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The Indian Pharmaceutical Industry

Regulatory, Legal and Tax Overview

April 2023

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Regulatory, Legal and Tax Overview

April 2023



Asia-Pacific
Most Innovative Indian Law Firm: 2019, 2017, 2016, 2015, 2014



Asia Pacific
Band 1 for FinTech, Technology Media & Telecoms: 2021
Band 1 for Employment, Lifesciences, Tax, TMT: 2021, 2020, 2019, 2018, 2017, 2016, 2015



Tier 1 for Private Equity: 2020, 2019, 2018, 2017, 2014
Deal of the Year: Private Equity, 2020



Asia-Pacific
Tier 1 for Data Protection, Dispute, Tax, Investment Funds, Labour & Employment, TMT, Corporate M&A: 2021, 2020, 2019, 2018, 2017, 2016, 2015, 2014, 2013, 2012



Asia-Pacific
Tier 1 for Government & Regulatory, Tax: 2020, 2019, 2018



'Outstanding' for Technology, Labour & Employment, Private Equity, Regulatory, Tax: 2021, 2020, 2019



Global Thought Leader — Vikram Shroff
Thought Leaders, India — Nishith Desai, Vaibhav Parikh, Dr. Milind Antani
Arbitration Guide, 2021 — Vyapak Desai, Sahil Kanuga
Eminent Lawyer in Sports and Gaming 2021: Tanisha Khanna



Young Lawyer of the Year (Law Firm) 2022: Aarushi Jain



Winner for Data Compliance and Cybersecurity, Labour and Employment, Media and Entertainment, Pharma and Life Sciences, Taxation (Direct), Taxation (Indirect): 2022



Fastest growing M&A Law Firm: 2018



Asia Mena Counsel
In-House Community Firms Survey: Only Indian Firm for Life Science Practice Sector: 2018

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Executive Summary

The Indian Pharmaceutical industry is expected to grow up to USD 130 billion in value by the end of 2030.¹ In FY22 India had exported pharmaceutical products worth USD 24.62 billion and it has been projected that Indian pharmaceutical exports will reach USD 27 billion in FY 2023.² India also has the largest number of manufacturing sites approved by the United States Food and Drug Administration (US FDA) outside of the United States.³

The industry is typically involved in four types of businesses: marketing of generic medicines, marketing of branded generic medicines, marketing of innovator medicines and manufacture and supply of active pharmaceutical ingredients, which are used as ingredients in medicines as well as finished formulations.

While there has been a push for more research and development (R&D) in India, the industry is primarily focused on manufacturing of generic medicines and export of bulk drugs. The focus on development of new drugs began with the introduction of amendments to India's patent regime in 2005 which permitted patenting of pharmaceutical products. Thus, while many domestic companies are investing substantial amounts in drug research and development, India is still not an innovator's market.

The Indian Pharmaceutical industry is witnessing healthy foreign direct investment, amalgamations and collaborations (such as licensing, co-development, joint distribution and joint ventures). Domestic manufacturers are looking to tap into international generic market which provide high margins. The number of Abbreviated New Drug Applications (ANDA) to the US FDA is also increasing every year. The Industry is witnessing a paradigm shift as the focus is shifting from the manufacturing of generic drugs to drug discovery and development (Glenmark, Sun Pharma, Cadilla Healthcare and Piramal Life Sciences, had applied for conducting clinical trials for numerous new drugs). With the passage of the New Drugs and Clinical Trial Rules, 2019 ("**CT Rules**") the clinical trial sector is also growing steadily with many choosing India as one of the trial sites when conducting global clinical trials. Reportedly, India's clinical trials market is expected to reach \$3.15 billion by 2025.⁴

The pharmaceutical industry, like all industries related to the healthcare sector, is heavily regulated. Right from manufacture of drugs to advertisement and promotion, each step in the drug manufacturing and marketing process is regulated. India's patent regime also contains specific provisions regulating pharmaceutical patents and the sector has seen some significant anti-trust issues on the subject of retail sale of drugs.

The COVID-19 pandemic also had a significant impact on the Indian pharmaceutical industry. The pandemic has both spurred and curtailed the growth of the industry in different instances. In some cases, it has led to growth in drug manufacturing backed by demand from the government and individuals alike for drugs that may be used in the treatment of COVID-19. It has also led to significant investments in India's vaccine manufacturing and supply chain to enable efficient delivery of the vaccine to all Indians. However, for non-COVID related drugs,

1 Business Today, Indian pharma in 2023: Industry experts give big thumbs up to the sector; here's what they are saying, available at: <https://www.businesstoday.in/industry/pharma/story/indian-pharma-in-2023-industry-experts-give-big-thumbs-up-to-the-sector-heres-what-they-are-saying-357290-2022-12-21>, last accessed on February 10, 2023.

2 Business Today, Pharma exports likely to touch all-time high of \$27 bn in FY23 riding on EU, available at: https://www.business-standard.com/article/economy-policy/pharma-exports-likely-to-touch-all-time-high-of-27-bn-in-fy23-riding-on-eu-122122500384_1.html, last accessed on February 10, 2023.

3 Report by United States Food and Drug Administration on the State of Pharmaceutical Quality, available at: <https://www.fda.gov/media/125001/download>, last accessed on February 10, 2023.

4 Fortune India, India now prime destination for big pharma's global clinical trials, <https://www.fortuneindia.com/enterprise/india-now-prime-destination-for-big-pharmas-global-clinical-trials/107141>, last accessed on February 10, 2023.

1. Executive Summary

prices of raw materials have increased, production schedules have been interrupted, factories have been shut down and shipping costs have increased.⁵ Overall, the Indian pharmaceutical industry has ably scaled up operations and adapted to the challenges raised by this pandemic.

The coming decade is expected to bring new highs for the pharmaceutical sector. Backed by strong intellectual property and regulatory framework, coupled with production linked incentives the Indian pharmaceutical industry seems poised on the edge of success.

5 COVID-19 and its impact of India Pharma Inc, available at: <https://www.expresspharma.in/latest-updates/covid-19-and-its-impact-on-india-pharma-inc/>, last accessed on February 10, 2023.

Introduction

The Indian pharmaceutical industry has been witnessing significant growth over the past few years and is expected to grow to USD 130 billion in value by the end of 2030.¹ The drugs and pharmaceuticals sector has also attracted cumulative foreign direct investment of approximately USD 699 million between April-September 2022 according to the data released by the Department for Promotion of Industry and Internal Trade (DPIIT).²

For a global pharmaceutical company seeking to enter the Indian pharmaceutical market today, the opportunities are exciting, and the potential is tremendous. Several factors attract global pharmaceutical companies to India:

- Low cost of production due to a variety of factors including relatively lower labour costs and raw material cost;
- Big market not only for life saving drugs but also for lifestyle drugs;
- Potential for conducting research and development activities in India — India has more than 300 medical colleges, over 20,000 hospitals;
- Existing manufacturing capability to produce active pharmaceutical ingredients (APIs) as well as intermediates at lower cost while maintaining quality;
- India has a maximum number of USFDA approved plants outside the US;
- Ease of conducting clinical trials and bioavailability and bioequivalence studies due to India's ability to provide speedier and less expensive trials without compromising quality and due to a vast patient pool.

India has also witnessed a keen interest on behalf of global pharmaceutical companies, seeking to either establish operations in India for research and development, manufacturing or distribution or to enter into collaborations for the same. India's low-cost research and development abilities help companies optimize costs in a shrinking economy.

For a trans-national entity seeking a presence in India, whether directly or through contractual arrangement, structuring of the investment arrangement from a tax and regulatory perspective is very critical. This is especially true because the Indian pharmaceutical market has become the hotbed of M&A activity. In 2022, 16 M&A deals worth nearly a billion dollars were reported in the pharmaceutical sector in India.³

Further e-commerce opportunities in the pharmaceutical sector is on the rise bringing within its ambit the online sale of pharmaceutical products creating an attractive stream for investments and businesses. Doorstep delivery of medicines paved the way for e-pharmacies in the country which run parallel to brick and mortar pharmacies until a legislation in this regard is introduced in the country.

1 Business Today, Indian pharma in 2023: Industry experts give big thumbs up to the sector; here's what they are saying, available at: <https://www.besinesstoday.in/industry/pharma/story/indian-pharma-in-2023-industry-experts-give-big-thumbs-up-to-the-sector-heres-what-they-are-saying-357290-2022-12-21>, last accessed on February 10, 2023.

2 Department for Promotion of Industry and Internal Trade Quarterly Fact Sheet From April, 2000 To September, 2022 , available at: https://dpiit.gov.in/sites/default/files/FDI_Factsheet_September_2022_0.pdf, last accessed on February 10, 2023.

3 Times of India, Indian pharma companies turn bullish on M&A route, available at: <https://timesofindia.indiatimes.com/business/india-business/indian-pharma-companies-turn-bullish-on-ma-route/articleshow/96329876.cms>, last accessed on February 10, 2023.

2. Introduction

On the surface, Indian law appears to be a complex set of regulations, notifications and approval requirements. However, with steps that India has already taken to honor its World Trade Organization (WTO) commitments, combined with the liberalization and the relaxation of the export-import policy, foreign companies seeking to enter this space will experience that most of the restrictions that existed on issues like pricing and licensing have now been relaxed to the extent that there is now a level-playing field for global and Indian companies.

In this paper we have outlined the entity structures, the tax regime, both direct and indirect, affecting the structuring of Indian operations, the regulatory aspects and the intellectual property issues that affect the pharmaceutical and life sciences industry.

India Entry Strategies

A basic understanding of the Indian legal system is a pre-requisite to do business in pharmaceuticals in India. International pharma companies or investors seeking to make investments in Indian pharma companies should structure their activities on the following three pillars:

Strategy	Law	Tax
<ul style="list-style-type: none"> ▪ Observing the economic and political environment in India from the perspective of the investment ▪ Understanding the ability of the investor to carry out operations in India, the location of its customers, the quality and location of its workforce 	<ul style="list-style-type: none"> ▪ Exchange Control Laws: Primarily the Foreign Exchange Management Act, 1999 and numerous circulars, notifications and press notes issued under the same ▪ Corporate Laws: Primarily the Companies Act, 2013 and the regulations laid down by the Securities and Exchanges Board of India ("SEBI") for listed companies in India ▪ Sector Specific Laws: Drugs & Cosmetics Act 1940 and the Drugs & Cosmetics Rules, 1945, The Patents Act, 2005 and other legislations, regulations and guidelines that affect the pharma industry 	<ul style="list-style-type: none"> ▪ Domestic Taxation Laws: The Income Tax Act, 1961; Goods and Services Tax and customs etc. ▪ International Tax Treaties: Treaties with favorable jurisdictions such as Mauritius, Singapore and the Netherlands.

A. Investment Climate in India

By and large foreign direct investments are now permitted in almost all the sectors in India without obtaining prior regulatory approvals (i.e. under the "**automatic route**") barring some exceptional cases like defense, housing and real estate, print media, etc. (commonly referred to as the "**negative list**"). If the investment is not in accordance with the prescribed guidelines or if the activity falls under the negative list, prior approval must be obtained from the concerned department ("**approval route**").

In case of the pharmaceutical sector, foreign direct investment is permitted up to 100%. However, permission from the Department of Pharmaceuticals is required to buy more than 74% shareholding in existing companies. It must be noted that a non-compete condition with the existing shareholders is no longer allowed except in special circumstances at the discretion of the government. The Central Government also has the right to add new conditions to an investment if the investor proposes to acquire more than 74% of an existing pharmaceutical company. However, there is no prior permission required to incorporate a wholly owned subsidiary in India.

3. India Entry Strategies

B. Government Production Linked Incentives

In the recent past, given the increased focus on domestic innovation and manufacturing, the Government has introduced various production linked incentive (“**PLI**”) schemes. In 2020, the Government announced the PLI Scheme for Promotion of Domestic Manufacturing of critical Key Starting Materials (KSMs)/ Drug Intermediates and Active Pharmaceutical Ingredients (APIs) in the Country with a financial outlay of approximately USD 841 million.

Further, in 2022, the Government launched the Scheme for Strengthening of Pharmaceuticals Industry with an object to address demands of support required to existing Pharma clusters and Micro, Small and Medium Enterprises to improve their productivity, quality and sustainability. This scheme has a financial outlay of USD 61 million. Most recently, in the allocation of budget for FY 2023–24, the Government has announced research linked incentives for the industry.

C. India’s Post-Trips Intellectual Property Environment

In March 2005, India’s patent law was amended to incorporate India’s obligations under World Trade Organization (WTO) regulations and, specifically, the Trade Related Aspects of Intellectual Property Rights Agreement (“**TRIPS**”). Prior to the adoption of TRIPS, protection of intellectual property rights (IPRs) in India was of concern to global pharmaceutical companies seeking to enter India. Post-TRIPS, India has well-established statutory, administrative, and judicial frameworks to safeguard IPRs.

A patented invention (including products) is now given twenty years of protection in India. Well-known international trademarks such as Volvo and Whirlpool have been protected in India through judicial decisions even when they were not registered in India. Computer software companies have successfully curtailed piracy through court orders. Computer databases and software programs have been protected under copyright. Computer programs having technical applications to industry and computer programs in combination with hardware can now be patented in India. Though trade secrets and know-how are not protected by any legislation, they are protected under the common law and through contractual obligations. The courts, on the ground of breach of confidentiality, accord protection to confidential information and trade secrets.

India’s patent law is also well placed to provide protection for pharmaceutical products developed and manufactured through innovative processes such as 3D printing. This is because, India recognizes both product and process patents for pharmaceutical products.

D. Form of the Indian Entity

Depending upon the proposed operations in India, the foreign pharma companies may consider setting up the following entities, which may either be unincorporated or incorporated.

3. India Entry Strategies

I. Unincorporated Entities

A foreign company can use unincorporated entities to do business in India via ‘offices’ of certain types. These options are as follows:

A. Liaison Office

Setting up a liaison office in a sector in which 100 percent FDI is allowed under the automatic route requires the prior consent of the Authorized Dealer (“AD”).¹ For the remaining sectors, RBI grants its approval after consultation with the Ministry of Finance. A liaison office acts as a representative of the parent foreign company in India.

However, a liaison office cannot undertake any commercial activities and must maintain itself from the remittances received from its parent foreign company. The approval for setting up a liaison office is generally valid for three years and can be extended by making an application to AD before the date of expiry of validity. It is an option usually preferred by foreign companies that wish to explore business opportunities in India.

B. Branch Office

Similar to a liaison office, the branch office of a foreign company in India must be set up with the prior consent of the AD² for sectors under which 100 percent FDI is permissible under automatic route, with approval under other sectors accorded after consultation with the Ministry of Finance. It can represent the foreign parent company in India and act as its buying or selling agent in India. However, a branch office cannot carry out any retail, manufacturing or processing activities. The branch office is permitted to remit surplus revenues to its foreign parent company subject to the taxes applicable. Operations of a branch office are restricted due to limitations on activities that it can undertake. The tax on branch offices is 40% plus applicable surcharges and the education cess. It is an option that is useful for companies that intend to undertake research and development activities in India.

C. Project Office

A foreign company, subject to obtaining approval from the AD, may set up a project office in India under the automatic route subject to certain conditions being fulfilled including the existence of a contract with an Indian company to execute a project in India. A project office is permitted to operate a bank account in India and may remit surplus revenue from the project to the foreign parent company. The tax on project offices is 40 percent plus applicable surcharges and the education cess. Project offices are generally preferred by companies engaged in one-time turnkey or installation projects.

Other unincorporated entities such as partnerships or trusts are not usually recommended structures for investment, as there are certain restrictions on the foreign direct investment in such structures.

¹ Application made from certain countries as well as for certain sectors still requires approval of the RBI. Available at: https://www.rbi.org.in/Scripts/BS_ViewMasDirections.aspx?id=10404#1, last accessed on February 10, 2023.

² Application made from certain countries as well as for certain sectors still requires approval of the RBI. Available at: https://www.rbi.org.in/Scripts/BS_ViewMasDirections.aspx?id=10404#1F, last accessed on February 10, 2023.

3. India Entry Strategies

II. Incorporated Entities

Incorporated entities in India are governed by the provisions of the Companies Act, 2013 or the Limited Liability Partnership Act, 2008.

A. Limited Liability Partnership (“LLP”)

An LLP is a form of business entity that permits individual partners to be shielded from the liabilities created by another partner’s business decision or misconduct. In India, LLPs are governed by the Limited Liability Partnership Act, 2008. LLP is a body corporate and exists as a legal person separate from its partners.

B. Limited liability Company

Companies may either be ‘private limited companies’ or ‘public limited companies’.

i. Private Limited Company

A private limited company has certain distinguishing characteristics. It must, in its articles of association, restrict the right to transfer shares and prohibit any invitation to the public to subscribe to the securities of the company. The number of members in a private limited company is a minimum of 2 and a maximum of 200 (excluding the present and past employees of the company).

Under the Companies Act, 2013 a natural person who is an Indian citizen and resident in India can also incorporate a one-person company. However, it shall be required to convert itself into a public or private company, in case paid up share capital of the company is increased beyond INR 5 million or its average annual turnover exceeds INR 20 million.

ii. Public Limited Company

A public limited company is defined as a company that is not a private company. However, private companies that are subsidiaries of a public company would be considered to be public companies. A public limited company is required to have a minimum of 7 members. There is no restriction on the number of shareholders of a public company and a public company may invite public to subscribe to its securities. A public limited company may also list its shares on a recognized stock exchange by way of an Initial Public Offering. Every listed company shall maintain public shareholding of at least 25% (with a maximum period of 12 months to restore the same from the date of a fall).

Between an LLP and a Limited Liability Company, an LLP structure is not preferred for a pharmaceutical manufacturing company because an LLP whose business is to manufacture drugs cannot receive foreign investment under the present foreign direct investment policy.

3. India Entry Strategies

C. Advantages and Disadvantages of a Private Company

i. Advantages

- Not as stringently regulated as a public company.
- More flexibility than public companies in conducting operations, including the management of the company, issuance of different types of securities and the payment of managerial remuneration.
- Faster incorporation process.

ii. Disadvantages

- Restrictions on invitation to the public to subscribe to securities.
- Limited exit options.

We have observed that most of the pharmaceutical companies consider incorporating a company in India based on the scope of services the company intends to carry on in India. Another common trend is to enter into a direct marketing and distribution arrangement with distributors in India. It has also been observed that the trend of joint ventures between pharmaceutical companies is emerging fast with more and more companies forming joint ventures either for co-development or for manufacturing, marketing and distribution.

E. Corporate Governance in India

Most global pharmaceutical companies would adhere to their corporate governance policies, which are usually formulated on a worldwide basis. In past, some global corporations have faced difficulties in India due to the vast difference in business practices in India and the country in which these companies have a principal place of business.

However, this scenario is changing, with India implementing policies to increase the ease of doing business in India. These policies include the removal of the strict licensing requirements, the reduction of tax rates and relaxation of exchange controls, all of which have significantly reduced the potential for bribery and corruption and have brought about greater transparency in the governmental and regulatory systems.

F. Anti-Corruption Framework

The Prevention of Corruption Act, 1988 (“PCA”) is India’s primary anti-corruption legislation. The PCA was amended significantly in 2018 to bring the law up to speed with current times. Some unique features of PCA, especially while comparing it to the UK Bribery Act and Foreign Corrupt Practices Act, 1977, are:

- i. The PCA criminalizes the offence of offering any ‘undue advantage’ to a public servant only and the receipt of such ‘undue advantage’ by the public servant. Due to this, both person offering and accepting the ‘undue advantage’ may be held liable.
- ii. The scope of the term ‘public servant’ is broad enough to cover anyone who is performing a public duty or is receiving public funds. It applies to both individuals as well as commercial organizations.
- iii. The PCA does not criminalize corrupt practices amongst private entities such as payments made beyond a contract, or payments made to fraudulently secure contracts in the private sector. It also does not criminalize bribes paid to foreign government officials or official of a public international organization.
- iv. It does not make any distinction between illegal gratification and facilitation payment.
- v. The term ‘undue advantage’ includes all gratification other than legal remuneration due to the public servant.

Commercial organizations are now specifically covered under the PCA where even officials in charge of such commercial organizations may be punished.

Legal and Regulatory Regime in India

A. Outline of Legal and Regulatory Framework

The legal and regulatory framework under which pharmaceutical business is carried out comprises mainly of the following laws:

- i. Drugs and Cosmetics Act, 1940
- ii. Drugs and Cosmetics Rules, 1945;
- iii. New Drugs and Clinical Trial Rules;
- iv. Essential Commodities Act, 1955 and Drugs (Price Control) Order, 2013 (DPCO);
- v. The Drugs and Magic Remedies (Objectionable Advertisements) Act, 1954;
- vi. The Drugs and Magic Remedies (Objectionable Advertisements) Rules, 1955;
- vii. The Narcotic Drugs and Psychotropic Substances Act, 1985;
- viii. Patents Act, 1970;
- ix. Trade Marks Act, 1999;
- x. Competition Act, 2002.

B. Regulatory Framework

The primary statute that regulates the Indian pharmaceutical industry is the Drugs and Cosmetics Act, 1940 (“DCA”) and the rules framed thereunder viz. Drugs and Cosmetics Rules, 1945 (“DCR”) and the New Drugs and Clinical Trial Rules, 2019 (“CT Rules”).

The DCA, DCR and the CT Rules seek to:

- Regulate the clinical trial, import, manufacture, distribution and sale of drugs.
- Ensure the availability of standard quality drugs and cosmetics to the consumer.

4. Legal and Regulatory Regime in India

I. Legal Definition of Drug

A drug is defined comprehensively under the DCA.¹ The definition of a drug includes medicines that are meant for internal as well as external use including substances used for the diagnosis, treatment or prevention of disease. It also includes components of drugs as well as devices that are used internally or externally for the diagnosis, treatment or prevention of disease.

Depending upon facts and circumstances of the case, the chemicals imported into India for pre-clinical studies, may not fall under the definition of drug and subsequently the provisions of the DCA and DCR may not apply in relation to their manufacture and import.

II. Authorities

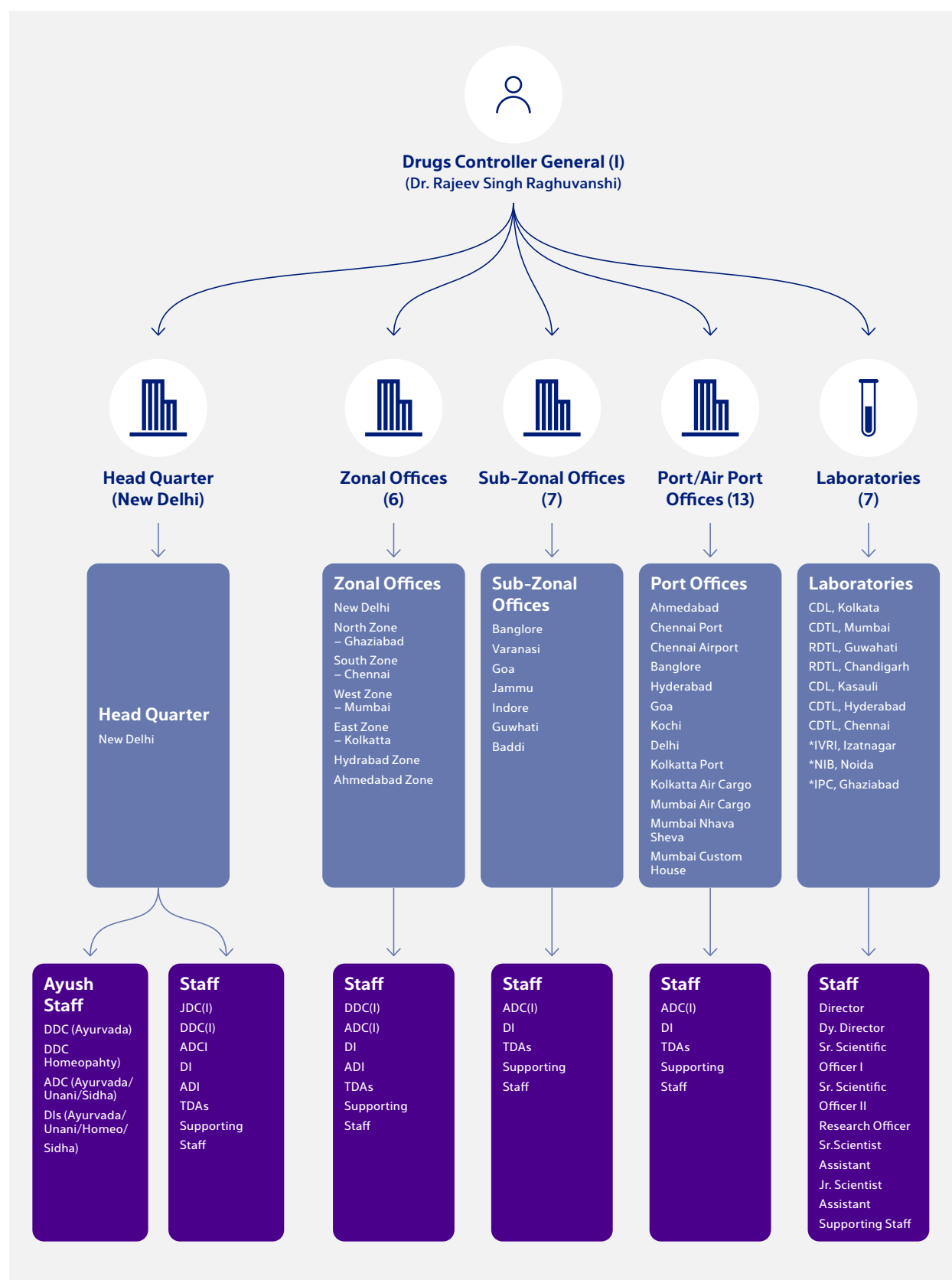
The Central Government and the State Governments are responsible for the enforcement of the DCA. The Central Drugs Standard Control Organization (“CDSCO”), headed by the Drug Controller General of India (“DCGI”) is primarily responsible for coordinating the activities of the State Drugs Control Organization, formulating policies, and ensuring uniform implementation of the DCA throughout India. The DCGI is responsible for handling matters of product approval and standards, clinical trials, introduction of new drugs, and import licenses for new drugs.

¹ Per Section 3 (b) of the DCA : “drug” includes —

- (i) all medicines for internal or external use of human beings or animals and all substances intended to be used for on in the diagnosis, treatment, mitigation or prevention of any disease or disorder in human beings or animals, including preparations applied on human body for the purpose of repelling insects like mosquitoes;
- (ii) such substances (other than food) intended to affect the structure or any function of the human body or intended to be used for the destruction of vermin or insects which cause disease in human beings or animals, as may be specified from time to time by the central government by notification in the official gazette;
- (iii) all substances intended for use as components of a drug including empty gelatin capsules; and
- (iv) such devices intended for internal or external use in the diagnosis, treatment, mitigation or prevention of disease or disorder in human beings or animals, as may be specified from time to time by the central government by notification in the official gazette, after consultation with the board.

4. Legal and Regulatory Regime in India

Organizational Structure of the Central Drugs Standard Control Organization (CDSCO)

Source: <https://cdsco.gov.in/opencms/opencms/en/About-us/Introduction>

4. Legal and Regulatory Regime in India

On the other hand, the approvals required for setting up manufacturing facilities, and obtaining licenses to sell and stock drugs are provided by the respective State Governments.

III. Licenses Required for Import, Sale, Manufacture and Loan of Drugs under the Drugs and Cosmetics Rules 1945²

All the license applications to be made to the DCGI may be made electronically via an online licensing portal called SUGAM accessible at cdscoonline.gov.in. We have provided a list of licenses under the DCA in **Annexure A**.

All the above licenses are periodic and are required to be renewed. The grant and renewal of all licenses are conditional upon the satisfaction of requirements under the DCA and DCR. The license also imposes certain conditions, which are required to be complied with, during the subsistence of a license. The CDSCO has also released a list of targeted timelines for approvals, as provided in **Annexure B**.

C. Proposed Law on Regulation of Pharmaceutical Products

In 2022, the Government released the draft of the Drugs, Medical Devices and Cosmetics Bill, 2022 (“**Proposed Drug Law**”) which proposes to overhaul the existing DCA to introduce a comprehensive regime for governing all drugs, medical devices, indigenous drugs and devices, clinical trials and marketing approvals and cosmetics in India. It also seeks to regulate online pharmacies. It is anticipated that the Proposed Drug Law may be enacted in 2023.

The key aspects of the Proposed Drug Law have been analysed in our paper titled here.³

D. Manufacturing a Drug in India

To manufacture a drug in India, both the premise and the drug have to be licensed. Once licensed, a drug manufactured at any place in India can be sold across the country without restriction, provided the purchaser is either an end consumer or a business with a license to purchase the drug and the seller is authorized to sell the drug to the purchaser.

Under the DCA, “manufacturing” includes any process (or part) for making, altering, ornamenting, finishing, packing, labeling, breaking up or otherwise treating or adopting any drug with a view to its sale or distribution. However, “manufacturing” does not include dispensing or packing at the retail sale level.

Since 2016, bioequivalence study for Schedule C, Schedule C (1) and Schedule X drugs is mandatory to obtain a manufacturing license. If the drug is a new drug (discussed later), then a clinical trial may have to be undertaken prior to the grant of a manufacturing license.

² Available at: <http://cdsco.nic.in/html/importdrugs.htm>, last accessed on February 10, 2023.

³ Draft Drugs, Medical Devices and Cosmetics Bill, 2022: Dawn of a New Era?, available at: <https://www.nishithdesai.com/SectionCategory/33/Pharma-Healthcare-Update/12/67/PharmaHealthcareUpdate/6264/1.html>.

4. Legal and Regulatory Regime in India

All manufacturing licenses are perpetual in nature, and a retention fee is required to be paid after five years for keeping the license alive. The manufacturer of the drug was solely liable for the quality of the drug and the regulatory compliances in respect of drug under the DCR. However, from March 01, 2021, this liability will be shared by both the manufacturer and the marketer of the drug. The DCR defines marketer as:

“a person who as an agent or in any other capacity adopts any drug manufactured by another manufacturer under an agreement for marketing of such drug by labeling or affixing his name on the label of the drug with a view for its sale and distribution”.

Marketers are now required to enter into an agreement for sale and distribution of the drug with the manufacturer of the drug prior to marketing the product.

E. Importing a Drug into India

The import of goods and services into India is regulated by the Foreign Trade (Development and Regulation) Act, 1992 (FTA). The FTA provides that a drug may be imported into India in accordance with the provision of the DCA and DRA.

The DCA says that to import a drug into India, the foreign manufacturing facility as well as the drug itself must be registered with the DCGI. To register, the foreign manufacturer, or its agent i.e. the importer, is required to submit the plant master file and drug master file in the stipulated format. Once registered, the importer in India is required to obtain an import license from DCGI. The registration certificate and import license is valid for three years. A drug cannot be imported without a registration certificate and import license, unless it is being imported for export.

It is a requirement for the importer to be based out of India and have either a license to manufacture any type of drug or a license to sell drugs by wholesale. Typically, the importer is also the authorized agent for the foreign manufacturer, responsible for the business of foreign manufacturer in India and resultant liability. The authorized agent is appointed by way of prescribed power of attorney. It is possible that there are two or more importers of the same drug in India.

In case the drug being imported into India is a new drug (discussed under the clinical trial section below), the foreign manufacturer is required to obtain a marketing permission prior to applying for registration, and the grant of such permission depends on the foreign manufacturer/importer's ability to show that the drug is safe and efficacious.

Before a drug is sold in India, it must comply with local labelling requirements. It is not always possible for a drug having a global label to carry India-specific declarations before it is imported into India. In such circumstances, a label carrying India-specific declarations on the drug package can be affixed at the custom bonded warehouse before it is cleared for consumption in India.

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F. Manufacture/Import of New Drugs

The term “New Drug” is defined under the CT Rules as follows:⁴

“new drug” means, -

- i. A drug, including active pharmaceutical ingredient or phytopharmaceutical drug, which has not been used in the country to any significant extent, except in accordance with the provisions of the act and the rules made there-under, as per conditions specified in the labelling thereof and has not been approved as safe and efficacious by the central licensing authority with respect to its claims; or
- ii. A drug approved by the central licensing authority for certain claims and proposed to be marketed with modified or new claims including indication, route of administration, dosage and dosage form; or
- iii. A fixed dose combination of two or more drugs, approved separately for certain claims and proposed to be combined for the first time in a fixed ratio, or where the ratio of ingredients in an approved combination is proposed to be changed with certain claims including indication, route of administration, dosage and dosage form; or
- iv. A modified or sustained release form of a drug or novel drug delivery system of any drug approved by the central licensing authority; or
- v. A vaccine, recombinant deoxyribonucleic acid (r-DNA) derived product, living modified organism, monoclonal antibody, stem cell derived product, gene therapeutic product or xenografts, intended to be used as drug;

Explanation — The drugs, other than drugs referred to in sub-clauses (iv) and (v), shall continue to be new drugs for a period of four years from the date of their permission granted by the central licensing authority and the drugs referred to in sub-clauses (iv) and (v) shall always be deemed to be new drugs.

To manufacture or import a new drug, safety and efficacy data of the new drug is required to be submitted. Such data is generated through a clinical trial. Additionally, it must comply with the shelf-life requirements under the DCR.

G. Clinical Trials

Like in most developed jurisdictions around the world, manufacturers and importers of new drugs must establish the safety and efficacy of the new drug to the satisfaction of DCGI before they may be permitted to be marketed in the territory of India. And, like most developed jurisdictions in the world, the safety and efficacy must be established using both animal data and clinical data. Clinical trials in India are conducted in four phases with each phase beginning upon the successful completion of the previous phase.

Permission from the CDSCO is required prior to beginning each phase of the clinical trial. There are certain unique characteristics in the Indian clinical trial regulations to be taken note of:

⁴ Rule 2(W) of CT Rules.

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- i. For drugs developed in India, all four phases of clinical trials are required to be conducted in India while for drugs developed outside India, data generated during Phase I clinical trials may be submitted as part of the application to conduct clinical trials and permission may be granted to repeat Phase I clinical trials or commence Phase II clinical trials alongside global clinical trials; Phase I clinical trial of a new drug developed outside India is not permitted in India.
- ii. The sponsor of global clinical trial also has to give an undertaking that the sponsor will apply for a marketing authorization in respect of the new drug upon the successful completion of clinical trials.
- iii. The permission granted to conduct a clinical trial is valid for two years. If the trial does not commence within this period, then a new permission has to be obtained.
- iv. There are extremely stringent reporting requirements in terms of format and time-period for reporting of serious adverse event.
- v. The medical management of the patient and its cost is the responsibility and liability of the sponsor for the course of the clinical trial.
- vi. The compensation for clinical trial related death or injury is calculated through a formula and is enforced by way of an administrative order.
- vii. Failure to provide medical management or compensation may result in debarment of the sponsor.
- viii. The sponsor is liable to pay compensation for the negligence of the clinical investigator.
- ix. There is no data exclusivity in India. An investigational new drug (i.e. first in human drug) gets limited data exclusivity for four years after receipt of marketing approval. In these four years, any drug, which is a copy of the investigation new drug, would also be required to submit safety and efficacy data on its own to obtain marketing approval. However, after the expiry of four years, there is no requirement to establish safety and efficacy by a drug which is a copy of the investigational new drug to obtain marketing approval. Biological products such as vaccines and rDNA derived drugs are, however, treated differently and must provide safety and efficacy irrespective of whether four years have elapsed or not.
- x. The CDSCO may waive local clinical trial requirements for drugs which have been approved in countries notified by the Ministry of Health and Family Welfare (“Health Ministry”) under Rule 101 subject to the following:
 - a. No unexpected serious adverse events have been reported in respect of the drug;
 - b. There is no probability or evidence, on the basis of existing knowledge, of difference in the enzymes or gene involved in the metabolism of the new drug or any factor affecting pharmacokinetics and pharmacodynamics, safety and efficacy of the new drug, between the Indian population and the population on which the drug was tested; and
 - c. The applicant for marketing authorization has given an undertaking in writing to conduct Phase IV clinical trial to establish safety and effectiveness of the new drug/vaccine as per the design approved by the CDSCO. However, this requirement may be relaxed by the CDSCO where the drug is indicated for life threatening or serious diseases, or diseases of special relevance to the Indian public health, or for a condition which has an unmet need in India (e.g. hepatitis C, H1N1 or malaria, or for rare diseases and orphan drugs).

The CDSCO is also empowered to grant an accelerated or expedited approval for a drug in the event taking into account the severity, rarity, prevalence of the disease and lack of alternative treatments or the life threatening and rare nature of the disorder respectively.

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Data management is also a key component of conducting clinical trials in India. Clinical trials require the collection and processing of health and medical information of an individual. Information relating to an individual's physical, physiological, and mental health condition as well as medical records and history is considered to be sensitive personal information under India's data privacy legislation — the Information Technology (Reasonable security practices and procedures and sensitive personal data or information) Rules, 2011 (“**SPDI Rules**”) framed under the Information Technology Act, 2000. The sponsor, contract research organization, institution where the trial is being conducted and the investigator are all required to comply with certain requirements under the SPDI Rules. Broadly, these include processing the sensitive personal information of the trial subject under and in accordance with the terms of consent provided by the trial subject. Further, the consent should be obtained after informing the trial subject regarding the types of data collected, the manner in which this data may be used and with whom it may be shared.

India has consistently attracted global clinical trials due its sizeable patient population, highly qualified and trained medical professionals, familiarity of the population with English, state of the art medical facilities and affordability. We have discussed the Indian clinical trial landscape in detail in our paper [here](#).⁵

H. Product Standards

No drug can be imported, manufactured, stocked, sold or distributed unless it meets the quality and other standards defined in the DCA. For instance, for patented or proprietary medicines (medicines not listed in the Indian or other pharmacopoeias), the product should comply with the ingredients displayed in the prescribed manner on the label or container and such other standards prescribed by the DCR. General standards for all patent or proprietary medicines, tablets, capsules, liquid orals, injections and ointments have been defined by the DCA. Drugs should not be misbranded, adulterated, or spurious.

The Central Government has the power to prohibit the import, manufacture or sale of any drug, including those that are deemed as “irrational drug combinations”. For instance, the import and manufacture of Fenfluramine and Dexfenfluramine is prohibited. Similarly, other banned drugs include fixed dose combinations of vitamins with anti-inflammatory agents, tranquilizers or analgesics or tetracycline and vitamin C.

I. OTC and Prescription Drugs

A license is required to buy and sell drugs in India. The law does not make a distinction between over the counter and prescription drugs for licensing purposes and a license is required to sell both types of drugs. However, certain drugs such as paracetamol, quinine and other anti-malaria drugs, antacid preparations etc. may be sold without a sale license. Such drugs are specified in Schedule K of the DCR.

Indian law does not specifically define over-the-counter (‘OTC’) drugs. The DCR provides an extensive list of prescription drugs under Schedule H, H1 and X. The drugs which are not mentioned in the said Schedules can be sold without the prescription by a medical professional and are generally referred to as OTC drugs. The prescription drugs cannot be advertised in the general media.

⁵ Clinical Trials in India, Nishith Desai Associates, accessible here: https://www.nishithdesai.com/fileadmin/user_upload/pdfs/Research_Papers/Clinical-Trials-in-India.pdf, last accessed on February 10, 2023.

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J. Pharmacy

It is mandatory for all pharmacies to be licensed. If the pharmacy sells prescription drugs, it is mandatory for the pharmacy to have a registered pharmacist. If it is found that a prescription was dispensed without the presence of a registered pharmacist, then the regulatory authority has the power to order suspension or permanent closure of the pharmacy.

The pharmacy has to keep records of the seller/manufacturer from whom it has procured medicine and the buyer/patient to whom it has sold medicine. In case of prescription drugs, the registered pharmacist is required to make a note of dispensation on the original prescription so that the same prescription is not re-dispensed without medical advice.

At the time of sale of any narcotic or psychotropic drug, the registered pharmacist is required to store and preserve one of the two prescriptions that are issued by the registered medical practitioner as per the requirement of law.

K. E-Pharmacy

Sale of medicine over the internet has recently picked up in India. At present, there are no direct rules for selling medicines online, in absence of which the current rules for brick-and-mortar sale have to be complied with. Therefore, the sale of medicines over the internet is facing some bad weather due to regulatory challenges such as:

- i. Acceptability of scan or photograph of an original prescription to dispense medicine
- ii. Requirement to obtain a license for offering medicines for sale over the internet
- iii. Obligation on the registered pharmacist to hand over the medicine to the patient or the caregiver
- iv. Prohibition on storing medicines by courier companies for logistics purposes without a license

The government has published draft E-pharmacy Rules, 2018 that seek to clarify the government's position on some of the above issues. For instance, the draft rules propose that every person who offers to sell medicines over the internet would be required to be registered. However, the draft rules are silent on the other challenges identified above.

On October 31, 2018, the High Court of Madras asked the Central Government to ensure that no prescription medicine is sold online without a license. The requirement to suspend business was subsequently stayed by the Madras High Court until final disposal of the case, given that the draft rules have already been released and is nearing notification, and in the meantime the drug authorities were still empowered to initiate action for illegal sale of prescription medication.

The Delhi High Court, on the other hand, passed an interim order injunctioning certain online pharmacies from selling medicines online, without a license. The matter is yet to be finally adjudicated. Subsequently, in November, the DCGI issued an order to drug controllers across India to ensure that the interim order of the Delhi High Court is enforced. While this was widely seen as imposing a ban on online pharmacies, the order did not explicitly ban e-pharmacies and merely required drug controllers to ensure that drugs were not sold online without a license. Eventually, the draft E-pharmacy Rules, 2018 were not enacted due to several parallel developments owing to COVID-19 pandemic and the Proposed Drug Law.

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In March 2020, in light of the COVID-19 pandemic in India, the Health Ministry issued a notification permitting doorstep delivery of drugs. Notably, the Notification was made under Section 26B of the D&C Act, which permits the Central Government to regulate the manufacture, sale or distribution of a drug in public interest e.g. in emergencies arising due to epidemic or natural calamities. It is currently unclear how long this notification would be in effect and whether similar home delivery models would be permitted once the COVID-19 pandemic subsides.

With the passage of the Proposed Drug Law, it is anticipated that the gap in regulation of online pharmacies will be remedied. The Proposed Drug Law mandates that a license be obtained for sale of drugs and medical devices through online mode. The current draft of the Proposed Drug Law does not contain the specific requirements and compliances that will be made applicable for online pharmacies, but empowers the Central Government to formulate rules to regulate aspects of this industry.

L. Labeling

Before a drug is sold or distributed in India, it must be labeled according to specifications outlined in the DCR. The DCR specifies labeling standards for non-homeopathic (Part IX), homeopathic drugs (Part IX-A) and biological and other special products (Part X). The ‘Scheduled’ drugs under the DCA are required to indicate the particular drug’s Schedule and must specify the required warnings and additional requirements per the DCR.

In respect of non-homeopathic drugs, the DCR prescribes the pack sizes of drugs meant for retail sale, the contents of the label such as name of the drug, a statement as to the net contents (in terms of weight, measure, volume), the contents of the active ingredient, license number, dates of manufacture, expiry, whether the medicine is for external or internal use, whether it is for human use or animal use, the name and address of the manufacturer and the address of the premises where the drug has been manufactured, the batch number, as well as the drug license number under which it is manufactured (if manufactured in India or elsewhere). Imported products must display the expiration date and potency of the active ingredient in addition to the import license number.

In February 2022, the DCR was amended to incorporate a labelling requirement for active pharmaceutical ingredients manufactured or imported into India. From January 1, 2023, the labels of APIs are to bear a Quick Response code (“QR Code”) to store data or information readable with software application to facilitate tracking and tracing of the product. The stored data associated with the QR code to include certain minimum particulars prescribed, which include name of the API, unique product identification code, brand name, batch number, batch size, date of manufacturing, date of expiry, etc.⁶

M. Shelf Life

Shelf life is the minimum validity that a drug must have at the time of its import. At the time of import into India, a drug must have a minimum of 60% shelf life.

6 Drugs (Amendment) Rules, 2022, available at: https://cdsco.gov.in/opencms/opencms/system/modules/CDS.CO.WEB/elements/download_file_division.jsp?num_id=ODEyMg==.

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N. Good Manufacturing Practices (GMP)

Schedule M of the DCR prescribes GMP guidelines which are compliant with international guidelines of the World Health Organization (WHO). Every pharmaceutical company manufacturing drugs must comply with the provisions of Schedule M. This has led to a significant increase in the quality of drugs manufactured in India and has led to the increase in the contract manufacturing activities whereby Indian companies manufacture bulk drugs or formulations for the contracting pharma company.

Penalty for Selling Adulterated or Counterfeit Drugs

The Ministry of Health and Family Welfare, Government of India (“Ministry”) in the year 2009 notified an amendment to the Drugs and Cosmetics Act, 1940 that attempts to strengthen the existing law against the menace of adulterated and spurious drugs. This amendment has changed certain provisions of the DCA that specifically relate to the offences of manufacture and trade of adulterated and spurious drugs.

Any person who is found guilty of manufacturing, sale, distribution, stocking or exhibiting or offering for sale or distribution of adulterated or counterfeit drug will be levied with a fine not less than INR 1,000,000 or 3 times the value of the drug confiscated, whichever is higher and imprisonment for ten years. The entire amount of fine that is realized from the person convicted for the offence of being dealing with adulterated or counterfeit drug is paid by way of compensation, to the person who consumes the adulterated or spurious drug in question. If the victim has died due to the effect of the adulterated or spurious drug, the relative of the victim is entitled to receive the same amount by way of compensation.

The trials for offences relating to trading in sub-standard drugs will start at the level of the Court of Session. The appeals from the Court of Session lie to the High Court and then to the Supreme Court. A provision of setting up special courts has been provided too and the Offences that relate to adulterated drugs and spurious drugs are now considered to be cognizable offences. Cognizable offence, under the Code of Criminal Procedure of India, is an offence for which a police officer does not require a “warrant” (sanction of a Magistrate) to arrest.

The Ministry also has set up a “whistleblower” policy that aims to reward citizens, who provide information on the trade and source of adulterated or counterfeit drugs.

O. Pricing of Drugs and Drug Price Control Order, 2013

The Drug Price Control Order, 2013 (“DPCO”), has been issued by the Government of India under Section 3 of the Essential Commodities Act, 1955 (“ECA”)⁷ to regulate the prices of drugs. It replaces the Drug Price Control Order, 1995. The DPCO is administered and enforced by the National Pharmaceutical Pricing Authority (“NPPA”). The main objective of the DPCO is to ensure the availability, at reasonable prices of essential lifesaving and prophylactic medicines specified in the National List of Essential Medicines, 2015 (“NLEM”).⁸ The NLEM is typically revised every five years and currently, the NLEM 2022 is in force. NLEM 2022 encompasses a wide range of drugs and devices including anti-cancer drugs, patented drugs, fixed dose combinations, modified release dosage forms etc.

⁷ Section 3 of the Essential Commodities Act, 1955.

⁸ NLEM 2022 is available at: <https://main.mohfw.gov.in/newshighlights-104>, last accessed on February 10, 2023.

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Price Determination and Revision of Prices

The NPPA annually fixes the price of all strengths and dosages of medicines which qualify as essential medicines under NLEM. The manufacturers, importers and marketers of such drugs should ensure that their product is not supplied in the market at a price higher than ceiling price notified by the NPPA.⁹ Separately, the DPCO also empowers the NPPA to also fix the price of drugs (which are not listed in the NLEM) in public interest.¹⁰ For other drugs in respect of which a price has not been fixed (either as a Scheduled Formulation or in public interest), the manufacturers/importers/marketers of the drugs are restricted from increasing the price of the drug by more than 10% over any given 12-month period.¹¹

The Department of Pharmaceuticals notified an order on January 03, 2019¹² amending the DPCO as follows:

- i. Manufacturers, importers and marketers of new drugs patented in India are exempted from price control for a period of five years from the date of commencement of commercial marketing in India (“**New Drug Exemption**”).
- ii. Drugs used to treat rare diseases would be exempted from price control if the Health Ministry decides to do so (“**Orphan Drug Exemption**”).
- iii. The Government can source Market Based Data required under the DPCO from any pharmaceutical market data specializing company. Earlier, the data could only be sourced from IMS Health.
- iv. Government is now empowered to consider market-based data for any month for fixing prices of drugs.

P. Advertisement and Sales Promotion

Advertisements of drugs and pharmaceuticals are also strictly regulated. The legislation does not allow advertisement of prescription medicines in any form in any kind of media, unless with prior permission of the central government. In addition to this restriction, making claims to provide prevention or cures of certain diseases and conditions identified under the Drugs and Magic Remedies (Objectionable Advertisement) Act, 1954 (“**DMRA**”) is also prohibited, as discussed below.

I. Drugs and Magic Remedies (Objectionable Advertisement) Act, 1954

The DMRA regulates direct-to-consumer advertisements of drugs in India. The DMRA prohibits the publication of advertisements of a drug in terms which may imply its use for:

- i. The procurement of miscarriage in women or the prevention of conception in women; or
- ii. The maintenance and improvement of the capacity of human beings for sexual pleasure; or
- iii. The correction of a menstrual disorder in women; or

⁹ Paragraph 13, DPCO.

¹⁰ Paragraph 19, DPCO.

¹¹ Paragraph 20, DPCO.

¹² Order dated January 03, 2019 by the Department of Pharmaceuticals, Ministry of Chemicals and Fertilizers available at: http://pharmaceuticals.OV.IN/SITES/DEFAULT/FILES/GAZETTE%20NOTIFICATION_DPCO.PDF, last accessed on February 10, 2023.

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The diagnosis, cure, mitigation or prevention of 54 diseases and conditions identified in the schedule to the DMRA (“**Scheduled Conditions**”). Some of the noteworthy diseases and conditions include cancer, cataract, diabetes, diseases and disorders of brain and heart diseases. The Health Ministry on February 03, 2020, published a draft amendment proposing to amend the DMRA (“**Proposed Amendment**”). Broadly, the Proposed Amendment:

- i. alters the definition of ‘advertisements’ to specifically include advertisements made over electronic media, the internet or websites,
- ii. provides a provision under which the Ayurvedic, Siddha and Unani Technical Advisory Board (the advisory board on the various systems of Indian medicine) may be consulted with respect to advertisement of Ayurveda, Siddha and Unani drugs, and
- iii. increases the penalties for the contravention of the DMRA. More significantly, the Proposed Amendment expands the list of Scheduled Conditions from 54 to 79. Overall, the contribution of the Proposed Amendment is limited to widening the list of disorders in the schedule to the DMRA. The proposed revision in the definition of ‘advertisement’, though significant, is essentially clarificatory in nature and does not alter the existing legal position. This is because the existing definition of ‘advertisement’ already covers promotional campaigns made over electronic media, social networking sites and websites. This proposed amendment has not been notified to date.

II. Consumer Protection Act, 2019

The Consumer Protection Act, 2019 (“**CPA**”) prohibits false and misleading advertisements. The Central Consumer Protection Authority (“**CCPA**”) has been established under the CPA to act as the watchdog of consumer rights and protect consumers from false and misleading advertisements. The CCPA is empowered to act upon a complaint or to take suo moto action, where necessary. The CCPA issued the Prevention of Misleading Advertisements and Endorsements for Misleading Advertisements, 2022 which describes what constitutes a valid advertisement, and what practices are not permissible.

III. Advertising Standards Council of India

The Advertising Standards Council of India (“**ASCI**”) (an industry body) is tasked with self-regulation of advertisement. All complaints of unjustified claims made in advertisements (regardless of whether such claims are in violation of DMRA) may be submitted to the ASCI. The validity of the complaint is adjudged for its compatibility with the ASCI’s Code for Self-Regulation in Advertising.

IV. Product Promotions Before Doctors

In response to the recent uproar regarding incentives being given to the doctors by various pharmaceutical companies, the DoP released a Uniform Code of Pharmaceutical Marketing Practices (“**UCPMP**”) in December 2014. The UCPMP has put various restrictions on the practices adopted by companies while marketing medicines to doctors including banning all kinds of gifts to doctors.

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At present, the UCPMP is voluntary and not legally binding. However, the UCPMP is expected to be enacted in the form of law soon and would subsequently be binding on the stakeholders.

Specific provisions relating to restrictions on benefits to be procured by doctors have also been incorporated in the Indian Medical Council (Professional Conduct, Etiquette and Ethics) Regulations, 2002 (“**MCI Code**”). registered medical practitioners in India are required to adhere to the MCI Code. In a recent amendment, the MCI Code has put restrictions on doctors in their dealings with the pharmaceutical and allied health sector industry. A similar restriction exists for dentists as well.

Moreover, several industry associations have also adopted self-regulatory code. For instance, the Organization of Pharmaceutical Producers of India had issued a Code of Pharmaceutical Marketing Practices in 2010 which was subsequently updated in 2019 the (“**OPPI Code**”). The OPPI Code has set out specific standards for the promotion of pharmaceutical products ethically to the doctors. It is based on the International Federation of Pharmaceutical Manufacturers and Associations (IFPMA) Code that has been in practice for the last two decades. However, the OPPI Code is a matter of self-regulation and self-discipline on part of the member companies.

As discussed before, in India, advertisements of prescription drugs are not permitted. Hence, pharmaceutical companies promote medicines to doctors to convince them to prescribe their medicines with a view to increase their companies’ sales. The sales representative of a pharmaceutical company, popularly known as a medical representative (“**MR**”) plays a vital role in this process. MRs meet with doctors and explain the benefits of the drug along with the safety and the side effects of the drugs.

A. Important Features of the Uniform Code of Pharmaceutical Marketing Practices

i. Timing of Promotion

The promotion can be carried out only after product authorization by the office of the Drug Controller General of India (DCGI). The promotion should be consistent with the terms of product authorization, e.g. if the product authorization is only for one indication, the drug cannot be promoted for any other indication.

ii. Information Supplied

The information supplied must be accurate, fair, objective, verifiable and must not be misleading. In case of a request for additional substantiation by medical or pharmacy professionals, the same has to be provided without delay.

iii. Claims

The DOP has expressed concern over the use of the words “safe” and “new” by the companies or their MRs. The UCPMP mentions that “safe” should not be used without qualification and it must not be stated categorically that a medicine has no side effects, toxic hazards or risk of addiction. If the drug is generally available in India for more than 12 months, then the term “new” should not be used.

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iv. Product Comparisons

As far as product comparisons are concerned, the UCPMP prescribes as follows:

- The comparisons of medicinal products must be factual, fair and capable of substantiation;
- Due care must be taken to ensure that comparison does not mislead by distortion, by undue emphasis, omission or in any other way;
- Brand names of the products of other companies should not be used without obtaining prior consent;
- Companies, their products, services or promotions as well as clinical and/or scientific opinions of members of healthcare professionals should not be disparaged, either directly or by implication.

v. Product Promotional Material

The UCPMP prescribes certain do's and don'ts in relation to promotional material ("PM") and also prescribes the contents to be incorporated in such material. An illustrative list of the do's and don'ts is provided below:

Do's	Don'ts
<ul style="list-style-type: none"> ▪ PM to be consistent with the UCPMP ▪ Date of printing or of the last review of PM to be mentioned ▪ Audio-visual material to be accompanied by printed material in compliance with the UCPMP 	<ul style="list-style-type: none"> ▪ The paid or secured PM in journals not to resemble the editorial matter ▪ Photographs or names of healthcare professionals should not be used ▪ Gifts should not give any kind of promise, offer or supply any kind of pecuniary advantage or benefits to doctors including gifts for personal benefits such as tickets to entertainment events etc.

vi. Samples

The free samples that are provided by the companies must be supplied only to the qualified professionals and that too in response to a signed and dated request from the recipient. Detailed records of samples provided are required to be maintained. Such samples can be supplied only on an exceptional basis and for the purpose of acquiring experience in dealing with such a product. The sample pack should be limited to the prescribed dosage for three patients and each sample pack shall not be larger than the smallest pack presented in the market. The UCPMP prohibits supply of samples of an antidepressant, hypnotic, sedative or tranquillizer.

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vii. Hospitality, Sponsorships and Meetings

As per the UCPMP, the companies are permitted to provide assistance to doctors for continuing education and facilitating doctors' genuine attendance in such events. This assistance could cover actual travel expenses, meals, refreshments, accommodation and registration fees to attend such an event. The UCPMP has, however, laid down certain conditions:

- i) events for which assistance will be provided must be held in India at an appropriate venue that is conducive to the main purpose of the event; and
- ii) such events should not coincide with sporting, entertainment or other leisure events or activities or organized at venues that are renowned for their entertainment or leisure facilities or are extravagant.

This assistance cannot be provided to a doctor's spouse unless the spouse is a doctor too and qualifies to attend such an event. The hospitality offered should be reasonable and strictly limited to the main purpose of the event. The funding provided should not be for the time spent attending the event.

viii. Medical Representatives

MRs employed by the company or on contract with third parties are required to maintain a high standard of ethical conduct in the discharge of their duties and comply with all relevant requirements of the UCPMP. They are restricted from employing any inducement or subterfuge to gain an interview and paying, under any guise, for access to the doctor. It is important to note that the companies are made responsible for the activities of their employees including MRs to ensure that the UCPMP has been complied with.

B. Complaint Handling

The UCPMP has stipulated that each association of pharmaceutical companies shall form a "committee for pharma marketing practices" that will handle all the complaints received by them. The associations will also be required to form a review committee that will review the complaints, in case the review of the decision is sought. The UCPMP has also included the methodology for lodging and handling of complaints. The associations will be required to submit a copy of the proceedings and the decisions once the proceedings in a complaint are completed, to the DOP.

C. National Medical Commission

The National Medical Commission Act, 2019 ("NMC Act") has been enacted to replace the Indian Medical Council Act, 1956 ("IMC Act") as the primary legislation to regulate medical education and the medical profession in India.

D. Code of Professional Ethics for Doctors

The MCI Code includes specific restrictive provisions for doctors and professional associations of doctors in their relationship with the pharmaceutical and the allied health sector industry. The MCI Code was initially enacted

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under the IMC Act but is now deemed to have been issued under the NMC Act by way of transitory provisions in the NMC Act.¹³ The MCI Code has imposed the following restrictions on the doctors:

- A medical practitioner shall not receive any gift from any pharmaceutical or allied health care industry and their salespeople or representatives;
- A medical practitioner shall not accept any travel facility inside the country or outside, including rail, air, ship, cruise tickets, paid vacations etc. from any pharmaceutical or allied healthcare industry or their representatives for self and family members for vacation or for attending conferences, seminars, workshops, CME program etc. as a delegate;
- A medical practitioner shall not accept individually any hospitality like hotel accommodation for self and family members under any pretext;
- A medical practitioner shall not receive any cash or monetary grants from any pharmaceutical and allied healthcare industry for individual purposes in individual capacity under any pretext. Funding for medical research, study etc. can only be received through approved institutions by modalities laid down by law / rules / guidelines adopted by such approved institutions, in a transparent manner. It shall always be fully disclosed;
- A medical practitioner may carry out, participate in or work on research projects funded by pharmaceutical and allied healthcare industries, after taking necessary clearances and fulfilling certain conditions;
- A medical practitioner shall not endorse any drug or product of the industry publicly.

In case of violation of these provisions by the medical practitioners, the MCI Code provides for disciplinary action. In the recent past, in view of the restrictions imposed, a practice of entering into consultancy arrangements with pharmaceutical companies has developed. Under the MCI Code, a medical practitioner may work for pharmaceutical and allied healthcare industries in advisory capacities, as consultants, as researchers, as treating doctors or in any other professional capacity.

The pharmaceutical companies will certainly be required to change their strategy to market the medicines to doctors and be more creative and innovative. Since MRs are actively involved in the promotion of prescription drugs, companies will be required to conduct intensive training so that even inadvertently the code is not violated. At present, though the UCPMP is voluntary, the MCI Code is mandatory.

A review of the global practices seems to indicate that in some respects, the UCPMP and the MCI Code may be more restrictive than the codes / regulations in other jurisdictions. However, there are certain other aspects that are covered in other jurisdictions that are still not covered in the Indian codes. Further, some of the provisions under the MCI Code are more onerous than that of the UCPMP. E.g., while the UCPMP permits companies to provide assistance for travel and events within India, the MCI Code prohibits doctors from accepting the same.

In early 2022, the draft of the Registered Medical Practitioner (Professional Conduct) Regulations, 2022 was circulated for public consultation. Once it comes into force, it will replace the MCI Code. This proposed law imposes similar obligations on registered medical practitioners with higher penalties for non-compliance.

¹³ Section 62, NMC Act.

4. Legal and Regulatory Regime in India

V. Bulk Drug/ API/Intermediate — Contract Manufacturing and Research

India is known as the pharmacy to the world, primarily because the Indian pharmaceutical sector industry supplies over 50 percent of global demand for various vaccines, 40 percent of generic demand in the US and 25 percent of all medicine in the UK.¹⁴

A lot of export of medicine happens under contract manufacturing arrangements. It must be noted here that though an active pharmaceutical ingredient or finished formulation may be manufactured strictly for export purposes only, it is still required to be manufactured under a valid export license only. Also, depending on the nature of the product and the destination to which the product is being shipped, an export NOC from DCGI may be required.

India is a sought — after destination for contract research because of its highly skilled manpower and cost-effectiveness. To manufacture a drug for contract research, a test license to manufacture is required. To import a drug for contract research into India, a test license for import is required. The test license typically notes the quantity of test drug that is covered by the contract and requires the license holder to destroy any quantity of drug that is left after conclusion of the drug. After the enactment of the CT Rules, the process of importing or manufacturing drugs for research purposes has become clearer with specific timelines in place within which the DCGI is required to give approval for such import/manufacture.

14 Source: <https://www.ibef.org/industry/indian-pharmaceuticals-industry-analysis-presentation>, last accessed on February 10, 2023.

The Anti-Trust Regulatory Framework

Anti-competitive agreements are prohibited by law in India. The framework for control and investigation of anti-competitive agreements is laid out in the Competition Act, 2002 (“**Competition Act**”).

The provisions of Section 3(3) and 3(4) of the Act pertain to agreements entered between enterprises restricting purchase/sale prices, curtailing supply/production of goods and services as well as entering into exclusive supply/ distribution arrangements, creating tie-in arrangements with the intention of adversely affecting the market.

The pharmaceutical companies holding valid patents could enter into agreements with hospitals/pharmacists restricting prices, or with generic drug manufacturers to stifle competition, which may lead to possible violations under the Competition Act.

Cartels by industry associations have been widespread across jurisdictions to set standard prices for both stockists and retailers but the same has often led to restricting prices. Although the provisions of the Competition Act recognize protection granted under intellectual property legislations, yet associations formed to exchange data and information serving purposes other than the protection of the right holders could invite possible competition law violations.

Mergers and Takeovers in the pharmaceutical sector have also grown considerably in the past few years. Section 5 of the Competition Act prescribes the thresholds under which combinations shall be examined whereas, Section 6 states that any combination which causes or is likely to cause an appreciable adverse effect on competition within the relevant market in India shall be void. Acquisition of one or more companies by one or more people or merger or amalgamation of enterprises is treated as ‘Combination’ of such enterprises and persons in the following cases when:

- i. the acquisition of control, shares, voting rights or assets of an enterprise by a person; or
- ii. the acquisition of control of an enterprise where the acquirer already has direct or indirect control of another engaged in identical business; or
- iii. a merger or amalgamation between or among enterprises; crosses the financial threshold stipulated in the Competition Act.

Unless specifically exempted, the Competition Act requires every ‘Combination’ to be notified to the Competition Commission of India (“**CCI**”) in the manner set out in the Competition Act read along with the CCI (Procedure in regard to the transaction of business relating to combinations) Regulation, 2011 (“**Combination Regulations**”) and seek its approval prior to effectuating the same.

The growth of the pharmaceutical industry though protected under several IP laws, raises competition law issues. The need to provide protection to pharmaceutical companies for their innovation is well recognized under the Competition Act however the same is restricted by providing specific inclusions under Section 3(5) of the Act.

In the recent past, following the precedent of EU and Asian countries like Malaysia, the Competition Commission of India has shown an inclination to launch an investigation into anti-competitive practices in the pharmaceutical industry.

Intellectual Property Landscape

A. Patent Protection

In furtherance of India's continued efforts to comply with its commitment under the Agreement on Trade-Related Aspects of Intellectual Property Rights, the Patents Act, 1970 ("**Patents Act**") was amended three times since 1995.¹ The first amendment to India's Patent Act was in 1999 whereby Articles 70.8 and 70.9 of TRIPS were incorporated to provide for mailbox applications and exclusive marketing rights (EMRs). The third amendment of 2005 introduced a product patent regime in India, which is discussed in detail later.

I. Invention

The term Invention is defined under Section 2(1) (j) of the Patents Act as "a new product or process involving an inventive step and capable of industrial application."²

In India, patent rights with respect to any invention are created only upon grant of the patent by the Patent Office following the procedure established by the Patents Act and the Rules. India follows a declarative system with respect to patent rights. Patents are granted on a "first to file" basis (rather than "first to invent" in the United States). The patent application can be made by either (i) the inventor or (ii) the assignee³ or legal representatives⁴ of the inventor.

II. Convention Application

India, a member of the Paris Convention, has published a list of convention countries under Section 133 of the Patents Act. The convention application has to be filed within one year from the date of priority and has to specify the date on which and the convention country in which the application for protection (first application) was made. A priority document must be filed with the application. Since India is a member of the Patent Co-operation Treaty, a National Phase Application can also be filed in India, within thirty one-months from the priority date.

Some of the salient features are as follows:

- The term of the patent is twenty years from the date of priority;
- In infringement suits in relation to 'process' patents, the 'burden of proof' is reversed.

Section 3 of the Patents Act, carves out certain exceptions from the patentable inventions. Under Section 3 (j) "plants and animals in whole or any part thereof (other than micro-organisms) including seeds, varieties and

¹ Although India became a signatory to the WTO (and thereby to TRIPS) in 1995, it was not required to adopt the policies of TRIPS until 2005.

² Section 2(1)(ac) of the Patent Act: "capable of industrial application in relation to an invention means that the invention is capable of being made or used in an industry."

³ Section 2(1) (ab) of the Patent Act: "Assignee includes an assignee of the assignee and the legal representative of the deceased assignee and references to the assignee of any person include references to the assignee of the legal representative or assignee of that person."

⁴ Section 2(1) (k) of the Patent Act: "legal representative means a person who in law represents the estate of a deceased person."

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species and essentially biological processes for the production of plants or animals” — cannot be patented. This is in line with Article 27.3 of TRIPS. Thus micro-organisms, which satisfy the patentability criteria, may be patented in India.

Section 3(d) of the Patents Act clarifies that mere discovery of a new form of a known substance, which does not result in the enhancement of the known efficacy of that substance is not an invention and therefore not patentable. For the purposes of this clause, salts, esters, ethers, polymorphs, metabolites, pure form, particle size, isomers, mixtures of isomers, complexes, combinations and other derivatives of known substances are to be considered to be the same substances, unless they differ significantly in properties with regard to efficacy. Therefore, Swiss Claims will not be allowed in India.

III. Infringement — Bolar Provision

If a patented invention is made, constructed, used sold or imported ‘solely’ for uses reasonably related to the development and submission of information required under any law (Indian or foreign) that regulates such activities, then such acts do not amount to an infringement. This provision, known as the ‘Bolar provision’, gained fresh importance in view of introduction of the product patent regime in India in 2005. A Bolar provision allows manufacturers to begin the research and development process in a timely manner in order to ensure that affordable equivalent generic medicines can be brought to market immediately upon the expiry of the product patent.

IV. Parallel Imports

Import of patented products in India from a person authorized by the patentee to sell or distribute the product does not amount to an infringement.

V. Enforcement

India has historically been viewed by the global community as a ‘poor patent enforcement’ territory. Two provisions have been introduced that are likely to improve the patent enforcement mechanism. The first provision, compliant with Article 34 of TRIPS, is Section 104A, which is a “reversal of burden of proof” provision. Section 104A is an exception to the normal rule and requires that a person provide proof of any claims or allegations made. In ‘process patent’ infringement suits, the defendant will have to prove that he has used a process different than the ‘patented process’ in order to arrive at an identical product produced by a ‘patented process’. Second, an amendment to Section 108 of the Act will enable the court to order seizure, forfeiture or destruction of infringing goods and also materials and implements, used for creation of infringing goods.

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VI. Compulsory License

One of the most controversial amendments has been on compulsory licenses (“CL”). Earlier, a CL can also be granted if the invention has not been ‘worked’ in India or if the invention has not been worked in India on a commercial scale due to the fact that it was imported to India. New grounds for the grant of a CL have been inserted, which include; circumstances of national emergency; a circumstance of extreme urgency; and cases of public non-commercial use, public health crises, relating to AIDS/ HIV, TB, malaria or other epidemics.

A new provision⁵ has been inserted in the Compulsory License chapter which provides that a license can be granted to manufacture and export a patented product to any country having insufficient or no manufacturing capacity in the pharmaceutical sector in order to address public health problems, provided that such compulsory license has been granted in that country or that such country has allowed importation of the patented pharmaceutical products from India. The amendment seeks to implement Paragraph 6 of the Doha Declaration on TRIPS and address public health. The amended provision will allow Indian companies to produce and export AIDS drugs to African and South East Asian countries.

On March 9, 2012, the Controller General of Patents Design and Trademarks of India, Mr. P.H. Kurian, marked his last day in office with a landmark judgment granting the first ever compulsory license to an Indian generic pharmaceutical company Natco Pharma to manufacture and sell a generic version of Bayer Corporation’s patent protected anti-cancer drug ‘Sorafenib Tosylate’ (NEXAVAR).⁶

The government of India has also been considering compulsory licensing of cancer drugs. However, in October, 2013, the patent office rejected the compulsory licensing application of BDR Pharmaceuticals to make a generic version of the US drug maker Bristol-Myers Squibb’s anticancer drug Dasatinib, sold under the brand name “Sprycel”, on the grounds that it did not make enough efforts to obtain voluntary licensing of the drug.⁷

VII. Mandatory Annual Filing

It is mandatory under Indian patent laws to file a statement as to the extent of commercial working in Indian Territory of a patent granted by the Indian Patent Office. The statement embodied in Form 27 of the Patents Rules, 2003 (“**Patent Rules**”) is required to be filed in respect of every calendar year within three months of the end of each year (i.e. before March 31st of every year). Non-compliance with this requirement may invite penalty of imprisonment which may extend to six months, or with fine, or with both.

VIII. Rights Prior to the Grant

From the date of publication of the application until the date of the grant of a patent, the applicant has the like privileges and rights as if a patent for the invention has been granted on the date of publication of the application. However, an applicant is not entitled to institute any proceedings for infringement until the patent has been granted.

⁵ Section 92A Patent Act, 1970.

⁶ Available at http://www.nishithdesai.com/new_hotline/ip/iplab_march2112.htm, last accessed on February 10, 2023.

⁷ Available at http://articles.economicstimes.indiatimes.com/2013-10-31/news/43561264_1_voluntary-licence-compulsory-licence-dasatinib, last accessed on February 10, 2023.

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IX. Secrecy Provisions⁸

Any person resident in India is not allowed to apply for grant of patent for any invention unless either of the following two conditions is satisfied:

- Obtaining written permission of the Controller of Patents. The Controller is required to obtain consent of the Central Government before granting such permission for invention relevant for defense purpose / atomic energy. The application is to be disposed of within three months. OR
- Patent application for the same invention has been first filed in India at least six weeks before the application outside India and there is no direction passed under Section 35 for prohibiting/restricting publication/ communication of information relating to invention.

This section is not applicable to an invention for which an application for protection has first been filed in a country outside India by a person resident outside India. However, this provision will apply if the first filing is intended to be made in the US, since US applications are required to be filed by the inventors and not assignees of the inventors.

X. Patent Linkage

There is no concept of patent linkage in India. Until 2017, there was a requirement to indicate the patent status of a drug at the time of making an application to seek marketing approval. However, the requirement has been removed. The licensing authority is not required to assess whether marketing of the product in question will infringe the patent of a drug at the time of according a manufacturing license.

B. Trademarks

In India, trademarks are protected both under statutory and common law. The Trade and Merchandise Marks Act, 1940 was India's first legislation with respect to trademarks and was later replaced by the Trade and Merchandise Marks Act, 1958 (TM Act, 1958). The TM Act was further updated in 1999 to comply with TRIPS and is now known as The Trade Marks Act, 1999 ("TM Act 1999"). The TM Act 1999 allows for the registration of service marks and three-dimensional marks.

India follows the NICE Classification of goods and services, which is incorporated in the Schedule to the Trade Marks Rules, 2017 ("Trade Mark Rules, 2017") under the TM Act, 1999.⁹ Pharmaceutical products are covered under Class-5, cosmetics under Class-3 and veterinary preparation under Class-1 and Class-5. Class-44 covers the services for Medical services, veterinary services and cosmetics; and Class-42 covers Scientific and technological services and research and design relating thereto.¹⁰

The TM Act 1999 provides a procedure to search trademarks. It is a prudent practice that often prevents potential litigation or opposition to conduct the search for conflicting trademarks (whether registered or pending) before using or applying for any trademark.

⁸ Sections 35 to 43 of the Patent Act.

⁹ Classes of Goods and Services: CLASSES 1 to 34 cover goods while CLASSES 35 to 45 cover services.

¹⁰ Available at: http://support.dialog.com/techdocs/international_class_codes_tmarks.pdf, last accessed on February 10, 2023.

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Any registered trademark must fulfill certain conditions. The TM Act 1999 has set forth absolute and relative grounds of refusal of trademark registration. These grounds are akin to the provisions of the UK Trade Mark Act of 1994. The trademark can be registered even if the mark is proposed to be used in India i.e. even if prior to the date of application no goods have been sold under the applied trademark. The term of registration and renewal is ten years. Foreign companies can license trademarks in India under the proper license/Registered User Agreement.

I. Well Known Trade Mark

The concept of “well-known trademark” has been recognized under the TM Act 1999. A well-known trademark prohibits registration of a mark which is merely a reproduction or imitation of a well-known mark, even if used in connection with different goods or services. The Trade Mark Rules, 2017 provide applicants with the opportunity to apply for recognition of their marks as “Well-Known Trademarks” in India. The Trade Marks Registry has issued guidelines regarding the procedure to file for recognition of a trademark as a Well-Known Trademark on May 22, 2017.

II. Unregistered Trade Mark

A trademark can be used without registration and can be protected under common law but not under the statutory law by bringing a suit for passing off. Recently Indian courts have held that copying international names (even if the product is not made in India) is not permissible. Several international companies are engaged in trademark litigation in India, including IBM, Apple, Microsoft, Dunhill, Whirlpool, Sony and Cartier.

III. Landmark Case Law: Cadila Health Care Ltd. vs. Cadila Pharmaceuticals Ltd. (Decided on March 26, 2001)¹¹

This case involves two companies which had taken over the Cadila group. Both companies were allowed to use the name. The appellant was selling a tablet named falcigo and the respondent came out with its own tablet called falcitab. Falcigo was manufactured for the treatment of cerebral malaria called falcipharum and the appellant got it registered with the Trade Marks Registry and got permission from the Drugs Controller of India by Oct 1996. The respondent got permission from the Drugs Controller to manufacture a drug containing mefloquine hydrochloride in April 1997. This drug was also used for the treatment of falcipharum. The appellant sought an injunction from the court against the respondent’s medicine as it claimed that the same would be passed off as their drug as there was a confusing similarity and the drugs were medicines of last resort. The respondents claimed that the term ‘falc’ was derived from the disease which the medicine was intended to cure and also these medicines were sold to hospitals and clinics and could not be sold over the counter. Hence the chance of confusion and deception was very remote.

The court pointed out that due to the lack of knowledge of the English language in India and therefore a stricter approach should be adopted while applying the test to judge the possibility of confusion of one medicinal product for another by the consumer. The court also stated that measures should be more stringent when

¹¹ Available at: <http://www.cci.gov.in/images/media/completed/pharmind230611.pdf>, last accessed on February 10, 2023.

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it comes to medicines of last resort. The court pointed out the Drugs and Cosmetics Act, section 17B where an imitation or resemblance of another drug in a manner likely to deceive is regarded as a spurious drug. Section 8 of Trade Marks Act states that no trademark or part of any trademark shall be registered which consists of, or contains, any scandalous design or any matter the use of which would by reason of its being ‘likely to deceive or cause confusion’. This creates direct implications for competition where usurpation of part of therapeutic names by competitors. Moreover, it is relevant in this context that prescription drugs may not create consumer confusion since the doctor is knowledgeable enough as compared to the average consumer. The Court stated that authorities before granting permission to manufacture a drug under a trade must be satisfied that there is no confusion or deception in the market. The court laid certain factors to be considered while deciding a question on deceptive similarity: the nature of marks- word, label or composite; degree of resemblance, phonetic similarity, similarity in idea; nature of goods; Similarity in nature, performance and character of goods; class of purchasers (intelligence, education, degree of care); mode of purchasing goods; other surrounding circumstances.

IV. Trademarks Under the DCA

There is no obligation on the CDSCO to verify whether the brand name of a drug infringes the trademark of another person under the TM Act 1999. However, the Health Ministry, by way of a notification dated November 06, 2019, amended the DCR to require manufacturers to use brand names that are not similar to other brand names or trade names of drugs already in existence as a condition for obtaining the manufacturing license.¹² The amendment also requires manufacturers to provide an undertaking to the relevant authority to the effect that the manufacturer has already undertaken a search of the proposed brand name in the trademarks registry, the central database maintained by the drug regulator, literature and reference books on drug formulations as well as the internet and is not aware of the existence of any drug with the same or similar proposed brand name.

V. Biological Diversity and IP Considerations

The Biological Diversity Act, 2002 (“**Biodiversity Act**”) aims to ensure the conservation of biological diversity in India, sustainable use of its components and fair and equitable sharing of the benefits arising out of the use of biological resources. “Biological diversity” means the variability among living organisms from all sources and the ecological complexes of which they are part and includes diversity within species or between species and of eco-systems. “Biological resources” means plants, animals and micro-organisms or parts thereof, their genetic material and by-products (excluding value added products) with actual or potential use or value but does not include human genetic material. Only selective provisions of the Biodiversity Act, 2002 namely, definitions provisions, provisions relating to the constitution of the National Biodiversity Authority (“**NBA**”) and rule-making powers of Government have been brought into force with effect from October 1, 2003. NBA will regulate the commercial/other uses of biodiversity by both Indian and non-Indian entities. Prior to applying for any IPR in respect of biological resources the applicant will be required to obtain approval of NBA.

¹² Notification dated November 06, 2019 by the Health Ministry, available at: https://cdsco.gov.in/opencms/opencms/system/modules/CDSCO.WEB/elements/download_file_division.jsp?num_id=NTlwNg, last accessed on February 10, 2023.

Tax Regime

A. Direct Taxes

I. General Overview

Taxation of income in India is governed by the provisions of the Income Tax Act, 1961 (“**ITA**”) as amended annually by the Finance Acts. Under the ITA, residents are subject to tax in India on their worldwide income, whereas non-residents are taxed only on Indian source income i.e. income that accrues or arises in India, is deemed to accrue or arise in India or which is received or is deemed to be received in India. A company is said to be resident in India if it is incorporated in India or its place of effective management (“**POEM**”) is located in India. In this regard, the Central Board of Direct Taxes (“**CBDT**”) recently released the final guidelines for the determination of POEM. (Please click [here](#) to read our hotline on the same).

Section 9 of the ITA deems certain income of non-residents to be Indian source income. Under section 9(1), “capital gains” are considered to have their source in India and are taxable in India if they arise directly or indirectly, through the transfer of a capital asset situated in India. Similarly, the “business income” of a non-resident is taxable in India only if it accrues or arises, directly or indirectly, through or from any business connection in India. The Indian tax rates applicable to non-residents could be up to 40% (all tax rates provided herein are the exclusion of surcharge and cess discussed below) on taxable business income and capital gains.

Section 90(2) of the ITA is a beneficial provision which states that, where the taxpayer is situated in a country with which India has a double tax avoidance agreement (“**Indian Tax Treaty**”), the provisions of the ITA apply only to the extent that they are more beneficial to the taxpayer. Rules under Indian Tax Treaties are generally more beneficial to the taxpayer than those under domestic law (ITA) and hence it is typically advantageous for a non-resident taxpayer to structure his investments or business through a jurisdiction which has signed an Indian Tax Treaty.

In recent times, the Indian income tax authorities have been adopting an aggressive approach to transactions where any form of exemption from taxation is sought by the taxpayer. Their approach is even more hostile when the transaction in question has an offshore element to it. Hence, it has become critical to ensure that offshore transactions are structured in a manner such that legitimate tax exemptions are not challenged by the tax department.

Before delving into specific tax issues concerning contract research and manufacturing, set out below is a snapshot of the taxation regime in India. The tax rates mentioned in this section are exclusive of applicable surcharge and education cess, unless otherwise specified. The surcharge applicable to income generated by resident companies for the financial year is 7% where the income exceeds INR 10 Million but does not exceed INR 100 Million and 12% where the income exceeds INR 100 Million. Additionally, the surcharge applicable to income generated by companies other than domestic companies, for the financial year is 2% only when the income exceeds INR 10 Million but does not exceed INR 100 Million and 5% when the income exceeds INR 100 Million.

7. Tax Regime

A. Taxes Applicable to Companies

Resident companies are taxed at the rate of 30%, while non-resident companies are taxed at the rate of 40%. A minimum alternative tax is payable by residents, and in certain circumstances, non-resident companies at the rate of around 18.5%. The corporate tax rate for domestic companies whose total turnover or gross receipts does not exceed INR 400 million (approx. USD 5.5 million) is 25%.

Further, on September 20, 2019, the Government promulgated the Taxation Laws (Amendment) Ordinance 2019, to primarily reduce corporate tax rates as a knee-jerk reaction to India's economic slowdown. ('Ordinance') effective from April, 2019. As per the Ordinance, domestic companies may choose to be taxed at the effective rate of 25.17% under the newly introduced section 115BAA of the ITA subject to certain conditions such as total income is computed without claiming certain specified deductions and exemptions under the Income-tax Act, 1961 ('Deductions');

- i. the company shall not be allowed to set off any carried forward losses from earlier assessment years if such loss is attributable to the Deductions;
- ii. the company claims depreciation in the manner prescribed barring any depreciation in respect of plant and machinery;
- iii. once exercised, the option to be taxed under this provision cannot be withdrawn and will continue to apply for subsequent assessment years etc.

The Ordinance also introduced section 115BAB to the ITA, as per which new manufacturing companies set up on or after October 1, 2019 may avail an effective tax rate of 17.16% subject to prescribed conditions, which are broadly similar to the conditions applicable for availing section 115BAA. Non-resident companies are taxed at the rate of about 42% (if net income is in the range of INR 1 crore – 10 crores) and approximately 43% (if net income exceeds INR 10 crores). While residents are taxed on their worldwide income, non-residents are only taxed on income arising to them from sources in India. A company is said to be resident in India if it is incorporated in India or has its POEM in India. Minimum alternate tax ("MAT") at the rate of 15% (excluding surcharge and education cess) is also payable on the book profits of a company, if the company's income due to exemptions is less than 15% of its book profits. The MAT rate was reduced from 18.5% to 15%, effective from April 1, 2019, by virtue of the Ordinance. Importantly, the Ordinance also provides that no MAT shall be applicable in case of companies opting to be taxed under section 115BAA / 115BAB. With respect to 'eligible start-ups' meeting certain specified criteria, a 100% tax holiday for any 3 consecutive assessment years out of a block of seven years beginning from the year in which such start up is set up has been provided for.

B. Dividends

Dividends distributed by Indian companies are subject to a dividend distribution tax ("DDT") at the rate of around 15% (calculated on a gross-up basis), payable by the company. However, no further Indian taxes are payable by the shareholders on such dividend income once DDT is paid, except in certain specified situations. Finance Bill, 2020 has proposed to abolish Dividend Distribution Tax (DDT). Accordingly, from April 1, 2020, dividends declared by an Indian company would be subject tax in the hands of the recipient at slab rates and subject to necessary withholding tax in the hands of the Indian payer company. Unlike in case of DDT, the foreign recipients of the dividends should now be able to avail treaty benefits in respect of the taxes paid on dividends. Further, the mechanism to claim foreign tax credit on the taxes paid on the dividends would be much easier as it was in case of payment of DDT. This is because DDT was tax paid by the distribution company

7. Tax Regime

and not the recipient and there needed to be necessary language in the laws of the relevant foreign jurisdiction / applicable treaty on availment of underlying tax credits for availing foreign tax credit in respect of DDT paid in India.

C. Interest, Royalties and Fees for Technical Services

Interest payable to non-residents on loans taken/debt securities issued in foreign currency is taxable at a beneficial rate of TDS at 5%. However, this benefit has a sunset clause stating that the benefits would only be available for loan agreements entered into/ bonds issued on or after July 1, 2012 and before July 1, 2020. The said beneficial 5% rate of TDS is also available in relation to Rupee Denominated Bonds (“**RDB**”) issued until July 1, 2020. Similarly, interest payable to foreign institutional investors (“**FII**”) on investments made by them in RDBs and government securities is taxable at the rate of 5%. This benefit also has a sunset period and is applicable only in respect of interest payable until July 1, 2020.

In all cases above, the Finance Act, 2020 has extended the end of the sunset period, wherever applicable, from July 1, 2020 to July 1, 2023. Additionally, as regards interest payments made by an Indian company to its associated enterprises/related party, the Thin Capitalization Rules would apply, as per which, interest payments exceeding 30% of the Earnings Before Interest, Taxes, Depreciation and Amortization (“**EBITDA**”) of the payer of interest shall not be deductible as an expense.

The withholding tax on royalties and fees for technical services earned by a non-resident is 10%. These rates are subject to available relief under an applicable tax treaty. In this context, it is important to note that the definition of royalties and fees for technical services under Indian domestic law is much wider than the definition under most tax treaties signed by India.

D. Capital Gains

Tax on capital gains depends on the period of holding of a capital asset. Short term gains may arise if the asset is held for a period lesser than three years. Long term gains may arise if the asset is held for a period more than three years. Gains from listed shares which are held for a period of more than twelve months are categorized as long term. Unlisted shares and immovable property (being land or buildings or both) are treated as long term only when held for more than twenty-four months.

Long term capital gains earned by a non-resident on sale of unlisted securities may be taxed at the rate of 10% (provided no benefit of indexation has been availed) or 20% (if the benefit of indexation has been availed) depending on certain considerations. Long term gains on sale of listed securities on a stock exchange used to be exempted and only subject to a securities transaction tax (“**STT**”). However, the Finance Act, 2018 removed this exemption and introduced a levy of 10% tax on LTCG arising from the transfer of listed equity shares, units of an equity oriented mutual fund, or units of a business trust where such gains exceed INR 100,000 (approx. USD 1500). This tax is applicable on LTCG arising on or after April 1, 2018 and no indexation benefits can be availed of. However, the Finance Act 2018 also introduced limited grandfathering in respect of protecting the gains realized on a mark to market basis up to January 31, 2018 and only an increase in share value post this date would be brought within the tax net. Further, earlier, for the purposes of obtaining the LTCG exemption, the Finance Act, 2017 had introduced an additional requirement for STT to be paid at the time of acquisition of listed shares.

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However, the CBDT had exempted certain modes of acquisition from this requirement. Pursuant to withdrawal of the exemption in Finance Act, 2018, the CBDT issued a notification specifying that the requirement to pay STT at the time of acquisition will not apply to

- i) share acquisitions undertaken prior to October 1, 2004,
- ii) share acquisitions undertaken on or after October 1, 2004 which are not chargeable to STT subject to certain exceptions for the purposes of obtaining the capital gains tax rate of 10% under section 112A. Short term capital gains arising out of sale of listed shares on the stock exchange are taxed at the rate of 15%, while such gains arising to a non- resident from sale of unlisted shares is 40%.

E. Withholding Taxes

Tax would have to be withheld at the applicable rate on all payments made to a non-resident, which are taxable in India. The obligation to withhold tax applies to both residents and non-residents. Withholding tax obligations may also arise with respect to specific payments made to residents and the failure to withhold tax could result in tax, interest and penal consequences.

II. Incentives Under the ITA

The Government of India has taken various policy initiatives in order to strengthen scientific research and development in various sectors, including the pharmaceutical sector. The term “scientific research” has been defined in the ITA to include activities for the extension of knowledge in the fields of natural or applied science. Scientific research can be carried out either in-house or by contributing to outside agencies engaged in scientific research.

Typically, in the pharmaceutical industry, fiscal incentives are awarded to research and development units towards the development of new drug molecules, clinical research, new drug delivery systems, new research and development setups and infrastructure provision.

A. In-house Research and Development

Companies that have incurred any expenditure on scientific research (not being expenditure in the nature of cost of any land or building) or in-house research and development facility as approved by the Department of Scientific and Industrial Research, are allowed a deduction of 100 percent of such expenditure. Expenditure on scientific research includes expenditure incurred on drug trials. Obtaining approval from any regulatory authority under any Central, State or Provincial Act and filing an application for a patent under the Patents Act, 1970.

B. Contributions Made to Other Institutions for Scientific Research

The ITA provides for a deduction of 100 percent of sums paid to any scientific research association (having as its object the undertaking of scientific research), or to any university, college or other institution, for the purpose of scientific research approved by the concerned authority.

7. Tax Regime

C. Capital Expenditure

Under Section 35(1)(iv) read with Section 35(2) of the ITA, the whole of any expenditure on scientific research (other than expenditure on acquisition of any land) being capital in nature, incurred after 31 March 1967 is allowed as a deduction. Further, under Explanation 1 to Section 35(2) of the ITA, the aggregate capital expenditure on scientific research incurred three years immediately prior to the commencement of business is allowed as a deduction in the year in which the business is commenced.

D. Incentive provided to Venture Capital Funds Investing in the Pharmaceutical Sector

In order to provide an impetus to venture capital investment in the pharmaceutical sector, the ITA has granted certain tax benefits to venture capital funds registered with the Securities and Exchange Board of India (SEBI) that invest into certain pharmaceutical businesses. Under section 10(23FB) of the ITA, income of a venture capital fund which arises as a result of investments into companies engaged in, inter alia, “bio-technology” and “research and development of new chemical entities in the pharmaceuticals sector”, is exempt from tax and such income is taxable only in the hands of the investors of the venture capital fund at the time of distribution of the income.

III. Potential Permanent Establishment Issues in Contract Research and Manufacturing

When a foreign enterprise proposes to outsource research and manufacturing functions to an Indian CRO/CMO, the outsourcing arrangement would have to be carefully structured in order to mitigate the risk of the Indian CRO/CMO being regarded as the Permanent Establishment (“PE”) of the foreign enterprise. The risk is significantly greater where significant manufacturing functions are outsourced by the foreign enterprise to an Indian CMO. The issue of creation of an Indian PE to the foreign enterprise is a significant one given that; if such PE is created, the business income (attributable to the PE) of the foreign enterprise, which may otherwise not be taxed in India, would be subjected to taxation at the rate of 40%.

Under the ITA, business income of a non-resident is taxable in India (at the rate of 40%) if it accrues or arises, directly or indirectly, through or from any ‘business connection’ in India. Similarly, under the Indian Tax Treaties, typically, the business income of a non-resident is taxable only to the extent that it is attributable to a Permanent Establishment (“PE”) of such non-resident in India. The concept of PE under typical Indian Tax Treaties is expressed as an exhaustive list of factors, as opposed to the “business connection” rule contained in the ITA, which has no exhaustive definition in the ITA and which has been afforded a wide interpretation by Indian courts in the past. Therefore, there may be situations where a non-resident is considered to have a business connection in India, but no PE. As mentioned earlier, since it is open for the non-resident taxpayer to choose to be treated under the more beneficial regime, a non-resident may rely on the PE rule under the applicable Indian Tax Treaty rather than the business connection rule in the ITA.

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The term PE has been succinctly defined by the Andhra Pradesh High Court in the case of CIT v. Visakhapatnam Port Trust,¹ as follows:

“In our opinion, the words permanent establishment postulate the existence of a substantial element of an enduring or permanent nature of a foreign enterprise in another country which can be attributed to a fixed place of business in that country. it should be of such a nature that it would amount to a virtual projection of the foreign enterprise of one country into the soil of another country.”

The Indian Tax Treaties typically lay down certain criteria to determine whether a foreign enterprise earning business income from India would be construed to have a PE in India. Some of these tests are discussed below, especially in the context of contract research and manufacturing.

- i. **Fixed place of business PE:** A foreign enterprise is deemed to have a PE in India if the business of foreign enterprise is, wholly or partly, carried on through a fixed place of business in India. The principle of fixed place of business PE is particularly relevant in the context of contract research and manufacturing.

As demonstrated below, unless such arrangements are structured carefully, there may be circumstances which may lead to the inference that the business of the foreign enterprise, which outsources the research and manufacturing functions to an Indian CRO/CMO, is being carried on through a fixed place of business in India. In a typical contract research and manufacturing model, it is common for the foreign enterprise to frequently send personnel to the offices of the Indian CRO/CMO to provide training services. Often, the foreign enterprise also sends its personnel to the offices of the Indian CRO/CMO to supervise and inspect the activities carried on by the Indian CRO/CMO, in order to ensure that such activities adhere to the prescribed standards. In both these instances, if these personnel, being employees of the foreign enterprise, have some premises (often even a desk or an office is regarded as premises) allotted to them for a reasonably long period of time within the Indian CRO/CMO, such premises, though not owned or rented by the foreign enterprise, is likely to be considered to be a “fixed place of the foreign enterprise”. In such a scenario, it may be claimed by the Indian tax authorities that the foreign enterprise is carrying on its business through a fixed place and hence a PE of the foreign entity exists in India. Therefore, in any arrangement to outsource research and manufacturing to an Indian CRO/CMO, it is critical to ensure that the outsourcing arrangement is structured in manner that mitigates the risk of the foreign entity having a PE in India.

- ii. **Service PE:** Further, under some Indian Tax Treaties, a foreign enterprise may be considered to have a PE in India due to the presence of its personnel in India, who render services beyond a specified time period or to a related enterprise. For instance, under the India-US tax treaty, a PE is said to be constituted where there is: “(l) the furnishing of services, other than included services as defined in article 12 (royalties and fees for included services), within a Contracting State by an enterprise through employees or other personnel, but only if:
 - a. activities of that nature continue within that State for a period or periods aggregating to more than 90 days within any twelve-month period; or

¹ 1983 144 ITR 146 AP.

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- b. the services are performed within that State for a related enterprise (within the meaning of paragraph 1 of article 9 (associated enterprises)).”

In the example discussed earlier, if the training and inspection personnel sent by the foreign enterprise to the offices of the Indian CRO/CMO are deemed to be “furnishing services” beyond the prescribed limit of 90 days, it is likely that the tax authorities may argue that the presence of such personnel constitutes a PE of the foreign enterprise in India.

- c. Agency PE: Indian Tax Treaties typically contain a provision whereby an Indian entity may be treated as a PE of a foreign enterprise if the Indian entity, acting on behalf of the foreign enterprise, has and habitually exercises an authority to conclude contracts on behalf of the foreign enterprise/plays a principal role in conclusion of the contracts.² Moreover, some Indian Tax Treaties, such as the India-US tax treaty, also contain an additional provision whereby an Indian entity may be regarded as a PE of the foreign enterprise, if the Indian entity maintains a stock of goods from which it regularly delivers such goods on behalf of the foreign enterprise and contributes to the sale of such goods. An agent of independent nature is considered as an exception to the Agency PE rule.

In the context of contract manufacturing, it may be contemplated in the arrangement that the Indian CMO would maintain and deliver the final pharmaceutical product on behalf of the foreign enterprise. In such cases, if the contract is not structured cautiously, the Indian CMO may be regarded as a PE of the foreign enterprise under the Agency PE clause in the applicable Indian Tax Treaty. The Indian CRO/CMO may also run the risk of being regarded as the PE of the foreign enterprise where the Indian entity, acting on behalf of the foreign enterprise, has and habitually exercises an authority to conclude contracts on behalf of the foreign enterprise. Although such rights are not ordinarily granted by the foreign enterprise to the Indian CRO/CMO, care should be taken to ensure that the Indian CRO/CMO does not have the right to even represent the foreign entity in any negotiations since, in the past, the exercise of such right has been held to constitute a PE of the foreign entity in India.

In cases of outsourcing by a foreign enterprise to its Indian subsidiary, a question arises as to whether there is added PE risk for the foreign enterprise as a result of the parent subsidiary relationship of the two entities. The answer to this lies in the Indian Tax Treaties itself. The principle which is embodied in typical Indian Tax Treaties is that the existence of a subsidiary company does not, by itself, constitute that subsidiary company a PE of its parent company. This follows from the principle that, for the purpose of taxation, such a subsidiary company constitutes an independent legal entity. Thus, where a foreign enterprise outsources its research and manufacturing functions to an Indian CRO/CMO, the fact that the Indian CRO/CMO is the subsidiary of the foreign enterprise, should not, by itself, constitute that Indian CRO/CMO to be a PE of the foreign enterprise.

As is clear from the discussion above, the issue as to whether any activity of a foreign entity in India results in a PE of that foreign entity in India depends on the facts and circumstances of each case. In the context of contract research and manufacturing, the answer lies in the manner in which the outsourcing arrangement is structured and the activity of the Indian CRO/CMO is managed and operated.

² This is as per the BEPS MLI – which is discussed below.

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IV. Issue of Taxation as an Association of Persons

Depending on the manner in which it is structured, a contract research and manufacturing arrangement could run the risk of being taxed under the ITA as a separate taxable unit called an association of person (“AOP”). This is a significant issue for the foreign enterprise which outsources these functions, given that, if such arrangement is treated as an AOP, the profits of the foreign enterprise attributable to such AOP, which otherwise would not have been subjected to tax in India (in the absence of a PE of the foreign enterprise in India), would be taxable at the maximum marginal rate of 40%.

Although there is no definition of AOP under the ITA, there have been a number of cases in which this issue has been discussed. In the case of *Commissioner of Income Tax v. Indira Balkrishna*,³ the Supreme Court has explained the concept of AOP as “an association of persons must be one in which two or more persons join in a common purpose or a common action, and as the words occur in a section which imposes a tax on income, the association must be one the object of which is to produce income, profits or gains.”

Further, in the case of *Deccan Wine and General Stores*,⁴ the Andhra Pradesh High Court further examined this concept and observed that “it is, therefore, clear that an association of persons does not mean any and every combination of persons. It is only when they associate themselves in an income-producing activity that they become an association of persons. They must combine to engage in such activity; the engagement must be pursuant to the combined will of the persons constituting the association; there must be a meeting of the minds, so to speak. In a nutshell, there must be a common design to produce income. If there is no common design, there is no association. Common interest is not enough. Production of income is not enough.”

Although there is lack of clarity in the Indian law on the concept of an AOP, broadly the essential conditions for constituting an AOP may be said to be:

- Two or more persons
- Voluntary Combinations
- A common purpose or common action with object to produce profit or gains.
- Combination in Joint Enterprise
- Some kind of scheme for common management.

The risk of a contract research and manufacturing arrangement being regarded as an AOP is particularly greater in cases where the Indian CRO/CMO co-develops the drug with its foreign partner based on a revenue sharing model. Such special arrangements, if not structured appropriately, could lend weight to the characterization of the arrangement as an AOP, namely, two persons joining in a common purpose or a common action the object of which is to produce income, profits or gains. Thus, in order to avoid such characterization, it becomes important to clearly demonstrate in the contract that the intention is not to carry out any business in common and that the Indian CRO/CMO will only execute a part of the job (i.e. research and manufacturing) according to its technical skill and capability. To the extent possible, the contract should convey that the work and income arising from the foreign enterprise’s contribution is quite distinct and independent of the Indian CRO/CMO’s work and income. Hence, it must be ensured that the arrangement is structured in a manner so as to mitigate any risk of it being regarded as a single assessable unit and liable to tax as an AOP.

³ [1960] 39 ITR 546 (SC).

⁴ [1977] 106 ITR 111 (AP).

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V. Structuring Investment into India – Use of Intermediate Jurisdictions

Foreign entities that are looking at incorporating subsidiaries in India for outsourcing research and manufacturing functions can achieve tax efficiency by use of a tax neutral intermediate jurisdiction which has signed an Indian Tax Treaty (“**Treaty Jurisdiction**”) rather than directly investing into the Indian company. The foreign entity can achieve tax efficiency by incorporating a company (or any other entity which is eligible to benefits of the relevant Indian Tax Treaty) in the Treaty Jurisdiction which would, in turn, invest into the underlying Indian company. The choice of an appropriate Treaty Jurisdiction, apart from tax neutrality and a good treaty network, would depend on factors such as political stability, ease of administration, availability of reliable administrators, favorable exchange controls and legal system, certainty in tax and legal framework and ease of winding up operations.

In the aftermath of the 2008 financial crisis, the Organization for Economic Co-operation and Development (‘OECD’) along with the G20 had launched the Base Erosion and Profit Shifting (‘BEPS’) project. The primary aim of the BEPS project was to align taxation of income with economic activities that generate them. As part of the BEPS project, in 2013 the OECD Committee on Fiscal Affairs (‘OECD CFA’) released the BEPS Action Plans to counter base erosion and profit shifting, i.e. ‘tax planning strategies that exploit gaps and mismatches in tax rules to artificially shift profits to low or no tax jurisdictions where there is little or no economic activity, resulting in little or no overall corporate tax being paid’.⁵

BEPS Action Plan 15 envisaged the development of a multilateral instrument to provide for an effective, swift and innovative approach to implement the BEPS Action Plans. In line with the same, the OECD CFA constituted an ad hoc group which drew up the coveted Multilateral Convention to Implement Tax Treaty Related Measures to Prevent Base Erosion and Profit Shifting (‘MLI’). Upon coming into effect, the MLI will not replace the existing treaty provisions; instead it will supplement, complement or modify the existing treaty provisions to bring them in line with recommendations in the BEPS Action Plans.

VI. Indian Transfer Pricing Issues in Contract Research and Manufacturing Services

Where entities are looking to outsource research and manufacturing functions to an associated enterprise, such as in cases of captive outsourcing, the fees payable to the service provider should take into account transfer pricing issues.

In India, transfer pricing regulations (“**TP Regulations**”) were introduced on April 1, 2001. The Indian Income Tax Act, 1961 lays down provisions that deal with the computation of income arising from “international transactions” between “associated enterprises”. The basic rule enshrined in the TP Regulations is that any income arising from an “international transaction” shall be computed having regard to the arm’s length price (discussed below). The TP Regulations define “associated enterprise” to include any enterprise that participates directly or indirectly or through one or more intermediaries in the management or control or capital of another enterprise. Enterprises may also be regarded as “associated” as a result of circumstances such as interdependence by virtue of borrowings, guarantees, licensing of trademarks, purchase, sales or where enterprises have “mutual interest” as may be prescribed by the revenue authorities. Here, “enterprise” is defined broadly and covers any entity (including a permanent establishment) which is or proposes to be engaged in any activity relating to the

5 OECD (2013), Action Plan on Base Erosion and Profit Shifting, OECD Publishing, <http://dx.doi.org/10.1787/9789264202719-en>.

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provision of goods/services of any kind, investment activity, dealing in securities and extending loans. The term “international transaction” has been defined as a transaction between two or more associated enterprises, either or both of which are non-residents. As mentioned earlier, the basic principle is that any income arising from such an “international transaction” shall be computed having regard to the “arm’s length price”.

The Finance Act, 2017 introduced the concept of secondary adjustment under the transfer pricing regulations through introduction of Section 92CE which requires a resident taxpayer who has entered into an international transaction to make a secondary adjustment in the event that a primary adjustment as per transfer pricing provisions:

- a. has been made suo moto by the taxpayer in his income tax return,
- b. has been made by the Assessing Officer and accepted by the taxpayer,
- c. has been determined by and advanced pricing agreement,
- d. is made as per safe harbor rules under the ITA,
- e. is a result of mutual agreement procedure (“**MAP**”) under a tax treaty

The provisions further prescribe that where, as a result of primary adjustment, there is an increase in the taxpayer’s total income or a reduction in allowable loss, a secondary adjustment shall have to be made. The secondary adjustment is intended to reflect the actual allocation of profits between the taxpayer and the associated enterprise. The purpose of such secondary adjustment is also to eliminate the imbalance between the taxpayer’s accounts and actual profits. The Section prescribes that the excess money (difference between the arm’s length price determined in the primary adjustment and the actual consideration price) shall be deemed to be an advance made by the taxpayer to its associated enterprise, if it is not repatriated to India within a prescribed time. Once deemed to be an advance, interest shall also be payable on the excess income until the obligation to repatriate such amount is discharged. While the rate of interest is to be calculated in a manner prescribed by the government, it should also be determined at an arm’s length price.

However, Section 92CE does not apply where the amount of primary adjustment made in any previous year does not exceed INR 10 million (approx. USD 150,000) and is made in respect of an assessment year commencing on or before the April 1, 2016.

Although secondary adjustments are an internationally accepted principle and are in line with OECD’s Transfer Pricing Guidelines, the implementation of Section 92CE may result in various practical difficulties. For example, the foreign country in which the associated enterprise is located may have exchange control provisions that make it difficult to repatriate the excess money to India, or it may have adjusted the transaction as per its own transfer pricing provisions and already taxed a portion of the funds Indian tax authorities consider as excess income. The introduction of these provisions and also those relating to thin capitalization show the increasing tendencies of the government to look at international practices in molding tax legislation in India.

Under the transfer pricing regime, arm’s length price is the price which is applied or proposed to be applied in a transaction between persons other than associated enterprises, in uncontrolled conditions. The OECD Transfer Pricing Guidelines for Multinational Enterprises and Tax Administrations, 2010 (“**Guidelines**”) provide that the application of the arm’s length principle is generally based on a comparison of all the relevant conditions in a controlled transaction with the conditions in an uncontrolled transaction. Under the Guidelines, comparability is achieved when there are no differences in the conditions that could materially affect the price or when reasonably accurate adjustments can be made to eliminate the effects of any such differences. The analysis of

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the controlled transactions with uncontrolled transactions is the very basis of ascertaining whether the controlled transactions adhere to the arm's length standard. The arm's length price in relation to an international transaction is to be determined by any of the following methods depending on which is the most appropriate given the business of the enterprises:

- Comparable uncontrolled price method;
- Resale price method;
- Cost plus method;
- Profit split method;
- Transactional net margin method;

A challenge faced by Indian pharmaceutical companies with respect to transfer pricing, is that the TP Regulations do not specifically deal with intangibles or provide a basis of computing the arm's length price, while dealing with the same. As opposed to transactions involving tangibles, where a pricing situation in controlled transaction can be compared with that of an uncontrolled transaction (provided all other conditions are similar or identical), in case of intangibles/intellectual property it is very difficult to identify comparable given the unique nature of the intellectual property involved. Hence, it becomes difficult to find a comparable based on which the arm's length price may be ascertained.

It is important to note that TP Regulations also require persons entering into international transactions to maintain prescribed documents and information, and to obtain and furnish to the revenue authorities an accountant's report containing prescribed details regarding the international transactions. Stringent penalties have been prescribed for non-compliance with the procedural requirements and for understatement of profits. The pharmaceutical industry in India has time and again faced issues with respect to arriving at a comparable arm's length price for the purpose of transfer pricing. The industry faced a significant setback earlier this year, when the Mumbai Income Tax Appellate Tribunal ("**Tax Tribunal**"), hearing an appeal by Serdia Pharmaceuticals India Private Limited ("**Serdia**") [Serdia Pharmaceuticals (India) Private Limited v. ACIT, ITA Nos: 2469/ Mum/07 and 2531/ Mum/ 08, held that the arm's length price for importing active pharmaceutical ingredients ("**API**") from related enterprises should be determined on the basis of price at which locally manufactured generic APIs are sold in the domestic market. Serdia, a pharmaceutical company, imported API from its related entities in France and Egypt for the purpose of manufacturing certain drugs.

In order to arrive at the correct arm's length price of the API which was imported into India, the tax payer had adopted 'Transactional Net Margin Method' ("**TNMM**"). However, the Income Tax Department contended that the APIs purchased were at prices that were higher than that paid for similar APIs by other companies in India and that the Comparable Uncontrolled Price ("**CUP**") was the most appropriate method to be adopted. On the basis of domestically available data, the tax department claimed that the arm's length price for the API should have been significantly lesser than that at which Serdia had imported these API. The Tax Tribunal ruled in favour of the tax department and held that the tax department was justified in applying the CUP Method without specifying the reasons for rejection of the TNMM method.

The Tax Tribunal did not accept Serdia's justification of the high import price, namely, that the APIs were manufactured on equipment standards set by the World Health Organisation, the British Good Manufacturing Practices (GMP) and as per HSE or health, safety and environment standards. The Tax Tribunal observed that the high-quality standards employed in manufacturing process conferred merely a certain degree of comfort

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pertaining to the minimum level of impurities and this did not necessarily affect its comparability with the same API manufactured by generic drug companies.

The Tax Tribunal's ruling in the Serdia case has adversely impacted pharmaceutical multinationals that are doing business in India. It has been seen that, post the Serdia ruling, the income tax department has been aggressively pursuing multinational pharmaceutical companies which are procuring APIs from their respective parent companies.

Another challenge faced by Indian pharmaceutical companies with respect to transfer pricing is that the TP Regulations do not specifically deal with intangibles or provide a basis of computing the arm's length price, while dealing with the same. As opposed to transactions involving tangibles, where a pricing situation in controlled transaction can be compared with that of an uncontrolled transaction (provided all other conditions are similar or identical), in case of intangibles/intellectual property it is very difficult to identify comparable given the unique nature of the intellectual property involved. Hence, it becomes difficult to find a comparable based on which the arm's length price may be ascertained.

The Indian contract research and manufacturing industry too has had its fair share of problems with the tax department as far as transfer pricing is concerned. This is once again attributable to the lack of comparable data for arriving at an appropriate arm's length price. The databases that provide comparable information are lacking in so far as they fail to provide information relating to companies engaged in pure contract research activities.

Typically, the information offered by these databases relate to companies that work on different models, such as, co-development of a drug by the Indian CMO in partnership with its foreign associate based on a revenue sharing arrangement. Hence, it becomes extremely difficult for Indian CROs/CMOs to arrive at a suitable arm's length price. As a result, the Indian tax department has time and again created issues for Indian CRO/CMOs by insisting on a significantly higher mark-up.

It is important to note that TP Regulations also require persons entering into international transactions to maintain prescribed documents and information, and to obtain and furnish to the revenue authorities an accountant's report containing prescribed details regarding the international transactions. Stringent penalties have been prescribed for non-compliance with the procedural requirements and for understatement of profits.

Safe Harbor Rules

To address litigation and uncertainty concerns raised by the industry and professionals, the Central Board of Direct Taxes has notified certain transfer pricing safe harbors. Under this regime, tax authorities will accept the transfer price set by the taxpayer if the taxpayer and transaction meet eligibility criteria specified in the rules.

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VII. Disallowance of Deduction of Expenses Incurred in Unethical Promotion

The Indian Medical Council (Professional Conduct, Etiquette and Ethics) Regulations, 2002 prohibit the medical practitioners and their professional associations from taking any Gift, Travel facility, Hospitality, Cash or monetary grant from the pharmaceutical and allied health sector Industries. The Central Board of Direct Taxes has issued instructions to the revenue department that the claim of any expense incurred in providing above mentioned or similar freebies in violation of the provisions of Indian Medical Council (Professional Conduct, Etiquette and Ethics) Regulations, 2002 shall be inadmissible as expense because it is an expense prohibited by the law.

B. Indirect Taxes

I. Goods and Services Tax

Goods and Services Tax (“**GST**”) system is an indirect tax regime, introduced in India by the Constitution (101st Amendment) Act, 2016. The GST has, inter-alia subsumed the following taxes:

- Service Tax
- Additional Customs Duty commonly known as Countervailing Duty (CVD)
- Special Additional Duty of Customs (SAD)
- Central Sales Tax
- Value Added Tax

The Central GST and the State GST are levied simultaneously on every transaction of supply of goods and services except on exempted goods and services, goods which are outside the purview of GST and the transactions which are below the prescribed threshold limits.

The Additional Duty of Excise or CVD and the Special Additional Duty or SAD earlier being levied on imports have been subsumed under GST. As per explanation to clause (1) of article 269A of the Constitution, Integrated GST (“**IGST**”) will be levied on all imports into the territory of India.

II. Customs Duty

Customs duties are levied whenever there is trafficking of goods through an Indian customs barrier i.e. levied both for the export and import of goods. Export duties are competitively fixed so as to give an advantage to the exporters.

Consequently, a large share of customs revenue is contributed by import duty. Customs duty primarily has a ‘Basic Customs Duty’ which has not been subsumed by the GST for all goods imported into India and the rates of duty for classes of goods are mentioned in the Customs Tariff Act, 1975 the (“**Tariff Act**”), which is based on the internationally accepted Harmonized System of Nomenclature (“**HSN**”). The general rules of interpretation with respect to tariff are mentioned in the Tariff Act. The rates are applied to the transaction value of goods

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(for transactions between unrelated parties) as provided under the Customs Act, 1962 the (“**Customs Act**”) or by notification in the official gazette.

Further, the Central Government, if satisfied that circumstances exist which render it necessary to take immediate action to provide for the protection of the interests of any industry, from a sudden upsurge in the import of goods of a particular class or classes, may provide for a Safeguard Duty. Safeguard Duty is levied on such goods as a temporary measure and the intention for the same is protection of a particular industry from the sudden rise in import.

Under Section 9A of the Tariff Act, the Central Government can impose an Anti-dumping Duty on imported articles, if it is exported to India at a value less than the normal value of that article, in other jurisdictions. Such duty is not to exceed the margin of dumping with respect to that article. The law in India with respect to anti-dumping is based on the ‘Agreement on Anti-Dumping’ pursuant to Article VI of the General Agreement on Tariffs and Trade, 1994.

A very important change is that earlier, anti-dumping and safeguard duties did not form part of the value for levy of CVD, whereas anti-dumping and safeguard duties, besides assessable value and basic customs duty, will be included in the value for the purpose of levy of IGST.

Key Issues and Challenges in Indian Pharma Industry

A. Promotion and Advertisement

Pharma companies are finding it increasingly difficult to engage physicians and patients in an information — intensive day and age. It is not possible under Indian laws for an Indian pharmaceutical company to pay for a physician's travel and accommodation in order to enable him to attend an educational event. It is also not possible under Indian laws to advertise prescription medicines or any medicines with claims that may induce a person to think that certain diseases and conditions could be treated or cured.

B. Price Control

India's drug price control regime is erratic in its implementation. The drugs whose prices are decided by the government are identified in the national list of essential medicines. The industry has no representation in deciding which medicines may be decided as essential and included in the list. The result is that the industry is always anxious prior to making sizeable investments in any drug, lest it should find itself under price control. The other aspect of India's price control regime is that once the government decides the price using a formula, the industry has put that into effect immediately even though it may be aggrieved with the calculation of the price. It may be several months before the government agrees to rectify the price, but until then the industry has potential to lose significant amount of money.

C. Labelling

For a very long time, there existed a strange dichotomy under Indian laws. Antibiotics did not require a declaration on the label that they are prescription products and must be sold under a valid prescription. It has been rectified now. However, a pressing consideration that still remains whether any labelling declaration that is inserted as a condition of marketing approval is required to be carried on in perpetuity or not. The background is that marketing approval is required for new drugs only. Thus, a generic drug does not require marketing approval. This results in a situation where the innovator drug carries a certain labelling declaration as part of the marketing approval, but the generic drug does not do it because it was not subject to marketing approval. So, the same drug exists in the market with different labelling declarations such as; whether or not the drug is to be sold under a prescription.

8. Key Issues and Challenges in Indian Pharma Industry

D. Environmental Diligence

Pharmaceutical manufacturing units in India have been accorded the highest rating in terms of the risk that they may pose to the environment, especially through contamination of groundwater sources. Therefore, to start and operate a pharmaceutical manufacturing unit, the following minimum consents and authorizations are required to be obtained from the Central or State-level Pollution Control Boards:

- Environmental Clearance after Environmental Impact Assessment.
- Consent to Establish and Operate under Water (Prevention and Control of Pollution) Act, 1974 and the Air (Prevention and Control of Pollution) Act, 1988.
- Authorization for generation and management of hazardous waste.

The fine print of the authorizations is important to be reviewed prior to making an investment into a pharmaceutical manufacturing company. Sometimes, there are limitations on the ability to manufacture a certain quantity of pharmaceuticals in the year or a certain type of pharmaceuticals in a year. Sometimes, there is a requirement to install expensive capital equipment for processing waste at the manufacturing premise as a precondition to start manufacture. Non-compliance with these requirements may result in suspension or permanent cancellation of the authorization, resulting in the closure of the manufacturing premise.

E. US CGMP or EU GMP Related Non-Compliances

Many a time, GMP inspectors from the US or EU find that Indian manufacturing facility that is approved to manufacture drugs that may be sold in their jurisdiction. This results in the issuance of a memo for explanation and/ or ban on import until the issue with GMP compliance is rectified.

Over the years, Indian companies have improved their ability to comply with GMPs. The Indian Government is now contemplating, to replace Indian GMP standards with WHO-GMP standards, to improve the exportability of drugs manufactured in India.

F. Fixed Dose Combinations

Since 1988, Indian law requires that any combination of drugs must be approved by the DCGI before they could be marketed in India. However, since the power to license the manufacturing of drugs is with the State-level Licensing Authority, and there is no requirement to submit proof of approval from the DCGI to the licensing authority at the time of making an application for manufacturing license. There resulted a situation where a large number of fixed-dose combination drugs were licensed in India, without any approval from the DCGI.

However, since September 2018, after months of protracted legal proceedings, the Government has been able to ban all drugs that were sold without approval or which did not have therapeutic justification for sale. All manufacturers of FDCs in India must ensure that their FDC has been approved by the DCGI before manufacturing it.

G. Overlap with other Industries such as Bio-Pharma and Med-Tech

With advancement of technology, new products that do not necessarily have a chemical basis can be used to treat human and animal diseases and conditions. In that sense, these products, though cannot be called pharmaceuticals, can still be called drugs. In India, the legislative Act that regulates drugs i.e. DCA was enacted in 1940 and the operational Rules under the DCA i.e. DCR were framed in 1945, when drugs were primarily made from chemicals. Hence, unfortunately, the law has not been able to keep up with the technology.

An immediate consequence of the out-of-date nature of Indian regulatory framework is that new technologies such as bio-pharma and med-tech products used for treating humans and animals now have to satisfy the same quality and efficacy (or efficiency) thresholds that a pharmaceutical drug had to. This results in difficulty in obtaining marketing approval for such drugs in India.

Conclusion

The Indian Pharmaceutical Industry has shown great potential and continues to grow consistently. While 2020 brought with it numerous hurdles for the pharma industry such as rising prices, reduced demand for prescription medicine, unavailability of essential medicines, break in the supply chain, etc. It also provided new opportunities for growth to the Indian manufacturing sector. The pandemic has also highlighted the importance of self-reliance across the supply chain as foreign trade of goods was severely impacted by the pandemic. Following the 2020 pharmaceutical trends, developed countries show steady growth in spending on medicine in 2021 which is influenced primarily by innovative technologies and new products entering the market.¹

India now appears to be a go to for foreign companies looking to outsource their manufacturing. The Indian generic drug sector is robust and is establishing its presence in foreign markets as well. The new- drug sector is also expected to record a healthy growth owing to a significant industry-wise increase in R&D expenditure and proposed new drug launches. However, since health is an important subject, the industry continues to be heavily regulated. Multiple Ministries continue to regulate the pharmaceutical industry such as the Health Ministry, Chemicals and Fertilizers Ministry, Science and Technology Ministry, Food Ministry etc. Numerous legislations, regulations and judgments affecting the industry have come into existence recently and numerous others have been proposed. The companies who achieve success in the Indian pharmaceutical market are certainly those which are able to navigate issues that arise under India's legal, regulatory and tax framework, effectively.

1 Available at: <https://www.avenga.com/magazine/pharmaceutical-industry-trends/>, last accessed on February 10, 2023.

Annexure A

List of Drug Licenses Under DCA

1

License Application for	Form required	Application Form	Drugs & Cosmetics Rules Act	Licensing Authorities
Import licenses	—	—	DCR and CT Rules	Authority appointed by the central Government under Rule 22
Import of drugs excluding those specified in Schedule X	Form 10	Form 8	21 of DCR	
Import of drugs specified in Schedule X	Form 10-A	Form 8-A	21 of DCR	
Import of new drug or investigational new drug for clinical trial, bioavailability or bioequivalence study or for examination, test or analysis	Form CT-17	Form CT-16	67 and 68 of CT Rules	
Import of drugs by a Government Hospital or Autonomous Medical Institution for the treatment of patient	Form 11-A	Form 12-AA	33A of DCR	
Import new drug for sale or for distribution	Form CT-19 and/or Form CT-20 as the case may be	Form CT-18	75 of CT Rules	

Any application for import license in Form 8 or Form 8-A, as the case may be, shall be accompanied by a copy of Registration Certificate issued in Form 41 under rule 27-A. An application for issue of a Registration Certificate shall be made to the licensing authority in Form 40.

2

License to sell, stock, exhibit or offer for Sale of Distribution of Drugs	Form required	Application Form	Part IV of DCR	Authority appointed by the State Government
Applications for the grant or renewal of a license for drugs other than those in Schedule X		Form 19 or Form 19-A, as the case may be	59(2) of DCR	Authority appointed by the central Government under Rule 22
Applications for the grant or renewal of a license for drugs included in Schedule X		Form 19-C	59(2) of DCR	

10. Annexure A

2

License to sell, stock, exhibit or offer for Sale of Distribution of Drugs	Form required	Application Form	Part IV of DCR	Authority appointed by the State Government
A license for drugs other than those specified in Schedule C, C (1) and X and by retail on restricted license or by wholesale.	Form 20, Form 20-A or Form 20-B, as the case may be	Form 8-A	61 of DCR	
A license for drugs specified in Schedule C and C (1) excluding those specified in Schedule X, by retail on restricted license or by wholesale.	Form 21, Form 21-A or Form 21-B, as the case may be	Form CT-16	61(2) of DCR	
A license for drugs specified in Schedule X by retail or by wholesale.	Form 20-F or Form 20-G as the case may be		61(3) of DCR	

3

Manufacture for Sale or Distribution	Form required	Application Form	Part VII of DCR	Authority appointed by the Central Government
For license to manufacture drugs other than those specified in Schedules C and C(1)			69 of DCR	
(122) in the case of repacking of drugs excluding those specified in Schedule X for sale or distribution	Form 25-B			
(b) in the case of manufacture of drugs included in Schedule X and not specified in Schedules C and C(1)	Form 25-F			
In any other case	Form 25	Form 24		
A license to manufacture for sale or for distribution of drugs specified in Schedules C and C(1) other than Large Volume Parenterals, Sera and Vaccines, drugs specified in Part X-B and Schedule X	Form 28	Form 27		
A license to manufacture for sale or for distribution of drugs specified in Schedules C and C(1) and Schedule X other than Large Volume Parenterals, Sera and Vaccines, drugs specified in Part X-B	Form 28-B	Form 27-B		
A license to manufacture for sale or for distribution of Large Volume Parenterals, Sera and Vaccines and recombinant DNA derived drugs	Form 28-D	Form 27-D		

10. Annexure A

3

Manufacture for Sale or Distribution	Form required	Application Form	Part VII of DCR	Authority appointed by the Central Government
If the person proposing to manufacture a drugs for the purpose of examination, test or analysis does not hold a license in Form 25 or Form 28	Form 29	Form 30		
If the person proposing to manufacture a drugs for the purpose of examination, test or analysis does not hold a license in Form 25 or Form 28	Form 29	Form 30		
Application for approval to manufacture new drug other than the drugs classifiable under Schedules C and C(1)	Form 46 and/or Form 46-A	Form 44		

4

Loan Licenses	Form required	Application Form	Part VII of DCR	Authority appointed by the central government
For the grant or renewal of loan licenses to manufacture for sale or for distribution of drugs other than those specified in Schedule C, Schedule C (1) and Schedule X	Form 25-A	Form 24-A	69-A of DCR	
Applications for the grant or renewal of loan of drugs specified in Schedules C and C(1)	Intending to avail the facilities as under Form 28 and Form 28-D	Form 27-A	75-A of DCR	

10. Annexure A

5

License to operate a Blood Bank	Form required	Application Form	Part V-B of DCR	Authority appointed by the central government
License to operate a Blood Bank for collection, storage and processing of whole human blood and/or its components for sale and distribution	Form 28-C		122-G of DCR	
License to manufacture and store blood products for sale or distribution	Form 28-E		122-G of DCR	
Certificate of renewal of license to operate a Blood Bank for collection, storage and processing of whole human blood and/or for preparation for sale or distribution of its components	Form 26-G		122-F of DCR	
Certificate of renewal of license to manufacture and store blood products	Form 26-I		122-I of DCR	

Annexure B

Targeted Timelines for Approval of License Applications

Sr. No	Type of Application	Timelines in Working Days
1	New Drugs/Investigational New Drugs ("IND"):	
	a. IND Applications in consultation with Subject Expert Committee ("SEC");	30
	b. New Drug including biological/clinical trials/global clinical trials/new claims in consultation with SEC;	90
	c. Subsequent New Drugs with SEC; and	90
	d. Fixed Dose Combination in consultation with SEC.	90
2	Import Registration of drugs and biological	270
3	Import License of drugs and biological	45
4	Import post approval changes for drugs:	
	a. Major changes;	180
	b. Minor changes	90
5	Endorsement of additional product in registration certificate	120
6	Rule 37 and neutral code	60
7	Grant of permission for manufacturing of:	7
	a. New drug or investigational new drug for clinical trial, bioavailability or bioequivalence study or for examination, test and analysis (CT-11);	
	b. Formulation of unapproved active pharmaceutical ingredient for the development of formulation for test or analysis or clinical trial or bioavailability or bioequivalence study (CT-14); and	
	c. Unapproved active pharmaceutical ingredient for the development of formulation for test or analysis or clinical trial or bioavailability or bioequivalence study (CT-15)	
8	CLAA in Form 28/28-D128-E/27-C	60
9	License to import new drug or IND for the purpose of clinical trial or bioavailability or bioequivalence study or for examination, test or analysis (CT-17)	7
10	Permission to conduct bioavailability or bioequivalence study for new drug or IND	90

11. Annexure B

Sr. No	Type of Application	Timelines in Working Days
11	Extension of shelf life report	45
12	Registration of cosmetics	90
13	Registration of Ethics Committee (CT-02)	45
14	Biological Post Approval Changes:	
	a. Major in consultation with Central Drugs Laboratory, SEC	180
	b. Minor	90
15	Permission for bioavailability or bioequivalence study and its post approval changes for export purpose	15
16	Registration of bioavailability or bioequivalence study center (CT-09)	90
17	Written confirmation as per European Union Directives	20
18	Permission to import small quantity of drugs for personal use	3

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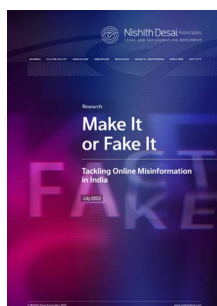
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