



RESEARCH ARTICLE

INDIA'S PHARMA AND MEDICAL DEVICES STRATEGIES: AN ASSESSMENT OF THE PRODUCTION LINKED INCENTIVE (PLI) SCHEME

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ABSTRACT

India has one of the largest pharmaceutical Industries in the world. It is the largest provider of generic medicines globally, occupying a 20% share in global supply by volume, and also supplies 62% of global demand for vaccines. India ranks third worldwide for production by volume and fourteenth by value. Despite India being one of the largest exporters for generic medicine, since many years has been majorly dependent on China for raw materials like APIs, which has been a hindrance in the growth of the domestic manufacturing units. With the COVID-19 pandemic and increase in tension with China, India has decided to halt the export of many materials from China which includes APIs for bulk drug manufacturing and medical devices. This led to the extension Of the production Linked Incentive (PLI) Scheme to the pharmaceutical industry which was already in place for the electronics industry. The pandemic highlighted the fragility and interdependence of the global supply chain for prescription drugs, thus highlighting the ostentatious yet incapacitated healthcare edifice present in most countries. The Indian Pharmaceutical Industry experienced splintery incidents relating to the logistics of raw materials, Active Pharmaceutical Ingredients (APIs), excipients, and formulations. To overcome the aforementioned challenge, there was a dire need for urgent and concrete steps to ensure that India is not only self-reliant but is also capable of reducing the over-dependency of the world only on a few countries. This article analyses the Production related challenges India could face post-implementation and provides unequivocal recommendations.

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INTRODUCTION

The pharmaceutical industry of India is the third largest by volume in the world and the fourteenth largest by value. India accounts for 3.5 percent of the total drugs exported globally. In spite of these achievements, however, India continues to rely on imports of some essential raw materials, such as bulk medicines, APIs, medical devices, etc. (1) For economic reasons, bulk drugs and APIs are majorly imported in India. (2) Pharmaceutical raw materials produced in China are cheaper by 25-30 per cent on average, compared to domestic products. (1) However, the recent Covid-19 pandemic and escalation at the border have exposed India's vulnerability in this area. (3) Sadananda Gowda, Minister of Chemicals and Fertilizers, has initiated four new schemes to contribute to India's self-reliance mission in the development of 53 essential Active Pharmaceutical Ingredients (APIs) or Key Starting Materials (KSMs) and medical devices, in line with the AtmaNirbhar Bharat mission of Prime Minister Narendra Modi. (4) A committee constituted by the Department of Pharmaceuticals on drug security collated the details of APIs imported in the country and identified 53 APIs for which the country is heavily dependent on imports. Drug security of the country is dependent on its capability to guarantee un-interrupted supply of standard bulk drugs and APIs and also on the ability to improve their production to meet the demands in critical situations.(5) Self-reliance in the manufacture of drugs is therefore much needed. .(6) With a view to achieve self-reliance and minimize the import dependence of critical APIs, a scheme called "Production Linked Incentive (PLI) Scheme was launched for promotion of domestic manufacturing of raw materials required in the pharmaceutical industry namely Key Starting Materials (KSMs)/ Drug Intermediates (DIs) and Active Pharmaceutical Ingredients (APIs) In India on 20th March, 2020.(7)

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Production Linked incentives of up to INR 3,420 Crore will be awarded in the scheme tenure. (4)

OBJECTIVE

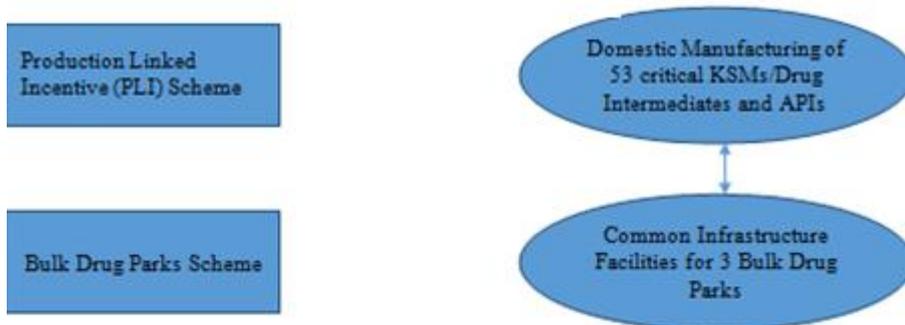
The government is likely to see the industry being benefitted from the scheme, even beyond the incentive period. The manufacturers who focus on investing in the implementation of advanced technologies are more inclined to lead the way. (8) According to the scheme, the manufacturer’s proposal would be considered if the implementation of a process can aid them to get the production commercialised earlier compared to other processes. (9). The Indian government has identified the medical devices as a priority sector for the flagship “Make in India” program and is committed to strengthen the manufacturing ecosystem.(5) India has acquired the position of being the fourth largest market for medical devices in the continent. (10) Currently the Indian market has high reliance on imports but in recent times the export have seen a surged. (11) AtmaNirbhar Bharat mission is providing an impetus to India’s vision of becoming a global manufacturing hub of medical devices. (10)

Industry Scenario

Four Indian firms are among the top 10 global generic firms. At present, the industry is estimated worth \$41 billion. Having a 71 percent market share, generic drugs form the largest segment in India. It is expected to rise as the generics exports to the US increase, as \$55 billion worth of branded drugs would go off-patent between 2017-2021. In the local market, Anti-Infectives (13.6 per cent), Cardiac (12.4 per cent) and Gastrointestinal (11.5 per cent) have the highest market division.

By 2024, it is expected that the Indian Pharmaceutical industry will reach to a \$65 bn industry.

SCHEME BRIEFING



- Application Process**
- 1) Submission of Application
 - 2) Prima Facia Examination
 - 3) Letter of Acknowledgement issued
 - 4) Application Appraisal
 - 5) Approval Letter to Applicant
 - 6) Submission of Bank Guarantee along with undertaking

- Disbursement Process**
- 1) Submission of Claim for Disbursement of Incentive
 - 2) Verification of Claims and Application for incentives
 - 3) Disbursement of Funds

Process Flow

- Proposal**
- 1) Proposal and selection
 - 2) Selection of proposal
 - 3) In Principal approval under the scheme
 - 4) Submission of DPR
 - 5) Final approval

Disbursement Process

MARKET SCENARIO

IMPORT: Production of active pharmaceutical ingredients (API) is a truly global industry. The international API supply chains are influenced by the changing demands from the drug industry, considering cost and regulatory enforcement as the highly significant factors of transition. While India is one of the leading exporters of formulations or generic medicines but for raw materials, intermediaries and APIs, China enjoys being a hegemon by staying at the number one position in the world. India imports 70% of its APIs and intermediaries from China. For the drug industry, it is a significant global source. As of 2018-19, India imported APIs and bulk drugs worth \$2.5 billion from China.(12)

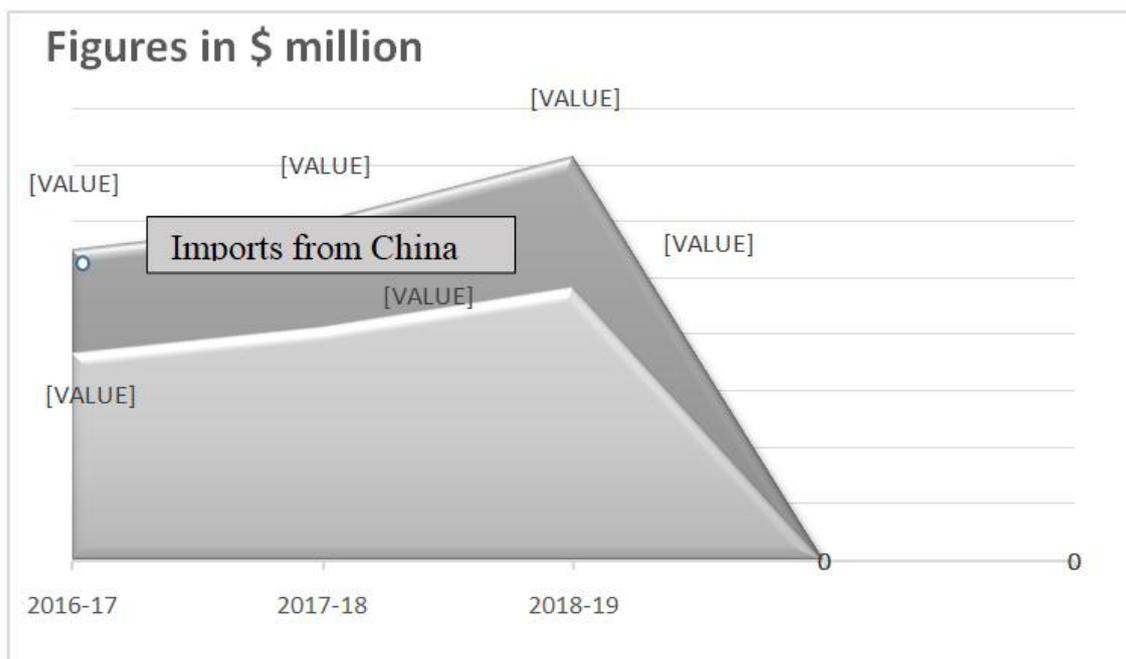
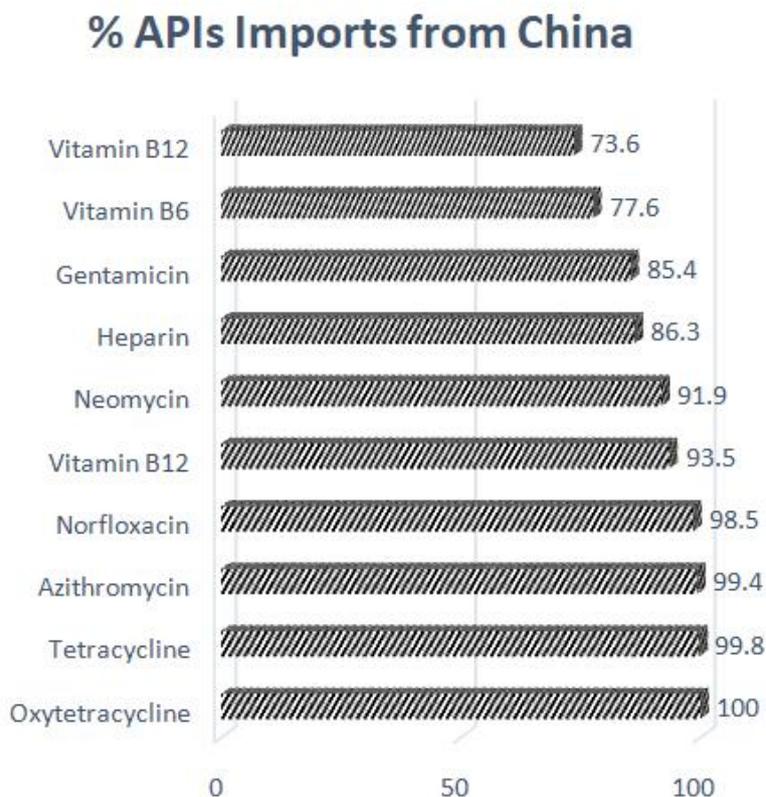


Figure 1. Total API Import.

There are many factors at play that offer China an edge, like:

-) 20-30 % lower API manufacturing cost than that of India.
-) The API production units in China are accounting for 70% of their capacity utilization. (13)
-) There are many government policies and tax incentive schemes.
-) The environmental regulations are more lax regarding hazardous chemicals which leads to a lower direct cost for manufacturers. (14)
-) It takes only 6 months to establish a factory in China.

The key drug classes where APIs are imported in large quantities from Chinese suppliers are antibiotics, ARVs, NSAIDs, Anti-epileptic, and basic cancer products. Several KSMs, solvents and nonactive ingredients are imported from China like 6APA, adenine and Penicillin G. (15) India is heavily reliant on China for various antibiotics and vitamins (shown in figure 2). Antibiotics like oxytetracycline (100%), tetracycline (99.8%), Azithromycin (99.4%), Norfloxacin (98.5%), China is the key supplier. India does not have crops to produce vitamins like; vitamin B12, Vitamin B6 and vitamin B1 and hence heavily dependent on China. Other than antibiotics and vitamins, China is also trading hormones-based medications in huge quantities to India. Production of potassium clavulanate needs strict temperature regulations and is therefore very expensive and is outsourced from China. Tinidazole is explosive in nature and manufacturing of such drugs emits a lot of pollutants, for which there are legal restrictions in India and is wholly being sourced from China. (16) According to FDA, there are three key WHO drugs whose API manufacturers are located solely in China. Two of the medicines are streptomycin and capreomycin which are used in the treatment of Tuberculosis and the third is sulfadiazine which is used for treatment of trachoma. (14) In 2018-19, bulk drugs comprised 63% of India's pharmaceutical imports. There was a total import of \$3560.35 million worth bulk drugs, out of which, \$2405.42 million worth were from China alone. That constitutes to 67.56 per cent of imports from China and resulting in two-thirds of the total imports of bulk drugs and drug intermediaries from China.(17) India largely imports bulk drugs of fermentation origins, antiviral and retroviral, and APIs used in treatment cardiovascular problems and central nervous systems and China accounts for 60% of these imports. (16) During 2007-08, China alone accounted for more than one-fifth of the imports (22.3%) from Asia.

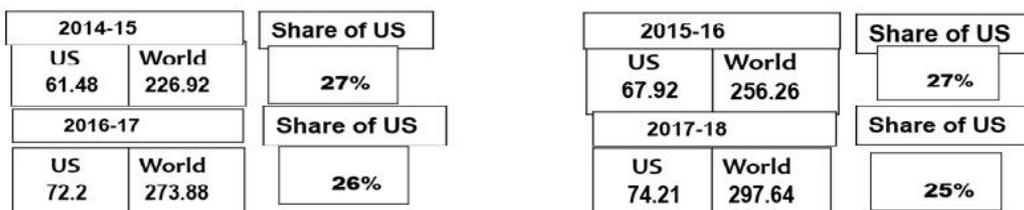


Source: KPMG-CII report.

Figure 2. Figures of FY19

In 1990-91, there was only one Asian country in the top five list for imports among the other western countries (Switzerland, USA, Italy, France) and that was Japan. During that time, China's share was very negligible, somewhere around 0.3 %.Imports from China have tremendously increased from 2001, when they started creating conducive environments to increase the production of bulk drugs in the country. This includes creating huge economic zones, technology zones, free trade zones, export processing zones and high-tech parks along with change in policies and government regulations to increase ease of doing business within the country. While China was focusing on strengthening the domestic companies, Indian companies were focusing on saving money on APIs, as it was more lucrative to outsource them rather than producing. This resulted huge trade deficit in bulk drugs and intermediates with China in pharma market and also heavy dependence on just that one country-China.(18)

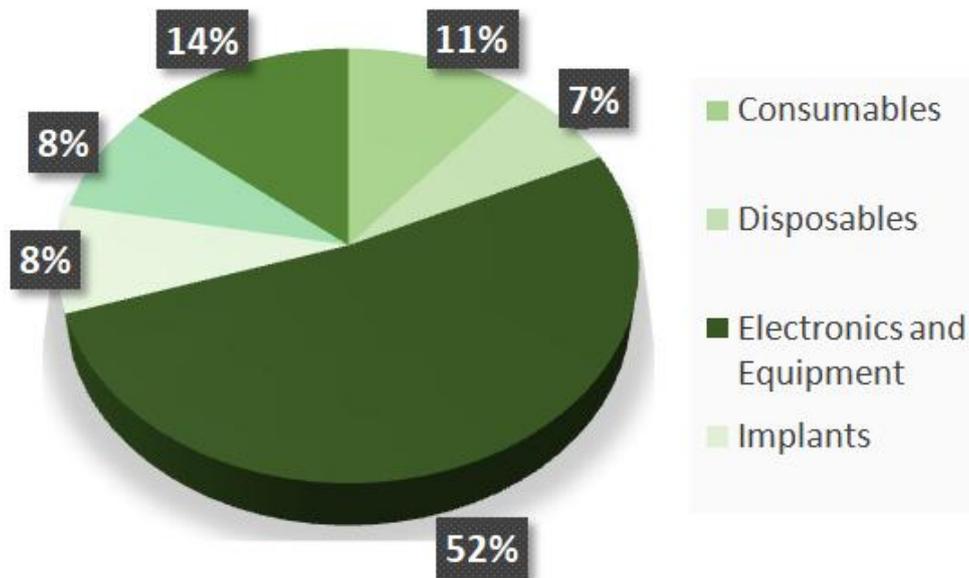
China even faced environmental repercussions, because of which many Chinese factories remained closed for almost a year to keep up with the environmental compliance. In those times, India started importing from different Asian and western countries, like; Singapore, Italy, Germany, Hong Kong, etc (19). India's medical device market is also heavily dependent on imports. Albeit, India is considered among the top twenty international medical devices market and is the fourth largest medical device market in the continent after Japan, China and Republic of Korea. (20). India's medical device market is valued close to INR 50,026 Crore for 2018-19. In FY2018-19, the imports of medical devices grew at 23.8% compared to 2017-18, around INR 43,365 Crore. According to the Government of India, the Indian medical device import market is expected to achieve a cumulative average growth rate of 17.9% from INR 35,016.2 Crore in 2017-18 to INR 79,720.1 Crore in 2021-2022.The exports in FY2018-19 were close to 16,300 Crore, way less than the imports and which brings us to the conclusion that the economy of Indian medical device market is import dependent. The USA is the largest exporter of medical devices to India. Nearly 25-30% of medical devices imported to India comes from the US. And 11% of them are from China and for some devices the dependence goes to more than 80% (21).



Source: business-standard.com

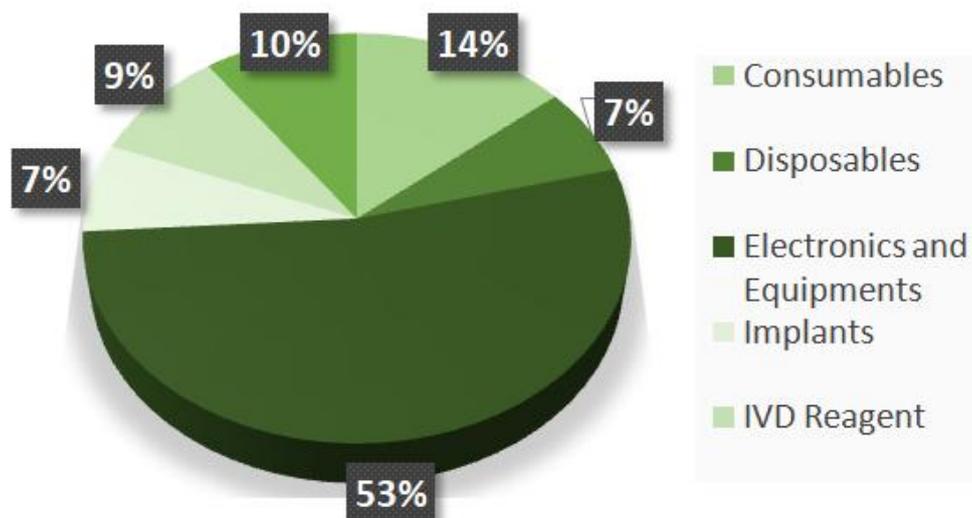
Figure 3. Import of Medical Devices

In India, the medical device market is divided into 6 major parts and electrical instruments forms the largest chunk. (Figure 4 and 5)(22).



Source: indiahealth-exhibition.com

Figure 4. Import summary of 6 Categories of Medical Devices-F.Y. 2018-19



Source: indiahealth-exhibition.com

Figure 5. Import summary of 6 categories of Medical Devices- F.Y. 2014-2015

EXPORT: India has one of the biggest active pharmaceutical ingredients industry and it has increased significantly since the 1990s. During that time the Indian API industry was quite dependant on Europe for exports of the API. From 2016 to 2022 the domestic consumption market for active pharmaceutical industry is expected to have a CGAR around 10-12%.

In the year 2022 the pharmaceutical industry is expected to reach a magnitude of 18.8 billion dollars, also as predicted by RNCOS, in the year 2016, Indian global generic API industry share was around 7.3%, being the third-largest reported by IBEF. (23) From that point, India's share has significantly improved and lead to the country becoming one of the top exporter to all major markets which also includes China. It was analysed that three years prior, India was bringing in API from china but now Indian organizations are trading to china. The major reason for this turned around situation is due to the quantity of educated researchers and drug specialists in India. (24) China's manufacturing companies have condensed bulk production because of environmental barriers. Now with the help of normalized and rigid worldwide administrative necessities, similar standards apply to all the makers in the industry. Chinese Pharmaceutical and drug industry contributes 3% to its GDP, yet represents 37% of generally contamination levels. As a result, the government of China is now engaged

more on the manufacturing and other industries. Whereas in India, the focus is majorly on the drug manufacturing and organic industry and also on ability, crude material accessibility and the ability to provide.(24)

BULK DRUGS AND DRUG FORMULATIONS: The trade of drugs and other formulations including bulk production was esteemed at 16.2 billion dollars(2015-2016). There was a very efficient and noteworthy improvement of 9.95 in the exports of the year 2016. It was noticed that bulk drugs export had decreased significantly in the year 2015 but yet, they showed improved development in the year 2015-16. In the year 2010-2011, the trades added up to 9.9\$ billion dollars enlisting development pace showing 16.5% , which expanded considerably further to a development pace of 25.3% in the next year. In any case, development rate drop down in the sequential year to 10.6% and decreased considerably further to 3.8% in 2013-2014. (25) Bulk drugs and formulations export got built by 3.5%(2014-2015) when contrasted with the year prior. Around 9.9% improvement in pace of export of pharmaceutical bulk formulations was observed in 2015-16.

Sr. No	HS Code	Product Description	EXPORTS 2018-19
1	901890	Other Instruments and appliances of Medical Science	1530
2	901839	Catheters and The Like; Other Needles	2100
3	902230	X-RAY Tubes	885
4	901819	Other Electro-Diagnostic Apparatus Including These For Functional Exploratory Examination Or For Checking Physiological Parameters	770
5	902290	Other, Including Parts and Accessories:	628
6	902214	Other, For Medical, Surgical or Veterinary Uses	427
7	382200	Compst Diagnostic/Laboratory Reagents Excl Goods of Heading. No. 3002/3006	385
8	902139	Other	341
9	902110	Orthopaedic Or Fracture Appliance	269
10	901832	Tubular Metal Needles and Needles for Suture	249
11	902780	Other Instruments and Apparatus of Heading 9027	238
12	901831	Syringes, W/N with Needles	225
13	901813	Magnetic Resonance Imaging Apparatus	223
14	300610	Sterile Surgical etc For Surgical Wound Closure sterile Laminaria etc Sterile Absorbable Surgical or Dental Haemostatics	219
15	901811	Electro-Cardiographs	211
16	902790	Microtome; Parts and Accessories of Heading 9027	206
17	901812	Ultrasonic Scanning Apparatus	199
18	901850	Other Ophthalmic Instruments and Appliances:	159
19	902131	Artificial Joints	133
20	902710	Gas or Smoke Analysis Apparatus	128
21	902750	Other Instruments and Apparatus Using Optical Radiations (UV, Visible, IR):	125
22	940290	Medical, Surgical, Veterinary Furniture and Parts	113
23	902190	Other Appliances of Heading 9021	102

(26) USA has held its capacity on the grounds of export of pharmaceutical formulations from 2010-11. (27) South Africa developed as the second biggest trade excursion spot in 2015-16 in contrast with the third greatest in 2010-11. The UK has improvised as it is now the third biggest market for drug formulation export from India eventually of the long term time frame 2010-11 to the year 2015-16. (28) Other business sectors that have developed as significant business sectors during the year 2015-26 are Brazil, Australia, Myanmar and Tanzania (29).

MEDICAL DEVICES: In 2018-19, exports of medical devices were valued at INR 14,867 crore whereas imports were INR 38948 crore with an annual growth rate of 25.29% and 24.2% respectively. The figure shows that India imports a large share of its medical device needs. (30)Its export in Asian nations of China and Thailand, also in Belgium has seen high development to the tunes of around 25% and 18% individually.

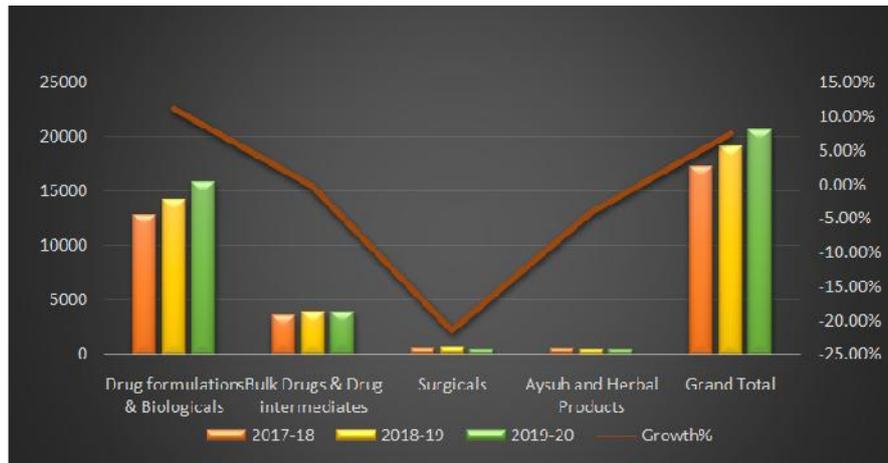
Indeed, even African nations like, South Africa has procured the most elevated CAGR of 32% during the long term length of 5 years. (31). The imports and exports have enlisted great development rates contrasted with the past three monetary years. While imports became 12%, 7% and 13% during the past three years, the export showed 5%, 14% and 1% growth. (32)

Indian Pharmaceutical Export is divided into the following categories

-) Drug formulations & Biologicals
-) Bulk Drugs & Drug intermediates
-) Surgical
-) Ayush and Herbal Products(33)

Export Market Share of India– Region-wise

Indian pharmaceutical companies export intermediates, bulk generic and branded drugs. Nonetheless, the bulk drugs that is 22% exported is quite low compared to the export of formulations and that would be 78%. (34)



Source: www.commerce.gov.in

Figure 7: Indian Class wise Exports (Value in USD Million)

EU (27) - 27 European Union countries

-) Ranking number 1 in the world for pharmaceutical exports.
-) Europe in 2015-2016 provided a contribution of 11.5% to total Indian total export of pharmaceutical products.
-) In 2015-2016 the following European countries contributed their share to Indian Export:
 - I.UK - 31.6% (Biggest share)
 - II.Germany – 10.3%
 - III.Netherlands – 10.4%
 - IV.France – 10.4%
-) Indian bulk drug export industry majorly depends on European countries
-) India exported bulk drugs worth 923.8 million dollars to European countries (2015-16). (36)

America (North):

-) Ranking 2nd in the world for pharmaceutical exports.
-) A huge contribution of 39.5% by the United States of America to Indian exports of pharmaceutical raw materials (2015-2016).
-) Indian pharmaceutical industry exports a great quantity to United States of America making them a major market. (37)
-) India exported bulk drugs worth 401.3 million dollars to USA. (2015 and 2016)
-) North America getting about 70.4% out of the total exports from India.(36)

African Regions

-) A major share of 17.7% for pharmaceutical products was provided by India to Africa , making India a big providing country for Africa
-) Countries providing pharmaceutical materials to Africa are as follows:
 - I.France – 18%
 - II.Switzerland – 6.4%
 - III.USA – 5.5%
-) Drug formulation exports of India were provided with 21.3% share from African regions (2015-2016).
-) India exported bulk drugs worth 378.5 million dollars to Africa. (2015 and 2016).(38)

Asian countries

-) Asia's contribution to India's total pharmaceutical exports of biologicals and drug preparations corresponded to 7.8%. (2015-2016)
-) Indian export of bulk formulations to various regions in Asia was worth 932.2 million dollars which corresponds to 25.7% of total bulk formulations.(38)

Latin American Regions:

-) Latin American regions contributed to India's total pharmaceutical exports of biologicals and drug preparations corresponding to 5.2%.(2015-2016)
-) India exported bulk drugs worth 233.3 million dollars to Latin American regions.(2015-2016)
-) Indian export of bulk drugs was majorly done to Brazil , resulting the Brazilian regions rank 3rd in export locations.(38)

Figure 8. Indian Pharmaceutical Exports Locality-wise (Value in USD Million)

Region	2017-18	2018-19	2019-20	Growth %
North America	5348	6145.67	7073.97	15.10%
Africa	3346.97	3436.44	3513.64	2.25%
EU	2752.64	3003.91	3140.76	4.56%
Aslan	1181.45	1310.14	1292.16	-1.37%
LAC	1135.15	1308.3	1341.37	2.53%
Middle East	869.05	1074.11	1068.22	-0.55%
South Asia	764.33	812.84	873.36	7.44%
CIS	733.17	788.27	905.23	14.84%
Asia (Excluding Middle East)	627.3	693.62	772.87	11.43%
Oceania	320.25	340.84	343.41	0.76%
Other European Countries	150.99	162.86	202.99	24.64%
Other America	52.48	57.38	57.83	0.80%
US Minor Outlying Islands	0	0.1	0.07	-34.97%
Others	0.02	0	0.02	
Grand Total	17281.81	19134.49	20585.89	7.59%

Source: DGCIS Database



Source: Trademap, ITC Geneva, Exim Bank Analysis

Figure 9. India's Exports to other Countries and India's contribution in Worldwide Exports

POTENTIALS OF PLI

With the implementation of PLI, the Indian Pharmaceutical Industry is going to see many opportunities opening up in the domestic market.

Boost in domestic manufacturing: India contributes 20 per cent of the world's generic medications by volume, and provides more than 60 per cent of the global demand for various vaccines and antiretroviral drugs, while India's import of APIs has continued to rise: CAGR increased by 8.3 per cent by 2019. India imports APIs from China (70%), USA (4%), Italy (3%), Hong Kong (2%) and Singapore as well. (39). When the pandemic hit, it opened the country's eyes to harsh reality and realised their standing when it came to raw material manufacturing and our dependence on China's imports. The situation caused the government to launch the PLI scheme in electronics which was then extended to the Pharmaceutical sector offering financial incentives to companies applying for manufacture of KSMs/APIs/Bulk Drugs. The Production Linked Incentive scheme aims to boost the local production of bulk drugs and medical devices. This will encourage more manufacturers to set up manufacturing plants and decrease India's reliability on other countries for import of raw materials. (40)

Generation of jobs: With the boost of domestic manufacturing, more companies will set up manufacturing plants and thus that will result in significant generation of jobs (41).

Development of non-industrial parts of the country especially north and north east: With the scheme, the government is proposing to offer grant-in-aid of Rs.1000 Crore per Bulk Drug Park or 90% of the project cost of Common Infrastructure Facilities for development in North-east regions or hilly areas compared to 70% for other regions. Though the policies do not intend to show partiality or favouritism to any state, North and North-East regions of the country have immense potential to provide which can be explored further by the manufacturing companies. (42)

Reduction in cost of the final product: With the Government providing financial incentives, there is a possibility that the KSMs/APIs/Bulk Drugs will have a lower price when supplied to the industry for manufacturing of formulations.

Attraction of foreign investment: With the financial incentives in play and India being a huge Pharma market, the PLI scheme will attract many foreign companies. The investment cost for foreign companies will be low considering the land and labour costs are relatively lower in India. Even though the policy is more focused on domestic sales for the time being, the policy can be modified for export which can provide a huge opportunity for India to become the next export hub for APIs and provide immense potential for foreign companies.

Fermentation based products and chemical based products: The PLI scheme offers more incentives on fermentation based KSMs/APIs/Bulk Drugs when compared to Chemical based. This will encourage more production of fermentation based products than chemical based (43)

Self-Reliance and decreased dependence on other countries: As we have experienced in the pandemic of 2020, the Indian Pharmaceutical Industry struggled to obtain starting materials when the pandemic hit and supply of raw materials from China came to a halt. To avoid this kind of situation, Governments all over the world are focusing on making their countries self-reliant in all kinds of industries. The PLI scheme launched by the Government of India will have a major impact on making India self-reliant and to avoid panic in case the world comes to a standstill. (44)

Emerging as a hub for global exports: Though the scheme talks about domestic sales, the scheme has potential to be modified to include export of the KSMs/APIs/Bulk Drugs (45)

The existing scheme provides various incentives and support to the Indian Pharma Industry and is already showing practical opportunities as around 29 companies have signed up for the Production Linked Incentive scheme and four states have signed up for establishing medical parks, but it still has a lot of room for improvement which will be explored later in the article. (46)

CHALLENGES:

Imported bulk drugs are cheaper compared to domestically manufactured bulk drugs: The biggest issue faced by Indian producers is the high production costs. And the actions taken, definitely moves in the right direction. But professionals from industry are in question as to whether filling the void will be enough. There is currently a 23 per cent gap in API production costs between China and India.(47)

Price capping might discourage investment: The benefits of the schemes are related to production capping. To obtain incentives, the players must continue to produce at capped limits. The reason China's price advantage is so big is due to economies of scale. And the lack of that creates a competitive disadvantage for the industry. This is the reason why economies of scale are giving rise to lower per-unit costs. Skilled labour and advanced technology boost production capacity. Also, lower per-unit costs that may come from bulk purchases from suppliers, larger advertising purchases, or lower capital costs. Also, the spread of internal costs across more units produced and sold, reduces the cost. Due to this reason many of the investors and big giants in the industry are not in favour of investing under this scheme.(48)

Green field project vs brownfield (unused capacity): Only 'greenfield' projects or the financing of new facilities are covered under the program. As a result, the real gain would take more than one year, the time required for setting up new facilities, in new or in existing plants. Free capacities of almost 30% for several existing units would not be eligible under the policy. (48). Though the existing manufacturer can also be eligible for the production of bulk drugs by adding some additional facilities and modifications as per requirements.(49)

Lack of ecosystem for growth of bulk drug industry: Even though India has advanced technological capabilities, skilled manpower and high quality manufacturing standards. But still lacks on various grounds like; Inadequate infrastructure, support for research and development, low government support and multiple regulatory bodies, high cost of finance, and delays in land acquisition and environmental clearances. Loans are available for the pharmaceutical industry typically at higher interest rates and over short term tenures. So the government should make provisions for the same for the growth of industry. On the other hand China has developed this ecosystem through subsidies, Loans at lower rates and tax holidays. The borrowing rate in China is 4 to 5 percent, while it is close to 12 to 14 percent in India. China is also higher in the Ease of Doing Business Rankings of the World Bank: it moved up from rank 46 in 2018 to 31 in 2019, while India moved from rank 77 to 63. Also, it takes around 1 year to set up an API manufacturing unit in China while it takes more than 4 years in India

for the same. So it is required that the government should broaden the scope of the schemes which will attract more players. (50)

Schemes in other countries: Countries such as Japan, America and Europe are also driving more firms to rely less on China. Japan is offering Japanese companies in China 23 billion Yen to switch to other countries. The US government also granted Phlow Corp a contract worth \$812 million to guarantee the production of ingredients and generics against drug shortages. In Europe, French drugmaker Sanofi SA is setting up a supplier of APIs to reduce China's dependency. India must therefore stand out in order to encourage more firms to invest in the PLI scheme. (39)

CONCLUSION

The Government introduced the schemes in accordance with Atma-Nirbhar-Bharat objectives and industry players opt the same, some variables like including the pricing of APIs by Indian producers, the value of formulations / APIs available on the market, demand in different areas, including local demand, logistics expenses and so forth cannot be ignored. The economic circumstances need to allow investors and players to create a positive value structure for India's manufacturing and expansion. It is a continuous process and strategic steps on the part of policy makers will help the API manufacturing sector to relive and shine.

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REFERENCES

1. Bureau FE 2020, July 24. *Govt notifies incentive schemes for API/medical devices manufacturing*. Retrieved from <https://www.financialexpress.com/industry/govt-notifies-incentive-schemes-for-api-medical-devices-manufacturing-check-details/2033277/>
2. Department of Pharmaceuticals, 2020. *Production Linked Incentive PLI. Scheme for promotion of domestic manufacturing of critical Key Starting Materials KSMs. / Drug Intermediates and Active Pharmaceutical Ingredients APIs. In India and Scheme for Promotion of Bulk Drug Parks*. Retrieved from <https://pharmaceuticals.gov.in/schemes/production-linked-incentive-pli-scheme-promotion-domestic-manufacturing-critical-key>.
3. TV Padma, 2020, April 06. *India looks to cut reliance on China for APIs*. Retrieved from <https://www.bioworld.com/articles/434213-india-looks-to-cut-reliance-on-china-for-apis>
4. Swarajya Staff 2020, July 23. *Modi Govt Unveils 3 Production Incentive Schemes Worth Rs 12,000 cr to Boost Local Manufacturing of API, Medical Devices and Bulk Drugs*. Retrieved from <https://swarajyamag.com/news-brief/modi-govt-unveils-3-production-incentive-schemes-worth-rs-12000-cr-to-boost-local-manufacturing-of-api-medical-devices-and-bulk-drugs>
5. Invest India last updated on 2020, October 29. *Schemes for Pharmaceutical Manufacturing*. Retrieved from <https://www.investindia.gov.in/schemes-for-pharmaceuticals-manufacturing>
6. Business Standards 2020, June 30. *Countries prod firms to reduce dependence on China but find few takers*. Retrieved from https://www.business-standard.com/article/international/countries-prod-firms-to-reduce-dependence-on-china-but-find-few-takers-120063001393_1.html
7. Department of Pharmaceutical, GOI 2020. *Schemes and Guidelines*. Retrieved from <https://pharmaceuticals.gov.in/schemes>.
8. Press Information Bureau, Government of India 2020, March 21. *Cabinet approves promotion of the Domestic Manufacturing of Medical Devices in country*. Retrieved from <https://pib.gov.in/Pressreleaseshare.aspx?PRID=1607485>
9. Pharmexcil, 2018, July 12. *Scheme for Development of Pharmaceutical Industry*. Retrieved from https://pharmexcil.com/uploadfile/ufiles/1632160518_Scheme%20for%20Development%20of%20Pharmaceutical%20Industry.pdf.
10. EP News Bureau, 2020, August 12. *Mission AtmaNirbhar in pharma*. Retrieved from <https://www.expresspharma.in/latest-updates/mission-atma-nirbhar-in-pharma/>.
11. Pharmexcil, 2018, July 12. *Scheme for Development of Pharmaceutical Industry*. Retrieved from <https://pharmexcil.com/circulars/scheme-for-development-of-pharmaceutical-industry/10179/1d03b0b5c487f2c6e8b666b7e630cb83.html>
12. The Economic Times, 2020, July 01. *Govt incentives will help Indian pharma cos reduce API imports from China: Tata Mutual Fund*. Retrieved from <https://economictimes.indiatimes.com/markets/expert-view/govt-incentives-will-help-indian-pharma-cos-reduce-api-imports-from-china-tata-mutual-fund/articleshow/76713281.cms>.

13. Deepika Khurana, Dr.Sobuhi Iqbal, 2020, January 03. *Why India depends heavily on China for drug raw materials?* Retrieved from <https://www.ha-asia.com/why-india-still-depends-on-apis-imported-from-china/>.
14. Patricia Van Arnun, 2019, November 20. *API Sourcing: The Supply Side for US-Marketed Drugs*. Retrieved from <https://www.dcatvci.org/6213-global-api-sourcing-which-countries-lead>.
15. The Economic Times 2020, February 19. *Coronavirus: Pharma stocks that may gain or lose from China disruption*. Retrieved from <https://economictimes.indiatimes.com/markets/stocks/news/coronavirus-pharma-stocks-that-may-gain-or-lose-from-china-disruption/high-dependence/slideshow/74204459.cms>
16. B. Krishna Mohan, 2020, June 25. *'Boycott China' to have side-effects on pharma*. Retrieved from <https://telanganatoday.com/boycott-china-to-have-side-effects-on-pharma>.
17. PIB Delhi, 2020, March 17. *Import of Bulk Drugs/APIs*. Retrieved from <https://pib.gov.in/PressReleaseIframePage.aspx?PRID=1606725>
18. Pharmacompass, 2016. *Indian Custom Trade Statistics*. Retrieved from <https://www.pharmacompass.com/import-api-india-hs-code>
19. Joseph, Reji. 2009. *India's Trade in Drugs and Pharmaceuticals: Emerging Trends, Opportunities and Challenges*. East Asian Bureau of Economic Research, Trade Working Papers. 26.
20. Informa markets, *Healthcare insights for India*. Retrieved from <https://www.indiahealth-exhibition.com/content/dam/Informa/indiahealth-exhibition/en/downloads/INDIA%20Health-Import%20Export%20Report.pdf>
21. Teena Thacker, 2020, February 02. *Government proposes health cess on import of medical equipment*. Retrieved from <https://economictimes.indiatimes.com/industry/healthcare/biotech/healthcare/government-proposes-health-cess-on-import-of-medical-equipment/articleshow/73839367.cms?from=mdr>
22. Make in India, 2017. *Sector survey: Medical devices*. Retrieved from <https://www.makeinindia.com/article/-/v/sector-survey-medical-devices>
23. IBEF, 2020, June. *Pharmaceutical Exports From India*. Retrieved from <https://www.ibef.org/exports/pharmaceutical-exports-from-india.aspx>.
24. GB Reports, 2020, March 17. *India's API Industry: Exporting to the World*. Retrieved from <https://www.gbreports.com/article/indias-api-industry-exporting-to-the-world>.
25. CPhI Worldwide, 2019, November. *Global API industry snapshot Pharma demands and evolving markets*. Retrieved from <https://www.cphi.com/content/dam/Informa/cphi/europe/en/2020/zone-pages/HLN19CPW-SP-API-article.pdf>.
26. Sumana Sarkar, Simaran Kaur, 2016. *Indian Pharmaceutical Industry: Challenges and Prospects*. Exim Bank India. 55.
27. Sumana Sarkar, Simaran Kaur, 2016. *Indian Pharmaceutical Industry: Challenges and Prospects*. Exim Bank India. 56.
28. Sumana Sarkar, Simaran Kaur, 2016. *Indian Pharmaceutical Industry: Challenges and Prospects*. Exim Bank India. 71-72
29. Sumana Sarkar, Simaran Kaur, 2016. *Indian Pharmaceutical Industry: Challenges and Prospects*. Exim Bank India. 73-74
30. Department of Pharmaceuticals, 2020, March 06. *Annual Report 2019-2020*. Retrieved from <https://pharmaceuticals.gov.in/sites/default/files/Annual%20Report%202019-20.pdf>.
31. EEPC India, 2013, December. *Strategy Paper to Boost India's Exports of Medical Device & Pharma Machinery Sector*. Retrieved from <https://www.eepcindia.org/download/MedicalDeviceStrategyPaper-170614122943.pdf>.
32. Vasundhara Rastogi, 2019, July 4. *India's Export and Import Trends 2018-19*. Retrieved from <https://www.india-briefing.com/news/indias-export-import-trends-2018-19-18958.html/>.
33. Department of Commerce, 2020, January 11. *Export Products Pharmaceuticals*. Retrieved from <https://commerce.gov.in/InnerContent.aspx?Id=506>.
34. Dr. Enrico T. Polastro, Arthur D. Little, 2016, January 28. *The Western API Industry*. Retrieved from https://www.contractpharma.com/issues/2016-01-01/view_features/the-western-api-industry/
35. Vasireddy, U. & Mohan, G.K. & Narasu, M.L. & Appaji, P.V.. 2011. *Impact of India's formulation and bulk drug registrations with U.S. FDA on its exports: A stochastic analysis*. *Der Pharmacia Lettre*. 3. 84-100.
36. EFPIA, 2018. *The Pharmaceutical Industry in Figures*. Retrieved from https://www.efpia.eu/media/361960/efpia-pharmafigures2018_v07-hq.pdf.
37. Reghu Balakrishnan, Shine Jacob, 2016, February 06. *No major impact on API import ban in US*. Retrieved from <https://www.livemint.com/Industry/4rAq0q5PwhPPiw7JcaU4wL/No-major-impact-on-API-import-ban-in-US.html>.
38. Sumana Sarkar, Simaran Kaur, 2016. *Indian Pharmaceutical Industry: Challenges and Prospects*. Exim Bank India. 58-59.
39. Pranit Sarda, 2020, September 2. *How to fix Indian pharma's Chinese import problem*. Retrieved from <https://www.forbesindia.com/article/healthcare-special/how-to-fix-indian-pharmas-chinese-import-problem/62239/1>.
40. G Naga Sridhar, 2020, June 18. *Pharma API imports from China: India moving towards self-reliance*. Retrieved from <https://www.thehindubusinessline.com/economy/pharma-api-imports-from-china-india-moving-towards-self-reliance/article31861501.ece>.
41. Our Bureau, 2020, July 29. *PLI scheme for promoting bulk drugs industry in India will help self-reliance in API production: FICCI*. Retrieved from <http://www.pharmabiz.com/NewsDetails.aspx?aid=129969&sid=2>.
42. Nandika Chand, 2020, September 26. *Production Linked Incentive PLI. scheme worth Rs 15,000 crore for Pharmaceutical Industry*. Retrieved from <https://mybigplunge.com/politics/atmanirbhar-bharat-self-reliance/production-linked-incentive-pli-scheme-worth-rs-15000-crore-pharmaceutical-industry/>.

43. Usha Sharma 2020, June 13. *Pharma MSMEs ask government to extend incentives of PLI scheme*. Retrieved from <https://www.expresspharma.in/latest-updates/pharma-msmes-ask-government-to-extend-incentives-of-pli-scheme/>
44. Pankaj Poddar, 2020, July 02. *Why Indian pharma companies should reduce dependency on import of APIs from China?* Retrieved from <https://www.timesnownews.com/business-economy/industry/article/why-do-we-need-to-be-self-reliant-in-apis/615239>
45. Ben Hargreaves, 2020, March 26. *India invests to boost domestic API manufacture*. Retrieved from <https://www.outsourcing-pharma.com/Article/2020/03/26/India-to-boost-domestic-API-industry>.
46. TimsyJaipuriya, 2020, October 8. *Pharma PLI scheme: 29 companies sign up to take benefits, more to apply soon*. Retrieved from <https://www.cnbc18.com/healthcare/pharma-pli-scheme-29-companies-sign-up-to-take-benefits-more-to-apply-soon-7130981.html>.
47. Sohini Das 2020, July 22. *Govt notifies incentive scheme for local API manufacturing to cut imports*. Retrieved from https://www.business-standard.com/article/companies/govt-notifies-incentive-scheme-for-local-api-manufacturing-to-cut-imports-120072201580_1.html
48. Teji Mandi, 2020, July 28. *Teji Mandi: Leaping towards self-reliance in Pharma*. Retrieved from <https://www.freepressjournal.in/business/teji-mandi-leaping-towards-self-reliance-in-pharma>.
49. Usha Sharma 2020, July 27. *PLI scheme guidelines evoke mix reviews from industry*. Retrieved from <https://www.expresspharma.in/expert-opinions/pli-scheme-guidelines-evoke-mix-reviews-from-industry/>.
50. Neetu Chandra Sharma, 2020, August 27. *Pharma firms worried about some provisions in production-linked incentive scheme*. Retrieved from <https://www.livemint.com/news/india/pharma-firms-worried-about-some-provisions-in-production-linked-incentive-scheme-11598529099195.html>
