



Confederation of Indian Industry

BOOSTING INDIA'S PHARMACEUTICAL EXPORTS

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Tel: +91-11-24629994-7, Fax: +91-11-24626149; Email: info@cii.in; Web: www.cii.in

Table of Contents

Introduction	1
Recent Trends – India and the World	3
Global Trends	3
Domestic Trends	5
Recent Policies and Initiatives in the Pharma Sector	9
Production Linked Incentive Schemes	9
Identifying Indian Pharma Exports of High Potential	11
Data and Methodology	11
Key Findings	12
Identifying Potential Export Destinations for India’s High Potential Pharma Exports	14
Current Challenges & Policy Prescriptions	16
Conclusion	22
References	27



List of Charts

Chart 1: World Export Values of Pharmaceutical Products, US\$ billion	3
Chart 2: India Export Values of Pharmaceutical Products, US\$ billion	5
Chart 3: India's Global Share of Pharmaceuticals	6
Chart 4: Top Potential Export Destinations for India /Top Importers	14
Chart 5: India's Score in International IP Index, 2021	18

List of Tables

Table 1: World Top Pharma Exports	4
Table 2: World Top Pharma Imports	8
Table 3: India's Top Pharma Exports	6
Table 4: India's Top Pharma Imports	7
Table 5: India's Top 5 Import and Export Partners for Pharma Products	12
Table 6: Top Export Destinations for Identified Exports	15

Annex

Table 1: PLI Scheme for Pharmaceuticals	23
Table 2: PLI Scheme for Bulk Drugs	24
Table 3: India's Potential Pharma Exports using RCA ^W (US\$ million)	25
Table 4: India's Potential Pharma Exports using RCA ^P (US\$ million)	26

Introduction

The Indian pharmaceutical industry enjoys a significant global presence and has witnessed notable growth over the last few years. India is the largest supplier of generic medicines in the world, occupying a 20% share in global supply. It is the third largest in the world in terms of pharmaceutical production by volume and ranks 14th¹ by value.

As per estimates of the Economic Survey 2021², the Indian pharma sector was valued at US\$ 41 billion and is expected to grow to US\$ 65 billion by 2024 and around US\$ 120-130 billion by 2030.

With a strong network of more than 10,500³ manufacturing facilities and more than 3000 pharma companies, India holds the record of having the highest number of US-FDA compliant pharma plants outside of USA.

India is also the largest producer of vaccines in the world and supplies 62%⁴ of global demand for vaccines. Presently, it is among the top 12 biotechnology destinations in the world and accounts for around 3% of the global biotech industry. The sector also plays a critical role in the global vaccine market as India leads the world supply of DPT, BCG and measles vaccines, among others.

India is also quickly emerging as a leading innovator in biosimilar production. It was among one of the first countries in the world to approve and market a biosimilar in 2000, following which more than 98 biosimilars were approved in India through September 2019⁵.

Over the five-year period between 2019-2025, the Indian biologics market is expected to grow at a CAGR of 22% to reach US\$ 12 billion by 2025. Thus, together with biosimilars, the biologics market presents a huge opportunity for India.

India is a major exporter of drugs and medicines and exports to more than 200 countries across the world including the USA, the UK, Canada, and the European Union, among others. Exports of India's drugs and pharmaceuticals reached US\$ 19.38 billion in FY 2020-21.⁶

The Indian pharma sector has been the recipient of steady foreign direct investment (FDI) flows over the years. Between April 2000 and September 2021, the industry received cumulative FDI inflows worth around US\$ 18.6 billion.

The Covid-19 pandemic has propelled the growth of the Indian pharma industry rapidly and presents several opportunities for higher growth in the future. India's pharma exports as a

1 <https://www.investindia.gov.in/sector/pharmaceuticals>

2 https://www.indiabudget.gov.in/economicsurvey/doc/vol2chapter/echap03_vol2.pdf

3 <https://www.investindia.gov.in/sector/pharmaceuticals>

4 <https://www.investindia.gov.in/sector/pharmaceuticals>

5 https://birac.nic.in/webcontent/Knowledge_Paper_Clarivate_ABLE_BIO_2019.pdf

6 <https://www.ibef.org/download/Pharmaceuticals-November-2021.pdf>



share of its total exports registered a sharp increase during the pandemic which provided the opportunity for India to be known as the “pharmacy of the world”. A skilled workforce, a significant raw material base, deep technical capabilities, and rich scientific acumen are some of the primary drivers that have helped India to grow as a global hub for generic medicines and emerge as a successful centre for innovation.

At the same time, the Covid-19 pandemic also triggered a move towards expanding domestic manufacturing, particularly in the Active Pharmaceutical Ingredients (API) segment. India’s domestic API consumption is expected to reach around US\$ 19 billion by FY 2022⁷. The country’s import dependence on APIs has been very high, with more than 60% sourced from emerging markets⁸. The sharp rise in the prices of APIs imported from China in recent years, combined with the supply shock as a result of supply chain disruptions in the aftermath of the Covid-19 pandemic⁹, has been a cause of great concern for India. This in turn has made indigenous production of APIs an imperative. The Production Linked Incentive (PLI) schemes for various segments of the industry introduced by the Government in September 2020, aggregating support of over US\$ 2 billion is a welcome move in this direction and will help strengthen domestic manufacturing.

While India is the third largest producer of pharmaceuticals in the world in terms of volume, it ranks 14th in terms of value, indicating that there is considerable scope for scaling up the value of production. It is important to consolidate the gains and take India’s pharmaceutical sector further up the value chain, with a focus on reducing import dependence in certain sectors and boosting indigenous production. In addition, although India’s share in global pharma exports has risen between 2011 and 2020, it still contributes less than 3% of global export value and the share has been stagnant in recent years. Given its skills to produce high volumes and meet stringent standards and norms in key global markets, the potential for further raising exports is significant. Identifying the right products which have high potential in international markets in terms of competitive advantage is critical in this regard. This in turn will help boost India’s exports, while also expanding global shares of its pharmaceutical products.

Given this background, this report undertakes a Revealed Comparative Advantage (RCA) analysis to identify India’s pharmaceutical exports with high potential or high competitive advantage in the world, at the HS 6-digit level, that would help bolster Indian trade and investments in the sector further. The novelty of this paper is that in addition to using the conventional RCA index which calculates a product’s comparative advantage in relation to aggregate world export share, it uses a modified RCA index which analyses the competitive advantage of Indian pharmaceutical products with respect to the global pharmaceutical space.

The paper also identifies the potential export destinations for India in the world for these products. In addition, this report provides a broad overview of the Indian Pharma Industry including recent trends and patterns, along with the policies and incentive schemes that are in place currently. Finally, policy prescriptions are provided for overall growth of the sector that would also help address the recent challenges faced by the industry.

7 <https://www.ibef.org/download/Pharmaceuticals-July-2019.pdf>

8 <https://www.ibef.org/download/Pharmaceuticals-July-2019.pdf>

9 <https://www.livemint.com/companies/news/can-india-still-be-pharmacy-of-the-world-while-reducing-import-dependence-of-apis-11600094236499.html>

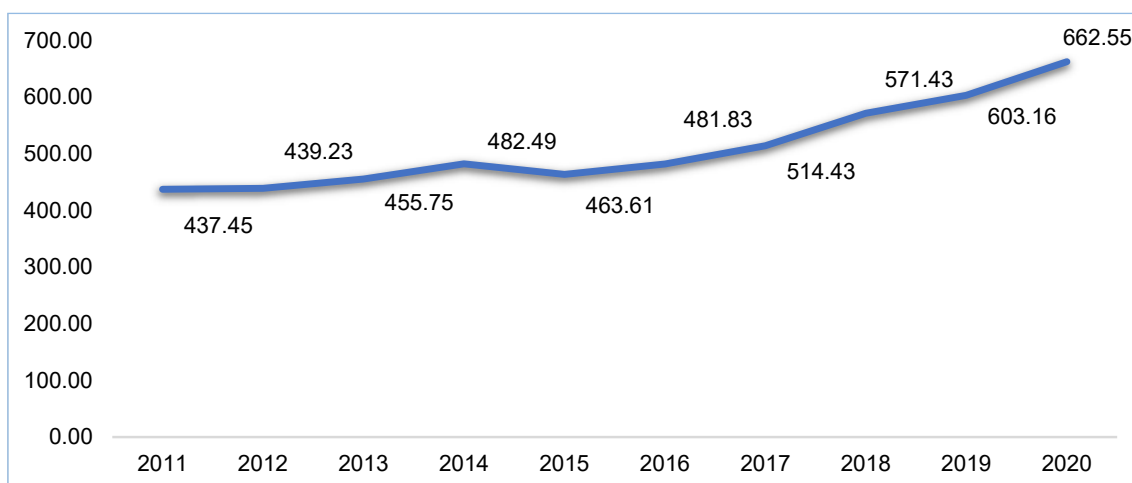
Recent Trends – India and the World

Global Trends

World Exported Values of Pharmaceuticals

Over the last decade, between 2011 and 2020, world exports of pharmaceuticals grew from US\$ 437.45 billion to US\$ 662.55 billion, recording a compound annual growth rate (CAGR) of 4.72% over the 10-year period.

Chart 1: World Export Values of Pharmaceutical Products, US\$ billion



Source: International Trade Centre

The top pharmaceutical export in the world at the HS 6-digit level is medicaments for therapeutic or prophylactic purposes (HS 300490), which recorded an exported value of around US\$ 307 billion in 2020. Other top pharmaceutical exports belong to the categories of immunological products (HS 300215); vaccines for human medicine (HS 300220); antisera and other blood fractions (HS 300212) and medicaments containing hormones or steroids used as hormones but not antibiotics (HS 300439), among others.



Table 1: World Top Pharma Exports

Product code	Product label	Exported value in 2020, US\$ billion
300490	Medicaments consisting of mixed or unmixed products for therapeutic or prophylactic purposes, ...	307.06
300215	Immunological products, put up in measured doses or in forms or packings for retail sale	128.97
300220	Vaccines for human medicine	30.53
300212	Antisera and other blood fractions	29.64
300439	Medicaments containing hormones or steroids used as hormones but not antibiotics, put up in ...	28.48
300420	Medicaments containing antibiotics, put up in measured doses "incl. those in the form of transdermal ...	14.86
300214	Immunological products, mixed, not put up in measured doses or in forms or packings for retail ...	13.57
300290	Human blood: animal blood prepared for therapeutic, prophylactic or diagnostic uses; toxins, ...	9.82
300432	Medicaments containing corticosteroid hormones, their derivatives or structural analogues but ...	9.58
300431	Medicaments containing insulin but not antibiotics, put up in measured doses "incl. those in ...	7.20

Source: International Trade Centre

World top pharma imports

Medicaments for therapeutic or prophylactic purposes (HS 300490) was the top pharmaceutical import in the world for the year 2020. Other top imports belonged to the categories of immunological products (HS 300215); medicaments containing hormones or steroids used as hormones but not antibiotics (HS 300439); vaccines for human medicine (HS 300220) and antisera and other blood fractions (HS 300212), among others.

Table 2: World Top Pharma Imports

Product code	Product label	Imported value in 2020, US\$ billion
300490	Medicaments consisting of mixed or unmixed products for therapeutic or prophylactic purposes, ...	332.31
300215	Immunological products, put up in measured doses or in forms or packings for retail sale	116.25
300439	Medicaments containing hormones or steroids used as hormones but not antibiotics, put up in ...	36.94
300220	Vaccines for human medicine	34.62

Product code	Product label	Imported value in 2020, US\$ billion
300212	Antisera and other blood fractions	29.18
300214	Immunological products, mixed, not put up in measured doses or in forms or packings for retail ...	23.55
300420	Medicaments containing antibiotics, put up in measured doses "incl. those in the form of transdermal ...	16.09
300290	Human blood; animal blood prepared for therapeutic, prophylactic or diagnostic uses; toxins, ...	10.60
300431	Medicaments containing insulin but not antibiotics, put up in measured doses "incl. those in ...	10.15
300432	Medicaments containing corticosteroid hormones, their derivatives or structural analogues but ...	10.00

Source: International Trade Centre

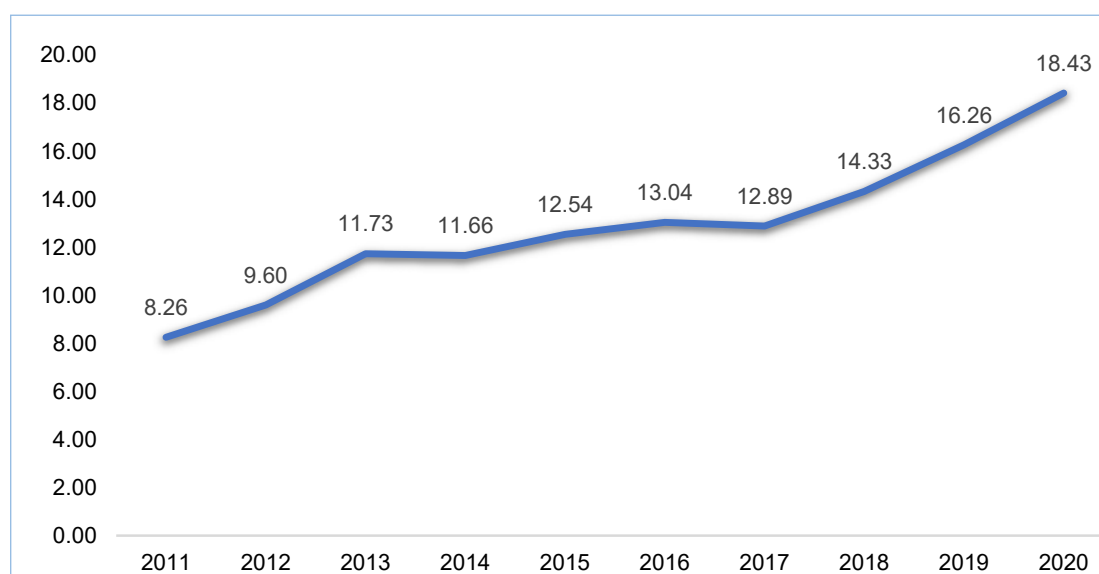
Domestic Trends

India Exported Values of Pharmaceuticals

Indian exports of pharmaceutical products grew from US\$ 8.26 billion in 2011 to US\$ 18.43 billion in 2020. Over the 10-year period, Indian pharma exports registered an impressive CAGR of more than 9%.

During the same decade, global share of Indian pharma exports increased from around 1.9% in 2011 to 2.78% in 2020.

Chart 2: India's Export Values of Pharmaceutical Products, US\$ billion



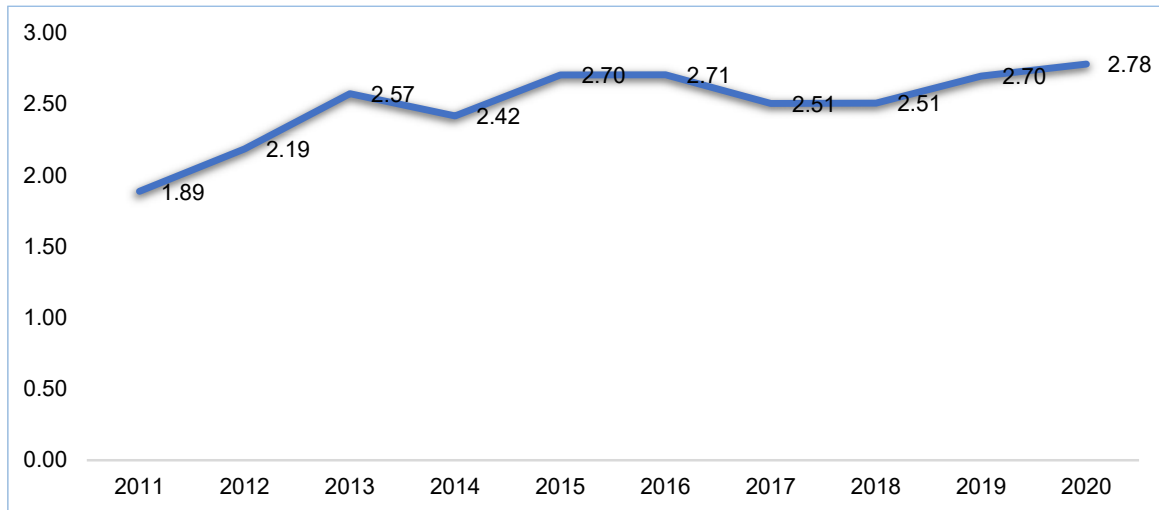
Source: International Trade Centre



India's Global Share of Pharma Products

Though the global share of Indian pharmaceutical products has increased over time, there is further potential for increasing the share by targeting products with high potential and boosting domestic manufacturing of identified products.

Chart 3: India's Global Share of Pharmaceuticals



Source: International Trade Centre

India's Top Pharma Exports

India is one of the largest producers of pharmaceutical products in the world and ranked 11th in 2020¹⁰. Its total pharmaceutical exports in 2020 stood at US\$ 18.43 billion with an impressive growth rate of around 29% in 2020 amidst the Covid-19 pandemic, as compared to 2019.

The Indian pharmaceutical market is dominated by generic drugs which consists of nearly 70% of the total, whereas over the counter drugs (OTC) and medicines and patented drugs make up (21%) and (9%) of the basket respectively¹¹.

Following are India's top pharma exports at the HS 6-digit level.

Table 3: India's Top Pharma Exports

Code	Product label	Exported Value in 2020, US\$ million
300490	Medicaments consisting of mixed or unmixed products for therapeutic or prophylactic purposes, ...	14059.37
300420	Medicaments containing antibiotics, put up in measured doses "incl. those in the form of transdermal ...	1213.57

¹⁰ International Trade Centre estimates

¹¹ <https://www.ibef.org/exports/pharmaceutical-exports-from-india.aspx>

Code	Product label	Exported Value in 2020, US\$ million
300220	Vaccines for human medicine	744.93
300410	Medicaments containing penicillins or derivatives thereof with a penicillanic acid structure, ...	579.90
300390	Medicaments consisting of two or more constituents mixed together for therapeutic or prophylactic ...	315.53
300450	Medicaments containing provitamins, vitamins, incl. natural concentrates and derivatives thereof ...	252.52
300215	Immunological products, put up in measured doses or in forms or packings for retail sale	187.84
300660	Chemical contraceptive preparations based on hormones, prostaglandins, thromboxanes, leukotrienes, ...	180.09
300460	Medicaments containing any of the following antimalarial active principles: artemisinin "INN" ...	177.42
300432	Medicaments containing corticosteroid hormones, their derivatives or structural analogues but ...	122.59

At the HS 6-digit level, medicaments for therapeutic or prophylactic purposes (HS 300490) was the top export product by far, which recorded a total value of US\$ 14.06 billion. Other top exports coming in at much lower values were in the categories of medicaments containing antibiotics (HS 300420); vaccines for human medicine (HS 300220); medicines containing penicillin (HS 300410) and medicaments consisting of two or more constituents mixed together for therapeutic or prophylactic (HS 300390) use, among others.

India's total imported value for pharmaceutical products during 2020 stood at US\$ 2.48 billion¹².

At the HS 6-digit level, India's top import was in the category of medicaments for therapeutic or prophylactic purposes (HS 300490), which recorded a total import value of US\$ 732.44 million. Other top Indian imports in pharmaceutical products were in the categories of antisera and other blood fractions (HS 300212); vaccines for human medicine (HS 300220); medicaments containing insulin but not antibiotics (HS 300431) and immunological products (HS 300215), among others.

Table 4: India's Top Pharma Imports

Code	Product label	Imported value in 2020, US\$ million
300490	Medicaments consisting of mixed or unmixed products for therapeutic or prophylactic purposes, ...	732.44
300212	Antisera and other blood fractions	416.17
300220	Vaccines for human medicine	339.49

¹² International Trade Centre estimates



Code	Product label	Imported value in 2020, US\$ million
300431	Medicaments containing insulin but not antibiotics, put up in measured doses "incl. those in ...	207.44
300215	Immunological products, put up in measured doses or in forms or packings for retail sale	170.91
300290	Human blood; animal blood prepared for therapeutic, prophylactic or diagnostic uses; toxins, ...	111.43
300190	Dried glands and other organs for organo-therapeutic uses, whether or not powdered; heparin ...	102.98
300219	Immunological products, n.e.s. (code possibly empty, preceding subheadings seem exhaustive)	57.18
300439	Medicaments containing hormones or steroids used as hormones but not antibiotics, put up in ...	52.86
300390	Medicaments consisting of two or more constituents mixed together for therapeutic or prophylactic ...	51.74

With a total exported value of around US\$ 6992 million and a share of 38% in total world exports, the US is India's largest export destination for pharma products. South Africa and the UK are also top destinations for Indian pharma products with export values accounting for 3.8% and 3.06% of its world exports. Other top destinations for Indian pharma products include the Russian Federation and Nigeria, among others.

Switzerland and Belgium are India's top import partners, with imported values of US\$ 348 million and US\$ 331 million, respectively. The two countries are closely followed by USA, South Korea and China as India's top import sources.

Table 5: India's Top 5 Import and Export Partners for Pharma Products

Top Export Partners	Exported Value in 2020, US\$ million	Top Import Partners	Imported Value in 2020, US\$ million
USA	6,991.64	Switzerland	347.82
South Africa	693.78	Belgium	331.42
UK	563.61	USA	300.75
Russian Federation	417.03	South Korea	275.67
Nigeria	410.16	China	184.86
World	18,426.75	World	2,477.41

Source: International Trade Centre

Recent Policies and Initiatives in the Pharma Sector

Production Linked Incentive Schemes

1. Production Linked Incentive Scheme for Pharmaceuticals

To boost domestic manufacturing and enhance the international competitiveness of the pharma sector, the Government of India approved the Production Linked Incentive (PLI) Scheme for the Pharmaceuticals sector that will promote self-reliance in critical drugs production, with a financial outlay of INR 150 billion (US\$ 2.01 billion).

The scheme is expected to contribute to greater value addition in exports and result in a wider availability and range of affordable medicines for consumers, while encouraging greater employment opportunities. Details of the scheme are included in the Annex (Table 1).

2. Production Linked Incentive Scheme for Bulk Drugs

India is significantly dependent on imports of bulk drugs, with more than 75% coming from China. Further, more than 60% of APIs are sourced from abroad. For certain APIs, India's import dependence is greater than 80-90%¹³.

Thus, with the aim of achieving self-reliance and reducing import dependence in these segments, the Department of Pharmaceuticals launched the PLI Scheme for promoting the domestic manufacturing of the segments including Key Starting Materials (KSMs)/Drug Intermediates and Active Pharmaceutical Ingredients (APIs), with a financial outlay of INR 69.4 billion (US\$ 930.97 million)¹⁴. The tenure of the scheme is between FY 2020-21 to FY 2029-30, with FY 2019-20 as Base Year.

Financial incentives will be provided to manufacturers of critical KSMs/DIs and APIs registered in India. The scheme aims to create global manufacturing champions in the sector by bolstering manufacturing capacities and attracting major international players. By encouraging greater diversification in the product mix, the scheme will also help India better integrate with the global value chain in the specified segments.

Details of the Scheme are included in the Annex (Table 2).

¹³ <https://www.ibef.org/news/govt-plans-bulk-drugs-parks-import-curbs-to-boost-manufacturing-in-india>

¹⁴ <https://www.ibef.org/news/approvals-accorded-under-production-linked-incentive-pli-scheme-for-promotion-of-domestic-manufacturing-of-critical-key-starting-materials-ksms-drug-intermediates-and-active-pharmaceutical-ingredients-apis>



Scheme for Bulk Drugs

For financing Common Infrastructure Facilities (CIF) in bulk drug parks, the Government approved the scheme for promotion of Bulk Drug Parks with a financial outlay of INR 30 billion. With a tenure of five years from 2020-21 to 2024-25, the scheme will provide grant-in-aid to 3 bulk drug parks, with a maximum limit of INR 10 billion per park or 70% of the project cost of CIF, whichever is less. For hilly states and the North East Region, the grant in aid would be INR 10 billion per park or 90% of the project cost of CIF, whichever is less.

Details of the scheme could be found [here](#).

Apart from the schemes above, several other initiatives and measures have been taken up by the Indian Government to strengthen the Indian pharma sector by reducing costs and healthcare expenses. Recent initiatives such as Mission Covid Suraksha for accelerated development and production of indigenous Covid vaccines, the focus on generic drugs and the thrust on rural development programmes are expected to fuel the growth of the sector further.

Identifying Indian Pharma Exports of High Potential

Data and Methodology

This section elaborates on the two indices that have been used in the paper to determine India's high potential pharma exports.

In this paper, the Revealed Comparative Advantage (RCA) index is used as well as a modified version of the index, to determine India's high potential exports in the pharmaceutical sector, at the HS 6-digit level.

Revealed Comparative Advantage (RCA) Index

The Revealed Comparative Advantage (RCA) index is a commonly used trade indicator in international economics, to assess a country's relative advantage or disadvantage in a specific class or category of products. This measure also provides valuable information about potential trade prospects with new partners.

World Bank's World Integrated Trade Solution (WITS) database defines the RCA index of country i for product j as the product's share in the country's exports in relation to its share in world trade:

$$RCA_{ij} = (x_{ij}/X_{it}) / (x_{wj}/X_{wt}) \dots (i)$$

Where x_{ij} and x_{wj} are the values of country i 's exports of product j and world exports of product j , and X_{it} and X_{wt} refer to the country's total exports and world total exports.

In other words, the numerator is the country's total exports of a specific product divided by country's total exports. On the other hand, the denominator is the world exports of the commodity divided by total world exports.

A value greater than one indicates that the country under consideration has a revealed comparative advantage in the product. Similarly, a value less than 1 signifies that the country has a revealed comparative disadvantage in the product.

RCA Index for Pharmaceuticals

Apart from using the conventional RCA index to identify the relative competitiveness of India's pharmaceutical products, in this paper, a slightly modified version of the index is also used,



that takes into account the global pharmaceutical industry instead of share of aggregate world exports. So based on formula (i) above, instead of world exports of the commodity and world total exports, world exports of pharmaceutical products and world total exports of pharmaceutical products are considered.

The first measure is called RCA^W , which indicates the competitiveness of the specific pharma products in the global market. The other measure, specific to the pharma industry is termed RCA^P , which indicates the relative competitiveness of the pharma products in the global pharmaceutical industry.

This exercise helps us determine the competitiveness of Indian pharmaceutical products in the global pharmaceutical space, instead of considering all exports. Accordingly, it identifies India's high potential pharma exports exclusively in the global pharmaceutical space.

The modified formula for the RCA index for the pharmaceutical industry is given below:

$$RCA^P = RCA_{ij} = (x_{ij}/X_{it}) / (x_{pj}/X_{pt})$$

Where x_{ij} and x_{pj} are the values of country i 's exports of product j and world exports of pharmaceutical product j , where X_{it} and X_{pt} refer to the country's total exports and world total exports of pharmaceutical products.

Along with the RCA indices, we also calculate global shares of the pharma products in our analysis.

Key Findings

Key Findings: RCA^W

Data on the 6-digit level for pharmaceutical products (HS 30) has been sourced from the International Trade Centre. There are a total of 42 products.

After collecting the data on relevant variables for the RCA index, including India's exported value, world exported value, total world exports and total Indian exports, the RCA value is computed for each of the 42 pharmaceutical products. Global shares are also calculated.

Thereafter, all commodities, for which the RCA has a value of less than 1 are excluded. This exercise leaves us with 11 commodities i.e. 11 products remain out of the total set with an RCA value greater than 1, indicating that the product has competitive advantage in the global market.

See Table 3 (Annex) for the list of products.

These include medicaments containing antimalarial active principles (HS 30046); medicaments containing antibiotics (HS 300420); malaria diagnostic kits (HS 300211); and vaccines for human medicines (HS 30022), among others.

Key Findings: RCA^P

After conducting the RCA analysis and excluding pharmaceutical products for which the RCA is less than 1, around 10 products are identified as high potential pharma exports which have high competitive advantage in the global pharma industry.

The products coincide with the world set, which ensures the reliability of the products in terms of the analysis as well as high competitive advantage.

See table 4 (Annex) for the list of products.

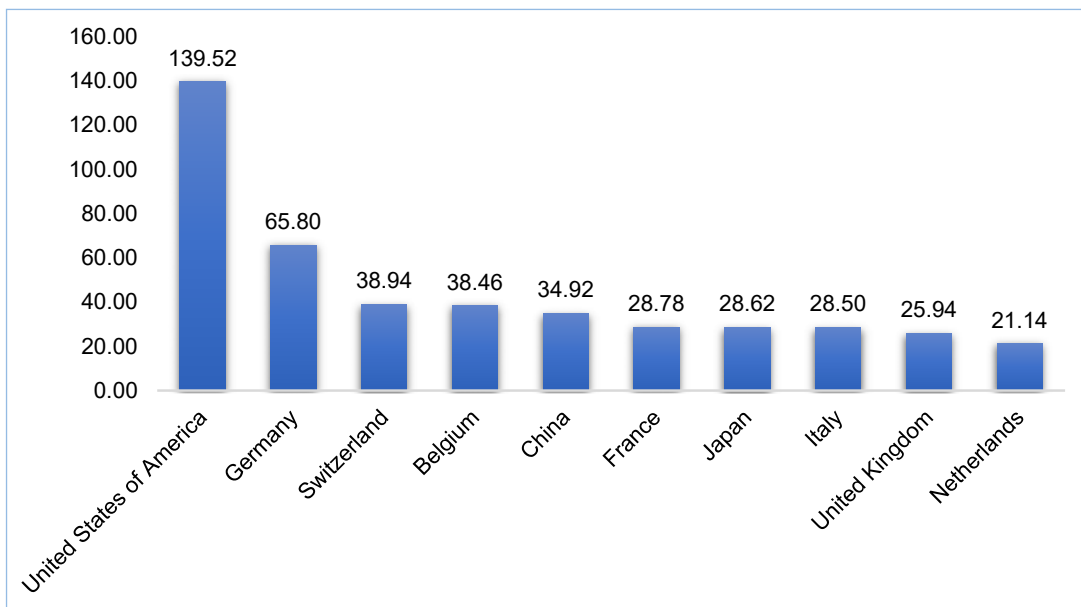
Section below analyzes India's top potential export destinations for the identified products.

Several identified products, under both the indices, are also in the categories of APIs (HS 300420; HS 300450; HS 300490). Expanding domestic production in these segments is particularly important and critical for India to achieve self-sufficiency as well as for becoming a global manufacturer of these products.

Identifying Potential Export Destinations for India's High Potential Pharma Exports

To determine India's top destinations for India's high potential exports, first the top importers of pharmaceutical products in the world are selected.

Chart 4: Top Potential Export Destinations for India /Top Importers



Source: International Trade Centre

United States is the biggest importer of pharmaceutical products, with an imported value of US\$ 140 billion and a share greater than 20% of total world imports, as of 2020. After US, Germany is the second largest importer of pharma products with an imported value of US\$ 66 billion. Switzerland, Belgium and China are other top importers of pharma products in the world and therefore potential destinations for India's exports as identified earlier.

The US is already India's top export destination and therefore focus must be on boosting exports of the identified products to the US, to step up India-US trade and investments.

This paper also determines top export destinations for India for its pharmaceutical products based on the identified exports. The top three importing partners for each of the high potential export as determined by the RCA analysis in the pharmaceutical space (RCAP) is included as a top export destination for India. The table below presents the top destinations for India's high potential exports.

Table 6: Top Export Destinations for Identified Exports

HS Code	Product Label	Top 3 Importers in the World
300460	Medicaments containing any of the following antimalarial active principles: artemisinin "INN" ...	Ukraine, Netherlands, Luxembourg
300410	Medicaments containing penicillins or derivatives thereof with a penicillanic acid structure, ...	USA, Germany, Saudi Arabia
300660	Chemical contraceptive preparations based on hormones, prostaglandins, thromboxanes, leukotrienes, ...	USA, China, Russia
300420	Medicaments containing antibiotics, put up in measured doses "incl. those in the form of transdermal ...	USA, Switzerland, China
300211	Malaria diagnostic test kits	Belgium, Spain, Bulgaria
300349	Medicaments containing alkaloids or derivatives thereof, not containing hormones, steroids . . .	Sweden, Denmark, Finland
300450	Medicaments containing provitamins, vitamins, incl. natural concentrates and derivatives thereof . . .	China, USA, Hong Kong
300490	Medicaments consisting of mixed or unmixed products for therapeutic or prophylactic purposes, . . .	USA, Germany, Belgium
300390	Medicaments consisting of two or more constituents mixed together for therapeutic or prophylactic . . .	UK, Ireland, Netherlands
300692	Waste Pharmaceuticals	USA, UK, France

Source: CII Calculations based on International Trade Centre Data



Current Challenges & Policy Prescriptions

Despite several success stories, the Indian pharma industry has faced many challenges over the past few years.

To address the many challenges the industry is facing and for making the industry more attractive, certain strategic steps need to be undertaken along with a well-defined roadmap. Several measures will be required across people, processes and infrastructure along with favourable Government policies and incentives, to make the Indian biopharma sector more globally attractive.

The section below discusses some of these challenges along with providing some possible policy prescriptions.

1. Improve access to funding and step up digital mechanisms

Over the past few years, funding has gone up by leaps and bounds in the pharmaceutical industry, worldwide. In India, the industry suffers from a considerable lack of funding, especially in terms of funding from private channels. As per the Kearney-CII report “Taking India’s life science to the global stage” there were only 80 rounds of funding for Indian biotech start-ups over the last decade, in contrast to more than 1,200 rounds of funding globally. With India’s biotech funding at 1/1000th of the global figure, this is a matter of serious concern for India. Thus, funding challenges need to be addressed, especially in the mid-stages and investments need to be stepped up for India’s biotech industry to grow further.

Indian start-ups should be permitted to access foreign markets, where risk capital is relatively easily accessible. The visibility of Indian start-ups must be increased in this context through investor meets and expos. For building greater connect between start-ups and investors and large companies, digital platforms and mechanisms such as creation of online marketplaces must be strengthened.

The State Governments can also play an active role, by setting up biotechnology investment funds for encouraging early-stage biotechnology ventures.

2. Favourable Government policies

For advanced markets, developing biosimilars requires high investments for a relatively long period, which have risky capital requirements. The Government needs to play a key role in lowering the risk burden of the biopharma industry, by ensuring that adequate incentives and favourable policies are put in place to augment risk investing. At the

same time, several discontinued policies will need to be extended for the benefit of the Indian companies.

While schemes such as Production Linked Incentive 2.0 and the patent box tax scheme of 2016 are steps in the right direction, policies such as the Service Export from India Scheme (SEIS) and Seed Enterprise Investment Scheme need to be restored along with an increase in incentives.

3. Human resource development

At present, there is a dearth of Indian talent in the biopharma sector that is skilled in industry-application oriented skills. Misalignment between Indian biotech academic curriculum and industry requirements is one of the major reasons behind this issue. Thus, augmenting human resource in both industry and academia is needed and efforts are required to enhance capabilities of Indian academia to bring it at par with global standards.

Efforts in three key areas are required to build a rich, productive and talented human resource pool in the biotech sector.

- (i) *Produce industry-ready talent in India:* Periodic revision of university curriculum in line with industry requirements and increased participation of industry in setting and designing courses is required.
- (ii) *Improve capabilities of Indian academia:* A national plan can be created similar to China's National Talent Plan that aims to build a highly talented and skilled national workforce. Global exchange programmes for Indian academia must be encouraged and multinational corporations may be invited to set up transnational research centres in India.
- (iii) *Promote industry-academia collaboration:* Industry-academia collaboration must be promoted, and efforts must be directed towards recruiting techno-commercial talent in industry, defining clear procedural standard operating procedures in academia and offering additional special R&D incentives on industry-academia collaboration among others.

4. Making world-class bio-clusters

Bio-clusters are known to be effective in fuelling innovation and research while also attracting large investments and encouraging the start-up eco-system. Singapore's Biopolis is one such world-class bio cluster, which has put the country on the world scientific map, alongside creating jobs, generating economic wealth and improving overall quality life. The success of Biopolis as a biomedical research hub was largely driven by the Singapore Government's favourable policies and investments.

In India, Genome Valley is a leading example of a best-practice bio-cluster. The biotech policies at the state level in India are the biggest enablers of successful bio-clusters. However, at present, around eight states do not have bio-tech policies and some of the existing policies are not robust enough to generate meaningful outcomes.



Therefore, developing as well as improving existing biotech policies is an imperative for all states. Further, developing specialized bio-clusters including biosimilars, vaccines and biotech raw materials is required for highly relevant and shared infrastructure and proximity of knowledge sources.

5. IPR reform and Government incentives

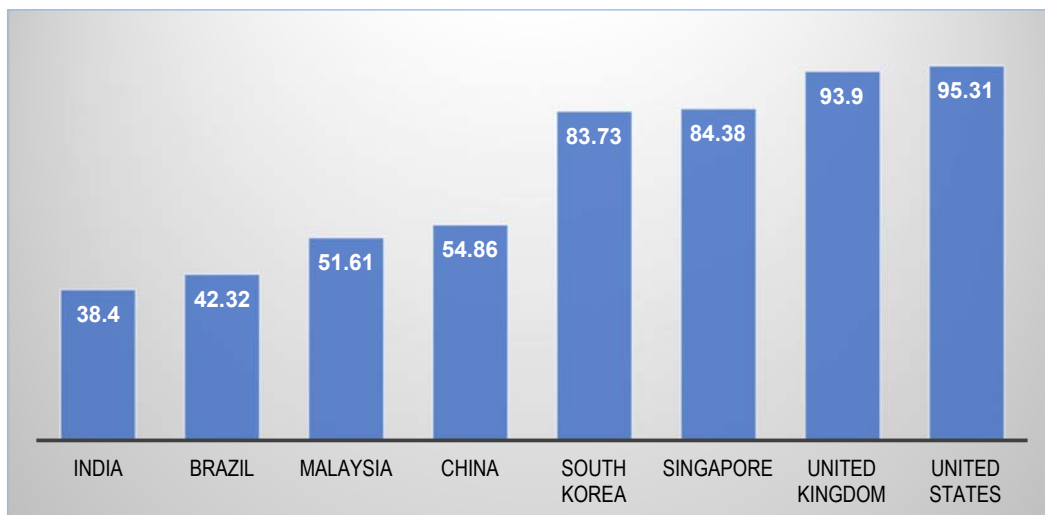
India occupies a low score and rank in the International Intellectual Property Index. Thus, greater investments in R&D and innovation, and IPR reforms are needed to strengthen its IPR regime.

Legal reforms are an important aspect to fast track dispute resolution and reinstate confidence among multinational corporations to introduce advance patented products in India or transfer technology.

The use of compulsory licensing¹⁵ has to be restrained and price control with minimum purchase commitments must be in place instead. The spillover of knowledge and expertise to domestic firms will boost innovation and also result in product-oriented R&D investments.

Global suppliers have started diversifying their manufacturing footprint for inputs of biosimilars and biologics, recognizing the potential of emerging markets and have been investing across diversified facilities across the globe. There is a dearth of similar scale investments in India.

Chart 5: India's Score in International IP Index, 2021



Source: International IP Index Report

Therefore, Government and private sector support is required to encourage partnerships in the country, especially in the raw materials manufacturing space. Further, for attracting global players, select policy incentives also need to be put in place.

¹⁵ When a Government allows someone else to produce a patented product or process without the consent of the patent owner or plants to use the patent-protected innovation itself.

6. Build indigenous raw materials

Based on the class of biosimilars and the intended market for drugs, India's dependence on imports for raw materials ranges from 20% to 90%. India's major countries for sourcing the raw materials are the US, France, China and South Korea, and as a result of additional import duties, the cost of raw material imports increases by almost 30%. The rising costs and uncertainties in lead times in production have necessitated the need for choosing suppliers close to home and for producing the required raw materials indigenously.

Categories such as buffers, packaging and sterilisers can significantly reduce India's import dependence by almost 30% over the next five years and help reduce overall costs by around 3 to 4%. Therefore, strategies must be developed for indigenizing these categories which represent significant opportunities for India.

At the same time, support and adequate incentives must be provided to biopharma companies trying to develop their own bio-reactor technology. Further, partnerships between biopharma players and domestic suppliers must be encouraged and strengthened.

7. Regulatory reforms

India's regulatory processes are considered to be very slow as well as prohibitive for innovation. Further, poor coordination among the ministries also results in considerable delays in processes.

Several steps could be taken as below to reduce time and cost for such processes that would require significant investments in infrastructure.

- (i) *Set up a single, autonomous and empowered regulatory body:* A single empowered regulatory body, with autonomy in policymaking is required that can implement processes in an effective, timely and transparent manner. The regulatory body could replace overlapping regulators much on the lines of China Food and Drug Agency.
- (ii) *Upskilling of regulatory body reviewers:* Upskilling of regulatory body reviewers must be taken up to build advanced capabilities in relevant areas with the help of both domestic and global regulatory bodies.
- (ii) *Set up a fast-track cell:* A fast-track cell needs to be set up to streamline processes and do away with redundant steps. Review times for biosimilar batches, which take up around 45 to 90 days currently must be reduced. Thus, advisory boards comprising of industry experts must be set up to provide guidance on matters including identifying and appointing subject matter experts, providing digital solutions, and setting up process service-level agreements, among others.
- (iv) *Zero-based Regulation:* To encourage time-bound periodic policy reviews and defining relevant policies for fuelling latest innovations, a culture of zero-based regulation needs to be encouraged.



8. PLI scheme for vaccines

The PLI schemes introduced so far for the Indian pharmaceutical industry will help to contribute significantly for achieving affordable healthcare in the country.

Indian industry has appealed to the Government to launch a PLI like incentive scheme for vaccine manufacturers as there is an urgent and critical need to encourage vaccine manufacturers to substantially augment their capacities.

Moving forward, Government should create research incentive schemes for both the pharmaceutical and the medical devices segments.

9. Identifying tariff and non-tariff barriers

With the changing global environment, new standards and regulations have been introduced in top global markets. Substantive trade barriers including tariff and non-tariff measures increase prices and hamper India's exports, including pharmaceuticals, vaccines and medical equipment.

Non-tariff barriers (NTBs) include procedural and legal measures that hinder market access. These include issues pertaining to multiple approvals by various regulatory authorities, drug registration fees, reference standards, and government procurement, among others.

For example, multiplicity of drug approval agencies such as the US FDA, the European Medicines Agency (EMA), the European Directorate for Quality Medicines (EDQM), etc. have different pharmaceutical standards and quality procedures that vary from country to country. As a result, the same US FDA approved product in India again requires a plant inspection elsewhere. These issues, including dual testing at entry points particularly for the UK and the EU, have raised drug registration and site inspection costs, along with procedural delays¹⁶.

Indian exporters face a large number of NTBs when trading with EU. WTO data on NTBs between EU and India reveal that Indian exporters face many challenges especially with respect to Technical Barriers to Trade (TBT) and sanitary and phyto-sanitary (SPS) measures, the most frequently imposed restrictive measure by the EU¹⁷.

Therefore, it is essential to undertake detailed analysis to identify and address these barriers for facilitating smoother and greater flows of medical products. It is also important to raise awareness among exporters on trade barriers, so that these are identified and are taken up by an institution like the Pharmaceuticals Export Promotion Council of India (Pharmexcil) with the export destinations.

Greater international cooperation on TBT and SPS measures is required for enabling greater market access. India as a leading player in the global industry can work towards discussion on this aspect for the pharma sector.

¹⁶ https://commerce.gov.in/wp-content/uploads/2020/02/MOC_635567633057176521_Report-Tas-Force-Pharma-12th-Dec-08.pdf

¹⁷ Non-tariff Measures in Indian Context and the European Union <https://ideas.repec.org/a/ibn/ijefaa/v10y2018i9p54.html>

Given the current pandemic situation, the free flow of health products is critical and therefore, liberalizing trade in these products through the elimination of restrictive measures is an imperative. For boosting pharma exports, India needs to take proactive measures and actively pursue talks to reduce NTBs and work towards concluding agreements with its large export destinations such as UK and EU.

10. Market promotion of identified export products

The identified exports must be promoted in the select markets with targeted strategies. For expanding the market share of the identified products, brand building initiatives and effective market promotion activities such as buyer seller meets, trade fairs, exhibitions, seminars, etc. must be undertaken on a regular basis.

Dedicated export marketing centres on the lines of Buy USA can be set up in the identified export markets. These centres must be engaged in export promotion, organization of business meets and connecting Indian exporters with local buyers.

11. Identify Champion Sectors

Appropriate policy incentives must be in place for promoting the identified sectors. The PLI schemes will help boost domestic manufacturing and strengthen India's Make in India programme. The schemes could be expanded to segments including vaccines, given their critical importance in present times.

Tailormade strategies must be designed to address the bottlenecks faced by the sectors, with separate working groups for each of the sectors with select stakeholders comprising of policymakers, regulators, senior corporate leaders and representatives for each sector.



Conclusion

Using data from the International Trade Centre, this paper analysed the competitiveness of Indian pharmaceutical products in the global pharmaceutical industry to determine high potential pharma exports from India. The paper deployed two indices – the conventional RCA index and a slightly modified version of the RCA index, to identify pharma exports of high competitive advantage in this paper.

The novelty of the research paper is that it uses the RCA index in the pharmaceutical space, instead of the global industry, to determine competitive pharma exports from India. This helps in identifying the competitiveness of India's pharma products within the pharmaceutical industry.

The paper also identified potential export destinations for India for the identified exports and provided policy prescriptions to boost India's exports in the select markets. Boosting the identified exports in the select markets could significantly benefit the Indian pharma industry and help step up its global shares and capture advanced markets.

These results are particularly important in the light of the current situation, which has triggered a move towards greater indigenous production of inputs in the country. The recent Covid-19 pandemic has thrown up many challenges for the India pharmaceutical industry, especially with respect to its dependencies on various emerging markets for API procurement. Thus, expanding domestic manufacturing in the identified segments, which also includes APIs, would not only boost India's Make in India and Atmanirbhar Programmes, but would also help India become a global manufacturing hub of medicines and generic drugs.

Table 1: PLI Scheme for Pharmaceuticals

Sector	Quantum of Incentive	Eligibility Criteria	Expected Outcomes/ Benefits
<p>Pharmaceuticals</p> <p>Target Segments</p> <p>Group A: Applicants having Global Manufacturing Revenue (FY 2019-20) of pharmaceutical goods more than or equal to INR 50 billion (US\$ 670.73 million)</p> <p>Group B: Applicants having Global Manufacturing Revenue (FY 2019-20) of pharmaceutical goods between INR 5 (inclusive) billion (US\$ 67.07 million) and INR 50 billion (US\$ 670.73 million)</p> <p>Group C: Applicants having Global Manufacturing Revenue (FY 2019-20) of pharmaceutical goods less than INR 5 billion (US\$ 67.07 million). Within this group, a sub-group for MSME industry will be made, given their specific challenges and circumstances.</p>	<p>Incentive Allocation is as follows:</p> <ul style="list-style-type: none"> o Group A: INR 110 billion (US\$ 1,475.60 million) o Group B: INR 22.5 billion (US\$ 0.30 billion) o Group C: INR 17.50 billion (US\$ 0.23 billion) <ul style="list-style-type: none"> • The rate of incentive on incremental sales (over base year) of pharmaceutical goods covered under Category 1 and 2 will be 10% for FY 2022-23 to FY 2025-26, 8% for 2026-27 and 6% for 2027-28 • The rate of incentive on incremental sales (over base year) of pharmaceutical goods covered under Category-3 will be 5% for FY 2022-23 to FY 2025-26, 4% for 2026-27 and 3% for 2027-28. 	<p>Eligibility for Selection</p> <ul style="list-style-type: none"> • The Project shall be a greenfield project as defined under the scheme guidelines • The net worth of the applicant (including that of Group Companies), as on the date of application, shall not be less than 30% of the total committed investment. The Applicant not meeting the said Net Worth criteria shall not be eligible • The proposed Domestic Value Addition (DVA) by the applicant shall be at least 90% in case of fermentation-based product and at least 70% in case of chemical synthesis-based product. • The applicant should not have been declared as bankrupt or wilful defaulter or reported as fraud by any bank or financial institution or non-banking financial company <p>Eligibility for Incentive</p> <ul style="list-style-type: none"> • The selected participants in the scheme will be eligible for incentives on incremental sales of pharmaceutical goods based on yearly threshold criteria of minimum cumulative investment and minimum percentage growth in sales. For a comprehensive list of eligibility criteria, see Annexure A 	<ul style="list-style-type: none"> • Benefit domestic manufacturers • Generate Employment for both skilled & unskilled personnel with an estimated 20,000 direct jobs and 80,000 indirect jobs • Contribute to the availability of wider range of affordable medicines for consumers • Promote production of high value products in the country and increase value addition in exports • Total incremental sales of INR 2,940 billion (US\$ 39.44 billion) & total incremental exports of INR 1960 billion (US\$ 26.30 billion) are estimated during six years from 2022-23 to 2027-28 • Scheme is expected to generate cumulative investments of around INR 150 billion (US\$ 2.01 billion) over a period of six years • Promote innovation for development of complex & high-tech products, including products of emerging therapies and in-vitro Diagnostic Devices • Promote self-reliance in important drugs

<https://pib.gov.in/PressReleasePage.aspx?PRID=1700433>

<https://www.investindia.gov.in/schemes-for-pharmaceuticals-manufacturing>

<https://static.investindia.gov.in/s3fs-public/inline-files/Eligibility%20Criteria.pdf>



Table 2: PLI Scheme for Bulk Drugs

Sector	Quantum of Incentive	Eligibility Criteria	Expected Outcomes/ Benefits
<p>Critical Key Starting Materials (KSMs)/ Drug Intermediates (DIs) and Active Pharmaceutical Ingredients (APIs)</p> <p>Target Segments (41 products based on criticality & import dependence, see Annexure A for detailed List)</p>	<p>Financial incentive under the scheme shall be provided on sales of 41 identified products for six years at the rates given below:</p> <ul style="list-style-type: none"> For fermentation-based products, incentive for FY 2023-24 to FY 2026-27 would be 20%, incentive for 2027-28 would be 15% and incentive for 2028-29 would be 5%. For chemical synthesis-based products, incentive for FY 2022-23 to FY 2027-28 would be 10%. 	<ul style="list-style-type: none"> Support under the scheme shall be provided only to manufacturers of critical KSMs/DIs and APIs registered in India. Eligibility shall be subject to threshold investment in green field projects as given in Annexure B Eligibility under the scheme shall not affect eligibility under any other scheme and vice versa. 	<ul style="list-style-type: none"> Will boost domestic manufacturing in the pharma sector while encouraging diversification of the product mix to complex generics, patented drugs Will help in going up the value chain Will encourage greater investments & create global champions Five applications with a committed investment of INR 37.61 billion (US\$ 504.52 million) have already been approved under Target Segment I. Eligible products under Target Segment III (Key Chemical Synthesis Based KSMs/Drug Intermediates) were considered as per the decided evaluation and selection criteria - setting up of these plants will lead to total committed investment of INR 8.62 billion (US\$ 115.63 million) by the companies and employment generation of about 1763. With this, a total of 19 applications with committed investment of INR 46.23 billion (US\$ 620.15 million) have been approved by the Government This in turn will promote self-reliance in the country, especially in the bulk drugs segment

<https://www.investindia.gov.in/schemes-for-pharmaceuticals-manufacturing>

<https://pharmaceuticals.gov.in/sites/default/files/Gazettee%20notification%20of%20bulk%20drug%20schemes.pdf>

https://www.ey.com/en_in/tax/pli-scheme-for-the-pharma-industry-likely-to-boost-india-bulk-drug-security

<https://pib.gov.in/Pressreleaseshare.aspx?PRID=1701048>

Table 3: India's Potential Pharma Exports using RCA^w (US\$ million)

Product code	Product label	World exported value in 2020, US\$ million	India Exported Value in 2020, US\$ million	RCA	Global Share
300460	Medicaments containing any of the following antimalarial active principles: artemisinin "INN" ...	746.74	177.42	14.78	23.76
300410	Medicaments containing penicillins or derivatives thereof with a penicillanic acid structure, ...	3509.92	579.90	10.28	16.52
300660	Chemical contraceptive preparations based on hormones, prostaglandins, thromboxanes, leukotrienes, ...	1928.88	180.09	5.81	9.34
300420	Medicaments containing antibiotics, put up in measured doses "incl. those in the form of transdermal . . .	14862.86	1213.57	5.08	8.17
300211	Malaria diagnostic test kits	353.75	24.05	4.23	6.80
300349	Medicaments containing alkaloids or derivatives thereof, not containing hormones, steroids ...	45.56	3.03	4.13	6.64
300450	Medicaments containing provitamins, vitamins, incl. natural concentrates and derivatives thereof ...	4212.04	252.52	3.73	6.00
300490	Medicaments consisting of mixed or unmixed products for therapeutic or prophylactic purposes, ...	307060.76	14059.37	2.85	4.58
300390	Medicaments consisting of two or more constituents mixed together for therapeutic or prophylactic ...	7160.72	315.53	2.74	4.41
300692	Waste pharmaceuticals	10.29	0.32	1.95	3.13
300220	Vaccines for human medicine	30525.01	744.93	1.52	2.44

Source: CII calculations based on International Trade Centre Data



Table 4: India's Potential Pharma Exports using RCA^P (US\$ million)

Product code	Product label	World exported value in 2020, US\$ million	India Exported Value, US\$ million	RCA Pharma
300460	Medicaments containing any of the following antimalarial active principles: artemisinin "INN" ...	746.74	177.42	8.29
300410	Medicaments containing penicillins or derivatives thereof with a penicillanic acid structure, ...	3509.92	579.90	5.77
300660	Chemical contraceptive preparations based on hormones, prostaglandins, thromboxanes, leukotrienes, ...	1928.88	180.09	3.26
300420	Medicaments containing antibiotics, put up in measured doses "incl. those in the form of transdermal ...	14862.86	1213.57	2.85
300211	Malaria diagnostic test kits	353.75	24.05	2.37
300349	Medicaments containing alkaloids or derivatives thereof, not containing hormones, steroids ...	45.56	3.03	2.32
300450	Medicaments containing provitamins, vitamins, incl. natural concentrates and derivatives thereof ...	4212.04	252.52	2.09
300490	Medicaments consisting of mixed or unmixed products for therapeutic or prophylactic purposes, ...	307060.76	14059.37	1.60
300390	Medicaments consisting of two or more constituents mixed together for therapeutic or prophylactic ...	7160.72	315.53	1.54
300692	Waste pharmaceuticals	10.29	0.32	1.09

Source: CII calculations based on International Trade Centre Data

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Confederation of Indian Industry

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Confederation of Indian Industry

The Mantosh Sondhi Centre
23, Institutional Area, Lodi Road, New Delhi – 110 003 (India)
T: 91 11 45771000 / 24629994-7
E: info@cii.in • W: www.cii.in

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