# Strategy for Leveraging ASEAN FTA and Trade Potential with the Middle East Countries for Pharma Sector in India

ISID Institute for Studies in Industrial Development
An institution of Indian Council of Social Science Research (Ministry of Education)
Policy Research to Foster India's Industrial Transformation
4 Vasant Kunj Institutional Area, New Delhi - 110070, India
https://isid.org.in | director@isid.org.in

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# Strategy for Leveraging ASEAN FTA and Trade Potential with the Middle East Countries for Pharma Sector in India

Dr Reji K Joseph
*Associate Professor*

Dr Dinesh Kumar
*Consultant*

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4 Vasant Kunj Institutional Area, New Delhi - 110 070, India
https://isid.org.in

# Foreword

Emergence of India as the supplier of good quality but affordable medicines to different developed and developing countries around the world over the past few decades has earned it the nickname 'Pharmacy of the World'. Several countries are turning towards generic medicines to contain healthcare costs. Furthermore, the Covid-19 pandemic has exposed the national security implications of excessive reliance on a single country for pharmaceutical supplies, especially APIs, forcing some countries to diversify their sources of supplies. These developments provide a good opportunity for the Indian pharmaceutical industry for further enhance exports of pharmaceutical products.

The pharmaceutical sector can also leverage the Free Trade Agreements (FTAs) and Comprehensive Economic Cooperation Agreements (CECAs) concluded by India including those with the ASEAN and the UAE, and other countries and regions and those in the pipeline.

This study analyses India's trade and investment engagements with ASEAN and the Middle East regions. India-ASEAN FTA came into force in 2010 and India has signed an FTA with UAE recently. India has also initiated negotiations with gulf countries (GCC) with the aim of concluding an FTA. The study analyses the impact of the India-ASEAN FTA on India's trade with this region in pharmaceutical products and the implications of the India-UAE FTA for the Indian pharmaceuticals sector. It also captures trends in FDI inflows from these two regions and FDI outflows from India to these regions in the pharmaceutical sector. It investigates the market access barriers faced by

Indian exporters in these two regions. This study also identifies emerging opportunities for the Indian pharmaceutical industry in these two regions.

This study has been conducted by ISID with the support of the Department of Pharmaceuticals, Ministry of Chemicals and Fertilizers, Government of India.

I am happy to commend this study to the policymakers and researchers interested in the subject.

**August 11, 2022**

**Prof Nagesh Kumar**
Director, ISID

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We acknowledge with thanks the data we received from the Department of Commerce, Ministry of Commerce and Industry, on country-wise FDI inflows in the pharmaceutical sector.

We are thankful to our colleagues at ISID who provided inputs to this study. Thanks are due to the Administration and IT cell of ISID for their support in the preparation of the research proposal and this report.

Project Team
Dr. Reji K. Joseph
*Associate Professor, ISID*

Dr. Dinesh Kumar
*Consultant, ISID*

Note:
The estimates on export and import of pharmaceutical products in this report is based on a classification using the International Standard Industrial Classification (ISIC). The methodology is explained in section 2.2.1. The estimates in this report should not be compared with estimates on export and import of pharmaceutical products provided by Pharmexcil/Department of Pharmaceuticals/Other Agencies.

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# List of Abbreviations

| | |
|---|---|
| APIs | Active Pharmaceutical Ingredients |
| ASEAN | Association of South-East Asian Nations |
| AYUSH | Ayurveda, Yoga and Naturopathy, Unani, Siddha and Homeopathy |
| BCPP | Bilateral Cooperation on Pharmaceutical Products |
| BIT | Bilateral Investment Treaty |
| BOT | Balance of Trade |
| CAGR | Compound Annual Growth Rate |
| CEPA | Comprehensive Economic Partnership Agreement |
| CIS | Commonwealth of Independent States |
| CMIE | Centre for Monitoring Indian Economy |
| CPC | Central Product Classification |
| DIs | Drug Intermediates |
| DPIIT | Department for Promotion of Industry and Internal Trade |
| DTAA | Double Taxation Avoidance Agreement |
| ECJ | European Court of Justice |
| EL | Exclusion List |
| EMEA | Evaluation of Medicinal Products' |
| EU-GMP | European Union Good Manufacturing Practices |
| FDI | Foreign Direct Investment |

| | |
|---|---|
| FOB | Free on Board |
| FTA | Free Trade Agreement |
| GCC | Gulf Cooperation Council |
| GCPs | Good Clinical Practices |
| GDP | Gross Domestic Product |
| GMPs | Good Manufacturing Practices |
| GTA | Global Trade Alert |
| HI | Herfindahl Index |
| HS | Harmonised Commodity Description and Coding System |
| HSL | Highly Sensitive List |
| IPR | Intellectual Property Rights |
| ISIC | International Standard Industrial Classification |
| KSMs | Key Starting Materials |
| ME | Middle East |
| MHRA | Medicines and Healthcare products Regulatory Agency |
| MNC | Multinational Corporation |
| MOH | Ministry of Health |
| NIDLP | National Industrial Development and Logistics Program |
| NT | Normal Track |
| OECD | Organisation for Economic Co-operation and Development |
| OFDI | Outward Flows of Foreign Direct Investment |

| | |
|---|---|
| PLI | Product Linked Incentive |
| RBI | Reserve Bank of India |
| RCA | Revealed Comparative Advantage |
| SL | Sensitive List |
| ST | Sensitive Track |
| SWOT | Strengths Weaknesses Opportunities Threats |
| TBT | Technical Barriers to Trade |
| UAE | United Arab Emirates |
| UK | United Kingdom |
| US | United States |
| USA | United States of America |
| USFDA | United states *Food and Drug Administration* |
| USTR | US Trade Representative |
| VOE | Value of Exports |
| VOM | Value of Imports |
| WHO | World Health Organisation |
| WITS | World Integrated Trade Solution |
| WTO | World Trade Organization |

# Executive Summary

This study, sponsored by the Department of Pharmaceuticals, Ministry of Chemicals and Fertilizers, is undertaken to analyse the trends in India's trade and investment with the ASEAN and the Middle East regions, identify challenges of market access and recommend strategies to promote trade with these regions taking advantage of India's FTAs with ASEAN and UAE keeping in view the strengths of the Indian pharmaceutical industry.

An International Standard Industrial Classification-based classification is used for compiling data on international trade in pharmaceutical products. It is found that India is the 11$^{th}$ largest exporter of pharmaceutical products globally in 2020 in terms of the value of exports and the 6th largest in terms of quantity of exports. Pharmaceutical products are classified into four categories – formulations, active pharmaceutical ingredients (APIs), bulk medicines and other pharmaceutical products. Out of the US$ 22 billion worth of pharmaceutical products that India exported in 2020, almost four-fifth share (79 per cent) was accounted for by formulations. India's share in the global export of formulations (in terms of the value of exports) has increased from one per cent in 2003 to 4.3 per cent in 2020. At the same time, the share in terms of quantity of exports has declined. This indicates that India is increasingly exporting more value-added formulations.

In APIs, it is found that India's share in global exports has increased from 1.3 per cent in 2003 to 3.8 per cent in 2020, even though India is reported to be heavily import dependent on APIs. Like in the case of formulations, in APIs also, the share of India in the global export of APIs, in terms of quantity of exports, declined from 1.9 per cent to 1.7 per cent. This indicates the shift of

the Indian pharmaceutical industry to the export of more value-added products.

India's export of pharmaceutical products to both ASEAN and Middle East regions increased between 2003 and 2021. The export to the ASEAN region increased from US$181 million to US$ 1,544 million and to the Middle East region from US$ 166 million to US$ 1,145 million. In imports, India is not found to be much dependent on these regions. It is interesting to observe that India is importing some formulations from ASEAN countries, such as vaccines (for polio) and traditional medicines/AYUSH medicines.

A category-wise analysis of exports shows that formulations is the leading category exported to both the regions (ASEAN 75 per cent in 2021 and Middle East 61 per cent) followed by APIs (ASEAN 22 per cent and Middle East 32 per cent). It is expected that FTA will help in promoting exports. A comparison of value of exports during the pre and post FTA period shows that exports have increased during the post FTA period. However, the rate of growth of export of India to ASEAN has declined during the post-FTA period, which is not expected. But as compared to India's total exports, the deceleration was milder in the case of pharmaceutical products. Even when all other countries were finding it harder to export formulations and APIs to ASEAN regions as reflected in their lower share in total exports to ASEAN, as compared to global exports, India is in a better position which is reflected in the rising RCA values for India. Surprisingly, there are instances where products not receiving tariff commitments exhibiting higher rate of growth in exports. For example, formulations falling under the exclusion list registered faster growth in exports as compared to formulations falling under the sensitive list. This indicates the probability of India's pharmaceutical exports performing no differently even in the absence of an FTA. Our observations from this analysis also point to other factors that influence exports other than tariffs.

Formulations and APIs account for the bulk of India's export of pharmaceutical products to the Middle East, having shares of 61 per cent and 32 per cent, respectively, in 2021. However, the share of formulations in India's total exports to this region is very low, although it is showing a rising trend since the early period of the last decade and reaching 1.2 per cent in 2021. APIs also account for only less than one per cent of India's total exports to the region.

UAE is the leading destination for the export of APIs to the region, accounting for 27.4 per cent during the 2018-20 period. However, in the case of formulations the share of UAE has in fact declined over the years from 14.7 per cent during 2003-05 to 6.9 per cent in 2018-20. The FTA with UAE that came into force in May 2022 offers tariff elimination for India in 32 API tariff lines, which may help in promoting India's API export to the country. In formulations, tariffs were already zero. But the Bilateral Cooperation on Pharmaceutical Products (BCPP), which is part of the FTA, addresses several technical barriers that Indian exporters of formulations face in the UAE. This will help in promoting the export of formulations from India.

The RCA analysis, which captures the comparative advantage that Indian products have in international markets, shows that India has a comparative advantage in both formulations and APIs in the global market. And, the advantage is steadily growing for both categories. The region-wise RCA analysis shows that India has a comparative advantage in ASEAN for both the categories and in the Middle East only for APIs.

Pharmaceuticals is an important sector for FDI inflows to India, accounting for 3.3 per cent of FDI equity inflows during the period between April 2000 and March 2022. Inflows from the ASEAN region constituted nearly one-fourth (22.8 per cent) of the FDI inflows that came to the pharmaceutical sector

during 2005-06 to 2021-22. Inflows from the Middle East, however, account for only 2 per cent of the inflows into the pharmaceutical sector. Since much of the FDI from the ASEAN region has come from Singapore, we do not know whether the investments originated from that country, or it was used as a base for routing the investments.

In the outward FDI from India, the pharmaceutical sector is a leading one. Investments originating from the manufacturing sector accounted for 31.6 per cent of the total OFDI during the period between 2008-09 and 2021-22. Within the manufacturing sector, the share of the pharmaceuticals sector in the annual outflow of investment has been continuously increasing. It has increased from 9 per cent in 2008-09 to 41 per cent in 2021-22. The share of ASEAN and the Middle East in India's OFDI from the pharmaceutical sector is 3.2 per cent and 5 per cent, respectively during the period between 2008-09 and 2021-22. While almost the entire investment to the ASEAN region went to Singapore, UAE and Cyprus in the Middle East were the leading destinations.

Indian exporters face a number of market access barriers in the two regions. Several countries in the two regions are keen to develop their own domestic pharmaceutical industries. To promote indigenous industries, they have put in place several measures comprising the use of local content requirements, support for R&D, public procurement policies in favour of domestically produced goods and pharmaceutical reimbursement schemes linked to domestic content certification. Indian exporters also face technical barriers in exporting to some of the countries in the region.

The initiatives by some countries to develop indigenous industries provide an opportunity for Indian pharmaceutical firms to expand their business by establishing their subsidiaries in those countries. This may also boost India's export of APIs to these countries. It is relatively easier for firms to acquire the

manufacturing capabilities in formulations as compared to APIs. API manufacturing is a more technology-intensive process, and it has a lot of environmental implications. It is likely that such countries will continue to import APIs even if they are successful in developing capabilities in the manufacturing of formulations. For example, Indonesia is a country that imposes restrictions on the import of formulations as it is striving for the development of an indigenous industry. However, India's export of APIs to this country has increased substantially over the years. The value of export of APIs to Indonesia increased from US$ 5.7 million during 2003-05 to US$ 51.3 million during 2018-20, with that country's share in India's export of APIs to the ASEAN region increasing from 9 per cent to 18 per cent during the same period.

And the pharmaceutical markets in these two regions are projected to grow faster in the coming years due to the increasing prevalence of chronic diseases, growing geriatric population and rising per capita healthcare expenditure. It has been reported that the patents over many lucrative medicines are going to expire in the coming years which is likely to create an opportunity worth US$ 240 billion over the next five years until 2026. This will add to the opportunity that is emerging from these regions. However, taking full advantage of this opportunity requires Indian pharmaceutical firms to establish their manufacturing facilities in those countries where the import of formulations is discouraged.

The weakness that India faces, however, is that the advantage that the Indian pharmaceutical products, have in the world, is determined by the import of cheaper raw materials (KSMs, DIs and some APIs) from China. This makes India very concerned about any disruption in the supplies from China, both in terms of price and quantity. There is a view among some countries, which are more concerned about the national security implications of excessive reliance on China for supplies, that India is not a reliable alternate source of supply for

APIs. This calls for improving the competence of production of APIs (and KSMs and DIs) in India.

There is scope for further expansion of India's exports to these regions. Several formulations are kept on the Exclusion List by some of the ASEAN countries. For those formulations, India's share in export to the ASEAN region is lower as compared to their share in India's global exports. The India-ASEAN FTA provides for an annual review of the products covered in the exclusion list. India should use the annual review process to get tariff concessions in those formulations where India is having a very low share in ASEAN as compared to global exports.

India should also negotiate with countries in the two regions with a view to overcoming the hurdles created by NTMs for Indian exporters. The BCPP of India-UAE FTA provides a useful template for such negotiations as far as technical barriers to trade are concerned. The government of India should also sensitise Indian pharmaceutical firms about the emerging business opportunities in the two regions.

CHAPTER 1

# Introduction

The Indian pharmaceutical industry is a shining example of how coordinated government interventions can create globally competitive industries. It is one of the leading exporters of generic medicines and active pharmaceutical ingredients (APIs) globally. Several countries are increasingly promoting the use of generic medicines to reduce healthcare expenses. Patents over several lucrative medicines are going to expire in the coming years, which is likely to create an opportunity worth about US$ 250 billion over the next five years. And the endeavour of countries to diversity their sources of supplies of pharmaceutical raw materials create new opportunities for producers of APIs and intermediates. All these developments have the potential for boosting India's export in pharmaceutical products.

Given this background, the Department of Pharmaceuticals, Ministry of Chemicals and Fertilizers, sponsored a study to look into India's trade and investment engagements with the Association of Southeast Asian Nations (ASEAN) and Middle East regions in the pharmaceutical sector. The scope of the study covers analysing trends in India's trade and investment with the two regions, identifying challenges of market access and suggesting strategies to leverage India's Free Trade Agreement (FTAs) with ASEAN and to further promote trade with the regions keeping in view the strengths of the Indian pharmaceutical industry.

India had entered into a Framework Agreement on Comprehensive Economic Cooperation (Framework Agreement, hereafter) with ASEAN in 2003. Based on this Framework Agreement, the India-ASEAN FTA was signed in 2009, which came into force the next year. And an agreement on investment was signed in 2014, which came into force in 2015. The Comprehensive Economic Partnership Agreement (CEPA) that India signed with the UAE in February 2022 was the first such engagement with any country in the Middle East region. The FTA as part of the CEPA came into force on 1 May 2022. Both countries also agreed to replace the existing Bilateral Investment Treaty (BIT), that was signed in 2013, with a new agreement on investment, as part of the CEPA.

This study analyses the impact of India-ASEAN trade and investment agreements on trade and investment flows between the two parties in the pharmaceutical sector and the likely implications of the India-UAE FTA on the Indian pharmaceutical sector. It also looks into the market access barriers that Indian exporters of pharmaceutical products face in these two regions and the potential for promotion of exports to these regions.

Chapter one is focused on trade engagements of India with ASEAN and Middle East regions in pharmaceutical products. An International Standard Industrial Classification (ISIC) based classification was used for identifying pharmaceutical products from international trade statistics. The trends in exports, imports and balance of trade in different categories of pharmaceutical products are captured in this chapter. It also examines the comparative advantage of pharmaceutical products from India at global and regional levels through Revealed Comparative Advantage (RCA) analysis. In order to examine whether Indian export of pharmaceutical products to the ASEAN region is becoming concentrated in certain product categories or whether they are getting diversified, the Herfindahl Index was estimated. This

chapter also identifies growth prospects for Indian pharmaceutical exports in the two regions.

Third chapter analyses FDI flows, both inflows and outflows, between India and countries in the two regions in the pharmaceutical sector. The analysis of FDI inflows is based on the country wise data provided by the Department of Commerce, Ministry of Commerce and Industry, for the pharmaceutical sector. The analysis of OFDI is based on the Overseas Direct Investment data provided by the Reserve Bank of India (RBI). This chapter identifies leading home countries of FDI inflows from the two regions and destinations of FDI outflows from India. It also identifies leading investors from India investing in these regions in the pharmaceutical sector.

Chapter four captures the market access barriers faced by Indian exporters. This analysis is carried out using the information collected from various sources - Global Trade Alert (GTA) database, questions raised by India during the trade policy review of its trading partners at the World Trade Organization (WTO), concerns raised by the US Trade Representative (USTR) in it's National Trade Estimate Reports on Foreign Trade Barriers, and media reports and studies.

Chapter five provides a SWOT analysis. This is based on the analysis covered in the previous chapters. And chapter six lists the key suggestions emerging from this study.

CHAPTER 2

# India's Trade with ASEAN and Middle East Countries in Pharmaceutical Products

## 2.1. Introduction

The combined GDP of the 10 ASEAN members in 2019 was $3.2 trillion, making this block the fifth largest region in the world (ASEAN 2020). The Middle East countries accounted for 5 per cent of global GDP in 2021[1]. These two regions play an important role in global trade. In 2020, these two regions accounted for 11 per cent of the world's total merchandise exports and 10 per cent of total merchandise imports.[2] India's merchandise exports to ASEAN was US$ 31.5 billion in 2020-21 and imports from ASEAN was worth US$ 47.4 billion, resulting in a trade deficit of US$15.9 billion.[3] Studies have shown that trade deficit with ASEAN has increased during the post FTA period. In the same year (2020-21), India's exports and imports with Middle East countries, as captured by trade with Gulf Cooperation Council (GCC) countries, stood at US$ 44 billion and US$ 110.7 billion, respectively, and thus having a trade deficit.[4] The GCC Members account for 10 per cent of India's exports and 18 per cent of India's

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1 Information available at https://www.worldeconomics.com/Regions/Middle-East/ (accessed on 2 August 2022).

2 Computed from World Trade Statistical Review 2021 (WTO 2021).

3 Information provided by Department of Commerce, Ministry of Commerce and Industry, Government of India, at https://commerce.gov.in/about-us/divisions/foreign-trade-territorial-division/foreign-trade-asean/ (accessed on 2 August 2022).

4 Information available at https://economictimes.indiatimes.com/news/economy/foreign-trade/indias-bilateral-trade-with-gcc-witnesses-rapid-expansion/articleshow/92038397.cms (accessed on 2 August 2022).

imports. The recently concluded FTA with UAE, which is a member of GCC and India's second largest export destination after United States (US), is expected to accelerate India's exports to that country. India had signed a Framework Agreement for enhancing and developing economic co-operation with GCC in 2004. It is reported that India has initiated the process for concluding an FTA with the GCC. This chapter analyses various aspects of India's trade engagement with these two regions in the pharmaceutical sector – trends in trade, India's export performance in these regions and implications of India's FTAs with countries in these two regions.

## 2.2. India's Trade in Pharmaceutical Products

India is a major exporter of pharmaceutical products. It's ability to export good quality generic medicines to different parts of the world has earned India the nickname Pharmacy of the World. But when it comes to making cross-country comparisons to analyse how competitive Indian pharmaceutical exports is, a major challenge is in the classification of pharmaceutical products. The most commonly used method of using World Customs Organization's Harmonised Commodity Description and Coding System (HS) of trade classification, Chapter 30 (HS Chapter 30) for the identification of pharmaceutical products from international trade statistics is not an appropriate one as it captures formulations, mostly, and a few other pharmaceutical products such as bandages. This chapter does not capture APIs, which is an important category of pharmaceutical products traded globally. It is also observed that some countries maintain their own classification of pharmaceutical products to compile data on exports and imports. Such classifications cannot be used for making cross-country comparisons as they are specific to concerned countries. Therefore, we are using the classification that is used by Joseph and Kumar (2022) in tracing trends in India's export and import of pharmaceutical

products. They have used International Standard Industrial Classification (ISIC, Rev.4) for the identification of pharmaceutical products from international trade statistics and categorised pharmaceutical products into four categories based on global best practices. This methodology is explained in the following section.

### 2.2.1. Methodology

The ISIC (Rev.4) division 2100 (Manufacture of pharmaceuticals, medicinal chemicals and botanical products) covers products of the pharmaceutical industry. ISIC Rev.4 was released in 2008. In the same year, India also released the National Industrial Classification 2008, based on the ISIC Rev.4. As there is no direct concordance between ISIC and HS, the Central Product Classification (CPC, Ver.2.1), which has concordance with ISIC and HS is used to trace the concordance of ISIC division 2100 with HS. The CPC division 352 (pharmaceutical products) has concordance with ISIC division 2100. CPC also provides the concordance between its sub-divisions and HS 2007 at 4-digit and 6-digit levels. However, at HS 2007, Indian pharmaceutical trade data is available from 2009 only. As one of the objectives of this study is to analyse the impact of the India-ASEAN FTA on pharmaceutical exports from India, we have used concordance between HS 2007 and HS 2002 to have trade data at least a few years before signing this FTA. Using HS 2002, we are able to get India's trade data since 2003. Using HS 2002, we have identified 100 HS 6-digit lines (Table 1) that are in concordance with ISIC division 2100. Joseph and Kumar (2022) categorised pharmaceutical products into four categories - Formulations, APIs, Bulk Medicines and Other Pharmaceutical Products. We are also using the same categorisation for this study.

**Table 1: Classification of Pharmaceuticals Products at HS 6-digit level using ISIC-CPC-HS Concordance (Codes from HS 2002)**

| | | | | |
|---|---|---|---|---|
| **Formulations** | 292419 | 293625 | 293919 | 294150 |
| 300220 | 292423 | 293626 | 293921 | 294190 |
| 300230 | 292424 | 293627 | 293929 | **Bulk Medicines** |
| 300410 | 292429 | 293628 | 293930 | 300310 |
| 300420 | 293229 | 293629 | 293941 | 300320 |
| 300431 | 293311 | 293690 | 293942 | 300331 |
| 300432 | 293319 | 293711 | 293943 | 300339 |
| 300439 | 293321 | 293712 | 293949 | 300340 |
| 300440 | 293352 | 293719 | 293951 | 300390 |
| 300450 | 293353 | 293721 | 293959 | **Other Pharmaceuticals** |
| 300490 | 293354 | 293722 | 293961 | 300110 |
| **APIs**[5] | 293355 | 293723 | 293962 | 300120 |
| 291821 | 293359 | 293729 | 293963 | 300190 |
| 291822 | 293369 | 293731 | 293969 | 300210 |
| 291823 | 293430 | 293739 | 293991 | 300290 |
| 292241 | 293500 | 293740 | 293999 | 300510 |
| 292242 | 293610 | 293750 | 294000 | 300590 |
| 292310 | 293621 | 293790 | 294110 | 300620 |
| 292320 | 293622 | 293810 | 294120 | 300630 |
| 292390 | 293623 | 293890 | 294130 | 300660 |
| 292411 | 293624 | 293911 | 294140 | |

Source: Based on Joseph and Kumar (2022).

The categorisation of pharmaceutical products into four categories is based on the definition of pharmaceutical products used by various international agencies. The WHO defines a pharmaceutical product as "any substance or combination of substances marketed or manufactured to be marketed for treating or preventing disease in human beings, or with a view to making a medical diagnosis in human beings, or to restoring, correcting or modifying

[5] This category may also consists of some drug intermediates (DIs). In some cases, APIs and DIs may come under the same HS code. For example, HS code 29419030 covers both Ciprofloxacin API and Ciprofloxacin Acid DI.

physiological functions in human beings".[6] The Directive of the European Union on Community Code for Medicinal Products also uses a similar definition.[7] Regarding the identification of a product based on implications for 'restoring, correcting or modifying physiological functions in human beings', the European Court of Justice (ECJ), in a few judgements, has directed that medicinal properties in a product should be the criteria for identification of medicinal products in such situations (MHRA 2020). Therefore, the use of ISIC for the identification of products belonging to the pharmaceutical industry is appropriate.[8]

The US Code of Federal Regulations Title 21, which is on food and drugs, defines a finished dosage form (formulation) as a "tablet, capsule, solution, etc. that contains an active drug ingredient generally, but not necessarily, in association with inactive ingredients" and API as "any component that is intended to furnish pharmacological activity or other direct effects in the diagnosis, cure, mitigation, treatment, or prevention of disease, or to affect the structure or any function of the body of man or other animals"[9]. In India, similar definitions of formulations and APIs are used in the guidelines of the Product Linked Incentive (PLI) Scheme for APIs, Drug Intermediates (DIs) and Key Starting Materials (KSMs). A formulation is defined as "a finished dosage form, for example, capsule, tablet, solution, injectable, ointment, semisolid,

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6 Definition of pharmaceutical products available in the glossary, https://extranet.who.int/pqweb/content/glossary (accessed on 2 August 2022)

7 See Article 1 of the Directive 2001/83/EC of the European Parliament and of the Council on Community Code for Medicinal Products for Human Use.

8 Although some international agencies define pharmaceutical products in the context of application to human beings, ISIC (2100) and CPC (352) includes some veterinary medicines as pharmaceutical products. HS 300230 consists of vaccines for veterinary use. However, their contribution in global trade of pharmaceutical products is negligible. Share of products coming under HS 300230 in India's total pharmaceutical exports in 2020 was 0.04 per cent.

9 Code of Federal Regulations, Title 21, Volume 4, https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?fr=210.3 (accessed on 2 August 2022).

etc. that contains an active drug ingredient along with other ingredients" and API is defined as "any substance or mixture of substances intended to be used in the manufacture of a drug (medicinal) product and that, when used in the production of a drug, becomes an active ingredient of that drug. Such substances are intended to furnish pharmacological activity or other direct effects in diagnosis, cure, mitigation, treatment, or prevention of disease or to affect the structure or function of the body".

Some publications (WTO, WIPO and WHO 2013 and Helble 2012) classify HS chapter 3003 as a separate category called Bulk Medicines. HS 3003 contains "medicaments constituting two or more constituents which have been mixed together for therapeutic or prophylactic uses, not put up in measured doses or in forms or packings for retail sale". This HS 4-digit heading contains APIs mixed with other ingredients. As products under this heading have not been put into dosage forms, they cannot be considered as formulations. The European Agency for the Evaluation of Medicinal Products' (EMEA) Note for Guidance on Start of Shell Life of the Finished Dosage Form (EMEA 2001) points out that the date of production of a batch (of formulations) is defined as the date in which the first step is performed for combining an API with other ingredients. Therefore, from that date onwards treatment of that product as an API will cease to exist. As they are mixed with other ingredients, they are no more APIs. And as they are not put into dosage forms, they can neither be treated as formulations. As the definition for formulations applied in India and other countries is focused on the 'dosage' of APIs, it will not be appropriate to treat mixtures of APIs which are not put into dosage forms as formulations. For this reason, a report jointly published by WTO, WIPO and WHO in 2013 (Promoting Access to Medical Technologies and Innovation: Intersections between public health, intellectual property and trade) classifies those APIs which are mixed with other APIs or excipients as a separate category called

bulk medicines. This report was published after a discussion in the WHO in 2011 on the need to treat such APIs separately. Therefore, we also categorise products under HS heading 3003 as a separate category, Bulk Medicines.

There are some pharmaceutical products like band-aids, apart from formulations, that are used in the treatment of diseases. Some of the regulatory agencies define disease to include injury. The Human Medicines Regulations 2012 of the UK defines disease to include "any injury, ailment or adverse condition, whether of body or mind".[10] Those pharmaceutical products, which are not formulations, but have some therapeutic uses and therefore are used in the treatment of diseases, come under the category of other pharmaceutical products. In CPC, these products are classified as other pharmaceutical products. Such products are classified as other pharmaceutical products.

### 2.2.2. Trends in India's Trade in Pharmaceutical Products

India is the 11th largest exporter of pharmaceutical products globally in 2020 in terms of value of exports and the 6th largest in terms of quantity of exports (Table 2).

In 2020, India exported US$ 22 billion worth of pharmaceutical products. Formulations accounted for the bulk of the exports (79 per cent) in 2020 (Figure 1). Export of formulations increased from US$ 4.2 billion in 2009 to US$ 17.4 billion in 2020. APIs had a share of 16 per cent in the same year. Bulk medicines and other pharmaceutical products constituted the remaining 5 per cent of exports.

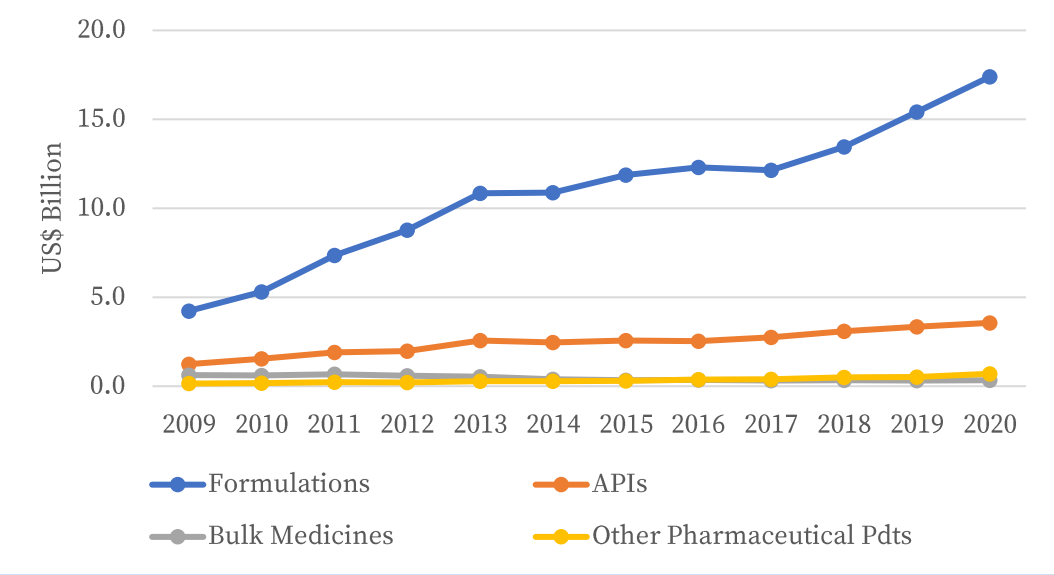
[10] The Human Medicines Regulations 2012, Regulation 8, https://www.legislation.gov.uk/uksi/2012/1916/regulation/8/made?view=plain (accessed on 2 August 2022).

**Table 2: India's Global Position in Trade in Pharmaceutical Products in 2020**

| *Value* | | | | *Volume* | | | |
|---|---|---|---|---|---|---|---|
| *Ranking* | *Country* | *Exports in 2020 (US$ Billion)* | *Share in World's Exports (%)* | *Ranking* | *Country* | *Exports in 2020 (in 1000 MT)* | *Share in World's Exports (%)* |
| 1 | Germany | 103 | 14.3 | 1 | China | 3,796 | 30.7 |
| 2 | Switzerland | 102 | 14.1 | 2 | Germany | 1,186 | 9.6 |
| 3 | Ireland | 80 | 11.1 | 3 | USA | 634 | 5.1 |
| 4 | USA | 52 | 7.2 | 4 | France | 597 | 4.8 |
| 5 | Belgium | 52 | 7.2 | 5 | Netherlands | 455 | 3.7 |
| 6 | France | 40 | 5.5 | 6 | India | 441 | 3.6 |
| 7 | Italy | 36 | 5 | 7 | Italy | 383 | 3.1 |
| 8 | China | 31 | 4.3 | 8 | Spain | 358 | 2.9 |
| 9 | Netherlands | 29 | 4.1 | 9 | UK | 358 | 2.9 |
| 10 | UK | 28 | 3.9 | 10 | Indonesia | 311 | 2.5 |
| 11 | India | 22 | 3 | 11 | Belgium | 302 | 2.4 |
| World's Exports (Value) | | 724 | | World's Exports (Volume) | | 12,383 | |

Source: Reproduced from Joseph and Kumar (2022)[11]

**Figure 1: India's Export of Pharmaceutical Products**




Source: Same as Table 2.

[11] This table is compiled based on the COMTRADE data accessed through World Integrated Trade Solution (WITS) database of World Bank using the ISIC-CPC-HS concordance.

In the global export of pharmaceutical products, India's share was 3 per cent in terms of value of exports in 2020. In some categories of pharmaceutical products, the share was even more. The following table (Table 3) gives the category-wise share in exports, both in terms of value and volume, and India's ranking in 2020.

**Table 3: India's Share (Category-Wise) in the World's Total Export of Pharmaceutical Products, both in Terms of Value and Volume of Exports (Per Cent)**

| *Category* | *Value* | | | | *Volume* | | | |
|---|---|---|---|---|---|---|---|---|
| | *2009* | *2015* | *2020* | *Ranking (2020)* | *2009* | *2015* | *2020* | *Ranking (2020)* |
| Formulations | 1.3 | 3.7 | 4.3 | 10 | 13.2 | 9.6 | 6.3 | 5 |
| APIs | 2.2 | 3.5 | 3.8 | 7 | 1.9 | 2.7 | 1.7 | 12 |
| Bulk Medicines | 8.8 | 3.1 | 3.5 | 10 | 22.3 | 7.5 | 8.2 | 2 |
| Other Pharmaceuticals | 0.2 | 0.3 | 0.3 | 21 | 2.6 | 1.4 | 1.4 | 16 |
| Total | 1.4 | 2.9 | 3 | 11 | 7.3 | 5.3 | 3.6 | 6 |

Source: Same as Table 2.

India's share in global export of formulations, in terms of value of exports, has increased from 1.3 per cent to 4.3 per cent during the period between 2009 and 2020. At the same time, the share in terms of quantity of exports has declined. This indicates that India is increasingly exporting more value-added formulations. It is interesting to find that in APIs, India's share in global exports has increased from 2.2 per cent in 2009 to 3.8 per cent in 2020, in spite of the fact that India is reported to be heavily import dependent on APIs. At the same time, India's share in the global export of APIs in terms of quantity of exports declined from 1.9 per cent to 1.7 per cent. This also indicates that India is increasingly exporting more value-added APIs. In bulk medicines, India ranks second in global exports in terms of quantity. But it may not be of much significance for India as bulk medicines account for only a very small share of pharmaceutical products from India. The value of India's exports of

bulk medicines has declined from US$ 600 million in 2009 to US$ 300 million in 2020.

India is having a surplus in the trade in pharmaceuticals in general (Table 4). However, when it comes to different categories of pharmaceutical products, formulations and bulk medicines have shown trade surplus consistently. In the case of other pharmaceuticals, there is a trade deficit in all the three time-points covered in the analysis. In APIs, the trade balance shows a surplus after 2009. Following table provides details of trade in different categories of pharmaceutical products. India's export and Import of the four categories of pharmaceutical products, in terms of both value and volume of exports, are given in annexures 1-4.

**Table 4: Category-Wise Trends in India's Global Trade in Pharmaceutical Products (in US$ Billion)**

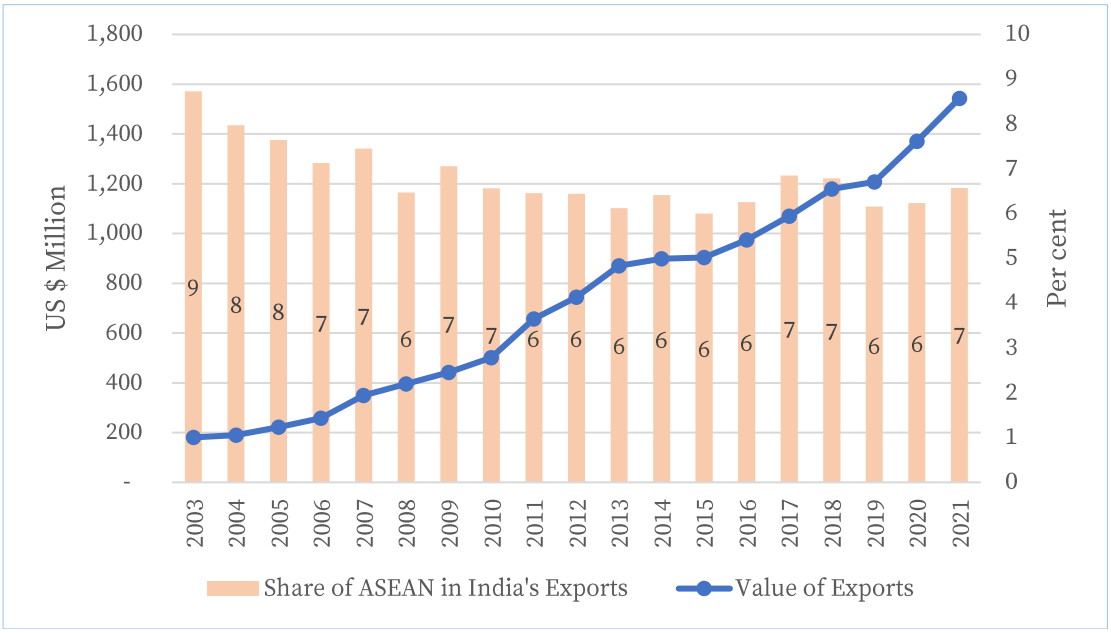
| *Category* | *2009* | | | *2015* | | | *2020* | | |
|---|---|---|---|---|---|---|---|---|---|
| | *Export* | *Import* | *BOT* | *Export* | *Import* | *BOT* | *Export* | *Import* | *BOT* |
| Formulations | 4.23 | 0.80 | 3.43 | 11.87 | 1.16 | 10.71 | 17.39 | 1.43 | 15.96 |
| APIs | 1.24 | 1.32 | -0.08 | 2.57 | 2.36 | 0.21 | 3.56 | 3.38 | 0.18 |
| Bulk Medicines | 0.63 | 0.05 | 0.58 | 0.33 | 0.03 | 0.29 | 0.34 | 0.07 | 0.27 |
| Other Pharmaceuticals | 0.15 | 0.23 | -0.08 | 0.30 | 0.42 | -0.12 | 0.70 | 0.98 | -0.28 |
| Total (all the above categories) | 6.25 | 2.40 | 3.85 | 15.07 | 3.98 | 11.09 | 21.99 | 5.85 | 16.13 |

Source: Same as Table 2.

## 2.3. India's Trade with ASEAN in Pharmaceutical Products

India's export of pharmaceutical products to ASEAN increased from US$181 million in 2003 to US$ 1544 million in 2021 (Figure 2). However, the share of ASEAN in India's global exports of pharmaceutical products declined from 9 per cent to 7 per cent during this period, indicating that exports to this region have grown at a slow pace as compared to exports to other countries.

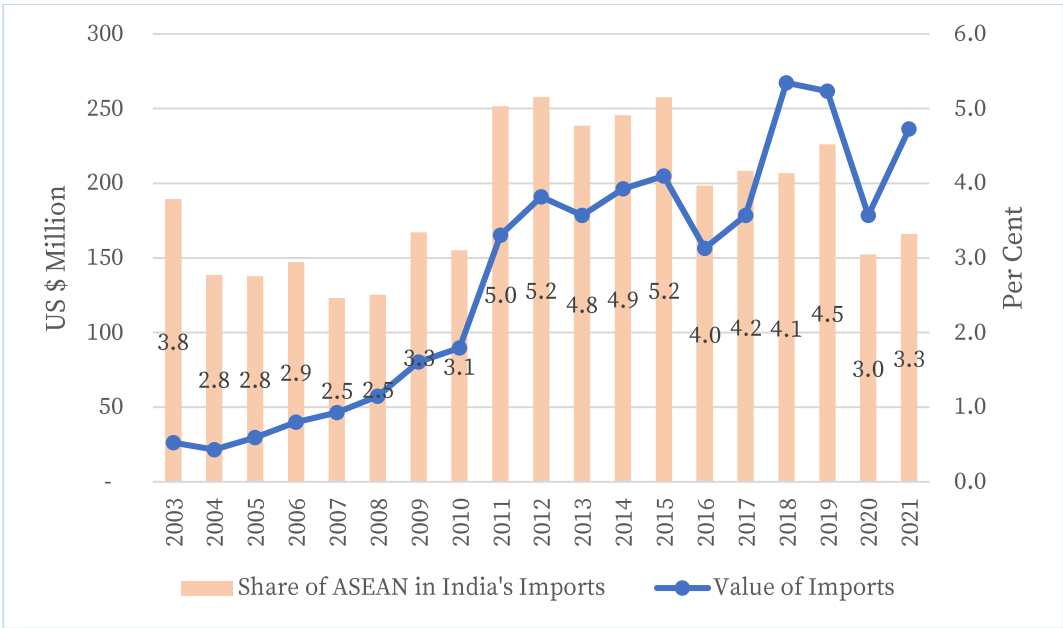
**Figure 2: Trends in India's Export of Pharmaceutical Products to ASEAN**




Source: Compiled using World Integrated Trade Solution (WITS), database.

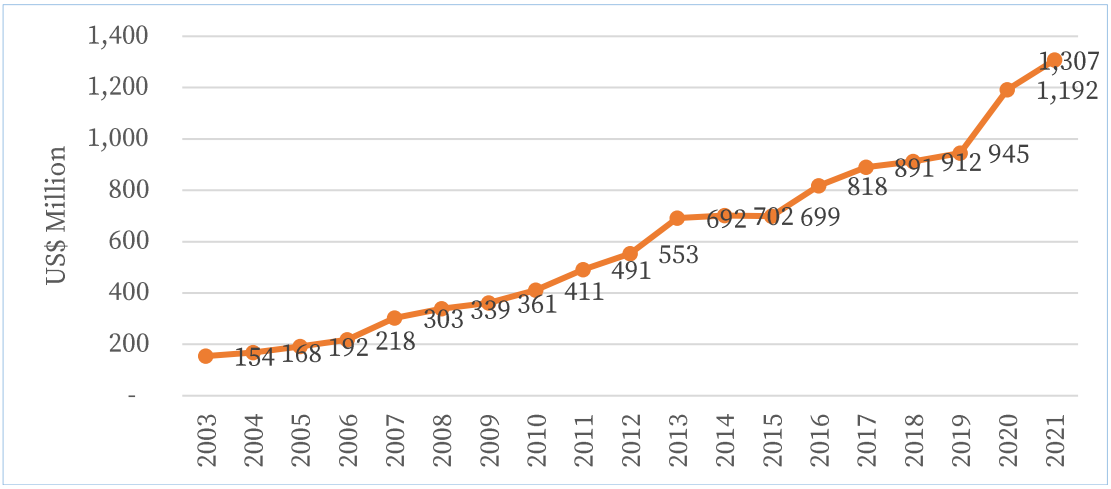
In imports, India is not found to be much dependent on ASEAN in pharmaceutical products. Import from ASEAN accounts for 3 per cent of India's total import of pharmaceutical products (Figure 3). As a result, India's trade with ASEAN in pharmaceutical products exhibits a steadily growing trade surplus (Figure 4).

**Figure 3: Trends in India's Import of Pharmaceutical Products from ASEAN**




Source: Same as Figure 2

**Figure 4: India's Balance of Trade with ASEAN in Pharmaceutical Products**

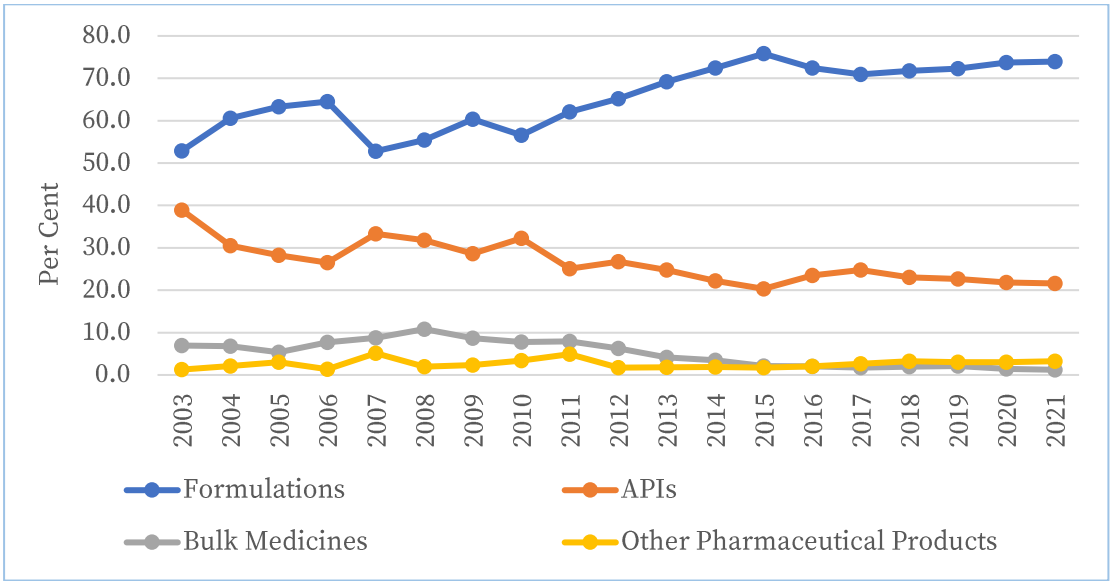



Source: Same as Figure 2.

## 2.3.1. Details of Pharmaceutical Products Exported to ASEAN Countries

A category-wise analysis of exports shows that formulations is the leading export category, accounting for a three-fourths share in 2021, followed by APIs with a share of 22 per cent in the same year (Figure 5). The other two categories of pharmaceutical products – bulk medicines and other pharmaceutical products account for only a very low share.

**Figure 5: Category-wise Distribution of India's Pharmaceutical Exports to ASEAN (in per cent)**




Source: Same as Figure 2

It is important to note that in 2003 the difference in the value of exports between formulations and APIs was not big. Since then, India's export of formulations to this region grew at a faster pace as compared to APIs (Table 5).

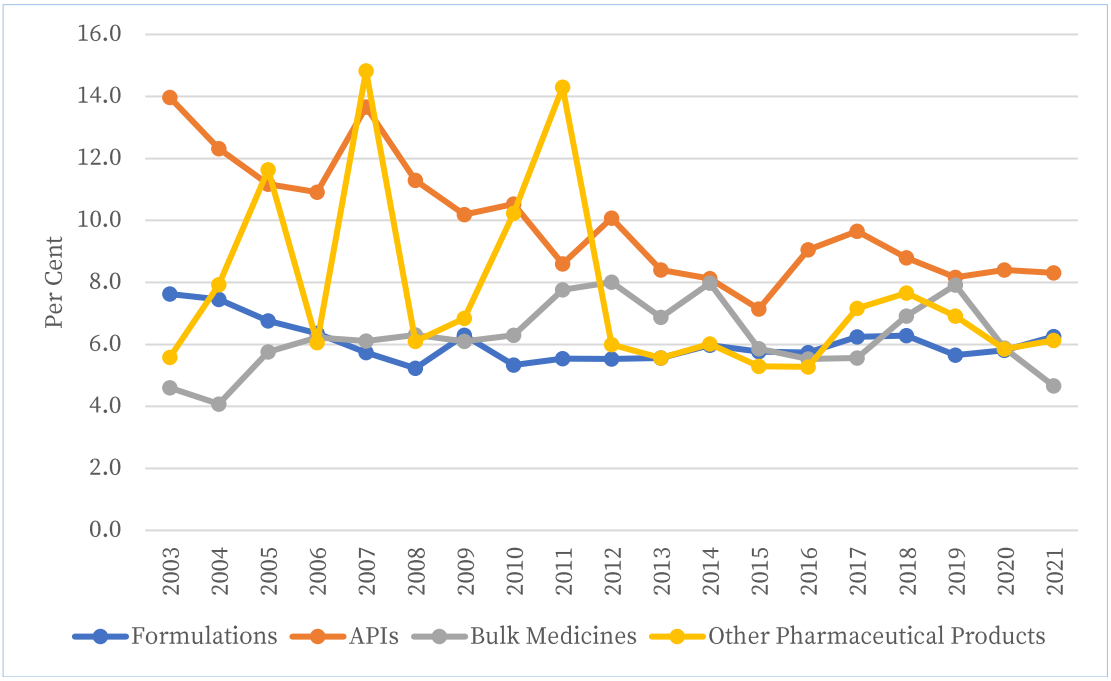
**Table 5: Category-wise Export of India's Pharmaceutical Exports to ASEAN (in $ Million)**

| | *Formulations* | *APIs* | *Bulk Medicines* | *Other Pharmaceutical Products* | *Total Pharmaceutical Products* |
|---|---|---|---|---|---|
| 2003 | 95.5 | 70.3 | 12.5 | 2.3 | 180.6 |
| 2004 | 114.9 | 57.9 | 12.9 | 4.0 | 189.6 |
| 2005 | 140.6 | 62.7 | 11.9 | 6.8 | 222.0 |
| 2006 | 166.3 | 68.3 | 19.8 | 3.5 | 257.9 |
| 2007 | 184.4 | 116.4 | 30.5 | 17.9 | 349.2 |
| 2008 | 219.5 | 125.7 | 42.8 | 7.8 | 395.9 |
| 2009 | 266.2 | 126.5 | 38.4 | 10.2 | 441.3 |
| 2010 | 283.1 | 161.6 | 38.8 | 17.2 | 500.6 |
| 2011 | 407.5 | 164.4 | 52.1 | 32.4 | 656.3 |
| 2012 | 485.3 | 199.0 | 46.8 | 13.1 | 744.3 |
| 2013 | 602.7 | 215.8 | 36.5 | 15.8 | 870.7 |
| 2014 | 650.9 | 199.4 | 31.1 | 17.2 | 898.6 |
| 2015 | 685.3 | 183.7 | 19.3 | 15.7 | 904.0 |
| 2016 | 705.7 | 229.1 | 19.5 | 20.1 | 974.4 |
| 2017 | 758.3 | 264.8 | 18.3 | 27.9 | 1069.2 |
| 2018 | 846.0 | 272.1 | 22.8 | 38.5 | 1179.4 |
| 2019 | 872.4 | 273.3 | 25.2 | 36.1 | 1206.9 |
| 2020 | 1010.9 | 299.2 | 19.8 | 40.9 | 1370.8 |
| 2021 | 1140.9 | 333.8 | 18.8 | 49.9 | 1543.6 |

Source: Same as Figure 2

However, the increase that is seen in the export of most category of pharmaceutical products has not result in an increased share of ASEAN in India's global export of pharmaceutical products (Figure 6). But, it can be seen in the case of formulations that it's share has been declining until 2010 and thereafter it's share has increased marginally.

**Figure 6: Share of ASEAN in India's Global Export of Pharmaceutical Products**




Source: Same as Figure 2

An analysis of growth in India's export of pharmaceutical products during the pre and post FTA periods shows that the growth has declined after 2010 (Table 6). This *prima facie* gives the impression that the FTA has not benefitted India in the pharmaceuticals sector. However, when we compare growth in the export of pharmaceutical products with that of India's total exports to the ASEAN region, a different picture emerges. During the pre-FTA period, India's total export was growing at a much higher rate as compared to pharmaceutical products. During the post-FTA period, the rate of growth of total exports declined drastically, from 25 per cent to 7.5 per cent. Although the rate of growth of pharmaceutical products also declined during the post-FTA period, it registers a higher rate of growth as compared to India's total exports[12].

[12] Average annual growth rate is used for this analysis as the number of years is more during the FTA period, in our study period.

**Table 6: Growth in India's Exports to ASEAN (average annual growth rate)**

| *Product Details* | *2003-2021* | *2003-09* | *2011-21* |
|---|---|---|---|
| Formulation | 15.2 | 18.7 | 14.0 |
| APIs | 10.4 | 13.1 | 7.3 |
| Bulk Medicines | 5.5 | 24.3 | -4.3 |
| Other Pharmaceutical Products | 40.7 | 80.2 | 16.7 |
| Total Pharmaceutical Products | 13.0 | 16.4 | 11.1 |
| India's Total Export to ASEAN | 14.5 | 25.0 | 7.5 |

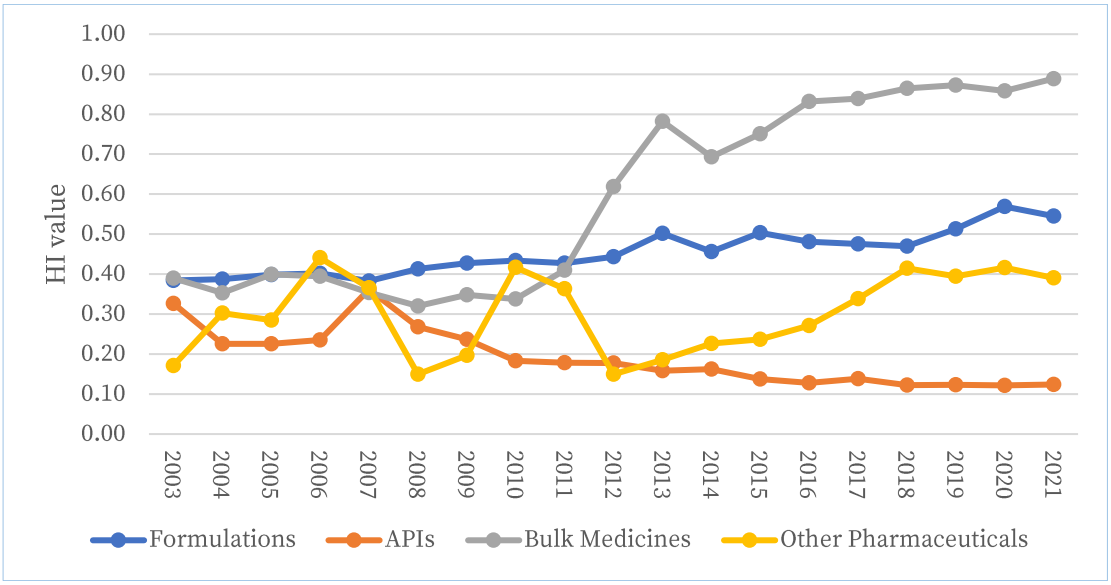
Source: Computed by authors based on data collected from WITS

In order to examine whether Indian export of pharmaceutical products to the ASEAN region is becoming concentrated in certain product categories or whether that is getting diversified, we have estimated Herfindahl Index (HI) for all four categories of pharmaceutical products. The HI for pharmaceutical products is defined as:

$$HI = \sum_{i=1}^{N} S_i^2$$

*where,* $S_i$ is the share of each HS line in total exports attributed to the product group and N is the number of HS lines. The normalized HI value lies between 0 and 1. A lower value of the index represents more product diversification in exports and vice versa. Values of the index for formulations and APIs are presented in Figure 7.

**Figure 7: Product Diversification Index for ASEAN Region**




Source: Same as Figure 2

As it is seen in the above figure (Figure 7), the index for pharmaceutical products, except for APIs, shows rising value. Whereas the export of APIs is increasingly getting diversified.

### 2.3.2. Details of Pharmaceutical Products Imported from ASEAN Countries

A more detailed analysis is carried out in order to have a better understanding of imported categories. Table 7 shows that India imports mostly formulations and APIs. Seventy-one per cent of formulations imported from the region is from Indonesia. Similarly, more than half of the APIs imported (57 per cent) is from Singapore. However, when compared to India's total import of pharmaceutical products, imports from this region accounts for only a small share; formulations (6 per cent) and APIs (2.5 per cent). Details of India's import of four categories of pharmaceutical products from the ASEAN countries, in terms of value of imports, is given in annexure 5.

**Table 7: India's Imports (Category-wise) from ASEAN in 2020 (in US$ Million)**

| *Country* | *Formulations* | *APIs* | *Bulk Medicines* | *Other Pharmaceuticals* | *Total* |
|---|---|---|---|---|---|
| Indonesia | 60 | 12 | - | 2 | 74 |
| Singapore | 18 | 47 | - | 8 | 73 |
| Malaysia | 5.5 | 18 | - | 0.1 | 23 |
| Vietnam | 0.0 | 4 | - | 0.2 | 4 |
| Thailand | 0.1 | 3 | 0.02 | 0.1 | 3 |
| ASEAN | 84 | 83 | 0.02 | 11 | 178 |
| Share in India's Total Imports from world (%) | 5.9 | 2.5 | 0.0 | 1.1 | 3.0 |

Source: Same as Figure 2

It is interesting to observe that India is importing some formulations from ASEAN countries, despite the fact that the Indian pharmaceutical industry is known for its competence in supplying generic formulations and vaccines globally. Table 8 gives details of the imported formulations from this region.

It is found that more than 60 per cent of the imports is vaccines, coming from Indonesia. The study of Joseph and Kumar (2022) which further looked into this, finds that vaccines for polio account for much of the vaccines imported from Indonesia. The other important imported formulation category is traditional medicines/AYUSH medicines (HS 300490), which account for a 36 per cent share.

**Table 8: Some Details of Formulations Imported from ASEAN Countries in 2020 (in US$ Million)**

| *HS 6-Digit Line* | *Indonesia* | *Malaysia* | *Philippines* | *Singapore* | *Thailand* | *ASEAN (Total)* |
|---|---|---|---|---|---|---|
| 300220 (Vaccines for human use) | 51.5 | 0.0 | 0.0 | 0.0 | 0.0 | 51.5 |
| 300410 (Containing penicillins and their derivatives) | 0.0 | 0.0 | 0.0 | 0.2 | 0.0 | 0.2 |
| 300420 (Certain antibiotics such as cephalosporins, fluoroquinolones, etc.) | 0.0 | 0.1 | 0.0 | 0.2 | 0.0 | 0.4 |
| 300431 (Insulin) | 0.0 | 1.2 | 0.0 | 0.0 | 0.0 | 1.2 |
| 300490 (Ayurvedic, Unani, Homoeopathic, Siddha or Biochemic systems medicaments) | 7.8 | 4.2 | 0.6 | 17.5 | 0.1 | 30.3 |
| Total | 59.8 | 5.5 | 0.7 | 18.0 | 0.1 | 84.1 |

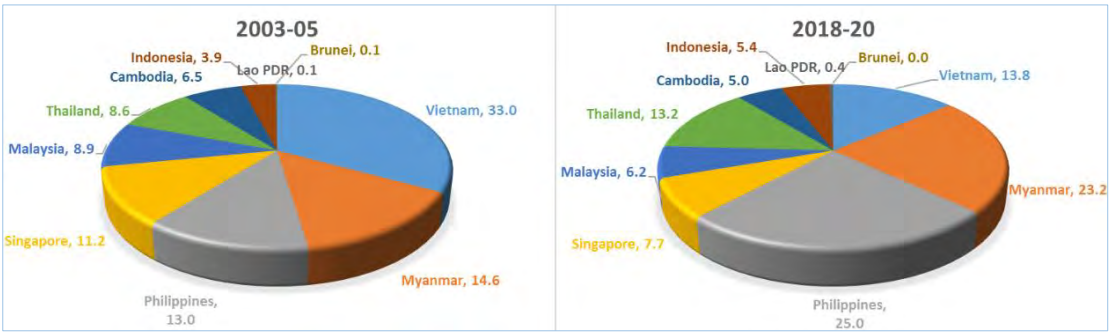
Source: Same as Figure 2

### 2.3.3. Export destinations in ASEAN

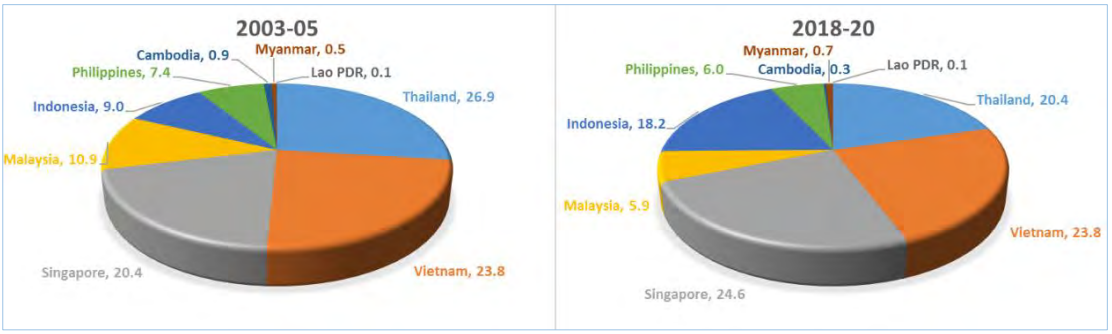
Following Figure (Figure 8) shows the key export destinations in the ASEAN region of the pharmaceutical products from India. A three-year average value of exports is used to identify key export destinations.

**Figure 8: India's Pharmaceutical Exports: Key Destinations in the ASEAN Region**

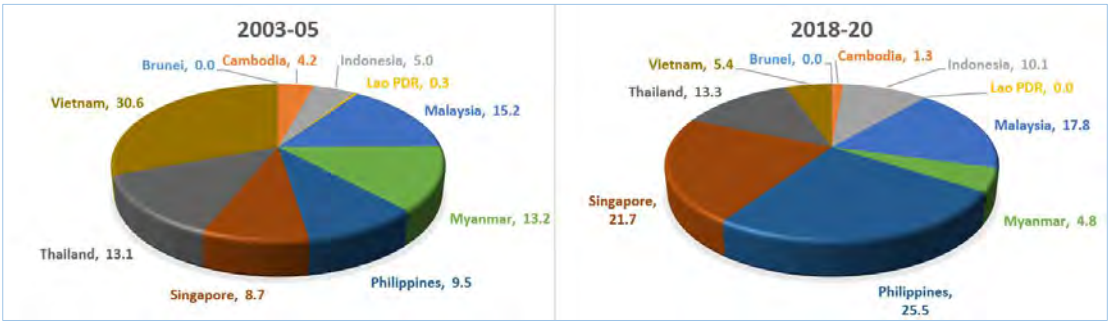
**Formulations**



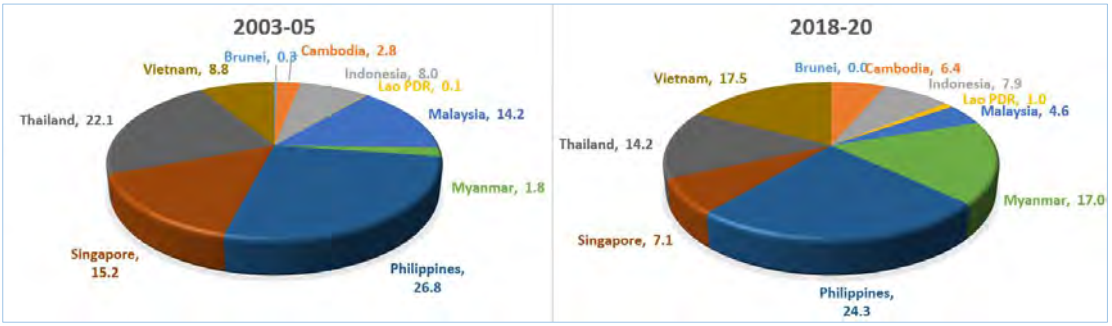

**APIs**




**Bulk Medicines**




**Other Pharmaceutical Products**




Source: Same as Figure 2

Myanmar, the Philippines and Vietnam are the key export destinations for formulations. These three countries had accounted for 61 per cent of India's

formulation exports to this region during 2003-2005 period with Vietnam being the top destination country. During 2018-20 period, these three countries remained leading destinations accounting for 62 per cent of exports to the region, with the Philippines and Myanmar considerably enhancing their shares.

With respect to APIs, Thailand, Vietnam and Singapore are the key destination countries, although their combined share has declined marginally from 71 per cent during 2003-05 period to 69 per cent during 2018-20 period. Over the years, Indonesia has emerged as another key export destination for APIs as its share increased from 9 per cent to 18 per cent between 2003-05 and 2018-20.

In Bulk Medicines, Vietnam and Philippines have emerged as the leading destinations accounting for nearly half of the export to the ASEAN region. In other pharmaceutical products, Philippines continues to remain as the leading destination. Over the years, Myanmar and Vietnam have also emerged as key destinations. The three countries together account for 59 per cent of the export to this region.

The domestic pharmaceutical industreis in the ASEAN countries are at various stages of development. In order to reduce cost of healthcare, many countries in the region are endeavouring to develop domestic pharmaceutical industries. Vietnam has been adopting measrues aimed at this since early 1990s. However, still 90 per cent of their requirements are met through imports.[13] And Vietnam is a leading destination for export of APIs and formulations from India. Thailand's pharmaceutical industry consists of public sector enterprises (PSEs) as well as private sector enterprises. Many of the western MNCs have established their operations in Thailand. They either

[13] Information available at https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5615513/ (accessed on 2 August 2022).

import patented medicines from their parent firms or producce within Thailand. Patented medicines account for 39 per cent of the pharmaceutical market in the country (Pharmexcil 2020). Since, many Indian firms have contract manufacturing arrangmeents for the supply of APIs to western MNCs (Joseph 2016), a part of the APIs exported to Thailand may be explained by such arrangements. The pharmaceutical industry of Singapore contributes 5 per cent of its GDP.[14] It has created an ecosystem for the grwoth of biomedical sector, focusing on reserch and development (R&D) and manufacturing. Leading global pharma MNC ssuch as Pfizer, Novartis, Roche, Sanofi, AbbVie and Amgen have a manufacturing presence in the country. Since India has the highest number of US FDA approved pharmaceutical manufacturing facilities outside the US and a number of Indian firms have contract manufacturing arrangements with MNCs, the manufactuirng firms from Singapore may find it convenient to import APIs from India.

### 2.3.4. RCA Analysis

An analysis of the revealed comparative advantage (RCA) of formulations and APIs that are exported from India to ASEAN is undertaken to get a better understanding of the advantage that these two categories of pharmaceutical products have in the region. RCA is an index of the export performance of a country with respect to a particular commodity that captures the comparative advantage of that commodity. The RCA of a particular commodity is measured by the share of that commodity in the country's total exports relative to the share of world exports of the same commodity in total world exports. The RCA of a particular commodity is measured using the following formula.

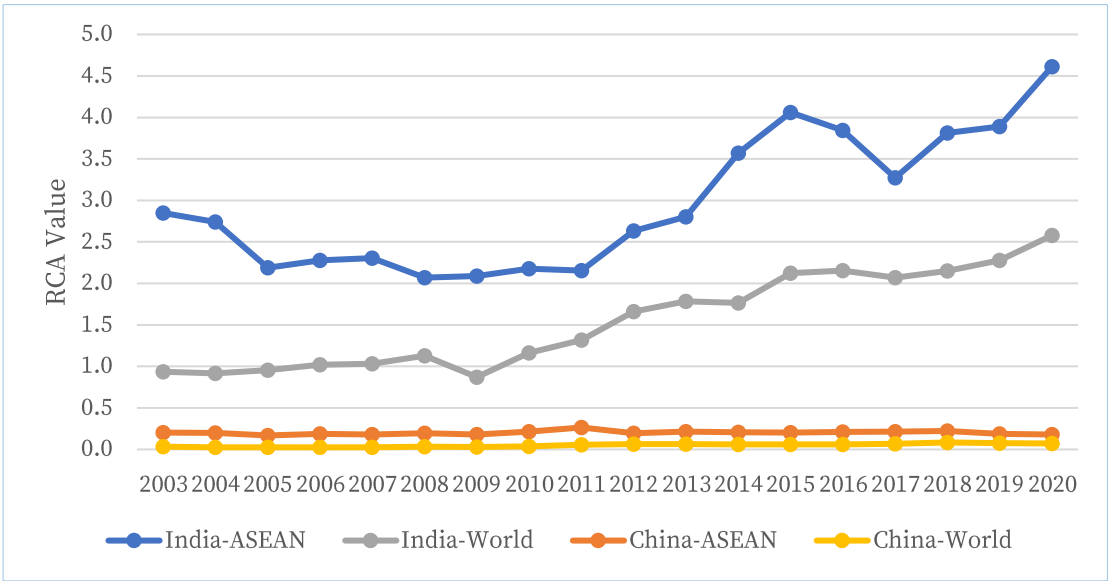
[14] Information available at https://www.pharmbiosingapore.com/articles/industry-articles/overview-of-the-singapore-pharmbio-sector (accessed on 2 August 2022).

$$RCA = (xij / \sum Xi) / (x_{w}j / \sum Xw)$$

*where,* 'x' represents exports, of country 'i' (or world 'w'), in commodity '*j*'. The index may take values from zero to infinity, with values greater than one indicating the existence of RCA or, in other words, the product is competitive in global market. As changes in a country's total export can have corresponding changes in the RCA index of a commodity, one needs to be cautious in interpreting the RCA results.

In formulations, the RCA value is above 1 for export to the ASEAN region and global exports (Figure 9). The higher RCA value for exports to the ASEAN region, as compared to India's global exports, indicates that formulations from India face a better advantage in the ASEAN region as compared to exports to the world. This is due to two reasons. One, rising share of formulations in India's total exports to ASEAN. The share of formulatios in India's exports to this region had declined from 1.9 per cent in 2003 to 1.5 per cent in 2009 (pre-FTA period). But in the post-FTA period, the share of formulations has increased from 1.2 per cent in 2010 to 2.8 per cent in 2021 (Table 9). The other reason is that share of formulations in total exports to ASEAN from the world is quite low compared to it's share in total exports to world. For instance, in 2020, share of formulations in total exports to ASEAN was 0.7 per cent while share of formulations in total exports to world was 2.4 per cent (in terms of value of exports). Other studies have also pointed out that the India-ASEAN FTA has led to shrinking in the grwoth of exports from India; exports to ASEAN declined from CAGR of 23.4 per cent during the pre-FTA period (2003-09) to CAGR 2.3 per cent during the post-FTA period (2010-2016) (PHDCCI 2018). Formulations is a product category that also face a deceleration in the rate of grwoth in exports during the post-FTA period, but performing better than India's total exports to the ASEAN.

**Figure 9: Overtime Trend of India's Global and Regional RCA in Formulations**




Source: Same as Figure 2

**Table 9: Share of Formulations in India's Global Exports and Export to ASEAN**

| *Year* | *Export to World* | | | *Export to ASEAN* | | |
|---|---|---|---|---|---|---|
| | *Total exports (US$ Million)* | *Export of Formulations (US$ Million)* | *Share of formulations (%)* | *Total exports (US$ Million)* | *Export of Formulations (US$ Million)* | *Share of formulations (%)* |
| 2003 | 59,361 | 1,252 | 2.1 | 5,072 | 95 | 1.9 |
| 2004 | 75,904 | 1,542 | 2.0 | 7,552 | 115 | 1.5 |
| 2005 | 1,00,353 | 2,078 | 2.1 | 10,286 | 141 | 1.4 |
| 2006 | 1,21,201 | 2,615 | 2.2 | 12,369 | 166 | 1.3 |
| 2007 | 1,45,898 | 3,213 | 2.2 | 13,824 | 184 | 1.3 |
| 2008 | 1,81,861 | 4,197 | 2.3 | 19,433 | 220 | 1.1 |
| 2009 | 1,76,765 | 4,232 | 2.4 | 17,899 | 266 | 1.5 |
| 2010 | 2,20,408 | 5,309 | 2.4 | 22,958 | 283 | 1.2 |
| 2011 | 3,01,483 | 7,351 | 2.4 | 34,498 | 407 | 1.2 |
| 2012 | 2,89,565 | 8,768 | 3.0 | 32,295 | 485 | 1.5 |
| 2013 | 3,36,611 | 10,847 | 3.2 | 37,885 | 603 | 1.6 |
| 2014 | 3,17,545 | 10,886 | 3.4 | 31,294 | 651 | 2.1 |
| 2015 | 2,64,381 | 11,873 | 4.5 | 26,428 | 685 | 2.6 |
| 2016 | 2,60,327 | 12,298 | 4.7 | 26,381 | 706 | 2.7 |
| 2017 | 2,94,364 | 12,148 | 4.1 | 35,412 | 758 | 2.1 |
| 2018 | 3,22,292 | 13,459 | 4.2 | 36,134 | 846 | 2.3 |
| 2019 | 3,23,251 | 15,423 | 4.8 | 34,250 | 872 | 2.5 |
| 2020 | 2,75,489 | 17,389 | 6.3 | 29,616 | 1,011 | 3.4 |
| 2021 | 3,94,814 | 18,239 | 4.6 | 40,678 | 1,141 | 2.8 |

Source: Same as Figure 2

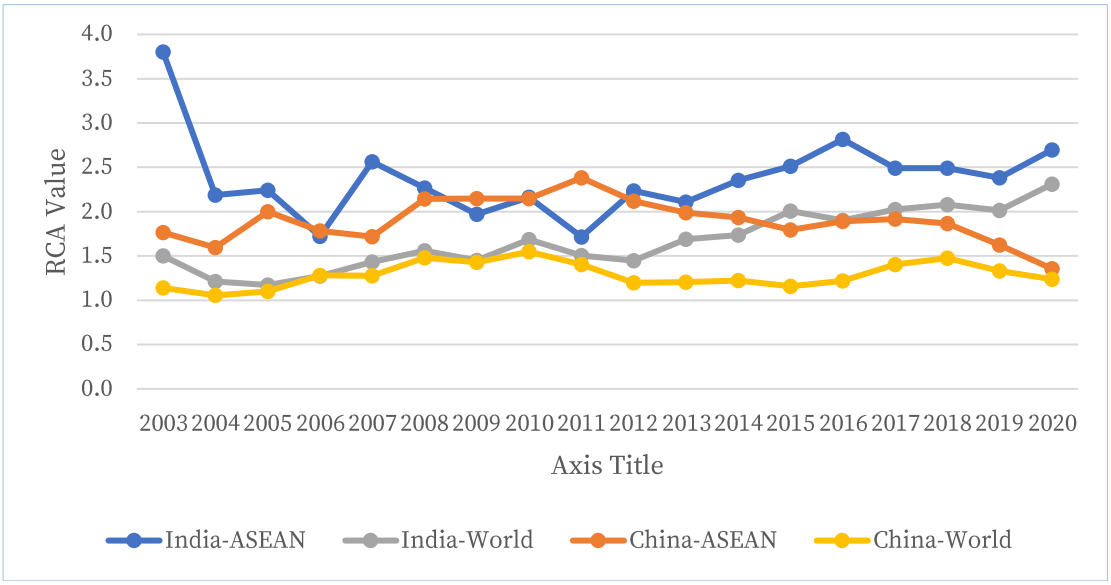
The RCA value of exports to the ASEAN region has been declining in the initial period and then remained stagnant till 2011. This was a period when the share of formulations in India's total exports to the region was falling (Table 7). Thereafter it began to grow. The India-ASEAN FTA seems to have played a role in this. Details of tariff commitments that India received in formulations is presented in section 2.3.5.

The China-ASEAN FTA had also come into force in the same year as that of the India-ASEAN FTA. China being a major exporter of pharmaceutical products, a comparison is also made with the RCA of formulations from China (Figure 11). It comes out that Chinese formulations do not have an advantage in ASEAN as the RCA value is less than one.

Similar is the case of APIs. India's exports to ASEAN register a higher RCA value as compared to global exports (Figure 10). The primary reason behind this is that share of APIs in total exports to ASEAN from the world is quite low compared to it's formulations export share in total exports to world. For instance, in 2020, share of APIs in total exports to ASEAN was 0.37 per cent while share of APIs in total exports to world was 0.56 per cent. In post FTA period, India's RCA value in ASEAN region increased primarily due to improvement in the share of APIs in the total exports from India to ASEAN while the the share of APIs in the total exports from world to ASEAN remained stagnant. The share of APIs in the total exports from India increased from 0.5% in 2011 to 1% in 2020 (Table 10).

The RCA of other two categories of pharmaceutical products is presented in the following figures (Figures 11 and 12).

**Figure 10: Overtime Trend of India's Global and Regional RCA in APIs**




Source: Same as Figure 2

**Table 10: Share of APIs in India's global exports and export to ASEAN**

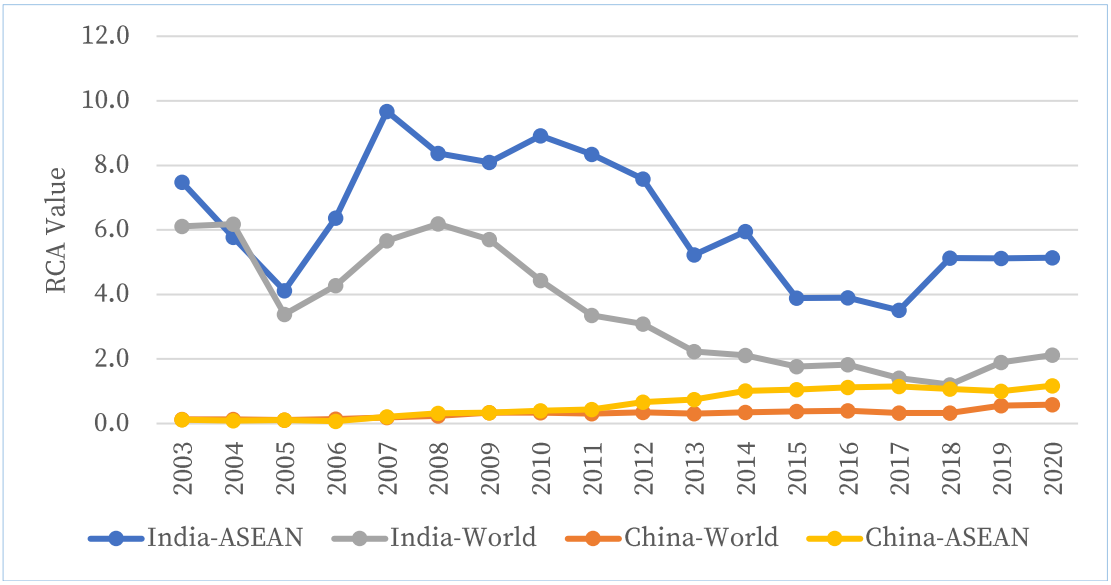
| *Year* | *Export to World* | | | *Export to ASEAN* | | |
|---|---|---|---|---|---|---|
| | *Total exports (US$ Million)* | *Export of APIs (US$ Million)* | *Share of APIs* | *Total exports (US$ Million)* | *Export of APIs (US$ Million)* | *Share of APIs* |
| 2003 | 59,361 | 503 | 0.8 | 5,072 | 70 | 1.4 |
| 2004 | 75,904 | 470 | 0.6 | 7,552 | 58 | 0.8 |
| 2005 | 1,00,353 | 562 | 0.6 | 10,286 | 63 | 0.6 |
| 2006 | 1,21,201 | 626 | 0.5 | 12,369 | 68 | 0.6 |
| 2007 | 1,45,898 | 852 | 0.6 | 13,824 | 116 | 0.8 |
| 2008 | 1,81,861 | 1,114 | 0.6 | 19,433 | 126 | 0.6 |
| 2009 | 1,76,765 | 1,241 | 0.7 | 17,899 | 126 | 0.7 |
| 2010 | 2,20,408 | 1,535 | 0.7 | 22,958 | 162 | 0.7 |
| 2011 | 3,01,483 | 1,911 | 0.6 | 34,498 | 164 | 0.5 |
| 2012 | 2,89,565 | 1,976 | 0.7 | 32,295 | 199 | 0.6 |
| 2013 | 3,36,611 | 2,569 | 0.8 | 37,885 | 216 | 0.6 |
| 2014 | 3,17,545 | 2,454 | 0.8 | 31,294 | 199 | 0.6 |
| 2015 | 2,64,381 | 2,573 | 1.0 | 26,428 | 184 | 0.7 |
| 2016 | 2,60,327 | 2,532 | 1.0 | 26,381 | 229 | 0.9 |
| 2017 | 2,94,364 | 2,743 | 0.9 | 35,412 | 265 | 0.7 |
| 2018 | 3,22,292 | 3,093 | 1.0 | 36,134 | 272 | 0.8 |
| 2019 | 3,23,251 | 3,346 | 1.0 | 34,250 | 273 | 0.8 |

| *Year* | *Export to World* | | | *Export to ASEAN* | | |
|---|---|---|---|---|---|---|
| | *Total exports (US$ Million)* | *Export of APIs (US$ Million)* | *Share of APIs* | *Total exports (US$ Million)* | *Export of APIs (US$ Million)* | *Share of APIs* |
| 2020 | 2,75,489 | 3,561 | 1.3 | 29,616 | 299 | 1.0 |
| 2021 | 3,94,814 | 4,019 | 1.0 | 40,678 | 334 | 0.8 |

Source: Same as Figure 2

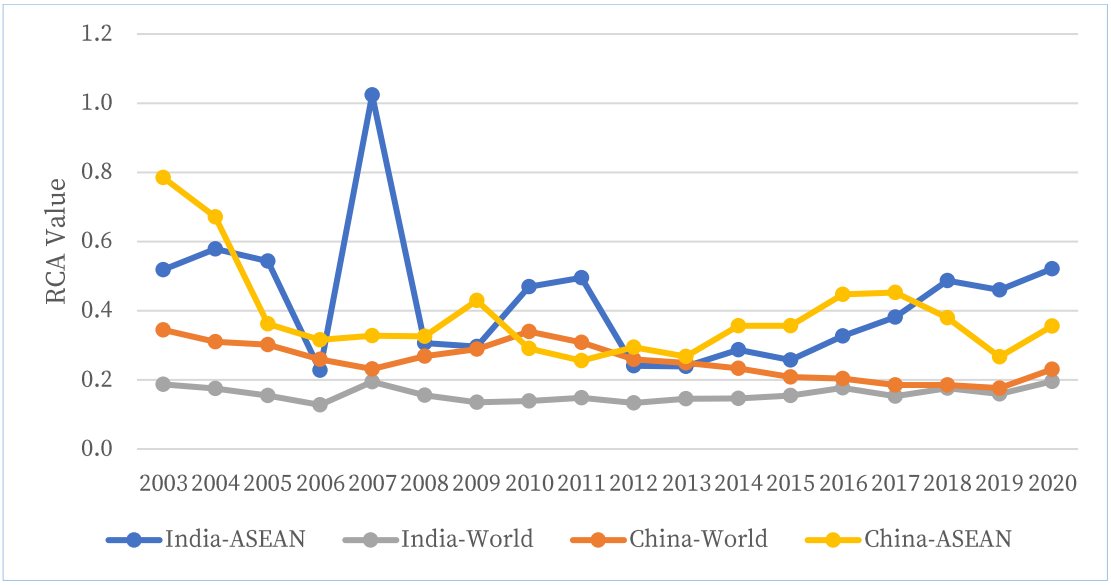
India's higher RCA value in the export of APIs, as compared to China, which is the largest supplier of KSMs/DIs/APIs globally is not surprising. The study of Joseph and Kumar (2021) which analysed the export performance of those APIs covered in the phase-1 Produce Lined Incentive (PLI) scheme in the pharmaceuticals sector found that exports from India registered higher RCA values in different categories of APIs. The Phase-1 PLI covered those APIs (and DIs and KSMs) in which India is heavily dependent on China for imports with the objective of reducing the import dependence. Joseph and Kumar (2021) point out that in most cases it is likely that the import from China is in KSMs and DIs, which unfortunately is not adequately captured due to data constraints. These products are then processed into APIs in India.

**Figure 11: Overtime Trend of India's Global and Regional RCA in Bulk Medicines**




Source: Same as Figure 2

**Figure 12: Overtime Trend of India's Global and Regional RCA in Other Pharmaceutical Products**




Source: Same as Figure 2

In bulk medicines, the RCA value has been declining since 2008 and there is no change in this trend even during the post-FTA period. In the case of other pharmaceutical products, the RCA value is less than 1, indicating that there is no comparative advantage for India.

### 2.3.5. Impact of FTA

In 2003, India signed the Framework Agreement with the ASEAN covering areas such as goods, services, investment, intellectual property rights (IPR), competition etc. Signing an FTA in goods with the ASEAN region was tough as it took almost six years of negotiations. The FTA was signed in 2009 and came into force on 1 January 2010. This agreement on trade in goods is called as India-ASEAN FTA, comprising 11 countries, including India. Under the schedules of tariff commitments in this FTA, member countries offered tariff concessions on their HS tariffs lines under various headings such as Normal Track, Sensitive Track, Highly Sensitive List and Exclusion List.[15]

[15] Singapore agreed to reduce tariffs to zero upon entry into force of the agreement. Therefore, no separate schedule for tariff commitments is made.

Under the Normal Track, the parties agreed to reduce tariffs and subsequently eliminate them. Sensitive Track consists of tariff lines in which countries are allowed to maintain tariffs up to 5 per cent.[16] The Highly Sensitive List consists of products in which countries could maintain tariffs up to 50 per cent and the Exclusion List consists of products in which no tariff commitments are made. However, in the case of the Exclusion List, the agreement provides that the list shall be subject to an annual tariff review with a view to enhance market access.

In India-ASEAN FTA, products are identified at HS 8-digit to 10-digit levels for tariff commitment schedules.[17] Thus, there is a long list of products. However, pharmaceutical products are not separately classified. In order to assess the impact of the FTA on India's export of pharmaceutical products to the ASEAN region, we identified pharmaceutical products based on the classification at HS 6-digit level as explained in section 2.2.1. In pharmaceutical products, most of the HS tariff lines belong to the Normal Track for all the member countries except for Indonesia, Thailand, Lao PDR, Myanmar and Vietnam (Table 11).

**Table 11: Number of Tariff Lines covered in the Pharmaceutical Sector, country-wise**

| *Country* | *Category* | *NT* | *ST* | *HSL* | *EL* | *Total* |
|---|---|---|---|---|---|---|
| Brunei | Formulations | 82 | | | | 82 |
| | APIs | 84 | | | | 84 |
| | Bulk Medicines | 11 | | | | 11 |
| | Other Pharmaceuticals | 22 | | | | 22 |
| | Total | 199 | | | | 199 |
| Indonesia | Formulations | 37 | 8 | | 4 | 49 |
| | APIs | 53 | 27 | | 8 | 88 |
| | Bulk Medicines | 6 | 3 | | | 9 |
| | Other Pharmaceuticals | 19 | 4 | | | 23 |
| | Total | 115 | 42 | | 12 | 169 |

[16] Upto 50 HS 8-digit lines in this list, countries are allowed to maintain tariffs upto 5 percent. For the remaining lines, tariffs are to be reduced to 4.5 per cent upon the entry into force of the agreement.

[17] Most countries have listed tariff lines at HS 8-digit level. But some countries have given tariff lines at HS 9-digit and 10-digit levels. For example, Malaysia at 9-digit level and Indonesia, Myanmar and Vietnam at 10-digit level.

| *Country* | *Category* | *NT* | *ST* | *HSL* | *EL* | *Total* |
|---|---|---|---|---|---|---|
| Malaysia | Formulations | 33 | | | | 33 |
| | APIs | 77 | 3 | | | 80 |
| | Bulk Medicines | 24 | | | | 24 |
| | Other Pharmaceuticals | 24 | | | | 24 |
| | Total | 158 | 3 | | | 161 |
| Thailand | Formulations | 8 | 14 | | 24 | 46 |
| | APIs | 85 | | | | 85 |
| | Bulk Medicines | | 3 | | 5 | 8 |
| | Other Pharmaceuticals | 4 | 12 | | 7 | 23 |
| | Total | 97 | 29 | | 36 | 162 |
| Cambodia | Formulations | 46 | | | | 46 |
| | APIs | 71 | 14 | | | 85 |
| | Bulk Medicines | 8 | | | | 8 |
| | Other Pharmaceuticals | 23 | | | | 23 |
| | Total | 148 | 14 | | | 162 |
| Lao PDR | Formulations | 20 | 26 | | | 46 |
| | APIs | 73 | 8 | | 4 | 85 |
| | Bulk Medicines | 4 | 4 | | | 8 |
| | Other Pharmaceuticals | 18 | 5 | | | 23 |
| | Total | 115 | 43 | | 4 | 162 |
| Myanmar | Formulations | 42 | | | 40 | 82 |
| | APIs | 68 | 14 | | | 82 |
| | Bulk Medicines | 2 | 4 | | 7 | 13 |
| | Other Pharmaceuticals | 7 | 9 | | 8 | 24 |
| | Total | 119 | 27 | | 55 | 201 |
| Vietnam | Formulations | 19 | 69 | | | 88 |
| | APIs | 78 | 3 | 4 | 1 | 86 |
| | Bulk Medicines | 10 | 3 | | | 13 |
| | Other Pharmaceuticals | 24 | | | | 24 |
| | Total | 131 | 75 | 4 | 1 | 211 |
| Philippines | Formulations | 46 | | | | 46 |
| | APIs | 90 | | | | 90 |
| | Bulk Medicines | 8 | | | | 8 |
| | Other Pharmaceuticals | 26 | | 1 | 1 | 28 |
| | Total | 170 | | 1 | 1 | 172 |

Source: Compiled using offer lists of India-ASEAN FTA member countries.
Note: NT – Normal Track, ST – Sensitive Track, HSL – Highly Sensitive List, EL – Exclusion List.

In order to access the impact of India-ASEAN FTA on Indian pharmaceutical exports, we have compared India's export performance during the pre-FTA

period (2003-09) and the post-FTA period (2011-20). The impact of India-ASEAN FTA on India's exports to each ASEAN country is evaluated pharmaceutical products category-wise and FTA list-wise. One limitation of this analysis is that there is no uniformity in the level of disaggregation of tariff lines (HS codes) among the FTA partners. Most countries have listed tariff lines at HS 8-digit level. But some countries have given tariff lines at HS 9-digit and 10-digit levels. Therefore, it is extremely difficult to gather data at the most disaggregated level. Moreover, the WITS database of the World Bank, which is widely used for cross-country trade analysis, provides trade data only up to HS 6-digit level. Therefore, we are constrained to do the analysis at HS 6-digit level. Some of the HS 6-digit lines contain tariff lines which come under both the exclusion list and tariff concession list; we have excluded such 6-digit lines from the analysis. However, these excluded lines account for only a very small share of the India's total export of pharmaceutical products, as can be seen from the following tables. For example, in the case of Brunai, our analysis captures an export of $0.149 million during the pre-FTA period whereas the India's total pharmaceutical export to that country was $0.150 million during the same period. Following tables (Table 12 to 22) present this analysis for the ASEAN region and each Member of the ASEAN.

**Table 12: India's Export of Pharmaceutical Products to the ASEAN Region During Pre and Post FTA Period**

| *Category* | *FTA Category* | *India's Average Exports (2003-09) (US$ 1000)* | *India's Average Exports (2011-20) (US$ 1000)* | *Change (%)* |
|---|---|---|---|---|
| Formulations | NT | 91,629 | 4,65,028 | 407.5 |
| | ST | 64,496 | 1,92,139 | 197.9 |
| | EL | 13,478 | 45,375 | 236.7 |
| | Total | 1,69,603 | 7,02,541 | 314.2 |
| APIs | NT | 79,740 | 2,02,808 | 154.3 |
| | ST | 4,807 | 18,924 | 293.7 |
| | HSL | 8,632 | 11,366 | 31.7 |
| | EL | 200 | 358 | 79.1 |
| | Total | 93,379 | 2,33,456 | 150.0 |
| Bulk Medicines | NT | 16,814 | 24,012 | 42.8 |

| *Category* | *FTA Category* | *India's Average Exports (2003-09) (US$ 1000)* | *India's Average Exports (2011-20) (US$ 1000)* | *Change (%)* |
|---|---|---|---|---|
| | ST | 4,871 | 7,039 | 44.5 |
| | EL | 895 | 1,783 | 99.2 |
| | Total | 22,580 | 32,834 | 45.4 |
| Other Pharmaceuticals | NT | 7,705 | 22,105 | 186.9 |
| | ST | 462 | 1,283 | 177.7 |
| | EL | 849 | 4,327 | 409.5 |
| | Total | 9,016 | 27,715 | 207.4 |
| India's Total Export of Pharmaceutical products | | 2,94,578 | 9,96,546 | 238.3 |

Source: Compiled from WITS using offer lists of India-ASEAN FTA member countries.

**Table 13: India's Export of Pharmaceutical Products to Brunei During Pre and Post FTA Period**

| *Category* | *FTA List* | *India's Average Exports (2003-09) (US$ 1000)* | *India's Average Exports (2011-20) (US$ 1000)* |
|---|---|---|---|
| APIs | NT | 0 | 13 |
| Bulk Medicines | NT | 9 | 7 |
| Formulations | NT | 106 | 172 |
| Other Pharmaceuticals | NT | 33 | 9 |
| India's pharmaceutical exports captured in our FTA analysis | | 149 | 202 |
| India's total pharmaceutical exports | | 150 | 202 |

Source: Same as Table 12

**Table 14: India's Export of Pharmaceutical Products to Cambodia During Pre and Post FTA Period**

| *Category* | *FTA List* | *India's Average Exports (2003-09) (US$ 1000)* | *India's Average Exports (2011-20) (US$ 1000)* |
|---|---|---|---|
| APIs | NT | 701 | 1,141 |
| APIs | ST | 69 | 77 |
| Bulk Medicines | NT | 1,342 | 535 |
| Formulations | NT | 10,902 | 35,340 |
| Other Pharmaceuticals | NT | 817 | 1,806 |
| India's pharmaceutical exports captured in our FTA analysis | | 13,831 | 38,899 |
| India's total pharmaceutical exports | | 13,870 | 38,899 |

Source: Same as Table 12

**Table 15: India's Export of Pharmaceutical Products to Indonesia During Pre and Post FTA Period**

| *Category* | *FTA List* | *India's Average Exports (2003-09) (US$ 1000)* | *India's Average Exports (2011-20) (US$ 1000)* |
|---|---|---|---|
| APIs | NT | 7,425 | 23,839 |
| APIs | ST | 4,297 | 17,889 |
| APIs | EL | 191 | 348 |
| Bulk Medicines | NT | 1,168 | 3,127 |
| Bulk Medicines | ST | 193 | 176 |
| Formulations | NT | 5,067 | 27,039 |
| Formulations | ST | 3 | 52 |
| Other Pharmaceuticals | NT | 569 | 1,458 |
| Other Pharmaceuticals | ST | 29 | 85 |
| India's pharmaceutical exports captured in our FTA analysis | | 18,941 | 74,014 |
| India's total pharmaceutical exports | | 20,194 | 74,846 |

Source: Same as Table 12

**Table 16: India's Export of Pharmaceutical Products to Lao PDR During Pre and Post FTA Period**

| *Category* | *FTA List* | *India's Average Exports (2003-09) (US$ 1000)* | *India's Average Exports (2011-20) (US$ 1000)* |
|---|---|---|---|
| APIs | NT | 4 | 36 |
| APIs | ST | 185 | 264 |
| Bulk Medicines | NT | 37 | 11 |
| Bulk Medicines | ST | 26 | 5 |
| Formulations | NT | 107 | 305 |
| Formulations | ST | 500 | 2,667 |
| Other Pharmaceuticals | NT | 254 | 203 |
| Other Pharmaceuticals | ST | 8 | 10 |
| India's pharmaceutical exports captured in our FTA analysis | | 1,122 | 3,501 |
| India's total pharmaceutical exports | | 1,122 | 3,501 |

Source: Same as Table 12

**Table 17: India's Export of Pharmaceutical Products to Malaysia During Pre and Post FTA Period**

| *Category* | *FTA List* | *India's Average Exports (2003-09) (US$ 1000)* | *India's Average Exports (2011-20) (US$ 1000)* |
|---|---|---|---|
| APIs | NT | 9,417 | 15,860 |
| APIs | ST | - | 26 |
| Bulk Medicines | NT | 2,542 | 2,798 |

| *Category* | *FTA List* | *India's Average Exports (2003-09) (US$ 1000)* | *India's Average Exports (2011-20) (US$ 1000)* |
|---|---|---|---|
| Formulations | NT | 14,275 | 45,250 |
| Other Pharmaceuticals | NT | 1,048 | 2,065 |
| India's pharmaceutical exports captured in our FTA analysis | | 27,281 | 65,999 |
| India's total pharmaceutical exports | | 27,304 | 66,006 |

Source: Same as Table 12

**Table 18: India's Export of Pharmaceutical Products to Myanmar During Pre and Post FTA Period**

| Category | FTA List | India's Average Exports (2003-09) (US$ 1000) | India's Average Exports (2011-20) (US$ 1000) |
|---|---|---|---|
| APIs | NT | 242 | 633 |
| APIs | ST | 255 | 636 |
| Bulk Medicines | NT | 1,162 | 499 |
| Bulk Medicines | ST | 144 | 86 |
| Bulk Medicines | EL | 810 | 959 |
| Formulations | NT | 20,719 | 1,29,276 |
| Formulations | EL | 8,918 | 30,443 |
| Other Pharmaceuticals | NT | 191 | 195 |
| Other Pharmaceuticals | ST | 143 | 818 |
| Other Pharmaceuticals | EL | 264 | 3,571 |
| India's pharmaceutical exports captured in our FTA analysis | | 32,849 | 1,67,117 |
| India's total pharmaceutical exports | | 34,594 | 1,67,576 |

Source: Same as Table 12

**Table 19: India's Export of Pharmaceutical Products to Philippines During Pre and Post FTA Period**

| *Category* | *FTA Category* | *India's Average Exports (2003-09) (US$ 1000)* | *India's Average Exports (2011-20) (US$ 1000)* |
|---|---|---|---|
| APIs | NT | 7,715 | 15,330 |
| Bulk Medicines | NT | 1,682 | 3,916 |
| Formulations | NT | 24,120 | 1,62,622 |
| Other Pharmaceuticals | NT | 1,167 | 7,204 |
| India's pharmaceutical exports captured in our FTA analysis | | 34,685 | 1,89,072 |
| India's total pharmaceutical exports | | 35,025 | 1,89,318 |

Source: Same as Table 12

**Table 20: India's Export of Pharmaceutical Products to Singapore During Pre and Post FTA Period18**

| *Category* | *India's Average Exports (2003-09) (US$ 1000)* | *India's Average Exports (2011-20) (US$ 1000)* |
|---|---|---|
| APIs | 16,106 | 51,568 |
| Bulk Medicines | 2,797 | 9,904 |
| Formulations | 11,591 | 51,057 |
| Other Pharmaceuticals | 2,800 | 3,814 |

Source: Same as Table 12

**Table 21: India's Export of Pharmaceutical Products to Thailand During Pre and Post FTA Period**

| *Category* | *FTA Category* | *India's Average Exports (2003-09) (US$ 1000)* | *India's Average Exports (2011-20) (US$ 1000)* |
|---|---|---|---|
| APIs | NT | 25,419 | 49,754 |
| Bulk Medicines | ST | 4,250 | 6,163 |
| Bulk Medicines | EL | 85 | 823 |
| Formulations | NT | 1,974 | 3,817 |
| Formulations | ST | 10,464 | 65,608 |
| Formulations | EL | 4,560 | 14,932 |
| Other Pharmaceuticals | NT | 174 | 1,433 |
| Other Pharmaceuticals | ST | 282 | 370 |
| Other Pharmaceuticals | EL | 585 | 757 |
| India's pharmaceutical exports captured in our FTA analysis | | 47,792 | 1,43,656 |
| India's total pharmaceutical exports | | 48,532 | 1,44,962 |

Source: Same as Table 12

**Table 22: India's Export of Pharmaceutical Products to Vietnam During Pre and Post FTA Period**

| *Category* | *FTA Category* | *India's Average Exports (2003-09) (US$ 1000)* | *India's Average Exports (2011-20) (US$ 1000)* |
|---|---|---|---|
| APIs | NT | 12,711 | 44,634 |
| APIs | ST | 0 | 31 |
| APIs | EL | 9 | 10 |
| APIs | HSL C | 8,632 | 11,366 |
| Bulk Medicines | NT | 6,074 | 3,214 |
| Bulk Medicines | ST | 258 | 609 |
| Formulations | NT | 2,769 | 10,151 |

[18] Singapore brought down all tariffs to zero upon the entry of the FTA.

| *Category* | *FTA Category* | *India's Average Exports (2003-09) (US$ 1000)* | *India's Average Exports (2011-20) (US$ 1000)* |
|---|---|---|---|
| Formulations | ST | 53,529 | 1,23,812 |
| Other Pharmaceuticals | NT | 653 | 3,918 |
| India's pharmaceutical exports captured in our FTA analysis | | 84,633 | 1,97,743 |
| India's total pharmaceutical exports | | 84,648 | 1,97,743 |

Source: Same as Table 12

This analysis shows that there is an increase in the exports to the ASEAN countries in the post-FTA period especially in formulations and APIs. But in some countries, products covered in the EL witnessed higher rate of growth as compared to products receiving tariff commitments. For example, in the case of Thailand, formulations under EL registered a growth of 227 per cent during the post FTA period as compared to formulations under NT registering 93 per cent growth.

In order to have a comprehensive view of the impact of the FTA on the two key pharmaceutical product categories, the following matrix is prepared (Table 23). It shows that the share of formulations in India's total exports increased while that of APIs declined. Export of formulations is increasingly getting concentrated on some category of formulations as indicated by an increasing HI value, whereas the export of APIs is increasingly getting diversified. India's ranking as trading partner in the export of formulations has improved in the post-FTA period as compared to the pre-FTA period.

**Table 23: Matrix of Impact of India-ASEAN FTA**

| *Indicator* | *Pre FTA Period (2003 to 2009)* | *Post FTA Period (2011 to 2020)* |
|---|---|---|
| Share of Formulation in total pharmaceutical products | 53% (2003), 63% (2009) | 62% (2011), 74% (2020) |
| Share of APIs in total pharmaceutical products | 40% (2003), 29% (2009) | 25% (2011), 22% (2020) |
| HI for Formulation | 0.38 (2003), 0.43 (2009) | 0.43 (2011), 0.57 (2020) |
| HI for APIs | 0.33 (2003), 0.24 (2009) | 0.18 (2011), 0.12 (2020) |

| *Indicator* | *Pre FTA Period (2003 to 2009)* | *Post FTA Period (2011 to 2020)* |
|---|---|---|
| Proportion of Pharmaceutical trade under tariff reduction commitments | 91.6 (2009) | 94.2 (2020) |
| Proportion of Formulation trade under tariff reduction commitments | 89.4 (2009) | 93.4 (2020) |
| Proportion of APIs trade under tariff reduction commitments | 92.0 (2009) | 95.8 (2020) |
| India's rank as trading partner (export) in formulations | 7 (2009) | 4 (2020) |
| India's rank as trading partner (export) in APIs | 3 (2009) | 3 (2020) |

Source: Computed by authors based on the data collected from WITS, World Bank.

Whether the FTA has benefitted India in the pharmaceutical sector is a difficult question to address. It is expected that FTA will help in promoting exports. A comparison of value of exports during the pre and post FTA period shows that exports have increased during the post FTA period (Table 12). At the same time, this analysis cannot be done in isolation from India's overall export to ASEAN and export from rest of the world to ASEAN. As we have seen already, the rate of growth of export of India to ASEAN has declined during the post-FTA period, which is not expected. As compared to India's total exports, the deceleration was milder in the case of pharmaceutical products. Even when all other countries were finding it harder to export formulations and APIs to ASEAN as reflected in their lower share in total exports to ASEAN, as compared to global exports, India is in a better position which is reflected in the rising RCA values for India. Surprisingly, there are instances where products not receiving tariff commitments exhibiting higher rate of growth in exports. For example, formulations falling under the exclusion list registered faster growth in exports as compared to formulations falling under the sensitive list. This indicates the probability of India's pharmaceutical exports performing no differently even in the absence of an FTA. Our observations from this analysis also point to other factors that influence exports other than tariffs.

As the number of products covered in the Exclusion List is substantial for some countries, we did an analysis to understand its impact on exports from India. The table below (Table 24) gives the results of this analysis for formulations, covering three countries as they maintain a substantial number of products in the Exclusion List. We collected data on the total import by these countries in the products covered by the Exclusion List and India's share in it by using the corresponding HS 6-digit lines.

**Table 24: India's Export in Formulations covered in the Exclusion List**

| *Country* | *HS 6 digit* | *Count of HS 8/10 digit lines* | *Country's Global Imports in 2019 (US$)* | *India's Share in Country's Imports (%)* | *India's Global Exports (US$ Million) in 2019* | *India's Global Share in 2019 (%)* |
|---|---|---|---|---|---|---|
| Indonesia* | 300440 | 3 | 9 | 1.9 | 18 | 0.4 |
| | 300490 | 1 | 462 | 2.7 | 12,477 | 4.6 |
| | Total | 4 | 471 | 2.7 | 12,495 | 4.5 |
| Myanmar* | 300410 | 7 | 14 | 1.8 | 537 | 16.1 |
| | 300420 | 18 | 24 | 74.3 | 1,101 | 7.6 |
| | 300431 | 1 | - | - | 114 | 1.8 |
| | 300432 | 4 | 1 | 10.0 | 76 | 0.8 |
| | 300439 | 2 | 10 | 2.6 | 85 | 0.4 |
| | 300440 | 8 | 2 | 6.1 | 18 | 0.4 |
| | Total | 40 | 51 | 36.5 | 1,930 | 3.1 |
| Thailand | 300410 | 5 | 32 | 13.3 | 537 | 16.1 |
| | 300420 | 7 | 82 | 0.7 | 1,101 | 7.6 |
| | 300431 | 1 | 25 | 16.9 | 114 | 1.8 |
| | 300432 | 2 | 48 | 0.0 | 76 | 0.8 |
| | 300440 | 5 | 7 | 0.4 | 18 | 0.4 |
| | 300450 | 4 | 34 | 2.2 | 232 | 6.0 |
| | Total | 24 | 227 | 4.3 | 2,077 | 4.9 |

Source: Compiled using Table 11 and WITS database.
Note: * Tariff lines given at HS 10-digit level.

It is found that the import of the three ASEAN countries from the rest of the world excluding India, in the pharmaceutical products covered by the Exclusion List, was US$ 708 million in 2019. A reduction in tariffs is likely to

increase India's exports to these countries. The analysis of the Exclusion List maintained by them, as captured in the above table, shows that in some cases at HS 6-digit level, the share of India's exports to these countries is much lower as compared to India's global share in the export of respective products. In the case of HS 300410 (formulations containing penicillin and streptomycin) India accounts for 16.1 per cent of global exports. But India's share in export of this category to Myanmar and Thailand is lower. Similarly in HS 300420 (formulations containing other antibiotics), although India is having a global share of 7.6 per cent, it's share in Thailand is only 0.7 per cent.

But in the case of APIs, the exclusion list is not having any impact on India in terms of exports as those countries' import on such products is very low and India's global exports of such products is also very low (Table 25).

**Table 25: India's Trade in API Tariff Lines Excluded by ASEAN Member Countries**

| *Country* | *HS 6 digit* | *Count of HS 8/10 digit lines* | *Country's Global Imports in 2019 (US$ Million)* | *India's Share in Country's Imports (%)* | *India's Global Exports in 2019 (US$ Million)* |
|---|---|---|---|---|---|
| Indonesia* | 292411 | 1 | 0.00004 | 0.0 | 0.2 |
| | 292424 | 1 | -- | -- | 0.1 |
| | 293353 | 1 | 0.05 | 15.8 | 5 |
| | 293355 | 1 | -- | -- | 0.04 |
| | 293911 | 1 | 0.63 | 0.0 | 1 |
| | 293919 | 1 | 0.80 | 26.2 | 16 |
| | 293991 | 2 | -- | -- | -- |
| | Total | 8 | 1.48 | 14.7 | 22 |
| Lao PDR | 293911 | 1 | -- | -- | 1 |
| | 293919 | 1 | -- | -- | 16 |
| | 293991 | 2 | -- | -- | -- |
| | Total | 4 | -- | -- | 17 |
| Vietnam* | 292241 | 1 | 64 | 0.0 | 2 |
| | Total | 1 | 64 | 0.0 | 2 |

Source: Using Table 6 and WITS database.
Note: * Tariff lines given at HS 10-digit level.

### 2.3.6. Growth Prospects for Indian Pharmaceutical Industry in ASEAN Region

In order identify the scope of opportunities available for Indian Pharmaceutical Exports in ASEAN region, this study has analysed import of this region in pharmaceutical products. There was a major decline in the import all categories of products in 2021 (Table 26). This could be due to disruptions on account of COVID-19 pandemic. Exempting this year from the analysis, it is the other pharmaceutical products category that has registered the highest growth since 2003. However, this category accounts for only 15 per cent of the total import of pharmaceutical products in 2020 and India's share is very low in this category. The two important categories of pharmaceutical products – formulations and APIs which account for 84 per cent of the total of import of pharmaceutical products as in 2020, has shown an impressive growth of CAGR above 10 per cent since 2003.

In formulations, which account for more than half of total import of pharmaceutical products by the ASEAN countries, India's share has increased over the years. In APIs, however, India's share has declined during the last decade.

**Table 26: ASEAN's Global Imports of Pharmaceutical Products and India's share in ASEAN's Imports**

| | *Formulations* | | *APIs* | | *Bulk Medicines* | | *Other Pharmaceutical Products* | | *Total Pharmaceutical Products* | |
|---|---|---|---|---|---|---|---|---|---|---|
| | *Import ($ Billion)* | *India's Share (%)* | *Import ($ Billion)* | *India's Share (%)* | *Import ($ Billion)* | *India's Share (%)* | *Import ($ Billion)* | *India's Share (%)* | *Import ($ Billion)* | *India's Share (%)* |
| 2003 | 1.2 | 1.7 | 0.8 | 6.8 | 0.1 | 5.7 | 0.2 | 0.8 | 2.2 | 3.5 |
| 2004 | 1.9 | 4.6 | 1.2 | 5.6 | 0.1 | 6.5 | 0.3 | 1.3 | 3.5 | 4.8 |
| 2005 | 2.2 | 5.3 | 1.2 | 6.6 | 0.1 | 8.4 | 0.5 | 0.3 | 4.1 | 5.1 |
| 2006 | 2.8 | 6.7 | 1.2 | 9.0 | 0.1 | 9.8 | 0.6 | 0.3 | 4.7 | 6.6 |
| 2007 | 3.7 | 5.8 | 1.5 | 10.3 | 0.1 | 9.5 | 0.7 | 0.8 | 6.0 | 6.4 |
| 2008 | 4.3 | 5.3 | 1.8 | 7.9 | 0.2 | 11.8 | 0.7 | 0.6 | 7.0 | 5.7 |
| 2009 | 5.0 | 5.9 | 1.8 | 8.4 | 0.1 | 12.8 | 0.8 | 1.0 | 7.7 | 6.1 |

| | *Formulations* | | *APIs* | | *Bulk Medicines* | | *Other Pharmaceutical Products* | | *Total Pharmaceutical Products* | |
|---|---|---|---|---|---|---|---|---|---|---|
| | *Import ($ Billion)* | *India's Share (%)* | *Import ($ Billion)* | *India's Share (%)* | *Import ($ Billion)* | *India's Share (%)* | *Import ($ Billion)* | *India's Share (%)* | *Import ($ Billion)* | *India's Share (%)* |
| 2010 | 5.8 | 7.1 | 2.5 | 7.2 | 0.2 | 12.7 | 1.3 | 0.4 | 9.8 | 6.4 |
| 2011 | 6.8 | 8.7 | 2.9 | 8.0 | 0.2 | 14.3 | 1.7 | 1.5 | 11.6 | 7.5 |
| 2012 | 7.5 | 7.8 | 3.2 | 7.6 | 0.2 | 14.2 | 1.6 | 0.5 | 12.4 | 6.9 |
| 2013 | 7.9 | 8.1 | 3.2 | 7.2 | 0.2 | 11.5 | 1.6 | 0.7 | 12.9 | 7.0 |
| 2014 | 8.2 | 8.5 | 3.4 | 7.2 | 0.2 | 11.4 | 1.7 | 1.4 | 13.4 | 7.3 |
| 2015 | 8.7 | 8.6 | 3.2 | 7.1 | 0.2 | 9.7 | 1.7 | 0.9 | 13.8 | 7.3 |
| 2016 | 9.3 | 8.5 | 3.4 | 7.8 | 0.2 | 7.9 | 1.8 | 1.1 | 14.7 | 7.5 |
| 2017 | 10.2 | 9.3 | 4.0 | 7.3 | 0.2 | 10.4 | 1.9 | 1.9 | 16.3 | 8.0 |
| 2018 | 10.8 | 9.3 | 4.5 | 6.9 | 0.2 | 13.8 | 2.4 | 1.9 | 17.9 | 7.8 |
| 2019 | 11.2 | 9.3 | 4.7 | 6.8 | 0.2 | 15.2 | 2.7 | 1.4 | 18.7 | 7.6 |
| 2020 | 12.1 | 9.4 | 5.1 | 6.3 | 0.2 | 29.7 | 3.0 | 1.5 | 20.4 | 7.7 |
| 2021 | 6.0 | 6.1 | 0.7 | 5.0 | 0.0 | 19.6 | 0.4 | 3.2 | 7.1 | 5.9 |
| CAGR 2003-2020 | 13.7 | -- | 10.8 | -- | 3.9 | -- | 16.2 | -- | 13.2 | -- |
| CAGR 2010-2020 | 6.9 | -- | 6.7 | -- | 0.0 | -- | 7.9 | -- | 6.9 | -- |

Source: Authors' estimation using WITS database.

In ASEAN region, formulations are largely sourced from developed countries (Table 27, Table 28). Three countries, Germany (12 per cent), USA (11.5 per cent) and France (9.8 per cent), captured slightly more than one-third share in ASEAN's global imports of formulations in 2020. On the other hand, APIs are largely sourced from China, which has more than 40 per cent share as in 2020. UK with 17.4 per cent share is another important sourcing country for ASEAN region in APIs. As India's share in ASEAN's global imports of formulations and as well as in APIs is small, there is scope for improving its exports in both categories of pharmaceutical products. India is the leading source of import in the case of bulk medicines. But as we have seen in the above table, this category accounts for a very low share (about 1 per cent) in the total import of pharmaceutical products.

Major variation has been observed in India's share in the global import across all ASEAN countries (Table 29). It may further be observed that India's share in major importers of formulations (in terms of value of imports) (Vietnam, Singapore, Thailand, Malaysia) in ASEAN region is relatively low when compared to other importing countries in the region. Similarly, in APIs, share of India in Singapore's global import of APIs (with US$ 2.1 billion imports, it is highest importer in the region) is only 3.5 per cent. Therefore, in formulation, India can enlarge its export to Vietnam, Singapore, Thailand and Malaysia and improve its share in their global imports. In APIs, Singapore is a country where India has an opportunity for extending its exports.

**Table 27: ASEAN's Major Sourcing Countries for its Import of Pharmaceutical Products in 2020**

| *SN* | *Formulations* | | *APIs* | | *Bulk Medicines* | | *Other Pharma Products* | |
|---|---|---|---|---|---|---|---|---|
| | *Major Sourcing Countries* | *Country's Share in ASEAN imports of Formulations (%)* | *Major Sourcing Countries* | *Country's Share in ASEAN imports of APIs (%)* | *Major Sourcing Countries* | *Country's Share in ASEAN imports of Bulk Medicines (%)* | *Major Sourcing Countries* | *Country's Share in ASEAN imports of Other Pharmaceutical Products (%)* |
| 1 | Germany | 12.0 | China | 41.2 | India | 29.7 | France | 18.3 |
| 2 | USA | 11.5 | UK | 17.4 | China | 17.7 | United States | 17.7 |
| 3 | France | 9.8 | India | 6.3 | Ireland | 10.8 | Germany | 13.3 |
| 4 | India | 9.4 | Ireland | 5.6 | United Kingdom | 5.4 | China | 8.5 |
| 5 | Switzerland | 4.7 | US | 5.2 | Thailand | 5.2 | Switzerland | 5.8 |
| 6 | Italy | 4.3 | Germany | 4.1 | United States | 4.0 | Ireland | 5.8 |
| 7 | Belgium | 4.3 | Italy | 2.8 | Austria | 3.6 | Korea, Rep. | 3.8 |
| 8 | UK | 3.4 | Switzerland | 2.6 | Italy | 3.2 | Netherlands | 3.5 |
| 9 | China | 3.3 | France | 2.3 | Japan | 2.8 | Sweden | 3.2 |
| 10 | Ireland | 3.1 | Korea, Rep. | 2.0 | Malaysia | 1.4 | Japan | 2.6 |

Source: Authors' estimation using WITS database.

**Table 28: ASEAN's Total Import of Formulations and Leading Source Countries for Imports in 2020**

| *HS 6-Digit Lines* | *ASEAN Global Imports in 2020 (US$ Billion)* | *Five Top sourcing Countries for ASEAN region (%)* |
|---|---|---|
| 300220 | 1.04 | France (26.3), United States (23.1), Belgium (21.5), India (7.7), China (5.3) |
| 300410 | 0.25 | United Kingdom (16), France (14.4), India (12.3), Italy (8.1), China (6.1) |
| 300420 | 0.68 | Italy (13.6), India (10.2), Germany (7.5), United States (7.2), Korea, Rep. (5.6) |
| 300431 | 0.20 | Brazil (26.3), France (17.1), Denmark (15.3), Germany (13.7), India (8.4) |
| 300432 | 0.27 | Belgium (14.7), Italy (14.1), United Kingdom (12), Sweden (10.4), United States (10.3) |
| 300439 | 0.39 | Germany (27.2), Netherlands (7.3), United States (6.7), France (6.6), Belgium (6.2) |
| 300440 | 0.04 | Germany (18), Australia (15), Italy (13.5), France (8.2), Denmark (6.9) |
| 300450 | 0.33 | Indonesia (25.8), China (11.2), India (7.3), United States (7.1), Australia (7.1) |
| 300490 | 8.36 | Germany (14.4), India (10.9), United States (10.1), France (8.5), Switzerland (6.3) |
| Total | 11.56 | Germany (12.5), United States (10.6), India (9.9), France (9.7), Switzerland (5) |

Source: Authors' estimation using WITS database.

**Table 29: ASEAN's Global Import of Pharmaceutical Products in 2020, Country-Wise**

| *Country* | *Formulations* | | *APIs* | | *Bulk Medicines* | | *Other Pharmaceutical Products* | |
|---|---|---|---|---|---|---|---|---|
| | *Country's Global Imports (US$ Million)* | *India's share in Country's Imports (%)* | *Country's Global Imports (US$ Million)* | *India's share in Country's Imports (%)* | *Country's Global Imports (US$ Million)* | *India's share in Country's Imports (%)* | *Country's Global Imports (US$ Million)* | *India's share in Country's Imports (%)* |
| Brunei | 200.0 | 0.1 | 4.0 | 0.2 | 3 | 3.1 | 6 | 6.8 |
| Cambodia | 200.0 | 14.8 | 29.0 | 1.7 | 1.4 | 4.0 | 8 | 20.9 |
| Indonesia | 900.0 | 8.3 | 700.0 | 8.1 | 27 | 28.5 | 236 | 1.3 |
| Lao PDR | 30.0 | 19.4 | 10.0 | 1.0 | 0.2 | 35.3 | 5 | 2.1 |
| Malaysia | 1,600.0 | 5.2 | 400.0 | 6.7 | 16 | 14.4 | 166 | 0.9 |
| Myanmar | 500.0 | 40.8 | 100.0 | 4.4 | 4 | 30.9 | 67 | 23.6 |
| Philippines | 1,600.0 | 16.8 | 300.0 | 6.4 | 15 | 26.6 | 183 | 6.2 |
| Singapore | 1,900.0 | 5.2 | 2,100.0 | 3.5 | 12 | 1.6 | 1,702 | 0.2 |

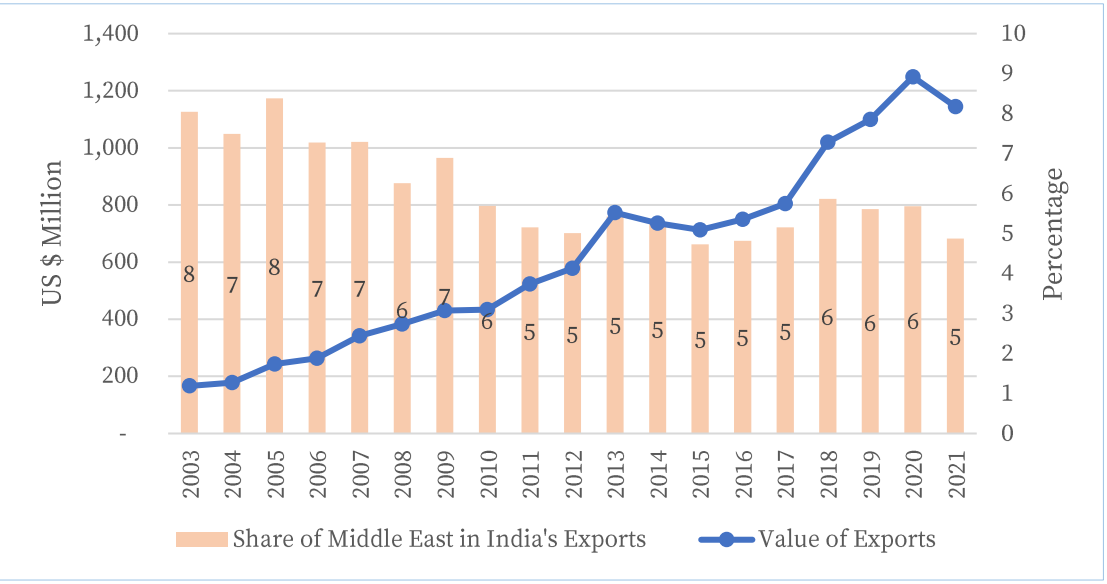
| Country | Formulations | | APIs | | Bulk Medicines | | Other Pharmaceutical Products | |
|---|---|---|---|---|---|---|---|---|
| | Country's Global Imports (US$ Million) | India's share in Country's Imports (%) | Country's Global Imports (US$ Million) | India's share in Country's Imports (%) | Country's Global Imports (US$ Million) | India's share in Country's Imports (%) | Country's Global Imports (US$ Million) | India's share in Country's Imports (%) |
| Thailand | 2,000.0 | 5.8 | 700.0 | 8.4 | 84 | 61.7 | 422 | 1.1 |
| Vietnam | 3,200.0 | 7.8 | 800.0 | 10.3 | 69 | 2.1 | 234 | 2.3 |
| ASEAN | 12,100.0 | 9.4 | 5,100.0 | 6.3 | 234 | 29.7 | 3,029 | 1.5 |

Source: Authors' estimation using WITS database.

## 2.3. India's Trade with Countries in the Middle East region in Pharmaceutical Products

India's export of pharmaceutical products to the Middle East region increased from US$ 166 million in 2003 to US$ 1249 million in 2020 and declined to US$ 1145 million in 2021 (Figure 13). However, the share of this region in India's global exports of pharmaceutical products declined from 8 per cent to 5 per cent during this period, indicating that exports to this region have grown at a slow pace as compared to exports to other countries.

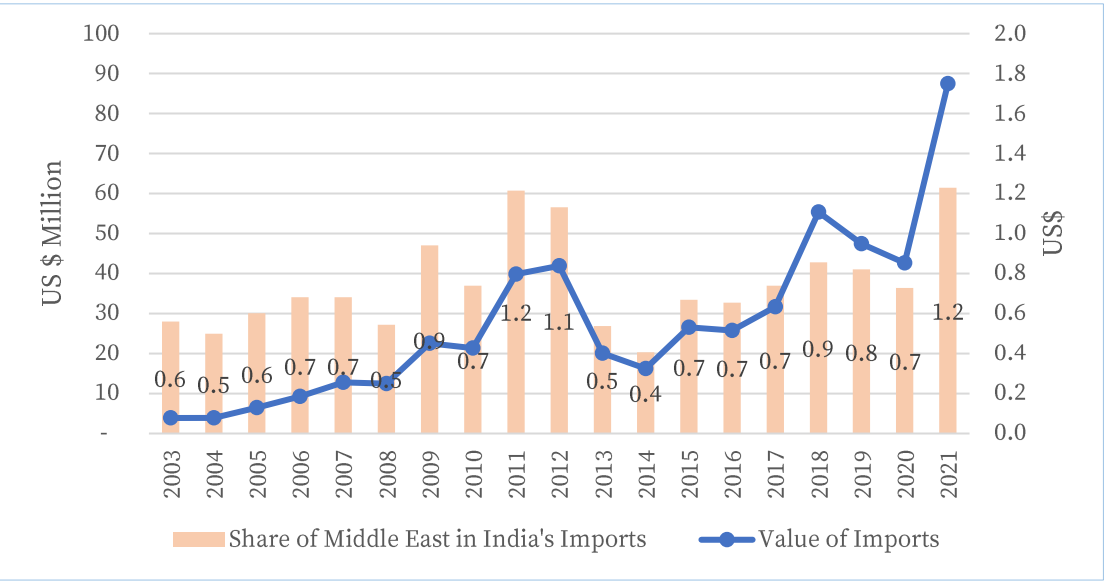
**Figure 13: Trends in India's Export of Pharmaceutical Products to Middle East Region**




Source: Same as Figure 2.

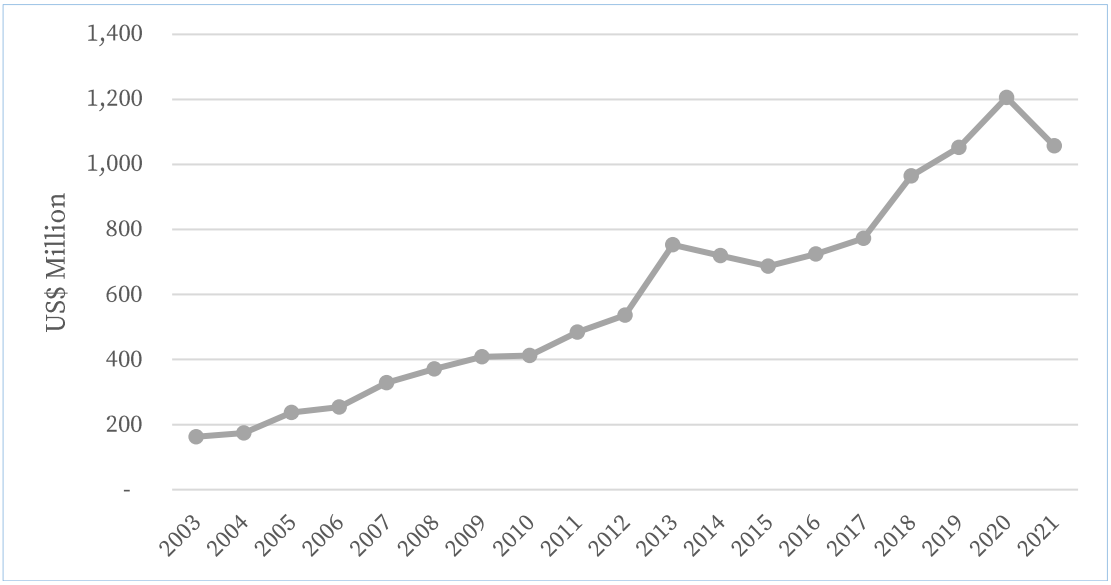
In imports, India is not found to be much dependent on the Middle East countries in pharmaceutical products. Imports from this region account for only 1.2 per cent of India's total import of pharmaceutical products (Figure 15). As a result, India's trade with the Middle East in pharmaceutical products exhibits a steadily growing trade surplus (Figure 16).

**Figure 15: Trends in India's Import of pharmaceutical products from the Middle East**




Source: Same as Figure 2.

**Figure 16: India's Balance of Trade with the Middle East in Pharmaceutical Products**

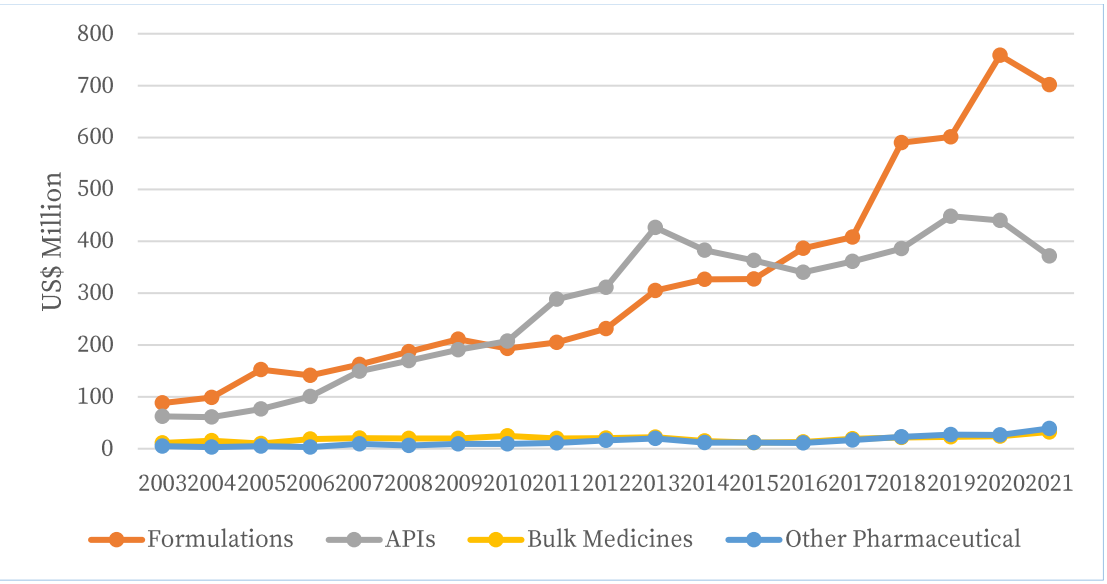



Source: Same as Figure 2.

### 2.3.1. Details of Pharmaceutical Products Exported to ASEAN Countries

A category-wise analysis of exports shows that formulations is the leading export category, followed by APIs (Figure 17). However, the relative significance of these two categories changed quite significantly over the years. Between 2003 and 2013, the export of APIs grew at a higher pace as compared to formulations. Thereafter, API exports to this region began to decline, although the export in 2020 had reached the 2013 levels. Export of the other two categories is very low. The other two categories – Bulk Medicines and Other Pharmaceutical Products account for a very low share in India's export to this region.

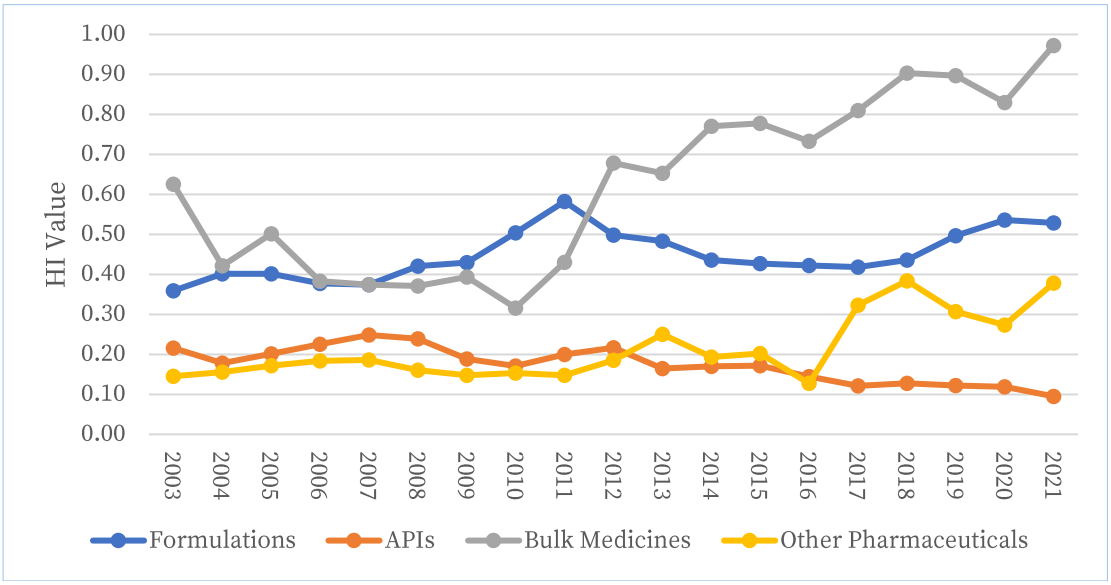
**Figure 17: India's Pharmaceutical Exports to the Middle East - Categorywise**




Source: Same as Figure 2.

In order to examine whether Indian exports of formulations and APIs to the Middle East region becoming concentrated in certain product categories or whether they are getting diversified, we have estimated the HI for all four categories of pharmaceutical products. The result is presented in Figure 18.

**Figure 18: Product Diversification Index in the Middle East Region**




Source: Same as Figure 2

As it is seen in the above figure, bulk medicines in the only category which is getting concentrated. The index for formulations was rising till 2011, but it began to decline thereafter indicating that formulation exports getting more diversified. Nevertheless, the index for the last few years shows a rising trend. Whereas the export of APIs is increasingly getting diversified.

### 2.3.2. Export Destinations in the Middle East

The UAE is the leading export destination in formulations, accounting for more than one-fourth share, followed by Iraq and Yemen (Table 30). In APIs, Turkey is the top destination accounting for 29 per cent share followed by Egypt and Iran. UAE is the leading destination for bulk medicines and Turkey for other pharmaceutical products.

The share of the Middle East region in India's global export of all categories of pharmaceutical products, except bulk medicines, have declined over the years. As in the case of ASEAN region, in the Middle East also, APIs has a higher share in India's global exports as compared other categories of pharmaceutical products.

**Table 30: India's Major Destinations for Formulations & APIs in Middle East Region (share in per cent)**

| *Country* | *Formulations* | | *APIs* | | *Bulk Medicines* | | *Other Pharmaceutical Products* | |
|---|---|---|---|---|---|---|---|---|
| | *2003-05* | *2018-20* | *2003-05* | *2018-20* | 2003-05 | 2018-20 | 2003-05 | 2018-20 |
| Bahrain | 0.5 | 0.9 | 0.1 | 0.1 | 2.8 | 0.6 | 1.0 | 0.9 |
| Cyprus | 0.7 | 0.7 | 4.7 | 2.5 | 1.2 | 3.4 | 0.8 | 0.2 |
| Egypt | 4.1 | 4.0 | 6.6 | 19.9 | 4.6 | 15.1 | 7.1 | 7.1 |
| Iran | 17.9 | 8.2 | 13.0 | 17.8 | 16.9 | 29.5 | 9.8 | 7.1 |
| Iraq | 7.8 | 17.4 | 1.8 | 0.9 | 1.9 | 2.5 | 1.0 | 3.1 |
| Israel | 7.9 | 2.8 | 20.2 | 5.3 | 4.6 | 1.3 | 1.0 | 1.3 |
| Jordan | 7.4 | 2.0 | 8.7 | 5.9 | 2.7 | 3.0 | 3.3 | 3.2 |
| Kuwait | 0.5 | 0.5 | 0.2 | 0.1 | 1.9 | 0.8 | 0.2 | 2.7 |
| Lebanon | 0.7 | 2.3 | 0.1 | 1.5 | 0.6 | 2.6 | 0.4 | 7.1 |
| Oman | 2.2 | 3.0 | 1.6 | 1.2 | 7.1 | 0.6 | 4.3 | 2.3 |
| Qatar | 0.3 | 0.8 | 0.0 | 0.2 | 0.4 | 0.2 | 0.3 | 1.5 |
| Saudi Arabia | 2.1 | 7.2 | 3.4 | 6.4 | 2.4 | 3.4 | 15.6 | 5.9 |
| Syria | 4.1 | 0.9 | 6.1 | 1.7 | 3.4 | 1.0 | 4.2 | 10.5 |
| Turkey | 14.7 | 9.5 | 18.4 | 28.8 | 11.7 | 19.7 | 10.7 | 19.4 |
| United Arab Emirates | 20.5 | 27.4 | 14.7 | 6.9 | 32.4 | 14.3 | 35.4 | 17.1 |
| Yemen | 8.7 | 12.3 | 0.4 | 0.5 | 5.2 | 1.7 | 5.3 | 10.6 |
| **Total for the above countries** | **100.0** | **100.0** | **100.0** | **100.0** | **100.0** | **100.0** | **100.0** | **100.0** |
| **Share of ME in India's Global Exports** | **7.0** | **4.2** | **13.0** | **12.7** | **4.6** | **6.9** | **8.7** | **4.4** |

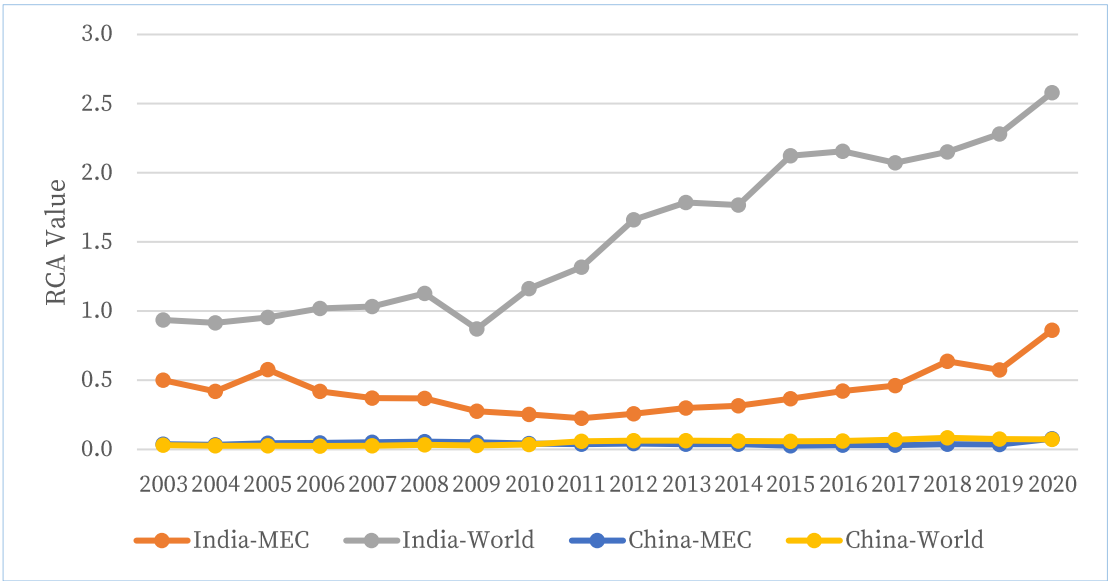
Source: Same as Figure 2

### 2.3.3. RCA Analysis

In the Middle East region, India's regional RCA value for formulations has remained less than one throughout the study period, suggesting a comparative disadvantage in this region (Figure 17, Table 31). Formulations accounts for only a very low share in India's total exports to this region. However, during the last decade, this RCA index has shown an improving trend and reached close to 1 in 2020. The RCA index of China remained close to zero during the entire period of the analysis.

Most of the countries in the Middle East are largely import dependent on western countries for formulations. They import originators' medicines and branded generics (Tantash 2012). The average price of generic medicines in the Middle East is 50 per cent of the originator's drug. It is likely that the branded generics supplied by the originator itself occupy much of the space created for generics after the expiry of patents thereby denying an opportunity for exporters of generic medicines from countries like India. In Bahrain, for example, generic medicines are imported from France, Germany, UK, Switzerland and US (Kanavos et. al. 2018). However, many of the countries in the Middle East are moving towards increased use of cheaper generic medicines, which is likely to provide a good opportunity for exporters of generic medicines from India.

**Figure 17: Overtime trend of India's Global and Regional RCA in Formulations**




Source: Same as Figure 2.

**Table 31: Share of formulations in India's global exports and export to Middle East Countreis**

| *Year* | *Export to World* | | | *Export to Middle East* | | |
|---|---|---|---|---|---|---|
| | *Total exports (US$ Million)* | *Export of Formulations (US$ Million)* | *Share of formulations* | *Total exports (US$ Million)* | *Export of Formulations (US$ Million)* | *Share of formulations* |
| 2003 | 59,361 | 1,252 | 2.1 | 9,120 | 88 | 1.0 |
| 2004 | 75,904 | 1,542 | 2.0 | 12,985 | 99 | 0.8 |
| 2005 | 1,00,353 | 2,078 | 2.1 | 16,195 | 152 | 0.9 |
| 2006 | 1,21,201 | 2,615 | 2.2 | 22,068 | 141 | 0.6 |
| 2007 | 1,45,898 | 3,213 | 2.2 | 28,408 | 162 | 0.6 |
| 2008 | 1,81,861 | 4,197 | 2.3 | 36,862 | 187 | 0.5 |
| 2009 | 1,76,765 | 4,232 | 2.4 | 40,253 | 211 | 0.5 |
| 2010 | 2,20,408 | 5,309 | 2.4 | 47,196 | 193 | 0.4 |
| 2011 | 3,01,483 | 7,351 | 2.4 | 60,891 | 205 | 0.3 |
| 2012 | 2,89,565 | 8,768 | 3.0 | 65,617 | 231 | 0.4 |
| 2013 | 3,36,611 | 10,847 | 3.2 | 73,705 | 305 | 0.4 |
| 2014 | 3,17,545 | 10,886 | 3.4 | 72,373 | 326 | 0.5 |
| 2015 | 2,64,381 | 11,873 | 4.5 | 57,157 | 327 | 0.6 |
| 2016 | 2,60,327 | 12,298 | 4.7 | 54,501 | 386 | 0.7 |
| 2017 | 2,94,364 | 12,148 | 4.1 | 55,662 | 408 | 0.7 |
| 2018 | 3,22,292 | 13,459 | 4.2 | 58,156 | 590 | 1.0 |
| 2019 | 3,23,251 | 15,423 | 4.8 | 60,189 | 601 | 1.0 |
| 2020 | 2,75,489 | 17,389 | 6.3 | 43,007 | 758 | 1.8 |
| 2021 | 3,94,814 | 18,239 | 4.6 | 60,367 | 702 | 1.2 |

Source: Same as Figure 2

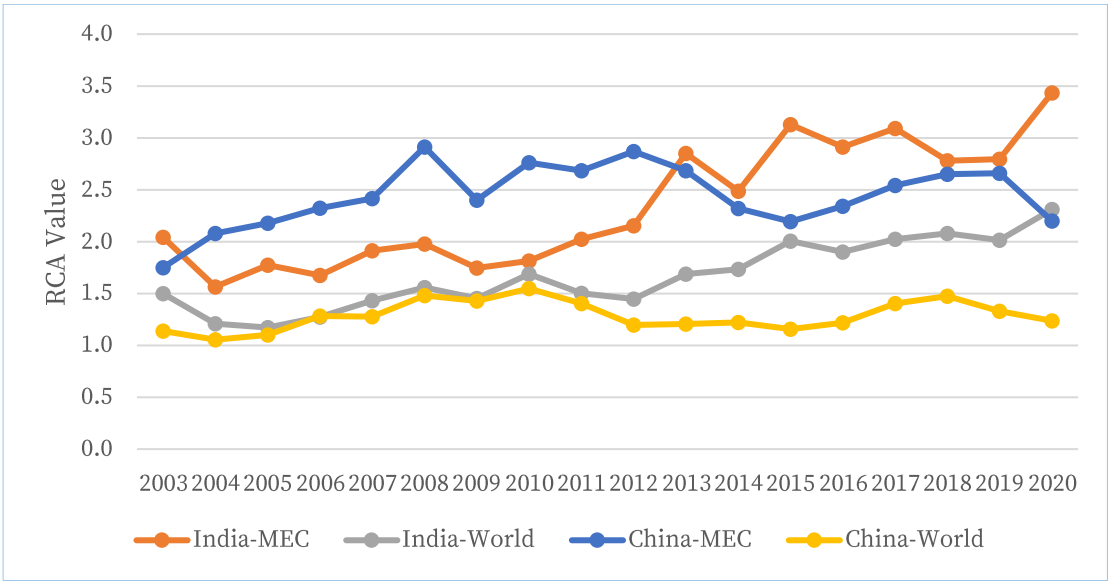
In an attempt to reduce health care costs, including costs of medicines, many countries in the region are encouraging domestic manufacturing. This issue is discussed in more detail in section 4. As it is not possibl to produce all the intermediates and APIs locally, the Indian pharmaceutical industry may find an opportunity in the export of APIs to the region. Unlike in the case of formulation, in APIs India already has an edge in the Middle East as compared to India's global export of APIs (Figure 18).

This is due to two reasons. One, rising share of APIs in India's total exports to Middle East region, especially since 2010. The share of APIs in India's exports

to this region has increased from 0.4 per cent in 2010 to 1 per cent in 2020 (Table 32). The other reason is that share of APIs in total exports to Middle East from the world is quite low compared to it's APIs export share in total exports to world. For instance, in 2020, share of APIs in total exports to Middle East was 0.3 per cent while share of APIs in total exports to world was 0.6 per cent.

Although China was better placed as compared to India till the early years of the last decade, the RCA value of Indian APIs has risen above that of Chinese APIs.

**Figure 18: Overtime Trend of India's Global and Regional RCA in APIs**




Source: Same as Figure 2

**Table 32: Share of APIs in India's Global Exports and Export to Middle East**

| *Year* | *Export to World* | | | *Export to Middle East* | | |
|---|---|---|---|---|---|---|
| | *Total exports (US$ Million)* | *Export of APIs (US$ Million)* | *Share of APIs* | *Total exports (US$ Million)* | *Export of APIs (US$ Million)* | *Share of APIs* |
| 2003 | 59,361 | 503 | 0.8 | 9,120 | 63 | 0.7 |
| 2004 | 75,904 | 470 | 0.6 | 12,985 | 61 | 0.5 |
| 2005 | 1,00,353 | 562 | 0.6 | 16,195 | 76 | 0.5 |
| 2006 | 1,21,201 | 626 | 0.5 | 22,068 | 101 | 0.5 |
| 2007 | 1,45,898 | 852 | 0.6 | 28,408 | 149 | 0.5 |
| 2008 | 1,81,861 | 1,114 | 0.6 | 36,862 | 170 | 0.5 |
| 2009 | 1,76,765 | 1,241 | 0.7 | 40,253 | 191 | 0.5 |
| 2010 | 2,20,408 | 1,535 | 0.7 | 47,196 | 207 | 0.4 |

| Year | Export to World | | | Export to Middle East | | |
|---|---|---|---|---|---|---|
| | Total exports (US$ Million) | Export of APIs (US$ Million) | Share of APIs | Total exports (US$ Million) | Export of APIs (US$ Million) | Share of APIs |
| 2011 | 3,01,483 | 1,911 | 0.6 | 60,891 | 288 | 0.5 |
| 2012 | 2,89,565 | 1,976 | 0.7 | 65,617 | 311 | 0.5 |
| 2013 | 3,36,611 | 2,569 | 0.8 | 73,705 | 426 | 0.6 |
| 2014 | 3,17,545 | 2,454 | 0.8 | 72,373 | 382 | 0.5 |
| 2015 | 2,64,381 | 2,573 | 1.0 | 57,157 | 363 | 0.6 |
| 2016 | 2,60,327 | 2,532 | 1.0 | 54,501 | 340 | 0.6 |
| 2017 | 2,94,364 | 2,743 | 0.9 | 55,662 | 361 | 0.6 |
| 2018 | 3,22,292 | 3,093 | 1.0 | 58,156 | 386 | 0.7 |
| 2019 | 3,23,251 | 3,346 | 1.0 | 60,189 | 448 | 0.7 |
| 2020 | 2,75,489 | 3,561 | 1.3 | 43,007 | 440 | 1.0 |
| 2021 | 3,94,814 | 4,019 | 1.0 | 60,367 | 371 | 0.6 |

Source: Same as Figure 2

### 2.3.4. India-UAE FTA

The India-UAE FTA came into force on 1 May 2022. As it is only a few months since the operationalisation of FTA, it is premature to conclude on the impact of this on India's pharmaceutical exports to UAE. However, a review of the commitments that are made in the pharmaceutical sector will give us some understanding of the likely implications of this FTA for India's exports. Under this FTA, there are 120 HS 8-digit tariff lines which belong to the pharmaceutical sector (Table 33). Out of 120 tariff lines, the tariffs were already zero in 85 lines. In 32 lines, which were having tariff of 5 per cent, the tariff reduced to zero at the entry into force of the FTA . This means that in 117 out of 120 HS 8-digit lines, tariff is zero now. In two lines, tariffs will be reduced from the current 5 per cent to zero in the fifth year of the FTA. One line remains prohibited (HS 29397110), which contains cocaine. It is interesting to observe that all tariff reduction commitments are in the category of APIs. This is likely to promote exports of APIs from India to the UAE.

**Table 33: Tariff Commitments by UAE in the India-UAE FTA in the Pharmaceutical Sector**

| *Tariffs* | *On the date of entry into force of the FTA (1 May 2022)* | | | *After 5 Years of the FTA* | *Prohibited* | *Grand Total* |
|---|---|---|---|---|---|---|
| | *Already zero* | *5% tariff got reduced to zero* | *Total* | *5% tariff will be reduced to zero* | *Prohibited* | |
| Formulations | 14 | | 14 | | | 14 |
| APIs | 41 | 32 | 73 | 2 | 1 | 76 |
| Bulk Medicines | 9 | | 9 | | | 9 |
| Other Pharmaceuticals | 21 | | 21 | | | 21 |
| Total | 85 | 32 | 117 | 2 | 1 | 120 |

Source: Compiled using India-UAE CEPA

In addition to the tariff reduction commitments, the India-UAE CEPA has included an annex on Bilateral Cooperation on Pharmaceutical Products (BCPP) in Chapter 5 that is on Technical Barriers to Trade (TBT). The BCPP covers finished pharmaceutical products (formulations), and certain biological products for human use. However, human blood, human plasma, human tissues, and organs have been kept outside the purview of BCPP. The BCPP covers TBTs measures which may affect trade in pharmaceutical products such as technical regulations, standards, conformity assessment, procedures, marketing authorisations, notification procedures, and inspections relating to Good Clinical Practices (GCPs) and Good Manufacturing Practices (GMPs). This is likely to facilitate exports of formulations from India to UAE.

Some of the provisions in the BCPP will benefit Indian exports of pharmaceutical products. It provides that those medicines and medical products which have obtained marketing approvals in any of the five countries - Australia, Canada, Japan, US and UK, and European Union (reference countries, hereafter), will be fast tracked for marketing approval in the UAE. In such cases, market authorisations will be issued within 90 days. And in

other cases, market authorisation will be issued within 270 days of the application. India is having the highest number of US FDA approved pharmaceutical manufacturing facilities outside the US. Therefore, this fast-tracking facility will benefit Indian exporters of formulations and APIs. The BCPP also contains a provision for the acceptance of other party's GMP and GCP inspections of manufactured pharmaceutical products provided that these products are approved by the regulatory authorities of the reference countries. And in those cases where is no prescribed standard in the Pharmacopeia of a Party for a pharmaceutical product, the other Party will accept all the standards relating to that product if that product has been accepted by the Pharmacopoeias of any of the reference countries.

### 2.3.5. Growth Prospects for Indian Pharmaceutical Industry in the Middle East Region

During the last two decades, the total import of formulations has grown significantly in the Middle East, from US$ 4 billion to close to US$ 20 billion (Table 34). However, same doesn't hold for other categories of pharmaceutical products. In formulation, there is scope of enlarging Indian formulation exports to the region owing to the fact that India's share in Middle East's imports of formulation has been hovering around between 1- 2 per cent during the last decade and, also its growing demand for formulations as reflected by its increasing imports.

India's share has remained comparatively low in largest importers of formulations (Saudi Arabia, UAE, Turkey, Israel, Egypt and Kuwait) in Middle East region when compared to its share in other importing countries in the region (Table 35). Currently, region is sourcing most of its formulation requirements from developed countries (Tables 36). Recently, India has signed FTA with UAE to leverage its exports, including pharmaceutical, to this

country. In 2020, India's share in UAE's formulation imports (US$ 3.6 billion) was only 6.7 per cent.

**Table 34: Middle East's Global Imports of Pharmaceutical Products and India's share in Middle East's Imports**

| *Year* | *Formulations* | | *APIs* | | *Bulk Medicines* | | *Other Pharmaceutical Products* | |
|---|---|---|---|---|---|---|---|---|
| | *ASEAN's Global Import ($Mn)* | *India's Share in ASEAN's Global Imports* | *ASEAN's Global Import ($Mn)* | *India's Share in ASEAN's Global Imports* | *ASEAN's Global Import ($Mn)* | *India's Share in ASEAN's Global Imports* | *ASEAN's Global Import ($Mn)* | *India's Share in ASEAN's Global Imports* |
| 2003 | 4073.7 | 0.7 | 912.9 | 11.6 | 836.9 | 1.4 | 526.4 | 0.1 |
| 2004 | 4855.8 | 0.3 | 1101.1 | 13.3 | 905.3 | 1.7 | 720.4 | 0.6 |
| 2005 | 5710.4 | 0.6 | 1179.0 | 15.7 | 1050.8 | 2.2 | 976.3 | 0.5 |
| 2006 | 5964.9 | 0.9 | 1120.2 | 17.4 | 1161.4 | 3.0 | 846.8 | 0.5 |
| 2007 | 7366.0 | 1.1 | 1292.1 | 15.7 | 1494.8 | 1.9 | 992.2 | 0.4 |
| 2008 | 10134.7 | 1.3 | 1800.9 | 15.5 | 1747.2 | 1.6 | 1255.9 | 0.9 |
| 2009 | 8877.6 | 0.8 | 1471.3 | 17.6 | 1777.2 | 1.0 | 1105.8 | 0.3 |
| 2010 | 11801.5 | 1.1 | 2022.0 | 16.8 | 1634.9 | 2.7 | 1508.3 | 0.4 |
| 2011 | 12566.1 | 1.0 | 2195.3 | 16.3 | 1843.3 | 2.4 | 1778.2 | 0.3 |
| 2012 | 13787.1 | 0.8 | 2060.4 | 17.5 | 884.5 | 4.8 | 2084.7 | 0.8 |
| 2013 | 17176.4 | 1.1 | 2316.8 | 16.8 | 1063.2 | 3.0 | 2774.7 | 0.3 |
| 2014 | 17563.3 | 1.3 | 2283.7 | 15.6 | 2313.4 | 1.5 | 3596.9 | 0.3 |
| 2015 | 17705.5 | 0.9 | 2142.0 | 17.6 | 1374.9 | 5.4 | 3553.5 | 0.5 |
| 2016 | 17418.9 | 1.1 | 2086.4 | 15.5 | 840.4 | 4.4 | 3789.4 | 0.1 |
| 2017 | 57315.6 | 0.4 | 2199.8 | 16.2 | 677.8 | 6.5 | 4016.7 | 0.2 |
| 2018 | 19782.4 | 2.1 | 2398.1 | 17.1 | 450.5 | 10.9 | 5217.1 | 0.5 |
| 2019 | 18462.3 | 2.1 | 1947.4 | 18.8 | 388.8 | 11.0 | 5423.2 | 0.4 |
| 2020 | 18564.7 | 2.3 | 2005.3 | 17.1 | 497.1 | 10.0 | 5986.6 | 0.4 |
| 2021 | 9030.3 | 0.9 | 1230.9 | 17.5 | 164.5 | 20.2 | 2505.6 | 1.1 |

Source: Authors' estimation using WITS database.

**Table 35: Middle East's Global imports of Pharmaceutical Products in 2020 and India's Share**

| *Country* | *Formulations (in 2020)* | | *APIs (in 2020)* | | Country's Global Imports (US$ Million) | India's share in Country's Imports (%) | Country's Global Imports (US$ Million) | India's share in Country's Imports (%) |
|---|---|---|---|---|---|---|---|---|
| | *Country's Global Imports (US$ Million)* | *India's share in Country's Imports (%)* | *Country's Global Imports (US$ Million)* | *India's share in Country's Imports (%)* | | | | |
| Cyprus | 340 | 3.0 | 60 | 33.5 | 5 | 0.0 | 27 | 0.2 |
| Egypt | 2120 | 0.7 | 450 | 18.6 | 20 | 14.9 | 123 | 3.6 |

| Country | Formulations (in 2020) | | APIs (in 2020) | | Country's Global Imports (US$ Million) | India's share in Country's Imports (%) | Country's Global Imports (US$ Million) | India's share in Country's Imports (%) |
|---|---|---|---|---|---|---|---|---|
| | Country's Global Imports (US$ Million) | India's share in Country's Imports (%) | Country's Global Imports (US$ Million) | India's share in Country's Imports (%) | | | | |
| Israel | 2230 | 1.1 | 280 | 9.6 | 20 | 1.0 | 1,055 | 0.0 |
| Jordan | 510 | 1.8 | 110 | 20.2 | 33 | 2.7 | 58 | 0.1 |
| Kuwait | 1190 | 0.2 | 20 | 4.6 | 14 | 15.9 | 383 | 0.1 |
| Lebanon | 770 | 1.6 | 10 | 46.4 | 3 | 0.0 | 413 | 1.0 |
| Qatar | 550 | 1.6 | 20 | 6.3 | 3 | 0.0 | 174 | 0.1 |
| Saudi Arabia | 4500 | 1.5 | 180 | 16.5 | 216 | 0.6 | 896 | 0.1 |
| Turkey | 2760 | 1.3 | 770 | 16.5 | 146 | 27.3 | 2044 | 0.5 |
| UAE | 3590 | 6.7 | 90 | 23.8 | 37 | 6.0 | 814 | 0.4 |
| Middle East | 18560 | 2.3 | 2010 | 17.1 | 497 | 10.0 | 5987 | 0.4 |

Source: Authors' estimation using WITS database.

**Table 36: Middle East's Major Sourcing Countries for its Imports of Pharmaceutical Products (in 2020)**

| SNo. | Formulations | | APIs | | Bulk Medicines | | Other Pharmaceutical Products | |
|---|---|---|---|---|---|---|---|---|
| | Major Sourcing Countries | Country's Share in ASEAN imports of Formulations (%) | Major Sourcing Countries | Country's Share in ASEAN imports of APIs (%) | Major Sourcing Countries | Country's Share in ASEAN imports of APIs (%) | Major Sourcing Countries | Country's Share in ASEAN imports of APIs (%) |
| 1 | Germany | 15.3 | China | 35.6 | Jordan | 33.6 | Germany | 21.3 |
| 2 | USA | 11.4 | India | 17.1 | India | 10.0 | United States | 15.8 |
| 3 | France | 10.0 | Italy | 5.9 | Germany | 9.2 | Switzerland | 15.1 |
| 4 | Switzerland | 8.8 | Switzerland | 5.1 | China | 6.7 | Korea, Rep. | 10.1 |
| 5 | UK | 6.0 | France | 4.6 | Italy | 4.5 | Ireland | 6.1 |
| 6 | Ireland | 6.0 | USA | 4.5 | Saudi Arabia | 4.1 | China | 4.3 |
| 7 | Italy | 5.6 | Germany | 4.4 | Sweden | 3.9 | Belgium | 3.8 |
| 8 | Belgium | 4.6 | UK | 3.6 | United Kingdom | 3.1 | Netherlands | 3.5 |
| 9 | Denmark | 4.2 | Spain | 3.4 | Switzerland | 3.0 | Italy | 3.4 |
| 10 | Sweden | 3.9 | Netherlands | 1.7 | France | 2.4 | France | 3.1 |

Source: Authors' estimation using WITS database.

CHAPTER 3

# Foreign Direct Investment

The pharmaceuticals sector is one of the prominent sectors in FDI inflows to India as well as FDI outflows from India. The cumulative FDI equity inflows to this sector from April 2000 to March 2022 was US$19.4 billion, accounting for 3.3 per cent of the total FDI equity inflows to India during this period (DPIIT 2022). Among the manufacturing industries, this industry ranks third after automobiles and chemicals. In outward flows of FDI (OFDI) from India, the pharmaceuticals sector accounts for an important share. The study of Joseph (2020) shows that this sector had accounted for seven per cent of total outflows and 16 per cent of outflows originating from the manufacturing sector during the period between 2008 and 2018. Our analysis, covering data upto April 2022, shows that the share of pharmaceutical sector in the OFDI from the manufacturing sector has increased to 26 per cent (see section 3.1.2).

## 3.1. ASEAN

### 3.1.1. FDI Inflows into the Pharmaceutical Sector

ASEAN is an important source of FDI in the Indian pharmaceutical sector. It accounts for 22.8 per cent of the total FDI that came into India during the period between 2005-06 and 2021-22 (Table 37).

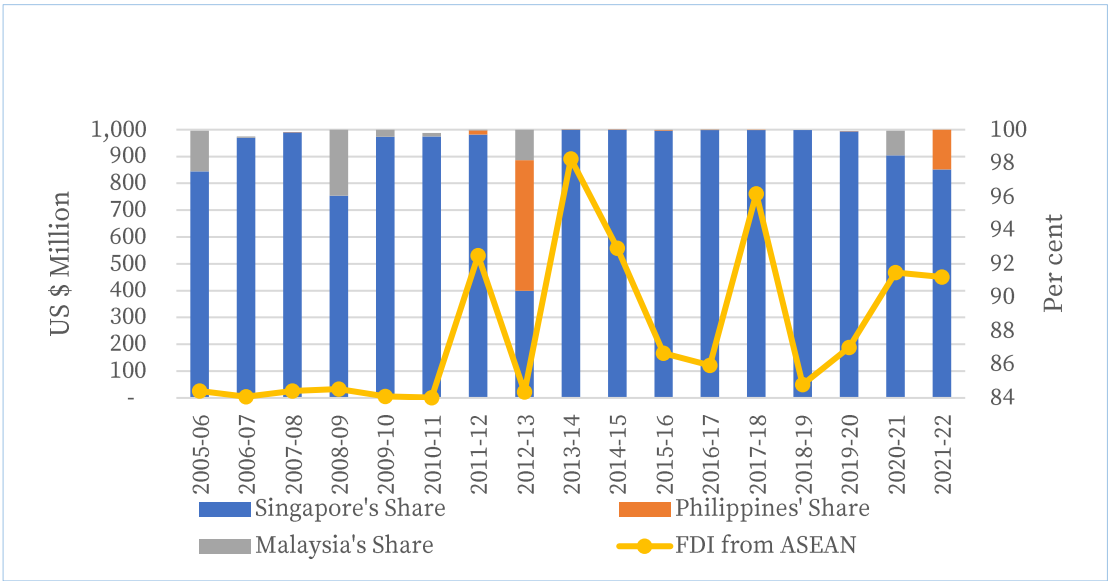
**Table 37: FDI Equity Inflows into Indian Pharmaceutical Sector**

| *Year* | *Total FDI in Indian Pharma Sector (US$ Million)* | *FDI from ASEAN countries in Indian Pharma Sector (US$ Million)* | *Share of ASEAN in Total FDI Inflows in Indian Pharma Sector (%)* |
|---|---|---|---|
| 2005-06 | 172.4 | 25.9 | 15.0 |
| 2006-07 | 224.2 | 4.9 | 2.2 |
| 2007-08 | 340.3 | 25.7 | 7.6 |
| 2008-09 | 4246.8 | 33.3 | 0.8 |
| 2009-10 | 213.1 | 5.8 | 2.7 |
| 2010-11 | 209.4 | 1.4 | 0.7 |
| 2011-12 | 3232.3 | 531.1 | 16.4 |
| 2012-13 | 1123.5 | 22.2 | 2.0 |
| 2013-14 | 1279.3 | 891.0 | 69.6 |
| 2014-15 | 1497.7 | 558.1 | 37.3 |
| 2015-16 | 754.3 | 166.5 | 22.1 |
| 2016-17 | 857.4 | 121.4 | 14.2 |
| 2017-18 | 1010.0 | 760.7 | 75.3 |
| 2018-19 | 266.0 | 50.1 | 18.8 |
| 2019-20 | 517.8 | 187.9 | 36.3 |
| 2020-21 | 1490.5 | 467.9 | 31.4 |
| 2021-22 | 1414.2 | 451.1 | 31.9 |
| Total | 18849.1 | 4305.0 | 22.8 |

Source: Computed using data provided by DPIIT

Almost the entire FDI inflows from this region during this period (2005-06 to 2021-22) have come from Singapore (99.4 per cent). Some investments have come from the Philippines and Malaysia (Figure 19). In most of the years, the entire investment from this region had come from Singapore. As we do not have the information about the investors from these countries and the investee firms in India, we are not able to analyse the objectives of the investments and their impacts on the Indian pharmaceutical sector.

**Figure 19: FDI in Pharmaceutical sector from the ASEAN Region: Major Source Countries**




Source: Same as Table 24.

As much of the FDI has come from Singapore, which is a tax haven, it is difficult to conclude that it has originated from the ASEAN countries; it may be possible that investors from other countries are using Singapore as a transit base to route their investments. Comparing India's FDI statistics from Singapore and Singapore's India bound OFDI statistics, which does not include investments routed through holding companies based in Singapore, it has been pointed out that the investments originating from that country is about half of what is reported as FDI coming from Singapore.[19] India has a Double Taxation Avoidance Agreement (DTAA) with Singapore which is in force since 1994.[20] India has Bilateral Investment Treaties (BIT) with many of the ASEAN Members: Malaysia (came into force in 1997, terminated in 2017), Vietnam (came into force in 1999, terminated in 2017), Indonesia (came into force in 2004, terminated in 2016), Thailand (came into force in 2001, terminated in 2017), Myanmar (came into force in 2009, terminated in 2020), Lao PDR (came

[19] Information available at https://www.india-briefing.com/news/singapore-business-hub-indian-companies-17090.html/ (accessed on 2 August 2022).

[20] This agreement was amended in 2016 with a view to prevent double non-taxation and round tripping.

into force in 2003, terminated in 2017), and Philippines (came into force in 2001).[21] But we do not see investments coming from those countries. Given the fact that almost the entire investment from this region is coming from Singapore, we cannot fully attribute the FDI inflows from the ASEAN region into the Indian pharmaceutical sector to the India-ASEAN investment agreement or the BITS with individual member countries.

### 3.1.2. OFDI from India to ASEAN

#### *3.1.2.1. Overview of OFDI from India*

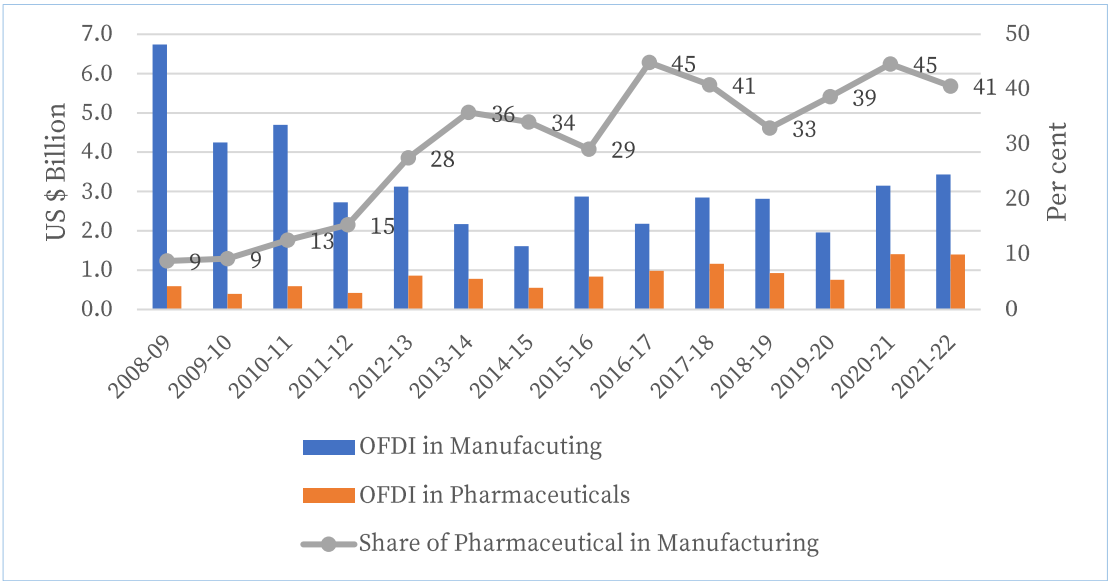
The Reserve Bank of India (RBI) provides investor-wise OFDI outflow data since July 2007. In order to have year-wise analysis, data was compiled from April 2008 to March 2022. There are 15479 investors invest US$ 167479.6 Million abroad during this period. About one-third of this investment (30 per cent) has originated from the manufacturing sector. This data, however, provides only the broad categories of economic activity. For example, it gives the information on whether the investment is originating from the manufacturing sector. But it doesn't give the more detailed sector focus of Indian investors who invest abroad. In other words, it doesn't give the information on how much investment has originated from the pharmaceutical sector.

Since the RBI data provides the name of the investor, it is possible to trace the sector focus of the investor and thus arrive at an estimate of the sector-wise contribution of OFDI. Identification of the focus sector of 15479 investors is a time-consuming process. Therefore, a cut-off of US$ 5 million is used to identify those investors who have invested $5 million or above in each tranche of investment during the period between April 2008 and March 2022. Thus, there are 1075 investors which invested an amount of US$ 140901.5 million during this period. This OFDI amount constitutes 84.1% of total OFDI during

[21] https://dea.gov.in/bipa

the same period. The Prowess database of Centre for Monitoring Indian Economy (CMIE) has been used as a handy source of information to identify the focus sector of the investors. However, the information that is available in Prowess is cross-checked with annual reports of investors and internet search. For those firms, which do not figure in prowess database, information was collected from their annual reports and internet search. After filtering the data, it is found that 31.6 per cent of the total OFDI during the period between 2008-09 and 2021-22 has originated from the manufacturing sector.[22] Within the manufacturing sector, the share of the pharmaceuticals sector in the annual outflow of investment has been continuously increasing. It has increased from 9 per cent in 2008-09 to 41 per cent in 2021-22 (Figure 20).[23] There are 57 investors from the pharmaceutical sector investing abroad worth US$ 11648 million during this period.

**Figure 20: OFDI from India in the Manufacturing Sector and Pharmaceutical Sector**




Source: Compiled using RBI data on Overseas Investment.

[22] Total OFDI during the period was US$ 140.9 billion and OFDI from the manufacturing sector was US$ 44.6 billion.

[23] The share of pharmaceuticals in manufacturing OFDI is 26.1 per cent during the period from 2008-09 to 2021-22.

### *3.1.2.2. OFDI to ASEAN in Pharmaceuticals Sector*

Indian investors from the pharmaceuticals sector have invested US$363 million in the ASEAN region during the period between 2008-09 and 2021-22 (Table 38). This region accounts for a very low share in the OFDI from India in the pharmaceuticals sector. During the analysis period, the share of ASEAN region in India's global OFDI from the pharmaceuticals sector was only 3.2 per cent.

**Table 38: India's OFDI to ASEAN from the Pharmaceutical Sector**

| *Year* | *India's OFDI from the Pharmaceutical Sector (US$ Million)* | | *ASEAN Share (%)* |
|---|---|---|---|
| | *To World* | *To ASEAN* | |
| 2008-09 | 594 | 5 | 0.8 |
| 2009-10 | 393 | 18 | 4.6 |
| 2010-11 | 593 | 81 | 13.6 |
| 2011-12 | 420 | 26 | 6.3 |
| 2012-13 | 861 | 10 | 1.2 |
| 2013-14 | 778 | 20 | 2.6 |
| 2014-15 | 549 | 25 | 4.6 |
| 2015-16 | 837 | 43 | 5.1 |
| 2016-17 | 979 | 59 | 6.0 |
| 2017-18 | 1,163 | 44 | 3.8 |
| 2018-19 | 927 | 31 | 3.3 |
| 2019-20 | 757 | - | - |
| 2020-21 | 1,404 | 7 | 0.5 |
| 2021-22 | 1,395 | - | - |
| Total | 11,648 | 369 | 3.2 |

Source: Same as Figure 25.

Ten pharma firms from India have invested in the ASEAN countries (Table 39). However, 94 per cent of the investment was made in a single country – Singapore. As much of the investment is going to Singapore, it is possible that the final destination may be different. In some of the cases, as seen from the above table, the entire investment went to Singapore.

**Table 39: Investors from Indian Pharmaceutical Sector into the ASEAN Countries**

| *Name of the Indian Pharmaceutical Company* | *ASEAN Country* | *Investment in ASEAN Country (US$ Million)* | *Firm's Global OFDI (US$ Million)* | *Share of ASEAN country in total OFDI of the Firm (%)* |
|---|---|---|---|---|
| Biocon | Malaysia | 16 | 223 | 7.2 |
| Bliss GVS Pharma | Singapore | 10 | 10 | 100.0 |
| Jubilant Life Sciences | Singapore | 62 | 75 | 82.6 |
| Matrix Laboratories | Singapore | 52 | 52 | 100.0 |
| MSN Laboratories | Singapore | 6 | 28 | 20.3 |
| Stelis Biopharma | Singapore | 7 | 7 | 100.0 |
| Strides Arcolab | Singapore | 128 | 357 | 35.9 |
| Strides Shasun | Singapore | 60 | 90 | 66.5 |
| Tenshi Life Sciences | Singapore | 22 | 22 | 100.0 |
| ACG Associated Capsules | Thailand | 7 | 48 | 14.0 |
| Total for the above firms | | 369 | 864 | 42.0 |

Source: Same as Figure 25.

## 3.2. Middle East

### 3.2.1. FDI Flows into the Pharmaceutical Sector

From the Middle East region, India has not received much FDI in the pharmaceutical industry. Investment from this region accounts for only 2 per cent of the total FDI that came into India in the pharmaceutical sector during the period between 2005-06 and 2021-22 (Table 40).

**Table 40: FDI Equity Inflows into Indian Pharmaceutical Sector**

| *Year* | *Total FDI in Indian Pharma Sector (US$ Million)* | *FDI from Middle East Region in Indian Pharmaceutical Sector (US$ Million)* | *Share of Middle East Region in Total FDI Inflows in Indian Pharma Sector (%)* |
|---|---|---|---|
| 2005-06 | 172 | - | - |
| 2006-07 | 224 | 4 | 1.6 |
| 2007-08 | 340 | 0 | 0.1 |
| 2008-09 | 4,247 | 27 | 0.6 |
| 2009-10 | 213 | 11 | 5.1 |
| 2010-11 | 209 | 3 | 1.4 |
| 2011-12 | 3,232 | 10 | 0.3 |

| *Year* | *Total FDI in Indian Pharma Sector (US$ Million)* | *FDI from Middle East Region in Indian Pharmaceutical Sector (US$ Million)* | *Share of Middle East Region in Total FDI Inflows in Indian Pharma Sector (%)* |
|---|---|---|---|
| 2012-13 | 1,123 | 31 | 2.8 |
| 2013-14 | 1,279 | 1 | 0.1 |
| 2014-15 | 1,498 | 5 | 0.4 |
| 2015-16 | 754 | 1 | 0.1 |
| 2016-17 | 857 | 8 | 0.9 |
| 2017-18 | 1,010 | 7 | 0.7 |
| 2018-19 | 266 | 19 | 7.0 |
| 2019-20 | 518 | 23 | 4.5 |
| 2020-21 | 1,490 | 225 | 15.1 |
| 2021-22 | 1,414 | 7 | 0.5 |
| Total | 18,849 | 382 | 2.0 |

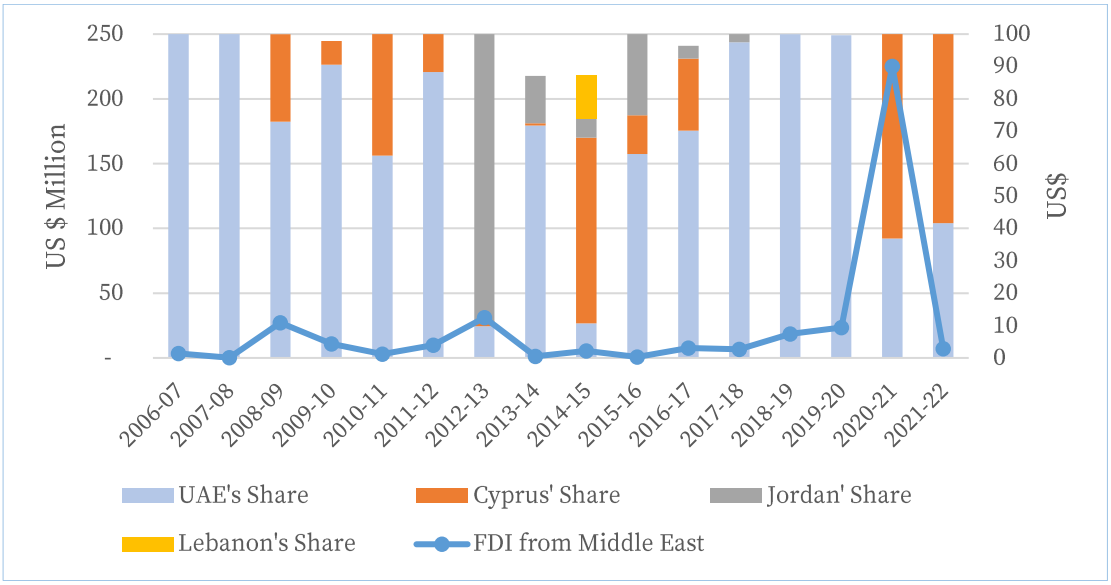
Source: Computed using data provided by DPIIT.

During this period (2005-06 to 2021-22), most of the FDI inflows from this region have come from UAE (49 per cent) and Cyprus (43 per cent) as they together account for 92 per cent of the FDI inflows. Some investments have come from Jordan (8%) as well (Figure 21). As we do not have the information about the investors from these countries and the investee firms in India, we are not able to analyse the objectives of the investments and their impacts on the Indian pharmaceutical sector.

India has BITs with most countries in the region, although all of them, except the one with UAE, were terminated in the recent past: Oman (came into force in 2000, terminated in 2017), Egypt (came into force in 2000, terminated in 2017), Qatar (came into force in 1997, terminated in 2017), Kuwait (came into force in 2003, terminated in 2018), Cyprus (came into force in 2004, terminated in 2017), Bahrain (came into force in 2007, terminated in 2021), Saudi Arabia (came into force in 2008, terminated in 2019), Jordan (came into force in 2009, terminated in 2020), Syria (came into force in 2009, terminated in 2020), and UAE (came into force in 2014). In the case of terminated BITs, the provisions

will be applicable for 15 more years. The UAE has been investing in India in the pharmaceutical sector even before the BIT was signed and Cyprus continued to invest in India even after the termination of the BIT with that country. It appears that the investment agreements that India has signed with the countries in the region is not a dominant factor in attracting investment from those countries in the pharmaceutical sector. There are many factors that influence the decision of foreign investors and investment agreement is only one among them.

**Figure 21: FDI in Pharmaceutical sector from the Middle East Region: Major Source Countries**




Source: Same as Table 14

### 3.2.2. OFDI to Middle East Countries in Pharmaceutical Sector

Indian investors from the pharmaceuticals sector have invested $582 million in the Middle East region during the period between 2008-09 and 2021-22 (Table 41). This region accounts for 5 per cent of the OFDI from India in the pharmaceuticals sector.

Investment from India to the Middle East has gone into two countries – UAE and Cyprus (Figure 22). UAE accounts for 53 per cent of the investment made

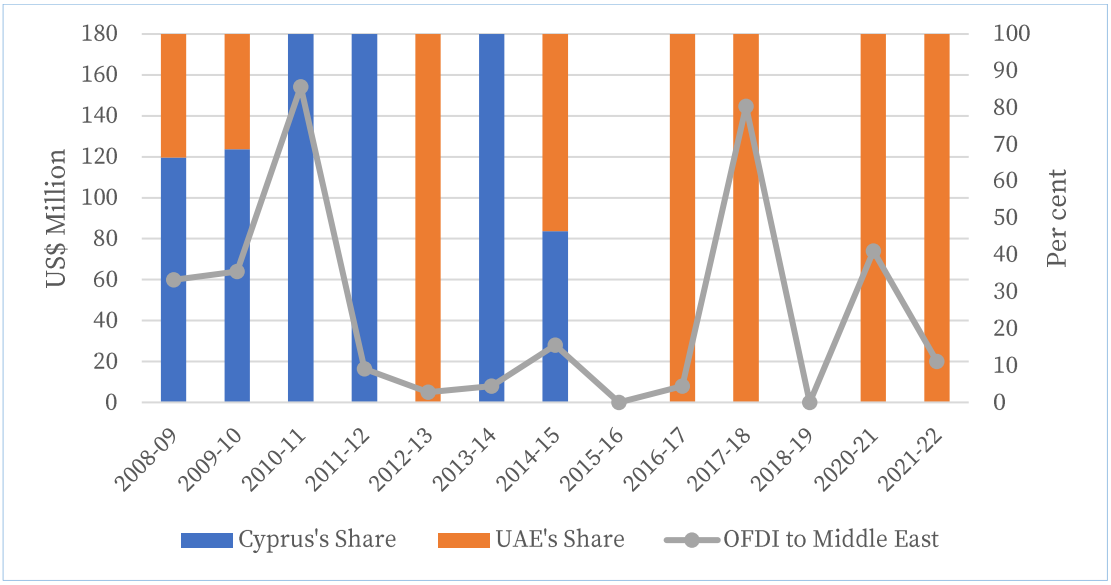
in this region. It is a key partner of India in the trade as it is the second largest export destination after the US and the third largest trade partner of India.

**Table 41: India's OFDI to Middle East from the Pharmaceutical Sector**

| *Year* | *India's OFDI from the Pharmaceutical Sector (US$ Million)* | | *ASEAN Share (%)* |
|---|---|---|---|
| | *To World* | *To Middle East* | |
| 2008-09 | 594 | 60 | 10.1 |
| 2009-10 | 393 | 64 | 16.3 |
| 2010-11 | 593 | 154 | 26.0 |
| 2011-12 | 420 | 16 | 3.9 |
| 2012-13 | 861 | 5 | 0.6 |
| 2013-14 | 778 | 8 | 1.0 |
| 2014-15 | 549 | 28 | 5.1 |
| 2015-16 | 837 | - | - |
| 2016-17 | 979 | 8 | 0.8 |
| 2017-18 | 1,163 | 145 | 12.4 |
| 2018-19 | 927 | - | - |
| 2019-20 | 757 | - | - |
| 2020-21 | 1,404 | 74 | 5.3 |
| 2021-22 | 1,395 | 20 | 1.4 |
| Total | 11,648 | 582 | 5.0 |

Source: Compiled using RBI data on Overseas Direct Investment.

**Figure 22: India's OFDI from Pharmaceutical Sector in the Middle East – Destination**




Source: Same as Table 28.

After coming into force of the India-UAE BIT in 2014, India's entire OFDI to the Middle East region was destined to UAE. Cyprus used to be considered as a tax haven until 2019 when it increased the corporate tax and OECD granted it a status similar to many European Countries and US in terms of compliance to standards set by the Global Forum on Transparency and Exchange of Information for Tax Purposes. After 2014-15, there is no investment going to this country. It may be possible that the investments that had gone into Cyprus were due to it's tax haven status. As it is also a member of the European Union, investments to Cyprus might have been destined to other European countries.

There are six firms from the Indian pharmaceutical sector investing in the Middle East (Table 42). Out of their total OFDI, 28.5 per cent was destined to the Middle East. Some of the investments were for establishing subsidiaries for exploring export opportunities in the Middle East countries. Cipla FZE was established in UAE in 2006 for this objective.[24] Some other investments were to claim a stake in pharmaceutical retail chains, also with the objective of promoting exports. Plethico acquired 20 per cent stake in Tricon Holdings in 2008, a Dubai based pharmaceutical retail chain which has operations in the Commonwealth of Independent States (CIS) region. This acquisition gives Plethico direct access to more than 300 retail pharmacies in Russia.[25] UAE has been targeting to double the number of pharmaceutical factories in it's main industrial free zone area, Jebel Ali Free Zone (Jazfa), by 2021.[26] JAFZA had held

[24] Information available at https://economictimes.indiatimes.com/industry/healthcare/biotech/pharmaceuticals/cipla-sets-up-subsidiary-in-dubai/articleshow/2105004.cms?from=mdr (accessed on 2 August 2022).

[25] Information collected from Dalal Street Investment Journal, at http://www.dsij.in/productattachment/brokerrecommendation/plethico.pdf (accessed on 2 August 2022).

[26] Information available at https://www.pharmaceutical-technology.com/pricing-and-market-access/new-import-substitution-initiatives-in-the-middle-east-2017-the-year-of-new-policies-html/ (accessed on 2 August 2022).

a series of workshops in India in the second half of last decade to create awareness among Indian investors of the business opportunities in UAE.[27]

**Table 42: Investors from Indian Pharmaceutical Sector into the ASEAN Countries**

| *Name of the Indian Pharmaceutical Company* | *Middle East Country* | *Investment in Middle East Country (US$ Million)* | *Firm's Global OFDI (US$ Million)* | *Share of Middle East country in total OFDI of the Firm (%)* |
|---|---|---|---|---|
| Dr. Reddy's Laboratories | Cyprus | 131 | 711 | 18.5 |
| Strides Arcolab | Cyprus | 144 | 357 | 40.3 |
| Cadila Healthcare | UAE | 233 | 544 | 42.8 |
| Cipla | UAE | 29 | 383 | 7.6 |
| Elder Pharmaceuticals | UAE | 5 | 5 | 100.0 |
| Plethico Pharmaceuticals | UAE | 40 | 40 | 100.0 |
| Total for the above firms | | 582 | 2040 | 28.5 |

Source: Same as Table 28.

[27] Information available at http://www.pharmabiz.com/NewsDetails.aspx?aid=94322&sid=1 (accessed on 2 August 2022).

CHAPTER 4

# Challenges of Market Access in ASEAN and Middle East Regions

This section is prepared based on the information obtained from: (1) Global Trade Alert (GTA) database, which provides information on non-tariff measures (NTMs), (2) questions raised by India during the trade policy review of its trading partners at the WTO, (3) concerns raised by the US Trade Representative (USTR) in it's National Trade Estimate Reports on Foreign Trade Barriers, and (4) media reports and studies.

The GTA database classifies Government's interventions into three categories, namely 'Green', 'Amber' and 'Red'. The government interventions are categorised as 'red', if they are already implemented and are almost certainly discriminate against foreign commercial interests. Measures coming under the 'amber' category are those measures when implemented, it is very much likely to adversely affect the foreign commercial interests. Those measures in the 'green' category are likely to promote foreign commercial interests. For this analysis, we have selected those policy interventions falling under the categories of amber and red. The result of this analysis is presented in Table 43.

**Table 43: Non-Tariff Measures Prevalent by ASEAN and Middle East Countries Pertaining to Pharmaceutical Products**

| *Country* | *Measure* | *Objective* | *Year of Implementation* |
|---|---|---|---|
| Thailand | Financial grant of $39.36 Million to Baiya Phytopharm Company | Towards R&D of COVID-19 vaccine project | 2021 |
| Indonesia | Capital injection of $143.7 Million in the form of equity to PT Bio Parma | To manufacture vaccines | 2020 |
| Indonesia | Reduced the threshold for import duty exemption from FOB $75 per consignment to FOB $3 per consignment. Further, import duty at 7.5 per cent is also imposed to a consignment with a value between FOB $3 per consignment to FOB $75 per consignment. | To protect domestic industry from the increase of imported goods | 2019 |
| Indonesia | In order to reduce dependence on imports, the Indonesian Government issued a Presidential Directive No. 6 of 2016 on the Acceleration of the Development of the Pharmaceutical and Medical Equipment Industry. Follow on regulations include provisions for prioritising the use of local raw materials with a view to reduce the import dependence in the pharmaceuticals sector from 94 per cent to 45 per cent by 2035 | To push local pharmaceutical and medical equipment industries | 2017 |
| Indonesia | Public procurement regulations prioritise procurement of medicines and medical equipment which use local raw materials. | To push local pharmaceutical and medical equipment industries | 2017 |
| Indonesia | Import duty proceeds used as production subsidies | To support local manufacturing | 2015 |
| Indonesia | Importer permit and distribution licence requirements for food and drugs | Not mentioned | 2013 |
| Vietnam | Devalued the national currency, the Dong | To curb the trade deficit | 2010 |
| Saudi Arabia | The Local Content and Government Procurement Authority has issued a list of 100 medicines which has to be produced locally. | Public procurement localisation | 2020 |

Source: Compiled using GTA database

Almost all of the NTMs captured in the above table are related to the efforts of countries to reduce import dependence and encourage domestic production. Such measures comprise of the use of local content requirements, support for R&D, public procurement policies in favour of domestically produced goods and management of exchange rates.

The country-wise market access barriers identified from other sources mentioned above are the following.

## Indonesia

The Ministry of Religion, Indonesia, issued a decree in October 2020 (No.464) that makes halal certification mandatory for the marketing of 48 types of products, including pharmaceuticals. Halal certification is required for pharmaceutical ingredients, formulations and traditional medicines. Different time periods have been set for different categories of medicines for compliance – Traditional medicines by October 2026, over the counter medicines by October 2029 and prescription medicines by 2034.[28]

It is alleged that the policies pursued by Indonesia to promote domestic manufacturing of medicines are having an adverse impact on market access. The Ministry of Health (MoH) Resagulation 1010/2008 requires foreign pharmaceutical companies to either manufacture locally or entrust another company that is already registered as a manufacturer in Indonesia on its behalf. Similarly, (MoH) Regulations 17/2017 and 6/2020 prioritize the use of domestic raw materials in pharmaceutical products and require the national

[28] Information collected from http://www.usdaindonesia.org/wp-content/uploads/2021/02/MORAs-Decree-No.-464_2020.pdf, https://www.trade.gov/market-intelligence/indonesian-halal-product-assurance-product-scope (accessed on 2 August 2022).

health insurance system to give priority to products which are having certified local content value. All these measures discriminate against foreign suppliers.

Lack of clarity on the Indonesian pricing and reimbursement system regarding how pharmaceutical products are selected for public procurement, how ceiling prices are determined, and how long such medicines will remain in the list is something that causes uncertainty among foreign firms that would like to supply medicines in the country or invest in the country.

## Thailand

Thailand launched a Government Procurement Program in 2016 to support local enterprises engaging in the commercialisation of local innovations. A Thai Innovation List was prepared to facilitate the government procurement programme. But Thai majority ownership was an essential requirement for getting listed in the innovation list. This prevents the majority owned foreign firms from listing in the innovation list and thus getting excluded from the government procurement programme.

## Vietnam

Foreign invested enterprises are prohibited from distributing pharmaceutical products in Vietnam. Vietnam hasn't opened up this service in its international commitments (in WTO, European Union-Vietnam FTA and Comprehensive and Progressive Agreement for Trans-Pacific Partnership). Foreign firms are allowed to import drugs and raw materials, but they are not allowed to distribute them within the country.

The circular issued by the MoH in 2018 (No. 32/2018/TT-BYT) on Marketing Authorization of Drugs and Medicinal Ingredients, and the follow-on circular in 2020 (No. 29/2020/TTBYT) require the suppliers to have EU-GMP

certification. This provision is cumbersome, especially for low-volume suppliers.

## Saudi Arabia

Pharmaceutical products are placed among the 23 categories of restricted products for imports. Import of these products requires special approval.

CHAPTER 5

# SWOT Analysis

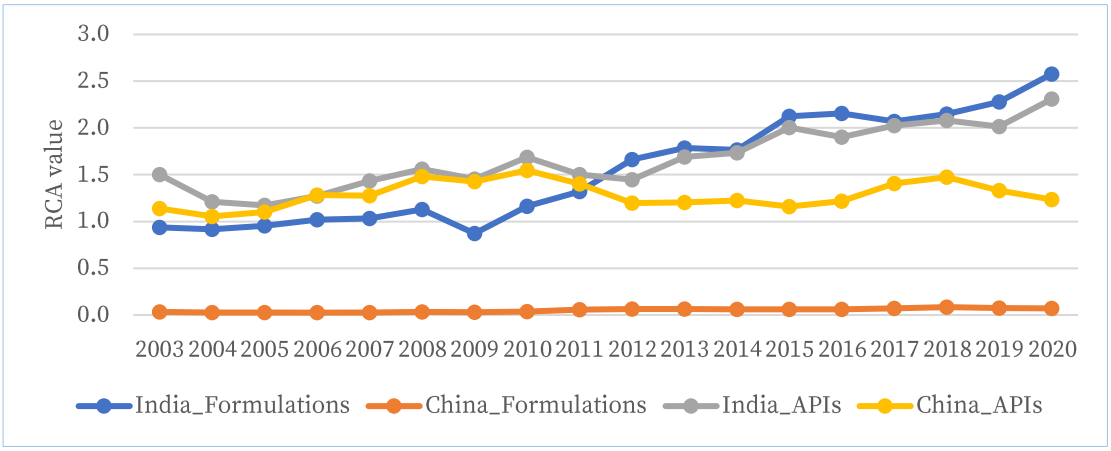
## 5.1. Strengths

- India is one of the leading countries in pharmaceutical exports, ranking 11 in terms of the value of exports and 6 in terms of volume of exports. In both formulations and APIs, which account for most of the pharmaceutical products that are traded globally, India is increasingly exporting more value-added products as indicated by rising share in terms of the value of exports and declining share of volume of exports.

- India's comparative advantage in the global export of formulations and APIs is rising as indicated by the increasing RCA Index. As compared to China, which is also a leading exporter of pharmaceutical products, the RCA index of these two categories is higher for India (Figure 23). The higher RCA values for India mean that in the given export basket of India vis-a-vis China, formulations and APIs are product categories in which India is better placed as compared to China in the global market.

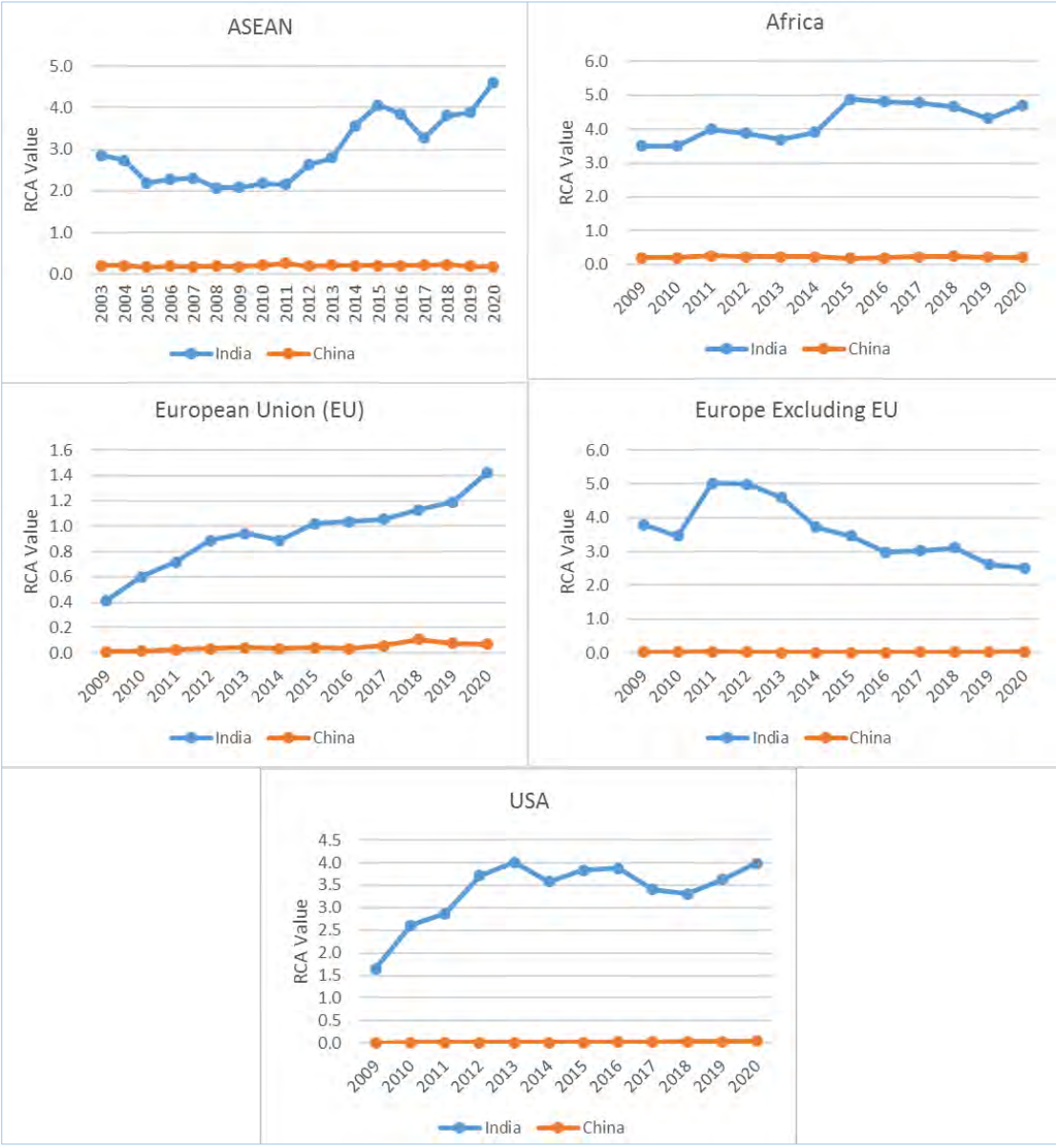
- In some regions, formulations and APIs from India are better placed as compared to their global advantages. In formulations, India is much better placed when compared to China in ASEAN, Africa, EU, Europe excluding EU and US (Figure 24). In APIs, India also has a comparative advantage in Middle East region in addition to the aforementioned regions for formulations (Figure 25). In ASEAN and Middle East regions, the RCA index of APIs for China shows a declining trend since the initial years of the last decade whereas it kept growing for India.

**Figure 23: RCA in formulations and APIs – A comparison of India and China**



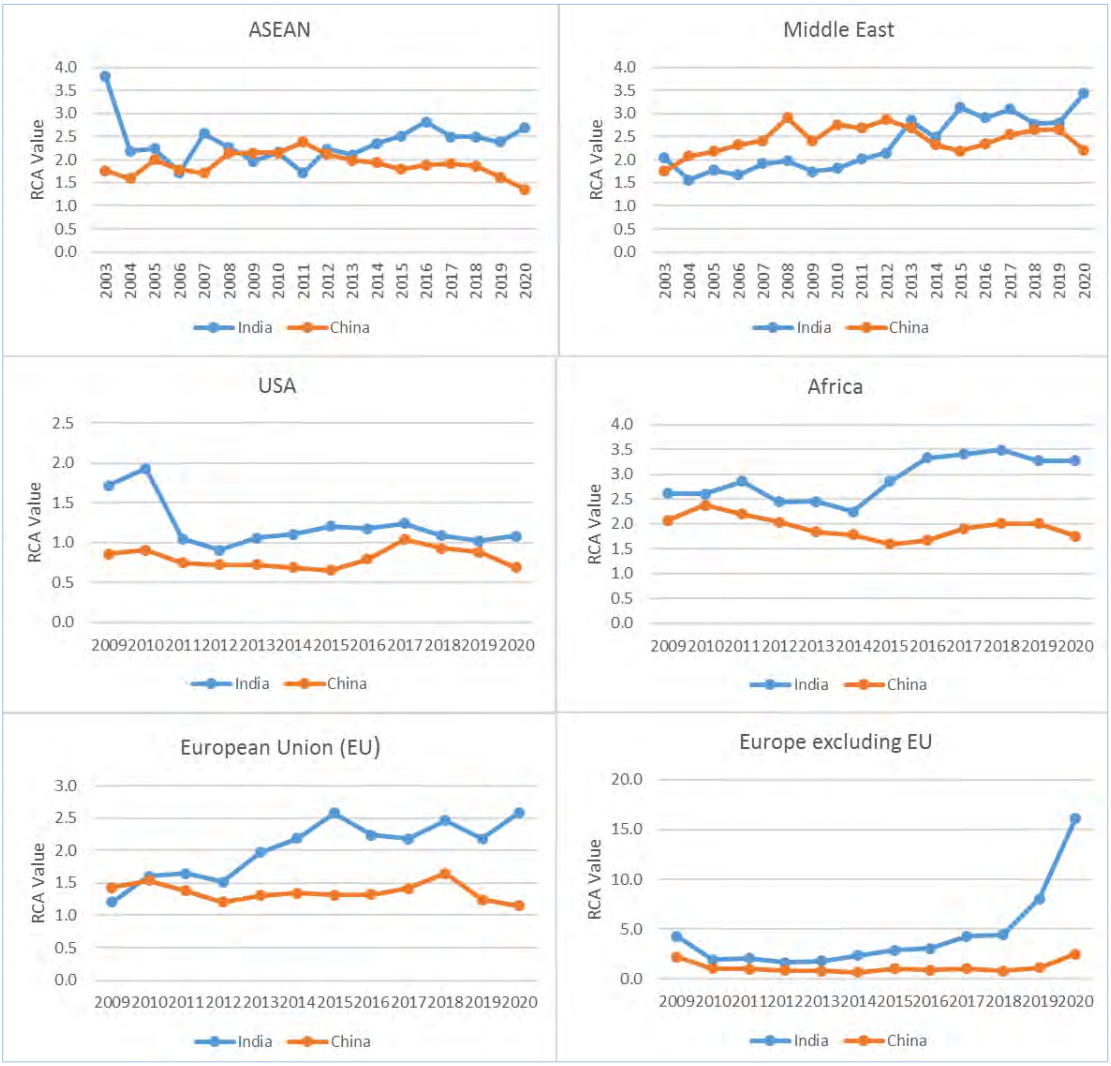

Source: Same as Figure 2.

**Figure 24: Region-wise RCA in the export of formulations for India and China**




Source: For ASEAN-Same as Figure 2 and the rest are reproduced from Joseph and Kumar (2022).

**Figure 25: Region-wise RCA in the export of APIs for India and China**




Source: For ASEAN and Middle East, same as Figure 2, and the rest are reproduced from Joseph and Kumar (2022).

- India has a reputation as a reliable supplier of pharmaceutical products. Pharmaceutical products are essential goods, especially in public health emergencies. While some leading supplier countries tend to use their supplies to yield favourable responses in their international affairs, as seen during the COVID-19 pandemic, India never attempted to use its capabilities in the manufacturing of pharmaceutical products to cater to its foreign policy objectives.

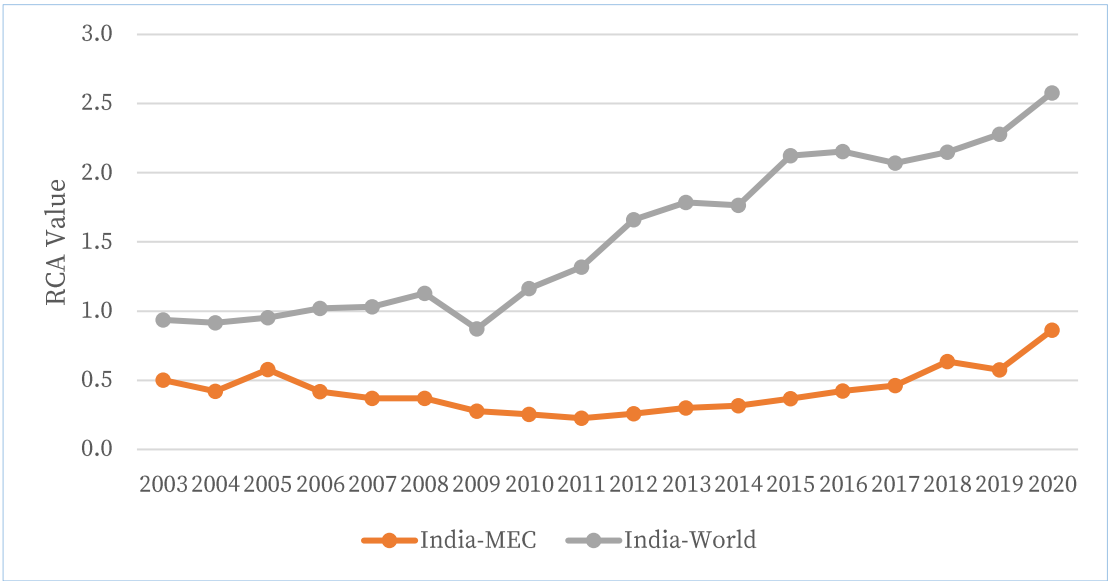
## 5.2. Weaknesses

- The advantage that Indian pharmaceutical products, especially APIs, have in the world, is determined by the import of cheaper raw materials (KSMs and DIs) from China. [29] This makes India very concerned about any disruption in the supplies from China, both in terms of price and quantity. Any disruption in the supplies from China is likely to adversely impact the advantages that the Indian formulations and APIs enjoy globally. The study of Dutta and Gajbhiye (2021), which investigated the drivers of India's exports in pharmaceutical products finds that it is the cheaper imports of raw materials and not the capabilities acquired through research and development (R&D) that are driving its exports. Cheaper imports from China have on the one hand made Indian pharmaceutical products, especially APIs, more competitive in the global market, but on the other, it made the Indian pharma industry complacent in acquiring innovation capabilities that would have made the industry even more competitive.

- In spite of the fact that India is a prominent player in the global export of formulations, it is not able to export much to some regions, like the Middle East. In other words, in regions like the Middle East, India doesn't have a comparative disadvantage in formulations as the RCA value is less than one (Figure 26).

[29] In the case of formulations, India is having the highest number of USFDA approved manufacturing facilities outside the US. This gives Indian formulations an edge over generic formulations from other countries in the highly regulated markets.

**Figure 26: India's Global and Regional (Middle East) RCA in Formulations**




Source: Same as Figure 2

## 5.3. Opportunities

- Until the onset of COVID-19, economic efficiency was the dominant consideration that drove the growth of global supply networks. The pandemic, however, exposed the national security implications of excessive reliance on foreign supplies, especially on a single country, in crucial sectors such as pharmaceuticals. A number of countries have already initiated measures for diversifying their supply sources of APIs. This provides India with an opportunity to pitch in as a reliable and competitive supplier of APIs.

- Given the strategic and public health implications of the pharmaceutical industry, some countries have adopted measures for the development of domestic pharmaceutical industries. For example, the National Industrial Development and Logistics Program (NIDLP) 2019 of Saudi Arabia has identified pharmaceuticals as a focus sector for domestic industrial development. It is relatively easier for the manufacturer of formulations to acquire the manufacturing

capabilities as compared to APIs. API manufacturing is more technology-intensive process, and it has a lot of environmental implications. It is likely that such countries will continue to import APIs even if they successfully develop capabilities in the manufacturing of formulations. For example, Indonesia is a country that imposes restrictions on the import of formulations as it is striving for the development of an indigenous industry. However, India's export of APIs to this country has increased substantially over the years. The value of export of APIs to Indonesia increased from US$ 5.7 million during the three year period 2003-05 to US$ 51.3 million during 2018-20, with that country's share in India's exports to the ASEAN region increasing from 9 per cent to 18 per cent during the same period (Figure 9).

- In an attempt to develop domestic manufacturing capabilities in the pharmaceutical sector, many countries in the ASEAN and Middle East regions, restrict the operations of foreign suppliers and strictly enforce local content requirements. For example, in Turkey, the Government decided in 2018 to subject the reimbursement of 54 main drugs to their production within the country.[30] This provides an opportunity for Indian pharmaceutical firms to establish their subsidiaries in these regions and expand their business there.

- It is reported that the patents over many lucrative medicines are going to expire in the coming years which is likely to create an opportunity

[30] Information available at https://www.pharmaceutical-technology.com/pricing-and-market-access/new-import-substitution-initiatives-in-the-middle-east-2017-the-year-of-new-policies-html/ (accessed on 22 March 2022).

worth US$ 240 billion over the next five years until 2026.[31] This provides a big opportunity for the Indian pharmaceutical industry not only in the US and European markets but also in regions like Middle East which are heavily dependent on imports from the West.

- The India-ASEAN FTA provides scope for the annual review of the exclusion list. It is found that in the pharmaceutical products covered by the exclusion list, the ASEAN countries imported more than US$ 708 million worth of imports in 2019 from other countries, excluding India. In some cases, the share of India's exports to these countries is much lower as compared to India's global share in the export of respective products. Bringing the exclusion list under the purview of tariff reduction commitments is likely to enhance India's export to these countries. India should, therefore, use the opportunity of annual review of the exclusion list.

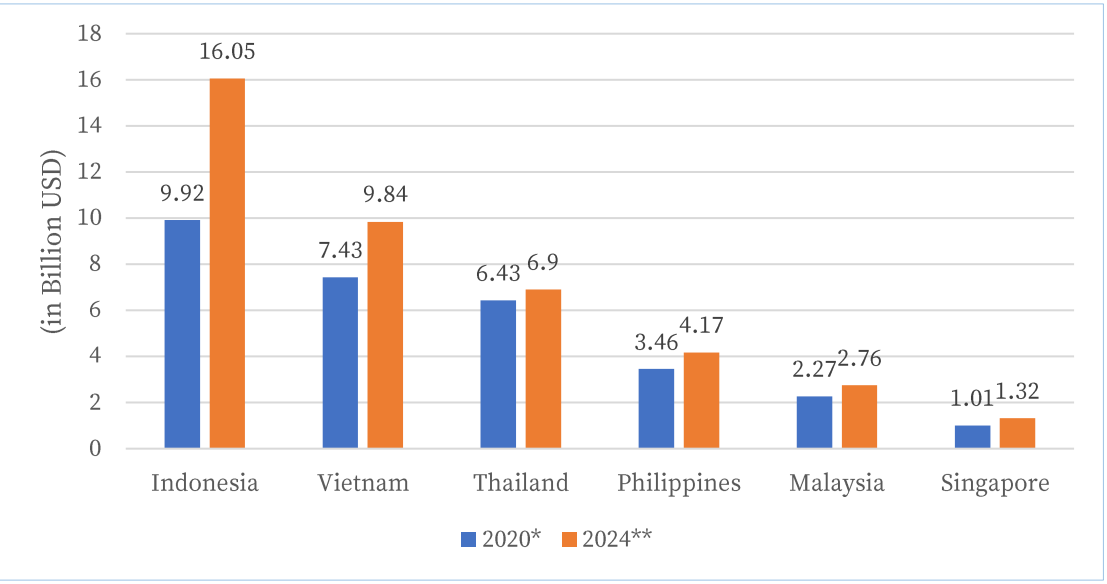
- The recently concluded India-UAE FTA has eliminated tariffs in many APIs. This will enhance the export of APIs to this country. The Bilateral Cooperation on Pharmaceutical Products (BCPP) between the two countries is addressing several technical barriers to trade, especially concerning to formulations. This will help in further enhancing India's export of formulations to this country.

- In the ASEAN region, the pharmaceutical market (in terms of sales) is projected to grow annually at 12.8 per cent during the period between 2021 and 2027. The increasing prevalence of chronic ailments, growing geriatric population, and increasing per capita healthcare expenditure

[31] Information collected from The Pharmaletter at https://www.thepharmaletter.com/article/india-expected-to-lead-patent-cliff-opportunity-in-the-usa (accessed on 2 August 2022).

are the key factors driving this growth.[32] Indonesia, the largest pharmaceutical market in the region is projected to grow from about US$ 10 billion in 2020 to around US$ 16 billion in 2024. The projected growth in the key pharmaceutical markets in the regions is presented in the following figure (Figure 27).

**Figure 27: Pharmaceutical Sales in Major ASEAN countries in 2020 with Forecast for 2024 (US$ Billion)**




Source: Compiled using data from Statista.com[33]
Note: (*) denotes Estimates & (**) Forecast

- In the Middle East, the pharmaceutical market is projected to grow from US$ 25 billion in 2018 to US$ 60 billion by 2025[34]. In Saudi Arabia, which is the largest pharmaceutical market of the region, the pharmaceutical market is projected to grow at an annual rate of 7.3 per cent over the next six years; the pharmaceutical market of Saudi Arabia

[32] Information available at https://www.researchandmarkets.com/reports/5310318/asean-pharmaceutical-manufacturing-market-2017#:~:text=ASEAN%20pharmaceutical%20manufacturing%20industry%20will,increasing%20per%20capita%20healthcare%20expenditure (accessed on 8 July 2022)

[33] Information available at https://www.statista.com/statistics/1294469/asean-pharmaceutical-sales-by-country/ (accessed on 7/7/2022)

[34] Information available at https://www.cartermurray.com/regional-focus/why-the-pharmaceutical-industry-in-the-middle-east-is-a-great-choice-for-marketers/ (accessed on 8 July 2022)

was estimated to be worth US$ 10.2 billion in 2021.[35] The pharmaceutical market of UAE, which is having the second largest pharmaceutical market in the region, is expected to grow by 27 per cent between 2021 and 2025 to reach a valuation of US$ 4.7 billion[36].

## 5.4. Threats

- The public procurement policies, reimbursement policies, and local content requirement policies of many of the countries in the ASEAN and Middle East regions discriminate against suppliers based in foreign countries. This is because these countries are striving to develop the pharmaceutical industry domestically. Therefore, they encourage suppliers based in foreign countries to establish their manufacturing facilities within their countries, rather than exporting.

- There is a view among some countries, which are more concerned about the national security implications of excessive reliance on China for supplies, that India is not a reliable alternate source of supply for APIs. This is because India is very much dependent on China for KSMs and DIs. This concern is expressed in the Biden administration's 100 Days Reviews on *Building Resilient Supply Chains, Revitalising American Manufacturing, and Fostering Broad-Based Growth* that "India, which supplies approximately 40 per cent of generic pharmaceuticals used in the United States, imports nearly 70 per cent of its APIs from China" (The White House 2021).

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[35] Information available at https://www.arabnews.com/node/1860886/business-economy (accessed on 9 July 2022).

[36] Information available at https://www.thenationalnews.com/business/2022/02/23/uae-pharma-market-to-be-valued-at-47bn-by-2025-as-it-boosts-local-manufacturing/ (accessed on 9 July 2022).

CHAPTER 6

# Suggestions

## Leveraging the India-ASEAN FTA

There is no conclusive evidence to suggest that the India-ASEAN FTA has helped in increasing India's export of pharmaceutical products to the ASEAN region. This study brings out three key observations, which suggest the areas where more attention is needed to enhance the market access by exporters of pharmaceutical products from India.

- Formulations, the major exported product category, face a number of non-tariff barriers in some of the major ASEAN countries.
- In some cases, export of products covered by the exclusion list grew at a higher pace as compared to products receiving tariff commitments, during the post FTA period. In an FTA arrangement, it is expected that products facing tariff reduction commitments will show a higher rate of growth in exports.
- In the case of some formulation categories, which are kept in the exclusion list, it is found that India's share in export to the ASEAN region is lower as compared to their share in India's global exports. And in some cases, for example, antibiotics (HS 300420 and 300410), India's share in exports to ASEAN is very low as compared to their share in global exports.

### Suggestion 1: Make use of the provision for annual review

The FTA provides for an annual review of the products covered in the exclusion list. India should use the annual review process to get tariff concessions in those formulations where India is having a very low share in ASEAN as compared to global exports.

In case there is a review of India-ASEAN FTA, a chapter/section needs to be added on bilateral cooperation on pharmaceutical products, like in the case of India-UAE FTA. India should persuade its FTA partners to recognise the Indian pharmacopeia, which has already been accepted by four countries. If this is not possible, India should insist on recognition of pharmacopoeias of a few countries, instead of one country, as reference points.

### Suggestion 2: Negotiate with countries on regulatory and other non-tariff measures.

Some of the regulatory and other requirements followed by countries in the ASEAN (and Middle East also) create hurdles for Indian exporters. For example, marketing authorisation for drugs and drug ingredients in Vietnam requires EU-GMP certification. This prevents those exporters from having GMP certification from other regulators such as USFDA. Instead of insisting on certification by a single foreign regulator, certification from among a pool of globally acclaimed regulatory agencies will be more desirable. This is what is done in the case of the Bilateral Cooperation on Pharmaceutical Products (BCPP) which is part of the India-UAE FTA. It provides that those medicines and medical products which have obtained marketing approvals in any of the five countries - Australia, Canada, Japan, US and UK, and EU, will be fast-tracked for marketing approval in the UAE.

## Meeting the challenges of reverse globalisation in the context of COVID-19

The COVID-19 pandemic has brought to the fore the national security implications of hyper globalisation, which is based on economic efficiency perspectives. As a result, some countries have started encouraging their firms to produce domestically and to diversify sources of supplies in crucial sectors. But even before the onset of the pandemic, some countries in the ASEAN and Middle East regions had initiated the process of development of indigenous pharmaceutical industries. Accordingly, they had put in place measures to discourage import of formulations and encourage local production. The COVID-19 pandemic has accentuated the efforts at the development of indigenous pharmaceutical industries. While this is not good news for exporters of formulations, it provides an opportunity for exporters of APIs and firms looking forward to investing abroad for expanding their business.

### Suggestion 1: Encourage Indian pharmaceutical firms to take advantage of the emerging opportunities in the ASEAN and Middle East regions by establishing their subsidiaries/joint ventures

It is found that several countries in both regions are increasingly adopting measures to promote the domestic manufacturing of medicines. To achieve this objective, they have put in place several barriers, such as local content requirements, for discouraging the export of formulations into their territories. Some of these countries are also encouraging the increased use of generic medicines to reduce healthcare costs. And the pharmaceutical markets in these two regions are projected to grow faster in the coming years due to the increasing prevalence of chronic diseases, growing geriatric population and rising per capita healthcare expenditure. It has been reported that the patents over many lucrative medicines are going to expire in the

coming years which is likely to create an opportunity worth US$ 240 billion over the next five years until 2026. This will add to the opportunity that is emerging from these regions. However, taking advantage of it calls for establishing manufacturing facilities in those countries.

### Suggestion 2: Sensitise Indian investors about opportunities in ASEAN and Middle East regions in the pharmaceutical sector

OFDI to these regions in the pharmaceutical sector is very low. Most of the investments are going to two countries – UAE and Singapore. Since Singapore is being used as a base for routing investments, we do not know how much of the investments were finally destined for that country. In the case of UAE, the business environment in that country could have definitely influenced the investors in India. But the UAE officials have also held workshops in India to sensitise the Indian investors about the business opportunities in that country. This might have also played an important role, other than the market conditions in that country, in UAE becoming an important destination for investments in the pharmaceutical sector from India. Sensitising Indian investors of the opportunities in other countries in these two regions will be useful.

### Suggestion 3: Improve competence in the production of APIs and intermediates

APIs from India have become as competitive as formulations in the international market as captured by the RCA analysis. However, this advantage is determined by the supply of cheaper KSMs and DIs from China and not by the innovation capabilities that Indian firms have acquired through their R&D efforts. To sustain the advantage that Indian pharmaceutical products enjoy (formulations and APIs) in the global market, the

vulnerabilities associated with excessive dependence on China for raw materials need to be addressed.

The PLI schemes in the pharmaceutical sector is a good initiative in this direction. However, this scheme needs to be backed by a R&D/technology component, which will facilitate the adoption of advanced technologies by the manufacturers in India so that they become more competitive at production.

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# Annexure

**Annexure 1: category-wise India's Global Exports of Pharmaceutical products (US$ Million)**

| *Year* | *Formulations* | *APIs* | *Bulk Medicines* | *Other Pharmaceuticals Pdts* |
|---|---|---|---|---|
| 2009 | 4,232 | 1,241 | 630 | 150 |
| 2010 | 5,309 | 1,535 | 616 | 168 |
| 2011 | 7,351 | 1,911 | 671 | 227 |
| 2012 | 8,768 | 1,976 | 584 | 219 |
| 2013 | 10,847 | 2,569 | 531 | 283 |
| 2014 | 10,886 | 2,454 | 390 | 287 |
| 2015 | 11,873 | 2,573 | 329 | 297 |
| 2016 | 12,298 | 2,532 | 352 | 382 |
| 2017 | 12,148 | 2,743 | 328 | 389 |
| 2018 | 13,459 | 3,093 | 329 | 503 |
| 2019 | 15,423 | 3,346 | 318 | 522 |
| 2020 | 17,389 | 3,561 | 337 | 699 |

**Annexure 2: category-wise India's Global Imports of Pharmaceutical products (US$ Million)**

| *Year* | *Formulations* | *APIs* | *Bulk Medicines* | *Other Pharmaceuticals Pdts* |
|---|---|---|---|---|
| 2009 | 800 | 1,323 | 47 | 230 |
| 2010 | 904 | 1,666 | 50 | 268 |
| 2011 | 1,090 | 1,808 | 42 | 343 |
| 2012 | 1,328 | 1,950 | 48 | 378 |
| 2013 | 1,218 | 2,077 | 40 | 406 |
| 2014 | 1,116 | 2,371 | 48 | 464 |
| 2015 | 1,163 | 2,364 | 35 | 416 |
| 2016 | 1,204 | 2,244 | 52 | 439 |
| 2017 | 1,295 | 2,518 | 51 | 423 |
| 2018 | 1,708 | 3,980 | 70 | 707 |
| 2019 | 1,703 | 3,262 | 81 | 738 |
| 2020 | 1,429 | 3,381 | 66 | 977 |

**Annexure 3: category-wise India's Global Exports of Pharmaceutical products (1000 Metric Tonnes)**

| *Year* | *Formulations* | *APIs* | *Bulk Medicines* | *Other Pharmaceuticals Pdts* |
|---|---|---|---|---|
| 2009 | 468 | 73 | 54 | 20 |
| 2010 | 17 | 21 | 3 | 4 |
| 2011 | 394 | 394 | 32 | 17 |
| 2012 | 324 | 117 | 24 | 11 |
| 2013 | 394 | 148 | 23 | 10 |
| 2014 | 389 | 132 | 26 | 12 |
| 2015 | 364 | 148 | 23 | 11 |
| 2016 | 368 | 168 | 21 | 12 |
| 2017 | 314 | 170 | 19 | 10 |
| 2018 | 306 | 130 | 16 | 9 |
| 2019 | 256 | 213 | 15 | 9 |
| 2020 | 295 | 114 | 20 | 13 |

**Annexure 4: category-wise India's Global Imports of Pharmaceutical products (1000 Metric Tonnes)**

| *Year* | *Formulations* | *APIs* | *Bulk Medicines* | *Other Pharmaceuticals Pdts* |
|---|---|---|---|---|
| 2009 | 3.2 | 109 | 1.6 | 1.4 |
| 2010 | 1.9 | 127 | 1.4 | 1.5 |
| 2011 | 1.0 | 132 | 1.1 | 1.5 |
| 2012 | 0.7 | 153 | 1.0 | 1.8 |
| 2013 | 0.7 | 179 | 0.8 | 2.1 |
| 2014 | 0.8 | 217 | 1.6 | 3.3 |
| 2015 | 1.1 | 235 | 1.3 | 3.4 |
| 2016 | 2.3 | 252 | 1.3 | 3.9 |
| 2017 | 3.9 | 232 | 3.0 | 4.9 |
| 2018 | 12.0 | 336 | 5.0 | 6.7 |
| 2019 | 16.4 | 270 | 5.9 | 6.6 |
| 2020 | 8.3 | 299 | 5.5 | 5.2 |

**Annexure 5: category-wise India's Imports of Pharmaceutical products from ASEAN region (US$ Million)**

| *Year* | *Formulations* | *APIs* | *Bulk Medicines* | *Other Pharmaceuticals Pdts* |
|---|---|---|---|---|
| 2003 | 8 | 16 | 1.8 | 0.6 |
| 2004 | 3 | 16 | 1.6 | 1.3 |
| 2005 | 2 | 25 | 1.6 | 1.4 |
| 2006 | 10 | 27 | 1.6 | 1.8 |
| 2007 | 13 | 28 | 1.8 | 3.2 |
| 2008 | 13 | 37 | 1.4 | 6.4 |
| 2009 | 32 | 40 | 1.0 | 6.8 |
| 2010 | 35 | 44 | 2.5 | 7.5 |
| 2011 | 84 | 65 | 2.2 | 14.0 |
| 2012 | 94 | 79 | 1.7 | 15.6 |
| 2013 | 109 | 58 | 1.5 | 9.6 |
| 2014 | 113 | 73 | 1.2 | 9.1 |
| 2015 | 129 | 58 | 0.8 | 16.2 |
| 2016 | 91 | 56 | 0.3 | 9.9 |
| 2017 | 111 | 60 | 0.9 | 6.8 |
| 2018 | 138 | 120 | 0.5 | 8.6 |
| 2019 | 141 | 104 | 0.002 | 16.0 |
| 2020 | 84 | 83 | 0.029 | 11.0 |
| 2021 | 100 | 122 | 0.011 | 14.8 |