



Study Of Indian Pharmaceutical Industry And Problems In Supply Chain Management Of Active Pharmaceutical Ingredient (API)

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Abstract: India is the 5th largest economy but its expenditure on public health sector is very poor and unfortunately less than some underdeveloped countries. Indian pharmaceutical industry is highly dependent upon the Chinese companies for raw material of generic product. Recently Indian government has restricted export of various medicines to maintain the stock for domestic use and launched several schemes to accelerate the production of API's in the country. The study is based on the published statistical data and attempted to analyse the challenges that have been faced by Indian pharmaceutical companies since long time and upcoming future opportunities.

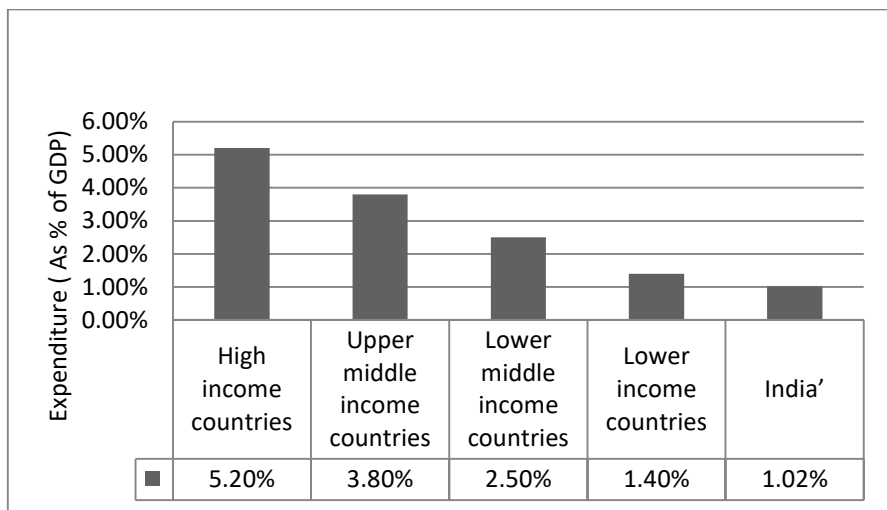
Index Terms - Active Pharmaceutical Ingredient (API's), Public health sector, Statistical data, Pharmaceutical companies.

Introduction

India is the 5th largest economy and GDP is about to reach US \$3 trillion. The vision of government of India is to reach US \$ 5 trillion by the end of 2024. But bitter truth is also unhidden. Expenditure of India on its health sector is lowest amongst the world. India spent only 1.02% of GDP on public health care sector. Countries like Maldives, Sri Lanka, Bhutan spent more than India, such as 9.4%, 1.6%, 2.5% respectively.

Expenditure on Public health care, by Income group (%)		
1	High income countries	5.2%
2	Upper middle income countries	3.8%
3	Lower middle income countries	2.5%
4	Lower income countries	1.4%
5	India'	1.02%

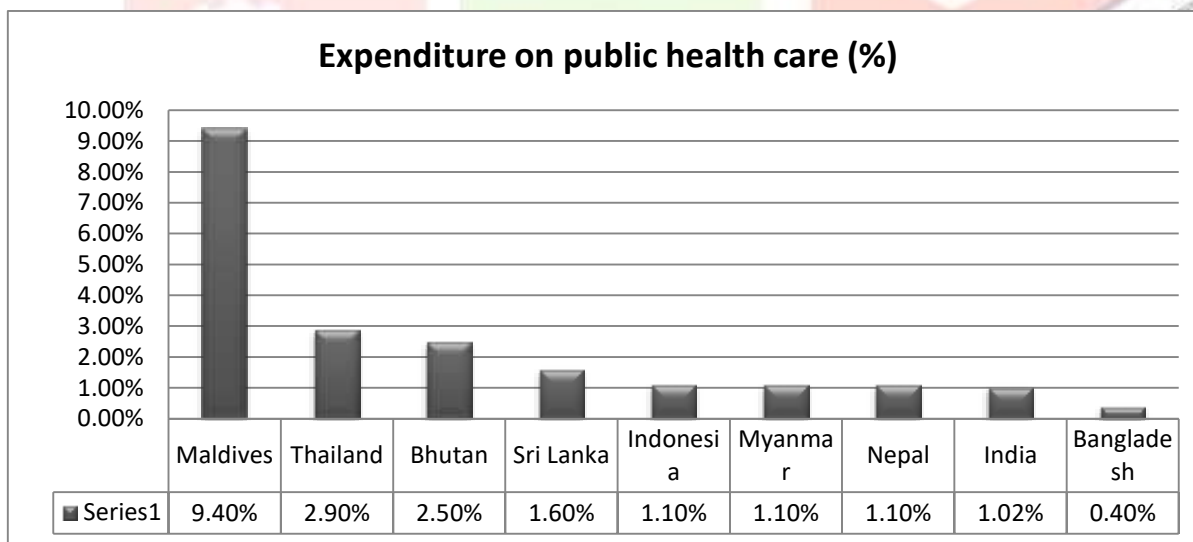
(Table 1.0, Source: National Health Profile-2018)



Expenditure on public health sectors, South East Asia.

S.No	Country	Expenditure in %	Expenditure in billion
1	Maldives	9.4%	770
2	Thailand	2.9%	160
3	Bhutan	2.5%	66
4	Sri Lanka	1.6%	63
5	Indonesia	1.1%	38
6	Myanmar	1.1%	14
7	Nepal	1.1%	8
8	India	1.02%	16
9	Bangladesh	0.4%	5

(Table 2.0, Source: National health profile-2018)



(Figure 2.0)

Indian pharmaceutical sector is likely to expand at CAGR of 22.4% over the period of 2015-2020 to achieve the value of US \$ 55 Billion [1]. The export figure of the India stood at US \$ 17 Billion in financial year 2017-2018 and US \$ 10.80 billion in financial year 2019. India is one of the largest producers of generic drugs worldwide. Industry of Pharmaceutical supplies over 50% of global demand. India supply 40% of its Pharmaceutical product to US and 25% of all medicine to UK. More than 80% of drug (antiretroviral) that are used to combat Acquired immune deficiency syndrome (A.I.D.S) are supplied by Indian pharmaceutical industries [2]. In 2017 Indian Pharmaceutical company received more than 300 abbreviated new drugs applications from United States Food and Drug administration (USFDA) and it received 415 product approvals and 73 tentative approvals from US in 2018 [3]. Turnover of Indian domestic pharmaceutical market turnover reached (US \$ 20.03 billion) Rs 1.4Lakh Crore in 2019. But on the other hand India is highly dependent on China. 70% if it's Active Pharmaceutical Ingredients

(API) imported from China. Out of US \$ 3.56 billion, every year Indian spent US \$ 2.4 billion on import from China. In simple words, any material or combination of substances that are used in making Finished Pharmaceutical Product (FPP) are known as API. The main objective is to enhance pharmaceutical activity or have direct effect on cure, treatment, diagnosis mitigation or prevention of disease. It must have effect in correcting restoring or modifying physiological function of human being (WHO) [4].

The above definition was changed by world health organisation (WHO) by deleting “combination/mixture” of different substance in technical report series NO. 961. Annex 10. [5]

Literature Review

World Health Organisation (WHO) defines the objective and definition of Active Pharmaceutical Ingredient Master File (APIMF) in Annex 4 [WHO technical report series, NO-948-2008] and explains how to manage and protects the confidential information of active pharmaceutical ingredient (API) [6]. Supply chain management is entitled to give better results (maximum profit) for all involved stakeholders. However the lack of awareness and proper knowledge about supply chain management reduces the benefits of collaboration. Theory of constraint (TOC) given by Eliyahu M. Goldroll [Book title: The Gold- 1984] [7] gives an overview to overall management philosophy that geared the organisation to continuously achieve their goals.

India is 3rd largest producer of Pharmaceutical products. But on the other hand Indian cold chain market facing number of challenges that directly or indirectly reduces the overall export figure. The cold chain is a system of transporting and storing vaccines at recommended temperature from the time of manufacturing to the point of end use (WHO) [8]. Some vaccines have loses their potency on exposure to heat above 80 degree Celsius. Similarly some vaccines lose their potency when it exposed to freezing temperature. And more importantly the damage is irreversible.

Objective of the study

- To analyse the problems of Indian Pharmaceutical sector
- To understand the limitations of supply chain management of API's
- To explore the recent government initiatives/policies to promote Indian Pharmaceutical sector.
- To analyse the future challenges and opportunities of.

Research Methodology

The study is attempted to analyse the limitations and opportunities of Indian Pharmaceutical industry. The analysis is based on secondary data, obtained from journals, official national and international websites and published article. The data has been analysed by bar graphs, table and line charts.

Indian Pharmaceutical market (Size and Potential)

Indian pharmaceutical market has emerged as one of the fastest growing network over past few decades. The pharmaceutical industry gives the growth of 18% per annum between 2005 to 2015 and it is expected to capture 6-7% of US \$ 760 Billion of world market by the end of 2020.

But novel corona virus has damaged the economic transaction and created many challenges for supply chain management (SCM). On 3rd of March 2020, Government of India has restricted the export of 26 Active Pharmaceutical Ingredients (API). It includes vitamin B1, B6, B12, female drug progesterone, paracetamol, antibodies that are used to treat vaginal infections like tinidazole. The step had been taken to avoid shortage of drug in the domestic market of India due to lockdown in Hubei's province of China. Hubei is one of the major sources of these raw materials. [9]

Some other substances such as metronidazol, tinidazole, progesterone acyclovir, chloramphenical, neomycin, erythromycin salts, clindamycin salts and ornidazole were other Active Pharmaceutical Ingredients that are restricted to export due to the outbreak of COVID-19. Italy is another major producer of API but they also face challenges because of corona outbreak.

API is also known as Bulk Drug. India import valued of US \$ 3.5 Billion of Active Pharmaceutical Ingredients every year. The Hubei province of China is hug of the API manufacturing industry. 70% of API's are imported from China that worth US \$ 2.5 Billion. It indicates that India is highly dependent upon the global market (majorly China) for API.

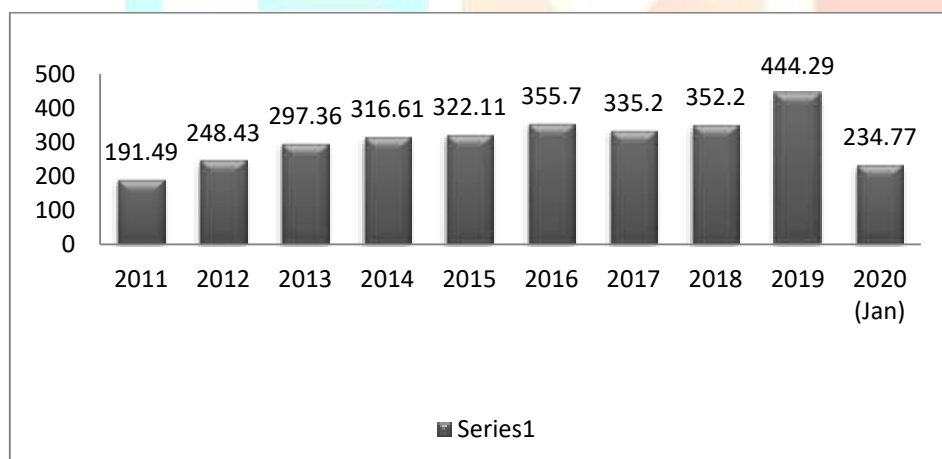
Dependency rate		
S.no	Bulk Drug	Imported from China (%)
1	Paracetamol	100%
2	Metformin	100%
3	Amoxicillin	90-95%
4	Ampicillin	100%
5	Ibuprofen	85-95%
6	Ciproflaxacin	100%

(Table 3, Data source: Pharmexcil-2018)

Import value of India's medical and Pharmaceutical product from 2011-2019

S.no	Year	Amount (in Billion)
1	2011	191.49
2	2012	248.43
3	2013	297.36
4	2014	316.61
5	2015	322.11
6	2016	355.7
7	2017	335.2
8	2018	352.2
9	2019	444.29
10	2020 (Jan)	234.77

(Table 4, source: stastica)

**(Import value of Indian medical industry)**

Recently India has prioritized production of 53 raw materials (API) as a part of “China-Plus-Policy” to fill the supply gap. Union cabinet has approved two schemes to promote domestic manufacturing of API's and Drug intermediates. The 1st scheme is **Promotion of Bulk Parks** and another is **Production Linked Incentive (PLC)** [10].

Characteristics of “*Promotion of bulk parks scheme*”

Key points	Description
No of parks	Union government plans to develop 3 Bulk drug parks in India with collaboration of state governments.
Funding	Sum of ₹ 3000crore has been approved by centre for next 5 years. State government can get “Grant-in-Aid” from central government with maximum of ₹1000crore for each bulk park.
Facilities	Park must have facilities like power and steam unit, distillation plant, solvent recovery plant, common effluent treatment plant and so on and so forth.
Objective	Main objective of the scheme is to reduce the dependency on other countries and to minimize the manufacturing cost of API's. Also aim to enhance the existing supply chain of domestic market.
Need of scheme	India is 3 rd largest by the volume of pharmaceutical industry but significantly dependent on other countries for basis raw materials.

Characteristics of “*Product linked Incentive scheme*”

Key points	Description
Aim	The main objective of PLI scheme is to promote domestic production of drug intermediates, key starting materials (KSM's) and Active Pharmaceutical Ingredients in India.
Funding	Under PLI scheme, financial aid would be provided to those companies that are eligible for manufacturing of 53 identified critical Active Pharmaceutical Ingredients by government. It will be decided by their incremental sales turnover of base year (2019-20). The fund will be allotted for next 8 years.
Impact	The scheme will reduce the India's dependency on other countries for API's and KSM's “It is expected that Product linked Incentive scheme will generate the sales of ₹46000crore and helps to generate employment for coming 8 years.

(Data source: Pharmaceuticals.gov)

Analysis

Not only Indian, but also countries like U.S.A, Germany, Italy have been facing problems in their pharmaceutical supply chain management. Every government are trying to minimize their overall damage. U.S.A has declared the public health emergency under the “*section 319 of PHS Act*” [11]. Due to COVID-19 outbreak Food and Drug Administration of America (FDA) has issued several guidelines to clarify the scope of health emergency exclusion and exemption under Drug Supply Chain Security Act (DSCSA).

India is also trying to minimize its damage by taking initiative like [12],

- Assistance to Bulk drug industry for common facility centre.
- Assistance to medical devices industries for common facility centre.
- Assistance of cluster development.
- Pharmaceutical promotion and development scheme (PPDS).

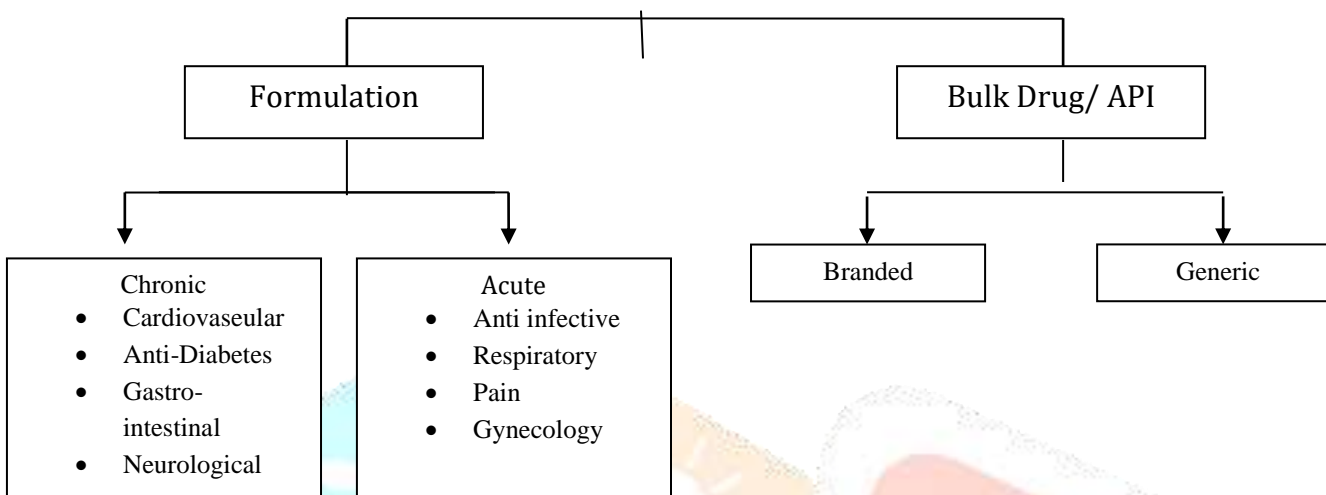
- Pharmaceutical Technology Up gradation Assistance Scheme (PTUAS)

The primary objective of all these schemes is to neutralize the damage been done COVID-19 and later on government could have focus on export to other countries.

Background of Indian pharmaceutical companies

Indian pharmaceutical industry can be broadly divided into two major segments. First one is Formulations and another is API's or Bulk Drug, bulk drug and API's can be classified as generic or branded that are used to treat chronic or acute diseases. [13]

Structure of Pharmaceutical sector



(Source – Umesh Chandra, Dr. Sridharan ISSN (e): 2321-3418, 2016)

Patent Granted to Indian companies

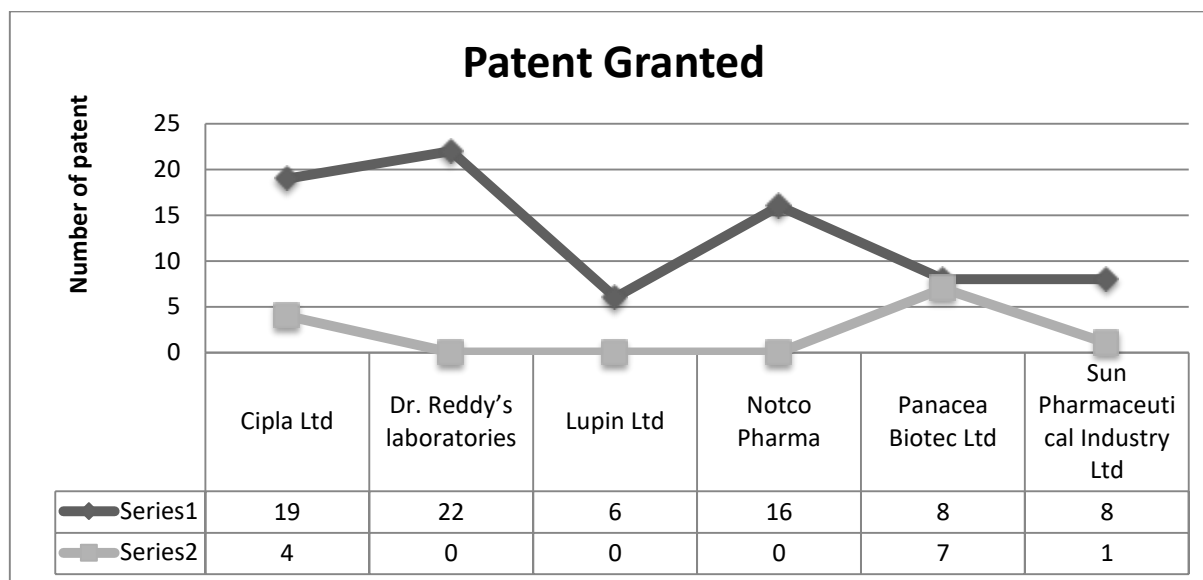
Indian government has clearly mentioned in its policy that companies will get clearance for manufacturing of 53 identified critical Active Pharmaceutical Ingredients only when they fulfil all the necessary criteria. Sales turnover of 2019-20 is one of the major criteria to enjoy the benefits given in the policy. [14]

Patents granted to Indian generic companies

Name of companies	2005-2009	2010-2013
Cipla Ltd	19	04
Dr. Reddy's laboratories	22	00
Lupin Ltd	06	00
Notco Pharma	16	00
Panacea Biotec Ltd	08	07
Sun Pharmaceutical Industry Ltd	08	01

(Table 4, source controller general of patent, design and trade mark-India)

Patent Granted



Analysis

It is visible in the above line chart that Indian pharmaceutical companies lose their patent rights over period of time. Companies like Natco Pharma and Lupin laboratories had not even file a single patent in India but on the other hand they have increased their world wide filing for patent.

Net worth of 20 largest pharmaceutical companies of India

Net worth by 2017-2016			Average annual growth rate (%)		
S.no	Company name	Net worth (US \$ Million)	Net worth (2016-2011)	Net worth (2011-2005)	Net worth (2005-1999)
1	Sun Pharmaceutical industry ltd	3165.7	32.6	33.6	28.8
2	Lupin ltd	2242.0	24.8	31.1	79.5
3	Cipla ltd	1941.7	5.4	25.2	22.8
4	Dr. Reddy laboratories ltd	1759.6	5.8	21.8	45.6
5	Glenmark Pharmaceutical ltd	1431.4	29.0	44.9	20.6
6	Aurobindo Pharma ltd	1281.7	21.2	19.6	28.5
7	Cadila healthcare	999.3	14.8	21.9	10.9
8	Biocon ltd	992.1	25.4	17.4	79.9
9	Divi laboratory ltd	820.5	13.9	35.7	32.2
10	Torrent Pharmaceutical ltd	675.6	21.2	21.1	11.6
11	Alkem laboratory ltd	666.3	12.2	20.3	40.8
12	Strides shusan ltd	490.3	19.1	40.3	17.2
13	IPCA laboratory ltd	375.5	8.6	21.6	17.3
14	Pfizer ltd	366.6	32.7	25.8	21.4
15	Glaxosmithkline Pharmaceutical ltd	307.7	-3.0	11.2	17.9
16	Nacto Pharma ltd	257.2	23.2	19.9	26.0
17	Samofi India ltd	255.6	4.1	12.0	26.3

18	Ajanta Pharma ltd	228.1	33.6	14.8	-3.1
19	IB chemicals & Pharmaceutical ltd	210.5	2.5	17.5	16.6
20	Abbott India ltd	210.4	11.8	16.3	11.9
Average			17.2	24.3	28.5

Source: The Centre for Monitoring Indian Economy (CMIE)

Sales turnover of 20 largest companies

Sales turnover		Average growth rate (%)		
Company name	in 2016-2017 US \$ Mn	1999-2000 to 2004-2005	2005-2006 to 2010-2011	2011-2012 to 2016-2017
Lupin ltd	1933.7	23.5	20.1	12.6
Cipla ltd	1665.0	25.9	13.0	3.6
Aurobindo pharma ltd	1483.7	12.5	18.9	11.4
Dr. Reddy laboratories ltd	1474.4	31.0	22.6	2.1
Glenmark pharmaceutical ltd	1228.0	27.3	23.5	35.2
Sum Pharmaceutical Ltd	1175.7	18.7	11.3	31.7
Alkem Laboratories ltd	706.0	-5.0	15.4	12.2
Torrent Pharmaceutical ltd	691.9	10.7	17.2	12.6
Divis Laboratories	616.9	16.1	31.8	10.9
Cadila Healthcare Ltd.	494.6	22.1	11.7	3.5
Ipca Laboratories Ltd	481.2	14.3	17.8	09
GlaxoSmithKline Pharmaceuticals Ltd	452.8	9.5	5.8	1.0
Abbott India Ltd	443.9	5.5	19.5	9.6
Biocon Ltd	398.8	40.2	14.1	4.9
Sanofi India Ltd	356.4	9.4	5.2	7.3
Wockhardt Ltd.	348.5	2.9	15.3	-3.7
Strides Shasun Ltd	321.0	13.1	14.8	25.9
Pfizer Ltd	310.7	15.2	5.9	11.7
Natco Pharma Ltd	306.2	14.9	15.8	32.0
Ajanta Pharma Ltd.	276.5	11.0	18.0	18.0
Average	1933.7	16.0	15.9	12.2

Source : The Centre for Monitoring Indian Economy (CMIE)

Analysis

Over period of time subsequent transformation has been seen in top 5 companies in terms of overall sales. In period of 1994-1995, 3 out of 5 companies are affiliation of foreign companies (GlaxoSmithLine, Aventis, Novartis) and two domestic companies are (Ranbaxy and Cipla). But scenario had changed in 2005-2006 when out of top 5 companies, 4 are generic companies (Ranbaxy, Dr. Reddy, Cipla and Lupin). Now in current scenario Cipla established itself as a market leader. [15]

Challenges in supply chain management (SCM) of Indian pharmaceutical industry.

- Indian pharmaceutical industry is lagging behind in research and development works. Because of insufficient R & D pharmaceutical companies fail to give real time good manufacturing. Indian companies should build their system in such a way that they can perform more effectively and efficiently. [16]
- Earning profit (maximum) is primary objective of any company/industry. But Indian pharmaceutical companies are either working under losses or with very low margin of profit. As a result pharmaceutical industry fails to attract new investors.
- Indian pharmaceutical industry of India is highly dependent upon China, especially for raw materials of generic medicines.
- Recently Indian government has launched various schemes to promote pharmaceutical sector of India, but government has to use easy and friendly policies to accelerate its domestic as well as foreign investments.
- In pharmaceutical sector skilled manpower is very essential. Government could have launched some programmes like “*Skilled India*” that focused on pharmaceutical sector.
- Continues monitoring in cold-chain market is very important, especially moving products and vaccines are required to be monitored till the time of manufacturing to end use. Companies have to ensure product received by the end users must be in appropriate and usable form.

Analysis

Most pharmaceutical companies have been using complex supply that caused ineffective and under-utilization of resources. New emerging technologies will help to grow and produce those medicines that are complex in nature. Current scenario is more challenging and dynamic. Maintaining inventories and warehouse is not sufficient now. Proper network utilisation is required to gain the effective result. It is also important for pharma companies to get ready for sudden increment in the demand in market and similarly they must have other options when they face inadequate supplies.

Collaboration between various parties (include suppliers, manufacturers, distributors), companies (both domestic and foreign) and government (state and union) is very crucial in current changing scenario. Their primary target should be to enhance the current supply chain and focus on ease of doing business to attract foreign investment.

Conclusion

The Indian pharmaceutical industry is huge and more or less it impacts the global market. But its overall contribution is not up to the mark and less than its actual potential. By taking necessary steps and implementing new policies India could dream to become the global market leader of pharmaceutical industry. India has to invest more on research and development (R & D) sector to become the market leader and attract foreign investors to expand worldwide.

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