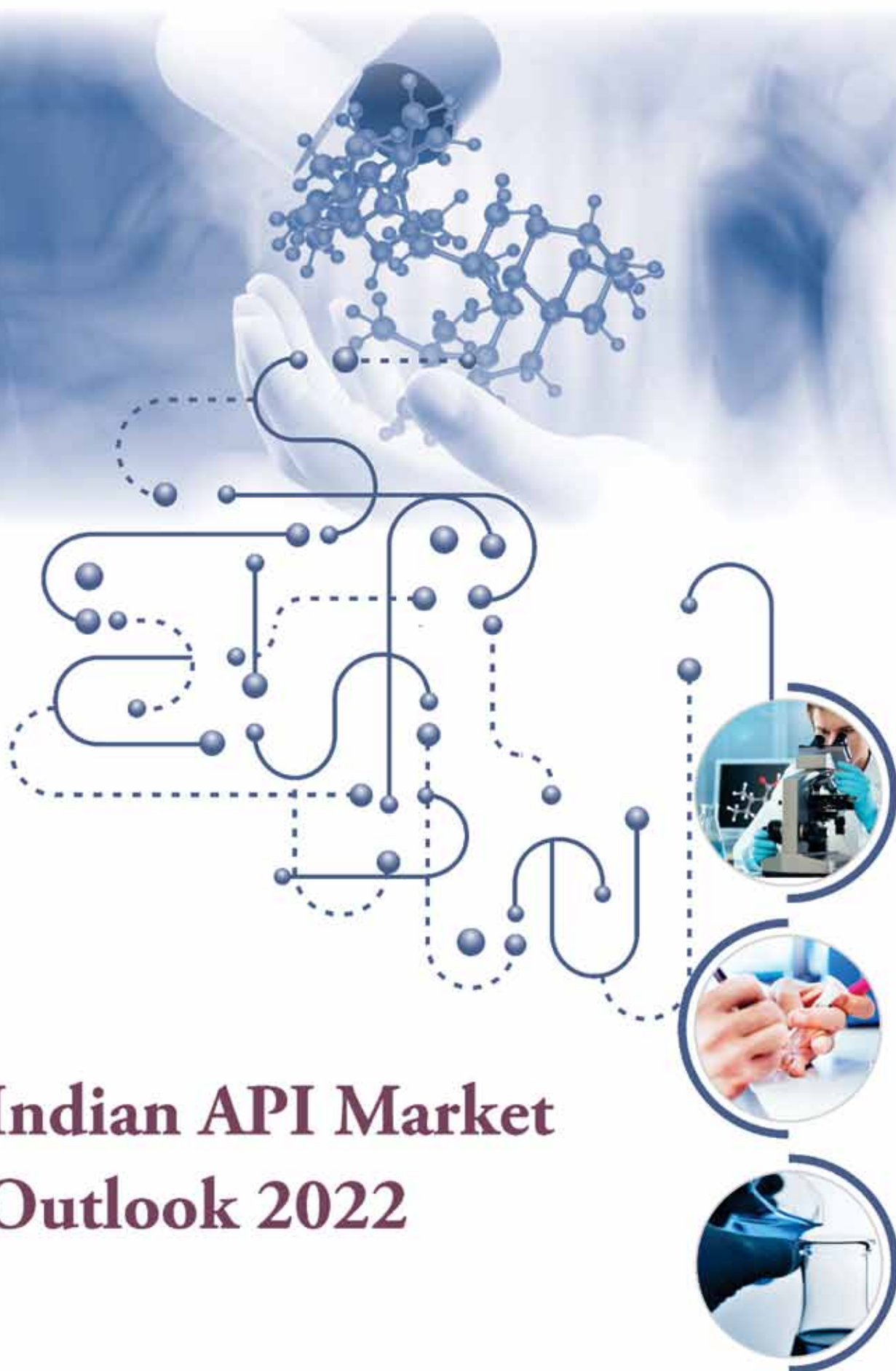


Knowledge Partner



# Indian API Market Outlook 2022





# Message



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# India API Industry Outlook

API manufacturers in India are making efforts to strengthen their marketing capacity in the regulated markets by improving production yields, modifying production processes, and increasing sales in the international markets. More than 30% of the APIs manufactured in India are exported to countries such as US, UK, Japan, etc. The total production market of API in India was valued at approximately US\$ 11 Billion in FY 2016. This market is forecasted to grow at a CAGR of around 9% during the period of FY 2016–FY 2022.

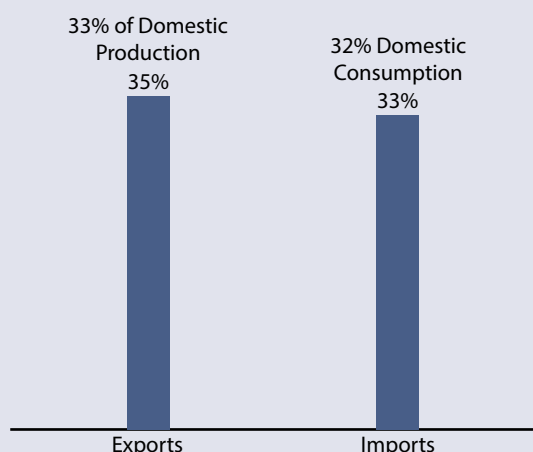
Of the total domestic consumption, approximately 32% was imported. Of the total imports, China alone accounts for 57-60% of the APIs imported by India<sup>1</sup>. The remaining imports are from countries such as Italy, Germany, Malaysia, and others. These facts indicate that there is plentiful scope for the domestic

API market to grow, if the manufacturers are able to produce the required amount of APIs on their own, rather than importing it from other countries.

## 1.1 Share of India in Global API Market

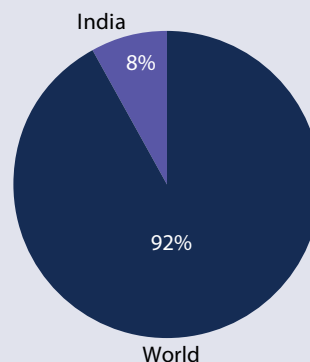
The Indian API industry has been supplying good quality API to top pharmaceutical companies, both domestically and globally. In FY 2016, the API market of India held a share of around 8% in the global API market. The ongoing global drug patent cliff is slated to further boost the revenues of API market in India. Moreover, the Indian API industry has gained recognition worldwide due to its high quality of APIs. The talent pool in India is also huge, who if given proper training, can help in the invention of novel API molecules. The increased initiatives by the government are driving small and medium-sized companies to enter the Indian API market, and capture the small and

**Figure 1-1** India API Market Trade (%), FY 2016



Source: RNCOS Estimation

**Figure 1-2** Share of India in Global API Market (%), FY 2016



Source: RNCOS

1. Ministry of Commerce Annual Report (FY 2015 – FY 2016)

niche segments. All these factors are bound to propel growth of the Indian API market, and increase its share in the global platform in the coming years.

## 1.2 Indian API Domestic Consumption Market Future Outlook

According to RNCOS' analysis, the Indian API domestic consumption market will grow at a CAGR of around 10% from FY 2016 to FY 2022. The Indian Government made the announcement of 2015 being the 'Year of APIs.' This has helped to increase awareness among people about APIs. Furthermore, the government is also taking various initiatives, such as allocating lands in various states for the development of API Mega Parks, increased investment in R&D, etc. to boost the industry. These initiatives will further propel the growth of the Indian API industry, as well as the domestic market for the APIs.

Key players, such as Sun Pharma, Dr. Reddy's, Cipla, Lupin, etc., are being lured to increase their investment in the Indian API industry by providing them various lucrative offers. Other factors such as patent expiry of blockbuster drugs and ever growing demand for drugs in India will help API manufacturers to capitalize on the domestic API demand. Apart from this, players are manufacturing complex APIs by using latest technologies. This serves as a key differentiating

factor of research of each company. Players are also expanding their global footprint, announcing new distribution channels and opening new manufacturing facilities.

## 1.3 Major APIs in the Indian API Market

There are many APIs currently available in the Indian API market. These APIs are manufactured by key players, such as Sun Pharma, Cipla, Dr Reddy's, Aurobindo Pharma, Lupin, etc. The companies manufacture APIs either in-house, or give contract to other companies. Currently, the APIs in the Indian market are mainly used for the development of generic drugs. Some of the common APIs in the Indian API market are Clopidogrel Bisulfate, Atorvastatin, Amoxycillin, Albendazole, Linagliptin, etc. The Clopidogrel Bisulfate API is marketed by Bristol-Myers Squibb and Sanofi under the brand name Plavix. It is used for the preparation of drugs for the treatment of blood clots, when heart attacks or blood strokes occur. Atorvastatin, another API, is used in the preparation of Lipitor drug used for the treatment of high cholesterol, and to prevent heart attack. There are many other APIs which are quite popular in the Indian API market. Some of them are listed in Table 3-1 below.

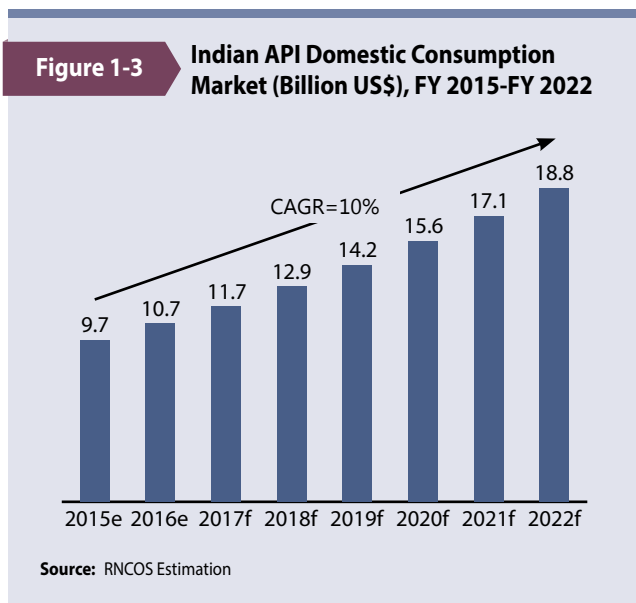


Table 1-1: Major APIs in the Indian API Market		
S.No.	APIs	Therapeutic Areas
1.	Clopidogrel Bisulfate	Cardiovascular and Hematopoietic System
2.	Acitretin	Dermatology
3.	Atorvastatin	Cardiovascular and Hematopoietic System
4.	Amisulpride	Anti-Psychotic
5.	Amoxycillin	Anti-infective System
6.	Abiraterone Acetate	Oncology
7.	Albendazole	Anti-infective System
8.	Mebendazole	Anti-infective System
9.	Alosetron Hydrochloride	Gastrointestinal
10.	Montelukast	Anti-Asthmatic
11.	Linagliptin	Anti-Diabetic
12.	Nateglinide	Anti-Diabetic

Source: Various Industry Sources





## Drivers & Challenges

### 2.1 Drivers

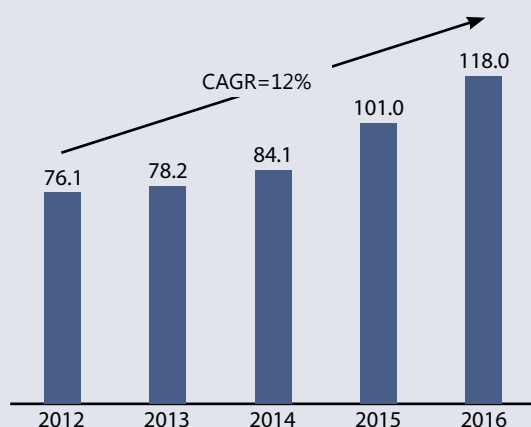
#### 2.1.1 Rising Healthcare Expenditure

India is witnessing a steady rise in healthcare expenditure from US\$ 76.1 per head in 2012 to US\$ 118 per head in 2016. Still, India remains among the bottom five countries with the lowest public health expenditure globally. A major chunk of the population (nearly 40% of Indians) lives on less than US\$ 1 per day, and most of them have to pay out of their own pockets for medical services<sup>2</sup>. Out-of-pocket spending in India is over four times higher than public spending on healthcare. Therefore, there is a rising need for advanced drugs that will help people to recover quickly at lower cost.

#### 2.1.2 Increasing Disposable Incomes

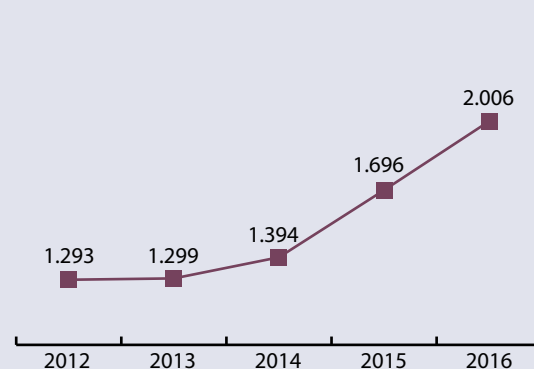
Personal disposable income in India has grown at a CAGR of approximately 12% during 2012-2016. With rise in income, consumption patterns have changed and a new middle class has emerged, which is growing at a fast pace. The rising middle class population will be a predominant factor for more value based healthcare facilities. Meanwhile, India has limited healthcare insurance coverage (both private and government) compared to other countries, which results in nearly 80% of the total out-of-the-pocket expenditure on medical facilities<sup>3</sup>. Consequently, there are significant opportunities for businesses to flourish in primary healthcare as well as wellness and disease management.

**Figure 2-1** Healthcare Expenditure (US\$ per head), 2012-2016



Source: Espicom

**Figure 2-2** Personal Disposable Income (Trillion US\$), 2012-2016



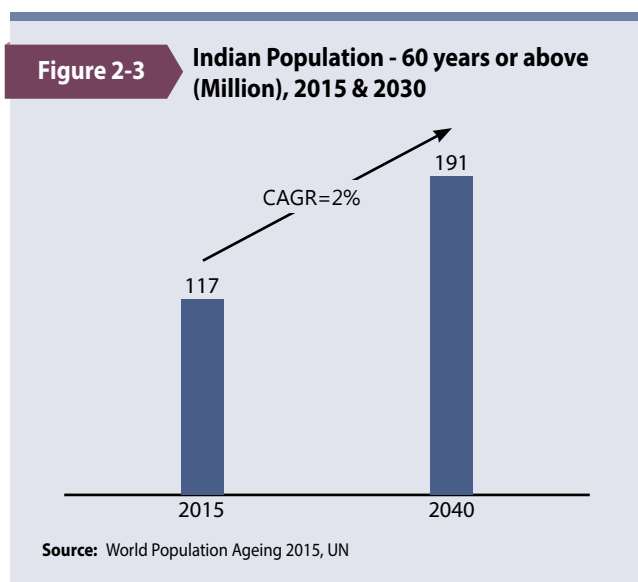
Source: EIU

2. Indian Journal of Medical Ethics Vol X

3. "Out of pocket expenditure among the households of a rural area in Puducherry, South India" Published by NCBI in 2014

### 2.1.3 Growing Geriatric Population

India is witnessing a rise in ageing population. According to UN estimates, the percentage of old people (60 years or above) in India will rise from 8.9% in 2015 to 12.5% in 2030. Furthermore, by 2050, 19.4% of the total India's population will age above 60 years<sup>4</sup>. The country will also witness rise in the old age dependency ratio from 13% in 2000 to 32.8% in 2050. Precisely, three Indians in the working age population will have to take care of one elderly by 2050<sup>5</sup>. The growing burden of an ageing population will increase the consumption of pharmaceutical products, which in turn will generate a greater demand for APIs.



### 2.1.4 Increasing Incidences of Chronic Diseases

The common chronic diseases affecting India are heart diseases, stroke, cancers, diabetes, obesity, HIV/AIDS, and arthritis. The course of these diseases once inflicted lasts for more than three months. As conditions of these diseases are long lasting, their treatment also takes a long time to get completed. So patients suffering from chronic diseases require medications for longer time.

According to WHO, NCDs are estimated to account for 60% of all deaths in India. This death toll is expected to increase from 38 Million in 2012 to 52 Million in 2030<sup>6</sup>. Therefore, the rising cases of chronic diseases will increase the demand for drugs, which in turn will increase the demand for APIs in India.

#### 2.1.4.1 Cardiovascular Diseases

Cardiovascular diseases are amongst the deadliest diseases in the world, with India also a victim of the same. These diseases account for 26% (2.5 Million) of the total deaths in India<sup>7</sup>. Furthermore, the total economic burden of non-communicable diseases (including mental health conditions) in India between 2012 and 2030 is estimated to reach US\$ 4.58 Trillion<sup>8</sup>. Cardiovascular diseases are expected to be responsible for almost half of the aforementioned loss. These deadly diseases lead to decline in the productivity level of the working population, ultimately hurting the profitability of businesses. Moreover, higher occurrence of cardiovascular diseases significantly reduces purchasing power of the population, who would have to spend much of their savings on their treatment.

#### 2.1.4.2 Diabetes

India is one of the fastest growing diabetes markets in the world. With India emerging as the nation with the largest population of diabetics, it is important that an involved company in the country takes on the disease with cost-effective and easily accessible treatment options. In 2015, there were 69.18 Million people with diabetes in India. By 2040, this number is estimated to increase to 123.5 Million<sup>9</sup>. Moreover, it is observed that the prevalence of diabetes in rural population is one-quarter that of the urban population for India and other Indian sub-continent countries, such as Bangladesh, Nepal, Bhutan, and Sri Lanka. A smaller proportion of the population is affected in states of

4. United Nations

5. FDDI

6. WHO

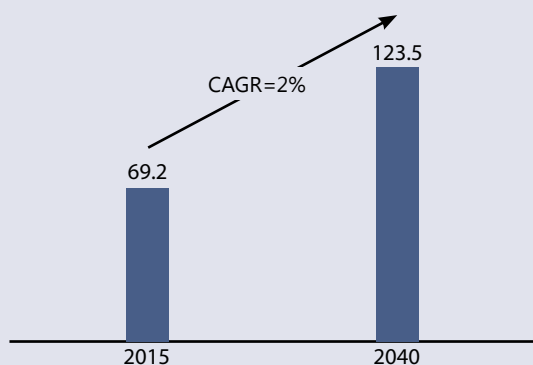
7. WHO NCD Country Profile 2014

8. World Economic Forum and the Harvard School of Public Health

9. IDF Diabetes Atlas, Seventh Edition

Northern India, such as Chandigarh (0.12 Million), Jharkhand (0.96 Million) compared to Maharashtra (9.2 Million) and Tamil Nadu (4.8 Million) in Southern India. The aetiology of diabetes in India is multi-factorial and includes genetic factors, coupled with environmental influences such as obesity associated with rising living standards, steady urban migration, and lifestyle changes. The economic burden imposed by diabetes gets magnified because it leads to related complications, such as of the heart, kidney, eye and foot.

**Figure 2-4** India - Number of People with Diabetes (Million), 2015 & 2040



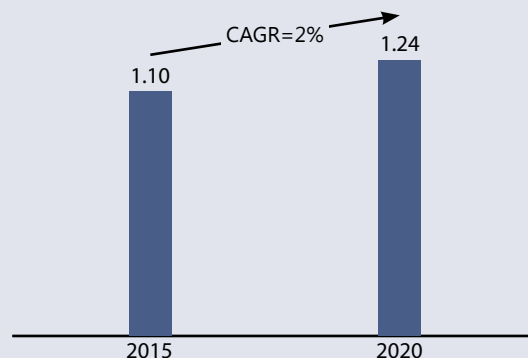
Source: IDF

#### 2.1.4.3 Cancer

India is progressively witnessing a considerable rise in cancer cases. Some of the major factors associated with the disease are changing lifestyles, unhealthy diet patterns, and use of tobacco and alcohol. Also, skewed doctor to patient ratio, expensive medication, and ignorance among the people contribute to high mortality from cancer. There is a requirement of 1 cancer care unit per 100,000 persons, a far cry from the current scenario.

According to GLOBOCAN, there were 1.10 Million new cases of cancer in 2015. This number is expected to grow by an approximate CAGR of 3% to reach a value of 1.24 Million by 2020. The maximum number of cases

**Figure 2-5** India - Number of New Cancer Cases (Million), 2015 & 2020



Source: GLOBOCAN

registered till date is that of lung and oral cancers among men, and cervix and breast cancers among women. Elderly men are more prone to prostate cancer; besides kidney, penis and intestine cancers.

#### 2.1.5 Patent Expiry of Blockbuster Drugs

A rise in geriatric population across the globe is making the countries move to cheaper APIs and formulations, which are India's strengths. It is estimated that around US\$ 40 Billion worth of drugs in the US and US\$ 25 Billion worth of drugs in Europe will be going off patent (series of patent expirations of important prescription drugs) in the coming years<sup>10</sup>. Patent expiry of Lipitor by Pfizer, Diovan by Novartis, Plavix by Bristol-Myers Squibb, etc. have already pushed Indian generic players to expand in international markets.

Subsequently, some of the other global pharma majors, such as Teva, GlaxoSmithKline, and Allergen, are likely to lose patent exclusivity of several drugs. This patent cliff will thus provide significant opportunity to Indian manufacturers to develop generic versions of respective patented drugs, for which they will be making use of generic APIs. The patent expiry of drugs will give impetus to the development of the API industry in India.

10. Pharmexcil

**Table 2-1: List of Blockbuster Drugs Losing Patent (2016-2022)**

Drugs	Year	Parent Company
Cretor	2016	AstraZeneca
Benicar	2016	Daiichi Sankyo
Benicar HCT	2016	Daiichi Sankyo
Cubicin	2016	Cubist Pharmaceuticals
Biotax	2016	Hospira
Zegerid	2016	Santarus
Tudorza Pressair	2016	Actavis
Alimta	2017	Eli Lilly
Velcade	2017	Otsuka
Seroquel IR	2017	AstraZeneca
Prozac Weekly	2017	Eli Lilly
Novolog	2017	Novo Nordisk A/S
Niaspan	2017	Abbott
Tricor	2018	Abbott
Zemiplar	2018	Abbvie
Prilosec	2019	AstraZeneca
Dexilant	2020	Takeda Pharma
Prolia/XGEVA	2021	Amgen
Nplate	2022	Amgen

**Source:** Various Industry Sources



## 2.1.6 Increased Consumption of Generic Drugs

India is a developing nation where a major portion of the population lives below the poverty line. According to World Bank, the poverty rate in India is 12.4%. These people and many others require medication which is economical. Consequently, there has been a rise in the demand for generic medicines, which are made with the help of APIs. A further increase in demand for generic medicines will propel growth of the Indian API market.

## 2.1.7 Invention of New Generation of APIs

The pharmaceutical industry in India is in an urgent need for new scientific advances that would yield innovative and effective drugs and therapies. This need is an important factor driving the growth of the API industry in the country, which has led to the invention of a new generation of APIs. One example of the new generation of APIs is ionic liquids. Ionic liquids with biological activity are used as APIs. There is a particular focus on efforts to overcome current hurdles encountered by APIs. Ionic liquids are organic salts with melting points below 100°C, and composed entirely of ions. These are known as 'designer solvents' because of their use as solvents at room temperature, a property that has enabled the use of ionic liquids as a reaction media to produce or improve the preparation of various pharmaceuticals. Apart from this, ionic liquids can also be used as pharmaceutical solvents or co-solvents for the delivery of drugs with poor water solubility. They are also applied in micro-emulsion systems, which can facilitate the dissolution of drugs that are insoluble or poorly soluble in water. Some ionic liquid micro-emulsions can be used as modern colloidal carriers for topical and transdermal delivery, while other ionic liquid systems have been used as entrapped/solubilized drug reservoirs for controlled release.

## 2.2 Challenges

### 2.2.1 Over dependence on China for Imports

India depends largely on China for the import of APIs. Active pharmaceutical ingredients for some of the

major drugs are imported from this particular country. India imports approximately 57-60% of API from China<sup>11</sup>.

**Table 2-2: API Import from China (Billion US\$), FY 2012 to FY 2015**

Year	API Import (Billion US\$)
2014-15	1.95
2013-14	1.96
2012-13	2.01
2011-12	1.82

**Source:** Ministry of Health Research (2014), Ministry of Commerce Annual Report (FY 2015 – FY 2016)

According to an article published in Pharmabiz, India is dependent on China for its APIs because importing raw material from China saves 15-20% of the overall costs for the Indian drug makers.

The reasons for low manufacturing cost of API in China are:

- The Chinese Government subsidizes its industry, giving China a cost advantage over India. For example, China assures around 13% tax incentives for the export of APIs.
- The Chinese have an advantage in built-up capacities. They have huge capacities built up by the government, and now managed by the private industry.
- They also have freedom, in terms of pollution norms and effluent treatment compared to units in India.

All these reasons contribute to the low cost of API manufacturing in China in contrast to India. In India, imported APIs are preferred over domestically manufactured APIs. However, Chinese APIs are of poor quality, which is a major cause of concern for India.

## 2.2.2 Complex License Renewal Procedure

Another problem faced by the Indian API industry is that the API manufacturers have to approach multiple authorities for application of license renewal. The

licenses are given after consent is obtained from multiple regulatory bodies, such as the DCG of India or State FDA. These are given for a period of one, two or three years. After that, the manufacturers of API have to apply for the renewal of their licenses. This increases load on the department, as well as the industry. Therefore, major players prefer to opt out of the API industry.

## 2.2.3 Few Manufacturers in the API Industry

India was once a favoured destination for sourcing low-cost, good quality API for manufacturing pharmaceutical formulations. However, China took over this market by creating huge capacities. Also, the price of APIs from China is 15-20% less than their production cost in India, making it more viable for the Indian companies to import. Consequently, several companies, such as Sun Pharma, Aurobindo Pharma, Lupin, and others, shifted their focus from the manufacturing of APIs to developing formulations. Another reason for the reduced number of API manufacturers is low profit margin in the API business compared to the formulations business. All these factors have therefore led to the decline in number of API manufacturers in India.

## 2.2.4 Inadequate Infrastructure Facilities

Infrastructure is the main area where India lacks in comparison with other countries. The small & medium enterprises engaged in API manufacturing face a lot of problems in terms of infrastructure, as they do not have enough supply of water or electricity; also they do not have warehouses where they can keep their excess stock or raw materials. In other countries such as China, there are 15 free trade zones, 53 high tech parks, and 56 export processing zones<sup>12</sup>. In India, the recommendations for the development of API parks are still under consideration, and will take time to get implemented. Therefore, infrastructure development for API production is extremely essential for the enterprises to manufacture the items to their maximum capacity.

11. Ministry of Commerce Annual Report (FY 2015 – FY 2016)

12. RIS Colloquium

### 2.2.5 Lack of Government Support

Governments of other countries provide incentives and subsidies to API manufacturers for land, water, electricity, etc. For example, Chinese Government provides 15-17% draw back duty on exports, which covers up the losses of Chinese API manufacturers<sup>13</sup>. It also assures around 13% tax incentives for the export of APIs in more than 54 Economic and Technology Zones. The power tariffs are also very low, and loan rates are 6.31% in China<sup>14</sup>. This significantly reduces the cost of API manufacturing in the country, and increases their popularity worldwide. In India, all these benefits are not provided by the government. The loan rates are almost double of those in China, and there is no provision for incentives. These therefore greatly affect the cost of API production in the country, and prevent new investors from entering the market.

### 2.2.6 Stringent Regulatory Policies

Companies entering the API manufacturing market are expected to keep in mind the good manufacturing practices, and then only they can succeed in the field. With the global regulatory, cGMP and inspection regimens tightening, it has become more difficult for companies to maintain ideal manufacturing conditions and clear all the clinical trials to reach the market. Inspectors from concerned departments determine whether the firms have the necessary facilities, equipment, and skills to manufacture such new drugs for which they have applied for approval. Decisions

regarding compliance with cGMP regulations are based upon inspection of the facilities, sample analysis, and compliance history of the firm. The companies get the approval to manufacture APIs only after they clear all the inspections.

Apart from this, the drug price control policy is also causing hindrance to the growth of Indian API industry. The launch of the drug price control policy in 2013 by the government has made the consumers happy, as their medicine bills got reduced. However, these price control measures have forced many brands out of the pharmaceutical market. This has resulted in a drastic slowdown of new drug launches in recent years. According to an article in the Times of India, in 2008, 270 new drugs were approved for sale in India, whereas it dropped to 44 and 35 in 2012 and 2013, respectively. In 2014, only 56 new medicines were approved till November, thus accounting for a significant 80% drop in new drug launches. Apart from this, a sharp decline has also been observed in the consumption of price controlled medicines since they offer low margins. As an alternative, people are pushed to go for options outside price control by the doctors and chemists. Consequently, big brands are eating into the share of smaller ones, making it unviable for many small and medium-sized companies to invest in the API business. Moreover, the proposed five-fold hike in regulatory fees for both import and domestic purpose by Health Ministry will also adversely affect the Indian API market. This proposal may make India an unattractive destination for both domestic as well as multinational pharmaceutical companies.

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13. RIS Colloquium

14. BBC News

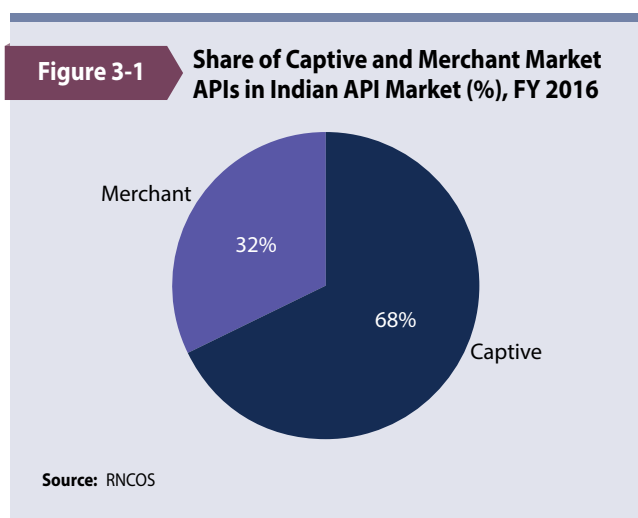




## Market Segmentation

### 3.1 By Type of Manufacturing

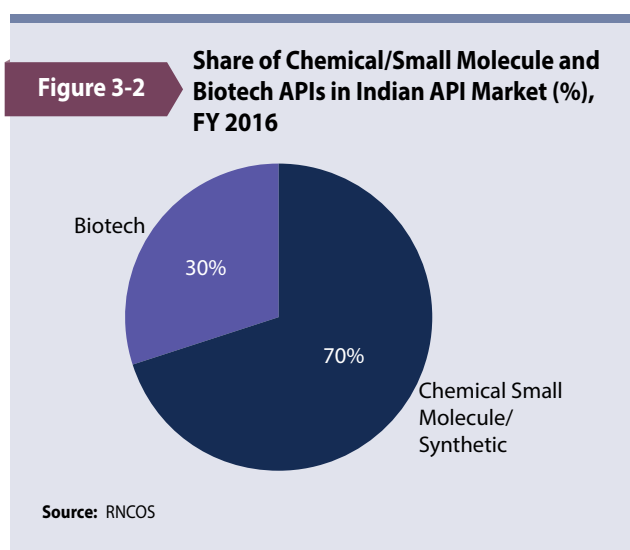
On the basis of the type of manufacturing process that an API producing company opts for, the API market is segmented into captive and merchant markets. The captive market includes the APIs produced by pharmaceutical companies themselves for their own needs, while the merchant market for APIs includes those APIs that are sold by third parties. In FY 2016, the captive market of APIs held a share of more than 65% in the Indian API market. On the other hand, the merchant market held a share of over 30%. Looking at the initiatives taken by the government to promote domestic manufacturing of APIs, the captive market is bound to grow in the coming years.



### 3.2 By Type of API

The domestic Indian API market is further segmented on the basis of the type of API, i.e. into chemical or small molecule API and biotech API. Chemical or small molecule APIs lead the market compared to the Biotech APIs. In FY 2016, Chemical APIs accounted for

70% of the Indian API market. The market of Biotech APIs was small, and was valued at more than US\$ 3 Billion. The share of biotechnology APIs is small because biotechnology usage in the pharmaceutical industry is quite a new concept. With growth in the biotechnology industry globally, usage of biological molecules in the pharmaceutical industry is also rising. Companies are spending on improving the healthcare systems. Increasing intricacy of diseases also favours the rising demand for biotech drugs. Thus, the share of Biotech APIs will considerably augment in the coming years.

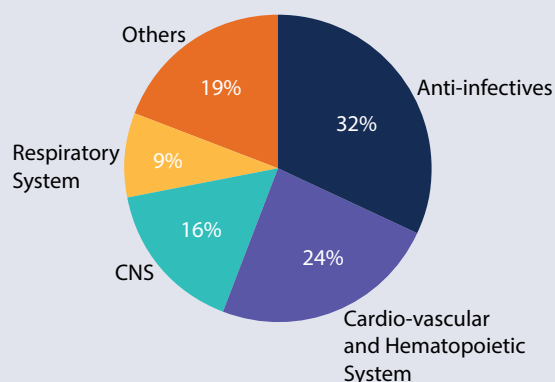


### 3.3 By Type of Therapeutic Area

The Indian API market is segmented on the basis of therapeutic areas as well, in which the drugs are used for treatment. The therapeutic areas in which the APIs are used are – anti-infectives, cardiovascular & hematopoietic, central nervous system, respiratory system and others. Out of these therapeutic areas, a major share of 32% was occupied by the anti-infectives

**Figure 3-3**

**Share of APIs by their Application in Therapeutic Areas in Indian API Market (%), FY 2016**



Source: RNCOS

in FY 2016. Anti-infectives are drugs that can either kill an infectious agent, or inhibit it from spreading. The growth of this segment is fuelled by rising incidences of lifestyle diseases.

The other therapeutic area that holds a significant share of 24% is cardiovascular and hematopoietic system. There has been a rise in the occurrence of stroke problems in the country due to huge obese population. This has led to the increase in demand for

cardiovascular drugs, and this in turn has increased the demand for cardiovascular APIs. In addition, patent expiry of GlaxoSmithKline's cardiovascular pill 'Lovaza' has opened the doors for Indian firms to develop APIs for the manufacture of generic medicines for cardiovascular diseases.

Another important therapeutic segment is the central nervous system diseases, which are the most prevalent disorders in the world. These diseases affect either the spinal cord or brain. Citalopram is one of the commonly used APIs in the Indian API market for the development of drugs in the treatment of central nervous system diseases. The respiratory disease segment also occupies a significant share in the Indian API market due to the increasing cases of respiratory disorders. Due to climate change and rising air-borne pollutants, the number of lung diseases is also soaring in India. According to 'WHO', Chronic Obstructive Pulmonary Disorder (COPD) was responsible for 11% of the deaths in India, in 2012. Presently, there is an urgent need to develop APIs for drugs that can slow down the prevalence of respiratory disorders. The other diseases or conditions, such as Gastrointestinal & Hepatobiliary, Musculo-Skeletal System, Oncology, Genito-urinary System, Endocrine & Metabolic System, etc. hold a small share in the therapeutic area of the API market.





## Mergers and Acquisitions

Companies carrying out manufacturing of APIs in India have been involved in mergers and acquisitions to enhance their existing capabilities. The activities provide them with the necessary impetus for their business, and strengthen their reach to the newer markets with a wider portfolio of products. Indian firms are also keen to enter into licensing deals with larger pharmaceutical

companies that are looking at emerging markets, such as India, to license out their products. Acquisitions on the global front create a number of opportunities for Indian API makers to acquire products and grow their businesses. For instance, the merger deal between Sun Pharma and Ranbaxy has been the biggest deal in the Asian pharmaceutical industry.

**Table 4-1: Mergers and Acquisitions in Indian Pharmaceutical Industry (2014-2016)**

S. No.	Company	Company (Acquired)	Year	Deal Value (US\$ Million)	Purpose
1	Zydus	Zoetis (Select brands and the manufacturing operations in Haridwar)	2016	Undisclosed	To expand its animal health business in India and gain access to manufacturing operations, which have also been catering to global markets.
2	Cipla	InvaGen Pharmaceuticals Inc., and Exelan Pharmaceuticals Inc.	2016	550	To give scale to the US business and launch pipeline of products in respiratory and injectables, among others.
3	Lupin	ZAO Biocom	2015	Undisclosed	To enter the Russian pharmaceutical market, and expected to be among the top 8 pharma markets in the world by 2018.
4	Cadila	Zydus	2015	7.34	Aiming to make Zydus its 100% subsidiary by acquiring 50% stakes of Zydus from BSV Pharma.
5	Torrent Pharmaceuticals	Zyg Pharma Pvt. Ltd.	2015	Undisclosed	To strengthen its position in dermatological market in developed markets, like US and Europe.
6	Strides Arcolab Limited (Strides)	Sun Pharmaceutical Industries Ltd	2015	24.91	To firmly consolidate the CNS business in India.
7	Cadila	Clarix LifeSciences	2015	564.40	To acquire generic sterile injectables business of Clarix.
8	Lupin	GAVIS Pharmaceuticals LLC & Novel Laboratories Inc. (GAVIS)	2015	880	To expand US Generics Business. Broadens Lupin's pipeline in dermatology, controlled substance products, and other high-value and niche generics.
9	Abbott	CFR Pharmaceuticals	2014	2,900	Exceeding generic capabilities in emerging markets, including India.
10	Strides Arcolab Ltd. (Strides)	Bafna Pharmaceuticals	2014	7.87	To acquire majority stake of Bafna's branded generic business.
11	Sun Pharmaceutical Industries Ltd.	Ranbaxy Laboratories Ltd	2014	3,200	Aiming to become 5th largest global pharma company with operations over 55 markets and 40 manufacturing facilities worldwide.

**Source:** Various Industry Sources



## Government Initiatives

The Government of India is taking various initiatives to help in the development of the API industry, as APIs constitute the backbone of the pharmaceutical industry; and so the sector needs to be incentivized to take on the challenges from cheaper imports. The Department of Pharmaceuticals has declared 2015 as the 'Year of APIs'. The government intends to take appropriate decisions soon, so as to make India self-sufficient in APIs.

### 5.1 Katoch Committee

In 2013, the 'Katoch Committee' was set up by the government to look into various issues concerning APIs. The committee's recommendations would be implemented, once approval is obtained from the Union Cabinet. Some of the recommendations are:

- Establishment of Mega Parks for APIs with common facilities, such as common Effluent Treatment Plants (ETPs); Testing Facilities; Captive Power Plants/Assured Power Supply by State Systems; Common Utilities/Services such as storage, testing laboratories, IPR management, designing, etc., maintained by a separate Special Purpose Vehicles (SPV).
- A scheme for extending financial assistance to states for acquiring land, and also for setting up common facilities.
- Revival of public sector units for starting the manufacture of selected and very essential critical drugs (e.g. penicillins, paracetamol, etc.).
- Financial investment by the Government to develop clusters, which may be in the form of a professionally managed dedicated equity fund for the promotion of manufacture of APIs.
- Extending fiscal benefits for the creation of the entire

community cluster infrastructure and individual unit infrastructure.

- Extension of fiscal and financial benefits to promote the bulk drugs sector.
- Promoting stronger industry-academia interaction.
- Synergizing R&D promotion efforts by various government agencies.
- Providing incentives to scientists.
- Exempting duty for capital goods imports.

### 5.2 'Make in India' Campaign

The government is adopting various measures to promote its 'Make in India' campaign in the pharmaceutical sector, so that there is 100% production of APIs domestically. For this purpose a committee has been established, which has studied the whole issue of APIs of critical importance by identifying important APIs; and then working out a package of interventions/concessions required to build domestic production capabilities and examine the cost implications. This committee has recommended the development of Mega Parks for APIs with common facilities such as:

- Effluent Treatments Plants (ETPs)
- Testing Facilities
- Captive Power Plants/Assured Power Supply by State Systems
- Common Utilities/Services such as storage, testing laboratories, IPR management, designing, etc.

### 5.3 Pharma Vision 2020

The Pharma Vision initiative is aimed at making India a global leader in end-to-end drug and API



manufacturing. This is being done by:

- Reducing approval time for new facilities to boost investments.
- The government also putting in place mechanisms, such as the Drug Price Control Order and the National Pharmaceutical Pricing Authority, to address the issue of affordability and availability of medicines.

Government of India has already taken some initiatives to promote the pharmaceutical sector, which are as follows:

- State governments, like Andhra Pradesh to provide necessary infrastructure, incentives and skill up-gradation facilities for the pharmaceutical industry. A similar push initiated in the states of Karnataka and Gujarat.
- The Government of India and the pharmaceutical industry to jointly float a trust to promote the brand image of Indian pharmaceutical globally and fight malicious campaigns.

## 5.4 Establishment of New NIPERs

The Government is setting up new NIPERs (National Institute of Pharmaceutical Education and Research) at 6 new places of India, such as Patna (Hajipur), Hyderabad, Ahmedabad, Rae Bareilly, Guwahati, and Kolkata. This is being done to strengthen the skill base, which can cater to the growing demand of pharmaceutical industry for highly trained manpower for continuous growth of the pharmaceuticals sector with increased focus on R&D. Also, these institutes will

fill the crucial existing gap in research and development of APIs.

## 5.5 Set-Up of Reviewing Committee

The Department of Pharmaceuticals has set-up an inter-ministerial coordination committee to periodically review the constraints and issues being faced by the pharmaceutical industry. This committee will coordinate and facilitate resolution of these issues. The setting up of this committee was a recommendation by the "Task Force on enabling private sector to lead the growth of Pharmaceutical Industry". This committee will be headed by the DoP Secretary, with other members including the representatives of Chairman of National Pharmaceutical Pricing Authority; Secretary, Department of Health and Family Welfare; Secretary, Ministry of Environment, Forests and Climate Change; Secretary, Department of Industrial Policy and Promotion; and Secretary, Department of Commerce, among others.

## 5.6 Launch of Fund by Government

The Department of Pharmaceutical has planned to launch a venture capital fund of INR 1,000 Crore. This fund will provide support to the start-ups in the pharmaceutical industry. The venture capital fund will be used by the companies to carry out research and development of novel active pharmaceutical ingredients and formulations. This move would give a boost to the domestic pharmaceutical industry, and provide cheaper loans to entities looking to establish or upgrade manufacturing facilities.



## Regulatory Scenario

The API industry in India is regulated by several regulatory bodies. These bodies monitor the development, marketing, price control and distribution of pharmaceutical products including APIs. The principal regulatory bodies entrusted with the responsibility of ensuring the approval, production and marketing of quality drugs and APIs in India are Central Drug Standards and Control Organization (CDSCO), the National Pharmaceutical Pricing Authority (NPPA), and Department of Pharmaceuticals. In the US, it is the USFDA; in Europe, it is the EC and European Medicines Agency; and in China, it is the SFDA; that looks into the matters relating to the approval, production and manufacturing of APIs.

**Central Drug Standards and Control Organization (CDSCO)** - This organization is a national regulatory body for Indian pharmaceuticals and medical devices. Within CDSCO, the Drug Controller General of India monitors all the necessary requirements from drug testing to its marketing authorization. The organization works under the Ministry of Health. Major functions of CDSCO are:

- Regulating control over the import of drugs, approval of new drugs and clinical trials.
- Regulating the Drugs Consultative Committee (DCC) and Drugs Technical Advisory Board (DTAB).
- Approving certain licenses, as Central License Approving Authority is exercised by the CDSCO headquarters.

**National Pharmaceutical Pricing Authority (NPPA)** - This is a government regulatory agency that controls the prices of pharmaceutical drugs in India. It has powers to implement and enforce the Drugs Price Control Order, 1995/2013. The agency carries out the following functions:

- Monitoring drug shortages and taking appropriate actions to rectify them.
- Collecting and maintaining data regarding the import and export of drugs, market share of companies and their profits.
- Handling legal disputes that arise from the policies created by it.
- Funding studies regarding pricing of drugs.

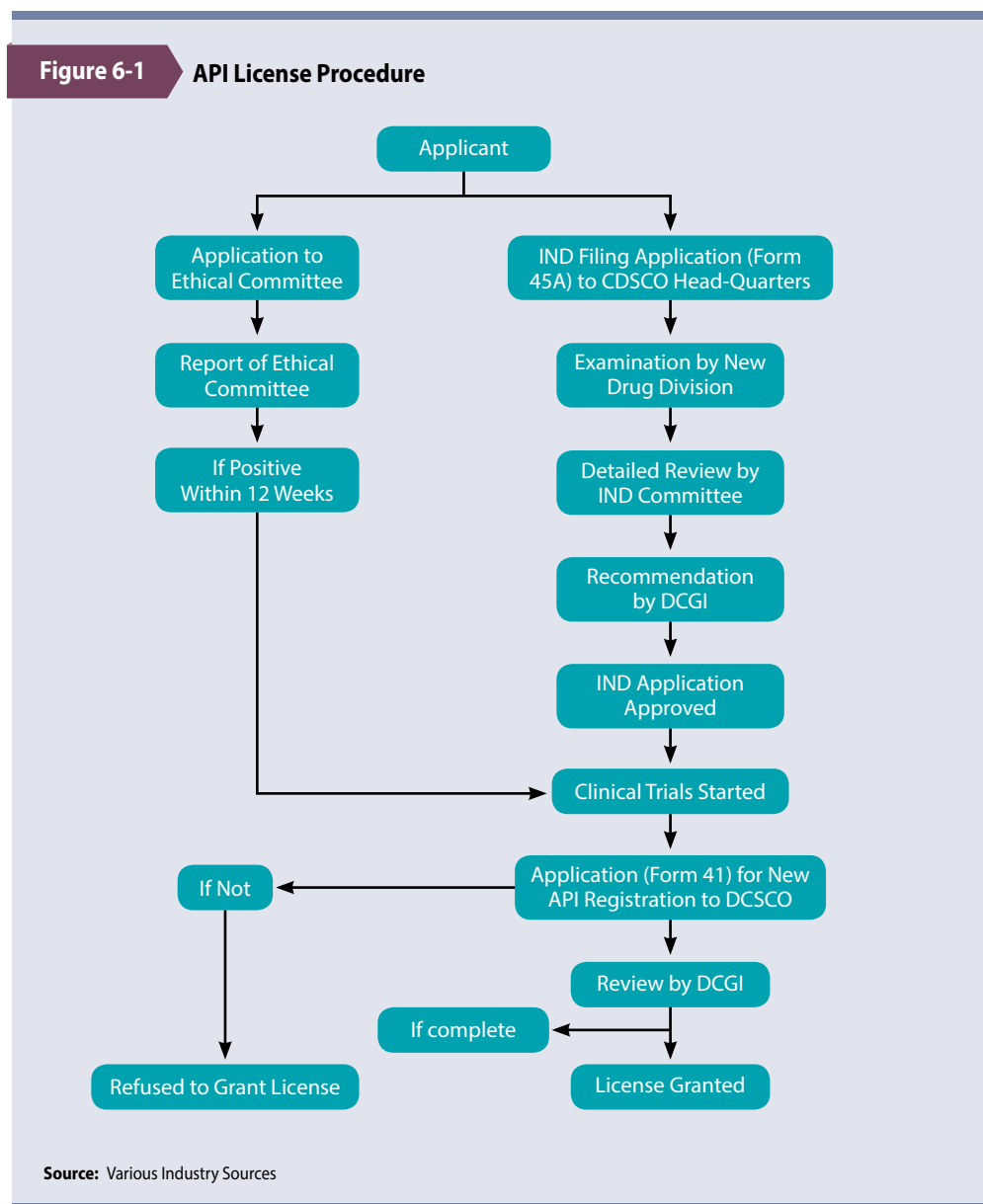
**Department of Pharmaceuticals (DoP)** - This department was created by the Ministry of Chemicals and Fertilizers, so as to provide greater focus on growth of the high potential pharmaceutical industry. The vision of this department is to make India the largest global provider of quality medicines at reasonable prices. In order to implement this vision and mission, the department has taken up the following initiatives to catalyze the growth of the pharma industry:

- Strengthen the NIPER of Mohali, Chandigarh.
- Establish new NIPERs.
- Implement the 'Jan Aushadhi' Scheme, so as to make quality drugs available to all at reasonable prices.
- Build up capacity of the pharmaceutical industry.

**State FDA Units** - The State FDA units grant and renew licenses for the Drug Manufacturing Units. State FDA has the following responsibilities:

- To approve plan of manufacturing premises for drugs.
- To grant licenses for repacking of drugs.
- To grant and renew licenses for drug selling units.
- To grant licenses for public testing laboratories.

The figure 6-1 below highlights the procedure, which is undertaken to obtain licenses for APIs in India.





# Opportunities and Recommendations

## 7.1 Opportunities

### Developing Next Generation APIs

Presently, Indian API industry has a major presence in the generic drug APIs market. If the government increases the budget for R&D, the pharma experts will be able to work better with increased resources towards the development of novel APIs such as ionic liquids. These ionic liquids with biological activity are being designed in such a way that they can be used as APIs. This has been done with a particular focus on efforts to overcome current hurdles encountered by APIs. These novel APIs can then be patented and revenue be earned from them. Thus, ample opportunities would open for the expansion of the Indian API market.

### Capitalizing on Captive API Market

The major requirements of APIs in India are met by imports from other countries such as China, Italy, Germany, France, Malaysia, etc. This situation can be converted into an area of opportunity if the government provides adequate infrastructure facilities, subsidies and loans at low interest rates because then the captive market of APIs can be better developed to meet the requirements of the domestic manufacturers.

### Revival of Generic Drug API Market

Presently, the generic drugs market is dominated by branded generic drugs. This is causing a hindrance to the sales of unbranded generic drugs by small or medium scale manufacturers in India. This in turn affects the generic drug API market. However, the revival of Jan Aushadhi Scheme and Free Essential Drug scheme by the state & central governments would prove to be an opportunity for the domestic

generic API manufactures to conquer the generic drug API market.

### Focus on Emerging Therapeutic Segments

The rising geriatric population in the country and increased awareness among people about healthcare is causing an increase in the demand for new medical products. Areas such as oncology, diabetes, respiratory disorders, cardiovascular diseases, etc. can be the potential focus segments. Research experts should focus on the development of novel APIs for these emerging therapeutic segments, which offer opportunities for growth to this industry.

### New Export Markets

Several compliance issues and stringent quality control regulations in the US/EU markets are acting as restraints for API exports by India. The country derives a major chunk of its export revenues from these developed markets. Markets such as GCC, Japan

#### Opportunities

- Developing Next Generation APIs
- Capitalizing on Captive API Market
- Revival of Generic Drug API Market
- Focus on Emerging Therapeutic Segments
- New Export Markets



and CIS still remain untapped. For example, India's presence in the world's second largest pharma market, Japan, is merely 1%. However, the ability of Lupin to successfully establish its footprint in Japan is a proven example for exploring other regions. In addition, Indian API manufacturers can look to establish their foothold in regulated markets such as South East Asia and Africa.

## 7.2 Recommendations

### Need for Infrastructure Development

The key players engaged in API manufacturing face a lot of problems in terms of infrastructure as they do not have enough supply of water or electricity. Also, they do not have warehouses where they can keep their excess stock or raw materials. Therefore, infrastructure development is greatly required so that enterprises can manufacture goods to their maximum capacity.

### Increasing Training for Pharma Graduates

India has a large pool of talented people in the pharma sector. They have sufficient theoretical knowledge in the field. All that they require is practical training to convert their theoretical knowledge into actual work in a proper manner. If the government increases its focus on practical knowledge starting at school and college levels, it will help in nurturing the talent of the people. That in turn will provide opportunity for the development of the Indian API industry.

### Development of Mega Parks

The government of India should focus on the development of Mega Parks for APIs across all the states in India. These parks should be provided with common facilities such as effluent treatment plants, testing facilities, power plants, storage, IPR management, designing, etc. These facilities should be maintained by a separate Special Purpose Vehicle.

#### Recommendations

- Need for Infrastructure Development
- Increasing Training for Pharma Graduates
- Development of Mega Parks
- Increase in Import Fees
- Single Authority for Better Governance
- Incentivize Exports and Innovations
- Provisions for Subsidies and Soft Loans
- Access to Modern Technology
- E-Filing of APIs

### Increase in Import Fees

Currently, large quantities of APIs are being imported from countries such as China. This can be due to the low cost of APIs from the countries like China with negligible import fees. To change this scenario, the import fees should be increased in line with other counterparts. Consequently, there will be a decrease in the large amounts of imports of APIs while the domestic API market would get promoted.

### Single Authority for Better Governance

Another issue faced by the API industry is the presence of multiple regulatory authorities for the regulation of this industry in India. API manufacturers have to approach different authorities for renewal of licenses that becomes a tedious affair. Therefore, a single committee of various government departments should be formed to regulate the API industry through a single window and audit of plants.

### Incentivize Exports and Innovations

The Indian API industry can also be strengthened by encouraging exports. This can be done by incentivizing the domestic API manufacturers with interesting schemes. The Foreign Trade Investment (FDI) policy should be modified in such a way that it gets simplified and maximum sectors are put on the automatic route, eliminating the need for government approval. Apart from this, the scientists should be motivated to work harder in their field by incentivizing innovations. Incentives will give the scientists necessary push to work towards the development of novel API molecules that will help in the growth of the API industry in India.

### Provisions for Subsidies and Soft Loans

The government of India should make provisions to provide electricity, water or raw materials at subsidized rates so that manufacturers in the API industry can obtain these necessary commodities at cheaper rates. The public and private banks should provide loans to API manufacturers at reduced interest rates and permit flexibility in loan repayment time. This will encourage new entrepreneurs to join the API industry.

### Access to Modern Technology

In an increasingly complex and competitive economic landscape, the need to align people, processes and technologies is stronger than ever. Access or availability of modern technology can help enterprises reduce cost and time taken to innovate and to offer sophisticated products and services. This will help key API manufacturers of the country differentiate from global peers.

### E-Filing of APIs

Currently, India does not have any database that maintains the record of approved APIs present in the market and the API manufacturers in India. The government should ask the department, which regulates the API market in India, to maintain a record of APIs and their manufacturers. This data should be made available online so that people who require the necessary information can access it easily.



## Notes

This image shows a full page of a handwriting practice worksheet. It consists of multiple sets of three horizontal dashed lines spaced evenly down the page, providing a guide for letter height and placement. The background is plain white, and there are no other markings or text present.

## Notes

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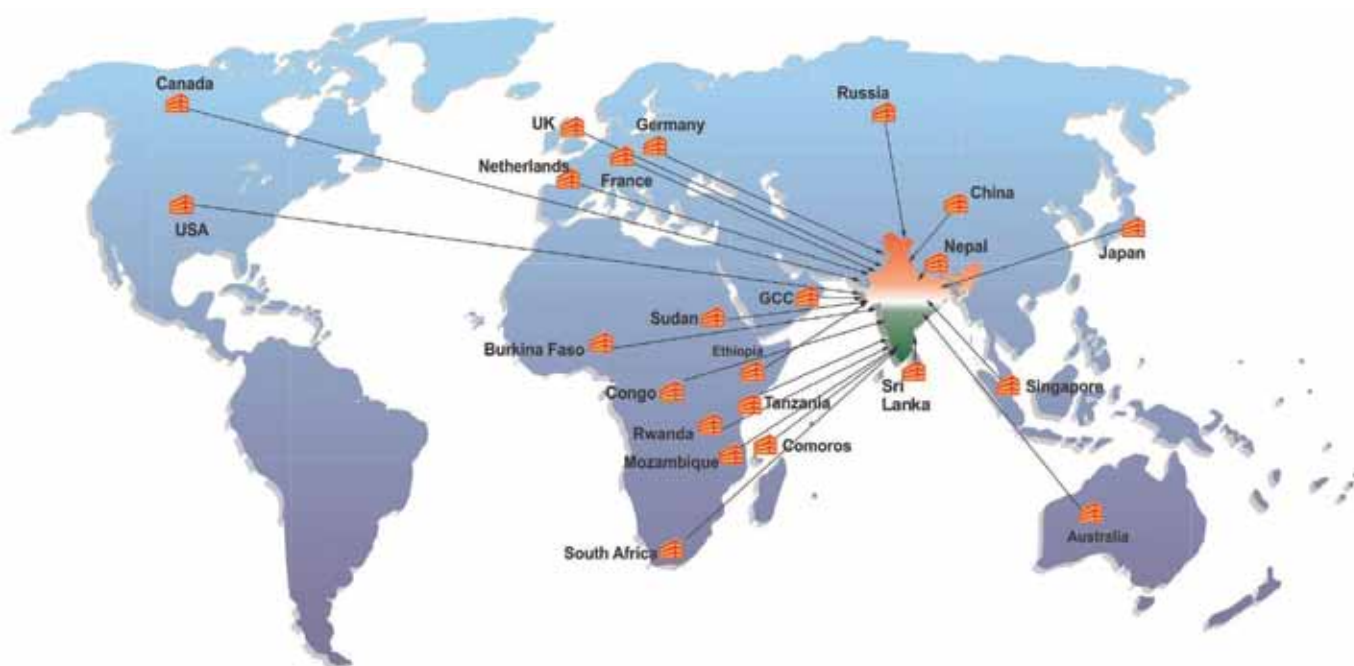
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The pictorial presentation of the world map does not purport to be the political and geographical maps of the world and India and is not drawn to scale. This is only indicative.

ASSOCHAM International Department

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