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The thrust of the RIS work programme has always been on moving towards achieving equitable world economic growth with emphasis on access and inclusion. In this conext, endogeneity in the growth process and self-reliance becomes all the more important. Keeping in view this conceptual framework and significance of 'Atmanirbhar Bharat', RIS undertook an indepth study on India-China trade linkages, particularly from the perspectives of the huge trade deficit between the two countries. This study was launched in August 2020, which received huge positive response. Based on the recommendations, six sectoral studies were initiated on pharmaceuticals, steel, automotive, electronics, telecommunication and solar sectors as follow-up of the aforesaid work on India-China trade relations.

The current study on 'India's Import Dependence on China in Pharmaceuticals: Status, Issues and Policy Options' by Professor Sudip Chaudhuri is part of this wider set of studies. Your valuable comments and suggestions are welcome at dgoffice@ris.org.in

India's Import Dependence on China in Pharmaceuticals: Status, Issues and Policy Options

Sudip Chaudhuri*

Abstract: India has one of the most advanced pharmaceutical industries among developing countries. Yet India is critically dependent on China for supplies of bulk drugs and drug intermediates with China accounting for about two-thirds of the total imports. In the early 1990s, China was relatively a minor source of bulk drugs imports for India. Imports increased since then and sharply accelerated after the early 2000s. By the mid-1990s, India was able to successfully develop a pharmaceutical industry. The policies that India pursued till then significantly influenced the transformation. The mid-1990s however saw the beginning of a series of policy changes in India in the pharmaceutical industry. Unlike China where the government intervened strongly, the role of the government was consciously diminished in India. As a result, India became increasingly dependent on bulk drugs supplied from China. India's critical dependence on China for bulk drug supplies was flagged from time to time in different circles. The government has been slow in responding to the situation but has now announced major schemes for promoting local production of bulk drugs, drug intermediates and key starting materials. These are expected to have a major impact. But the paper argues that these deal with only a part of the problem and suggests the other policy steps that need to be taken.

Keywords: Pharmaceuticals, bulk drugs, drug intermediates, formulations, China, India, import dependence, industrial policy, market access, incentives, R&D, bulk drugs parks.

I. Introduction

India has one of the most advanced pharmaceutical industries among developing countries. The Indian pharmaceutical industry is the third largest in the world in volume terms and the thirteen largest in value

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terms. India is the largest supplier of generic medicines accounting for about 20 per cent of global demand in volume terms. About 60 per cent of the global demand for vaccines and HIV/AIDS medicines are sourced from India.[1] India has received world-wide recognition as a supplier of internationally acceptable quality products at low prices. India exports pharmaceutical products to more than 200 countries including to developed countries which have stricter regulatory standards. USA is currently the largest destination of India's pharmaceutical formulation products.[2] India is also a major bulk drugs (active pharmaceutical ingredients - APIs) exporter. India has 664 manufacturing plants approved by the US Food and Drug Administration (USFDA). This is the highest in any country outside the US. Product wise, Indian companies have filed 4500 DMFs for active pharmaceutical ingredients (as on 30 September 2019) and have received 5029 ANDA market authorisations for formulations (as on 30 June 2020).[3] Yet India is critically dependent on China for supplies of bulk drugs and drug intermediates with China accounting for about two-thirds of the total imports. For many products China is the sole exporter as we will discuss in Section II below.

As we will see below, India's import dependence on China in pharmaceuticals is mainly in bulk drugs and not in formulations. We focus in this paper on bulk drugs.[4] The objective of the paper is to analyse the nature of India's dependence in bulk drugs on China and to examine the steps which have been taken and what else needs to be done to reduce the dependence. Section II will provide a statistical picture of the nature of India's import dependence in pharmaceuticals on China. In Section II, we will also discuss how India's pharmaceuticals export and import trade in bulk drugs and formulations have evolved over time with China and the rest of the world. This will provide a background to the subsequent discussion on the status of the pharmaceutical industry in India vis-à-vis China.

In the early 1990s, China was relatively a minor source of bulk drugs imports for India. Imports increased since then and sharply accelerated

after the early 2000s. Historical perspective is required to understand the problem and to take corrective action. By the mid-1990s, India was able to successfully develop a pharmaceutical industry. The policies that India pursued till then significantly influenced the transformation. The mid-1990s however saw the beginning of a series of policy changes in India in the pharmaceutical industry. Unlike China where the government intervened strongly, the role of the government was consciously diminished in India. In Section III, we will focus on what China did and what India did and more importantly what India did not, and how as a result India became increasingly dependent on bulk drugs supplied from China.

India's critical dependence on China for bulk drug supplies was flagged from time to time in different circles. The government in India has been slow in responding to the situation but has now announced major schemes for promoting local production of bulk drugs, drug intermediates and key starting materials. In Section IV, we will summarise the recent initiatives. These are expected to have a major impact in the bulk drugs industry. But we will argue that these deal with only a part of the problem. In the light of what are being proposed, we will explore in Section V what else needs to be done.

II. Nature of Import Dependence in Pharmaceuticals

Extent of dependence in bulk drugs

In 1990 and 1991, India imported bulk drugs worth less than US $ 1 million and China's share was less than 1 per cent (Annexure Table 1). From US $ 6.25 million in 1992 (2.5 per cent), it increased to US $ 73.43 million (21.1 per cent) in 1995. After being stagnant in the late 1990s, it started accelerating since the early 2000s. Imports grew at a compound annual rate of growth (CARG) of about 40 per cent between 2000 and 2007 with the share increasing from 23 per cent to 58.9 per cent. The growth has decelerated since then but China's share is still around 50 per cent (Annexure Table 1). This is in sharp contrast to formulations imports from China. In formulations, India relies on China for only about 3 per cent of total imports. Unlike bulk drugs where the

import ratio has increased substantially over time, for formulations the ratio has remained low all through (Annexure Table 1).

Since 2013-14, DGCI&S, the main official trade data source in India provides trade data specifically for bulk drugs and drug intermediates. This makes possible precise estimation of the degree of import dependence on China. If we use this data series, we find that the dependence is actually higher. As can be seen from Annexure Table 2,(Col 2) the share of China in India's total imports of bulk drugs and drug intermediates was 63.5 per cent in 2013-14. This has reached 68 per cent in 2020-21.[5]

Annexure Table 3 provides data on product wise bulk drugs and drug intermediates dependence on China for the year 2019-20. In 151 products accounting for almost one fourth of the value of imports from China, the share of China is 90 per cent or more. In another 132 products accounting for more than half the imports, the share is between 60 per cent and 90 per cent.

In Annexure Table 4 we have listed products each with imports of more than US $ 1 million in 2019- 20 and with import share of China of 90 per cent or more. As can be seen from the table, import share is very high for such important and common bulk drugs such as Paracetamol (China's share, 91 per cent), Penicillin/salts (95.8 per cent), Streptomycin (100 per cent), Sulphadimidine (100 per cent), Norfloxacin/salts (99.6 per cent), Vitamin B12 (98.1 per cent), Rifampicin (97.3 per cent), Ibuprofane (95.2 per cent), Neomycin (95.2 per cent) and others.

In Annexure Table 5, we have selected some important bulk drugs with imports from China exceeding US $ 10 million in 2019-20 to see how the dependence on China has changed over time. Import dependence has remained high in the last one and a half decade for most of these bulk drugs, for example Paracetamol, Penicillin, Tetracycline/

Oxytetracycline, Ciprofoxacin, Ibuprofane. Import dependence has worsened in Amoxicillin, Erythromycin and Rifampicin. In Amoxicillin, for example, China's share has gone up from 17.2 per cent in 2008-09 to 89.9 per cent in 2019-20. And in Erythromycin, from 25 per cent in 2004-05 to 83 per cent in 2019-20.

Sources other than China for bulk drugs

Import dependence on China can be reduced if India produces more and replaces imports from China and/or if India buys more from other countries rather than from China. Let us now discuss how important other countries are as sources of imports.

Whereas China accounted for 47.5 per cent of India's total bulk drugs imports in 2020, 15 other countries contributed another 47.1 per cent (Annexure Table 6). Each of these countries have a share of more than 1 per cent and except South Korea (Republic of Korea), the other countries are mainly developed countries such as the USA, Switzerland, France. The 75 other countries from which India imports bulk drugs are minor sources. Together they accounted for only about 5.4 per cent.

If we consider the total exports of bulk drugs by different countries, again we find a similar pattern. Only 17 countries accounted for 96.5 per cent of world exports of bulk drugs in 2020. Share of China, South Korea and India are 6.4 per cent, 2.4 per cent and 1.1 per cent respectively. The share of the remaining 14 countries out of these 17 countries was 86.5 per cent and all of these are developed countries. 55 other countries including all the other developing countries accounted for only 3.5 per cent of world exports (Annexure Table 7).

Thus, apart from China, South Korea and major developed countries, there are hardly any other significant sources of bulk drugs supply. The developed countries mainly focus on patented products and biologicals. They are not competitive sources for much of the requirements of imports of off-patent and matured products. South

Korea is also not a competitive source except for more technologically intensive products. Depending on how the bulk drug industry in other developing countries develop, they can emerge as possible sources of supplies. But for the present, developing local production in India appears to be a more practical strategy to follow to reduce India's dependence on China.

India's status in bulk drugs external trade

Though India is currently dependent on China in the aggregate and for many bulk drug products, India is also a major player globally in the bulk drug international trade. India has her own strengths which can be exploited for revitalising the industry in India.

As we have mentioned above, developed countries dominate the exports of bulk drugs in the world. Just five countries – Switzerland, USA, Ireland, Germany and Belgium accounted for two-thirds of bulk drugs exports in 2020 (Annexure Table 7). Among developing countries, India is a major exporter (1.1 per cent of world exports) after China (6.4 per cent) and South Korea (2.4 per cent). In the last 10 years, the rate of growth of exports of bulk drugs has been higher in India than in China. Whereas the CARG for China during 2010 to 2020 is 6 per cent, it is 8 per cent for India. India has been able to maintain a level of about 20 per cent of China's exports in the last 10 years (Annexure Table 8).

The largest export destination of bulk drugs from India is the US, which has the strictest regulatory standard, followed by Brazil, Bangladesh, Turkey, China, Netherlands, Nigeria, Vietnam, Egypt and others (Annexure Table 9). India is among the top five suppliers of bulk drugs in many developing countries, for example Bangladesh, Nigeria, Vietnam, Egypt, Iran Pakistan. (Annexure Table 10). In Nigeria, India is a larger supplier of bulk drugs than China. India accounted for 13.9 per cent of bulk drugs imports of Nigeria compared to China's 7.3 per cent. In other countries China is a larger supplier but India is also a substantial exporter. Bangladesh imported 22.9 per

cent of her its total bulk drugs imports from India in 2020 compared to 25.1 per cent from China (Annexure Table 10).

That China is also one of the major bulk drugs export destinations of India may appear to be surprising. The problem really is that while India exported US $ 92.81 million to China, the magnitude of imports (US $ 1561.87 million) is much larger leading to a massive trade deficit of US $ 1496.06 million in 2020. For each of the other countries mentioned above, India enjoys a trade surplus in bulk drugs (Annexure Table 9).

Out of 201 countries to which India exported bulk drugs in 2020, India had a trade surplus with 178 countries. Among the 23 countries with which India had a trade deficit, China and China Hong Kong SAR accounted for 64.7 per cent of the deficit and South Korea 10.2 per cent. The remaining countries are primarily developed countries such as Belgium, Switzerland and France (Annexure Table 11).

India had a small trade surplus with China in bulk drugs in 1989. But in each of other years since 1988 India suffered deficit though in earlier years the magnitude was small (Annexure Table 12). With the rest of the world too India had trade deficits till 1997. But since then, India has been experiencing surplus. But the surplus with the rest of the world is not large enough to compensate for the deficit with China and hence overall India is suffering from trade deficits. For example, in 2020, whereas the surplus with the rest of the world was US $ 1016.71 million, the deficit with China was US $ 1469.06 million leading to an overall deficit of US $ 452.35 million (Annexure Table 12).

India's status in formulations external trade

As in the case of bulk drugs, developed countries dominate the export trade of formulations. Just five developed countries contributed to half of total formulations exports in the world in 2020 and 10 developed countries about three-fourths (Annexure Table 13). India is the largest formulations exporters among developing countries (4.4 per cent share) followed by China (1.4 per cent).

For all the years since the early 1990s when data became available, India's exports of formulations exceeded that of China's. In 1992, China's exports of formulations were about two-thirds of India's exports. By the mid-2000s it had reduced to about a fifth. Currently it is about a third (Annexure Table 14).

Unlike bulk drugs, since 1988 when data became available, India's total exports of formulations always exceed total imports of formulations. In fact, India's trade surplus in formulations has improved and accelerated since the early 2000s, From US$ 712.37 million in 2000 trade surplus increased to US$ 16024.58 million in 2020 (CARG of 17 per cent) (Annexure Table 15).

With China too India traditionally had a trade surplus in formulations. But the situation has deteriorated since 2009. In several years between 2009 and 2020, India suffered from a deficit (Annexure Table 16). The magnitude of the deficit is much lower than that in bulk drugs. For example, it was US$ 21.82 million in 2015 compared to US$ 1126.46 million for bulk drugs in the same year. Nevertheless, trade deficits in formulations might appear surprising since India has a much more developed formulations industry than China. The Indian pharmaceutical industry has been complaining for some time that China protects its formulation industry through non- tariffs barriers. One of the methods employed is to delay and frustrate efforts to get regulatory approval for marketing the products in China.[6] Providing free access to the Indian market but not being able to ensure the same privilege in China reflects a policy failure which requires urgent rectification.

III. Reasons for Import Dependence

Policies in India before the mid-1990s

By the early 1990s when dependence on China started rising, India was able to establish a successful pharmaceutical industry. It was the government which guided the process and supported the private sector to realise its potential. What made this possible were public investments in drug manufacturing and R&D and setting up

of development financial institutes (DFIs) in the 1950s and 1960s, enactment of Patents Act, 1970 and the Drug Policy of 1978 and 1986.[7] The establishment of public sector companies, Indian Drugs and Pharmaceuticals Ltd (IDPL) and Hindustan Antibiotics Ltd (HAL) and the setting up of a number government R&D laboratories helped the development of technological skills necessary for the pharmaceutical industry at a time when the private sector was not yet equipped. DFIs provided long term funds at reasonable rates of interest when traditional financial channels such as commercial banks were not very keen to provide loans to new projects in a new industry. Many pharmaceutical companies which are now big and successful were set up by entrepreneurs not with an affluent background. The DFIs provided loans without a personal collateral. The collateral in fact was the plants that the DFIs funded. The Patents Act, 1970 by abolishing product patent protection in pharmaceuticals, eliminated the legal barriers and provided the Indian companies the space of operations which the earlier patent regime denied. Drug Policy of 1978[8] and 1986[9] promoted bulk drug production rather than just formulations. In the 1950s and 1960s the industry was dominated by the multinational corporations (MNCs) which were more keen to formulate imported bulk drugs rather than manufacture bulk drugs in the country. A basic objective of the Drug Policy, 1978 following the recommendations of the Committee on Drugs and Pharmaceutical Industry, 1975 (Hathi Committee) was to incentivise production of bulk drugs both by the MNCs and the Indian firms. This was done through a very innovative policy of denying permission to manufacture formulations unless the firms also manufactured bulk drugs in specified ratios. For the Indian companies the ratio parameter was 1:10, i.e., they could not formulate more than 10 times the value of bulk drugs manufactured provided further that imported bulk drugs did not constitute more than one-third the total value of bulk drugs used for the purpose of formulations. The parameter was 1:5 for MNCs and they were also subjected to additional restrictions under the Foreign Exchange Regulation Act, 1973. The Drug Policy of 1986 brough about further policy changes to stimulate bulk drug production. It introduced the "Phased Manufacturing Programme" with the objective

of ensuring that bulk drugs are produced from more basic stages and not just processing of later intermediates. The ratio parameters were further revised. For MNCs the ratio was changed to 1:4 and for Indians companies 1:5 when value of formulation production exceeded Rs 250 million.

These conscious policy interventions had the desired impact. Firms were not allowed to just import bulk drugs and process these into finished products. They had to produce bulk drugs if they wanted to manufacture and sell formulations. As a result, what developed was not only the formulation sector but also the bulk drugs sector.

The strong presence of the public sector companies, IDPL and HAL which focused on bulk drugs also helped the process. The 1978 Policy in fact assigned to the public sector a leading role and reserved some products for them. But by the early 1980s, the public sector units started facing problems for various reasons and the Policy of 1986 talked about rehabilitation and restructuring plans. The number of products reserved for them was actually reduced. Despite playing a major role in laying the foundations of the industry in India, the public sector continued to suffer and the private sector became the more dominant and dynamic part of the industry.

Between 1978-79 when the Drug Policy of 1978 was put in place and 1994-95, bulk drug production increased at CARG of 14 per cent from Rs 2000 million to Rs 15180 million. For formulations the annual increase in production was 13 per cent from Rs 10500 to Rs 79350 million during the same period.[10]

By the mid-1990s, India became a major exporter of formulations. By 1988 (when formulations trade data are available from the UNCOMTRADE database), exports exceed imports. Between 1988 and 1995 whereas exports increased at CARG of 14 per cent, imports declined. As a result, trade surplus increased by CARG 18 per cent (Annexure Table 15). Growth continued thereafter and as mentioned above India became the largest exporter of formulations among developing countries surpassing China.

India also became a major exporter of bulk drugs. In fact, between 1988 and 1995, bulk drugs exports expanded at a faster rate than that of formations. The CARG between 1988 and 1995 was 29 per cent (Annexure Table 15). But bulk drug imports also increased and till the late 1990s India suffered from trade deficits. Since then, the situation improved with the rest of the world – India has been experiencing trade surplus in the last two decades. But trade deficit with China in bulk drugs not only continued but widened with imports from China expanding at a much faster rate than exports to China (Tables 12 and 15). The rising dependence on China is the major focus of this study and we attribute this to policy changes in India and China.

Policies in India after the mid-1990s

Starting from the mid-1990s, drastic policy changes have been made in stages in the pharmaceutical industry. Among the important steps taken were:

- Abolition of industrial licensing
- Abolition of the ratio parameters and phased manufacturing programme
- Elimination of non-tariff barriers and lowering of tariff rates

In the "Modifications in Drug Policy 1986" announced in September 1994[11], industrial licensing was abolished for bulk drugs, their formulations and intermediates, except for (a) five bulk drugs reserved for the public sector, (b) bulk drugs involving use of re-combinant DNA technology (c) formulations based on use of specific cells/tissue. Bulk drug reservation for the public sector was abolished in February 1999[12] and by September 2005 the pharmaceutical industry was totally de-licensed.[13]

Another decision taken in 1994 was the abolition of the ratio parameters linking bulk drugs and formulations production and limiting the use of imported bulk drugs. Thus, firms were free to import bulk drugs and process these for formulations for sales in the domestic market or abroad. This turned out to be one of the most critical factors behind rising imports of bulk drugs.

Indian pharmaceutical industry including the bulk drugs sector was protected from foreign competition through non-tariff barriers (import licensing) and high tariff rates. Since the 1990s, in stages, non-tariff barrier has been eliminated and tariff rates have been reduced to very low levels. As Table 1 here shows, for 317 commodities accounting for 82 per cent of the total number of 385 commodities, the applied tariff, i.e., the actual rate is only 7.5 per cent. For another 40 commodities, the rate is even lower, 5 per cent. There are a few commodities with rates below 5 per cent and some above 7.5 per cent.

Table 1: Applied Tariff Rates for Chapter 29, 6-digit Groups, India, 2020

Applied tariff rate, 2020	No of Chapter 29 6-digit commodities	Share
0	4	1.04
2	1	0.26
2.5	17	4.42
5	40	10.39
6.3	1	0.26
7.5	317	82.34
10	3	0.78
20	2	0.52
	385	100.00

Source: Calculated from http://tariffdata.wto.org/ReportersAndProducts.aspx (accessed on 15 June, 2021).

The basic idea behind these measures is that government intervention is not required and the unregulated private sector can be more productive. As Bhagwati and Srinivasan[14] put it succinctly in a report prepared for the Government of India, the intention was:

> " … to remove the government from areas of economic decision-making where our own and more extensive international experience (not ideology) has shown in the postwar period that governments harm, rather than help, the development process."

This line of thinking had a profound and pervasive impact in policy circles and the role of the government was consciously diluted independent of the negative impact it had.

When and where the private sector is strong enough and matured enough, government support may not always be required. In fact, deregulation can be helpful. As we have mentioned above, by the mid-1990s, India was able to develop a competitive formulations sector. India is the largest exporter of formulations among developing countries (Annexure Table 13). There are a large number of Indian firms which have developed competencies to develop products satisfying regulatory requirements for getting marketing approvals and to set up plants to manufacture the products. USA which has the strictest regulatory standard is India's largest export destination for formulations exports with a 40 per cent share in 2020. Delicensing may have helped the formulation exporters to start manufacturing without delay and restrictions. Abolition of ratio parameters permitted them to stop bulk drug production and reduction of import barriers made it possible for them to import bulk drugs and process these and export the finished formulations.

In bulk drugs too there are many Indian firms which have developed competencies particularly in more technologically intensive products for sales both in the domestic market and abroad. We have mentioned above that India is also a successful bulk drug exporter catering to different markets including the developed countries with tougher regulatory standards. For bulk drugs too, USA is the largest export destination of India (Annexure Table 9). As mentioned above, India has the largest number of manufacturing plants for formulations and bulk drugs approved in the US.

But as the government in China intervened strongly to support the industry there, as the government in India withdrew from economic decision making and did not provide the necessary support, huge cost differentials emerged between the two countries, particularly in low value, high volume bulk drugs. And as the policy of mandatory bulk

drug production was withdrawn and as trade barriers were reduced, domestic production was displaced by imports for a large number of bulk drugs.

As the private sector did not find it profitable to manufacture these bulk drugs, the public sector could have made a difference. But the public sector companies have been suffering from financial stress for a long time. IDPL in fact was declared as sick by the Board for Industrial and Financial Reconstruction (BIFR) as early as in August 1992 and HAL in March 1997.[15] These companies are still in existence but despite the talk of rehabilitating them from time to time, the government did not undertake the necessary investments to empower them and strength them for the purpose of local production of bulk drugs.

Nature of government intervention in China

Huge cost differentials emerged between China and India in bulk drugs production. Cost of production is on the whole 20-30 per cent lower in China. In India, raw material cost is 25-30 per cent higher, electricity 20 per cent higher, other costs (financing, logistics etc) 30 per cent higher. Among the major components of costs, only labour is cheaper (1.8 times) in India.[16]

This has been the result of the implementation of a well-coordinated strategy in China. The government in China has intervened comprehensively both directly and by supporting the private sector. The government invested in infrastructure, facilitated large scale manufacturing, promoted exports, enhanced technical capabilities, provided access to finance and ensured supply of inputs.

Large special economic zones and bulk drugs parks were set up with common utilities, common effluent treatment plants, uninterrupted power supply and steam, R&D facilities. Large-scale manufacturing was encouraged by the government to reap economies of scale. Chinese SEZs are 10-15 times larger than in India.[17] Average capacities of Chinese firms are much higher. For example, 14,000 MT per annum in China for Amoxycillin compared to 5,000 MT in India and 500 MT for Simvastatin in China compared to 150 MT in India.[18]

Electricity is a major part of the operating cost of bulk drug production. China has invested heavily to ensure adequate and stable supply of electricity. China generates more than 4 times electricity than India. China also reduced electricity cost through common utility initiatives involving also the small and medium sectors.[19]

China has a more developed chemical industry supplying raw materials to the pharmaceutical industry and in the last 10 years has consciously adopted backward and forward linkages to ensure efficient supplies at lower costs.[20]

China provides various financial assistance. Exporters of bulk drugs enjoy 13 per cent tax incentives. Manufacturers are also exempted from payment of several taxes. Long term loans are provided with favourable terms. Borrowing costs are 5-7 per cent in China compared to 11-14 per cent in India.[21]

China's proficiency in bulk drug production is not only due to lower costs of utilities, raw materials, lower interest rates, tax incentives and other such factors. It is also the result of significant investments made in creating and improving technological capabilities. The government has invested heavily in R&D. Several R&D parks have been set up with infrastructural support and other benefits. An R&D ecosystem has been developed involving funding, providing incentives and encouraging networks including industry academia collaboration. An innovative initiative was the introduction of the "Thousand Talents Plan" to attract over 50,000 non-resident Chinese scientists from around the world through generous research funding (up to US$ 75,000 per year) with the objective of stimulating R&D collaboration involving foreign universities and firms also.[22]

Absence of government support in India since the 1990s

In contrast to China, the pharmaceutical industry in India suffered from inadequate infrastructural investments and lack of proper government support for creating large scale manufacturing capacities especially in fermentation products, developing technological

competencies, generating demand, reducing finance, utilities, operating and other costs.

To counter the Chinese competition, it was possible to have a strategy based on the strengths the industry has largely due to previous efforts. But the government failed to utilise the opportunities. Let us give few examples.

The congenial environment created by the setting up of the large plant by the public sector firm, IDPL in Hyderabad attracted a large number of bulk drug manufacturing units in that area. This could have been used by the government to promote manufacturing clusters and bulk drugs parks. But this was not done.

As we have mentioned above, India is a successful bulk drugs exporter particularly for high end bulk drugs. There are a few pharmaceutical SEZs developed by state governments, most notably the Jawaharlal Nehru Pharma City at Visakhapatnam by the government of Andhra Pradesh in partnership with a private firm, Ramky Pharma City. There are also a few SEZs set up by private firms, for example Divi's Laboratories, Hetero, Biocon, Dr Reddys and Sun Pharmaceuticals.[23] There are few formulations manufacturing clusters in India, most notably at Baddi in Himachal Pradesh which followed the grant of attractive excise concessions and tax exemptions by the Central government. However, industrial parks or clusters dedicated to production of bulk drugs have been conspicuous by their absence in India. If what is being planned now had started earlier, the damage that imports from China have done could have been mitigated at least to some extent.

India has a very good R&D infrastructure particularly in the government sector. Several government laboratories were instrumental in developing manufacturing technologies used in the private sector. The network of R&D institutions in the industry could have been used to develop an R&D ecosystem that China did. Some steps were taken to promote R&D. But as we will discuss in the last section, these

have been inadequate and much more can be and should be done for developing technological competencies.

Erosion of bulk drug manufacturing capacity

Inability to face competition from China, import liberalisation and rising imports have led to discontinuation of production and closure of many plants which were earlier set up. And even the capacity which exists have remained idle for many bulk drugs. Fermentation based products have been among the worst affected where the industry in China is way ahead due to factors such as large fermentation capacities and superior fermentation processes. In fermentation plants, the cost of utilities is an important component of costs. The cost differentials in electricity have narrowed down but earlier that too played a significant role in India's inability to face Chinese competition. As the illustrative list in Annexure Table 17 shows, plants set up in the early 1960s (Penicillin and Streptomycin), in the early 1970s (Kanamycin and Vitamin B12), in the early 1980s (Tetracycline and Oxytetracycline), in the late 1980s (Gentamycin, Griseofulvin) in the early 1990s (Cephalosporin C, Bleomycin) and in the late 1990s (Cyclosporin A, Pravastatin) have stopped functioning.

India manufactures and supplies about 50 per cent of the domestic demand for bulk drugs.[24] But the materials required for bulk drug production – catalysts, reagents, intermediates and key starting materials (KSM) etc are sourced from China to a large extent. For example, for the manufacture of HIV and oncology bulk drugs where India is a dominant manufacturer, only the final steps are done in India.[25]

It was essentially the segment of the pharmaceutical industry in India producing low value high volume bulk drugs and intermediates which suffered due to competition from China. The formulations sector actually benefitted from the availability of low-priced bulk drugs from China. India emerged as the largest exporter of formulations products among developing countries, surpassing even China (Annexure Table 13).

In bulk drugs too many firms started specialising in high value and complex products utilising advanced chemistry skills. Indian firms have tie ups with MNCs for supply of bulk drugs. As we have mentioned above, India is also a major bulk drug exporter among developing countries with developed countries also as destinations (Tables 7 and 9).

IV. Recent government initiatives

The above discussion shows that government intervention in China and economic liberalisation in India have been major contributing factors behind India's rising import dependence on China. The policy conclusion that follows is that the role of the government in India must be re-oriented. The purpose is not to crowd out the private sector. The objective is rather to regulate and support the private sector so that they may contribute more to development of local capacities and reduce import dependence. The objective must also be for the government to intervene more directly when the private sector is unable or unwilling to take up activities necessary for national interests.

Even when it became known that import dependence on China is attaining critical proportions, the appropriate response from the government in India has been slow or missing altogether. A Committee was appointed in October 2013 under the Chairmanship of V M Katoch, the then Secretary, Department of Health Research to study the problem and recommend measure for building domestic capabilities in bulk drugs. The Report was submitted in February 2015. A Task Force was set up under the Chairmanship of the Secretary, Department of Pharmaceuticals in October 2014. The Report was released in July 2015. A series of recommendations were made including support for funding, R&D and setting up of bulk drug parks and clusters.[26]

The government announced a number of schemes including "Cluster Development Programme for Pharma Sector (CDP-PS)" in 2014-15; "Financing Common Facility Centres (CFCs) at Bulk Drug Parks" in 2016-17 and the "Scheme for Development of Pharmaceutical Industry" in 2018-19.[27]

But no urgency was noticed in implementing the schemes approved and announced.

It is after the Covid-19 pandemic that the government has started taking some concrete actions:

- In March 2020, government announced two schemes (notified in July 2020): (i) "Production Linked Incentive (PLI) Scheme for promotion of domestic manufacturing of critical Key Starting Materials (KSMs)/ Drug Intermediates (DIs) and Active Pharmaceutical Ingredients (APIs) In India" and (ii) Promotion of Bulk Drug Parks.[28]
- In March 2021 another scheme, "Production Linked Incentive scheme for Pharmaceuticals" was announced.[29]

These schemes have the potential to have a major impact in the industry. The objective of the March 2020 PLI scheme with a financial outlay of Rs 69,400 million is to attract greenfield investments and boost production for self-reliance. Financial incentives based on sales will be provided to 41 fermentation-based and synthesis based KSMs/ drug/intermediates classified into four groups. In all these products, import dependence is high as identified by a drug security committee constituted by the government. As Annexure Table 18 shows, the financial incentives will vary between 20 per cent and 5 per cent for fermentation-based products for the years 2023-24 to 2028-29 and 10 per cent for synthesis-based products for 2022-23 to 2027-28. Only projects with investments varying between Rs 500 million and Rs 4000 million for fermentation-based products and Rs 200 million and Rs 500 million for synthesis-based products will be eligible for incentives.

The objective of the March 2020 bulk drug promotion scheme is to reduce manufacturing costs and increase competitiveness by providing access to common infrastructural facilities to bulk drug manufacturers in the parks. Three bulk drugs will be selected for financial assitance of Rs 30,000 million from among the proposals submited by state governments.

Financial assistnace will be for 70 per cent of the project cost (90 per cent for few states) subject to a maximum of Rs 10000 million per bulk drug covering the period 2020-21 to 2024-25. Common facilities would include effluent treatment plant, steam generation, cooling systems, laboratory testing etc.

The March 2021 scheme on "Production Linked Incentive scheme for Pharmaceuticals" is not limited to KSMs/drug intermediates/bulk drugs. The basic objective is to contribute to product diversification to high value goods in the pharmaceutical industry. Another objective is to create "global champions out of India". The scheme covers three categories of goods: (1) products such as biopharmaceuticals, complex generics, patented drugs; (2) KSMs/drug intermediates/bulk drugs and (3) repurposed drugs and drugs such as anti-cancer, anti-diabetic, cardiovascular, anti-retroviral drugs not included in Category 1. A total amount of Rs 150,000 million has been earmarked for the scheme for three groups of firms based on global manufacturing value. The rate of financial incentives on incremental sales (over base year, 2019-20) will 10 per cent for Category 1 and 2 for 2022-23 to 2025-26, 8 per cent for 2026-27 and 6 per cent for 2027-28. The rates for Category 3 will be 5 per cent, 4 per cent and 3 per cent respectively. Minimum cumulative investments have been specified for the companies in the three groups.[30]

The financial outlay of the March 2021 scheme (Rs 150,000 million) is significantly higher than that of the two other schemes announced in March 2020 more specifically related to bulk drugs (Rs 69,400 million and Rs 30,000 million). This may appear surprising in view of the greater attention that the question of bulk drugs import dependence has attracted in government committees and official announcements in the recent past.

Nevertheless, the two schemes of March 2020 mark a significant departure from the way the pharmaceutical industry has been managed in the last two decades or so. These reflect a change in the attitude of the government that the government can and needs to play a role.

As on March 2021, already 13 proposals have been made by state governments for establishment of bulk drug parks.[31] For the PLI scheme, 215 applications have been made. Government has approved 33 applications from 28 companies for 24 products. The companies include Aurobindo Pharma, Natural Biogenex, Mcleods Pharmaceutical, Rajasthan Antibiotcs and Hetero Drugs. The products cover, Penicillin G, 7-ACA, Rifampicin, Vitamin B1, Streptomycin and Aspirin.[32]

These initiatives have been influenced by what China had done. But China also took several other important steps as we have discussed above. The schemes announced by the government are necessary but not sufficient. What is required is a strategic intervention on the part of the government to coordinate the different components that are necessary. The next section provides some indications in this context.

V. What else the government needs to do

As we have discussed in Section II, apart from China there are hardly any other significant competitive sources of bulk drugs supply. Hence developing local production in India is the practical option to reduce India's dependence on China.

Bulk drug parks and incentives scheme started by the government will have the effect of reducing manufacturing cost and improving profitability. This is very important for promoting local production. But some other factors are also important to attract a sufficiently large number of firms to invest and produce and make the initiatives sustainable.

Entrepreneurs require funds to set up plants. The development financial institutes (DFIs) played a major role in the development of the pharmaceutical industry as we have mentioned above. But these have been disbanded and insistence on full collateral for borrowing funds from commercial banks is a major hindrance at present. There are some government funding schemes. Apart from the small quantum of finds, it also takes a long time to get the funds.[33] Mechanisms and schemes will have to be devised so that interested entrepreneurs get the funds required.

Potential investors also need assurance of a market to be able to produce and sell the goods and earn the expected profits. If the prospects of successfully competing against the Chinese products are poor, then even the attraction of the facilities at the bulk drugs plant may not be enough to induce the investments in the first place. Again, the incentives are paid as a percentage of sales. Firms will be able to benefit from the incentives and improve profitability only when they are able to sell the products manufactured. Thus, ensuring adequate demand for Indian firms is of critical importance. We discuss below some steps that can be taken to provide a larger market for domestic manufacturers. Another important issue we take up below is the question of R&D and technological development

Market access

If the schemes announced by the government enable Indian firms to produce and sell more, then imports from China will indeed go down. But depending on the prices charged by the Chinese firms, Indian firms may not be able to currently compete. In that case, the incentives will remain unutilised or underutilised and the intention of regulating Chinese imports will not materialise. If the government is unable or unwilling to further subsidise production through incentives or other means, the option is to ensure larger domestic demand. One concrete step that can be taken in this regard is to protect the domestic industry against international (Chinese) competition. This is very controversial. There is strong opposition to adoption of protective measures on the ground that it will make the industry uncompetitive. But what is missed in such deliberations is that elimination of non-tariff barriers and lowering of tariff rates did not make the industry more competitive. It resulted in plants closing down and erosion of manufacturing capacities as discussed above. Moreover, the dangers of protection should not be exaggerated. Protection eliminates foreign competition, not domestic competition. In India there is a large number of bulk drug manufacturers. It is not difficult to ensure adequate number of domestic payers in the protected products. It is also important to keep in mind that Indian bulk drug manufacturers have severely suffered due to import liberalisation.

As they get a larger space of operations and as they grow, it is expected that their competencies will also improve. And protection need not be permanent – depending on the progress, some of the measures may be withdrawn.

While there is so much opposition to adoption of protective measures in India, China does not hesitate to protect its industry wherever required. India has a much more developed formulation sector. But as we have mentioned above, China protects its formulation industry through non- tariff measures and as a result India has suffered from trade deficits with China (Annexure Table 16).

Without violating India's obligations under WTO, two possible steps that the government can take to enhance market access are:

- Increasing tariff rates to bound levels
- Using the "Security Exception".

Increasing tariff rates: This can help the Indian firms to compete against Chinese imports and benefit from the incentives announced. As we have mentioned above, for most of the bulk drugs and drug intermediates, the applied tariff rates, i.e., the actual rates are very low – between 5 per cent and 7.5 per cent. But the bound rates are much higher. The bound rate is the maximum rate that a country has committed itself to. Contrary to popular perception that countries cannot increase tariff rates, WTO does allow countries to increase tariff rates, though ordinarily not beyond the bound rate.

Table 2: Bound tariff rates for Chapter 29, 6-digit Groups, India, 2020

Bound rate, 2020	No of Chapter 29 6-digit commodities	Share
25%	16	4.75
40%	317	94.07
70%	1	0.30
150%	3	0.89
	337	100.00

Source: Calculated from http://tariffdata.wto.org/ReportersAndProducts.aspx (accessed on 15 June, 2021.

As can be seen from Table 2, for 317 commodities accounting for 94 per cent of the 337 commodities, the bound rate is 40 per cent. Thus, India has the option to increase tariff rates to 40 per cent for these 317 commodities. For most of these commodities the corresponding applied (actual) rate is 7.5 per cent. For example, in each of the commodities under Vitamins and Antibiotics where import dependence is very high, the actual and bound rates are 7.5 per cent and 40 per cent respectively. Thus, there is sufficient scope for increasing tariff rates in a WTO consistent manner.

The tariff rates need not be increased across board. The rates should be fixed after careful examination of cost differentials and the nature of competition. A differential approach may be adopted. Tariff policy should be used also as an industrial policy measure. The objective should be to help the development of bulk drugs which are currently not competitive but can be made competitive in future.

Security Exception: As the Gazette Notification of 21 July, 2020 announcing the government schemes mentioned, the high dependence on imports is a matter of drug security of the nation. In fact, the list of 41 products selected for providing incentives were decided on the basis of the recommendations of a committee on drug security. The incentive scheme is a step in the right direction. But the problem of uncertain demand remains. Matters related to security should not be left to market considerations alone. Under Article XXI of GATT, 1994. WTO, member countries cannot be prevented "from taking any action which it considers necessary for the protection of its essential security interests." India can use this clause and restrict imports of bulk drugs which have security implications. To start with this may be done for the 41 bulk drugs, drug intermediates and KSMs. These products are not only those with high import dependence but also have the potential to develop with necessary support. The incentives proposed together with the market assurance will surely have a significant impact.

Using security exception is not new in India. In 2012 the government in fact tried to use this exception to restrict imports and

create a market for domestic manufacturers in specified electronic products with security implications. But the draft notification was withdrawn in 2013 not because of any WTO strictures but because of stiff resistance from interested and affected parties.[34] It is up to the present government to contain possible opposition and explore measures which are required in national interest.

Government procurement: WTO's Agreement on Government Procurement imposes some conditions on government procurement but this is not a multilateral agreement but a plurilateral one. India has not yet signed and joined this agreement and hence enjoys some flexibilities with respect to government procurement policies. This is a potentially powerful policy to contain imports. As a part of the Make in India campaign, the government has taken some steps to encourage participation of local producers in government procurement.[35] The Draft Pharmaceutical Policy 2017[36] has proposed that formulations manufactured from locally produced bulk drugs and intermediates should be given preference in government procurement. Public sector companies in India are currently minor players. And drugs procured by government is relatively a small part of the over-all market. The Covid-19 pandemic has exposed the limitations of public health infrastructure in most parts of the country and has highlighted the need for better public health facilities. Expansion and improvement of such facilities can have a significant impact on the volume of medicines purchased by central and state governments. A properly designed government procurement policy can stimulate local production and restrict imports.

R&D and technological development

In some bulk drugs, where Indian firms have technological capability, infrastructural support, incentives and demand assurance may be adequate for the growth. But in fermentation based bulk drugs and also in a host of other bulk drugs, drug intermediates and KSMs, there is a technology gap in India. The Report by TIFAC[37] discusses the technological status product wise for 82 bulk drugs and intermediates

in terms of current availability and further research required. R&D is required to take care of the deficiencies and to develop and improve the necessary technologies. The Report by TIFAC[38] also provides a list of specific processes/technologies which require attention.

As the experience in different countries shows, private firms on their own typically underinvest in R&D because of the long time it takes, the large investments required and uncertainty. Hence in the absence of active government and support, the necessary R&D investments may not be forthcoming.

Government support for R&D and technology development can be broadly classified between "push" and "pull" incentives. Push programmes are designed to stimulate R&D by providing funds and inputs and reducing the costs. Pull mechanisms are essentially market enhancing. These create a market or increase the certainty of a market. In the absence of the latter, entrepreneurs are unlikely to invest in R&D for technological development. Ensuring demand for domestic manufacturers is vital for mitigating R&D risks. We have discussed above some measures that are possible to provide a larger demand for domestic players.

Push incentives can be broadly classified between:

- Direct R&D spending by government
- R&D support to industry
  - » R&D tax incentives
  - » R&D grants, loans and capacity building measures

Direct R&D spending by government

The government is the main spender of R&D in India. Government accounted for 56.4 per cent, private sector 36.8 per cent and educational institutions 6.8 per cent of the total R&D expenditure of Rs 1138250 million in 2017-18.[39] But industrial production and technology got only 9.8 per cent of the total expenditure in 2017-18. The bulk of government R&D expenditure is directed towards defence, space,

atomic energy etc. Defence Research and Development Organisation, Department of Atomic Energy and Department of Space accounted for 61.4 per cent of the total R&D expenditure in 2017-18 by major scientific agencies including those by the Department of Science and Technology (DST), the Council of Scientific and Industrial Research (CSIR), the Indian Council of Agricultural Research (ICAR).[40]

R&D tax incentives

In India, government mainly supports the private sector through indirect R&D tax incentives. The R&D tax incentives in India include tax deductions, accelerated depreciation allowance for R&D assets, tax holiday, and tax exemptions (excise and customs). As a cross country comparison[41] shows these are among the best in the world. But government has started diluting the incentives. For example, earlier R&D expenditure used to be deducted 200 per cent of the expenditure for tax purposes. It was reduced to 150 per cent in April 2017 and further to 100 per cent in April 2000.[42] Commenting on the modest growth of private sector R&D despite generous incentives, the *Economic Survey, 2020-21*[43], has advised the private sector to do more R&D. But it is important to note the limitations of such indirect support to industry and to stress the importance of a more direct role of the government. Indirect incentives enhance the R&D propensity of firms already developed. Firms benefit from these incentives only when they have the capacity to do R&D and are engaged in R&D. In the first place to be able to use such incentives the firms must have the capacity to do R&D. Providing such incentives are not adequate to develop such capacities in the private sector. That is why in developed countries such as the USA and in developing countries such as China, the government plays a more direct role in promoting R&D capacity and spending.

R&D loans, grants and capacity building measures

There are a number of schemes under the Department of Science and Technology (DST), the Department of Biotechnology (DBT), Council of Scientific and Industrial Research (CSIR) etc under which direct support in the form of grants and loans are provided to the private

sector. Under the "Drugs and Pharmaceutical Research Programme", DST supports joint research projects of industry and public R&D institutions. Both facilities and funds are shared. The basic idea is to synergise the strengths of publicly funded R&D institutions and Indian pharmaceutical industry.

Another interesting example though not restricted to pharmaceuticals is the "New Millennium Indian Technology Leadership Initiative" (NMITLI) conducted by CSIR. Here too, the basic objective is to synergise the facilities and competencies of the government and private sectors. Apart from collaborative projects, NMITLI also provides financial support through loans to the private sector.

But the extent is limited. The total extramural R&D funding by 21 government funding agencies accounted for only 4.3 per cent of the total central sector R&D expenditure of Rs 569200 million in 2016-17.[44] In India, as we have noted above, government support for R&D for private sector is mainly indirect through R&D tax incentives unlike in countries such as the US.

Developing an R&D ecosystem

Ingredients for developing such an R&D ecosystem already exists in India. If the government accords it top priority, it should not be a difficult task.

In the aggregate, a relatively small proportion of the R&D expenditure is devoted to industry. But there are 49 government institutions engaged in pharmaceutical R&D – 13 under CSIR (for example, Central Drug Research Institute, Lucknow and Indian Institute of Chemical Technology, Hyderabad), 11 under DBT (for example, National Institute of Immunology, New Delhi and Bharat Immunologicals and Biologicals Corporation, Bulandshahar) and 25 under the Department of Health Research (for example, National Institute of Virology, Pune and National Institute of Malaria Research, New Delhi.)[45] Again, though the funding is limited, India also has the experience of organising government-industry collaborative projects.

What is required is a Big Push forward in a National Mission mode with a focused strategy to develop technologies for bulk drugs, intermediates and KSMs (and also for other products where India is technologically deficient as in biosimilars). A National Pharmaceutical R&D Commission may be set up. The main task of the commission will be to draw up and implement technology development programmes with defined targets. To start with a manageable list of products and technologies may be identified. This may be done in broad based consultation with knowledgeable persons. As in the NMITLI programme of CSIR, these may be "Nationally evolved projects." For each such project, a definite plan may be prepared with clear objectives. The huge skills and infrastructure in the government R&D laboratories may be used and coordinated for developing the technologies. The private firms also should be an integral part of the process. Existing public-private partnership programmes of DST, CSIR and DBT need to be significantly scaled up with clear focus.

Once the broad objectives and targets are agreed upon, outside interferences must be prevented. Any such initiative even when these are in national interests may upset some vested interests in India and abroad. The success of such initiatives will depend on the backing that the government provides against attempts to disrupt the efforts.

India has a vibrant private sector in the pharmaceutical industry and in the attempts to revitalise the bulk drug industry with government support, the private sector surely will play a huge role. But to effectively compete against the Chinese competition, huge investments need to be made for example in the fermentation sector. If and where the private sector is not willing to undertake such investments despite the incentives and support, the government must intervene and set up the plant(s). This recommendation is perhaps more controversial than the one relating to tariff protection discussed above. But the matter must be put in proper perspective. It is not a question of government vs private sector. It is a question of what government needs to when the private sector is unable and unwilling to do it but the activity is in national interest. The

fact that pharmaceutical public enterprises have not been performing well should not be an argument not to set up public sector plants or to re-structure existing ones even when the private investment is not forthcoming. It is a question of the priority of the government. As the experience of the public sector organisation, Centre for Development of Telematics (C-DoT) in the late 1980s shows, if the government provides proper funding, gives a free hand to pursue clearly stated objectives and supports it against opposition and lobbying of vested interests, there is no reason why public sector cannot deliver. C-Dot was able to indigenously design, develop and commercialise digital electronic switching systems within a short period of time. However, with liberalisation in the 1990s and different priority of the government, the situation changed.[46]

A strong public sector is also required in emergency situations. The absence of adequate public sector capacity to manufacture vaccines is strongly felt in the Covid-19 pandemic. Reminiscent of the period of the 1950s and 1960s when the public sector played a strategic role, the entire public sector policy must be re-examined.

Endnotes

[1] See, KPMG and Confederation of Indian Industry, *Indian API Industry – Reaching the* Full Potential, April, 2020, pp. 4-7 (https://www.medicpresents.com/medicfiles/4d15_65793.indianapiindustryreachingthefullpotentialkpmgciithoughtleadershipreport2020.pdf).

[2] Bulk drugs are the active pharmaceutical ingredients (APIs) present in the drugs and formulation production is processing of the bulk drugs into finished dosage forms such as tablets and injections.

[3] Pharmexcil, *16th Annual Report 2019-20*, p. 29.

[4] Production of bulk drugs is based on drug intermediates and key starting materials (KSMs). As explained in Notes to Table 2, for long term trend and cross-country comparison, we have used bulk drug trade data available from the UNCOMTRADE database (Table 1 and Tables 6 to 16). Again, as explained in Notes to Table 2, for product wise analysis, we have used DGCI&S Chapter 29, 8-digit groups, which include apart from bulk drugs, also KSMs and drug intermediates.

[5] DGCI&S and UNCOMTRADE are the two data sources used in this paper. Bulk drugs/drug intermediates are included in different groups in these data bases. As explained in the Notes to Table 2, for longer time series including the period

before 2013-14, we have used UNCOMTRADE database for SITC, Rev 3 group 541 for bulk drugs. For disaggregated data, we have used DGCI&S Chapter 29, 8 digit groups.

[6] Report of the Working Group on Drug and Pharmaceuticals for 12th Plan, p. 49.

[7] For an account of the rise and growth of the pharmaceutical industry in India, see Sudip Chaudhuri, *The WTO and India's Pharmaceuticals industry: Patent Protection, TRIPS and Developing Countries*, Oxford University Press, 2005.

[8] "Statement on Drug Policy 1978", Guidelines for Industries: Part I, Policy and Procedures, 1982, Indian Investment Centre, New Delhi

[9] "Drug Policy 1986" (http://www.nppaindia.nic.in/en/drug-policies/drug-policy-1986).

[10] See Chaudhuri, *WTO and India's Pharmaceuticals industry, supra* note *7,* Table 2.4 (pp. 40-41)

[11] Press Note No 4 ((1994 Series), *Compendium of Industrial Policy and Procedures,* August, 2000, Department of Industrial Development, Department of Industrial Policy and Promotion, pp. 120-22.

[12] Press Note No 3 ((1999 Series), *Compendium of Industrial Policy*, *supra* note 11, pp. 192-93.

[13] Gazette Notification, 23 September, 2005.

[14] Jagdish Bhagwati and T. N. Srinivasan, "India's Economic Reforms", Government of India, 1993, p.6.

[15] Ministry of Chemicals and Fertilizers, Department of Chemicals and Petrochemicals, *Annual Report 2007-08.*

[16] KPMG and Confederation of Indian Industry, *Indian API Industry, supra* note 1, provides a good account of the cost differentials that have emerged between China and India. The figures cited in this part are from these two studies.

[17] PWC, *Reviving India's API Industry: From the view Point of COVID-19 Outbreak,* 2020, p.8 (https://www.ipa-india.org/wp-content/uploads/2020/10/press-27820c_compressed.pdf).

[18] KPMG and Confederation of Indian Industry, *Indian API Industry, supra* note 1. Table 6, p. 51.

[19] KPMG and Confederation of Indian Industry, *Indian API Industry, supra* note 1, p. 44.

[20] KPMG and Confederation of Indian Industry, *Indian API Industry, supra* note 1, p. 42.

[21] PWC, *Reviving India's API Industry, sura* note 17, p. 8.

[22] PWC, *Reviving India's API Industry, sura* note 17, p. 8.

[23] "List of States/UTs-wise Operational SEZs as on 31.10.2020" (http://sezindia.nic.in/upload/uploadfiles/files/Operationa.pdf).

[24] PWC, *Reviving India's API Industry, sura* note 17, p. 5.

[25] Technology Information, Forecasting & Assessment Council (TIFAC), *Active Pharmaceutical Ingredients: Status, Issues Technology Readiness and*

Challenges, July, 2020, pp. 11-13. (https://dst.gov.in/sites/default/files/Active%20Pharmaceutical%20Ingredients%20%28API%29%20- Status%2C%20Issues%2C%20Technology%20Readiness%20and%20Challenges_0.pdf).

[26] "Salient Features of the Recommendations of Katoch Committee Report on Active Pharmaceutical Ingredients (APIs)" 24 September 2015 (https://pharmaceuticals.gov.in/sites/default/files/Katoch%20Committe%20Report.pdf); Department of Pharmaceuticals, *Annual Report 2015-16*, pp 71-72.

[27] For a description of these schemes, Department of Pharmaceuticals, *Annual Report 2015-16*, p. 73; *Annual Report, 2016-17*, pp. 9-10 and *Annual Report 2019-20*, pp. 5-7.

[28] Gazette Notification, 21 July, 2020 (https://pharmaceuticals.gov.in/sites/default/files/Gazettee%20notification%20of%20bulk%20drug%2 0schemes_0.pdf).

[29] Gazette Notification, 3 March 2021 (https://pharmaceuticals.gov.in/sites/default/files/Gazette%20Notification%20of%20PLI%20scheme %20for%20Pharmaceuticals_0.pdf).

[30] Gazette Notification, 3 March 2021, *supra* note 29.

[31] Lok Sabha Unstarred Question No 3439 answered on 16 March, 2021.

[32] Lok Sabha Unstarred Question No 3317 answered on 16 March, 2021

[33] TIFAC, *Active Pharmaceutical Ingredients*, supra note 25, p. 25.

[34] Sudip Chaudhuri, "Import Liberalisation and Premature Deindustrialisation in India", *Economic and Political Weekly*, October 14, 2015.

[35] Lok Sabha Unstarred Question No 1698 answered on 21 September, 2020; Lok Sabha Unstarred Question No 4799 answered on 24 March, 2021.

[36] Accessed from: http://www.indiaenvironmentportal.org.in/files/file/draft%20pharmaceutical%20policy%202017.pdf

[37] TIFAC, *Active Pharmaceutical Ingredients*, supra note 25, pp 27- 36.

[38] TIFAC, *Active Pharmaceutical Ingredients*, supra note 25, pp. 42-44.

[39] Department of Science and Technology, *Research and Development Statistics, 2019-20* (http://www.nstmis-dst.org/Pdfs/R&DStatisticsFullReport2019-20.pdf).

[40] DST, *Research and Development Statistics*, supra note 39.

[41] Sabyasachi Saha and Prativa Shaw, "A Review of R&D and Sectoral Incentives in Manufacturing in Industrialised and Emerging Economies: Lessons for 'Make in India'," Discussion Paper # 233, Research and Information System for Developing Countries, 2018, p. 17.

[42] Department of Scientific and Industrial Research, *R&D Efforts of DSIR approved Industries on Covid-19: A Report,* 2021, Forward.

[43] Volume 1, p. 281 (https://www.indiabudget.gov.in/economicsurvey/).

[44] DST, *Research and Development Statistics*, *supra* note 39.

[45] Report of the Working Group, *supra* note, 6, pp. 141-42.

[46] Sudip Chaudhuri, "Manufacturing Trade Deficit and Industrial Policy in India", *Economic and Political Weekly*, February 23, 2013.

Table 1 Growth of India's pharmaceutical imports from China, 1988-2020

	Bulk drugs Total imports (US $ million)	Bulk drugs China's Share (%)	Formulations Total imports (US $ million)	Formulations China's Share (%)
1988	1.99	2.0	0.9	1.4
1989	0.03	0.0	0.0	0.0
1990	0.46	0.4	0.3	0.2
1991	0.40	0.3	0.1	0.1
1992	6.25	2.5	0.3	0.5
1993	15.17	7.2	0.9	2.0
1994	36.82	14.7	0.4	0.8
1995	73.43	21.1	0.6	1.0
1996	58.06	21.6	0.5	1.4
1997	64.54	19.9	0.9	1.4
1998	69.91	23.0	1.4	1.8
1999	71.77	24.7	1.2	1.4
2000	64.69	23.0	1.0	1.1
2001	82.36	27.2	1.2	1.2
2002	139.97	34.6	2.3	1.6
2003	171.29	36.5	3.5	2.5
2004	187.88	38.0	4.7	2.5
2005	316.54	47.8	4.9	1.8
2006	429.33	54.4	9.8	2.5
2007	648.17	58.9	10.8	2.1
2008	672.37	55.9	15.8	2.4
2009	685.51	52.2	22.7	3.1
2010	913.39	57.1	25.7	3.1
2011	890.62	49.5	44.6	4.8
2012	908.88	47.6	57.3	4.9
2013	1059.78	51.9	20.7	2.0
2014	1178.15	51.6	39.2	4.3
2015	1186.00	52.3	43.9	5.0

Table 1 continued....

Table 1 continued....

2016	1127.08	51.7	35.3	3.6
2017	1225.37	54.0	32.7	2.9
2018	1531.56	52.6	41.2	3.5
2019	1509.82	50.0	45.9	3.2
2020	1561.87	47.5	32.4	2.8

Source: Calculated from UNCOMTRADE database, commodity groups, SITC, Rev 3, 541 (for bulk drugs) and 542 (for formulations) (https://comtrade.un.org/).

Note: Data separately for 541 and 542 are not available in the UNCOMTRADE database before 1988.

Table 2 China's Share in bulk drugs and drug intermediates imports by India, 1988-2020

Year	DGCI&S - Bulk drugs, drug intermediates China share (%)	DGCI&S - Medical and Pharmaceutical products China share (%)	DGCI&S - Chapter 29 China share (%)	UN-COMTRADE, SITC Rev 3, 541 China share (%)	UN-COMTRADE, Chapter 29 China share (%)
1988	NA	NA	NA	2.0	1.0
1989	NA	NA	NA	0.0	0.1
1990	NA	NA	NA	0.4	0.3
1991	NA	NA	NA	0.3	0.1
1992	NA	NA	NA	2.5	3.2
1993	NA	6.2	6.9	7.2	6.9
1994	NA	12.5	9.4	14.7	9.3
1995	NA	18.3	10.7	21.1	10.7
1996	NA	19.1	9.8	21.6	9.8
1997	NA	16.8	12.1	19.9	12.1
1998	NA	18.6	14.2	23.0	14.3
1999	NA	19.6	14.3	24.7	14.3
2000	NA	18.7	15.5	23.0	15.6
2001	NA	24.7	18.6	27.2	16.5
2002	NA	25.3	21.2	34.6	21.8

Table 2 continued....

Table 2 continued....

2003	NA	28.7	20.6	36.5	20.6
2004	NA	28.7	19.7	38.0	20.2
2005	NA	34.7	25.5	47.8	23.6
2006	NA	36.3	28.3	54.4	28.0
2007	NA	41.2	29.4	58.9	29.3
2008	NA	37.0	32.8	55.9	32.1
2009	NA	34.5	32.0	52.2	32.7
2010	NA	39.8	30.5	57.1	30.9
2011	NA	31.7	29.0	49.5	29.1
2012	NA	32.9	31.5	47.6	30.4
2013	63.5	41.3	31.6	51.9	31.0
2014	64.3	42.0	35.7	51.6	34.4
2015	65.3	42.9	38.9	52.3	38.8
2016	66.7	40.4	36.3	51.7	37.9
2017	68.7	41.1	36.9	54.0	36.6
2018	67.5	41.3	38.4	52.6	37.8
2019	68.0	39.6	40.2	50.0	40.1
2020	68.0	41.6	NA	47.5	45.2

Sources: For cols 2, 3 and 4, DGCI&S through CMIE Tradedx database (based on DGCI&S database). For cols 5 and 6, UNCOMTRADE database.

Notes: For UNCOMTRADE series in cols 5 and 6, data are for calendar years and for DGCI&S series in cols 2, 3 and 4, data are for financial years. Thus, for 2013, DGCI&S data are for 2013-14, i.e., April 2013 to March 2014 and for UNCOMTRADE, January to December 1993.

DGCI&S provides two long term data series – one on "Medicinal and pharmaceutical products" (col 3) and the other on Chapter 29 (Organic chemicals)) (col 4). The former includes apart from bulk drug/intermediates, formulations, biologicals, surgical and herbal products. The latter provides data on "Organic chemicals" classified up to 8-digit groups. It includes bulk drugs, intermediates and Key Starting Materials (KSMs) and also other chemicals.

In the UNCOMTRADE database, bulk drugs are included in Standard International Trade Classification (SITC), Rev 3 group 541 ("Medicinal and pharmaceuticals products other than medicaments of group 542" available since 1988 (col 5) and in the Harmonised System (HS) under Chapter 29 (Col 6).

As mentioned in the text, DGCI&S provides data separately for bulk drugs and intermediates only from 2013-14. Hence for longer term analysis we need to rely on other data series. As the second-best option, for longer term time series analysis in this paper, we use SITC, Rev 3, 541 group (col 5) since the figures are closest to actual bulk drug and intermediates data (in col 2).

Disaggregated data for Chapter 29 are provided by both DGCI&S and UNCOMTRADE. But whereas UNCOMTRADE database provides data at 5-digit level of disaggregation, DGCI&S provides data at 8-digit level of disaggregation. Hence for detailed product wise analysis in this paper, we have used DGCI&S Chapter 29, 8-digit groups.

Table 3 Product wise share of China in India's bulk drugs and drug intermediates imports, 2019-20

Share of China in India's imports	No of products	No of products (%)	Imports from China (US $ million)	Imports from China (%)
100%	70	12.8	239.02	3.0
90% to 99%	81	14.9	1608.91	20.3
80% to 89%	47	8.6	1277.3	16.1
70% to 79%	41	7.5	1976.33	25.0
60% to 69%	44	8.1	1184.57	15.0
50% to 59%	44	8.1	409.38	5.2
25% to 49%	88	16.1	819.63	10.4
10% to 24%	60	11.0	265.44	3.4
< 10%	70	12.8	128.99	1.6
	545	100.0	7909.57	100.0

Source: Calculated from CMIE Tradedx database for Chapter 29 8-digit groups (based on DGCI&S database).

Note: See Notes to Table 2.

Table 4 China's share in selected bulk drugs and drug intermediates imports by India, 2019-20

Chapter 29 8-digit commodity code	Commodity Name	Imports from China in US $ million	China's share in total imports of India (%)
29222913	Para aminophenol	76.12	100.0
29049950	Para nitrochlorobenzene	17.74	100.0
29222934	Para cresidine	14.11	100.0
29222160	H-acid	14.09	100.0
29214234	Sulphanilic acid	9.18	100.0
29163400	Phenylacetic acid & its salts	9.09	100.0
29214516	Sodium naphthionate	6.72	100.0
29071510	Alpha naphthol	5.89	100.0
29420026	Cysteanune hcl	5.85	100.0
29182920	Beta hydroxy naphthoic acid	5.34	100.0
29202400	Triethyl phosphite	5.15	100.0
29037400	Chlorodifluoroethanes	4.47	100.0
29242910	Acetanilide	3.86	100.0
29412010	Streptomycins	3.01	100.0
29359014	Sulphadimidine	2.3	100.0
29214222	Diethylaniline	1.68	100.0
29331940	Phenyl-methyl pyrazolone	1.38	100.0
29332920	Metronidazole	6.76	99.9
29419060	Norfloxacin & its salts	2.69	99.6
29071520	Beta naphthol	29.86	99.6
29171920	Malonic acid	2.21	99.5
29411050	6 - APA	173.17	99.5
29359013	Sulphadiazine	4.69	98.5
29182310	Methyl salicylate	2.6	98.5
29049930	Meta nitrochlorobenzene	2.87	98.3
29143930	Benzophenone	5.08	98.3
29359024	Sulphamide	3.37	98.3

Table 4 continued....

Table 4 continued....

29362610	Vitamin B12	39.53	98.1
29039910	Chloroflurobenzene	2.91	98.0
29419011	Rifampicin	29.9	97.3
29181400	Citric acid	52.56	96.9
29419030	Ciprofloxacine & its salts	14.43	96.4
29411010	Penicillins and its salts	95.64	95.8
29224220	Monosodium glutamate	38.3	95.8
29419040	Gentamycin & its salts	7.81	95.2
29130010	Ortho-chloro-benzaldehyde	7.4	95.2
29420012	Ibuprofane	28.05	95.2
29419050	Neomycin	2.57	95.2
29124910	Anisic aldehyde	1.99	94.3
29181610	Calcium gluconate	7.88	93.9
29062920	Phenylethyl alcohol	1.86	93.0
29242920	Aceto acetanilide	5.05	92.8
29182110	Salicylic acid	32.24	92.4
29214110	Aniline	68.84	91.6
29222933	Paracetamol	12.7	91.0
29214236	Methyl dopa	7.65	90.7
29061910	Berneol	1.18	90.1

Source: Same as in Table 3.

Notes: The commodity codes are for bulk drugs and drug intermediates. See Notes to Table 1 and Table 3. This is a sub-set of products with imports from China exceeding US $ 1 million in 2019-20 and China's share of 90% or more.

Table 5 China's share in selected bulk drugs imports by India, 2004-05 to 2019-20

	Paracetamol (%)	Vitamin B12 (%)	Cortisone, hydrocortisone, prednisone (%)	Penicillin (%)	Amoxycilline (%)
2004-05	73.6	88.2	53.9	69.7	0.1
2005-06	99.7	70.0	63.7	94.2	1.0
2006-07	93.5	66.4	65.8	99.2	23.7
2007-08	84.5	98.1	74.7	99.0	6.1
2008-09	97.9	97.8	60.6	93.3	17.2
2009-10	96.5	99.0	70.7	93.9	52.5
2010-11	99.1	96.9	68.1	94.5	69.2
2011-12	87.0	81.1	74.2	83.0	49.5
2012-13	97.8	94.9	76.9	94.7	77.8
2013-14	96.2	98.0	76.8	96.1	79.6
2014-15	95.5	96.6	74.4	94.3	94.5
2015-16	84.4	97.9	69.7	95.7	92.7
2016-17	97.1	99.7	67.1	95.7	81.3
2017-18	89.9	99.4	67.4	94.7	80.4
2018-19	85.6	93.5	71.4	94.4	89.5
2019-20	91.0	98.1	80.4	95.8	89.9

	Doxy-cyline (%)	Tetracycline oxytetracy-cline (%)	Erythro-mycin (%)	Rifampicin (%)	Ciproflox-acine (%)	Ibupro-fane (%)
2004-05	100.0	100.0	25.0	71.6	92.5	100.0
2005-06	100.0	99.8	52.4	51.4	96.9	99.2
2006-07	100.0	98.4	55.6	72.3	99.3	96.1
2007-08	99.5	97.9	38.8	82.7	98.1	96.1
2008-09	99.3	96.9	57.9	78.3	100.0	95.1
2009-10	100.0	93.9	58.9	93.0	99.3	86.5
2010-11	97.9	99.7	69.8	97.4	96.2	81.6
2011-12	86.4	80.0	67.9	74.7	84.0	67.3

Table 5 continued....

Table 5 continued....

2012-13	96.0	88.0	78.1	89.5	95.4	76.4
2013-14	81.1	96.1	77.4	97.4	99.2	97.7
2014-15	77.6	99.8	73.0	91.3	95.4	96.9
2015-16	68.0	99.4	62.8	93.0	92.6	95.8
2016-17	56.8	100.0	75.7	80.1	94.2	95.6
2017-18	63.7	99.6	68.4	91.3	95.8	96.3
2018-19	57.5	99.8	62.8	94.8	95.1	98.8
2019-20	73.6	99.0	83.0	97.3	96.4	95.2

Source: Same as in Table 3.

Table 6 Imports of bulk drug by India from different countries, 2020

Country	Imports (US $ million)	Share (%)
China	1561.87	47.5
Rep. of Korea	285.09	8.7
Belgium	195.60	5.9
USA	182.22	5.5
Switzerland	167.45	5.1
France	127.55	3.9
Italy	87.43	2.7
Netherlands	71.15	2.2
Spain	69.54	2.1
Germany	67.53	2.1
China, Hong Kong SAR	62.55	1.9
Indonesia	54.77	1.7
Austria	53.11	1.6
United Kingdom	46.25	1.4
Singapore	44.97	1.4
Denmark	35.07	1.1
75 other countries	178.95	5.4
Total	3291.09	100.0

Source: Calculated from UNCOMTRADE database for commodity group, SITC Rev 3, 541.

Table 7 Global exports of bulk drugs by different countries, 2020

Country	Exports (US$ million)	Share (%)
Ireland	42866.51	16.6
Switzerland	41597.06	16.1
Germany	36180.22	14.0
USA	29746.35	11.5
Belgium	23464.77	9.1
China	16519.49	6.4
Italy	10307.83	4.0
France	10027.96	3.9
Netherlands	8130.74	3.2
United Kingdom	6924.25	2.7
Rep. of Korea	6276.84	2.4
Spain	3150.09	1.2
Sweden	2889.78	1.1
India	2838.75	1.1
Denmark	2621.58	1.0
Hungary	2617.12	1.0
Japan	2579.55	1.0
55 other countries	9117.18	3.5
Total	257856.07	100.0

Source: Same as in Table 6.

Table 8 Global bulk drugs exports of China and India, 1992 to 2000

	China's total bulk drugs exports (US $ million)	India's total bulk drugs exports (US $ million)	India/China (%)
1992	651.30	59.75	9.2
1993	671.38	73.05	10.9
1994	925.30	101.56	11.0
1995	1259.97	141.24	11.2
1996	1204.45	174.26	14.5
1997	1241.81	222.62	17.9

Table 8 continued....

Table 8 continued....

1998	1393.21	250.54	18.0
1999	1420.57	265.30	18.7
2000	1514.77	341.83	22.6
2001	1673.80	363.26	21.7
2002	2020.47	451.65	22.4
2003	2516.46	516.51	20.5
2004	2830.39	482.48	17.0
2005	3280.47	543.05	16.6
2006	3904.23	644.48	16.5
2007	5173.21	900.77	17.4
2008	6962.33	1015.00	14.6
2009	7416.87	1322.13	17.8
2010	9192.76	1356.86	14.8
2011	9409.07	1828.55	19.4
2012	9099.37	1871.00	20.6
2013	9336.30	2329.71	25.0
2014	10189.05	2242.90	22.0
2015	10048.50	2338.93	23.3
2016	10199.18	2427.13	23.8
2017	11101.37	2228.96	20.1
2018	12438.11	2440.02	19.6
2019	12357.07	2704.92	21.9
2020	16519.49	2838.75	17.2

Source: Same as in Table 6.

Table 9 Top 10 destinations of India's bulk drugs exports, 2020

Country	Exports (US$ million)	Imports (US $ million)	Exports – imports (US $ million)
USA	246.77	182.22	64.55
Brazil	162.11	2.42	159.68
Bangladesh	115.34	0.00	115.33
Turkey	111.45	1.23	110.22
China	92.81	1561.87	-1469.06
Netherlands	85.13	71.15	13.98
Nigeria	76.14	0.08	76.06
Viet Nam	75.34	3.76	71.58
Egypt	72.35	0.66	71.68
Iran	67.95	3.77	64.18

Source: Same as in Table 6.

Table 10 Imports of bulk drugs from India by selected developing countries, 2020

Bangladesh (Countries)	Bangladesh (Share)	Nigeria (Countries)	Nigeria (Share)	Pakistan (Countries)	Pakistan (Share)	Vietnam (Countries)	Vietnam (Share)	Egypt (Countries)	Egypt (Share)	Iran (countries)	Iran (Share)
China	25.1	Belgium	27.0	China	27.1	China	28.3	China	21.1	China	20.0
India	22.9	Denmark	23.3	Belgium	14.2	USA	11.9	USA	18.7	Germany	16.5
Denmark	15.7	Singapore	17.3	India	11.9	France	11.8	India	12.2	UAE	12.5
Belgium	5.4	India	13.9	France	10.0	Belgium	9.7	Switzerland	8.3	India	8.9
Singapore	4.3	China	7.3	Denmark	6.7	India	8.7	Germany	7.6	France	7.8

Source: Same as in Table 6.

Note: The countries listed in col 1 are the top five sources of bulk drugs imports by Bangladesh and the share is the share of these countries in total imports by Bangladesh in 2020. Similarly for other cols.

Table 11 Country-wise trade deficit of India in bulk drugs, 2020

Country	Exports (US$ million)	Imports (US $ million)	Trade deficit (US $ million)
China	92.81	1561.87	-1469.06
Rep. of Korea	41.41	85.09	-243.68
Belgium	30.25	195.60	-165.34
Switzerland	36.51	167.45	-130.94
France	32.76	127.55	-94.79
China, Hong Kong SAR	7.47	62.55	-55.08
Austria	6.14	53.11	-46.97
Spain	35.17	69.54	-34.37
Singapore	12.16	44.97	-32.80
Denmark	3.71	35.07	-31.35
Italy	62.78	87.43	-24.65
Germany	50.60	67.53	-16.93
Slovenia	5.23	20.64	-15.41
Australia	8.22	15.40	-7.18
Portugal	3.91	10.15	-6.23
Czechia	1.55	7.58	-6.02
Bulgaria	1.32	5.20	-3.88
Indonesia	52.35	54.77	-2.42
New Zealand	2.31	4.49	-2.19
Israel	5.41	6.71	-1.30
Ukraine	4.04	4.48	-0.44
Eswatini	0.17	0.41	-0.24
Luxembourg	0.00	0.11	-0.11
Total			-2391.39

Source: Same as in Table 6.

Table 12 India's trade deficit in bulk drugs with China and the Rest of the World, 1988-2000

Year	Total Trade deficit US $ million	Trade deficit with China US $ million	Trade deficit with Rest of the World US $ million
1988	-76.09	-1.74	-74.35
1989	-71.18	0.07	-71.25
1990	-69.07	-0.32	-68.75
1992	-191.21	-6.21	-185.00
1993	-139.10	-14.99	-124.11
1994	-149.41	-35.70	-113.71
1995	-206.90	-69.79	-137.11
1996	-95.01	-51.00	-44.00
1997	-101.61	-54.37	-47.24
1998	-53.01	-58.18	5.17
1999	-24.92	-64.14	39.22
2000	60.68	-55.46	116.14
2001	60.30	-68.07	128.37
2002	47.68	-120.02	167.70
2003	47.74	-154.13	201.87
2004	-11.44	-176.60	165.16
2005	-119.40	-279.37	159.97
2006	-144.79	-403.78	258.98
2007	-200.43	-611.27	410.83
2008	-188.52	-625.31	436.79
2009	9.71	-643.27	652.98
2010	-241.67	-861.45	619.78
2011	29.17	-819.44	848.61
2012	-37.17	-853.86	816.69
2013	287.40	-1006.93	1294.33
2014	-38.19	-1116.09	1077.90
2015	70.85	-1126.46	1197.30
2016	247.65	-1086.24	1333.89
2017	-38.23	-1133.60	1095.37
2018	-470.70	-1469.86	999.16
2019	-316.90	-1416.50	1099.60
2020	-452.35	-1469.06	1016.71

Source: Same as in Table 6.

Note: China export figures are not available for 1991 and hence 1991 is excluded above.

Table 13 Global exports of formulations by different Countries, 2020

Country	Exports of formulations (US $ million)	Share (%)
Germany	63,011.33	16.1
Switzerland	48,566.14	12.4
France	28,656.45	7.3
Italy	27,449.44	7.0
USA	26,283.19	6.7
Belgium	25,366.93	6.5
Ireland	23,355.03	6.0
Netherlands	20,778.77	5.3
United Kingdom	18,991.64	4.9
India	17,191.18	4.4
Denmark	16,831.74	4.3
Spain	11,150.56	2.8
Sweden	9,268.22	2.4
Canada	7,704.12	2.0
Slovenia	7,336.48	1.9
China	5,445.87	1.4
Japan	5,225.89	1.3
Hungary	4,463.03	1.1
56 other countries	24,202.18	6.2
Total	3,91,278.19	100.0

Source: UNCOMTRADE database, commodity group SITC Rev 3, 542.

Table 14 Global formulations exports of India and China, 1992-2020

Year	China's exports US $ million	India's exports US $ million	China/India (col 2/col 3) (%)
1992	243.84	371.49	65.6
1993	233.68	409.83	57.0
1994	260.00	484.20	53.7
1995	321.99	582.91	55.2
1996	311.66	639.73	48.7
1997	294.43	724.59	40.6
1998	299.12	683.16	43.8
1999	258.14	802.87	32.2
2000	273.72	805.15	34.0
2001	304.70	959.12	31.8
2002	303.10	1157.09	26.2
2003	344.09	1455.40	23.6
2004	403.92	1789.09	22.6
2005	497.26	2218.79	22.4
2006	582.01	2771.65	21.0
2007	828.18	3575.95	23.2
2008	1128.56	4807.75	23.5
2009	1196.87	4599.41	26.0
2010	1487.69	5767.21	25.8
2011	2400.93	7674.07	31.3
2012	2820.58	8988.69	31.4
2013	2970.41	10844.68	27.4
2014	3173.19	10692.42	29.7
2015	3432.04	11564.17	29.7
2016	3385.66	11964.37	28.3
2017	3884.69	12047.03	32.2
2018	4883.86	13315.32	36.7
2019	4801.89	15154.40	31.7
2020	5445.87	17191.18	31.7

Source: Same as in Table 13.

Table 15 India's exports and imports of bulk drugs and formulations, 1988-2020

Period	Formulations Export (US$ million)	Formulations import (US$ million)	Formulations, Export - Import (US$ million)	Bulk drugs Export (US$ million)	Bulk drugs Import (US$ million)	Bulk drugs Export - import (US$ million)
1988	230.83	62.28	168.55	23.70	99.79	-76.09
1989	395.99	135.45	260.54	39.11	110.29	-71.18
1990	400.43	136.65	263.78	52.38	121.45	-69.07
1991	437.13	97.18	339.95	46.34	130.55	-84.20
1992	371.49	62.83	308.66	59.75	250.96	-191.21
1993	409.83	45.69	364.14	73.05	212.15	-139.10
1994	484.20	47.51	436.70	101.56	250.96	-149.41
1995	582.91	56.92	526.00	141.24	348.14	-206.90
1996	639.73	37.40	602.34	174.26	269.26	-95.01
1997	724.59	64.64	659.95	222.62	324.22	-101.61
1998	683.16	80.73	602.43	250.54	303.55	-53.01
1999	802.87	82.59	720.28	265.30	290.22	-24.92
2000	805.15	92.78	712.37	341.83	281.15	60.68
2001	959.12	97.56	861.57	363.26	302.96	60.30
2002	1157.09	141.88	1015.20	451.65	403.98	47.68
2003	1455.40	141.15	1314.25	516.51	468.77	47.74
2004	1789.09	186.37	1602.71	482.48	493.92	-11.44
2005	2218.79	275.31	1943.48	543.05	662.45	-119.40
2006	2771.65	392.23	2379.41	644.48	789.27	-144.79
2007	3575.95	515.12	3060.83	900.77	1101.20	-200.43
2008	4807.75	666.04	4141.71	1015.00	1203.53	-188.52
2009	4599.41	735.51	3863.90	1322.13	1312.43	9.71
2010	5767.21	835.86	4931.35	1356.86	1598.53	-241.67
2011	7674.07	935.66	6738.41	1828.55	1799.38	29.17
2012	8988.69	1161.03	7827.66	1871.00	1908.18	-37.17
2013	10844.68	1018.99	9825.69	2329.71	2042.31	287.40
2014	10692.42	907.33	9785.09	2242.90	2281.08	-38.19

Table 15 continued....

Table 15 continued....

2015	11564.17	880.24	10683.93	2338.93	2268.08	70.85
2016	11964.37	980.01	10984.35	2427.13	2179.48	247.65
2017	12047.03	1129.04	10917.99	2228.96	2267.19	-38.23
2018	13315.32	1178.28	12137.04	2440.02	2910.72	-470.70
2019	15154.40	1434.51	13719.90	2704.92	3021.82	-316.90
2020	17191.18	1166.60	16024.58	2838.75	3291.09	-452.35

Source; UNCOMTRADE database, commodity group SITC Rev 3, 541 (bulk drugs) and 542 (formulations).

Table 16 India's trade balance with China in bulk drugs and formulations, 1988-2020

	Bulk drugs Export – Imports (US$ million)	Formulations Export - Imports (US$ million)
1988	-1.74	-0.82
1989	0.07	0.20
1990	-0.32	-0.18
1992	-6.21	0.67
1993	-14.99	0.70
1994	-35.70	3.49
1995	-69.79	5.48
1996	-51.00	10.18
1997	-54.37	12.37
1998	-58.18	12.97
1999	-64.14	16.66
2000	-55.46	13.36
2001	-68.07	23.12
2002	-120.02	25.02
2003	-154.13	21.37
2004	-176.60	19.53
2005	-279.37	18.58
2006	-403.78	11.38
2007	-611.27	15.88

Table 16 continued....

Table 16 continued....

2008	-625.31	9.37
2009	-643.27	-4.37
2010	-861.45	0.40
2011	-819.44	-2.01
2012	-853.86	7.28
2013	-1006.93	32.75
2014	-1116.09	-8.73
2015	-1126.46	-21.82
2016	-1086.24	-16.46
2017	-1133.60	-1.44
2018	-1469.86	3.00
2019	-1416.50	-7.60
2020	-1469.06	16.37

Source; same as in Table 15.

Table 17 Illustrative list of non-operational bulk drugs manufacturing plants

Name of Bulk Drug	Producers	Production commenced in	Status
Penicillin G/V	Alembic, Sarabhai, IDPL, JK Torrent, Ranbaxy, Standard	Early '60s	Plant stopped
Streptomycin	Alembic, Sarabhai, IDPL	Early '60s	Plant stopped
Tetracycline	Sarabhai, IDPL, Pfizer	Early '80s	Plant stopped
Oxytetracycline	Sarabhai, IDPL, Pfizer	Early '80s	Plant stopped
Kanamycin	Alembic	Early '70s	Plant stopped
Erythromycin	Alembic, Themis, IDPL, Standard	Early '80s	Partially in operation for captive consumption
Gentamycin	HAL, Themis	Late '80s	Closed
Sisomycin	Themis	Late '80s	Closed
Vitamin B 12	Alembic, Themis, MSD	Early '70s	Closed
Cephalosporin 'C'	Alembic	Early '90s	Closed
Pravastatin	Themis, Biocon, Mylan	Late '90s	Closed
Griseofulvin	Glaxo	Late '80s	Closed
Cyclosporin A	Biocon, Mylan	Late '90s	Closed
Bleomycin	Themis	Early '90s	Closed
Mitomycin 'C'	Themis	Early '90s	Closed
Citric acid	Citurgia, Citric India, Themis	Early '80s	Closed
Ascorbic Acid	Sarabhai, Jayant Vitamin	Early '80s	Closed

Source: KPMG and Confederation of Indian Industry, *Indian API Industry – Reaching the* Full Potential, April, 2020, Table 2, p. 20.

Table 18: Incentive scheme for bulk drugs, drug intermediates and KSMs

Group	No of products	Financial incentives as % of sales	Threshold investments (Rs million)
Fermentation based KSMs/drug intermediates	4	20023-24 to 2026-27: 20% 2027-28: 15% 2028-29: 5%	4000
Fermentation based niche KSMs/drug intermediates/APIs	10	20023-24 to 2026-27: 20% 2027-28: 15% 2028-29: 5%	500
Key synthesis based KSMs/drug intermediates	4	2022-23 to 2027-28: 10%	500
Other synthesis based KSMs/drug intermediates/APIs	23	2022-23 to 2027-28: 10%	200

Source: Gazette Notification, 21 July, 2020 (https://pharmaceuticals.gov.in/sites/default/files/Gazettee%20notification%20of%20bulk%2 0drug%20schemes_0.pdf).

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