paracetamol while taking this medicine" needs to be mentioned too.[468]

459. The Human Medicines Regulations 2012, Regulation 267.
460. The Human Medicines Regulations 2012, Regulation 259.
461. Human Medicines Regulations 2012, Regulation 272: "regulated medicinal product" means a medicinal product containing aspirin, paracetamol or more than 24mg of elemental iron, in the form of tablets, capsules, pills, lozenges, pastilles, suppositories or oral liquids, but does not include— (a) effervescent tablets containing not more than 25% of aspirin or paracetamol by weight; (b) medicinal products in sachets or other sealed containers which hold only one dose; (c) medicinal products which are not intended for retail sale or for supply in circumstances corresponding to retail sale; or (d) medicinal products which are for export only..."
462. The Human Medicines Regulations 2012, Regulation 273.
463. The Human Medicines Regulations 2012, Regulation 273.
464. The Human Medicines Regulations 2012, Regulation 273.
465. The Human Medicines Regulations 2012, Regulation 275.
466. For the exact wording of the warning text, please refer to The Human Medicines Regulations 2012, Schedule 27 Part 2.
467. The Human Medicines Regulations 2012, Schedule 25 Part 4.
468. The Human Medicines Regulations 2012, Schedule 25 Part 4.

SUGGESTIONS

Such requirements are fairly standard across the world and are unlikely to impact multinational pharmaceutical companies. However, this may be a cause for concern for the MSME sector as it may increase their costs

TRADE REMEDIAL MEASURES

- The **Trade Remedies Authority**[469] ("**TRA**") is the relevant investigating authority to assess injury to UK industries that may be caused by unfair trading practices and unforeseen surges in imports. Relevant provisions for investigation and levy of anti-dumping, countervailing duty, and safeguard measures are provided in Taxation (Cross-border Trade) Act 2018.[470]
- The trade remedy measures imposed by the European Commission were adopted by the UK post-Brexit.[471]
- There have been no specific trade remedy actions against Indian pharmaceutical products. However, in certain countervailing investigations[472] following schemes/ benefits prevailing in India were considered to be countervailable:

469. Government of the United Kingdom, "Trade Remedies Authority" available at <https://rb.gy/yp4qe4> last accessed August 29, 2022.
470. Please refer to Taxation (Cross-border Trade) Act 2018, ss 13, 14, 15 along with Schedule 4 and 5.
471. Government of the United Kingdom, "Guidance – Apply for manufacturer or wholesaler of medicines licences" available at <https://rb.gy/qycfeq> last accessed September 17, 2022.
472. See Commission Implementing Regulation (EU) 2022/433 – imposing definitive countervailing duties on imports of stainless steel cold-rolled flat products originating in India and Indonesia and amending Implementing Regulation (EU) 2021/2012 imposing a definitive anti-dumping duty and definitively collecting the provisional duty imposed on imports of stainless steel cold-rolled flat products originating in India and Indonesia [2022] OJ L 88/24.; European Commission (2021/C 90/06) on the Notice of initiation of an expiry review of the anti-subsidy measures applicable to imports of tubes and pipes of ductile cast iron originating in India [2021] OJ C 90/8; and Request for the initiation of an expiry review of the anti-subsidy measures on imports of certain graphite electrode systems originating in India, Executive summary, European Commission.

SUGGESTIONS

- Considering there are no trade remedial investigations launched by the UK concerning imports of pharmaceuticals in India, this does not represent a significant barrier for Indian exporters.
- However, if any Indian pharmaceutical company has availed the benefit of any of the schemes that have been listed above, then the exports of those companies may be subjected to countervailing duty only if there is a domestic industry in the UK that complains to the UK trade-remedial authority.
- Further, it would be advisable to reaffirm that countervailing measures should be limited to excess remissions only and not extend to the full amount of assistance provided and that parties be notified in advance of any expected initiation of investigations, as a part of FTA negotiations.
- Additionally, the Indian government should request that provisions requiring the UK to provide a reasonable opportunity for consultations before proceeding to initiate a trade remedial investigation be incorporated in the future FTA. Similar provisions exist in some of India's existing FTAs, such as the India-Korea CEPA for example.

INTELLECTUAL PROPERTY PROTECTION

A. PATENT

- The Patent Act 1977[473] regulates granting of patents in the UK and the governing body responsible for granting patents is the UK Intellectual Property Office ("**IPO**").
- A patent may be granted in respect of an invention if the invention is new, it involves an inventive step, it is capable of industrial application; and it is not specifically excluded from protection as a patent.[474] No patent protection is, however, available for[475] :
  - A method of treatment of the human or animal body by surgery or therapy, or
  - A method of diagnosis practiced on the human or animal body.
- The process of obtaining a patent generally takes up to 5 years.[476] The typical stages involved in this process are:[477]
  - Filing of application
  - Basic examination by IPO to ascertain if the application is complete and is in the right format
  - Search by IPO within 6 months from the application to confirm if the invention is new
  - Publication of the patent application by IPO (normally with the search report) – this is 18 months after the date of filing of the application
  - Substantive examination by IPO of the application
  - Addressing examiner's objections
  - Grant of patent
- Once patent protection is granted, it lasts for 20 years. But for it to remain in force for 20 years, it must be renewed on the 4th anniversary of the filing date and every year after that.[478] The following costs are expected to be incurred by the applicant seeking patent protection.[479]

473. Government of the United Kingdom, "Statutory guidance – The Patents Act 1977" available at <https://rb.gy/ffpw3b> last accessed September 17, 2022.
474. The Patents Act 1977, Section 1.
475. The Patents Act 1977, Section 4A.
476. Government of the United Kingdom, "Apply for a Patent" available at <https://rb.gy/eozfhr> last accessed August 29, 2022.
477. Thomson Reuters, "Pharmaceutical IP and Competition Law in the UK: Overview" available at <https://rb.gy/nftmuv> last accessed September 17, 2022.
478. The Patents Act 1977, Section 25.
479. Government of the United Kingdom, "Apply for a Patent – Overview" available at <https://rb.gy/he5nhu> last accessed September 17, 2022; Government of the United Kingdom, "Apply for a Patent" available at <https://rb.gy/eozfhr> last accessed August 29, 2022.

Stage	If application filed online	If application filed by post or email
Filing an application (if you pay when you apply)	GBP 60	GBP 90
Filing an application (if you pay later)	GBP 75	GBP 112.50
Search	GBP 150 (plus GBP 20 for each claim over 25 claims)	GBP 180 (plus GBP 20 for each claim over 25 claims)
Substantive examination	GBP 100 (plus GBP 10 for each page of description over 35 pages)	GBP 130 (plus GBP 10 for each page of description over 35 pages)

Pre-grant opposition/observation is allowed under the Patent Act wherein the application can be opposed once it is published and before the patent is granted. The IPO is required to take the same into consideration.[480]

SUGGESTIONS

The patent opposition system may provide generic manufacturers with an avenue to oppose patents in the UK. The Indian government may consider discussing whether the UK patent system/patent opposition system is a concern for Indian manufacturers in any manner.

480. The Patents Act 1977, Section 21.

B. PATENT TERM EXTENSION

- In the UK, an SPC of up to 5 years is granted to a patent holder protecting the active ingredient. While it does not extend the patent itself, it is seen as a tool to compensate for the long time needed to obtain regulatory approvals and effectively accord extended protection to the patented product.[481]
- An SPC can be granted only to a patent holder of the active ingredient. At the same time, marketing authorization must have been granted to place the active ingredient on the UK market, as a pharmaceutical or plant protection product.[482]
- SPC enters into force when the patent expires, and it lasts for 5 years.[483]

SUGGESTIONS

In general, the duration of patent extensions is shorter in the UK than in countries such as Canada and the United States. The Indian government should maintain the position that this period should not be extended further.

Separately, the Indian generic companies cannot do a 'Day One' launch in the UK during the SPC term. It is recommended that the Indian Government discusses the possibility of exports of drug products being allowed into the UK from India immediately after the patent term expiry to allow for a 'Day One' launch. If the UK Government provides an SPC waiver to Indian companies, these companies would be able sell the product on 'Day One' of the SPC expiry. This would be advantageous since it would help Indian generic companies to enter the market on time and it would ease the burden on the supply chain.

C. MARKET EXCLUSIVITY

- The UK also provides market exclusivity for a period of 8 years and generic companies can apply for authorization to sell a drug after 8 years of the originator receiving the authorization. It takes up to 10 to 11 years for generic companies to receive authorization.[484] Once the generic companies receive the authorization, it has to wait until the expiry of the patent or SPC (if available) and/or the market exclusivity given to the originator.[485]
- The period of exclusivity granted in the UK is largely in line with and in some cases shorter than other highly regulated markets such as the EU and USA. For example, in the USA, market exclusivity for new drugs is 12.4 to 12.5 years.[486]

SUGGESTIONS

In general, the duration of exclusivity is shorter in the UK than in countries such as the USA. The Indian government should maintain the position that this period should not be extended further.

481. Government of the United Kingdom, "Guidance – Apply for manufacturer or wholesaler of medicines licences" available at <https://rb.gy/qycfeq> last accessed September 17, 2022.
482. Government of the United Kingdom, "Guidance – Apply for manufacturer or wholesaler of medicines licences" available at <https://rb.gy/qycfeq> last accessed September 17, 2022.
483. Government of the United Kingdom, "Guidance – Apply for manufacturer or wholesaler of medicines licences" available at <https://rb.gy/qycfeq> last accessed September 17, 2022.
484. British Generic Manufacturers Association Evidence, available at <https://rb.gy/ej1tmn> last accessed September 17, 2022.
485. Government of the United Kingdom, "Guidance – Apply for manufacturer or wholesaler of medicines licences" available at <https://rb.gy/qycfeq> last accessed September 17, 2022.
486. Henry G Grabowski and others, "Evolving Brand–Name and Generic Drug Competition May Warrant a Revision of The Hatch–Waxman Act" (2011) 30(11) Health Affairs 2157.

BROAD SUBSIDIES

A. MEDICINES AND DIAGNOSTICS MANUFACTURING TRANSFORMATION FUND

- The UK government launched a GBP 20 million fund for promoting life sciences companies and also expanding manufacturing in the UK.[487]The private sector manufacturers, upon meeting certain mandatory criteria, inter alia, as follows are allowed to apply for this fund:
- If a private sector business making investments in the UK is the applicant?
- The manufacturer is engaged in manufacturing the following items are said to be eligible for the funds[488] :
  - Human medicines
  - Medical diagnostics
  - Medical technologies
- If the eligible costs are no lower than GBP 8 million. (The government has not set any upper limit on the size of projects).[489]
- The last date for submitting the application under this fund was 2021.[490]

SUGGESTIONS

The Indian government may consider discussing with the industry if they applied for and/or availed of the fund and if so, have they faced any constraints throughout the process. The Indian government may also consider discussing any concerns the industry may have about this policy.

487. Government of the United Kingdom, "New £20 million fund to grow UK life sciences manufacturing opens for applications" (April 7, 2021) available at <https://rb.gy/eygg6e> last accessed August 29, 2022.
488. Government of the United Kingdom, "Medicines and diagnostics manufacturing transformation fund (closed to applications) (last updated May 21, 2021) available at <https://rb.gy/jezhub> last accessed August 29, 2022.
489. Government of the United Kingdom, "Medicines and diagnostics manufacturing transformation fund (closed to applications) (last updated May 21, 2021) available at <https://rb.gy/jezhub> last accessed August 29, 2022.
490. Government of the United Kingdom, "Medicines and diagnostics manufacturing transformation fund (closed to applications) (last updated May 21, 2021) available at <https://rb.gy/jezhub> last accessed August 29, 2022.

RESTRICTIONS ON GOVERNMENT PROCUREMENT

- The UK public procurement law in the UK was based on EU directives and general principles of the **Treaty on the Functioning of the European Union** ("**TFEU**") prior to Brexit.[491] The said directives were implemented into the UK law through regulations.[492] The said regulations that are currently in force are[493] :
  - The Public Contracts Regulations 2015
  - The Utilities Contracts Regulations 2016
  - The Concession Contracts Regulations 2016
  - The Defense and Security Public Contracts Regulations 2011
- NHS is the relevant agency in the UK that procures pharmaceutical products.[494] However, certain bidders may be excluded from the process for a variety of criminal offences and in other specific situations.[495]
- As a result of the UK joining the GPA on January 1, 2021,[496] not only do the GPA suppliers continue to have access to the majority of the UK's public procurement contracts but also UK suppliers continue to have access to global public procurement opportunities.[497]
- On December 24, 2020, trade and cooperation negotiators from the UK and the EU reached an agreement called the EU-UK Trade and Co-operation Agreement ("**TCA**"). As part of the TCA, UK and EU agreed to provide wider access to each other's procurement markets and to boost the transparency of the public procurement process.[498] The TCA confirms that regardless of coverage requirements, UK suppliers established in an EU member state must be treated no less favorably to domestic suppliers in regard to any procurement, and vice versa.[499]
- Canada-UK Trade Continuity Agreement also contains requirements with regard to government procurement.[500] As more treaties are signed, their influence on government procurement in the UK will continue to expand.

SUGGESTIONS

Given almost entirety of the pharmaceutical market is controlled by NHS, it is critical that India is not discriminated in government procurement contracts and therefore, it must protect its interest in the potential FTA with the UK for easier access to the UK market.

491. Government of the United Kingdom, "Public procurement policy" (last updated January 8, 2021) available at <https://rb.gy/2fznkd> last accessed August 29, 2022.
492. Government of the United Kingdom, "Public procurement policy" (last updated January 8, 2021) available at <https://rb.gy/2fznkd> last accessed August 29, 2022.
493. Government of the United Kingdom, "Public procurement policy" (last updated January 8, 2021) available at <https://rb.gy/2fznkd> last accessed August 29, 2022.
494. Institute for Government, "NHS Procurement" available at <https://rb.gy/huvi2e> last accessed August 29, 2022.
495. Government Commercial Function, "Annex A: Applying Exclusions in Public Procurement, Managing Conflicts of Interest and Whistleblowing, A Guide for Commercial and Procurement Professionals" available at <https://rb.gy/rewwwz> last accessed August 29, 2022.
496. World Trade Organization, "UK and Switzerland confirm participation in revised government procurement pact" (December 2, 2020) available at <https://rb.gy/bgfr6w> last accessed August 29, 2022.
497. Out-law Guide, Pinsent Masons, "Public procurement in post-Brexit UK" (January 22, 2021) available at <https://rb.gy/lpnmam> last accessed August 29, 2022.
498. UK public procurement post-Brexit (Lexology), available at <https://rb.gy/mh6ytt> last accessed September 17, 2022.
499. UK public procurement post-Brexit (Lexology), available at <https://rb.gy/mh6ytt> last accessed September 17, 2022.
500. Canada-UK Trade Continuity Agreement.

INVESTMENT BARRIERS RELEVANT TO THE PHARMACEUTICAL SECTOR

The UK government enacted the **National Security and Investment Act** ("**NSI**")[501] on January 4, 2022.[502] The NSI empowers the UK government to make orders in connection with national security risks arising from the acquisition of control over certain types of entities and assets.[503] This is seen as significantly strengthening the UK's existing investment screening powers.[504]

The NSI introduces certain requirements for about 17 core sectors including data infrastructure, energy, defence, transport, etc,[505] and the pharmaceutical sector seems to have not been included. Thus, there seem to be no specific restrictions on foreign investment in the pharmaceutical sector.

SUGGESTIONS

There are no significant barriers to investments in pharmaceutical sector in the UK.

501. National Security and Investment Act 2021.
502. National Security and Investment Act 2021.
503. National Security and Investment Act 2021, Introduction.
504. U.S. Department of State, "2021 Investment Climate Statements: United Kingdom" available at <https://rb.gy/yftqrp> last accessed August 29, 2022.
505. Covington Alert, "UK FDI: National Security & Investment Law is Approved by Parliament" (May 3, 2021) available at <https://rb.gy/edqnq9> last accessed August 29, 2022.

USA

EXECUTIVE SUMMARY

INTRODUCTION

India exports the largest share of pharmaceutical products to the **United States of America** ("**United States**" or "**USA**" or "**U.S.**"). Indian pharmaceutical exports to the USA were estimated to be valued at Indian pharmaceutical exports to the USA were estimated to be valued at USD 6.47 billion in 2021. This constitutes 33.34% of India's total exports of pharmaceutical products to the world.

KEY FINDINGS, ISSUES AND RECOMMENDATIONS

Customs and Tariff Barriers

- Most products falling under Chapter 30 are subject to Nil duties. The only product groups that are subject to duties are certain lubricants and waste pharmaceuticals. Hence, tariff barriers do not appear to be a significant concern.

Drug registration requirements

- A drug manufacturer or potential marketer of a drug must obtain market approval before the drug can be sold in the market. The primary regulator in the process is the Food and Drugs Administration ("**FDA**").
- First, the drug must undergo clinical trials where its safety and efficacy are investigated. This takes place in 3 phases, through an application to the FDA known as the 'Investigational New Drug Application.'
- Second, once the third phase of the clinical trials is completed and the 'Investigation New Drug Application' has been approved, a 'New Drug Application' may be filed with the FDA.
- The application and program fees for these approvals are high. The clinical trials may take several years, and there may be several administrative delays. Expedited programs for serious conditions are available but are restricted to drugs for serious diseases and conditions. The FDA also accepts foreign clinical studies as the basis for marketing approval applications. However, the manufacturers have to demonstrate that the production takes place in accordance with the requirements of the law of the United States.
- Therefore, the Indian government may propose that pharmaceutical goods which are recognized by regulatory authorities of certain other countries[506] are also recognized by the United States. This approach has been taken in the India – United Arab Emirates Comprehensive Economic Partnership Agreement as well. This will reduce the time taken for approvals. This is particularly important for complex pharmaceutical products. We understand that the European Medicines Agency is a regulatory authority that is likely to be accepted by the U.S. government for the purposes of recognition.
- India may also propose the commercialization of products which have already been approved in regulated markets such as Canada, the United Kingdom, and the European Union. This would further encourage Indian companies to form base in the United States, incentivizing investment, and employment opportunities in the United States.
- Last, India may also suggest applying lower fees to such types of approvals that are based on a mutual recognition agreement or on recognition from a reference regulatory authority.

Generic Drug Review process

- For a generic drug to be considered equivalent to the patented drug, a drug developer must apply for an 'Abbreviated New Drug' approval. The bioequivalence of the listed drug and the new drug must be demonstrated, along with information concerning the active ingredient(s) present in the new drug and the corresponding listed drug.
- The Indian government should emphasize the need to broaden the scope of bioequivalence for generic products in the United States. Commitments in this regard may be sought. Furthermore, it may be relevant to bring to the United States' notice the significant time taken for generic approvals and request expedited approvals where such product has established bioequivalence in other jurisdictions.

506. Such regulatory authorities of other countries are termed "Reference regulatory authorities"

Good Manufacturing Practices/GMP

- The Current Good Manufacturing Practice Regulations or the CGMP Regulations contain minimum requirements for the proper design, monitoring, and control of manufacturing processes and facilities. The failure to comply with the CGMP Regulations renders a drug 'adulterated' and the person responsible for the failure to comply is subject to regulatory action.
- The FDA conducts on-site inspections of a drug manufacturer's premises to ensure compliance with good manufacturing practices. In the event that the investigator(s) observe conditions which may violate the U.S. law, Form 483 is issued to firm management. The FDA Form 483 notifies the company's management of objectionable conditions. At the conclusion of an inspection, the FDA Form 483 is presented and discussed with the company's senior management. The Form 483 is not a final determination of violation, but is considered, along with the responses made by the manufacturing company, while making the final determination.
- Based on discussion with stakeholders we understand that a full-fledged mutual recognition agreement is highly unlikely to be agreed upon with the United States, given the vastly differing standards of good manufacturing practices being followed in India. Therefore, as a first step India should move towards harmonizing good manufacturing practices and other compliances with global standards, which will then allow India to bargain for a mutual recognition agreement in the future.
- In the absence of such mutual recognition agreement, the need for site inspections for the purposes of compliance with good manufacturing practices may be highlighted as unnecessary in cases where Indian drug manufacturers have received good manufacturing practices recognition in a third-party reference country.

Labelling Requirements

- Based on stakeholders' feedback, we understand that labelling requirements do not cast significant burden on large Indian pharmaceutical companies. However, varying labelling requirements may be a cause for concern for the micro, small and medium enterprises. For example, the United States has the following label content requirements, among others: principal intended action(s) of the drug and possible side effects of the drug. However, Indian law does not have any such labelling requirements. Such requirements are likely to drive up costs for small players.

Intellectual Property Rights

- Data exclusivity provides the holder of an approved new drug application protection from new competition in the marketplace for the innovation represented by its approved drug product. Therefore, during the period of data exclusivity of innovative drugs, generic drug applications and new drug applications which are based on the protected data (as evidence) do not get approved. The period for data exclusivity for different drugs ranges from 3-7 years.
- Anti-competitive practices through duplicative patents such as patent thickets and product hopping are causes of concern for generic drug manufacturers. Such practices allow brand pharmaceutical companies to gain monopoly over drugs for several decades.
- The United States, like India, has established formal procedures for pre and post grant opposition. During negotiations, India should not make any commitment relating to altering its patent opposition system.
- Patent term extension are available under the U.S. law. The law allows the extension of the term of a patent claiming a product that requires regulatory approval prior to being sold, or a method of using or manufacturing the product.
- In the United States, the principle of extraterritoriality can be extended in the following situations: (i) Direct infringement of patent, (ii) Contributory and induced infringement of patent, (iii) Extraterritorial Discovery, and (iv) International Exhaustion. The Indian government should strongly put forth the position that the scope of patent protection should be national and not extend into India.

Price Controls

- The Inflation Reduction Act of 2022 signed in August 2022, includes critical provisions for the pricing of prescription drugs. The Inflation Act of 2022 allows the U.S. health agencies to negotiate prices for certain high-cost drugs covered by Medicare, and to implement the negotiated prices starting in 2026. The drugs will be selected on an annual basis, in a staggered manner, for drug price negotiation.
- The Indian government may discuss the implications of such price controls with industry stakeholders.

Trade Remedies

- It may be useful to re-affirm that countervailing measures, if any, should be limited to excess remissions only and not extend to the full amount of assistance provided. Additionally, the Indian government should request that provisions requiring the United States to provide a reasonable opportunity for consultations before proceeding to initiate a trade remedial investigation be incorporated any future trade agreement.

Procurement

- India is not a party to the Government Procurement Agreement and hence imports from India to federal agencies are subject to the strict local content requirements of the United States. This may be a factor relevant to negotiations with the United States, and principles of non-discrimination may be agreed upon. Further, emphasis may be placed on appropriate dissemination of information regarding tenders.

COUNTRY SNAPSHOT

Sr. No.	Parameter	Description
1.	Region	North America
2.	Country	United States of America
3.	Capital	Washington D.C.
4.	Population	333,902,000 (2023 est.)
5.	Population growth rate (%)	0.47% (2023 est.)
6.	GDP (PPP)	USD 25,400 billion (2022 est.)[507]
7.	GDP – real growth rate (%)	1.6% (2022 est.)[508]
8.	GDP – per capita (PPP)	USD 75,180 (2022 est.)[509]
9.	Population below the poverty line	11.6% (2021 est.)
10.	Disease Profile	The top 10 causes of total number of deaths in 2019 across all ages were ischaemic heart disease, Alzheimer disease and other dementias, chronic obstructive pulmonary disease, stroke, trachea, bronchus, lung cancers, kidney disease, drug use disorders, hypertensive heart disease, colon and rectum cancers and diabetes mellitus.[510]
11.	Life Expectancy	79.1
12.	Current Health Expenditure per capita	16.8% of GDP
13.	OOP Health Expenditure as % of Health Expenditure	11.31% (2019)
14	Age structure (%) (2020 est.)	0–14 years – 18.46% (male 31,374,555/ female 30,034,37)
15.	Age structure (%) (2020 est.)	15–24 years – 12.91% (male 21,931,368/ female 21,006,463)
		25–54 years – 38.92% (male 64,893,670/female 64,564,565)
		55–64 years – 12.86% (male 20,690,736/female 22,091,808)
		65 years and above – 16.85% (2020 est.) (male 25,014,147/female 31,037,419)
		North America

Source: World Fact Book 2022[511] ,World Bank Data[512] , International Monetary Fund World Economic Outlook[513] , and U.S. Census Bureau[514]

507. IMF, "GDP, current prices", available at <https://rb.gy/vhs34g> last accessed February 24, 2023.
508. IMF, "Real GDP growth", available at <https://rb.gy/jcxwni> last accessed February 24, 2023.
509. IMF, "GDP per capita, current prices", available at <https://rb.gy/mumvqr> last accessed February 24, 2023.
510. World Health Organization, "The Global Health Observatory" available at < https://rb.gy/426oti> last accessed February 20, 2023.
511. The World Factbook 2022 "United States of America" Central Intelligence Agency, Federal Government of the United States available at < https://rb.gy/zurwkl> last accessed November 23, 2022.
512. World Bank, "World Bank Data" available at < https://rb.gy/b62kmv> last accessed November 23, 2022.
513. International Monetary Fund, "World Economic Outlook" available at <https://rb.gy/lzriu5> last accessed February 23, 2022
514. United States Census Bureau, "Income and Poverty in the United States: 2020" available at < https://rb.gy/fql96k> last accessed October 31, 2022.

India exports the largest share of pharmaceutical products to the **United States of America** ("**United States**" or "**USA**" or "**U.S.**"). USA constitutes 33.34% of India's total exports of pharmaceutical products to the world. [515]

In FY 2021-2022, Indian pharmaceutical exports to the US slightly dipped from about USD 7.1 billion to USD 6.47 billion in 2021-2022.

Details of India's pharmaceutical exports to the USA disaggregated at the HS 4-digit level are provided below:

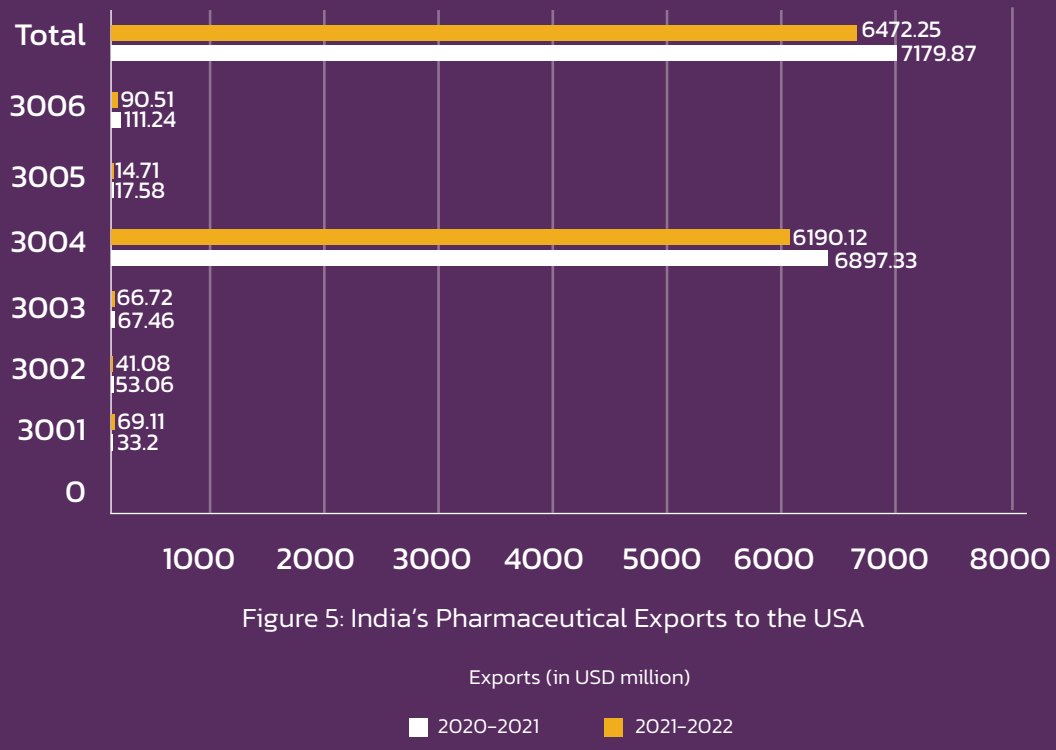


Figure 5: India's Pharmaceutical Exports to the USA

OVERVIEW

515. Export-Import Data Bank Version 7.1, Department of Commerce, Government of India available at < https://rb.gy/41jtxg> last accessed on November 23, 2022.

Figure 6: Exports of Pharmaceuticals to the USA

Heading	Description	Exports in FY 2020-2021 (in Million USD)	Exports in FY 2021-2022 (in Million USD)
3001	Glands, other Organs; Extracts of Glands or Other Organs	33.2	69.11
3002	Human or Animal Blood, Antisera and Other Blood Fractions, Vaccines, Toxins	53.06	41.08
3003	Medicaments	67.46	66.72
3004	Medicaments (Put up in Packings for Retail Sale)	6,897.33	6,190.12
3005	Wadding, Gauze, Bandages and Similar Articles	17.58	14.71
3006	Misc. Pharmaceutical Goods	111.24	90.51
	Total	**7179.87**	**6472.25**

Source: DGCI&S

A. REGULATING BODIES IN UNITED STATES

- The United States Department of **Health and Human Services** ("**HHS**") is the primary agency responsible for health regulation in the country.[516] The **Food and Drug Administration** ("**FDA**") is 1 of the 11 divisions of the HHS, which ensures the safety and purity of human and animal drugs, among other things.[517]
- The FDA consists of 9 organizations. **Center for Evaluation and Research** ("**CDER**") is tasked with regulation of over the counter and prescription drugs, including biological therapeutics and drugs.[518] CDER is the organization which reviews new drug applications, and has oversight responsibilities for prescription, over-the-counter and generic drugs.[519]

B. LAWS & POLICIES

- The **Federal Food, Drug, and Cosmetic Act** ("**FD&C Act**") is the key law governing marketing, distribution, and sale of drugs. It is intended to assure the consumer that the drugs and devices are safe and effective for their intended uses among others.[520]
- The **Manual of Policies and Procedures** ("**MaPPs**") provides official instructions for internal practices and procedures which are to be followed by the CDER to standardize the drug review process. [521]
- The 1984 Drug Price Competition and Patent Term Restoration Act (also known as the Hatch-Waxman Act) contains the process for identifying and litigating innovator companies' patent claims to determine when a generic firm can launch a competitor.[522]

516. FDA, "FDA Overview Organization Chart" available at <https://rb.gy/pzndk1> last accessed September 15, 2022
517. FDA, "FDA Overview Organization Chart" available at <https://rb.gy/pzndk1> last accessed September 15, 2022
518. FDA, "FDA Overview Organization Chart" available at <shttps://rb.gy/pzndk1> last accessed September 15, 2022
519. Narang, S., "Pharmaceutical Regulations in the United States. Pharmaceutical Medicine and Translational Clinical Research" (2018).
520. FDA, "Laws, Regulations, Policies and Procedures for Drug Applications" available at <https://rb.gy/wpnzhl> last accessed September 15, 2022.
521. FDA, "Laws, Regulations, Policies and Procedures for Drug Applications" available at <https://rb.gy/wpnzhl> last accessed September 15, 2022.
522. 21 U.S. Code § 355

TARIFF & CUSTOMS BARRIERS

The **Harmonized Tariff Schedule of the United States** ("**HTS**") provides the customs tariff for goods imported into the USA.[523] The **United States International Trade Commission** ("**USITC**") maintains and publishes the HTS pursuant to the Omnibus Trade and Competitiveness Act of 1988. However, the **Customs and Border Protection** ("**CBP**"), Department of Homeland Security is responsible for interpreting and enforcing the HTS.[524]

A majority of products falling under Chapter 30 of the HTS are subject to zero duties, barring certain lubricants, placeboes, and waste pharmaceuticals.[525] The tariffs applicable on such headings are as follows:

S No.	HS Code	Description	Unit of Quantity	MFN Tariff Rate
1	G3006.70.00	Gel preparations designed to be used in human or veterinary medicine as a lubricant for parts of the body for surgical operations or physical examinations or as a coupling agent between the body and medical instruments	kg	5%
2	3006.91.00	Appliances identifiable for ostomy use	kg	4.2%
3	3006.93.20	Waste Pharmaceuticals: Placeboes and clinical trial kits containing over 10 percent by dry weight of sugar	kg	4 0 ¢ / k g + 10.4%
4	3006.93.50	Waste Pharmaceuticals: Placeboes and clinical trial kits containing ingredients having nutritional value, in which starch or other foodstuff predominates by weight	-	6.4%
5	3006.93.60	Waste Pharmaceuticals: Placeboes and clinical trial kits in liquid form for oral intake.	Liters	0.2¢/liter
6	3006.93.80	Waste Pharmaceuticals: Placebos and clinical trial kits containing other chemicals other than medicaments	-	5%

SUGGESTIONS

Considering the above, tariff barriers do not appear to be a significant concern for Indian exporters of pharmaceuticals to the USA, and tariff commitments may not be a key factor in future negotiations with the USA as far as the pharmaceutical sector is concerned.

523. United States International Trade Commission, "Harmonized Tariff Information" available at <https://rb.gy/0scntd> last accessed September 15, 2022.
524. United States International Trade Commission, "Harmonized Tariff Information" available at <https://rb.gy/0scntd> last accessed September 15, 2022.
525. Chapter 30, HTS Revision 9 (2022) available at <https://rb.gy/rmzoyh> last accessed September 15, 2022.

A. MARKET AUTHORIZATION

Companies exporting drugs to the United States are required to register with the FDA. [526] Further, the new drugs and biological products must be approved by the FDA before they are marketed.[527]

i. Drug Review Process

Investigational New Drug Application

An **Investigational New Drug** ("**IND**") is a drug which has not been approved for general use by the FDA. It must undergo clinical trials where its safety and efficacy are investigated.

527. FDA, "Is It Really 'FDA Approved?' available at <https://rb.gy/kwivi0> last accessed September 15, 2022.

A manufacturer or potential marketer (referred to as "**sponsor**" or "**applicant**" in this section) is required to submit an **Investigational New Drug application** ("**IND Application**") with the FDA to start clinical trial on humans.[528] The clinical investigation of a previously untested drug is divided into 3 phases, which may overlap.[529] The 3 phases of an investigation are as follows:

Phase	Objective	Number of Subjects	Description
Phase 1	Initial introduction of an investigational new drug into humans[530]	20-80 subjects[531]	• Sufficient information about the drug's pharmacokinetics and pharmacological effects should be obtained • Studies of drug metabolism, structure-activity relationships, and mechanism of action in humans, as well as studies in which investigational drugs are used as research tools to explore biological phenomena or disease processes are conducted.[532]
Phase 2	Effectiveness and side-effects of the drug[533]	Several hundred subjects[534]	• Controlled clinical studies conducted to evaluate the effectiveness of the drug for a particular indication or indications in patients with the said disease or condition are conducted • Determination the common short-term side effects and risks associated with the drug[535]
Phase 3	Overall benefit-risk analysis[536]	Several hundred to several thousand subjects.[537]	• Expanded controlled and uncontrolled trials are conducted • Trials are performed after preliminary evidence suggesting effectiveness of the drug has been obtained and are intended to gather the additional information about effectiveness and safety that is needed to evaluate the overall benefit-risk relationship of the drug and to provide an adequate basis for physician labelling. [538] • The applicant receives an IND approval at the end of the Phase 3 trials.

528. 21 CFR § 312.1; 21 CFR § 312.20(a), (b).
529. 21 CFR § 312.21.
530. 21 CFR § 312.21(a)(2).
531. 21 CFR § 312.21(a)(2).
532. 21 CFR § 312.21(a)(2).
533. 21 CFR § 312.21(b).
534. 21 CFR § 312.21(b).
535. 21 CFR § 312.21(b).
536. 21 CFR § 312.21(c).
537. 21 CFR § 312.21(c).
538. 21 CFR § 312.21(c).

New Drug Application

- Through a **New Drug Application** ("**NDA**"), sponsors formally request the FDA to approve a new pharmaceutical for sale and marketing in the U.S. An NDA can only be filed once the drug has successfully passed all phases of clinical trials.
- The NDA is made to the **Centre for Drug Evaluation and Research** ("**CDER**") which evaluates a drug's safety and effectiveness data, inspects the facilities where the finished product will be made, and checks the proposed labelling for accuracy.[539]
- There are generally 2 types of NDAs that a manufacturer may submit:
  - **A 505(b)(1) NDA:** Contains full reports of investigations of safety and effectiveness conducted by or for the applicant. For investigations which have been conducted by the applicants themselves, the applicants have a right of reference/use. [540]
  - **A 505(b)(2) NDA**: Contains full reports of investigations of safety and effectiveness, where some of the information required for approval comes from studies not conducted by or for the applicant. In this case, neither does the applicant have a right of reference/use, nor has the applicant obtained a right of reference or use. For example, the reliance on published literature, FDA's finding of safety and/or effectiveness for a listed drug for the purposes of approval.[541]
- An NDA must contain the details of the applicant, the drug, the identification number of the IND and all other relevant details. The NDA must contain a summary, technical sections (chemistry, manufacturing, controls, non-clinical pharmacology and toxicology, human pharmacokinetics and bioavailability, microbiology, clinical data, statistical data, pediatric use), samples and labelling, case report forms and tabulations, patent information and certification, claimed exclusivity and other relevant information.[542]
- The CDER inspects regulated facilities and considers 3 overall aspects in its review of an NDA:
  - The condition or illness for which the drug is intended and the current treatment available for such condition or illness. This allows an analysis of the drug's risks and benefits. [543]
  - Evaluation of clinical benefit and risk information submitted by the drug maker. The CDER takes into account uncertainties that may result from imperfect or incomplete data. [544]
  - Analysis of risk management strategies including an FDA-approved drug label, which clearly describe the drug's benefit and risks, and how the risks can be detected and managed.[545]

539. Congressional Research Service, "How FDA Approves Drugs and Regulates Their Safety and Effectiveness" available at <https://rb.gy/rv5jdg> last accessed September 15, 2022.
540. Section 505(b)(1), FD&C Act.
541. Section 505(b)(1), FD&C Act.
542. 21 CFR § 314.100.
543. FDA, "Development and Approval Process" available at <https://rb.gy/amihdm> last accessed September 15, 2022.
544. FDA, "Development and Approval Process" available at <https://rb.gy/amihdm> last accessed September 15, 2022.
545. FDA, "Development and Approval Process" available at <https://rb.gy/amihdm> last accessed September 15, 2022.
546. 21 CFR § 312.40(b)(1).
547. 21 CFR § 314.101(a)(1).
548. FFDCA §505(c)(1).

a. Timelines for Review

- The FDA review team has thirty days to review an IND submission.[546] However, once approved, the completion of clinical trials may take several years. Once the clinical trials are over, the drug developer may file an NDA.
- The FDA has 60 days to decide whether or not to accept the NDA to review.[547] The review team must review an NDA submission within 180 days after the filing of an application, or an additional period agreed upon by FDA and the applicant. In case of deficiencies, the applicant is informed of the deficiencies by the CDER, and upon amendment of the NDA to address such deficiencies, a marketing approval is given by the FDA.[548]

b. Costs of Review

The prescription drug user fees for 2020-21 and 2021-22 are as follows[549]:

Type	2021	2022
Application Fee – Clinical Data Required	USD 2,875,842	USD 3,117,218
Application Fee – No Clinical Data Required	USD 1,437,921	USD 1,558,609
Program Fee	USD 336,432	USD 369,413

SUGGESTIONS

The regulatory requirements of FDA for establishing and operating a pharmaceutical company are stringent. Administrative delays result in longer timelines and high costs of new drug approvals in the United States.

The Indian government may propose that pharmaceutical goods which are recognized regulatory authorities of certain other countries are also recognized the U.S. This approach has been taken in the India – UAE Comprehensive Economic Partnership Agreement as well. This will reduce the time taken for approvals. This is particularly important for complex pharmaceutical products since the approval processes for such products may take longer. We understand that the U.S. has Mutual Recognition Agreements in place with the European Union and the United Kingdom respectively. In light of the same, we understand that the European Medicines Agency and the Medicines and Healthcare products Regulatory Agency (United Kingdom) are regulatory authorities that may be more amenable to being accepted by the U.S. government for the purposes of recognition.

India may also propose the commercialization of products which have already been approved in regulated markets such as Canada, the United Kingdom, and the European Union. This would encourage Indian companies to form base in the United States, incentivizing investment, and employment opportunities in the United States.

Lastly, India may also suggest applying lower fees to such types of approvals that are based on an MRA or on recognition from a reference regulatory authority.

549. FDA, "Prescription Drug User Fee Amendments" available at <https://rb.gy/qvne3j> last accessed September 15, 2022.

ii. Drug Review Process for Generic Medicines

- A 'generic drug' is which compares to a reference/branded drug in dosage form, route of administration, strength, quality, safety, and performance characteristics.[550]
- In order to get a generic drug approved, a drug developer must apply for an **Abbreviated New Drug Application** ("**ANDA**") approval. There are two types of ANDA approval:
    i. Full Approval: The FDA may grant full approval if all valid patents and exclusivities for the reference listed drug have expired. Further, all legal issues that may block the approval of the ANDA must have been settled.
    ii. Tentative Approval: A tentative approval is granted when the FDA concludes that a drug product has met all required quality, safety, and efficacy standards, but because of existing patents and/or exclusivity rights, it cannot yet be marketed in the United States.
- An application to the FDA may be filed under Section 505(j)(10) of the FD&C Act. The application must contain information to show that the conditions of use prescribed, recommended, or suggested in the labelling proposed for the new drug have previously been approved for a listed drug. Similarly, it must also contain information demonstrating that the route of administration, the dosage form, and the strength of the new drug are the same as the listed drug. The bioequivalence of the listed drug and the new drug must be demonstrated, along with information concerning the active ingredient(s) present in the new drug and the corresponding listed drug.[551]
- The application must be supplemented with patent information of the listed drug. The applicant is required to provide a certification for each patent listed in the Orange Book for the listed drug. The certification is required to state one of the following[552] :
    i. Required patent information relating to such patent has not been filed;
    ii. Such patent has expired;
    iii. Patent will expire on a particular date; or
    iv. Such patent is invalid or will not be infringed by the drug for which approval is being sought.
- In the event that the applicant claims that the patent is invalid or will not be infringed by the new generic drug, a litigation process starts wherein the courts are required to determine the validity of the applicant's claim before the expiration of the patent.[553] The first applicant to file a substantially complete ANDA containing a certification with such claim will be eligible for a 180-day period of exclusivity.[554]
- After review, an Acceptance/**Refuse to Receive** ("**RTR**") letter is issued based on the completeness of the ANDA. If all the information submitted by the applicant is acceptable, the Office of Generic Drugs issues market approval.
- Depending on the complexity of the drug and completeness of application, the approval process may take any time between 6 months to several years.
- The application fee for FDA approval has been hiked significantly in FY 2021-22. The generic drug user fee rates for 2020-21 and 2021-22 are as follows[555] :

550. . 21 CFR § 314.92(a)(1).
551. 21 CFR § 314.94.
552. 21 CFR § 314.94(a)(12)(i)(A).
553. 21 CFR § 314.94.
554. 21 CFR § 314.94.
555. FDA, "Generic Drug User Fee Amendments" available at <https://rb.gy/eq4hos> last accessed September 15, 2022.

User Fee Type		FY 2021	2022
ANDA		USD 196,868	USD 225,712
Drug Master File[556]		USD 69,921	USD 74,952
Program Fee[557]	Large Size[558]	USD 1,542,993	USD 1,536,856
	Medium Size[559]	USD 617,197	USD 614,742
	Small Size[560]	USD 154,299	USD 153,686
Facility for	Domestic Active Pharmaceutical Ingredient	USD 41,671	USD 42,557
	Foreign Active Pharmaceutical Ingredient	USD 56,671	USD 57,557
	Domestic Finished Dosage Form	USD 184,022	USD 195,012
	Foreign Finished Dosage Form	USD 199,022	USD 210,012
	Domestic Contract Manufacturing Organization	USD 61,341	USD 65,004
	Foreign Contract Manufacturing Organization	USD 76,341	USD 80,004
Backlog[561]	USD 17,434	USD 17,434	USD 1,536,856

SUGGESTIONS

The Indian government should emphasize the need for the FDA to consider a more liberal approach to determining bioequivalence between the claimed generic products and the listed drugs. Commitments in this regard may be sought. Furthermore, it may be relevant to bring to the United States' government's notice the significant time taken for generic approvals and request expedited approvals where such product has established bioequivalence in other jurisdictions.

556. Only DMFs that cover the manufacture of an API for use in a generic drug application incur fees.
557. Each company and its affiliates will be assessed an annual program fee depending on the number of approved ANDAs in their portfolio. To determine the fee amount, there are 3 tiers of the Program fee: small, medium, and large.
558. 20 or more approved ANDAs.
559. between 6 and 19 approved ANDAs.
560. 5 or fewer approved ANDAs.
561. Each person that owns an original ANDA that is pending on October 1, 2012, and that has not been tentatively approved on that date will be required to pay a backlog fee for that ANDA.

iii. Expedited Programs for Serious Conditions – Drugs and Biologics

- The FDA has introduced 4 programs to expedite review of new drugs for the treatment of serious or life-threatening conditions. All 4 programs are directed towards addressing an 'unmet medical need in the treatment of a serious condition'.
- A serious disease or condition has been defined as follows:

  [..] a disease or condition associated with morbidity that has substantial impact on day-to-day functioning. Short-lived and self-limiting morbidity will usually not be sufficient, but the morbidity need not be irreversible if it is persistent or recurrent. Whether a disease or condition is serious is a matter of clinical judgment, based on its impact on such factors as survival, day-to-day functioning, or the likelihood that the disease, if left untreated, will progress from a less severe condition to a more serious.[562]
- The proposed drug must be intended to have an effect on a serious condition or a serious aspect of a condition, including the following[563] :
  - A diagnostic product intended to improve diagnosis or detection of a serious condition in a way that would lead to improved outcomes
  - A product intended to mitigate or prevent a serious treatment-related side effect (e.g., serious infections in patients receiving immunosuppressive therapy)
  - A product intended to avoid or diminish a serious adverse event associated with available therapy for a serious condition (e.g., product that is less cardiotoxic than available cancer therapy)
  - A product intended to prevent a serious condition or reduce the likelihood that the condition will progress to a more serious condition or a more advanced stage of disease
- An unmet medical need is a condition whose treatment or diagnosis is not addressed adequately by available therapy. An unmet medical need includes an immediate need for a defined population or a longer-term need for society. Therapy which has been approved or licensed in the United States and is relevant to current U.S. standard of care is considered 'available therapy.'[564]

562. 21 CFR 312.300(b)(1); FDA, "Guidance for Industry Expedited Programs for Serious Conditions – Drugs and Biologics" available at <https://rb.gy/4yya9p> last accessed September 15, 2022.s
563. FDA, "Guidance for Industry Expedited Programs for Serious Conditions – Drugs and Biologics" available at <https://rb.gy/4yya9p> last accessed September 15, 2022.
564. FDA, "Guidance for Industry Expedited Programs for Serious Conditions – Drugs and Biologics" available at <https://rb.gy/4yya9p> last accessed September 15, 2022.

- There may exist situations in which there exists available therapy, but the FDA may still consider there to be an 'unmet medical need.' An applicant must demonstrate the following to establish that the new treatment is addressing an unmet medical need[565]:
  - The new treatment has as an effect on a serious outcome of the condition that is not known to be influenced by available therapy (e.g., progressive disability or disease progression when the available therapy has shown an effect on symptoms, but has not shown an effect on progressive disability or disease progression)
  - The new treatment has an improved effect on a serious outcome(s) of the condition compared with available therapy (e.g., superiority of the new drug to available therapy when either used alone or in combination with available therapy (i.e., as demonstrated in an add-on study))
  - The new treatment has an effect on a serious outcome of the condition in patients who are unable to tolerate or failed to respond to available therapy
  - The new treatment can be used effectively with other critical agents that cannot be combined with available therapy
  - The new treatment provides efficacy comparable to those of available therapy, while (1) avoiding serious toxicity that occurs with available therapy, (2) avoiding less serious toxicity that is common and causes discontinuation of treatment of a serious condition, or (3) reducing the potential for harmful drug interactions
  - The new treatment provides safety and efficacy comparable to those of available therapy but has a documented benefit, such as improved compliance, that is expected to lead to an improvement in serious outcomes
  - The new treatment addresses an emerging or anticipated public health need, such as a drug shortage

565. FDA, "Guidance for Industry Expedited Programs for Serious Conditions – Drugs and Biologics" available at <https://rb.gy/4yya9p> last accessed September 15, 2022.

The 4 programs are as follows:

Program	Timeline	Requirements	Procedure
Fast-Track Designation	**60 calendar days of receipt of request**	A drug may qualify as a fast-track drug if it is a 'qualified infectious disease product' or if: (i) it is intended for the treatment of a serious or life-threatening disease, and (ii) non-clinical or clinical data demonstrate the potential to address unmet medical need. [566]	A request to provide a 'fast-track' designation to the drug must be placed with the approved IND. Ideally, the request should be placed no later than the pre-NDA meeting. There are opportunities for frequent interactions with the review team for a fast-track product. These include meetings with FDA, including pre-IND meetings, end-of-Phase 1 meetings, and end-of Phase 2 meetings to discuss study design, extent of safety data required to support approval, dose-response concerns, and use of biomarkers. Other meetings may be scheduled as appropriate (e.g., to discuss accelerated approval, the structure and content of an NDA, and other critical issues).[567]
Breakthrough Therapy	60 calendar days of receipt of the request	A drug may qualify as breakthrough therapy if: (i) it is intended for the treatment of a serious or life-threatening disease, and (ii) preliminary clinical evidence indicates that the drug may demonstrate substantial improvement on a clinically significant endpoint(s) over available therapies. [568]	A request to provide a 'breakthrough therapy' designation to the drug must be placed with the approved IND. Ideally, the request should be placed no later than the meeting scheduled post-Phase 2 trials. For drugs designated as 'breakthrough therapy' drugs, the FDA provides intensive guidance on efficient drug development. Additionally, the development and review of the drug is expedited by involving senior managers and other staff in a proactive, collaborative, cross disciplinary review.[569]
Accelerated Approval	N/A	A drug may qualify for accelerated approval if: (i) it is intended for the treatment of a serious or life-threatening disease, (ii) it provides a meaningful advantage over available therapies, and (iii) demonstrates an effect on a surrogate endpoint that is reasonably likely to predict clinical benefit.	Drugs granted accelerated approval must meet the same statutory standards for safety and effectiveness as those granted traditional approval.[570] Therefore, applicants are still required to conduct studies to confirm the anticipated clinical benefit, also known as Phase 4 confirmatory trials. The applicant is required to submit copies of all promotional materials, including promotional labelling as well as advertisements, intended for dissemination or publication within 120 days following marketing approval. Further, post-marketing confirmatory trials are required to be conducted to verify the claimed effect or clinical benefit of the drug.[571]
Priority Review	6 months	A drug may qualify for priority review in any of the following situations[572] : (i) If a drug treats a serious condition and would provide a significant improvement in safety or effectiveness (ii) If a supplement proposes a labelling change pursuant to a report on a pediatric study under Section 505A (iii) If the drug is a qualified infectious disease product (iv) The application is submitted with a priority review voucher	FDA decides on the review designation for every application. An applicant may expressly request priority review. The priority review designation does not affect the length of the clinical trial period.

566. FDA, "Guidance for Industry Expedited Programs for Serious Conditions – Drugs and Biologics" available at <https://rb.gy/4yya9p> last accessed September 15, 2022.
567. FDA, "Guidance for Industry Expedited Programs for Serious Conditions – Drugs and Biologics" available at <https://rb.gy/4yya9p> last accessed September 15, 2022.
568. FDA, "Guidance for Industry Expedited Programs for Serious Conditions – Drugs and Biologics" available at <https://rb.gy/4yya9p> last accessed September 15, 2022.
569. FDA, "Guidance for Industry Expedited Programs for Serious Conditions – Drugs and Biologics" available at <https://rb.gy/4yya9p> last accessed September 15, 2022.
570. FDA, "Guidance for Industry Expedited Programs for Serious Conditions – Drugs and Biologics" available at <https://rb.gy/4yya9p> last accessed September 15, 2022.
571. FDA, "Guidance for Industry Expedited Programs for Serious Conditions – Drugs and Biologics" available at <https://rb.gy/4yya9p> last accessed September 15, 2022.
572. FDA, "Guidance for Industry Expedited Programs for Serious Conditions – Drugs and Biologics" available at <https://rb.gy/4yya9p> last accessed September 15, 2022.

iv. Pre-Launch Activities Importation Requests ("PLAIR")

- Parties interested in importing finished drugs, which have yet not been granted market approval by the FDA, may file a PLAIR. This allows importers to make such drugs available to the market as soon they receive market approval.[573] PLAIRs are typically submitted in preparation to commence market launch of the new drug in the United States.
- In order to qualify for a PLAIR, the new drug must have a pending NDA, ANDA or Biologics License Application ("BLA") with the FDA.[574] The unapproved drugs intended for importation must either be in final packaged form or should call for minimal further processing such as final packaging or labelling.[575] A PLAIR should be submitted at least 30 days prior to the proposed entry date of the shipment.[576]
- Once the imported drug arrives at the port of entry, the FDA issues a "Notice of FDA Action–Detained."[577] Upon approval of the NDA/ANDA/BLA by the FDA, the FDA issues a "Release after Detention," and releases the drug to the importer.[578] Such drug is permitted to be sold in the United States. However, if the FDA rejects the NDA/ANDA/BLA, or 6 months lapse without FDA approval, the FDA may issue a "Notice of FDA Action – Refusal of Admission,"[579] and the importer is required to export or destroy the product within 90 days. [580]

573. FDA, "Pre-Launch Activities Importation Requests (PLAIR) Guidance for Industry" (March 2022) available at <https://rb.gy/qirtsb> last accessed October 18, 2022.
574. FDA, "Pre-Launch Activities Importation Requests (PLAIR) Guidance for Industry" (March 2022) available at <https://rb.gy/qirtsb> last accessed October 18, 2022.
575. FDA, "Pre-Launch Activities Importation Requests (PLAIR) Guidance for Industry" (March 2022) available at <https://rb.gy/qirtsb> last accessed October 18, 2022.
576. FDA, "Pre-Launch Activities Importation Requests (PLAIR) Guidance for Industry" (March 2022) available at < https://rb.gy/qirtsb> last accessed October 18, 2022.
577. FDA, "Pre-Launch Activities Importation Requests (PLAIR) Guidance for Industry" (March 2022) available at <https://rb.gy/qirtsb> last accessed October 18, 2022.
578. FDA, "Pre-Launch Activities Importation Requests (PLAIR) Guidance for Industry" (March 2022) available at < https://rb.gy/qirtsbs> last accessed October 18, 2022.
579. FDA, "Pre-Launch Activities Importation Requests (PLAIR) Guidance for Industry" (March 2022) available at < https://rb.gy/qirtsb> last accessed October 18, 2022.
580. FDA, "Pre-Launch Activities Importation Requests (PLAIR) Guidance for Industry" (March 2022) available at < https://rb.gy/qirtsb> last accessed October 18, 2022.

v. Acceptance of Foreign Clinical Studies

- The FDA accepts foreign clinical studies as support for an IND, NDA, or an ANDA, as long as it can be demonstrated that these studies have taken place in accordance with **good clinical practice** ("**GCP**").[581]
- GCP has been defined as 'a standard for the design, conduct, performance, monitoring, auditing, recording, analysis, and reporting of clinical trials in a way that provides assurance that the data and reported results are credible and accurate and that the rights, safety, and well-being of trial subjects are protected.'[582]
- GCP includes the following practices:
  - Review, approval, or provision of a favourable opinion by an independent ethics committee before initiating a study
  - Continuing review of an ongoing study by an independent ethics committee
  - Documentation of the freely given informed consent of the subject / subject's legally authorized representative (except in life-threatening situations where informed consent is not feasible)
  - Existence of protocol/measures to protect the rights, safety, and well-being of the subjects
- FDA may validate the data from the study through an on-site inspection if the FDA considers such inspection necessary.
- Although there exist flexibilities in the marketing approval process, the law states that an application based solely on foreign clinical data may be approved if: [583]
  - The foreign data are applicable to the U.S. population and U.S. medical practice;
  - The studies have been performed by recognized clinical investigators; and
  - The data may be considered valid without the need for an on-site inspection by the FDA. If the FDA considers such an inspection to be necessary, FDA is able to validate the data through an on-site inspection or other appropriate means.

581. 21 CFR § 312.120.
582. 21 CFR § 312.120.
583. 21 CFR § 314.106.

B. GOOD MANUFACTURING PRACTICES

- The **Current Good Manufacturing Practice Regulations** ("**CGMP Regulations**") contain minimum requirements for the proper design, monitoring, and control of manufacturing processes and facilities. The failure to comply with the CGMP Regulations renders a drug 'adulterated' and the person responsible for the failure to comply is subject to regulatory action. Key areas covered by CGMP Regulations are as follows:
- Organization Personnel: The United States requires the existence of a quality control unit in every manufacturing unit, which would be responsible for the approval and rejection of all components, drug products containers, closures, in-process materials, labels, etc. Further, 21 CFR § 211.25 lists down the qualifications personnel engaged in the manufacture, processing, packaging, or holding of any drug products must have. The United States also has laws dictating the qualifications which must be held by consultants advising on the manufacture, processing, packing, or holding of drug products.
- Building, Facilities, and Equipment: 21 CFR Part 211 Subpart C and D contain specific requirements for buildings, facilities, and equipment used by manufacturing units. The CGMP Regulations provide detailed requirements to be followed by manufacturing units with regard to design and construction features, lighting, ventilation, air filtration, air heating and cooling, plumbing, sewage and refuse, washing and toilet facilities, sanitation, and maintenance. The regulations also contain standards for equipment design, size, location, construction, cleaning, and maintenance.
- Containers: The FDA has prescribed requirements for the receipt, identification, storage, handling, sampling, testing, and approval or rejection of components and drug product containers and closures so as to prevent contamination.
- Production and Process Controls: The CGMP Regulations provide a detailed framework for ensuring quality production and process controls. The FDA requires the procedures for production and process control to be written and designed to ensure that the drug products have the identity, strength, quality, and purity they are represented to possess. The procedures should be drafted, review and approved by organizations, and further reviewed and approved by the quality control unit. In case there is any deviation from the written procedures, such deviation should be recorded and justified in writing.
- Further, to ensure batch uniformity, the manufacturing unit must have control procedures in place. Such control procedures must describe the in-process controls, tests, examinations on appropriate samples of in-process materials of each batch. These control procedures must also be designed to monitor the output and validate the manufacturing process in place. Additionally, there are detailed regulations regarding the charge-in of components, calculation of yield, equipment identification, control of microbiological contamination and reprocessing.
- Packaging and Labelling: The laws also mandate procedures for receipt, identification, storage, handling, sampling, examination, and/or testing of labelling and packaging materials.
- Holding and Distribution: The CGMP Regulations mandate procedures regarding the holding and distribution of drugs. They require that written procedures for warehousing drugs are established, which should include (a) quarantine of drug products before release by quality control unit, and (b) storage of drug products under appropriate weather and light conditions to ensure that the quality of the drug products are not affected. Written procedures must also be established for distribution of drug products. It is required that the oldest approved stock of a drug must be distributed first. Manufacturers are also

required to ensure a system by which each log of drug products can be recalled if required.

- Laboratory Requirements: Manufacturing units are required to maintain written laboratory controls, which should include the establishment of scientifically sound and appropriate specifications, standards, sampling plans, and test procedures designed to assure that components, drug product containers, closures, in-process materials, labelling, and drug products conform to appropriate standards of identity, strength, quality, and purity.
- There must be appropriate laboratory determination of satisfactory conformance to final specifications for the drug product, including the identity and strength of each active ingredient, prior to release. There must be tests performed to assess the stability characteristics of drug products. There are also requirements concerning reserve samples and laboratory animals.
- Other: 21 CFR Part 211 Subpart J and K contain procedures to be followed with regard to maintenance of records and reports and returned and salvaged drug products.
- The FDA conducts on-site inspections of a drug manufacturers' premises to ensure GMP compliance. These inspections can be conducted as (i) 'pre-approval' inspections, which are followed by (ii) 'post-approval' inspections, (iii) 'surveillance' inspections, and (iv) for cause inspections.
- A pre-approval inspection can be conducted for a market authorization approval if it is the first time a facility is named in an application, first application by the application, first ANDA for an approved drug, new molecular entity, narrow therapeutic range drug, new manufacturing process or dosage form for the facility, high risk API, 'official action indicated' status, or no recent inspection. They may also conduct inspections if it is a drug which is difficult to manufacture, on the basis of the site's compliance record and recent inspections, and other supply chain risks.[584]
- Once the product has been approved by the FDA, the FDA may also conduct 'product-specific inspections' also known as 'post-approval inspections.' Post-approval inspections are intended to evaluate commercial-scale processes, process validation lifecycle, manufacturing changes and any changes in perceived product risks.[585]
- On the other hand, a surveillance inspection may take place on the basis of the compliance history of the establishment, records linked to the establishment, inherent risk of the drug manufactured or processed at the establishment, inspection frequency of the establishment, inspection by a foreign government, patent exposure, hazard signals, import alert, or a warning letter close-out.[586]
- In the event that the investigator(s) observe conditions which may violate the FD&C Act, Form 483 is issued to firm management.[587] The FDA Form 483 notifies the company's management of objectionable conditions. At the conclusion of an inspection, the FDA Form 483 is presented and discussed with the company's senior management. The Form 483 is not a final determination of violation, but is considered, along with the responses made by the manufacturing company, while making the final determination. Notably, in 2022, at least 5 Indian companies[588] have been issued Form 483 by the FDA.
- The FDA may also conduct specific 'for-cause inspections' in response to a specific incident or communication. These triggers may include recalls, outbreaks, and information from whistle-blowers.[589]

584. Compliance Program Guidance Manual 7448.832; Jerry Chapman "Yes, FDA is still performing pharma inspections, using risk-based criteria: What is your risk for inspection?" available at <https://rb.gy/rizfhf> last accessed September 17, 2022.
585. Akin Gump Strauss Hauer & Feld LLP, "A Client's Guide to FDA Inspections" (2019) available at <https://rb.gy/wc89g5> last accessed October 18, 2022.
586. MAPP 5014.1; Jerry Chapman "Yes, FDA is still performing pharma inspections, using risk-based criteria: What is your risk for inspection?" available at <https://rb.gy/rizfhf> last accessed September 17, 2022.
587. FDA, "FDA Form 483 Frequently Asked Questions" available at <https://rb.gy/3g1bpa> last accessed September 15, 2022.
588. Dr Reddy's Laboratories, Sun Pharma, Cipla, Zydus and Aurobindo Pharma.
589. Akin Gump Strauss Hauer & Feld LLP, "A Client's Guide to FDA Inspections" (2019) available at <https://rb.gy/wc89g5> last accessed October 18, 2022.

SUGGESTIONS

The multiple levels of inspections conducted by the FDA result in long timelines for market approval. The Indian government may recommend conducting different inspections together to avoid inefficient timelines.

Based on discussion with stakeholders we understand that a full-fledged mutual recognition agreement is highly unlikely to be agreed upon with the United States, given the vastly differing standards of GMP being followed in India. Therefore, as a first step India should move towards harmonizing GMP and other compliances with global standards, which will then allow India to bargain for a mutual recognition agreement in the future.

In the absence of such MRA, the need for site inspections for the purposes of GMP compliance may be highlighted as unnecessary in cases where Indian drug manufacturers have received GMP recognition in a third-party reference country. Further, the Indian government may emphasize the need for more transparency on the instances in which a GMP inspection may be conducted.

C. LABELLING REQUIREMENTS

- A prescription drug product's FDA-approved labelling is a compilation of information about the product. The labelling contains information necessary to consider the product safe and effective for use.
- Drug labels are expected to contain the drug name, name, and place of business of manufacturer, packer or distributor, **National Drug Code Numbers** ("**NDC**"), statement of ingredients, expiration date and lot number. It must also provide adequate directions for use, including the statement of all conditions, purposes or uses the drug is intended for, the quantity of dose, frequency, duration, route or method of administration, and preparation for use. The FDA prescribes additional labelling requirements for drugs containing tartrazine or sulphites. Separately, there exist bar code label requirements or all prescription drug products which are sold to or used in hospitals.
- Labels for prescription drugs and insulin must clearly identify the drug. The labelling must also indicate the net quantity and weight of contents, along with a statement of ingredients and recommended dosage. Specific information with regard to warnings, dosage during pregnancy, drug interactions, precautions, adverse reactions, dosage and administration, etc. must also be specified on the labels for prescriptions drugs and insulin. An over-the-counter drug's label must contain the sodium, calcium, magnesium, and potassium content if they exceed the prescribed threshold.
- Drugs are exempt from labelling that lists adequate directions for use if they are in possession of a hospital, clinical pharmacy, public health agency, or a licensed practitioner. In such situations, the label must display the statement 'Rx only', along the with the recommended dosage, route of administration, quantity, and control number.

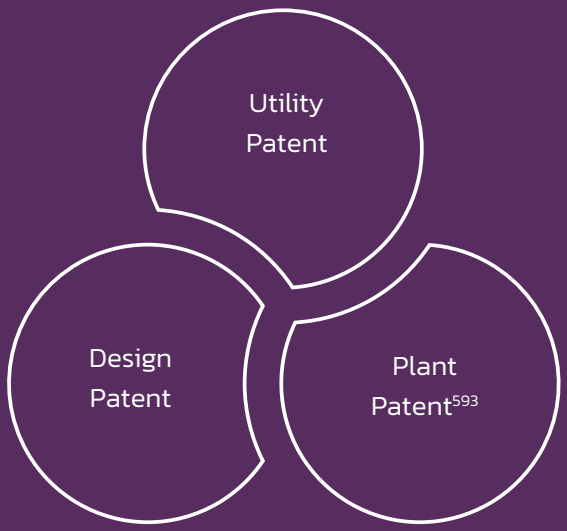
SUGGESTIONS

While we understand that labelling requirements may pose a trade barrier, we do not anticipate significant business impact on large corporations as a result of these requirements. Such requirements are fairly standard across the world and are unlikely to impact multinational pharmaceutical companies. However, this may be a cause for concern for the MSME sector.

INTELLECTUAL PROPERTY RIGHTS REGIME

The primary legislations relevant to pharmaceutical patents are the Patent Act 1952 ("Patent Act")[590] , and the FD&C Act.[591] The Patent Act established the **United States Patent and Trademark Office** ("**USPTO**") which is responsible for granting U.S. patents and registered trademarks.[592]

The USPTO grants 3 different types of patents:



For the pharmaceutical industry, the relevant kind of patent is utility patent, since utility patents are those that may be granted those who invent or discover any new and useful process, machine, article of manufacture, or composition of matters, or any new useful improvement thereof. The U.S. follows a "first-inventor to file system" which means the first person to file a patent application can be awarded a patent, irrespective of the fact whether they were the first to invent it. Consequently, this rule further extends to market exclusivity governed under the FDA Law.[594]

590. Title 35, United States Code.
591. FD&C Act.
592. The United States Patent and Trademark Office, "Introduction, Manual of Patent Examining Procedure" available at <https://rb.gy/yun66h> last accessed November 23, 2022.
593. The United States Patent and Trademark Office, "Patent Process Overview" available at <https://rb.gy/0otfxc>, last accessed November 23, 2022.
594. U.S. Food & Drug Administration, "Frequently Asked Questions on Patent and Exclusivity" available at <https://rb.gy/t0qffs> last accessed November 23, 2022.

A. DATA EXCLUSIVITY OF INNOVATIVE DRUGS

- New Drug Product Exclusivity is provided under Section 505(c)(3)(E) and 505(j)(5)(F) of the FD&C Act. Exclusivity provides the holder of an approved new drug application protection from new competition in the marketplace for the innovation represented by its approved drug product.
- Therefore, during the period of data exclusivity of innovative drugs, the following applications by competitors do not get approved:
  - Certain 505(b)(2) applications: Section 505(b)(2) of the FD&C Act expressly permits FDA to rely on data not developed by the applicant such as published literature or the agency's finding of safety and effectiveness of a previously approved drug. Therefore, a 505(b)(2) application is an application for which or more of the investigations relied upon by the applicant for approval "were not conducted by or for the applicant and for which the applicant has not obtained a right of reference or use from the person by or for whom the investigations were conducted."[595]
  - Certain abbreviated new drug applications (ANDAs): An abbreviated new drug application, or an application for generic drugs, is described under Section 505(j) of the FD&C Act. It as an application that contains information to show that the proposed product is identical in active ingredient, dosage form, strength, route of administration, labelling, quality, performance characteristics and intended use, among other things to a previously approved application (the reference listed drug (RLD). ANDAs do not contain clinical studies as required in NDAs but are required to contain information establishing bioequivalence. In general, the bioequivalence determination allows the ANDA to rely on the agency's finding of safety and efficacy for the reference listed drug.
- The period for data exclusivity for different drugs is as follows:

Period of Data Exclusivity	Type	Explanation
5 years	New Chemical Entities	New Chemical Entities are drugs with an 'active moiety' which has not been approved in any other New Drug Application (NDA) before. Active Moiety is defined as any ion or molecule which is attributed to the drug's physiological or pharmacological action. However, there is no bar on filing an NDA with the same component/active moiety if its intended use is different for indications. It may be noted that the USMCA also obligates the United States to provide data exclusivity to New Chemical Entities for a period of 5 years.
3 years	Clinical Investigations	This protection extends to changes to already marketed products as a result of additional clinical trials. During the period of exclusivity, no ANDA can be granted on the modification so added however an ANDA can be accepted on the previous version of the drug or the original drug. There is also no bar on acceptance of the ANDA during the 3 years and initiation of review, just that they cannot be granted during the 3-year duration. There is also no bar for a competing generic drug manufacturer on gaining approval based on their own clinical trials.[596]
7 years	Orphan Drugs	Orphan drugs are attributed to conditions that affect 200,000 or fewer people in the US or which have no return on investment in the market. During this period of exclusivity, the FDA can accept but not approve an ANDA application on the drug.

595. 21 U.S.C. 355(b)(2).
596. FDA, "Small Business Assistance: Frequently Asked Questions for New Drug Product Exclusivity" available at <https://rb.gy/mra6oa > last accessed September 15, 2022.

- Additionally, the Best Pharmaceuticals for Children Act grants exclusivity for 6 months attached to the other 3 exclusivities or the patent term itself. The exclusivity is granted on the basis of the paediatric studies conducted and the development of useful information or results from it. The paediatric studies are conducted on a drug which already has NDA approval and, in response to a request from FDA to conduct such a study, and the report of which has to be submitted to FDA. Even if the study fails or the results are unsuccessful the exclusivity is independent of it. The exclusivity is granted to all of the applicant's dosages or formulations and indications for the drugs with an existing marketing exclusivity or a patent with the same active ingredient.

i. Patent Thickets

- Certain pharmaceutical companies apply for excessive number of duplicative patents that represent no significant innovation. There exist a large number of patents that cover a single product or minor variations on a single product.[597] Studies reveal that 78% of all pharmaceutical patents between 2005 and 2015 were issued on old, previously patented medicines, and not on new drugs or biologics.[598] According to a study by I-MAK, there are 125 patent applications filed and 71 granted patents per drug.[599]
- These duplicative patents allow pharmaceutical companies to extend their exclusivity rights on drugs for decades, and therefore delaying the timeline for when generics and biosimilars can legally enter the market. This significantly limits the competition in the U.S. market, which also allows for pharmaceutical companies to charge exorbitant prices for drugs which are protected by a patent.
- Since these duplicative patents are not "new and useful" as required by the Patent Act, many of these patents are ruled to be invalid.[600] However, in order to achieve the ruling of invalidity, generic and biosimilar companies are required to engage in time-intensive and expensive patent litigation.
- Another method to block competition from generics through patents is called "product hopping." Drugs can be categorized as "extended release" and "immediate release" medications, depending on the period of relief granted by the drugs. Immediate release medications relieve pain immediately but are required to be consumed every few hours. On the other hand, extended-release medications are required to be consumed only once or twice a day, since they are designed to provide a pre-designated amount of medication throughout the day. Therefore, upon nearing the expiration of the patent of an immediate release drug, the company obtains a new patent covering an extended-release version of the drug and starts advertising the new product aggressively. In certain cases, it may also disparage the immediate release version of the drug and take it off the market, thereby forcing a switch in consumer preferences.[601] Therefore, a product hopping strategy can render the original drug and its generic forms obsolete.[602]

597. Letter from United States Senators Patrick Leahy, John Cornyn, Richard Blumenthal, Susan M. Collins, Mike Braun, Amy Klobuchar addressed to Director Vidal, U.S. Patent and Trademark Office dated June 8, 2022, available at < https://www.leahy.senate.gov/imo/media/doc/20220608%20Letter%20to%20PTO%20on%20repetitive%20patents.pdf> last accessed October 18, 2022.
598. Letter from FDA addressed to U.S. Patent and Trademark Office dated September 10, 2021.
599. I-MAK, "Overpatented, Overpriced: How Excessive Pharmaceutical Patenting is Extending Monopolies and Driving Up Drug Prices" available at <https://rb.gy/umhuc4> last accessed October 18, 2022.
600. CAPA, "Who We Are" available at < https://www.capanow.org/who-we-are/ > last accessed November 23, 2022.
601. Dmitry Karshtedt, "The More Things Change: Improvement Patents, Drug Modifications, and the FDA" 104 IOWA L. REV. 1129 (2019) available at <https://rb.gy/xvjg5f> last accessed October 18, 2022.
602. Dmitry Karshtedt, "The More Things Change: Improvement Patents, Drug Modifications, and the FDA" 104 IOWA L. REV. 1129 (2019) available at < https://rb.gy/xvjg5f> last accessed October 18, 2022.

SUGGESTIONS

Since a majority of the drugs exported by India are generics, the Indian government may consider emphasizing the need to combat patent thickets and product hopping through legislation and policy. Pharmaceutical companies should not be allowed to apply for patents over minor variations of a patented drug.

B. PATENT OPPOSITION

- The Leahy-Smith **America Invents Act** ("**AIA**") provides for options for challenging patent validity. A post-grant review is a time-bound inter-parties review mechanism, which provides a time limit of 9 months after the grant of a patent to file a petition.[603]
- The post-grant review is a trial proceeding conducted at the **Patent Trial and Appeal Board** ("**PTAB**") to review the patentability of or more claims in a patent on the following grounds:
- Invalidity of the patent or any claim in suit on any ground specified as a condition for patentability, i.e., novelty, usefulness, non-obvious subject matter, etc.
- Invalidity of the patent or any claim in suits for failure to comply with the requirements of specification or reissuance of defective patients.
- The post-grant review process begins with a third party filing a petition on or prior to the date that is 9 months after the grant of the patent or issuance of a reissue patent. The petition has to contain the payment of a fee, provide for the grounds including evidence to those grounds, which is then made public.
- The patent-owner may provide a preliminary response to the petition within a set time period. A post-grant review may be instituted upon a showing that it is more likely than not that at least claim challenged is unpatentable. An additional ground may also be that the petition raises a novel or unsettled legal question that is important to other patents or patent applications If the proceeding is instituted and not dismissed, a final determination by the Board will be issued within 1 year, extendable up to 6 months.
- In the post-grant review, the petitioner shall have the burden of providing a proposition of unpatentability by a preponderance of the evidence. Either party may appeal the final decision of the Patent Trial and Appeal Board to the Court of Appeals for the Federal Circuit.
- The AIA also allows for pre-issuance submissions by third parties. These submissions can be made before (1) the later of 6 months after the date of publication or (ii) the date of a first Office action on the merits rejecting any claims, or (2) before the date of a notice of allowance, if earlier.[604] Notably, third party submissions cannot be filed for a provisional application, issued patent, reissue application or re-examination proceeding. Also, a third-party submission can be filed anonymously.

603. WIPO, "Opposition Systems: United States of America" available at <https://rb.gy/qo5shv> last accessed September 15, 2022.
604. 35 U.S. Code § 122(e).

C. PATENT TERM EXTENSIONS

- **Patent term extension** ("**PTE**") is available under the 1984 Drug Price Competition and Patent Restoration Act, also known as the Hatch-Waxman Act. The law allows the extension of the term of a patent claiming a product that requires regulatory approval prior to being sold, or a method of using or manufacturing the product.
- The patent owner must file an application within 60 days of the mailing date of a marketing approval of the product. The applicant must file a complete application with all the requirements.
- A patent extension cannot be longer than over 5 years, and the total patent term cannot be longer than 14 days from the date of receipt of marketing approval.

D. EXTRATERRITORIALITY OF PATENTS

Extraterritoriality of patent law is when a country's patent law extends to production of a good outside its territory. In the U.S., such liability arises when:

01 A substantial portion of the components of an invention patented in the United States are exported for assembly outside the U.S.[605]

02 Components of patented invention that have been especially made/adapted for use in such patented invention are exported for assembly outside the U.S. [606]

03 A product that has been produced using a method that is patented in U.S. imported into the U.S. Therefore, while there may be no patent covering the product in the U.S., a patent covering the method of production can be infringed in another country. [607]

SUGGESTIONS

The Indian government may consider putting forth the position that the scope of patent protection should be national and not extend into India.

605. 35 U.S. Code § 271(f)(1).
606. 35 U.S. Code § 271(f)(2).
607. 35 U.S. Code § 271(g).

E. COMPULSORY LICENSE

- The US law does not provide for specific compulsory licensing provisions. Often called a "rarity" in the US framework for patents,[608] compulsory licensing is still invoked through 28 U.S.C. § 1498(a)[609] and the Bayh-Dole Act, 1980.
- The 28 U.S.C. § 1498(a) dealing with patent and copyright cases under the US Court of Federal Claims, provides for the governmental use of patents wherein the US government or any authorized entity (express or implied authorization a patented invention in case of a national emergency, public health threat or a strong societal interest in access to the invention, etc. This provision not only grants protection from liability for patent infringement but also waives off sovereign immunity of the US government by providing due compensation to the patent owner[610] whereby the government simply acquires what is necessary at a time and pays compensation thereafter.
- Moreover, the Bayh-Dole Act, 1980 also grants "March-in Rights" wherein the government enjoys the right to grant a compulsory license for any patent provided that the same was a result of federal funding.[611] The additional criteria before invoking these rights is that the action must be necessary: first, because the patent holder has not taken effective steps to achieve practical application of the invention; second, to alleviate health or safety needs which are not reasonably satisfied by the patent holder; third, to meet the public use requirements laid under Federal regulations which may not be met by the patent holder; and last, to grant an exclusive right to use the patented invention to another without obtaining the promise that the invention will be manufactured substantially in the United States.
- Although the March-in Rights confer overwhelming power on the federal agencies, they have not been invoked till date. In several matters, specifically in the pharmaceutical sector, like Norvir (2004),[612] Xalatan (2004)[613] and Fabrazyme (2010),[614] these rights were requested to be invoked by the applicants, but the grounds were not considered appropriate by the National Institute of Health. It was further clarified that these distinct rights are not to be applied with the objective of controlling prices.

608. Dawson Chemical Co. v. Rohm & Haas Co, 448 US 176 (1980).
609. This provision allows the United States (or a third party authorized by the United States) to use or manufacture a patented item without a license. While the owner of the patent may sue the U.S. for damages in the United States Court of Federal Claims, the remedies the owner may seek are limited to damages, not injunctive relief. This gives the U.S. government or a third party operating on its behalf a compulsory license to use the patent, subject to compensation to the patent owner.
610. Madey v. Duke University, 307 F.3d 1351, 1359 (Fed. Cir. 2002).
611. 35 U.S.C. §203.
612. NIH, "In the Case of Norvir" available at https://rb.gy/7fnwbg> last accessed September 15, 2022.
613. NIH, "In the Case of Xalatan" available at < https://rb.gy/7fnwbg> last accessed September 15, 2022.
614. NIH, "In the Case of Fabrazyme" available at < https://rb.gy/7fnwbg> last accessed September 15, 2022.

PRICE CONTROLS

Currently, there exist no price controls for drugs in the United States. Currently, **Pharmacy Benefit Managers** ("**PBM**") manage prescription drug benefits on behalf of health insurers, certain Medicare plans, large employers, and other payers.[615] PBMs are companies which operate in the 'middle' of the distribution chain for prescription drugs and influence their prices.

PBMs develop lists of covered medications on behalf of health insurers, negotiate rebates and discounts from drug manufacturers, and contract directly with individual pharmacies to reimburse for drugs dispensed to beneficiaries.[616] Since PBMs receive rebates that are calculated as a percentage of the manufacturer's list price, PBMs have incentive to favour high priced drugs.[617] This results PBMs excluding low-priced generics from lists of medicines covered by health insurance.[618]

Further, the **Inflation Reduction Act of 2022** ("**Inflation Act**"), signed in August 2022, includes critical provisions for the pricing of prescription drugs. In particular, the Inflation Act allows the HHS to negotiate prices for certain high-cost drugs covered by Medicare[619], and to implement the negotiated prices starting in 2026. The HHS will select drugs on an annual basis, in a staggered manner, for drug price negotiation.

Negotiation-eligible drugs will be selected from drugs having the highest total expenditures during the most recent 12-month period prior to the selected drug publication date.[620] Drugs selected for negotiation will be subject to a maximum fair price. Eligible drugs for selection are restricted to small molecule drugs that have been approved by the FDA for at least 7 years with no generic on the market and biologics that have been licensed for at least 11 years with no biosimilar on the market.

615. The Commonwealth Fund, "Pharmacy Benefit Managers and Their Role in Drug Spending" (April 22, 2022) available at < https://rb.gy/g5lcji> last accessed October 18, 2022.
616. The Commonwealth Fund, "Pharmacy Benefit Managers and Their Role in Drug Spending" (April 22, 2022) available at < https://rb.gy/g5lcji> last accessed October 18, 2022.
617. The Commonwealth Fund, "Pharmacy Benefit Managers and Their Role in Drug Spending" (April 22, 2022) available at < https://rb.gy/g5lcji> last accessed October 18, 2022.
618. Erin Trish, PhD, Karen Van Nuys, PhD, and Robert Popovian, PharmD, "PBMs Are Inflating the Cost of Generic Drugs. They Must Be Reined In." (July 5, 2022) available at https://rb.gy/0oer1e> last accessed October 18, 2022.
619. A federal health insurance program for people aged 65 years or older and those with certain disabilities.
620. 50 prescription drugs (Part B) and 50 drugs which are administered in the doctor's clinic as a part of their service (Part D).

The timeline for the same is as follows:

Initial Price Applicability Years	Number of Drugs	Kind of drugs
2026	10	Prescription Drugs[621]
2027	15	Prescription Drugs
2028	15	Prescription Drugs or certain drugs which are administered in the doctor's clinic as a part of their service[622]
2029 or later	20	Prescription Drugs or certain drugs which are administered in the doctor's clinic as a part of their service

The HHS will select and publish the list of selected drugs subject to price negotiation at least 2 years prior to the initial price applicability year. There exist concerns that the 'maximum fair price' set by the HHS may force other manufacturers reduce prices to avoid exclusion in insurance lists.[623] It may also be noted the Inflation Act caps annual out-of-pocket drug spending by beneficiaries for prescription drugs. The Inflation Act, therefore, is likely to impact the pricing of drugs that may be selected by the HHS for the purposes of the legislation.

Separately, starting in 2023, the Inflation Act requires manufacturers to pay a mandatory quarterly rebate if drug prices increase faster than inflation for certain Medicare Parts D and B drugs. Failure to comply with the drug rebate requirements for a calendar quarter will be subject to civil monetary penalties of at least 125 percent of the rebate amount specified for such quarter. The first rebates would be payable in 2023, using 2021 as the base year for initial inflation calculations.

SUGGESTIONS

The Indian government may discuss the implications of price controls with industry stakeholders.

621. Drugs which are included in Medicare Part D. Medicare Part D is offered by private insurance companies and is approved by Medicare for prescription drugs. It is a supplemental health insurance.
622. Part B drugs, i.e., drugs which aren't self administered. Part B drugs are generally given in a doctor's office as a part of their service.
623. IQVIA, "Market Prognosis 2022-2026 Key Findings" (September 2022).

TRADE REMEDIAL MEASURES

- The primary legislation governing the application of the anti-dumping and countervailing measures in the USA is the Tariff Act of 1930[624] and the safeguard measures are the Trade Act of 1974.[625]
- The United States **Department of Commerce** ("**DOC**") and the USITC are both responsible for conducting anti-dumping and countervailing investigations. With regard to safeguard investigations, while the USITC is responsible for conducting the investigations, the President makes the final decision on whether to provide relief of safeguard measures.[626]
- As of the date of this report, there are presently no anti-dumping, countervailing, or safeguard measures in force in the USA against pharmaceutical products from India.
- However, certain subsidy schemes granted by India that may also be utilized in the pharmaceutical sector have been previously challenged by the USA (albeit in the context of non-pharmaceutical products) at the WTO. These are:
  - **Export Oriented Units** ("**EOU**")
  - Electronics Hardware Technology Park and Bio-Technology Park (EHTP/BTP) Scheme
  - **Export Promotion Capital Goods Scheme** ("**EPCG**")
  - The **Special Economic Zones** ("**SEZ**") schemes
  - The **Duty-Free Imports for Exporters Scheme** ("**DFIS**"); and the **Merchandise Exports from India scheme** ("**MEIS**")

SUGGESTIONS

As a part of its dialogue with U.S. government, the Indian government should emphasize on the existing international obligation on the U.S. government to comply the well-established law that countervailing measures, if any, should be limited to excess remissions only and not extend to the full amount of assistance provided.

Additionally, the Indian government should request that provisions requiring United States to provide a reasonable opportunity for consultations before proceeding to initiate a trade remedial investigation be incorporated in any future trade agreement. Similar provisions exist in some of India's existing FTAs, such as the India-Korea CEPA for example.

624. United States International Trade Commission, "Understanding Anti-Dumping and Countervailing Duty Investigations" available at <https://rb.gy/nverau> last accessed September 15, 2022.
625. United States International Trade Commission, "Understanding Anti-Dumping and Countervailing Duty Investigations" available at < https://rb.gy/nverau> last accessed September 15, 2022.
626. United States International Trade Commission, "Understanding Anti-Dumping and Countervailing Duty Investigations" available at < https://rb.gy/nverau> last accessed September 15, 2022.

In the U.S., billions of dollars are contributed towards the research and development in the pharmaceutical sector. The federal government impacts the development of new drugs through subsidizing prescription drugs by way of its various programs, for instance, Medicare, Medicaid, TRICARE, the Veterans Health Administration, the Children's Health Insurance Program, and health insurance marketplaces established by the Affordable Care Act, etc. These initiatives aid in subsidizing purchase of a considerable volume of prescription drugs for several sections of society like retirees, veterans, persons with disabilities, and low-income households.

A. ORPHAN DRUG TAX CREDIT

- As per the United States' latest notification to the WTO Committee on Subsides and Countervailing Measures under Article XVI:1 of the GATT, 1994 and Article 25 of the Agreement on Subsidies and Countervailing Measures dated July 14, 2021, the U.S. government provides an Orphan Drug Tax Credit to companies undertaking qualified research on orphan drugs.
- The provision provides a 25% tax credit for qualified clinical testing expenses incurred in testing of certain drugs for rare diseases or conditions, referred to as "orphan drugs". Qualified testing expenses are costs incurred to test an orphan drug after the drug has been approved for human testing by the FDA, but before such drug is approved for sale.[627]
- A rare disease or condition is one that affects less than 200,000 persons in the United States, or affects more than 200,000 persons, but for which there is no reasonable expectation that businesses could recoup the costs of developing a drug for such disease or condition from U.S. sales of the drug.[628]
- The credit originally was enacted as a temporary provision in 1983 under the Orphan Drug Act and was extended on several occasions. The credit expired after December 31, 1994, and later was reinstated for the period July 1, 1996, through May 31, 1997. The Taxpayer Relief Act of 1997 made the credit permanent. The Tax Cuts and Jobs Act of 2017 reduced the credit rate from 50 to 25%. The orphan drug credit is authorized Section 45C of the Internal Revenue Code.[629]
- The U.S. government forewent USD 1550 million in fiscal year 2019 and USD 1720 million in fiscal year 2020.[630]

627. G/SCM/N/372/USA.
628. G/SCM/N/372/USA.
629. G/SCM/N/372/USA.
630. G/SCM/N/372/USA.

B. INCENTIVES TO BOOST LOCAL PRODUCTION OF PHARMACEUTICAL PRODUCTS

- On February 24, 2021, President Biden signed Executive Order 14017 to 'secure America's critical supply chains.' In pursuance of the same, in February 2022, the White House released the "Executive Order on America's Supply Chains: A Year of Action and Progress" report. The report revealed that the efforts have been made to manufacture APIs locally in the U.S. HHS invested more than USD 105 million which drove 'significant advancements' in the chemistries and process development for continuous production of APIs including dexmedetomidine, rocuronium, and fentanyl.
- Additionally, in order to address long-term supply chain resilience concerns in the broader economy, the Biden administration announced new supply chain policies focused on rebuilding domestic production and innovation.[631] One of these initiatives include providing capital to businesses to fill 'critical supply chain gaps' especially in areas such as biotech and biomedical products in the form of export credit.[632]

SUGGESTIONS

It is clear that the United States is moving towards promoting domestic manufacturing of pharmaceutical products and is providing subsidies and incentives to promote the same. This presents both opportunities and obstacles to Indian pharmaceutical businesses.

631. Center for Strategic and International Studies, "Takeaways from President Biden's Supply Chain Plan for 2022" available at < https://rb.gy/o4vpfj> last accessed September 17, 2022.
632. Reuters, "U.S. EXIM Bank approves 'Make More in America' initiative to boost manufacturing" available at < https://rb.gy/lts3zr> last accessed September 17, 2022.

RESTRICTIONS ON GOVERNMENT PROCUREMENT

In 2021, the U.S. government-spending amounted to USD 6.82 trillion, out of which USD 796 billion (3rd largest spending domain) was spent on healthcare alone.[633] Federal procurement is subject to multiple regulations that stipulate country requirements, domestic preference, and country of origin requirements akin to multilateral/bilateral obligations.

The U.S. government has been focused on increasing domestic production of drugs and reducing dependence on foreign APIs in supply chains.

Currently, the **Buy American Act** ("**BAA**") requires that the products procured by federal agencies are comprised of domestic components exceeding 55% of the total cost of components. These requirements only apply to direct purchases by the U.S. federal government value at more than USD 10,000.[634]

However, effective from October 2022, the domestic content threshold for non-iron and steel products will be increased in a staggered manner:

Year	Domestic Content Requirement
October 25, 2022	60%
2024	65%
2029	75%

The new rules also create a 'fallback threshold' which allows agencies to use the old 55% threshold for products or construction materials that are not available or are of an unreasonable cost. The fallback threshold is available only until calendar year 2030.

633. Office of Chief Data Officer, Bureau of Fiscal Service, Department of the Treasury, "Data Lab" available at <https://rb.gy/39n766> last accessed November 23, 2022.
634. Government of Canada, "Export Guides and Statistics, U.S. Government Procurement: The Buy American Act and Buy America requirements" available at <https://rb.gy/dlflxa> last accessed November 23, 2022.

The BAA establishes a price preference for government procurement of domestic end products, over foreign goods. Notably, federal agencies are not prohibited from purchasing foreign products if it is less costly after a comparative price evaluation test. Essentially, under the comparative price evaluation test, the contracting officer marks up the prices of the foreign products by the percentage prescribed by law. If the cost of the foreign goods is still lower than the cost of the domestic goods, the federal agencies may procure the foreign goods. The 'penalty' in terms of percentage of price offered is as follows:

Type of Procurement		Penalty on Bid of Foreign Product
Civil Agency Procurement	Large domestic business	20%
	Small domestic business	30%
Department of Defense		50%

A. EXCEPTIONS

In certain circumstances, a product, project, or consignment will qualify for an exception under the Buy American provisions. The U.S. government may procure goods not originated in the United States if it is in public interest, the cost of U.S. originating goods is unreasonable, or the U.S. originating good are not produced in commercial quantities or are not of a satisfactory quality. [635]

Separately, the Trade Agreements Act allows for the waiver of the application of any law, regulation, or practice regarding government procurement which would discriminate against eligible products or suppliers from certain countries. This is to ensure that the United States complies with its international obligations under various trade agreements, including the WTO Government Procurement Agreement.

Most free trade agreements entered into by the United States echo the obligations of the United States under the Government Procurement Agreement. Such obligations include national treatment and most-favored-nation treatment to foreign suppliers. Simply put, U.S. Federal Agencies must grant foreign suppliers' treatment no less favorable than other domestic or foreign goods, services, and suppliers (who are Members to the GPA or any other trade agreement which contains such a provision). If a WTO Member party to the GPA or a country party to a U.S. free trade agreement believes a U.S. government procurement measure violates the agreement, it could potentially challenge the measure in a dispute settlement proceeding in accordance with the relevant agreement.

635. 8302, 41 U.S. Code.

Accordingly, the United States Trade Representative has waived the BAA for eligible products from (i) Parties to the WTO GPA, (ii) parties to most U.S. free trade agreements, (iii) certain least developed countries, and (iv) certain Caribbean Basin countries.[636] Annexes to the WTO GPA and U.S. free trade agreements indicate which products and services of a particular country are covered for procurement by the United States, often by either including or excluding certain products and services under the terms of the agreement. It may also be noted that such annexes also specify the entities which are bound by the procurement obligations. Therefore, not all public entities are bound by the principles of non-discrimination embedded in these trade agreements. Notably, the TAA carves out an exception for certain acquisitions including ones set aside for small businesses, of end products for resale and certain non-competitive acquisitions.

However, it may be noted that in August 2020, the Trump Administration signed Executive Order 13944, which was aimed at reducing dependence on foreign drugs and devices which are critical to the U.S. public health sector. Executive Order 13944 requires federal agencies to facilitate the domestic production of such medicines that the FDA deems essential to public health. Critically, Executive Order 13944 mandated the exclusion of 'critical' drug input items from the U.S.'s government procurement commitments under the Government Procurement Agreement and other free trade agreements. However, such action has not been enforced yet.

SUGGESTIONS

India is not a party to the GPA and hence imports from India to federal agencies are subject to the provisions of the BAA. This may be a factor relevant to negotiations with the United States, and principles of non-discrimination may be agreed upon. Further, emphasis may be placed on appropriate dissemination of information regarding tenders.

636. Congressional Research Services, "The Buy American Act and Other Federal Procurement Domestic Content Restrictions" available at < CBP, "Importing into the United States" available at < https://rb.gy/ldukq1 > last accessed September 15, 2022> last accessed September 15, 2022.

INVESTMENT BARRIERS RELEVANT TO PHARMACETICAL SECTOR

As elaborated above, the stringent market authorizations surrounding duplicative patents create significant barriers of entry for Indian investments in the U.S. pharmaceutical sector.

SUGGESTIONS

Investment barriers can be set on the agenda of the next session of the United States-India Trade Policy Forum:

- The Indian government may consider emphasizing the need to combat patent thickets and product hopping through legislation and policy. Pharmaceutical companies should not be allowed to apply for patents over minor variations of a patented drug.
- The regulatory requirements of FDA for establishing and operating a pharmaceutical company are stringent. Administrative delays result in longer timelines and high costs of new drug approvals in the United States. It may be recommended to make the process more flexible in order to incentivize investment in the pharmaceutical sector in the U.S.

India may also propose the commercialization of products which have already been approved in regulated markets such as Canada, the United Kingdom, and the European Union. This would encourage Indian companies to form base in the United States, incentivize investment, and employment opportunities in the United States.

QUANTITATIVE RESTRICTIONS

A. LICENSING REQUIREMENTS

Licensing requirements that act like Quantitative Restrictions on biological products for human consumption are regulated under the Public Health Service Act.[637] Domestic as well as foreign manufacturers must obtain a U.S. license for both the manufacturing establishment and for the product intended to be produced or imported.[638]

B. PROHIBITIONS

Largely, it is illegal for individuals to import drugs or devices in the U.S. for personal use. But, according to FDA's prior notice requirements, some exceptions to this prohibition are available. These exceptions include[639]–

01 The product is for a serious condition for which effective treatment may not be available domestically either through commercial or clinical means.

02 There is no known commercialization of the product to persons residing in the U.S.

03 The product does not represent an unreasonable risk.

04 The quantity is generally not more than a 3-month supply

637. CBP, "Importing into the United States" available at < https://rb.gy/ldukq1> last accessed September 15, 2022.
638. CBP, "Importing into the United States" available at < https://rb.gy/ldukq1 > last accessed September 15, 2022.
639. FDA, "Person Importation" available at <https://rb.gy/frcmum> last accessed September 15, 2022.

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