

## Indian Pharmaceuticals Industry

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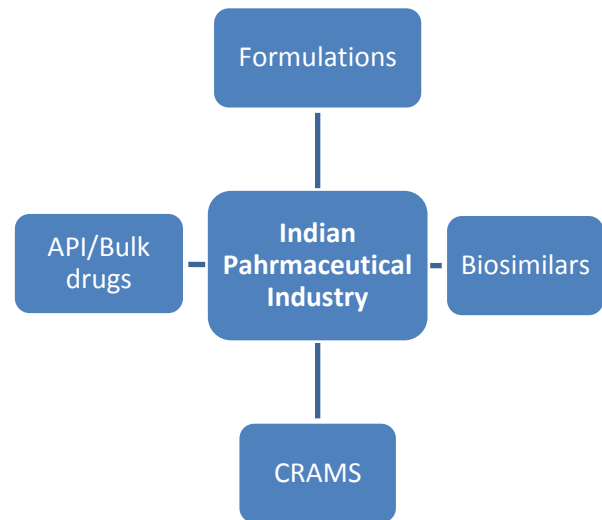
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*The Indian Pharmaceuticals Industry (IPI) earns around 70% of its revenues from sale of generic drugs and generates around 50% of its revenues from exports. In the financial year 2016-17, the industry faced slew of issues with increased scrutiny of regulatory authorities, increase in competition in generics market of one of its primary export destination, United States of America. This, in turn, resulted in marginal growth in exports to USA. Also, the stricter enforcement of Drug Price Control Order has impacted revenue growth rate of the industry in domestic market.*

*In 2017-18, the industry is expected to continue to see pricing pressure in both the markets: domestic and exports. However, CARE believes that the steady growth in demand from domestic market coupled by a likely increase in export volumes to North American and African markets will support the industry's growth.*

### Indian Pharmaceutical Industry

**Chart 1: Structure of Indian Pharmaceutical Industry**



The pharmaceutical industry in India mainly comprises four segments:

**Formulations** – These are the final products of the drug manufacturing process and they can be in the form of tablets, capsules, injectables, syrups, gel, paste, powder, ointment etc. These can be consumed directly by patients.

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API/Bulk drugs (intermediates) – Active Pharmaceutical Ingredients (API) is the primary active ingredient that is manufactured in the initial stage of pharmaceutical and drug production. It is the ingredient that results in desired therapeutic effect in the human body. Bulk drugs are active chemical substances and are used in the manufacturing of pharmaceutical and drug formulations. API/bulk drugs can be considered as inputs that are used in making of formulations.

CRAMS – Contract Research and Manufacturing Services (CRAMS) is an outsourcing process that implies outsourcing of research and product manufacturing services at a lower cost.

About USD 55 billion is the expected sales gain to generics drugs on account of branded drugs going off patent during 2017-19. After these patents lose coverage, there will be a requirement to manufacture these drugs in a cost-effective manner to keep them price competitive. This, in turn, will create an opportunity for India that is one of the low-cost manufacturing centres in the world.

Biosimilars - Biosimilars can be referred as medicines that are generic version of biological products. Biosimilars can be manufactured by new companies only after the patent expiry of the original biological product. A biological product is a medical product produced using biotechnology.

The immense potential of India in biosimilars market can be supported by the fact that India is equipped with sophisticated Research & Development facilities meeting international standards, cost effective labour.

### **Position of Indian pharmaceutical industry**

The Indian pharmaceutical industry holds a strong position in terms of production volumes in the global pharma market as the country contributes around 10% of the world production volumes and in terms of value, India holds a share of around 2.4% globally.

The Indian pharmaceutical industry is largely dominated by generics drugs as the industry earns around 70% of its revenues from the same. This can also be implied from the fact that India holds 13<sup>th</sup> position in terms of production value in spite of holding third position in terms of production volume globally.

IPI registered revenue of around USD 33 billion in 2016. Exports form a major part of the industry's turnover and over 50% of the sales comes from exports. Lower cost of production coupled by efficient scientific and technical skills of human resources are the prime reasons for growth in exports from India. The cost of drugs manufactured in India is one of the lowest in the world.

**Table 1: Relative cost comparison in India**

Relative Comparison of major cost advantage in India	
Cost in developed countries	100%
Production cost in India	50%
R & D Cost in India	12.5%
Clinical Trial Cost in India	10%

Source: Pharmexcil

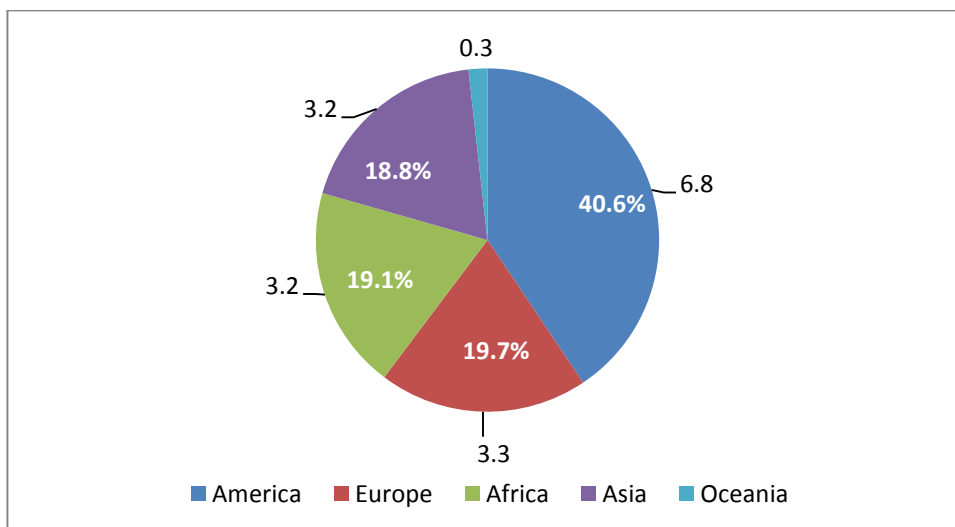
Note: Costs in India as % of costs in developed countries

According to IBEF, the cost of production in India is approximately 60% lower compared to US and almost half when compared to Europe.

**Pharma Exports from India**

Of the total exports of USD 16.8 billion during the year 2016-17, majority of the exports, accounting for 40.6% were to the American continent followed by 19.7% to Europe, 19.1% to Africa and 18.8% within Asia.

**Chart 2: Continent-wise Exports of Drugs & Pharmaceuticals in 2016-17 (USD billion)**



Source: CMIE

**Significance of USA in Indian pharma exports (a major export destination)**

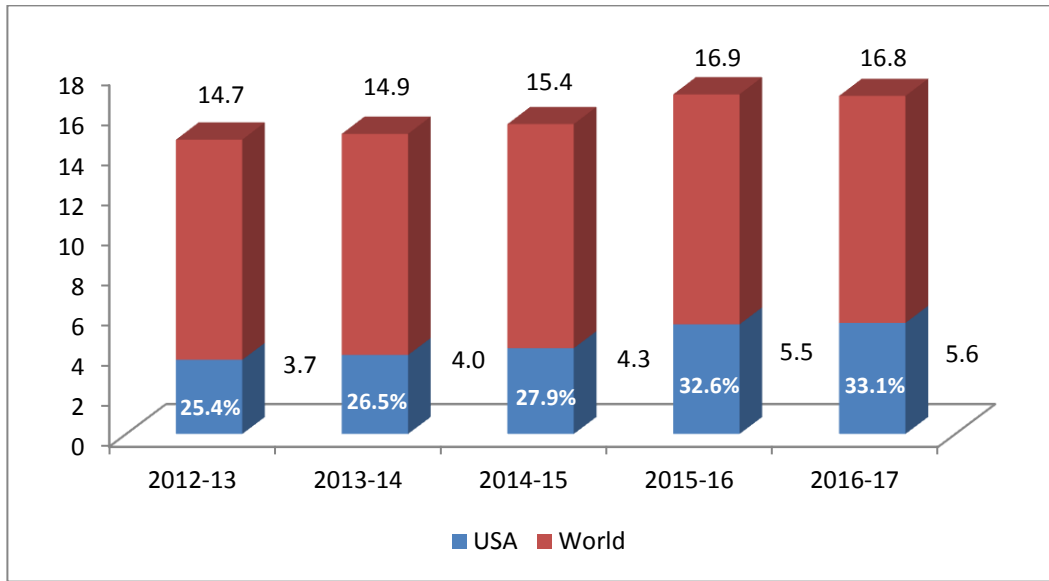
Among the countries, United States of America is the primary export destination for India. Exports to USA have been on a rise since more than a decade. The exports are mainly driven by the cost advantage that India has. The share of exports to USA in total drugs & pharma exports from India which was 25.4% in 2012-13 increased to 33.1% in 2016-17. For other countries like UK, South Africa, Nigeria, Russia, Brazil, Germany, Australia, the share of each of these countries in total drugs & pharma exports remained in the range of 1.4%-3.3% in 2016-17.

In 2012-13, exports to USA grew by 14.2% y-o-y to USD 3.7 billion and increased in single digit in each of the following two years. In 2015-16, exports to USA surged by 27.8% to USD 5.5 billion on a y-o-y basis. However, the export scenario to USA weakened and it grew by a marginal 1.3% to USD 5.6 billion in 2016-17.

The prime reasons for the weak exports were price erosion in the generic market in USA due to consolidation among customers i.e. the distribution channels, increase in competition, absence of blockbuster drugs going off patent and regulatory issues faced by Indian Pharma companies.

**Blockbuster drugs:** A blockbuster drug generally generates sales of at least USD 1 billion. A blockbuster drug like any other drug has a patent coverage and the company loses the exclusive right to sell the drug once the patent for the drug expires.

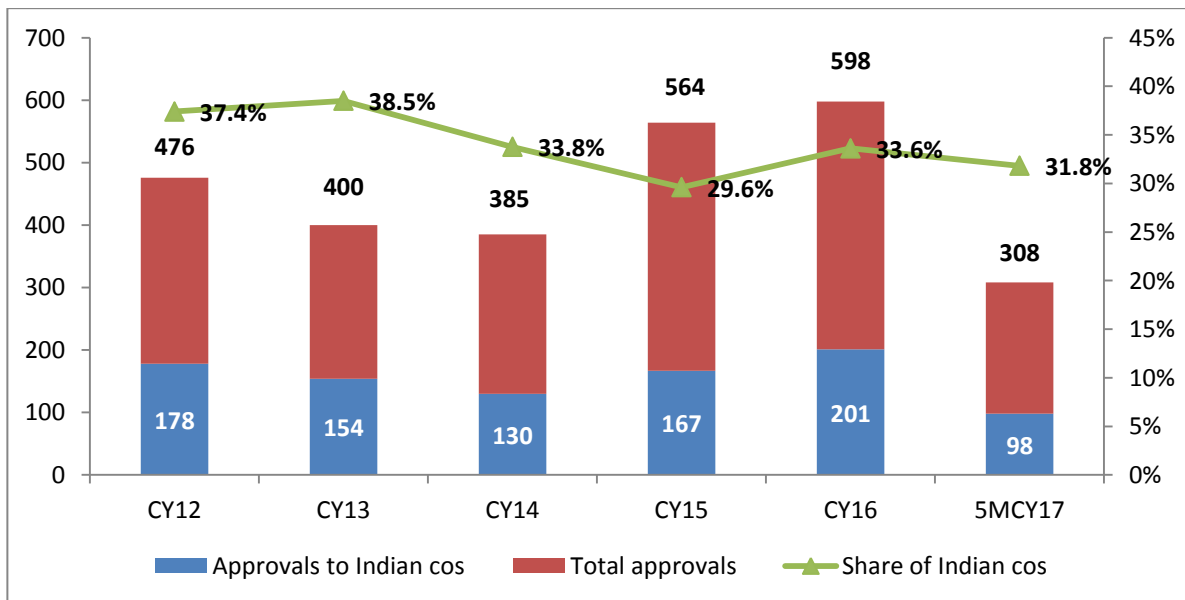
**Chart 3: Pharmaceuticals Exports by India and share of USA in total exports (USD billion)**



Source: CMIE

This situation continued even during the initial months of the current financial year 2017-18 and exports to USA declined by 23% y-o-y to USD 723.4 million during April-May 2017. The total exports from India during the same period fell by 8.5% to USD 2.5 billion.

**Chart 4: Approval of Abbreviated New Drug Application (ANDA) by USFDA**



Source: USFDA

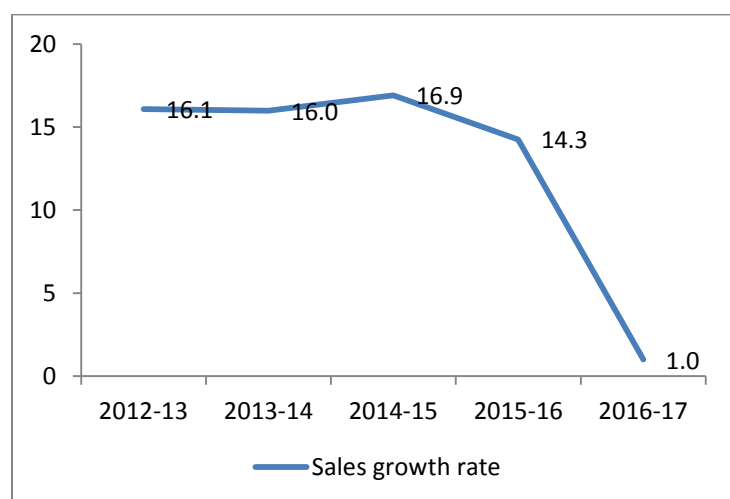
From the above chart it can be seen that India has a substantial share in ANDA approvals. In CY12, there were 476 total approvals and the share of India was 37.4% i.e. 178 approvals. The share of India increased further to 38.5% in CY13 but declined in the following two years. In CY16, the share of India in ANDA approvals increased to 33.6% which was at 201 of the

total 598 ANDA approved. For the first five months in CY17, the ANDA approvals to India stood at 98. This implies that of the total ANDA approvals given by USFDA, India had a share of 31.8%.

The significant share of approvals to India of the total approvals by USFDA can be attributed to the Indian Pharma companies' efficiency to make high-quality medicines at competitive prices.

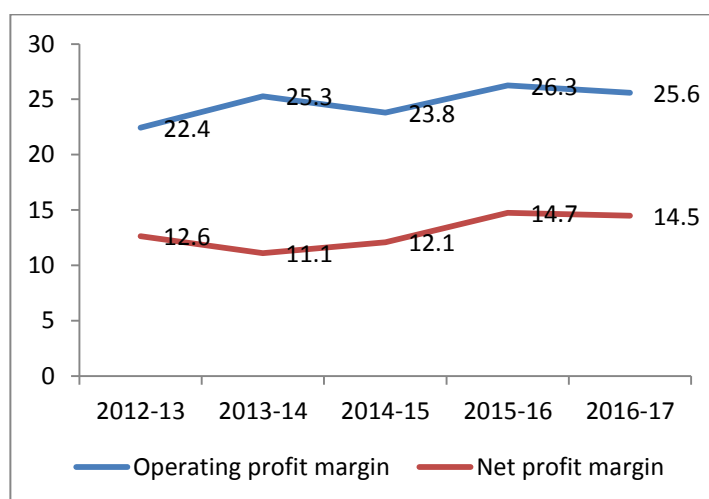
**Financials of drugs & pharmaceutical industry**

**Chart 5: Sales growth rate (in %)**



Source: Ace Equity

**Chart 6: Operating and net margin (in %)**



Source: Ace Equity

On a y-o-y basis, sales of the IPI grew in double digits in each of the years during the period 2012-16. The sales growth rate however started slowing down in the March 2016 quarter and the industry's sales growth remained dull in the financial year 2016-17 compared with the corresponding period a year ago. Industry's sales grew by 1% in 2016-17. The financials are based on the results of 132 companies.

The slowdown in sales growth was on account of issues faced by the industry on both the both fronts, domestic and exports. Pharma exports to USA account for a major share of the Indian pharma exporters and the exports to USA grew by a marginal 1.3% on a y-o-y basis to USD 5.6 billion during 2016-17. Increase in scrutiny, regulatory intervention which raised quality and compliance issues with the USFDA impacted the export sales. This was also coupled by price erosion in the generic market in USA due to consolidation of distribution channels and increase in competition.

On the domestic front, some regulatory interventions by the government impacted the industry's sales. The government in order to make essential medicines affordable enlarged the National List of Essential Medicines (NLEM) in December 2015 and the government also banned fixed dose combination (FDC) drugs in March 2016 citing its safety and efficacy as concerns.

In the financial year 2016-17, the profit margins of the industry remained almost at the year ago level. The industry's operating margin contracted by 70 basis points to 25.6% and the net margin eroded by 20 basis points to 14.5% on a y-o-y basis.

**Outlook**

**Domestic market:** As per the Union Budget 2017-18, the government wants to ensure the availability of drugs at reasonable prices and so it may continue with the drug price control regime which can have an impact on prices. The domestic demand

for formulations however is expected to grow steadily backed by growth in presence of chronic diseases, increasing per capita income, improvement in access to healthcare facilities and penetration of health insurance.

**Export market:** The Indian pharmaceutical industry is likely to face competition from other countries to get ANDA approval. Apart from this, the Indian pharma companies will continue to witness pricing pressure in the US generics market due to consolidation of distribution channels and increase in competition.

The pharma export volumes from India to US however are expected to rise. This will be backed by about USD 55 billion expected sales gain to generics drugs on account of branded drugs going off patent during 2017-19 which will create an opportunity for CRAMS segment. We expect growth rate for CRAMS to be higher compared to average growth rate of the industry. These factors are likely to support pharma exports from India.

### **Goods and Services Tax (GST) and pharma industry**

Post implementation of GST, logistics cost for the industry is likely to reduce. Under the pre-GST regime, the companies had to pay 2% Central Sales Tax (CST) on inter-state sales. To avoid this cost, the companies maintain warehouses in each state. Now with the implementation of GST, the CST will get subsumed with GST, this will create an option for the companies where they can prefer not to have warehouses in each state thus reducing their dependency on CFA. The companies can therefore set up warehouses keeping in mind the logistics benefits rather than considering CST.

With the implementation of GST, most medicines fall under the category of 12% whereas essential drugs including insulin fall under the category of 5%. In the pre-GST regime, the formulations including excise duty and VAT were taxed at around 9% and the tax on inputs of bulk drugs was 12.5%.

We believe that with implementation of GST, there will be no major change in the prices of medicines and we expect that the government will continue to keep a check on the prices of controlled as well as non-controlled drugs.

### **Concluding remarks**

- *Post implementation of GST, logistics cost for the industry is likely to reduce as there will be an option for pharma companies where they can prefer not to have warehouses in each state thus reducing their dependency on CFA. The companies can therefore set up warehouses keeping in mind the logistics benefits rather than considering CST.*
- *We believe that with implementation of GST, there will be no major change in the prices of medicines and we expect that the government will continue to keep a check on the prices of controlled as well as non-controlled drugs.*
- *The domestic demand for formulations is expected to grow steadily backed by growth in presence of chronic diseases, increasing per capita income, improvement in access to healthcare facilities and penetration of health insurance.*
- *We believe pharma export volumes from India to US will rise as branded drugs of about USD 55 billion are expected to go off patent during 2017-19 which will create an opportunity for CRAMS segment.*
- *The immense potential of India in biosimilars market can be supported by the fact that India is equipped with sophisticated Research & Development facilities meeting international standards, cost effective labour.*

**Appendix**

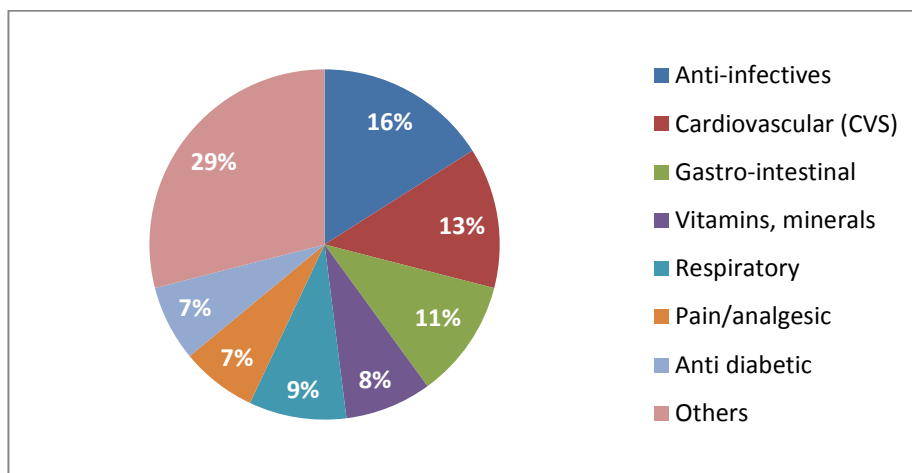
**Generic drugs:** A generic drug contains the same active ingredients as the branded drug and gives the same therapeutic effect as branded drugs. It is not necessary for them to contain the same inactive ingredients. It is identical in strength, dosage form and route of administration and has the same use indications. It meets the same batch requirements for identity, strength, purity and quality and matches the same strict standards of branded drugs. The generic drugs can be sold in the market only after the patent expiry of the branded drug.

**Branded drugs:** A branded drug is originally developed and manufactured by a pharmaceutical company with a huge investment in research & development and the drug is exclusively sold by the company in the market with patent protection so that the company can recover the investments it made for the manufacturing of the drug. Resultantly, the branded drugs are sold at higher price when compared to generic drugs.

**ANDA:** Drug manufacturers need to clear the Abbreviated New Drug Application (ANDA) process with the United States Food and Drug Administration (USFDA) to market the generic drug. It involves seeking of approval from the USFDA by drug formulators through submission of supporting documents to market a generic drug in USA.

**NDA:** To market the drug in USA, the pharmaceutical company has to submit New Drug Application (NDA) to the USFDA and get an approval from it regarding the safety and efficacy of the drug.

**Chart 1: Indian pharmaceutical market segments by value (FY 15)**



Source: IBEF

The above mentioned segments can be broadly classified into two categories: Chronic and Acute

**Table 1: Chronic and acute segment**

Chronic	Acute
Cardiovascular (CVS)	Anti-infectives
Anti-diabetic	Pain
Gastro-intestinal	

Source: IBEF

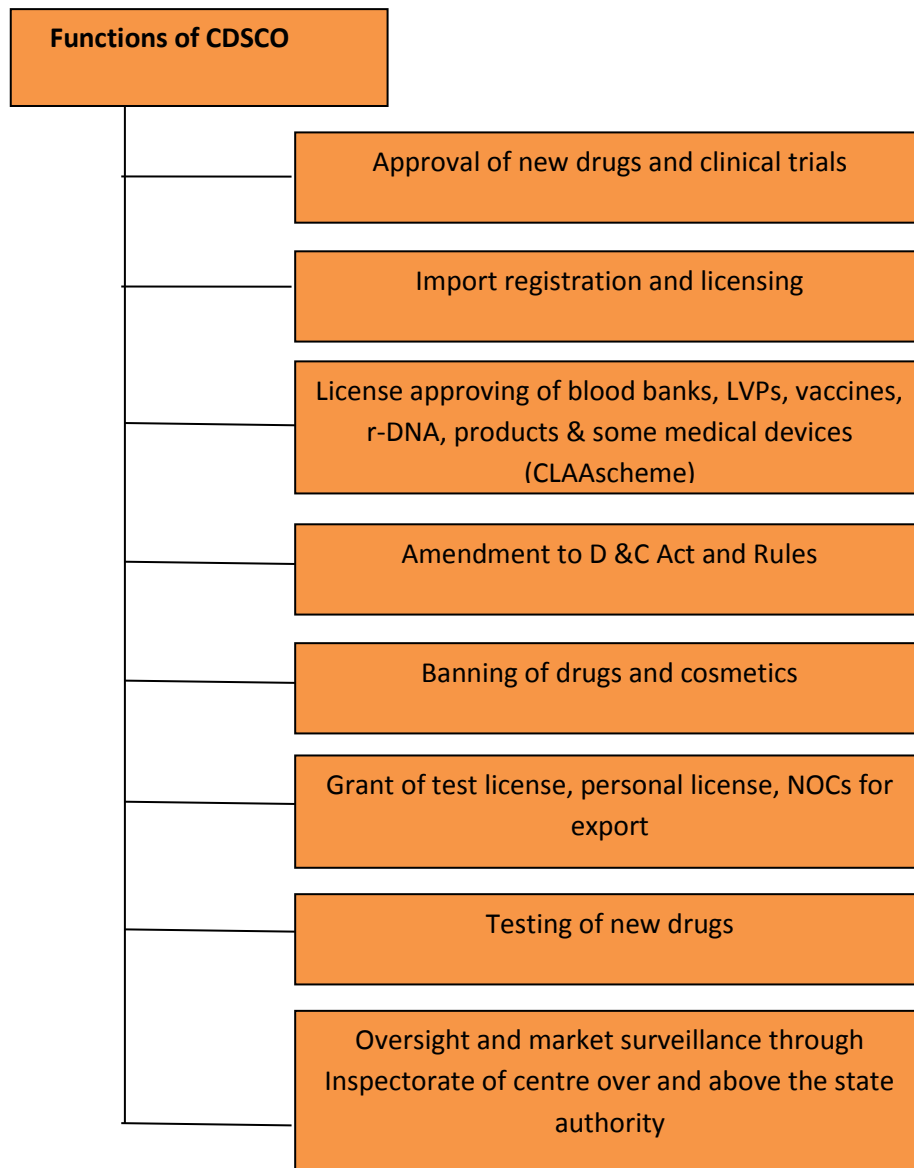
**Chronic disease:** This kind of disease is long lasting in nature. It develops gradually and stays over a long period of time.

**Acute disease:** This kind of disease arises suddenly and stays for a short period of time.

**Regulatory structure for drugs & pharmaceutical industry in India**

**Central Drug Standards and Control Organisation (CDSCO):** It acts as a Central Drug Authority that discharges functions assigned to the central government under Drugs and Cosmetics Act. Some of the major functions of CDSCO are regulatory control over the import of drugs, approval of new drugs and clinical trials.

Under the Drugs and Cosmetics Act, while the state authorities are primarily concerned with regulation of manufacture, sale and distribution of drugs, the central authorities are responsible for the functions stated in the chart below.



Source: CDSCO

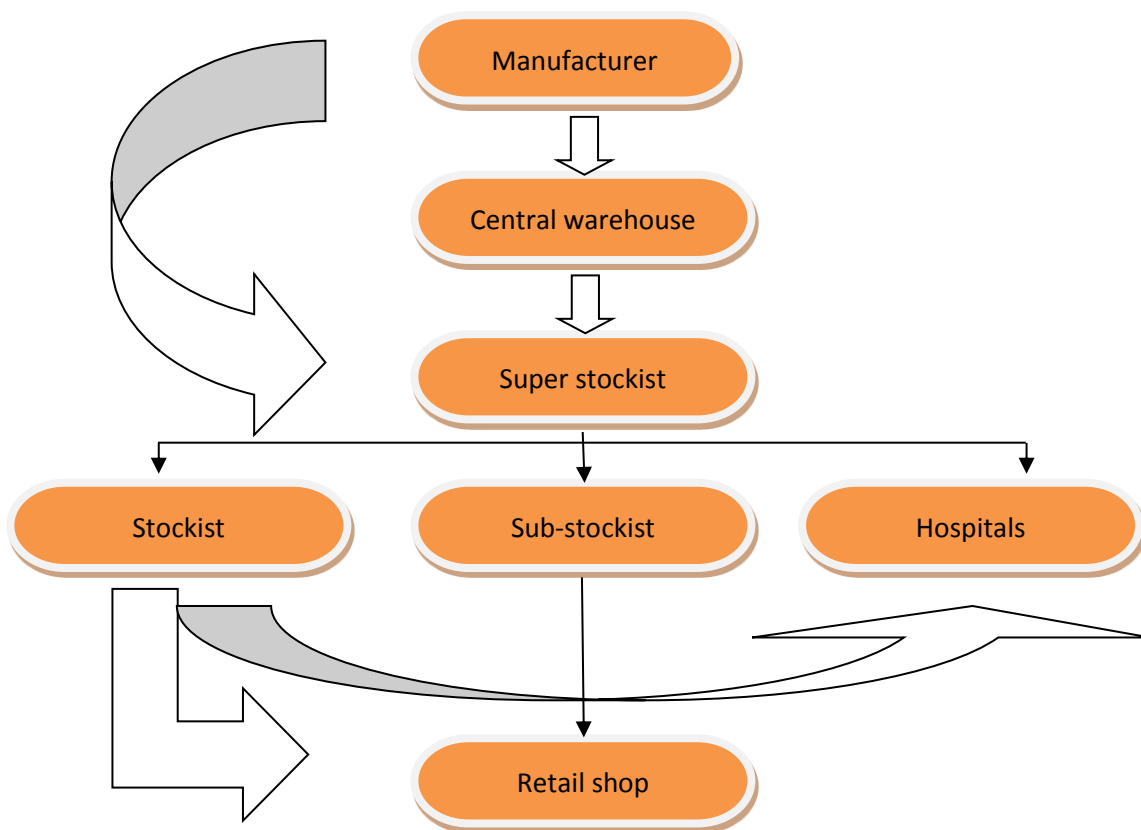


**Drug Controller General of India:** This authority looks after approval of licenses of specified categories of drugs such as blood and blood products, I.V. Fluids, vaccine and sera.

**National Pharmaceutical Pricing Authority (NPPA):** It is an organisation established by the Indian government to fix/revise the prices of controlled bulk drugs and formulations. It also enforces prices and availability of medicines in India under the Drug (Prices Control) Order, 1995. Besides, the authority also monitors prices of decontrolled drugs so as to keep them at reasonable levels.

The NPPA notifies the prices of medicines listed under the National List of Essential Medicines (NLEM) notified by The Ministry of Health & Family Welfare and can also fix the prices of non-essential drugs in the interest of public.

**Supply-chain for distribution of drugs in India**



Source: BioPlan Associates

The drug manufacturers pass drugs through their company-owned central warehouses to the super stockist or Clearing & Forwarding Agents (CFA). The CFA supplies drug either to the stockist, sub-stockist or hospitals. The retailers get the stock from stockist or sub-stockist which is then finally sold to consumers. Some small drug manufacturers supply their drugs directly to super stockist. Most companies have 1-3 CFAs in each state.

**OTC drugs (Over the counter drugs):** OTC drugs refer to those drugs which do not require prescription from doctors for its purchase and are sold over the counter. These drugs can be easily bought from local chemists, general stores, supermarkets etc. In India, only those drugs that are not included in the list of prescription drugs can be sold over the counter. As per IBEF, revenues of OTC products reached around USD 6.3 billion in 2015.

Vitamins, minerals, supplements, cough, cold, allergy and gastrointestinal are some of the segments that have a share in sale of OTC drugs.

Rising awareness among consumers, tendency of self-medication, easy availability of OTC drugs, consumers looking for quick solutions to health problems, increase in advertisements and promotions of these drugs are driving the growth of this market and these factors are expected to continue to drive OTC sales in future.

### **Alternatives to drugs & pharmaceutical industry**

Apart from treatment through the use of drugs or medicines, consumers also have the option or alternative to seek treatment through age old therapies like Ayurveda, Homeopathy or Unani.

Seeing the growth potential in these markets, the government laid focus on the Indian Traditional Systems of Medicine and the Department of AYUSH was granted the status of Ministry with effect from November 2014. This department is responsible for policy formulation, development and implementation of programs for the growth, development and propagation of Ayurveda, Yoga and Naturopathy, Unani, Siddha and Homeopathy (AYUSH) systems of Health Care. Sowa Rigpa is the latest entry to the current family of AYUSH systems.

The National Health Policy 2017 acknowledges the need to support AYUSH system of medicine, through development of infrastructural facilities of teaching institutions, improving quality control of drugs, capacity building of institutions and professionals.

The National Health Policy would continue mainstreaming of AYUSH with general health system but with the addition of a mandatory bridge course that gives competencies to mid-level care provider with respect to allopathic remedies. The policy also involves establishing forward and backward market linkages in processing of medicinal plants with the engagement of local communities and the policy also considers taking steps that will encourage the farming of herbal plants.

These therapies have their own intrinsic advantages like diversity, modest cost, low level of technological input and the increasing support of natural plant based products, mainly in the under-served, remote and tribal areas. Also, these therapies are believed to have no side-effects or lesser side-effects compared to side-effects that allopathy can have.

Some Facts on AYUSH: The government allocated Rs.1, 428.6 crore for the Ministry of AYUSH in the Union Budget 2017-18. This implies a growth of 9.3% compared to revised estimate of Rs.1, 307.4 crore for 2016-17.

In 2014, the traditional (ayurvedic) medical care market in India was valued around USD 2.7 billion and it grew at a CAGR of 20% during 2011-15 according to IBEF.

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