

The Indian Pharmaceutical Industry

Business, Legal & Tax
Issues

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Our research oriented approach has also led to the team members being recognized and felicitated for thought leadership. Consecutively for the fifth year in 2010, NDAites have won the global competition for dissertations at the International Bar Association. Nishith Desai, Founder of Nishith Desai Associates, has been voted 'External Counsel of the Year 2009' by Asian Counsel and Pacific Business Press and the 'Most in Demand Practitioners' by Chambers Asia 2009. He has also been ranked No. 28 in a global Top 50 "Gold List" by Tax Business, a UK-based journal for the international tax community. He is listed in the Lex Witness 'Hall of fame: Top 50' individuals who have helped shape the legal landscape of modern India. He is also the recipient of Prof. Yunus 'Social Business Pioneer of India' – 2010 award.

We believe strongly in constant knowledge expansion and have developed dynamic Knowledge Management ('KM') and Continuing Education ('CE') programs, conducted both in-house and for select invitees. KM and

CE programs cover key events, global and national trends as they unfold and examine case studies, debate and analyze emerging legal, regulatory and tax issues, serving as an effective forum for cross pollination of ideas.

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1. Executive Summary

On the morning of April 7, 2014, India woke up to the news of a USD 3.2 Billion domestic acquisition of Ranbaxy Laboratories Ltd. by Sun Pharmaceutical Industries Ltd. resulting in creation of the largest pharmaceutical company in India and fifth-largest specialty generics company in the world. This news followed the news of successful cross-border acquisition of Agila Specialities from Strides Arcolab by Mylan Laboratories for USD 1.75 billion and domestic acquisition of Elder Pharma by Torrent Pharma for around USD 300 Million. The news reinforced belief of many in the potential of the Indian pharmaceutical industry.

The Indian Pharmaceutical industry (domestic, import and export) as per Market Publishers Forecast, is valued at USD 27.4 Billion. It is growing steadily at a CAGR of 10+ %. The industry is typically involved in four types of businesses- production of branded medicines, production of branded generic medicines, product of unbranded generic medicines and production of active pharmaceutical ingredients which are used as ingredients in medicines. India has also become a popular destination for outsourced contract research and manufacturing service. The Contract manufacturing and research industry has grown more than 60 % CAGR between 2007 and 2010, and has a market size of USD 1.5 Billion. The industry is primarily focused on manufacturing of generic medicine and export of bulk drugs. The focus on development of new drugs began with introduction of new Patent regime in 2005 which permitted patenting of pharmaceutical products. However, compulsory licensing remains a concern.

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 change 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 in 2010). However, the clinical trials industry is on decline due to various reasons like regulatory delays, compensation issues etc.

As the pharmaceutical industry operates in the sensitive health sector, there are a plethora of laws which affect it. Right from manufacture of drugs to advertisement and promotion, each step in drug marketing process is regulated. India introduced a patent protection regime in 2005 to protect 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 and also 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, 2011 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 sometime back to check improper promotions of drugs before medical practitioners.

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 18 Billion in 2012.¹ By 2020, India's pharmaceuticals market is expected to reach US\$45 billion and become the sixth largest pharmaceutical market in the world.² The drugs and pharmaceuticals sector has attracted FDI worth USD 11,391 million between April 2000 and September 2013, according to data published by Department of Industrial Policy and Promotion (DIPP).³ The FDI into the Indian pharmaceutical industry has more than doubled during the April-December 2013 as compared to the same period last fiscal.⁴ The Government plans to set up a US\$ 639.56 million venture capital (VC) fund to give a boost to drug discovery and strengthen the pharma infrastructure in the country.⁵ The Indian Government, in efforts to boost R&D in the pharmaceutical sector, has established six National Institutes of Pharmaceutical Education and Research (NIPER) in 2002. The Government of India has declared NIPER as an 'Institute of National Importance'⁶

For a global pharmaceutical company seeking to enter India today, the opportunities are exciting and the potential is tremendous.

Several factors attract global pharmaceutical companies to India:

- India is considered a significant market not only for life saving drugs but also for lifestyle drugs;
- Tremendous potential for conducting research and development activities in India – India has more than 300 medical colleges, over 20,000 hospitals;
- Producer of active pharmaceutical ingredients (APIs) as well as intermediates for the generic market, at lower cost but maintaining quality. India has maximum number of USFDA approved plants outside USA which are over 169⁷ in number.
- India's potential for 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 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. Piramal Life Science Ltd (PLS) and Eli Lilly and Company signed landmark new drug development collaboration in 2007. Also in 2007, Ranbaxy and GSK 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. In March 2009, 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. In April 2009, Johnson & Johnson (J&J) announced its plans to make India a global hub for late-phase development of its new drugs.⁸ 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 to have a presence in India, whether directly or through contractual arrangement, structuring of the investment/

1. <http://www.ibef.org/industry/pharmaceutical-india.aspx> (last visited April 29, 2014)

2. <http://www.ibef.org/industry/pharmaceutical-india.aspx> (last visited April 29, 2014)

3. <http://www.ibef.org/industry/pharmaceutical-india.aspx> (last visited April 29, 2014)

4. www.brandindiapharma.in (last visited April 29, 2014)

5. Website: www.ibef.org. (Last Visited October 4, 2010)

6. <http://www.niper.ac.in/index.htm>

7. <http://www.pharmabiz.com/article/detnews.asp?articleid=55411§ionid=>

8. http://www.indianembassy.org/Economic_News/2009/India%20Economic%20News%20Volume%20V%20Issue%209.pdf

arrangement from a tax and regulatory perspective is very critical. Recently lots of mergers and acquisition activities are seen in pharmaceutical sectors like Abbot-Piramal, Sanofi-Shanta Biotech, Daichi Sankyo-Ranbaxy etc.

On the surface, Indian law appears to be a quagmire 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

International pharma companies or investors seeking to make investments in Indian pharma companies need to appraise and structure their activities on three pillars:

Strategy	Law	Tax
<ul style="list-style-type: none"> Observing the economic and political environment in India from the perspective of the investment Understanding the ability of the investor to carry out operations in India, the location of its customers, the quality and location of its workforce 	<ul style="list-style-type: none"> <i>Exchange Control Laws:</i> Primarily the Foreign Exchange Management Act, 1999 and numerous circulars, notifications and press notes issued under the same <i>Corporate Laws:</i> Primarily the Companies Act, 1956 and the regulations laid down by the Securities and Exchanges Board of India (“SEBI”) <i>Sector Specific Laws:</i> Drugs & Cosmetics Act 1940 and the Drugs & Cosmetics Rules, 1945, The Patents Act, 1970 and other legislations, regulations and guidelines that affect the pharma industry 	<ul style="list-style-type: none"> <i>Domestic Taxation Laws:</i> The Income Tax Act, 1961; indirect tax laws including laws relating to value added tax, service tax, customs, excise <i>International Tax Treaties:</i> Treaties with favorable jurisdictions such as Mauritius, Cyprus, Singapore and the Netherlands

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 has to be obtained from the Foreign Investment Promotion Board (“**FIPB**”) (“**approval route**”).

In the case of pharmaceutical sector, foreign direct investment is permitted to the extent of 100% under the automatic route for green field companies.

However foreign direct investment in brownfield companies requires FIPB approval. A non-compete condition with the existing shareholders is no longer allowed except in special circumstances with the approval of the Foreign Investment Promotion Board.⁹

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

9. Press Note 1 of 2014, DIPP: http://dipp.nic.in/English/acts_rules/Press_Notes/pn1_2014.pdf

of intellectual property rights (IPRs) in India were of concern 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.

3. Legal & Regulatory Perspective

I. 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

Unincorporated entities permit a foreign company to do business in India via 'offices' of certain types. These options are as follows:

i. Liaison Office

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. Setting up a liaison office requires the prior consent of the Reserve Bank of India ("RBI"). The approval for setting up a liaison office is valid for 3 years. It is an option usually preferred by foreign companies that wish to explore business opportunities in India.

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 RBI. 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. The tax on branch offices is 40 per cent 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.

iii. Project Office

A foreign company 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 per cent plus applicable surcharges and the education cess. Project offices are generally preferred by companies engaged in one-time turnkey or installation projects. This option may not prove efficient for a pharma company.

iv. Limited Liability Partnership

A Limited Liability Partnership ("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. The LLP is a body corporate and exists as a legal person separate from its partners. Foreign investment in LLPs is permitted under the government approval route only in LLPs operating in sectors where 100 per cent FDI is allowed through the automatic route and there are no performance linked conditions.

Other entities such as partnership, or trust are not usually recommended structures, 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, 2013. The authority that oversees companies and their compliances is the Registrar of Companies ("RoC"). Companies may either be 'private limited companies' or 'public limited companies':

i. Private Limited Company

A private limited company must have a minimum paid-up share capital of INR 100,000 (approx. USD 1667¹⁰). It carries out business in accordance with its memorandum and articles of association. A private limited company has certain distinguishing characteristics: (i) it must, in its articles of association, restrict the right to transfer shares; (ii) the number of members are limited to 200 members (excluding the present and past employees of the company); its (iii) Articles of Association must

10. As per the exchange rate as on May 6, 2014

prohibit (a) any invitation to the public to subscribe to the securities of the company; (b) the invitation or acceptance of deposits from persons other than members. It takes about 4-6 weeks to incorporate a private limited company. The timeline may vary from State to State.

ii. Public Limited Company

A public limited company must have a minimum paid-up share capital of INR 500,000 (approx. USD 8333¹¹). It 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 company can only commence business after being issued a 'Certificate of Commencement of Business' by the RoC. A public limited company may have more than 200 shareholders and may invite deposits from the public. A public limited company may also list its shares on a recognized stock exchange by way of an initial public offering ("IPO").

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 and acceptance of public deposits
 - 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.¹²

II. Corporate Governance Issues 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.

The scenario is changing, with India completing decades of liberalization entailing the removal of the license *raj*, 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.

Under Prevention of Corruption Act, it is an offence to give bribe to government official. There are no exceptions for "small-time" expenses under Indian law as there are under the Foreign Corrupt Practices Act, 1977 ("FCPA"). A separate police department investigates into bribery allegations and seeks to control the bribery in government offices. The said legislation is applicable only in relation to government servants as defined under the said Act, unlike the UK Bribery Act, 2010 which extends to private persons too.

III. Legal And Regulatory Regime in India

The primary statute that regulates the Indian pharmaceutical industry is the Drugs and Cosmetics Act, 1940 ("Drugs Act") and the rules framed thereunder viz. Drugs and Cosmetics Rules, 1945 ("Drugs Rules").

The Drugs Act and Drugs Rules seek to:

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

11. As per the exchange rate as on May 6, 2014

12. Please refer to our joint venture paper for detailed discussion on the legal, regulatory and tax regime affecting joint ventures and the possible structures.

A. Legal Definition of Drug

A drug is defined comprehensively under the Drugs Act.¹³ 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. The government have through notification have included fourteen specific medical devices as drugs and prescribed guidelines regarding the same.¹⁴ Under a proposed amendment to the Drugs Act, 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 Drugs Act and Drugs Rules 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 Drugs Act. 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 Drugs Act 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.

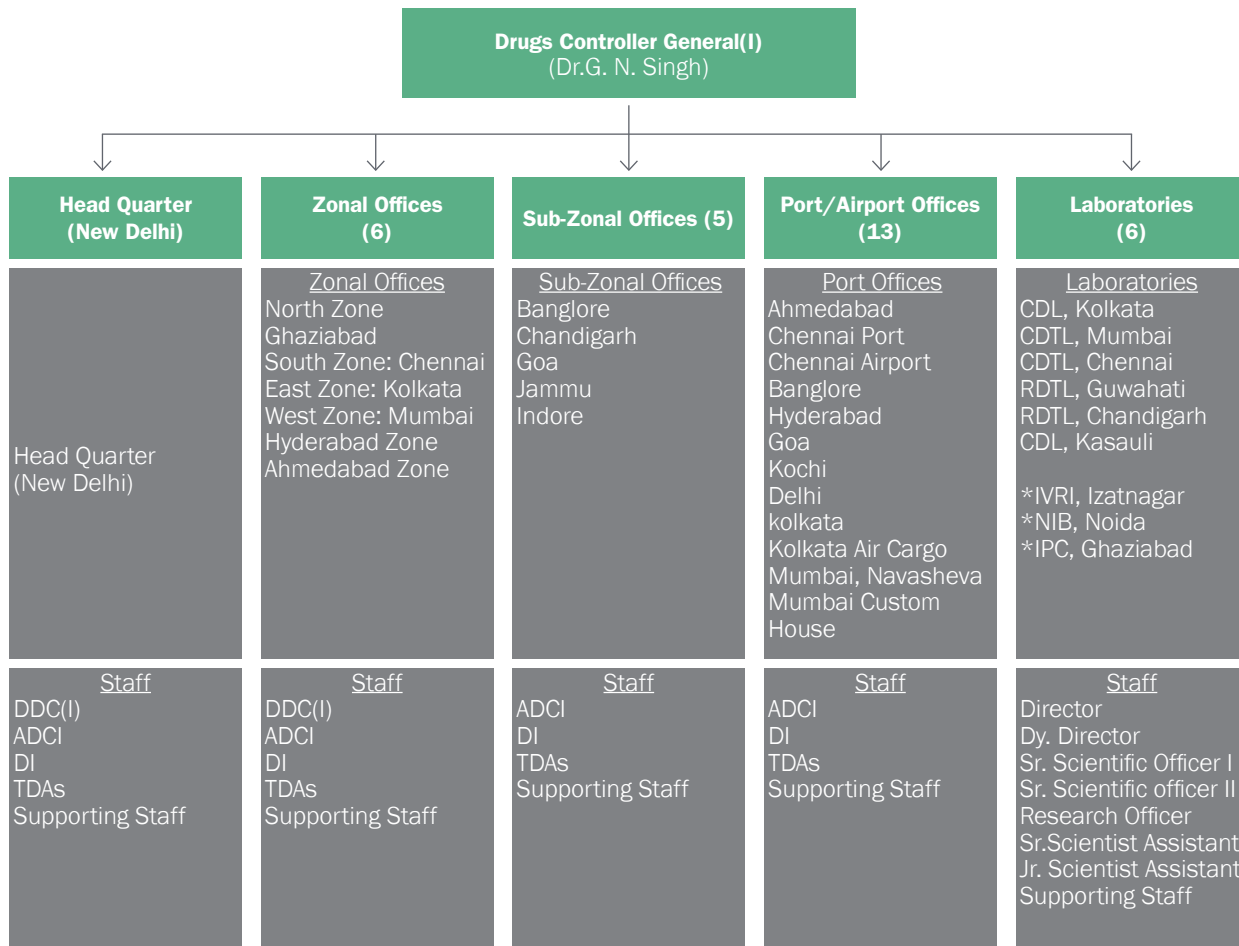
Organizational structure of the Central Drugs Standard Control Organisation (CDSCO)

13. Per Section 3 (b) of the Drugs Act: “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.”

14. <http://www.cdsc0.nic.in/medical%20device%20A42.html>

Organisation Chart Central Drugs Standard Control Organisation



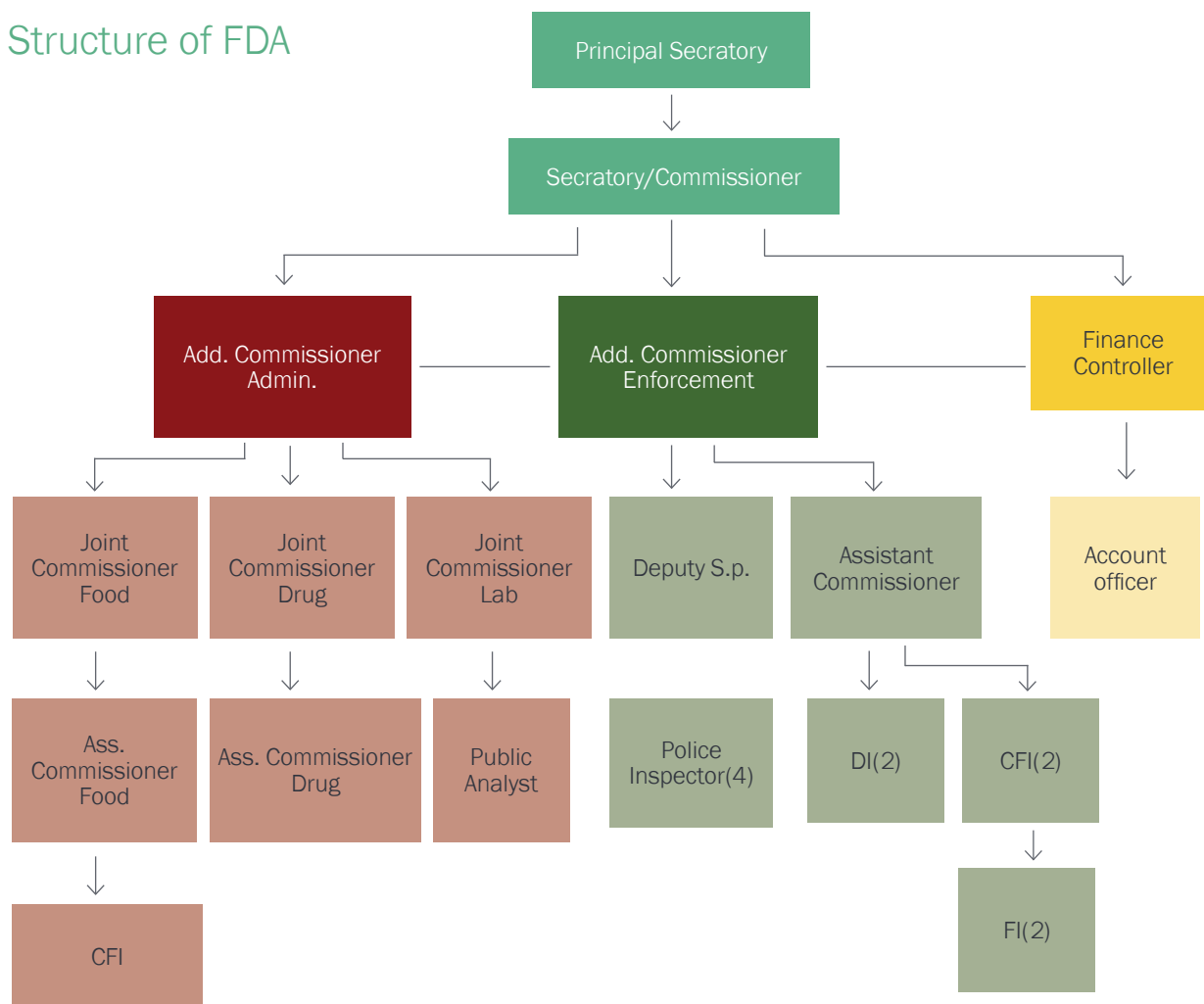
Abbreviations: CDSCO- Central Drugs Standard Control Organisation; CDL- Central Drug Laboratories; CDTIL- Central Drug Testing laboratories; RDTL- Regional Drug Testing laboratories; IVRI- Indian Veterinary Research Institute; NIB- National Institute of Biologicals; IPC- Indian Pharmacopoeia commission;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

*Source: www.cdsc0.nic.in/forms/list.aspx?lid=1368&Id=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.

Organisational Structure of the Indian Food and Drug Administration

Structure of FDA



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

C. Approvals

The Drugs Act and the Drugs Rules provides procedure for obtaining approvals for the following activities:

- Manufacturing of drug at own facility – Separate licenses and respective processes are applicable for drug and new drug.¹⁵

- Loan License - to manufacture drug for manufacturing drug in a factory owned by another party.

D. Licenses Required for Import, Sale, Manufacture and Loan of Drugs Under the Drugs and Cosmetics Rules 1945¹⁶

Sr. No	License Application for	Form required	Application form	Drugs and Cosmetics Rules 1945	Licensing Authority
1.	Import licenses			Part IV	Authority appointed by the central Government under Rule 22

¹⁵. Insert definition of new drug here

¹⁶. <http://cdsco.nic.in/html/importdrugs.htm>

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Provided upon request only

import of drugs excluding those specified in Schedule X	Form 10	Form 8	21	
import of drugs specified in Schedule X	Form 10-A	Form 8-A	21	
Import of drugs for examination, test or analysis	Form 11	Form 12	33	
Import of drugs by a Government Hospital or Autonomous Medical Institution for the treatment of patient	Form 11-A	Form 12-AA	33A	
Application for permission to import new drug for clinical trial or marketing	Form 45 and/ or Form 45-A as the case may be	Form 44	122-A	

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

2.	License to sell, stock, exhibit or offer for sale or distribution of drugs,			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			Part VII	Authority appointed by the central Government
	For license to manufacture drugs other than those specified in Schedules C and C(1)			69	
	(a) in the case of repacking of drugs excluding those specified in Schedule X for sale or distribution	Form 25-B	Form 24-B		
	(b) in the case of manufacture of drugs included in Schedule X and not specified in Schedules C and C(1)	Form 25-F	Form 24-F		
	(c) in any other case	Form 25	Form 24		
	A license to manufacture for sale or for distribution of drugs specified in Schedules C and C(1) other than Large	Form 28	Form 27	76	

	Volume Parenterals, Sera and Vaccines, drugs specified in Part X-B and Schedule X				
	A license to manufacture for sale or for distribution of drugs specified in Schedules C and C(1) and Schedule X other than Large Volume Parenterals, Sera and Vaccines, drugs specified in Part X-B	Form 28-B	Form 27-B	76	
	A license to manufacture for sale or for distribution of Large Volume Parenterals, Sera and Vaccines and recombinant DNA derived drugs	Form 28-D	Form 27-D	76	
	If the person proposing to manufacture a drugs for the purpose of examination, test or analysis does not hold a license in Form 25 or Form 28	Form 29	Form 30	89	
	Application for approval to manufacture new drug other than the drugs classifiable under Schedules C and C(1)	Form 46 and/or Form 46-A	Form 44	122-B	
4.	Loan Licenses			Part VII	
	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			Part V-B	Authority appointed by the central Government
	License to operate a Blood Bank for collection, storage and processing of whole human blood and/or its components for sale and distribution	Form 28-C		122-G	
	License to manufacture and store blood products for sale or distribution	Form 28-E		122-G	
	Certificate of renewal of license to operate a Blood Bank for collection, storage and processing of whole human blood and/or for preparation for sale or distribution of its components	Form 26-G		122-F	
	Certificate of renewal of license to manufacture and store blood products	Form 26-I		122-I	

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 Drugs Act and Drugs Rules. The license also imposes certain conditions, which are required to be complied with, during the subsistence of a license.

E. Suspension / Cancellation of License

The Licensing Authority may, if the conditions for

licensing have not been fulfilled and after giving the licensee an opportunity to show cause why such an order should not be passed by an order in writing stating the reasons therefore, cancel a license issued under this Part or suspend it for such period as he thinks fit, either wholly or in respect of some of the substances to which it relates, if in his opinion, the licensee has failed to comply with any of the conditions of the license or with any provisions of the Act or Rules. Provided that, where such failure or contravention is the consequence of an act or omission on the part of an agent or employee under the following Rules:

Rule	Suspension / Cancellation of license
29	Suspension and cancellation of import license under
29-A	Suspension and cancellation of Registration Certificate under
35	Cancellation of license for examination, test or analysis
66 (1)	Suspension and cancellation of license to sell under
93(1)	Suspension and cancellation of manufacturing license for examination, test or analysis under
122-DB	Suspension or cancellation of Permission/Approval under
122-0	Cancellation and suspension of licenses for operation of Blood Bank under

Section 24 (1) Provides that an application for an import license shall be either by manufacturer himself having a valid wholesale license for sale or distribution of drugs under these rules, or by the manufacturer's agent in India either having a valid license under the rules to the manufacture for sale of a drug or having a valid wholesale license for sale or distribution of drugs under these rules, and shall be accompanied by a license fee of one hundred rupees

for a single drug and an additional fee at the rate of one thousand rupees for each additional drug and by an undertaking in Form 9 duly signed by or on behalf of the manufacturer

Therefore, for a manufacturer to obtain an import license he must first obtain a wholesale license for sale or distribution

F. Stipulated Timelines for Regulatory Approvals by CDSCO

Sr. No	Type of Application	Timeline in days
1.	a. New Drug including Biological, Medical Devices/Clinical Trials/ Global Clinical Trials/ New Claims in consultation with NDAC/MDAC	180
	b. IND Applications in consultation with IND Committee	180
	c. Subsequent New Drugs	120
	d. Clinical Trial Protocol Amendments (if Consultation of NDAC is not required)	60
2.	Fixed Dose Combination in consultation with NDAC	180
3.	Import Registration of Drugs and Medical Devices	270
4.	Endorsement of additional product on registration	120
5.	Rule 37 & Neutral Code	60
6.	NOC for Form 29 (Biological and Medical devices)	60*
7.	CLAA in Form 28128-D/280-E127-C etc	60
8.	Import License in Form 10	45
9.	Test License in Form 11	45
10.	BA/BE NOC	45
11.	Extension of Shelf Life for export	45

12.	Export of Biological samples	45 [#]
13.	Registration of Cosmetics	90
14.	Registration of Ethics Committee	100
15.	Post approval changes (major) subjected to clearance of CDL,NDAC	180
16.	Post approval changes (minor)	90
17.	BA/BE Site approval (after receipt of Joint Inspection report)	60
18.	Issue of Written Confirmation as per EU Directives.	30

* If inspection is not involved for grant of NOC for Form 29

After obtaining BA/BE NOC.

IV. Manufacturing a Drug in India

A separate license for each manufacturing location and each drug at such manufacturing location is required.

Under the Drugs Act, “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.

In a move to curb the spread and sale of counterfeit drugs, the Drugs Control Department of the National Territory of Delhi has made procuring of search reports from the Registrar of Trade Marks mandatory before the approval of any drug-manufacturing license under a particular brand name

The above-mentioned initiative by the Delhi Drugs Authority is in pursuance of the observations in the decisions of the Supreme Court’s decision in Cadila Health Care Ltd. vs. Cadila Pharmaceuticals Ltd. (decided on March 26, 2001).¹⁷ If adopted by the other states of India, this decision will eliminate approval of a deceptively similar and look-alike brand of drugs.

V. Importing a Drug into India

A. EXIM Policy

The import of pharmaceutical products in India is governed under the provisions of the Export and Import Policy (EXIM Policy).¹⁸ We have discussed in detail under Exim Policy later in this paper.

B. Drugs Act

Drugs Act has prescribed norms regarding quality of the drug as well as restrictions regarding prohibition of import of certain drugs.¹⁹ The activity of import of drug into India requires an import license from the office of the Drugs Controller General of India. In order to get an import license, there is a mandatory requirement of registration of the drugs sought to be imported as well as the premise where such drugs will be manufactured with the office of the DCGI.

The registration is certified by grant of a registration certificate. An application for grant of a registration certificate may be made by the manufacturer himself if it has a valid wholesale license for sale or distribution of drugs under the Rules or his authorized agent in India, either having a valid license under the Drug Rules to manufacture for sale of a drug or having a valid wholesale license for sale or distribution of drugs in India. Many

17. In paragraph 41 of the judgment, the Supreme Court observed: “Keeping in view the provisions of Section 17-B of the Drugs and Cosmetics Act, 1940 which, *inter alia*, indicates an imitation or resemblance of another drug in a manner likely to deceive being regarded as a spurious drug it is but proper that before granting permission to manufacture a drug under a brand name the authority under that Act is satisfied that there will be no confusion or deception in the market. The authorities should consider requiring such an applicant to submit an official search report from the Trade Mark office pertaining to the trade mark in question which will enable the drug authority to arrive at a correct conclusion.”

18. *Infra*, Discussions on the EXIM Policy.

19. The Drugs and Cosmetics Act Chapter 3, Section 10

a times, foreign manufacturers do not have an Indian subsidiary which has a wholesale license for sale or distribution of drugs. Hence, the manufacturers choose to appoint a third party as an authorized agent to make the application for grant of registration certificate. The authorization by a manufacturer to his agent in India must be documented by a power of attorney.

VI. Manufacture/Import of New Drugs

The term “New Drug”²⁰ is defined under the Drugs Act and special provisions apply to the manufacture, import and marketing of new drugs into India as well as clinical trials prior to getting manufacturing and marketing approvals.

VII. Clinical Trials

India witnessed significant increase in the conduct of clinical trials due to the advantages India is offering some time ago.²¹ However, the clinical trials are on decline for two years due to regulatory issues. The sector has witnessed intense media scrutiny in recent times owing to allegations made by some non-governmental organizations that the present regulatory framework provides inadequate protection to clinical trial subjects. The Supreme Court of India has issued certain guidelines to increase administrative oversight and to strengthen protection of interests of clinical trial subjects. However, the turn of events has led to over-scrutinization and administrative delays. In January 2013, India formalized compensation rules which obligate the sponsor or sponsors representative in India to pay for clinical trial related injury or death and for medical management of trial subjects. Our research paper on clinical trials has analyzed clinical trial scenario in India in detail.

VIII. Product Standards

No drug can be imported, manufactured, stocked, sold or distributed unless it meets the quality

and other standards defined in the Drugs Act. 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 Drugs Rules. General standards for all patent or proprietary medicines, tablets, capsules, liquid orals, injections and ointments have been defined by the Drugs Act. 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.

IX. OTC and Prescription Drugs

Indian law does not define over-the-counter (‘OTC’) drugs. The Drug Act provides an extensive list of prescription drugs under schedule H. The drugs which are not mentioned in the Schedule can be sold without the prescription by a medical professional. These prescription drugs cannot be advertised in the general media.

X. Labeling

Before a drug is sold or distributed in India, it must be labeled according to specifications outlined in the Drugs Rules. The Drugs Rules 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 Drugs Act are required to indicate the particular drug’s Schedule and must specify the required warnings and additional requirements per the Act.

In respect of non-homeopathic drugs, the Drugs Act prescribes the pack sizes of drugs meant for retail sale, the contents of the label such as name of the

20. *New Drug means and includes: A drug (as defined by the Drugs Act), 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 recognised 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.*

21. Please refer to our clinical trial paper for details discussion on regulatory and legal regime in relation to clinical trials.

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.

The Standards of Weights and Measures Act, 1976 and the Packaged Commodities Rules, 1977 provide additional labeling requirements.

XI. Good Manufacturing Practices (GMP)

Schedule M of the Drugs Rules prescribes GMP guidelines which are compliant with international guidelines of the World Health Organization (WHO). Every pharmaceutical company manufacturing drugs have to 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.

XII. Penalties Under the Drugs Act

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 Drugs Act that specifically relate to the offences of manufacture and trade of adulterated and spurious drugs.

The penalties under the Act were found to be inadequate to act as a deterrent for persons involved in drug offences. The penalties have been significantly enhanced through the amendment

for manufacture, sale, distribution, stocking or exhibiting or offering for sale or distribution of the various classes of substandard drugs viz fine from Rs 100,00 to 100,000 or 3 times the value of the drug confiscated, whichever is higher and imprisonment for 10 years for adulterated or spurious drug leading to death or grievous hurt. The entire amount of fine that is realized from the person convicted for the offence of being dealing with adulterated or spurious drug being payable, now will be 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 now start at the level of the Court of Session. The appeals from the Court of Session lie to the High Court and then to the Supreme Court. This change is expected to accelerate the prosecution of these offences. 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 spurious drugs.

XIII. Exim Policy

Imports and exports are regulated by the Foreign Trade (Development and Regulation) Act, 1992 along with the Customs Act, 1962 and the Export-Import Policy, issued by the Ministry of Commerce and Industry of the Government of India. The current EXIM policy also known as New Foreign Trade Policy covers the period 2009 – 2014. Most pharmaceuticals, provided they are approved by the DCGI and are life-saving, can be imported duty free under the provisions of the Export and Import Policy (EXIM Policy).²² All other pharmaceutical products are subject to import duty. The purpose of the EXIM policy is to develop export potential, improve export performance, encourage foreign trade and create a favorable balance of payments positions. The EXIM policy contains a list of restricted drugs. An import license is valid for a year, up to December 31st of

22. Infra, Discussions on the EXIM Policy.

the year following the year in which the license was granted, and has to renew thereafter.

Indian companies may not be hurt as much as they derive their profits from export market.²⁷

XIV. 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”)²³ in order 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 life saving and prophylactic medicines specified in National List of Essential Medicines, 2011 (“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 annually fixes the maximum retail price of all strengths and dosages of medicines which qualify as essential medicines under National List of Essential Medicine, 2011.²⁴ 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”).

It is likely that the DPCO and consequent price control will have a deep on the impact the industry in the years to come as essential medicines cover about thirty (30) percent of pharmaceutical market²⁵ in India, while on the other hand it will benefit the consumers as the new pricing policy will certainly bring down prices of essential drugs. It has been reported that Indian subsidiaries of multi-national pharma companies will be worst hit as all their profits are derived from sale of medicines in India.²⁶

XV. Advertising 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. There are recent instances where strong actions were taken by the authorities against some companies regarding the same. Apart from the restraint on advertising of prescription drugs, and making claims to provide prevention or cures of certain diseases under the Drugs and Magic Remedies (Objectionable Advertisement) Act, 1954, there are no legal constraints on advertising. The salient features of the Drugs and Magic Remedies (Objectionable Advertisement) Act, 1954 are set forth below:

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

This Act makes advertising of sex tonics and sex stimulants, abortion, contraception, uterine tonics and menstrual disorder regulators cognizable offenses. The Act prohibits advertisements about diagnosis, cure, mitigation or prevention of 54 diseases and listed disorders such as cancer, diabetes, epilepsy, leucoderma, paralysis, sexual impotence etc. The billboards in Delhi, the local train railway compartments in Bombay, advertisement pages of news papers and glossy and not so glossy magazines, and now the electronic media, are, however, in constant breach of the Act.²⁸

The advertising standards are self regulated. The complaints of unjustified claims made in advertisements should be submitted to the Advertising Standards Council of India. The Advertising Standards Council of India is a voluntary association [specify details] formed with the support of all four sectors connected with Advertising,

23. Section 3 of the Essential Commodities Act, 1955.

24. NLEM is available on <http://www.cdsc.nic.in/writereaddata/National%20List%20of%20Essential%20Medicine-%20final%20copy.pdf>

25. Quote by Ranjit Shahani, President, Organisation of Pharmaceutical Producers of India (OPPI) in Times of India, September 27, 2012 available at <http://timesofindia.indiatimes.com/business/india-business/Regulating-drug-prices-Group-of-Ministers-clears-pharma-policy/articleshow/16579986.cms> (last accessed October 9, 2012)

26. ‘What is new drug pricing policy?’, Moneycontrol.com, October 01, 2012 available at www.moneycontrol.com/smentor/mentorade/policy/what-is-new-drug-pricing-policy-763346.html (last accessed October 9, 2012).

27. Id.

28. <http://www.nihfw.org/ndc-nihfw/html/Legislations/TheDrugsAndMagicRemedies.htm> (as visited on May 8, 2009).

viz. Advertisers, Ad Agencies, Media (including Broadcasters and the Press) and others like PR Agencies, Market Research Companies etc. Its main objective is to promote responsible advertising thus enhancing the public's confidence in Advertising. ASCI has published the Code for Self-Regulation in Advertising Pertinent Extracts which is now a part of ad code under Cable TV Act's Rules. Violation of ASCI's Code is now violation of Govt. rules. ASCI's membership of The European Advertising Standards Alliance (EASA) ensures that it gets valuable advice, learning and even influence at the international level²⁹ ("Code"). ASCI The Code applies to all forms of advertising and aims to maintain high standards of advertising. The Code has the objectives of ensuring truthfulness and honesty of representations and claims, safeguarding against misleading advertising, ensuring that advertisements are not offensive to general standards of decency, safeguarding against the indiscriminate use of advertising for products that are regarded as hazardous to society or to individuals to an unacceptable degree, and ensuring that advertisements observe fairness in competition so that the consumer's need to be informed about products in the market are balanced with generally accepted competitive behavior in business. The ASCI has the discretion to require the advertiser to withdraw or modify the advertisement in question if it deems fit. The ASCI, however, does not have effective powers of enforcement. The industry, advertisers, agencies and associations use the mechanism of ASCI, though its orders are not enforceable. If either party is unable to reach a satisfactory settlement using the ASCI, it may have to resort to the Court.

XVI. The Competition Act, 2002

The growth of pharmaceutical industry though protected under several IP laws, raises competition law issues (otherwise called anti-trust issues). The need to provide protection to pharmaceutical companies for their innovation is well recognized under the Competition Act, 2002 ("Act") however the same is restricted by providing specific inclusions under Section 3(5) of the Act. Horizontal agreements in the pharma sector would involve agreements entered at same level between pharmaceutical companies to restrict supply/fix prices similar to situations including "payment of delay" as prevalent in United States whereas vertical agreements are entered between players at different levels in the supply chain being pharmaceutical companies

and pharmacists/hospitals in the form of tie-in arrangements.

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 if unregulated by the Drug Price Control Order ("DPCO") and entry in the absence of generic drug manufacturers, as well as inter-se between pharmaceutical companies 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 Act recognize protection granted under IP 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 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.

On February 19, 2013, the Competition Commission of India ("CCI") passed a significant order, which has the potential of re-defining the way drug manufacturers and importers in India market their products domestically. In the reasoned order, the CCI has held certain practices of All India Organization of Chemists and Druggists ("AIOCD") to be violative of the Competition Act, 2002 ("Competition Act") and inter-alia ordered the organization to cease and desist from engaging in those practices. The AIOCD is a national level association of chemists and druggists, Over the years, AIOCD has functioned as a single-window for distribution-related negotiations between Drug Manufacturers and chemists and druggists throughout India. The alleged practices in question which under the lenses of CCI were:

- i. Before appointment of any clearing & forwarding agent, super-distributor, distributor or stockist

29. <http://www.ascionline.org/index.php/asci-about/61-cat-about-asci-progress/asci-thegenesisofasci/36-asci-thegenesis>

- in a state, the drug manufacturer had to apply to state-level chemists and druggists association' ("SLA") affiliated to AIOCD requesting for a "No Objection Certificate" ("NoC") or "Letter of Consent / Co-operation" ("LoC") from the SLA
- ii. All SLAs publish a Product Information Services ("PIS") bulletin in periodic intervals, which contains description of new medicines to be launched in market. The drug manufacturers are charged a one-time fee for publication of an entry containing description of their medicine in the bulletin. It was an unwritten by-law of the AIOCD that a medicine which is not described in a PIS bulletin published by a SLA will not be sold in the market of the State to which the SLA belongs.
 - iii. There exists a uniform whole sale and retail margin ("**Trade Margin**") for sale of all drugs in India. The Trade Margin for drugs whose prices are controlled by the Central Government through Drug Price Control Order, 1995 ("DPCO") are fixed by law. The Trade Margins of uncontrolled drugs were, however, fixed by AIOCD. It had become industry practice for drug manufacturers to offer 10% margin to wholesalers and 20% margin to retailers for sale of their drugs.
 - iv. In the past, AIOCD and its affiliate associations have boycotted Drug Manufacturers to ensure that the requirements of NoC, publication in PIS bulletin and uniform Trade Margins are adhered to.

The order of CCI described above is bound to have a deep impact on the distribution of medicines in India as well as prices charged to the customers. Effective February 19, 2013, a Drug Manufacturer may appoint any person or agency, and any number of persons and agencies, at any level in its distribution chain as it may deem fit without any fear of repercussions from the traders' body. It may also set up an exclusive distribution channel managed by itself for distribution and sale of its medicines. In cases of appointment for distributor, a Drug Manufacturer now has the option to negotiate the Trade Margin. Further, Drug Manufacturers can launch and distribute their new products without publishing information of their products in PIS bulletins.

The players in the distribution chain such as stockist, distributors and retailers can offer discounts to the consumer without fear of boycott from AIOCD and its affiliates.

In case any Drug Manufacturer or concerned party is victim of any anti-competitive practice described above, it may notify the CCI who will take appropriate action as required, usually amounting to criminal proceedings against the guilty associations and its office-bearers, and imposition of heavy monetary penalty.

XVII. Patent Protection

In India's continued efforts to comply with its commitment under WTO, the Patents Act was amended three times since 1995.³⁰ 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.

The legislation is supported by the Patents Rule, 2003, ("**Rules**").

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 step³¹ and capable of industrial application."³²

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 assignee³³ or legal representatives³⁴ of the inventor.

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

31. Section 2(1) (ja) of the Patents Act: "inventive step means a feature of an invention that involves technical advance as compared to the existing knowledge or having economic significance or both and that makes the invention not obvious to a person skilled in the art."

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

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

34. Section 2(1) (k) of the Patents Act: "Legal representative means a person who in law represents the estate of a deceased person."

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. Under Section 3 (j) Plants and animals in whole or any part thereof (other than micro-organisms) including seeds, varieties and species and essentially biological processes for the production of plants or animals – cannot be patented. This is in line with Article 27.3 of TRIPS. Thus micro-organisms, which satisfy the patentability criteria, may be patented in India.

Section 3(d) 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.

i. 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.

ii. 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.

D. 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.

E. Compulsory License

One of the most controversial amendments has been on compulsory licenses ("CL"). Currently, a CL can be also 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 provision³⁵ 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 Tosylate' (NEXAVAR).³⁶

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.³⁷

F. 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.

G. Secrecy Provisions³⁸

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.

XVIII. 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

35. Section 92A

36. http://www.nishithdesai.com/New_Hotline/IP/IPLab_March2112.htm

37. http://articles.economictimes.indiatimes.com/2013-10-31/news/43561264_1_voluntary-licence-compulsory-licence-dasatinib

38. Sections 35 to 43 of the Patents Act; Can you keep a secret? <eco-times/2005/Can-you-keep-a-secret-Feb-14-2005.htm>, February 13, 2005

discussions with stakeholders.

XIX. 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 Rules under the TM Act, 1999.³⁹ Pharmaceutical products are covered under Class-5, cosmetics under Class-3 and the veterinary preparation under Class-1 and Class-5. [specify about services...]

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.⁴⁰

Class 44: Medical services; veterinary services; hygienic and beauty care for human beings or animals; agriculture, horticulture and forestry services.

Class 42: Scientific and technological services and research and design relating thereto; industrial analysis and research services; design and development of computer hardware and software.

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.

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.

A trademark can be used without registration and can be protected under common law but not under the statutory law. 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.

A. Cadila Health Care Ltd. vs. Cadila Pharmaceuticals Ltd. (decided on March 26, 2001)⁴¹

This case involves two companies which had taken over the Cadila group. Both companies were allowed to use the name. The appellant was selling a tablet named falcigo and the respondent came out with its own tablet called falcitab. Falcigo was manufactured for the treatment of cerebral malaria called falcipharum and the appellant got it registered with the Trade Marks Registry and got permission from the Drugs Controller of India by Oct 1996. The respondent got permission from the Drugs Controller to manufacture a drug containing mefloquine hydrochloride in April 1997. This drug was also used for the treatment of falcipharum. The appellant sought an injunction from the court against the respondent's medicine as it claimed that the same would be passed off as their drug as there was a confusing similarity and the drugs were medicines of last resort. The respondents claimed that the term '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.

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

39. *Classes of Goods and Services: Classes 1 to 34 cover goods while classes 35 to 45 cover services.*

40. http://support.dialog.com/techdocs/international_class_codes_tmarks.pdf

41. <http://www.cci.gov.in/images/media/completed/PharmInd230611.pdf>

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

XX. 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 eco-systems. "Biological resources" means plants, animals and micro-organisms or parts thereof, their genetic material and by-products (excluding value added products) with actual or potential use or value, but does not include human genetic material. Only selective provisions of the Biodiversity Act, 2002 namely, definitions provisions, provisions relating to the constitution of the National Biodiversity Authority ("NBA") and rule-making powers of Government have been brought into force with effect from October 1, 2003. NBA will regulate the commercial/other uses of biodiversity by both Indian and non-Indian entities. Prior to applying for any IPR in respect of biological resources the applicant will be required to obtain approval of NBA.

4. Tax Issues

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 his investments or business through a jurisdiction which has signed an Indian Tax Treaty.

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

Before delving into specific tax issues concerning contract research and manufacturing, set out below is a snap shot of the taxation regime in India. All tax

rates mentioned herein are exclusive of surcharge on tax (for companies with total income exceeding INR 10 million but less than 100 million) which is presently at 5% for domestic companies and 2% for foreign companies and an education cess on tax which is presently at 3%.

i. Taxes Applicable to companies

Under the ITA, the corporate income tax rate is 30% for an Indian company and 40% for a foreign company (where such income is taxable in India). Further, dividend paid by Indian companies is exempt from income tax in the hands of all shareholders, irrespective of their residential status. However, the company distributing the dividends is required to pay a dividend distribution tax of 15%.

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 under the ITA which will be deemed to be 18.5% of such book profits. The carry over and set-off is allowed only up to ten assessment years immediately succeeding the assessment year in which such tax credit becomes allowable and is governed by the following basic principles:

- i. The amount of tax credit that is allowed shall be the difference of the Minimum Alternate Tax paid and the amount of tax payable by the taxpayer on his total income as per the other provisions of the ITA.
- ii. 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 Minimum Alternate Tax provisions.

iii. Interest

Interest received by a non-resident from Indian on foreign currency denominated loans is generally taxable at the rate of 20% as per the provisions of the ITA (though it may be reduced to 10/15% under some of the Indian Tax Treaties) and is required to be withheld at source by the resident payer. 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 a withholding tax at the rate of 25% as per the provisions of the ITA on gross as proposed in budget 2013. Further, where royalties or FTS is paid to a foreign company and is effectively connected to a PE of the foreign company in India, then such payments would be taxed as business profits on “net income” basis.

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. Shares of a company, 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 gains. These gains are taxed as follows:

- Long-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 exempt from tax in India.
- 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.

The exemption on long term capital gains and reduction of rate for short term capital gains on the sale/transfer of the equity shares on a recognised stock exchange in India is only allowed where the applicable Securities Transaction Tax has been paid on the transaction.

B. Incentives Under the ITA

The Government of India has taken various policy initiatives in order to strengthen scientific research and development in the 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 200 percent of such expenditure. 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.

Currently, this deduction is available for expenses incurred prior to March 31, 2017.

ii. Contributions made to other Institutions for Scientific Research

The ITA provides for a deduction of 200 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, “bio-technology” and “research and development of new chemical entities in the pharmaceuticals sector”, is exempt from tax and such income is taxable only in the hands of the investors of the venture capital fund at the time of distribution of the income.

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 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 Permanent Establishment of the foreign enterprise is a significant one given that, if such Permanent Establishment is created, the business income (attributable to the Permanent Establishment) of the foreign enterprise, which may otherwise not be

taxed in India, would be subjected to taxation at the rate of 40%.

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

The term PE has been succinctly defined by the Andhra Pradesh High Court in the case of CIT v. Visakhapatnam Port Trust⁴², 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

42. 1983 144 ITR 146 AP

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 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*⁴³, 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*⁴⁴, 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

43. [1960] 39 ITR 546 (SC)

44. (1977) 106 ITR 111 (AP)

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.

Indian Tax Treaties aim to prevent double taxation of income and capital gains for a person or entity resident in another jurisdiction. For instance, under the India Mauritius DTAA, capital gains earned on sale of Indian securities by a Mauritius company would be taxable only in Mauritius. Further, currently the Mauritius domestic tax laws provide an exemption on most categories of capital gains. By investing through such a jurisdiction, a foreign investor need only pay capital gains tax in its home jurisdiction. Further, in selecting an appropriate Treaty Jurisdiction, it is important for a foreign investor to select a jurisdiction that gives it the specific benefits it requires. For instance, while investing in debt and extracting returns in the form of interest, Cyprus proves to be better placed than Mauritius, even though the latter is widely used by investors making investments into India.

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, 2010 (“**Guidelines**”) provide that the application of the arm’s length principle is generally based on a comparison of all the relevant conditions in a controlled transaction with the conditions in an uncontrolled transaction. Under the Guidelines, comparability is achieved when there are no differences in the conditions that could materially affect the price or when reasonably accurate adjustments can be made to eliminate the effects of any such differences. The analysis of 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 (till date, no other method that may be considered appropriate in determining the arm’s length price has been

prescribed).

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 recently 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:

- The rules will be applicable for 5 years beginning assessment year 2013-14. A taxpayer can opt for the safe harbour regime for a period of his choice but not exceeding 5 assessment years. Once opted for, the mutual agreement procedure would not be available.
- 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.
- 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 - 29% 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 instructions⁴⁵ to the revenue department that the claim of any expense incurred in providing above mentioned or similar freebies in violation of the provisions of Indian Medical Council (Professional Conduct, Etiquette and Ethics) Regulations, 2002 shall be inadmissible as expense because it is an expense prohibited by the law.

II. Indirect Taxes

India has a well-developed tax structure with clearly demarcated authority between Central and State Government and local bodies. The Indian Central Government levies taxes on income (except tax on agriculture income, which the State Government can levy), custom duties, central excise and service tax. On the other hand, Value Added Tax (Sales tax in states where VAT is not yet in force), stamp duty, land revenue and tax on professions are levied by the State Government.

Although the cost of labour and production in India is significantly lower than other countries, the ultimate price of the goods is on the higher side on account of a multi-layer and multi-stage levy of indirect taxes. As a result, traditionally the growth of Indian industry, including the pharmaceutical industry, has been stunted. Further, the greater concern is that the appreciation in the cost of goods, as a result of levy of such taxes, is indirectly passed on to the end customer, namely, the common man, who bears the brunt especially in case of essential products such as pharmaceuticals. The reason for the significant increase in the price of goods post taxation is more on account of the multi-layer and multi-stage indirect taxation framework. It is for this reason that efforts are being made to replace the existing indirect tax system (which provides for a multi-layer and multi-stage levy for goods and services) with a unified Goods and Services Tax (“GST”) system.

A. Service Tax

Service tax was introduced vide Chapter V to the Finance Act, 1994 and further widened in scope by the subsequent Finance Acts. The Finance Act 2012 has brought about substantial changes in the provisions of Finance Act 1994 dealing with levy and collection of service tax. Section 66B of the Finance Act 1994 specifies the charge of service tax which is essentially that the service tax shall be levied on all services provided or agreed to be provided in a taxable territory, other than services specified in the negative list or otherwise exempt under notification. Currently, service tax is levied at the rate of 12.36% on gross basis on the specified taxable services. Service tax from April 1, 2011 is payable on accrual basis instead of realization of value of taxable service. Some of the taxable services are management consulting services, consultancy or technical services by a consulting engineer, business auxiliary services, intellectual property services, etc.

Until July 10, 2014, services provided by way of technical testing or analysis of newly developed drugs, including vaccines and herbal remedies, on human participants by a clinical research organization approved to conduct clinical trials by the Drug Controller General of India, were exempt from service tax. However, this exemption is no longer available. Export of services is not subject to service tax in India while in case of import of service, the recipient is liable to pay service tax. In order to qualify as an export under the Export of Service Rules 2005, inter alia the service must be

45. Circular No. 5/2012 [F. No. 225/142/2012-ITA.II], dated 1-8-2012.

rendered from India but consumed outside India and the consideration must be paid in convertible foreign exchange. Additional conditions are imposed depending upon the type of service provided.

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' 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. A further duty, known as Additional Customs Duty or the Countervailing Duty ("**CVD**") is imposed to countervail the appreciation of end price due to the excise duty imposed on similar goods produced indigenously. To bring the price of the imported goods to the level of locally produced goods which have already suffered a duty for manufacture in India (excise duty), the CVD is imposed at the same rate as excise duty on indigenous goods. In addition to the above, there are also Additional Duties in lieu of State and local taxes ("**ACD**") which are also imposed as a countervailing duty against sales tax and value added tax imposed by States. The ACD is currently levied at the rate of 4 per cent.

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. In the Indian pharmaceutical Industry, given that a large number of companies are involved in the import and subsequent resale of unpackaged pharmaceutical products, such import is subject to a levy of a special duty termed as Special Additional Duty (SAD). An exemption has been provided to pre-packaged goods where the sale price has been declared on

the package. The SAD paid is only available as a refund if it is proved that state level VAT is paid on the subsequent sales of the imported products. The issue often faced by companies is that the process of obtaining refunds of SAD is tedious and time consuming and the time limit for filing the refund is stipulated as one year, which often leads to a failure in obtaining rightful refunds.

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.

C. Sales Tax and Value Added Tax

Central Sales Tax ("**CST**") is imposed on the sale of goods in the course of inter-state trade or commerce. Sales of goods are deemed to take place in the course of inter-state trade if they result in the movement of goods from one state to another, or if such sales are effected by the transfer of documents of title to the goods during their movement from one state to another. No CST is levied on direct imports or exports or the purchase or sale effected in the course of imports or exports. The process of phasing out CST commenced with a reduction in the CST rate from 4 per cent earlier to 2 percent on April 1, 2008.

Value Added Tax ("**VAT**") is levied on the sale of goods within a particular state at the two main VAT rates of 4 per cent and 12.5 per cent. VAT is a state specific levy and most states in India have introduced specific legislations for VAT based on the Model VAT legislation circulated by the Empowered Committee of State Finance Ministers. Further, under the VAT regime, a system of tax credits on input goods procured by the dealer is also available, to avoid the cascading effect of taxes that was prevalent under the erstwhile sales tax regime.

D. Cen Vat

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 10.3 %, the generic excise duty rate on finished formulations is 4.12 %. 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.

E. Research and Development Cess

All payments made towards the import of technology are subject to a cess of 5% under the Research and Development Cess Act, 1986. Technology includes any special or technical

knowledge or any special service required for any purpose whatsoever by an industrial concern under any foreign collaboration, and includes designs, drawings, publications and technical personnel.

F. Synopsis of Benefits available to units setup in Special Economic Zones

The following benefits are available to units located 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.
- 100 per cent service tax exemption.
- 100 per cent exemption from securities transaction tax.
- Exemption from the levy of taxes on the sale or purchase of goods other than newspapers under the Central Sales Tax Act, 1956 if such goods are meant to carry on the authorized operations by the Developer or entrepreneur

5. Recent Developments

I. Bar Coding Requirement for Secondary Level Packaging of Exported Medicines Enforced

The bar-coding requirements for secondary level packaging of pharmaceuticals exported out of India, as mandated under Director General of Foreign Trade's (DGFT) notification dated January 10, 2011⁴⁶ (the 'Notification'), have been enforced from January 1, 2013. Readers may recall that the Notification required all manufacturer and exporters, who are engaged in export of pharmaceutical products, to develop track and trace capability for their exports.

The impact of the Notification has been discussed at length in the public domain by pharmaceutical associations and industry players. The requirements imposed by the Notification have led to increase in packaging cost. It may also lead to additional process burden, since the existing label approved from the country of import will have to be modified (that is, to add extra text / bar code).

However it is undeniable that the bar code system will reduce number of spurious drug which are exported out of India and assist in curbing the menace of spurious drugs.

II. Launching of New Drug in 6 Months Made Mandatory

As per a recent circular⁴⁷ issued by Drugs Controller General of India ("DCGI") on January 10, 2013 ("Circular Date"), all manufacturers of 'new drug' (explained later) are required to launch the new drug within six months from the date of the grant of the permission by the DCGI, failing which the permission received from the DCGI will be cancelled. Manufacturing of new drug after cancellation of permission would constitute violation of the Drugs and Cosmetics Act, 1940⁴⁸ ("The Act"), and those who deal with new drug produced after cancellation of such permission would be liable to be punished

under the Act⁴⁹.

It will be beneficial for the industry as well as the Regulator if a more balanced approach in dealing with newer issues is adopted. Instead of by-passing the due process by issuing circulars and notifications to add a provision of law, the existing rules may be examined thoroughly and implemented with vigor to ensure meeting of larger public interest.

III. Product Promotions - Pharma Companies Under Restrictions

In view of the recent uproar regarding incentives being given to the doctors by various pharmaceutical companies to make sure they prescribe their medicines, the Department of Pharmaceuticals in India ("DOP") released a Code of Marketing Practice for the Indian Pharmaceutical Industry ("DOP Code") in June, 2011. The DOP Code 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 DOP Code is voluntary. However, the Government will review the implementation by companies after a period of six months and then the Government may consider making it a statutory code if not implemented effectively.

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.

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

46. DGFT Public Notice No.21 (RE-2011)/2009-2014, available at <http://dgft.gov.in/exim/2000/pn/pn10/pn2110.htm> (last checked 09.01.13).

47. DCGI Circular F.No. 12-01/12-DC Pt-127 dated January 10, 2013, available at http://cdso.nic.in/cancellation_of_permission.pdf (last viewed on 17.01.13).

48. S. 18 of the Act.

49. S. 27 (d) r/w S. 18 of the Act.

“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.

In this update, we have examined the combined effect of the DOP Code and the amendments to the MCI Code.

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.

Important features of the DOP Code:

A. 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.

B. 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.

C. Claims

The DOP has expressed concern over the use of the words “safe” and “new” by the companies or their MRs. The DOP Code 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.

D. Product Comparisons

- As far as product comparisons are concerned, the DOP Code 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.

E. Product Promotional Material

The DOP Code prescribes certain do’s and don’ts in relation to promotional material (“PM”) and also prescribes the contents to be incorporated in such material. An illustrative list of the do’s and don’ts is provided below:

Do’s

- PM to be consistent with the DOP Code
- Date of printing or of the last review of PM to be mentioned
- Audio-visual material to be accompanied by printed material in compliance with the DOP Code

Dont’s

- The paid or secured PM in journals not to resemble the editorial matter
- Photographs or names of healthcare professionals should not be used

F. Gifts

Companies should not give any kind of gifts or 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.

G. 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 DOP Code prohibits supply of samples of an antidepressant, hypnotic, sedative or tranquillizer.

H. Hospitality, Sponsorships and Meetings

As per the DOP Code, the companies are permitted to provide assistance to doctors for continuing education facilitating doctors' genuine attendance in such events. This assistance could cover actual travel expenses, meals, refreshments, accommodation and registration fees to attend such an event. The DOP Code has, however, laid down certain conditions: (i) events for which assistance will be provided must be held in India at an appropriate venue that is conducive to the main purpose of the event; and (ii) such events should not coincide with sporting, entertainment or other leisure events or activities or organized at venues that are renowned for their entertainment or leisure facilities or are extravagant. This assistance cannot be provided to a doctor's spouse unless the spouse is a doctor too and qualifies to attend such an event. The hospitality offered should be reasonable and strictly limited to the main purpose of the event. The funding provided should not be for the time spent in attending the event.

I. 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 DOP Code. 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 DOP Code has been complied with.

J. Complaint Handling

The DOP Code 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 DOP Code 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.

IV. MCI Code

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:

- i. A medical practitioner shall not receive any gift from any pharmaceutical or allied health care industry and their sales people or representatives;
- ii. 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;
- iii. A medical practitioner shall not accept individually any hospitality like hotel accommodation for self and family members under any pretext;
- iv. 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;

- v. 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;
- vi. 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, the DOP Code is voluntary, but the MCI Code is mandatory. After six months, if the DOP Code is incorporated as a statutory code, then pharma companies are likely to face prosecution or penalties in case of violation.

A review of the global practices seems to indicate that in some respects, the DOP Code 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 DOP Code. E.g., while the DOP Code permits companies to provide assistance for travel and events within India, the MCI Code prohibits doctors from accepting the same. Hence, the government should, once again, take a look at both the codes, and re-align the same for more cohesive implementation.

6. 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 too. 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 Industry will have to realign itself with these legal changes in order to ensure continuance of its success story.

7. The Pharma Team @ NDA

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NDA Insights

TITLE	TYPE	DATE
Jet Etihad Jet Gets a Co-Pilot	M&A Lab	January 2014
Apollo's Bumpy Ride in Pursuit of Cooper	M&A Lab	January 2014
Diageo-USL- 'King of Good Times; Hands over Crown Jewel' to Diageo	M&A Lab	January 2014
File Foreign Application Prosecution History With Indian Patent Office	IP Lab	02 April 2013
Warburg - Future Capital - Deal Dissected	M&A Lab	01 January 2013
Public M&A's in India: Takeover Code Dissected	M&A Lab	» August 2013
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Research has offered us the way to create thought leadership in various areas of law and public policy. Through research, we discover new thinking, approaches, skills, reflections on jurisprudence, and ultimately deliver superior value to our clients.

Over the years, we have produced some outstanding research papers, reports and articles. Almost on a daily basis, we analyze and offer our perspective on latest legal developments through our *"Hotlines"*. 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 *NDA Insights* 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 papers and disseminate them through our website. Although we invest heavily in terms of associates' 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.

Our research has also contributed to public policy discourse, helped state and central governments in drafting statutes, and provided regulators with a much needed comparative base for rule making. Our *ThinkTank* discourses on Taxation of eCommerce, Arbitration, and Direct Tax Code have been widely acknowledged.

As we continue to grow through our research-based approach, we are now in the second phase of establishing a 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. The center will become the hub for research activities involving our own associates as well as legal and tax researchers from world over. It will also provide the platform to internationally renowned professionals to share their expertise and experience with our associates and select clients.

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