The Indian Pharmaceutical Industry

Business, Legal & Tax Perspective

February 2019
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1. Executive Summary

The Indian Pharmaceutical industry was valued at USD 33 Billion in 2017. The exports from India alone stood at USD 17.27 Billion. The industry is expected to grow at a CAGR of 22.4% between 2015-2020 and achieve a market size of USD 55 Billion, of which the domestic generic market is expected to contribute USD 27.9 Billion. India has also become a popular destination for outsourced contract research and manufacturing service. The contract manufacturing and research Industry is expected to have grown at 18-20% CAGR in 2018, and is expected to have a market size of USD 18 Billion.

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.

However, the industry is primarily focused on manufacturing of generic medicine and export of bulk drugs. The focus on development of new drugs began only with introduction of new 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 with high margins. The Abbreviated New Drug Applications (ANDA) to the US FDA is 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 (Sun Pharma, Cadilla Healthcare and Piramal Life Sciences, had applied for conducting clinical trials on for numerous new drugs). The clinical trials industry is also growing steadily after witnessing a brief lull due to regulatory issues such as delay in obtaining approvals, compensation issues etc. which have since been clarified and resolved by the concerned regulatory authority.

As the pharmaceutical industry operates in the sensitive health sector, there are a plethora of laws which regulate it. Right from manufacture of drugs to advertisement and promotion, each step in drug manufacturing and marketing process is regulated. As mentioned earlier, India introduced a patent protection regime in 2005 to protect both process as well as product innovation. India now also has its own competition law to address anti-trust issues which arise in course of day to day operation of the industry as well as owing to the numerous collaborations which the Industry is witnessing.

The industry has witnessed numerous changes in the regulatory regime in the recent past. A new price control order has been enforced and prices of all essential medicines under the National List of Essential Medicines, 2015 have been brought under price control. India has implemented a compulsory primary, secondary and tertiary barcoding requirement on all its exports in a phased manner. A new compensation regime has been introduced for clinical trial subjects wherein grounds for compensation have been specified. A voluntary uniform code for marketing practices of pharmaceutical companies was introduced.

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sometime back to check improper promotions of drugs before medical practitioners. A large number of fixed dose combination drugs have been banned due to their unapproved use.

Backed by a strong intellectual property and regulatory framework, the Indian pharmaceutical industry seems poised to achieve greater heights.
2. Introduction

Indian pharmaceutical industry has been witnessing significant growth over past few years. The size of the Indian pharmaceutical market increased from USD 6 Billion in 2005 to USD 33 Billion in 2017.5 By 2020, India’s pharmaceuticals market is expected to reach USD 55 Billion and become one of the largest pharmaceutical market in the world.6 The pharmaceuticals sector has attracted FDI worth USD 15.72 Billion between April 2000 and March 2018, according to data published by Department of Industrial Policy and Promotion (DIPP).7 The Government also has plans to set up a US$ 700 million venture capital (VC) fund to give a boost to drug discovery and strengthen the pharma infrastructure in the country.8 The Indian Government, in efforts to boost R&D in the pharmaceutical sector, has established six National Institutes of Pharmaceutical Education and Research (NIPER) and declared them as ‘Institute of National Importance’9

For a global pharmaceutical company seeking to enter 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 variety of factors including cheap labor 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 maximum number of USFDA approved plants outside USA which are over 16910 in number.
- Ease of conducting clinical trials and bio availability and bioequivalence studies due to India’s ability to provide speedier and less expensive trials without compromising quality and vast patient pool;
- Product patent regime;

As anticipated, the new patent regime has caused a shift towards discovery research within Indian industry. 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. Recent recessionary times have created additional pressure on global pharmaceutical companies to manage resources more efficiently – India’s low-cost research and development abilities provide solace.

Co-development arrangements between Indian and multinational pharmaceutical companies have created a busy atmosphere in research laboratories in India. The Indian pharmaceutical market is witnessing a rise in collaborations with global companies such as Glenmark Pharmaceuticals, GlaxoSmithKline (“GSK”), Merck and Eli Lilly. In 2018, within a span of a month, Glenmark announced an exclusive licensing agreement with Australian company Seqirus for an allergy drug and another with Chinese biopharmaceutical firm Harbour Biomed for its oncology molecule. Piramal

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8. https://www.livemint.com/Politics/BxZA8g8x8s9lAdho84U1MGovt-to-set-up-$500-crore-venture-capital-fund-for-pharma.in. html. (Last Visited, September 10, 2018)
Life Science Ltd (PLS) and Eli Lilly and Company have signed a landmark new drug development collaboration. Also Ranbaxy and GSK have launched a New Drug Discovery Research team to advance into preclinical investigation in the chronic obstructive pulmonary disease (COPD) and other anti-infectives therapeutic areas. PLS also initiated drug discovery efforts with Merck & Co. to discover and develop new drugs in oncology. Zydus Cadila entered into a new drug discovery and development agreement with Eli Lilly to develop potential new drugs to cure cardiovascular disease. India is also becoming a hub for late-phase research. Johnson & Johnson (J&J) announced its plans to make India a global hub for late-phase development of its new drugs. With this initiative, all future new drugs and compounds from J&J will undergo final pre-production testing in India. Many domestic companies are getting more involved in such collaborative arrangements.

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 2017, 46 M&A deals worth USD 1.47 billion were reported in the pharmaceutical sector. Some of the noteworthy ones are acquisition of OctoPlus N.V, a Netherlands-based company, by Dr Reddy Laboratories to get access to the Poly Lactic-CoGlycolic Acid (PLGA) technology for the formulation of complex injectables. Similarly, acquisition of a portfolio of anti-spasticity and pain management drugs from US based drug maker – Mallinckrodt by Piramal Enterprises.

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 pharma and life sciences industry.

I. India Entry Strategies

A basic understanding of the Indian legal system is a pre-requisite to do business of 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:

II. 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 the case of pharmaceutical sector, foreign direct investment is permitted up to 100%. However, a 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. There is no prior permission required to incorporate a wholly owned subsidiary in India.

III. India’s Post-Trips Intellectual Property Environment

In March 2005, new patent laws were passed in India to comply with 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 were 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 20 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 application to industry and computer programs in combination with hardware can be 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.
IV. Form of the Indian Entity

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

A. Unincorporated Entities

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

i. Liaison Office

Setting up a liaison office in a sector in which 100% FDI is allowed under the automatic route requires the prior consent of the AD. 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 3 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.

13. Application made from certain countries as well as for certain sectors still requires approval of the RBI. For details please refer to https://rbidocs.rbi.org.in/rdocs/notification/PDFS/22ENT04042016CCF68741715DA73FR8yDE2387B850A83A.PDF

ii. 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 AD for sectors under which 100% FDI is permissible under automatic route, with approval under other sectors accorded after consultation with 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 limitation on the 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.

14. Application made from certain countries as well as for certain sectors still requires approval of the RBI. For details please refer to https://rbidocs.rbi.org.in/rdocs/notification/PDFS/22ENT04042016CCF68741715DA73FR8yDE2387B850A83A.PDF

iii. 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 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% 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 partnership or trust are not usually recommended structures for investment, as there are certain restrictions on the foreign direct investment in such structures.

B. Incorporated Entities

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

i. A Limited Liability Partnership

A LLP is a form of business entity which 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.
ii. 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; the number of members in a private limited company is minimum of 2 and a maximum of 200 members (excluding the present and past employees of the company); its Articles of Association must prohibit any invitation to the public to subscribe to the securities of the company.

Under the Companies Act, 2013 a natural person who is an Indian citizen and resident in India can incorporate a one person company. However, it shall be required to convert itself into public or private company, in case its paid up share capital 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 which is not a private company (but includes a private company that is the subsidiary of a public company). A public limited company shall have a minimum of 7 members but may have more than 200 shareholders and 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 IPO. 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 a LLP and Limited Liability Company, a LLP structure is not preferred for a pharmaceutical manufacturing company because a LLP whose business is to manufacture drugs cannot receive foreign investment under the present foreign direct investment policy.

V. Advantages and Disadvantages of a Private Company

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

We have observed that most of the pharma companies are considering incorporating a company considering the scope of services the company intends to carry on in India. Another common trend is to enter into direct marketing and distribution arrangement with distributors in India. It has also been observed that the trend of joint ventures between pharma companies is emerging fast with more and more companies forming joint ventures either for co-development or manufacturing using technology or marketing and distribution.15

VI. 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.

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15. Please refer to our joint venture paper for detailed discussion on the legal, regulatory and tax regime affecting joint ventures and the possible structures.
The scenario is changing, with India completing decades of liberalization entailing the removal of the strict licensing requirements, 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.

VII. Anti-Bribery Framework

India has a strong anti-bribery legislation called the Prevention of Corruption Act, 1988 (as amended in 2018) (“PCA”). Some unique features of PCA, especially while comparing it to UK Bribery Act and Foreign Corrupt Practices Act, 1977, are:

- The PCA punishes ‘bribe’ offered to, or accepted by, a public servant only. The scope of ‘public servant’ is broad enough to cover anyone who is performing a public duty or is receiving public funds. It applies to both individual as well as commercial organizations.

- The PCA does not provide 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 bribe paid to foreign government officials or official of a public international organization.

- It does not make any distinction between illegal gratification and facilitation payment.
3. Legal and Regulatory Regime in India

I. Outline of Legal and Regulatory Framework

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

1. Drugs and Cosmetics Act, 1940 and Rules, 1945;
2. Essential Commodities Act, 1955 and Drugs (Price Control) Order, 2013 (DPCO);
4. The Narcotic Drugs and Psychotropic Substances Act, 1985;
5. Patents Act, 1970;
6. Trade Marks Act, 1999
7. Competition Act, 2002

II. 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").

The DCA and DCR seek to:

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

A. Legal Definition of Drug

A drug is defined comprehensively under the DCA.16

The definition of drug includes medicines that are meant for internal as well as external use including substance used for the diagnosis, treatment or prevention of disease. It also includes components of drug as well as devices that are used internally or externally for the diagnosis, treatment or prevention of disease. Under a proposed amendment to the DCA, recombinant DNA derived products, Living Modified Organisms, monoclonal antibodies, stem cells, gene therapeutic products and xenografts which are intended to be used as drugs may be brought within the definition of drug.

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 provisions of the DCA and DCR may not apply in relation to their manufacture and import.

B. 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.

16. 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.”
C. Organizational Structure of the Central Drugs Standard Control Organisation (CDSCO)

Organisation Chart Central Drugs Standard Control Organisation

Drugs Controller General(I)
(Dr. G. N. Singh)

Head Quarter
(New Delhi)

Zonal Offices
(6)

Sub-Zonal Offices
(5)

Port/Airport Offices
(13)

Laboratories
(6)

Staff

Staff

Staff

Staff

DDC(I)
ADCI
DI
TDAs
Supporting Staff

DDC(I)
ADCI
DI
TDAs
Supporting Staff

ADCI
DI
TDAs
Supporting Staff

ADCI
DI
TDAs
Supporting Staff

Director
Dy. Director
Sr. Scientific Officer I
Sr. Scientific officer II
Research Officer
Sr. Scientist Assistant
Jr. Scientist Assistant
Supporting Staff

Abbreviations: CDSCO - Central Drugs Standard Control Organisation; CDL - Central Drug Laboratories; CDTIL - Central Drug Testing laboratories; RDTL - Regional Drug Testing laboratories; IVRI - Indian Veterinary Research Institute; NIB - National Institute of Biologicals; IPC - Indian Pharmacopoeia commission; DDC(I) - Deputy Drugs Controller (I); ADC(I)- Assistant Drugs Controller(I); DI- Drugs Inspectors; TDAs- Technical Data Associates

*Source: [www.cdsco.nic.in/forms/list.aspx?id=1368&ld=0](http://www.cdsco.nic.in/forms/list.aspx?id=1368&ld=0)
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.

D. Organizational Structure of the Indian Food and Drug Administration

Structure of FDA

E. Licenses Required for Import, Sale, Manufacture and Loan of Drugs Under the Drugs and Cosmetics Rules 1945

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

*Source: fda.up.nic.in/org_structure.htm

<table>
<thead>
<tr>
<th>Sr. No</th>
<th>License Application for</th>
<th>Form required</th>
<th>Application form</th>
<th>Drugs and Cosmetics Rules 1945</th>
<th>Licensing Authority</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.</td>
<td>Import licenses</td>
<td></td>
<td></td>
<td>Part IV</td>
<td>Authority appointed by the central Government under Rule 22</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Form 10</td>
<td>Form 8</td>
<td>21</td>
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<td>Form 10-A</td>
<td>Form 8-A</td>
<td>21</td>
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<td>Form 11</td>
<td>Form 12</td>
<td>33</td>
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<td>Form 11-A</td>
<td>Form 12-AA</td>
<td>33A</td>
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<tr>
<td></td>
<td>Application for permission to import new drug for clinical trial or marketing</td>
<td>Form 45 and/or Form 45-A as the case may be</td>
<td>Form 44</td>
<td>122-A</td>
<td></td>
</tr>
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<td></td>
<td>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</td>
<td></td>
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</tbody>
</table>

2. License to sell, stock, exhibit or offer for sale or distribution of drugs,

| Applications for the grant or renewal of a license for drugs other than those specified in Schedule X, | Form 19 or Form 19-A, as the case may be | Part VI | Authority appointed by the State Government |
| Applications for the grant or renewal of a license for drugs included in Schedule X | Form 19-C | 59(2) |
| 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 | 61 |
| 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. | 61(2) |
| 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) |

3. Manufacture for sale or distribution

| For license to manufacture drugs other than those specified in Schedules C and C(1) | Part VII | Authority appointed by the central Government |
| a. in the case of repacking of drugs excluding those specified in Schedule X for sale or distribution | Form 25-B | 69 |
| b. in the case of manufacture of drugs included in Schedule X and not specified in Schedules C and C(1) | Form 25-F | Form25-F |
| c. in any other case | Form 25 | Form 24 |
4. **Loan Licenses**

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 |

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 |

5. **License to operate a blood bank**

| Form 28-C | 122-G |

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-E | 122-G |

License to manufacture and store blood products for sale or distribution

| Form 26-G | 122-F |

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-I | 122-I |

Certificate of renewal of license to manufacture and store blood products

All the above licenses are periodic and are required to be renewed. The grant and renewal of all licenses is conditional upon satisfaction of the 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.
F. Stipulated Timelines for Regulatory Approvals by CDSCO

<table>
<thead>
<tr>
<th>S. No</th>
<th>Type of Application</th>
<th>Timeline in days</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.</td>
<td>a. New Drug including Biological, Medical Devices/Clinical Trials/ Global Clinical Trials/ New Claims in consultation with NDAC/MDAC</td>
<td>180</td>
</tr>
<tr>
<td></td>
<td>b. IND Applications in consultation with IND Committee</td>
<td>180</td>
</tr>
<tr>
<td></td>
<td>c. Subsequent New Drugs</td>
<td>120</td>
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<tr>
<td></td>
<td>d. Clinical Trial Protocol Amendments (if Consultation of NDAC is not required)</td>
<td>60</td>
</tr>
<tr>
<td>2.</td>
<td>Fixed Dose Combination in consultation with NDAC</td>
<td>180</td>
</tr>
<tr>
<td>3.</td>
<td>Import Registration of Drugs and Medical Devices</td>
<td>270</td>
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<tr>
<td>4.</td>
<td>Endorsement of additional product on registration</td>
<td>120</td>
</tr>
<tr>
<td>5.</td>
<td>Rule 37 &amp; Neutral Code</td>
<td>60</td>
</tr>
<tr>
<td>6.</td>
<td>NOC for Form 29 (Biological and Medical Devices)</td>
<td>60*</td>
</tr>
<tr>
<td>7.</td>
<td>CLAA in Form 28128-D/280-E127-C etc</td>
<td>60</td>
</tr>
<tr>
<td>8.</td>
<td>Import License in Form 10</td>
<td>45</td>
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<tr>
<td>9.</td>
<td>Test License in Form 11</td>
<td>45</td>
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<tr>
<td>10.</td>
<td>BA/BE NOC</td>
<td>45</td>
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<tr>
<td>11.</td>
<td>Extension of Shelf Life for export</td>
<td>45</td>
</tr>
<tr>
<td>12.</td>
<td>Export of Biological samples</td>
<td>45*</td>
</tr>
<tr>
<td>13.</td>
<td>Registration of Cosmetics</td>
<td>90</td>
</tr>
<tr>
<td>14.</td>
<td>Registration of Ethics Committee</td>
<td>100</td>
</tr>
<tr>
<td>15.</td>
<td>Post approval changes (major) subjected to clearance of CDL, NDAC</td>
<td>180</td>
</tr>
<tr>
<td>16.</td>
<td>Post approval changes (minor)</td>
<td>90</td>
</tr>
<tr>
<td>17.</td>
<td>BA/BE Site approval (after receipt of Joint Inspection report)</td>
<td>60</td>
</tr>
<tr>
<td>18.</td>
<td>Issue of Written Confirmation as per EU Directives</td>
<td>30</td>
</tr>
</tbody>
</table>

* If inspection is not involved for grant of NOC for Form 29
# After obtaining BA/BE NOC.

(source: cdscoonline.gov.in)

III. 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 an end consumer or a business with license to purchase the drug.

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 manufacturing license. If the drug is a new drug (discussed later), then a clinical trial may have to be undertaken prior to grant of manufacturing license.

All manufacturing licenses are perpetual in nature, and a retention fee is required to be paid after five years for keeping the license alive.

IV. 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 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 must for the importer to be based out of India, and possess at least a license to manufacture any type of drugs 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 part), then the foreign manufacturer is required to obtain a marketing permission prior to applying for registration, and the grant of such permission depends on its 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, one 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.

V. Manufacture/Import of New Drugs

The term “New Drug” is defined under the DCA. 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.

VI. Clinical Trials

Like in most developed jurisdictions around the world, manufacturers and importers of new drugs must establish their safety and efficacy 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 (Phase I - IV).

There are certain unique characteristics in the Indian clinical trial regulations to be taken note of:

1. Phase I clinical trial of a new drug developed outside India is not permitted in India.
2. For global clinical trials, the sponsor of the trial has to satisfy the threshold of unmet medical need and innovation vis-à-vis existing therapeutic options;
3. The sponsor of global clinical trial also has to give an undertaking that the new drug would be marketed in India if the sponsor elects to market the new drug in any other jurisdiction.
4. If the trial does not commence within a year of receipt of the permission for conducting clinical trial, then a new permission has to be obtained.

New Drug means and includes: A drug (as defined by the DCA), including bulk drug substances, which has not been used in India to any significant extent under the conditions prescribed, recommended or suggested in the labeling thereof and has not been recognized as effective and safe by the Licensing Authority for the proposed claims; A drug, which is already approved by the Licensing Authority for certain claims, is now being proposed to be marketed with modified or new claims, namely indication, dosage etc.; A fixed dose combination of two or more drugs, individually approved earlier for certain claims, which are now proposed to be combined for the first time in a fixed ratio, or if the ratio of combination is already approved and marketed then the same is proposed to be changed, with certain claims, namely indication, dosage etc.
5. There are extremely stringent reporting requirements in terms of format and time-period for reporting of serious adverse event.

6. The medical management of the patient and its cost is the responsibility and liability of the sponsor for the course of the clinical trial.

7. The compensation for clinical trial related death or injury is calculated through a formula and is enforced by way of an administrative order.

8. Failure to provide medical management or compensation may result in debarment of the sponsor.

9. The sponsor is liable to pay compensation for the negligence of the clinical investigator.

10. 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 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. Vaccines and rDNA derived drugs are, however, treated differently and must provide safety and efficacy irrespective of whether four years have elapsed or not.

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. In 2013, in response to a supreme court directive to ensure that the rights of subjects of clinical trials are protected, the Indian government introduced certain amendments to the rules for conduct of clinical trials which made it very onerous for sponsors of global clinical trials to undertake clinical trials in India. This resulted in decline of global clinical trials in India. The amendments have since been rationalized, and India has once again begun to attract global clinical trials. The government is also expected to notify New Drugs and Clinical Trials Rules, 2018 soon, which would further rationalize the requirements to undertake global clinical trials in India.

VII. 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 pharmacopoeia), 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.

VIII. 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.

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.
IX. 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.

X. 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:

1. Acceptability of scan or photograph of an original prescription to dispense medicine
2. Requirement to obtain a license for offering medicines for sale over the internet
3. Obligation on the registered pharmacist to hand over the medicine to the patient or the carer
4. Prohibition on storing medicines by courier companies for logistics purposes without 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. The government is expected to circulate a revised draft of E-pharmacy Rules, 2018 after addressing these issues.

On October 31, 2018, the High Court of Madras has 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, has passed an interim order injunction certain online pharmacies from selling medicines online, without a license. The matter is yet to be finally adjudicated.

XI. Labeling

Before a drug is sold or distributed in India, it must be labeled according to specifications outlined in the DCR. The DCR specify 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, 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.

XII. 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.

XIII. 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 significant increase in the quality of drugs manufactured in India and has led to the increase in the contract manufacturing activities whereby Indian company manufacture bulk drugs or formulation for the contracting pharma company.

XIV. 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 10 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 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 starts 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 “whistle blower” policy that aims to reward citizens, who provide information on the trade and source of adulterated or counterfeit drugs.

XV. 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”) to regulate the prices of drugs. It replaces the Drug Price Control Order, 1995. The main objective of the DPCO is to ensure the availability, at reasonable prices of essential lifesaving and prophylactic medicines specified in National List of Essential Medicines, 2015 (“NLEM”). The DPCO provides the list of price-controlled drugs, procedures for fixing the prices of drugs, methods of implementation prices and penalties for contravention of provisions. The drug regulator

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annually fixes the maximum retail price of all strengths and dosages of medicines which qualify as essential medicines under NLEM. The earlier DPCO of 1995 fixed drug prices based on the manufacturing costs. However, the present DPCO aims to set a ceiling prices based on the selling price by taking simple average of all the drug brands having a market share of more than 1%. The DPCO does not cover patented drugs.

The formulations, which fall within the purview of the legislation, are called scheduled formulations. The items in the schedule can be added or deleted. The authority which is responsible for fixing the ceiling prices is called the National Pharmaceutical Pricing Authority (“NPPA”).

XVI. 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 is also prohibited, as discussed hereinafter.

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

The Drug and Magic Remedies (Objectionable Advertisement) Act, 1954 prohibits advertisements of a drug or medical device in terms which may imply its use for diagnosis, cure, mitigation or prevention of 54 diseases and conditions identified in the schedule to the Act. Some of the noteworthy diseases and conditions are: Cancer, Cataract, Diabetes, Diseases and Disorders of brain and Heart diseases.

It is worth noting, however, that there is an industry body entrusted with self-regulation of advertisement. All complaints of unjustified claims made in advertisements may be submitted to the Advertising Standards Council of India. The validity of the complaint is adjudged for its compatibility with the Code for Self-Regulation in Advertising.

B. Product Promotions Before Doctors

In response to the recent uproar regarding incentives being given to the doctors by various pharmaceutical companies, the Department of Pharmaceuticals in India (“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.

At present, the UCPMP is voluntary and not legally binding.

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, issued by the Medical Council of India, under the provisions of section 20A read with section 33(m) of the Indian Medical Council Act, 1956. 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 dentist as well.

Moreover, the Organization of Pharmaceutical Producers of India had issued a Code of Pharmaceutical Marketing Practices 2010 (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 the 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.

i. Important Features of the Uniform Code of Pharmaceutical Marketing Practices:

1. 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.

2. 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.

3. 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 medicines are generally available in India for more than 12 months, then the term “new” should not be used.

4. 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.

5. 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:

<table>
<thead>
<tr>
<th>Do’s</th>
<th>Don’ts</th>
</tr>
</thead>
<tbody>
<tr>
<td>PM to be consistent with the UCPMP</td>
<td>Date of printing or of the last review of PM to be mentioned</td>
</tr>
<tr>
<td>Date of printing or of the last review of PM to be mentioned</td>
<td>The paid or secured PM in journals not to resemble the editorial matter</td>
</tr>
<tr>
<td>Audio-visual material to be accompanied by printed material in compliance with the UCPMP</td>
<td>Photographs or names of healthcare professionals should not be used</td>
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</table>
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.

6. 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 prescribed dosage for 3 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.

7. Hospitality, Sponsorships and meetings

As per the UCPMP, the companies are permitted to provide assistance to doctors for continuing education facilitating doctors' genuine attendance to 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 in attending the event.

8. 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 activities of its employees including MRs to ensure that the UCPMP has been complied with.

9. 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.

ii. Code of Professional Ethics for Doctors

The Medical Council of India has amended the MCI Code to include 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 has imposed the following restrictions on the doctors:

a. A medical practitioner shall not receive any gift from any pharmaceutical or allied health care industry and their sales people or representatives;

b. 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 programme etc as a delegate;

c. A medical practitioner shall not accept individually any hospitality like hotel accommodation for self and family members under any pretext;

d. 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;

e. 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;

f. 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, but 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.

iii. National Medical Commission

In September 2018, the Medical Council of India, the apex body that administers the MCI Code, was abruptly reconstituted with new appointees because there were serious allegations of dereliction of duty against the old members. The Central Government has now proposed to replace the Medical Council of India with a National Medical Commission, which will give more control over medical education and standards to the Government than it currently has.

XVII. Bulk Drug/ API/ Intermediate – Contract Manufacturing and Research

India is known as the pharmacy to the world, primarily because Indian pharmaceutical sector industry supplies over 50 per cent of global demand for various vaccines, 40 per cent of generic demand in the US and 25 per cent of all medicine in UK.\(^{21}\)

A lot of export of medicine happens under contract manufacturing arrangement. It must be noted here that though an active pharmaceutical ingredient or finished formulation may be manufactured strictly for export purposes only, it still ought 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 much 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.

\(^{21}\) Source: [https://www.ibef.org/industry/indian-pharmaceuticals-industry-analysis-presentation (last checked October 29, 2018)](https://www.ibef.org/industry/indian-pharmaceuticals-industry-analysis-presentation (last checked October 29, 2018)).
XVIII. The Competition Act, 2002

Anti-competitive agreements are prohibited by law in India. The framework for control and investigation of anti-competitive agreement 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 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 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 protection of the right holders could invite possible competition law violations.

Mergers and Takeovers in the pharmaceutical sectors 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 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 Indian has shown inclination to launch an investigation in anti-competitive practices in the pharmaceutical industry.

XIX. Patent Protection

In India’s continued efforts to comply with its commitment under WTO, the Patents Act was amended three times since 1995.22 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 product patent regime in India, which is discussed in detail later.

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

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 assignee or legal representatives of the inventor.

B. 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 31 months from the priority date.

Some of the salient features are as follows:
- The term of the patent is 20 years from the date of priority;
- In infringement suits in relation to ‘process’ patents, the ‘burden of proof’ is reversed.
- Section 3 of the Act, carves out certain exceptions from the patentable inventions.

Section 3(d) 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.

C. Infringement

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,’ will gain importance in view of introduction of the product patent regime in India. 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.

D. 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.
E. Protection of Generic Manufacturers

Product patents granted in pursuance of black box applications have been treated differently to protect the interests of generic manufacturers. Enterprises which have made significant investment and were producing and marketing the concerned product prior to January 1, 2005 and which continue to manufacture the product covered by the patent on the date of grant of the patent, are protected and the patentee cannot institute infringement suits against them but would be entitled to receive reasonable royalty from them. It is not clarified as to how the reasonableness of royalty would be determined. This provision would prejudice the rights of a patentee in respect of exploitation of its patent.

F. 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 to 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.

G. Compulsory License

One of the most controversial amendments has been on compulsory licenses ("CL"). Currently, 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 provision has been inserted in the Compulsory License chapter. The provision 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 9th March, 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 Tosyalte' (NEXAVAR). 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 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.

H. 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 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 3 months of the end of each year (i.e. before March 31 of every year). Non-compliance with this requirement may invite penalty of imprisonment which may extend to 6 months, or with fine, or with both.

I. 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, applicant is not entitled to institute any proceedings for infringement until the patent has been granted. Prior to the Third Amendment, only upon acceptance of the application did the applicant enjoy like privileges and rights.

J. Secrecy Provisions

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 3 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 US, since US applications are required to be filed by the inventors and not assignees of the inventors.

K. Data Exclusivity

When the Indian government began the process of introducing the 2nd Amendment to the Patents Act, 1970 in 2002, multinational companies approached the Government with a recommendation to introduce a data exclusivity provision consistent with Article 39.3 of TRIPS. However, the Government had refused to accede to such a request.

Satwant Reddy committee that was formed to study and recommend on Data Exclusivity submitted its report in 2008. Recent reports suggest that the Government has accepted the recommendations on data exclusivity and may offer ‘protection against disclosure’ to the pharma companies. However, the government may take some more time to announce its decision on ‘Protection against unfair commercial use’ as the Union ministry of health and the Department Of Pharmaceuticals wants further discussions with stakeholders.

L. 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.

XX. 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. Pharmaceutical products are covered under Class-5, cosmetics under Class-3 and the 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.

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.

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 10 years. Foreign companies can license trademarks in India under the proper license / Registered User Agreement.

A. 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.

B. 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.

C. Landmark Case Law:
Cadila Health Care Ltd. vs. Cadila Pharmaceuticals Ltd. (Decided On March 26, 2001)

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 falticab. 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 ‘falci’ 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.

31. Classes of Goods and Services: Classes 1 to 34 cover goods while classes 35 to 45 cover services.
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 it comes to medicines of last resort. The court pointed out 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 trade mark or part of any trade mark 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.

XXI. Biological Diversity Act, 2002 (“Biodiversity Act”)

The 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 ecosystems. “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.
4. Tax Regime

I. Direct Taxes

A. 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. 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 exclusive 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 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 is 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. All tax rates mentioned herein are exclusive of surcharge on tax (which varies according to the quantum of income) and a health and education cess on the tax and surcharge which is presently at 44%.

i. Taxes Applicable to Companies

Under the ITA, a domestic company is taxed at a flat rate of 30% on its global taxable income. However, the applicable tax rate is 25% where the turnover or the gross receipts of such company in the previous year 2016-17 did not exceed INR 2.5 billion. The tax so determined is increased by a surcharge levied at 7% on the amount of income-tax if net income exceeds INR 10 million but does not exceed INR 100 million; and at 12% where net income exceeds INR 100 million. The amount of income tax and surcharge is increased further by a health and education cess of 4%. In addition to the corporate level tax (including surcharge and cess), the domestic company is liable to pay a Dividend Distribution Tax on dividends issued by it, which comes to approximately 20%. This dividend is thereafter exempt from income tax on receipt by the company’s shareholders, regardless of the residential status of such shareholder.

A foreign company is taxed at a flat rate of 40% on its Indian-sourced income, increased by a surcharge levied at 2% on the amount of income-tax if net income exceeds INR 10 million but does not exceed INR 100 million; and at 5% where net income exceeds INR 100 million. The amount of income tax and surcharge is increased further by a health and education cess of 4%.

In some cases, a foreign company can be deemed to be an Indian tax resident if its 'Place of Effective
Management’ is in India. In these cases, the foreign company would be taxed in India on its global income (like an Indian tax resident) and not only on its Indian-sourced income.

ii. Minimum Alternate Tax

If the tax payable by any company, including a foreign company taxable in India, is less than 18.5% of its book profits, it will be required to pay Minimum Alternate Tax (“MAT”) under the ITA which will be deemed to be 18.5% of such book profits. Carry forward and set-off of MAT credit is allowed only for a period of 15 years immediately succeeding the assessment year in which such credit becomes allowable and is governed by the following basic principles:

1. The amount of tax credit that is allowed shall be the difference of the MAT paid and the amount of tax payable by the taxpayer on his total income as per the other provisions of the ITA.

2. Set off in a future assessment year in respect of brought forward tax credit is allowed only to the extent of the difference between the tax payable by the taxpayer on his total income and the tax that would have been payable under the MAT provisions.

iii. Interest

Interest received by a non-resident from an Indian company on foreign currency denominated loans or in respect of rupee-denominated offshore bonds, could be subject to beneficial tax rate of 5% where certain qualifying conditions are met. Else such interest is generally taxable at the rate of 20% as per the provisions of the ITA. Where the type of interest does not meet the conditions specified for beneficial rates, the interest could be taxable at 30% (individuals and most entities) or 40% (foreign company). Some beneficial rates may be availed of where provided under an applicable tax treaty (rate may be reduced to 10/15% under some of the Indian Tax Treaties). In all cases, tax is required to be withheld at source by the resident payer at the applicable rate. Further, interest is a tax-deductible expense for the Indian payer company, provided the applicable tax has been withheld before making the payments to the non-resident.

iv. Royalties/Fees for Technical Services

Payments towards royalty and Fees for Technical Services (FTS) currently attract tax at the rate of 10% under the provisions of the ITA, which is required to be withheld by the Indian resident payer. Lastly, royalties and fees for technical services accruing or arising to a foreign company (which has a permanent establishment in India) have been excluded from chargeability of MAT if tax payable on such income is less than 18.5% (exclusive of surcharge, education cess, etc.). Hence given the applicable rate is 10%, there should be no MAT on such income. Further, where royalties or FTS are paid to a foreign company and they are effectively connected to a PE of the foreign company in India, then such payments would be taxed as business profits on “net income” basis, at the rate of 40% applicable to business profits of a foreign company.

v. Capital Gains

Under the ITA, capital gains earned upon the transfer of capital assets are classified into short-term capital gains and long-term capital gains depending on the period of holding of the asset prior to transfer.

Securities listed on a recognized Indian stock exchange if held for more than 12 months are treated as long-term capital assets, and if held for 12 months or less are treated as short-term capital assets. The gains from transfer of these assets are taxed as follows:

- Long-term capital gains in excess of INR 100,000 from sale of equity shares or units of an equity-oriented fund where Securities Transaction Tax (STT) has been paid, is subject to tax at 10% without the benefit of indexation of costs. These provisions apply to transfers made on or after 1 April 2018.

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34 Securities Transaction Tax (STT) is applicable on all equity shares which are sold or bought on a stock exchange. Any sale/purchase which happens on a stock exchange is subject to STT.
Short-term capital gains arising on transfer of listed equity shares (including units of an equity oriented mutual fund) on a recognized stock exchange in India will be taxed at the rate of 15%.

Capital gains realised on sale of listed equity shares not executed on a recognised stock exchange in India would be taxed at the rate of 10% for long-term gains and as normal income in case of short-term gains.

Capital gains realised on sale of unlisted Indian securities would be taxed at the rate of 20% for long-term gains and as normal income in case of short-term gains, and the applicable period of holding for these unlisted shares would be 24 months and 36 months for other securities.

B. 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 set ups and infrastructure provision.

i. In-House Research and Development

Companies engaged in the business of biotechnology or in the business of manufacture or production of any drugs, pharmaceuticals, chemicals, etc. and who have incurred any expenditure on scientific research (not being expenditure in the nature of cost of any land or building) on in-house research and development facility as approved by the Department of Scientific and Industrial Research, are allowed a deduction of 150 percent of such expenditure from 01.04.2017 to 31.03.2020. Expenditure on scientific research includes expenditure incurred on clinical drug trial, 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.

It should be borne in mind here that no company would be entitled to the aforementioned deduction unless it enters into an agreement with the Department of Scientific and Industrial Research for co-operation in such research and development facility and for audit of the accounts maintained for that research and development facility.

ii. Contributions Made to other Institutions for Scientific Research

The ITA provides for a deduction of 150 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.

iii. 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.

iv. 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 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, “biotechnology” 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.

C. Potential Permanent Establishment Issues in Contract Research and Manufacturing

Where 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 of 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 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. This is more so as the scope of ‘business connection’ under the ITA has been further widened by the Finance Act 2018, while treaties have not been amended to the same effect as yet. 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.

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

i. 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

ii. 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.

iii. 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. 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.

D. 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 separately 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, 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, 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 an 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.

E. 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, favourable exchange controls and legal system, certainty in tax and legal framework and ease of winding up operations.

F. 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 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”.

i. Arm’s Length Price

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, 2017 ("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 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;
- Such other method that may be prescribed by the Central Board of Direct Taxes (this has been prescribed as “any method which takes into account the price which has been charged or paid, or would have been charged or paid, for the same or similar uncontrolled transaction, with or between non-associated enterprises, under similar circumstances, considering all the relevant facts”).

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 API 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 the 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 CUP Method without specifying the reasons for rejection of 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 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 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.

ii. 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. Key features of these rules are:

- Safe harbour margins have been prescribed for provision of: (i) IT and IteS services; (ii) Knowledge Process Outsourcing services; (iii) contract R&D services related to generic pharmaceutical drugs and to software development; (iv) specified corporate guarantees; (v) intra-group loan to a non-resident wholly owned subsidiary; (vi) manufacture and export of core and non-core auto components; and (vii) receipt of low-value adding intra-group services

- The prescribed safe harbour margin in case of for Contract R&D services, with insignificant risks, wholly or partly relating to generic pharmaceutical drugs is an operating profit margin to operating expense - 24% or more

G. 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 freebees 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.

II. Indirect Taxes

A. 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:

38. Circular No. 5/2012 [F. No. 225/142/2012-ITA.II], dated 1-8-2012.
a. Service Tax
b. Additional Customs Duty commonly known as Countervailing Duty (CVD)
c. Special Additional Duty of Customs (SAD)
d. Central Sales Tax
e. 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.

B. 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 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 (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 Antidumping 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.

C. CENVAT

Cenvat is a duty of excise which is levied on all goods that are produced or manufactured in India, marketable, movable and covered by the excise legislation. The peak duty rate was reduced from 16 per cent to 14 per cent by the Finance Act, 2008 and was further reduced to 8 per cent, although there are other rates ranging upwards, or based on an ad valorem/quantity rate.

In order to avoid the cascading of excise duty and double taxation, the CENVAT scheme has been framed under the Central Excise Act and the CENVAT Credit Rules. Under the CENVAT Credit Rules, a manufacturer of excisable goods can avail of credit of duty paid on certain inputs and capital goods barring certain inputs used in the specified manufacture of certain products. The credit can be utilized towards the duty payable on removal of the final product. It must also be noted that the CENVAT scheme also takes into account credits with respect to any service tax paid by the manufacturer on input services received.
In the pharmaceutical industry, the excise duty rate on inputs has always been higher than the excise duty rate applicable to the finished products. While the generic excise duty rate on the inputs (Active Pharmaceutical Ingredients or APIs) is currently at 12.5%, the generic excise duty rate on finished formulations is 6%. The net result has been that the CENVAT Credit has accumulated in the books of the drug manufacturer who is unable to use it efficiently. The manufacturers catering to the domestic market have borne the brunt of this issue since neither can they set off the entire CENVAT Credit nor can they claim refund for the same, unlike their counterparts who export pharmaceutical products and are eligible to refund of the unutilized CENVAT Credit. One can only hope that, in the days to come, the Indian Government will either align the excise duty rates of APIs (inputs) with that of the finished formulations or provide for a refund mechanism for the unutilized CENVAT Credit.

Another issue commonly faced by pharmaceutical companies is the low abatement percentage for pharmaceutical products. The assessable value for the purpose of levy of excise duty for pharmaceutical products is calculated by providing certain abatement from the Maximum Retail Price (“MRP”) of the product. At present, an abatement of 35% of MRP is permitted for pharmaceutical products. The pharmaceutical industry has claimed that the abatement is not sufficient given that the industry faces trade margins, R&D costs and other costs specifically associated with the pharmaceutical industry.

D. Research and Development CESS

Under the GST regime, Research and Development cess has been abolished.

Synopsis of benefits available to units setup in Special Economic Zones ("SEZ units") in India:

- During the financial year beginning April 1, 2005 SEZ units will get the following exemptions:
  - 100% exemption of profits and gains from business for the first 5 years;
  - 50% exemption on profits and gains from business for the next 5 years;
  - 50% exemption to the extent that such amounts are re-invested in the SEZ Special Reserve Account;
  - Exemption from capital gains arising on transfer of capital assets in case of shifting of industrial undertaking from urban areas to any SEZ, provided that, 1 year before, or 3 years after the transfer (i) machinery/plant was purchased for the business of the industrial undertaking in the SEZ, (ii) building or land was acquired or building was constructed in the SEZ, (iii) the original asset was shifted and the establishment was transferred to the SEZ and (iv) the assessee incurred such other expenses as are notified by the Central Government;
  - 100 per cent customs duty exemption on the import of goods or services into the SEZ. However, any goods removed from the SEZ into a domestic tariff area will be subject to customs duty.
  - 100 per cent excise duty exemption on goods brought from a domestic tariff area into the SEZ.
  - Exemption from Central Sales Tax, service Tax and State Sales Tax. These have now subsumed into GST and supplies to SEZs are zero rated under IGST Act, 2017.
  - 100 per cent exemption from securities transaction tax.
5. Key Issues and Challenges in Pharma Industry

I. 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.

II. 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 lost significant money.

III. 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 it part of the marketing approval, but the generic drug does not do it because it was not subject to a marketing approval. So, the same drug exists in market with different labelling declarations such as whether or not the drug is to be sold under a prescription or not.

IV. Clinical Trials

All sponsors who are part of global clinical trials are required to give an undertaking that upon successful completion of clinical trials and marketing of drug in other jurisdictions, the sponsor will market in India as well. Thought the objective behind the taking the undertaking is to be appreciated, this creates a situation where the sponsor is required to commit upfront that the drug will be marketed in India. It is difficult to give this undertaking because decision to market a drug depends on many considerations, foremost amongst which is pricing. The lack of data exclusivity and patent linkage provisions in India is also a deterrent for some companies to market the drug in India.

V. 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 ground water 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, 1981
- 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 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 closure of the manufacturing premise.

VI. US cGMP or EU GMP Related Non-Compliances

Many a times, 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 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 replacing India GMP standards with WHO GMP standards, to improve the exportability of drugs manufactured in India.

VII. 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 manufacture of drugs is with the State-level Licensing Authority and there is no requirement to submit proof of approval from 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 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.

VIII. 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.
6. Recent Developments

I. Drug Pricing Authority Excludes Patented New Drugs And Orphan Drugs From Price Control

The DoP notified an order on January 03, 2019 (“Order”) amending the Drugs (Prices Control) Order 2013 (“DPCO”), stating the following:

1. Manufacturers, importers and marketers (“Manufacturers”) of patented new drugs in India are exempted from price control for a period of five years (“New Drug Exemption”). The five-year window starts from the date when the Manufacturer starts commercial marketing in India.

2. Drugs used to treat rare diseases would be exempted from price control if the Ministry of Health and Family Welfare decides to do so (“Orphan Drug Exemption”).

3. The Government can source Market Based Data required under the DPCO (“Drug Price Data”) from any pharmaceutical market data specializing company. Earlier, the data could only be sourced from IMS Health.

4. Government is now empowered to consider Drug Price Data for any month for fixing prices of drugs and medical devices.

Currently, the prices of all drugs and notified categories of medical devices (“Notified Medical Devices”) are monitored and fixed by the NPPA. The NPPA fixes the ceiling prices of drugs and Notified Medical Devices that are listed in the schedule appended to the DPCO (“Scheduled Formulations”).

No manufacturer can price or sell its Scheduled Formulations above the ceiling price fixed by the NPPA. The drugs and Notified Medical Devices that are not part of the schedule to the DPCO (“Non-Scheduled Formulations”) are under strict price surveillance. The prices of Non-Scheduled Formulations cannot be increased by more than 10% in any preceding 12 month period.

Prior to the Order, exemption from price control was limited to only those manufacturers who were producing new drugs protected by a product patent that were (i) developed through indigenous (i.e. local) research and development and (ii) not produced elsewhere. The New Drug Exemption has removed localization requirements associated with claiming the price control exemption. Therefore, even importers and marketers of patented new drugs developed and manufactured outside India should now be eligible for price control exemption for a period of five years from the start of its commercial marketing. Conversely, domestic manufacturers who manufactured patented new drugs in India and outside India have also become eligible for price control exemption, which was not the case earlier.

The policy decision to remove the localization requirements as a criterion for price control exemption is expected to make the Indian market attractive to multi-national pharmaceutical companies and to encourage them to introduce new drugs into India. In the past, India’s price control regime had forced exit of innovative products out of India. Additionally, many innovative lifesaving drugs that are available to foreign patients are not available to Indian patients. For instance, from 2010 to 2014, only seven oncology drugs were introduced in India even though 50 breakthrough cancer therapies were rolled out globally in the

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same period. However, there remain some ambiguities on (i) how the five year period for the New Drug Exemption will be calculated, (ii) the nature of benefit that would be available to different Manufacturers of the same drug under the New Drug Exemption and (ii) whether a patented drug will continue to be exempt after it has ceased to be a new drug under the Drugs & Cosmetics Rules 1945.

There is also some ambiguity with respect to the criteria that the Ministry of Health and Family Welfare will employ when determining whether a drug is eligible for the Orphan Drug Exemption due to the absence of disease prevalence data. Clarifications with respect to the ambiguities are likely to be issued by the Government in due course. Nonetheless, the Orphan Drug Exemption is expected to encourage domestic companies to develop drugs for orphan diseases and to foreign pharmaceutical companies to market their drugs in India.

To know more about the Order, read our hotline on the subject [here].

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41. India got only 7 out of 50 global cancer drugs in 5 years available at: https://timesofindia.indiatimes.com/india/india-got-only-7-of-50-global-cancer-drugs-in-5-years/articleshow/58087833.cms (last checked January 31, 2019).

7. Conclusion

The Indian Pharmaceutical Industry has shown great potential and continues to grow consistently. 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 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 Indian pharmaceutical market are certainly those which are able to navigate issues that arise under India’s legal, regulatory and tax framework effectively.
About NDA

At Nishith Desai Associates, we have earned the reputation of being Asia’s most Innovative Law Firm – and the go-to specialists for companies around the world, looking to conduct businesses in India and for Indian companies considering business expansion abroad. In fact, we have conceptualized and created a state-of-the-art Blue Sky Thinking and Research Campus, Imaginarium *Aligunjan*, an international institution dedicated to designing a premeditated future with an embedded strategic foresight capability.

We are a research and strategy driven international firm with offices in Mumbai, Palo Alto (Silicon Valley), Bangalore, Singapore, New Delhi, Munich, and New York. Our team comprises of specialists who provide strategic advice on legal, regulatory, and tax related matters in an integrated manner basis key insights carefully culled from the allied industries.

As an active participant in shaping India’s regulatory environment, we at NDA, have the expertise and more importantly – the VISION – to navigate its complexities. Our ongoing endeavors in conducting and facilitating original research in emerging areas of law has helped us develop unparalleled proficiency to anticipate legal obstacles, mitigate potential risks and identify new opportunities for our clients on a global scale. Simply put, for conglomerates looking to conduct business in the subcontinent, NDA takes the uncertainty out of new frontiers.

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We are a trust based, non-hierarchical, democratic organization that leverages research and knowledge to deliver extraordinary value to our clients. Datum, our unique employer proposition has been developed into a global case study, aptly titled ‘Management by Trust in a Democratic Enterprise,’ published by John Wiley & Sons, USA.

A brief chronicle our firm’s global acclaim for its achievements and prowess through the years –

- **Chambers and Partners Asia Pacific 2019**: Band 1 for Employment, Lifesciences, Tax and TMT
- **IFLR1000 2019**: Tier 1 for Private Equity and Project Development: Telecommunications Networks.
- **AsiaLaw 2019**: Ranked ‘Outstanding’ for Technology, Labour & Employment, Private Equity, Regulatory and Tax
- **Merger Market 2018**: Fastest growing M&A Law Firm
- **IFLR**: Indian Firm of the Year (2010-2013)
- **Asia Mena Counsel’s In-House Community Firms Survey 2018**: Only Indian Firm for Life Science Practice Sector
- **Legal 500 2019**: Tier 1 for Dispute Resolution, TMT (Technology, Media & Entertainment and Telecom,) Tax, Investment Funds, Employment Law and Corporate M&A.

- **IDEX Legal Awards 2015**: Nishith Desai Associates won the “M&A Deal of the year”, “Best Dispute Management lawyer”, "Best Use of Innovation and Technology in a law firm” and “Best Dispute Management Firm”
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Our dedication to research has been instrumental in creating thought leadership in various areas of law and public policy. Through research, we develop intellectual capital and leverage it actively for both our clients and the development of our associates. We use research to discover new thinking, approaches, skills and reflections on jurisprudence, and ultimately deliver superior value to our clients. Over time, we have embedded a culture and built processes of learning through research that give us a robust edge in providing best quality advices and services to our clients, to our fraternity and to the community at large.

Every member of the firm is required to participate in research activities. The seeds of research are typically sown in hour-long continuing education sessions conducted every day as the first thing in the morning. Free interactions in these sessions help associates identify new legal, regulatory, technological and business trends that require intellectual investigation from the legal and tax perspectives. Then, one or few associates take up an emerging trend or issue under the guidance of seniors and put it through our “Anticipate-Prepare-Deliver” research model.

As the first step, they would conduct a capsule research, which involves a quick analysis of readily available secondary data. Often such basic research provides valuable insights and creates broader understanding of the issue for the involved associates, who in turn would disseminate it to other associates through tacit and explicit knowledge exchange processes. For us, knowledge sharing is as important an attribute as knowledge acquisition.

When the issue requires further investigation, we develop an extensive research paper. Often we collect our own primary data when we feel the issue demands going deep to the root or when we find gaps in secondary data. In some cases, we have even taken up multi-year research projects to investigate every aspect of the topic and build unparallel mastery. Our TMT practice, IP practice, Pharma & Healthcare/Med-Tech and Medical Device, practice and energy sector practice have emerged from such projects. Research in essence graduates to Knowledge, and finally to Intellectual Property.

Over the years, we have produced some outstanding research papers, articles, webinars and talks. Almost on daily basis, we analyze and offer our perspective on latest legal developments through our regular “Hotlines”, which go out to our clients and fraternity. These Hotlines provide immediate awareness and quick reference, and have been eagerly received. We also provide expanded commentary on issues through detailed articles for publication in newspapers and periodicals for dissemination to wider audience. Our Lab Reports dissect and analyze a published, distinctive legal transaction using multiple lenses and offer various perspectives, including some even overlooked by the executors of the transaction. We regularly write extensive research articles and disseminate them through our website. Our research has also contributed to public policy discourse, helped state and central governments in drafting statutes, and provided regulators with much needed comparative research for rule making. Our discourses on Taxation of eCommerce, Arbitration, and Direct Tax Code have been widely acknowledged.

Although we invest heavily in terms of time and expenses in our research activities, we are happy to provide unlimited access to our research to our clients and the community for greater good.

As we continue to grow through our research-based approach, we now have established an exclusive four-acre, state-of-the-art research center, just a 45-minute ferry ride from Mumbai but in the middle of verdant hills of reclusive Alibaug-Raigadh district. Imaginarium AliGunjan is a platform for creative thinking: an apolitical ecosystem that connects multi-disciplinary threads of ideas, innovation and imagination. Designed to inspire ‘blue sky’ thinking, research, exploration and synthesis, reflections and communication, it aims to bring in wholeness – that leads to answers to the biggest challenges of our time and beyond. It seeks to be a bridge that connects the futuristic advancements of diverse disciplines. It offers a space, both virtually and literally, for integration and synthesis of knowhow and innovation from various streams and serves as a dais to internationally renowned professionals to share their expertise and experience with our associates and select clients.

We would love to hear your suggestions on our research reports. Please feel free to contact us at research@nishithdesai.com
The Indian Pharmaceutical Industry