Social Science & Medicine 312 (2022) 115386

Contents lists available at ScienceDirect

Social Science & Medicine

journal homepage: www.elsevier.com/locate/socscimed

Antibiotic geographies and access to medicines: Tracing the role of India's pharmaceutical industry in global trade

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ARTICLE INFO

Keywords:
Access to medicines
Antibiotics
Antibiotic resistance
India
Pharmaceutical industry
Pharmaceutical trade

ABSTRACT

Access to medicines has become a major concern for countries worldwide during the COVID-19 pandemic, as pharmaceutical production and trade have been disrupted in the course of the crisis. Antibiotics are one group of medicines where worries about access have been raised. Access to the right antibiotic at the right time is important not only for curing infections of individual patients, but also for curbing antibiotic resistance globally. Reliable pharmaceutical supply is key to ensuring access to medicines. The global supply of generic medicines has over the last decades been transformed by the rise of India's pharmaceutical industry. In this paper, I trace the changing role of this industry for the global export of antibiotics, by mapping and describing changes in Indian antibiotic exports and discussing these in light of historical processes and events. The paper offers a novel approach to analyse global antibiotic trajectories by using international trade data from publicly available resources combined with a secondary literature review. I show that India's pharmaceutical industry today holds a key role as one of the world's biggest exporters of antibiotic medicines, but with an increasing dependency on China as a supplier of antibiotic ingredients. This produces both opportunities and concerns for access to antibiotics globally.

1. Introduction

The COVID-19 pandemic has highlighted that the world's supply of life-saving medicines relies on complex global value chains. As pandemic restrictions have been imposed by governments, disruptions have been seen in the production and trade of pharmaceuticals (Chatterjee, 2020; UNAIDS, 2020). While evidence suggests that such disruptions were rapidly overcome in high-income countries due to various measures and changes in demand (e.g., see Romano et al., 2021), the pandemic still brought renewed attention to an old concern: the lack of access to medicines in many settings around the world. It is estimated that nearly 2 billion people globally have no access to basic medicines, and that this 'is one of the most complex – and vexing – problems that stand in the way of better health' (WHO, 2017, p. 16).

Antibiotics are a group of medicines where lack of access can have fatal results. First, access to antibiotics is vital for the treatment and prevention of common infectious diseases and medical conditions in humans and animals, reducing illness, disabilities and deaths. Second, lack of access to suitable first- and second-line antibiotic treatments may lead to the use of less effective or more broad-spectrum antibiotics, known to be a driver of antibiotic resistance. Access to antibiotics is a major global problem, despite the considerable rise in global consumption of antibiotics over the last decades (Klein et al., 2018) and the fact that the majority of antibiotics are off-patent generics. No access to or delays in access to antibiotics is estimated to kill more people than antibiotic resistance globally (Laxminarayan et al., 2016). Yet, global efforts to address universal access to antibiotics have mostly been 'isolated and uncoordinated, with little focus on sustainable and international solutions' (Årdal et al., 2016, p. 296), and there is a great need to support access enablers such as affordability, procurement and distribution (Mendelson et al., 2016). Recognising that barriers to access medicines are complex, more knowledge is needed on the production and global distribution of antibiotics.

In this paper, I contribute to build much-needed knowledge on global antibiotic trajectories by exploring India's trade in antibiotics. I trace the changing role of India's pharmaceutical industry for the global supply of antibiotics, by mapping and describing changes in Indian antibiotic exports, and discussing findings in light of historical processes and events. The paper also contributes with insights into the import of antibiotic ingredients that underpins India's production of antibiotics. The article's approach is inspired by the concept 'pharmaceutical geographies' used by historian Jeremy A. Greene (2016), which draws

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https://doi.org/10.1016/j.socscimed.2022.115386
Received 24 March 2022; Received in revised form 10 June 2022; Accepted 16 September 2022
Available online 21 September 2022

attention to the importance of thinking about places and spaces and their specific historical circumstances in our understandings of the uneven distribution of medicines in different parts of the world. I offer a novel approach to trace what I call antibiotic geographies, by analysing international trade data on antibiotics from publicly available databases and resources, combined with a secondary literature review. Thinking through antibiotic geographies highlights how antibiotics are highly mobile objects as part of international trade, but also that their mobilities are shaped by social and material histories of places and their relations.

Often called 'the World's pharmacy', India has the third largest pharmaceutical industry in the World in terms of volume and tenth largest in terms of value. India is the largest provider of generic drugs globally, accounting for about 20% of global exports in generics (not specified whether this is in terms of value or volume; Department of Pharmaceuticals, 2020a). The country's generic industry is known for its contribution to lowering prices on medicines and increasing access internationally (Löfgren, 2017) – the most famous case being that of generic antiretrovirals for the treatment of HIV. The foundation of India's generic industry has largely been attributed to the country's abolition of product patents and shift to process patents on pharmaceuticals in the 1970s, allowing production of generic versions of patented drugs through 'reverse-engineering'. These conditions changed in 2005 with the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) of the World Trade Organization (WTO), requiring India to reintroduce product patents on pharmaceuticals on a twenty-year term. However, as most antibiotics were discovered before the 1960s, they were already off-patent before TRIPS. This new patent regime did therefore not directly impact the production of antibiotics.

Many studies have covered different aspects of India's pharmaceutical industry (e.g., Chaudhuri, 2005; Halliburton, 2017; Joseph, 2016; Löfgren, 2017), but hardly any studies have focused specifically on India's antibiotic industry, with a few exceptions on the early history of penicillin production (Tyabji, 2004) and on environmental pollution from antibiotic factories (e.g., Bengtsson-Palme et al., 2014). Research on antibiotic pharmaceutical industries has generally been dominated by perspectives from the global North, with studies covering the history of antibiotic production, marketing and regulation in the U.S., Germany and the U.K. (e.g., Bud, 2007; Gradmann, 2016; Kirchhelle, 2020; Podolsky, 2015). In this article, I challenge the Western centric perspective in previous research, by providing novel insights into India's antibiotic industry. Existing knowledge on Indian antibiotic exports has so far only been anecdotal, for instance in reports from EPHA (2016) and WHO (2018). This article therefore fills an important knowledge gap by analysing historical and up-to-date data on India's trade in antibiotics.

2. Materials and methods

To study India's role as a global exporter of antibiotics, I used international trade data from three publicly available databases and resources. Data was used descriptively to analyse antibiotics trade in value and in share of total value, as well as the destinations and sources for exports and imports of antibiotics over time. A secondary literature review was also conducted as part of the research, including academic and grey literature (e.g., reports, working papers, government documents) on the history and current status of India's pharmaceutical and antibiotic industry.

2.1. Classification and definitions

Understanding how medical products are categorised in international trade data requires some work. When products cross borders through regular trade, they are usually recorded in trade registers using the international nomenclature referred to as the Harmonized System (HS) developed by the World Customs Organization (WCO). The categories of this system are named and structured based on the history, logics and laws of international trade and industry, and contains more than 5000 commodity groups, which are divided in 21 sections and 97 chapters. Products are usually identified by a six-digit code (WCO, n.d.).

To my knowledge, there are no previous studies that have investigated the global flows of antibiotics based on the use of international trade data. To decipher how antibiotics are classified in the HS nomenclature, I therefore collected information from the WCO's website, WTO's Pharma Agreement, WTO (2012), GOV.UK (2015), and from conversations with a supply chain manager and a chemist working in the pharmaceutical industry. The categories used are old and not always obvious to the present-day reader. The results are summarised in Fig. 1, showing that HS's chapter 29 (heading 2941) and chapter 30 (heading 3003 and 3004) cover different antibiotic products. The figure also illustrates how antibiotic products may be divided into two main categories: antibiotic ingredients and antibiotic medicines. I use 'antibiotic ingredients' in this article to refer to what is often called either Active Pharmaceutical Ingredients (APIs), raw chemicals, key starting materials or bulk drugs. Antibiotic ingredients are the active substances used in producing antibiotic medicines, together with excipients. When using the term 'antibiotic medicines' in this article, it refers to what is often called formulations, which are mixed medicines prepared for therapeutic or prophylactic uses that are exported either in doses or packings for retail sale or in bulk without packaging. Antibiotic medicines are usually classified in the HS as pharmaceutical products under chapter 30, while antibiotic ingredients are classified as organic chemicals under chapter 29 and HS heading 2941. Antibiotic medicines are further divided into two main sub-categories in customs: (1) penicillins, streptomycins and their derivates, categorised under HS heading 3003.10 (not in doses/packing) and 3004.10 (in doses/packing), and (2) other types of antibiotics, categorised under HS heading 3003.20 (not in doses/packing) and 3004.20 (in doses/packing). This categorisation probably reflects the history of antibiotic production, as penicillins and streptomycins were two of the first antibiotics to be mass produced and exported. There is no distinction between antibiotics for human and animal use in the HS, and I therefore assume that both are included under the mentioned headings.

The way antibiotics are categorised has implications for how to analyse the globalisation of antibiotic production and the flow of antibiotic materials between countries. While some countries, such as India, have specialised in the production of medicines, other countries are leaders in manufacturing pharmaceutical ingredients, for instance China. There are many factors influencing this division, such as the technologies, materials, skills, infrastructures, finances and government support required in manufacturing, business and trade operations. The landscape of antibiotic manufacturing in India consists of companies producing both antibiotic ingredients and medicines, according to Gandra et al. (2017). I therefore include trade data on both in this article.

2.1. Data sources, collection and analysis

I started data collection by compiling annual data on India's antibiotic exports from the Government of India's Export Import Data Bank, presenting data collected by The Directorate General of Commercial Intelligence and Statistics (DGCI&S) according to the recommendations of the United Nations Statistical Division (UNSD). This data bank provides HS commodity-wise, country-wise and region-wise monthly and annual import and export figures in monetary value and quantity for India. Value is recorded in Indian Rupees (INR) and US dollars (USD), and conversion is done using the average monthly exchange rate as provided by the Reserve Bank of India (DGCI&S, n.d.). Annual data is presented according to India's fiscal year system, which starts from 1st April and ends on 31st March. I collected commodity-wise data on India's annual exports between 1996-1997 and 2018–2019 using the HS codes on antibiotics mentioned above. I recorded the values manually from the website into Excel, as datasets were not available for direct

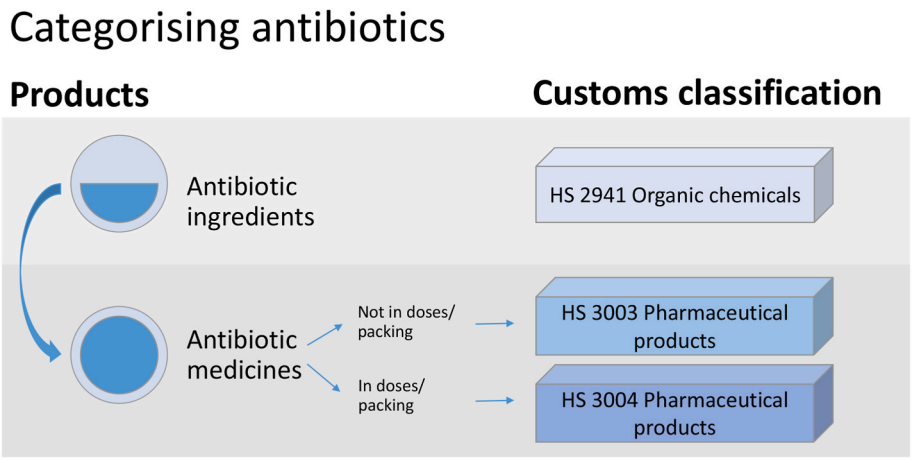

Fig. 1. Categorisation of antibiotic products in manufacturing and trade as used in this article. Illustration by author.

download. After the collection of data, I could calculate the total annual value of all antibiotics exported by adding all HS codes, and the total value of antibiotic medicines exported by adding 3003 and 3004 codes.

As I expanded my research on India's trade in antibiotics, I found two additional online resources that provide international trade data sets for download and visualisation. The Trade Map of the International Trade Centre (ITC) was used to collect and visualise data on other countries' trade in antibiotics with India. For data and visualisations comparing India's share of global trade in antibiotics with other countries, I used the Tree Map tool of the Observatory of Economic Complexity (OEC). Data from both these resources are mainly based on UN Comtrade, the world's largest database of trade statistics maintained by the UNSD and based on trade data submitted by national statistic agencies, enabling cross-country analysis of trade. OEC and ITC provide commodity-wise and country-wise annual import and export figures for all countries in USD value, and ITC also provides figures in quantity and unit value. Commodity values are in UN Comtrade converted from the national currency into USD using exchange rates supplied by the reporter countries, or derived from monthly market rates and volume of trade (UNSD, 2021).

I collected commodity-wise and country-wise data on India's annual exports and imports between 2001 and 2019 from ITC's Trade Map, using the same HS codes as above. I downloaded the datasets directly from their website and used these to create figures as presented in this article. I collected commodity-wise and country-wise data on countries' share of antibiotic exports and imports in per cent through OEC's Tree Map tool. The tree maps presented in the appendix of this article were created directly through the OEC's website for download (used in this article with permission).

For the analysis, the data collected was used in a descriptive manner to analyse trends, patterns and features central to India's antibiotic industry and India's exports and imports of antibiotics. I use monetary value (USD) as an indicator of trade throughout, and not quantity (volume in kilogram) or unit value (price per kilogram). This is because the antibiotic products I analyse are heterogenous in their physical characteristics, i.e., tablets, capsules, syrups, powders, creams, ointments or liquids, in bulk or in doses with excipients added. Working with volume or unit value was therefore not found relevant in this study.

Table 1
India's annual export of antibiotic ingredients and medicines, value in million USD. Compiled by author based on data from the Government of India.

Fiscal year	Antibiotic ingredients	Antibiotic medicines not in doses/packings		Antibiotic medicines in doses/packings		Total
	HS 2941 Antibiotics	HS 300310 Penicillins, streptomycins and deriv.	HS 300320 Other antibiotics	HS 300410 Penicillins, streptomycins and deriv.	HS 300420 Other antibiotics	
1996–1997	107.14	0.88	2.09	76.18	81.72	268.01
1997–1998	102.75	3.6	0.47	80.13	79.61	266.56
1998–1999	135.05	0.76	0.34	72.07	81.28	289.50
1999–2000	150.09	0.43	0.82	73.13	104.86	329.33
2000–2001	177.41	3.76	1.36	81.31	112.84	376.68
2001–2002	186.14	4.71	6.58	85.88	100.98	384.29
2002–2003	256.68	6.31	18.95	77.23	150.55	509.72
2003–2004	301.35	14.26	42.09	91.63	161.61	610.94
2004–2005	236.43	17.56	125.49	117.09	213.13	709.70
2005–2006	309.52	10.3	52.12	160.93	301.99	834.86
2006–2007	330.81	12.81	62.81	171.73	378.42	956.58
2007–2008	572.62	22.98	108.35	215.27	607.06	1526.28
2008–2009	581.82	26.62	145.8	243.55	763.08	1760.87
2009–2010	702.67	53	102.78	220.99	547.71	1627.15
2010–2011	721.47	67.57	116.87	312.44	653.15	1871.50
2011–2012	899.77	32.22	30.16	333.93	885.15	2181.23
2012–2013	889.23	18.89	9.97	379.28	857.36	2154.73
2013–2014	887.51	11.31	9.61	552.48	847.13	2308.04
2014–2015	860.17	7.81	20.1	573.41	924.44	2385.93
2015–2016	828.43	2.75	17.28	416.62	972.31	2237.39
2016–2017	827.3	3.97	14.83	407.16	960.26	2213.52
2017–2018	840.92	4.19	9.74	445.54	942.23	2242.62
2018–2019	879.19	2.37	8.39	519.8	1040.13	2449.88

3. Results: tracing India's pharmaceutical industry in antibiotic geographies

3.1. Value of India's antibiotic exports

The results presented in Table 1 shows that the export of antibiotics from India has seen a tremendous growth over the last two decades. In the fiscal year of 2018–2019, India exported antibiotic ingredients and medicines for a value of 2.4 billion USD, compared to 268 million USD in 1996–1997. According to the Indian Department of Pharmaceuticals (2020a), India's total export of medicines and medical devices towards the end of the last decade stood at around 20 billion USD (not specified whether this includes pharmaceutical ingredients). This indicates that antibiotics today constitute a substantial share of Indian pharmaceutical exports, at around 12% of total exports.

The annual growth of total antibiotic exports since 1996–1997 is further illustrated by Fig. 2. It shows that the largest increase in antibiotic exports from India occurred from the middle of the 2000s, in the decade following the completed integration of TRIPS into India's patent laws and policies, as this was gradually integrated from 1995 to 2005. The total export of antibiotics from India increased from 710 million USD in 2004–2005 to 2.4 billion USD in 2014–2015.

The detailed results covering each antibiotic category from Table 1 are visualised in Fig. 3. It shows that the largest share of antibiotic exports from India in recent years have been in the category of formulated medicines, and that this is the segment of Indian antibiotics export with the highest growth rate over the last two decades. In 1996–1997, India exported antibiotic medicines in doses/packings to the world for a value of 158 million USD. In 2018–2019, this number had grown to almost 1.6 billion USD. In the case of antibiotic ingredients, the exported value increased from 107 million in 1996-97 to 879 million USD in 2018–19. This means that around two-thirds of the value of antibiotic exports from India today are formulated medicines.

3.2. India's share of global antibiotic exports

My analysis of data from the OEC shows that India was the world's biggest exporter of the oldest types of antibiotic medicines in the category of penicillins, streptomycins and derivates in doses, and also one of the biggest global exporters of other antibiotic medicines and antibiotic ingredients in 2019. India's export of antibiotic medicines in doses accounted for over 13% (penicillins, streptomycins and derivates) and 7% (other antibiotics) of the total global exported value in 2019. In the same year, India also accounted for around 7% of the antibiotic ingredients exported globally. Fig. 4 compares India's share of global antibiotics exports in value with China, known to be another major exporter of antibiotic ingredients (WHO, 2018). It shows that of the two, India was the biggest exporter of antibiotic formulations in 2019, while China dominated in the export of antibiotic ingredients. See the Appendix Fig. 12, Fig. 13 and Fig. 14 for a visualisation of the results including other countries than India and China.

3.3. Destinations for Indian antibiotics export

Tracing the geographical distribution of India's antibiotic exports, it becomes clear that a major share of the antibiotic medicines that are manufactured in India are exported to countries in the global North, such as the United States (US). The US was the single largest destination for Indian antibiotic exports in 2019 in terms of exported value. Fig. 5 shows that the US imported 25% of the penicillins, streptomycins and derivates and as much as 41% of the other antibiotics medicines in doses exported from India that year, in terms of value. Several European countries are also on the list of top importers, including the United Kingdom (UK), Germany, France, Belgium and Malta, as well as Russia. For instance, 5% of the exported value from India in the penicillin category was shipped to the UK in 2019. At the same time, countries in the global South also increasingly important destinations for antibiotics exported from India. In 2019, India was a major supplier of antibiotic medicines to Nigeria and South Africa, as well as to Asian countries such

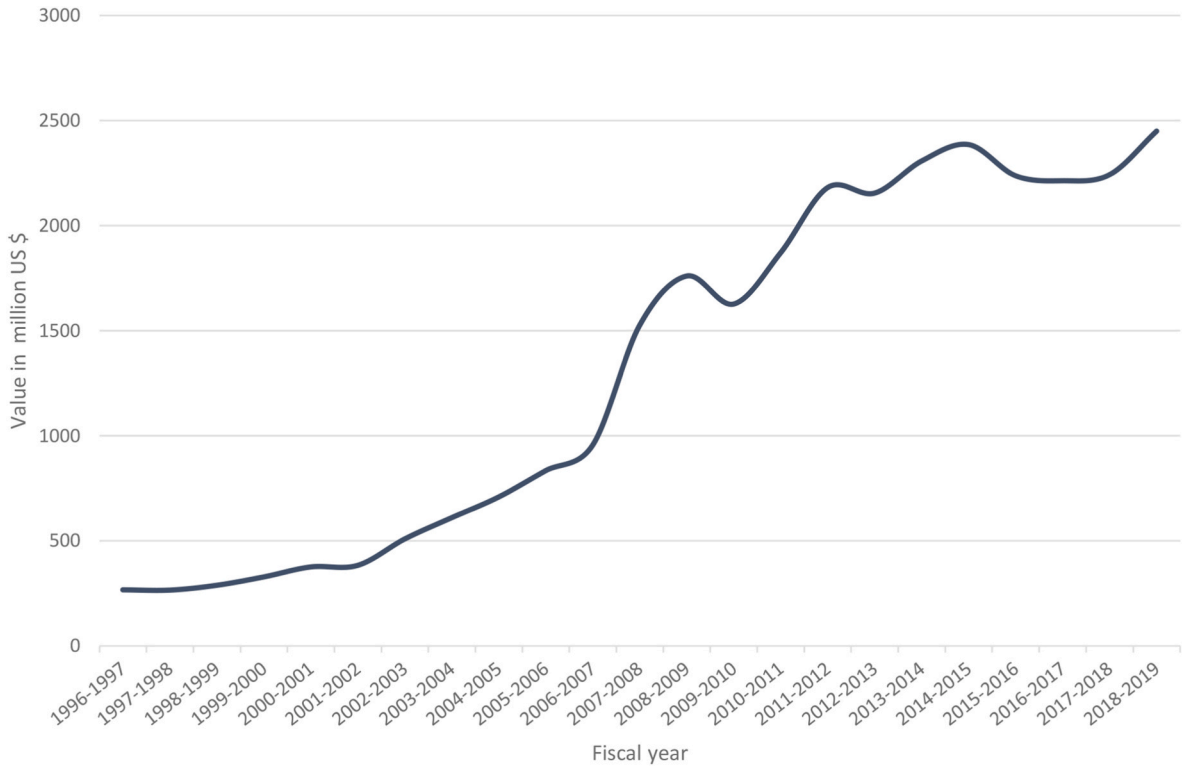

Fig. 2. Trend in India's total annual export of antibiotics medicines and ingredients. Compiled by author based on data from the Government of India.

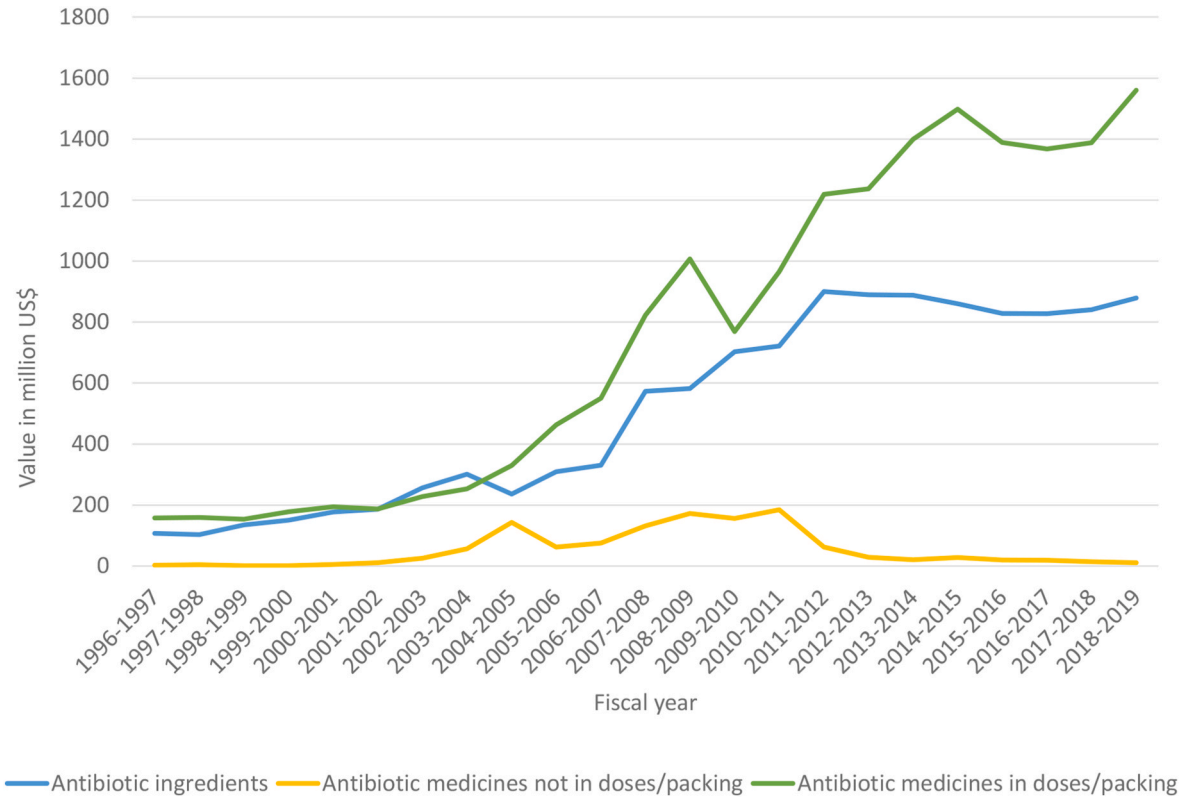

Fig. 3. Trends in India's annual export of antibiotic ingredients and medicines by category. Compiled by author based on data from the Government of India's Export Import Data Bank. (For interpretation of the references to colour in this figure legend, the reader is referred to the Web version of this article.)

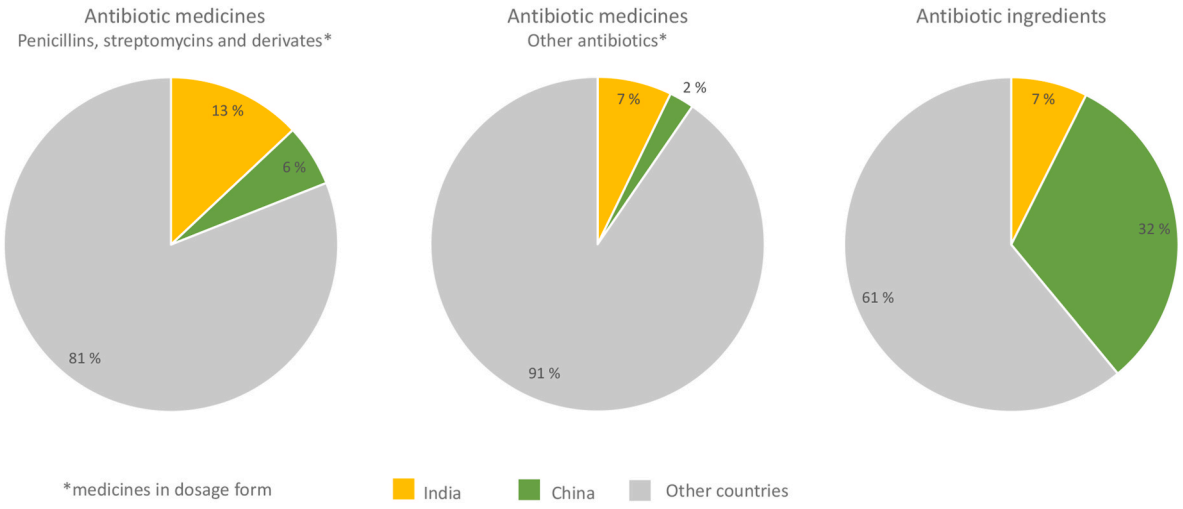

Fig. 4. India's and China's share of global antibiotic exports in 2019 by category, in per cent of USD value. Compiled by author based on OEC data, https://oec.world/. (For interpretation of the references to colour in this figure legend, the reader is referred to the Web version of this article.)

as the Philippines, Vietnam, Myanmar and Nepal. 3% of India's exported value of antibiotic medicines in both categories was imported by South Africa, while 4% (penicillins, streptomycins and derivates) and 2% (other antibiotics) was imported by Nigeria.

Trends in exports of antibiotic medicines from India to the top importing countries are illustrated in the figures that follow. As the relative value of India's exports to the US is very high compared to other countries, I present it in a separate figure (Fig. 6). For comparison, the trend in exports to the UK is also included in this figure, as it was the second largest importer of antibiotics (penicillins and streptomycins) from India in 2019. Fig. 6 shows the extensive growth of India's export to the US, in which the total export of antibiotic medicines in doses expanded from a value of 14 million USD in 2001 to 584 million USD in 2019. While the same numbers for the export to the UK seem very small compared to the US, as also illustrated in Fig. 6, India still recorded an export growth from almost 2 million in 2001 to a total of 39 million USD to the UK in 2019. Trends in antibiotic exports from India to other top importing countries, excluding the US, are found in Fig. 7 and Fig. 8. It shows a period of overall export growth between 2001 and 2019.

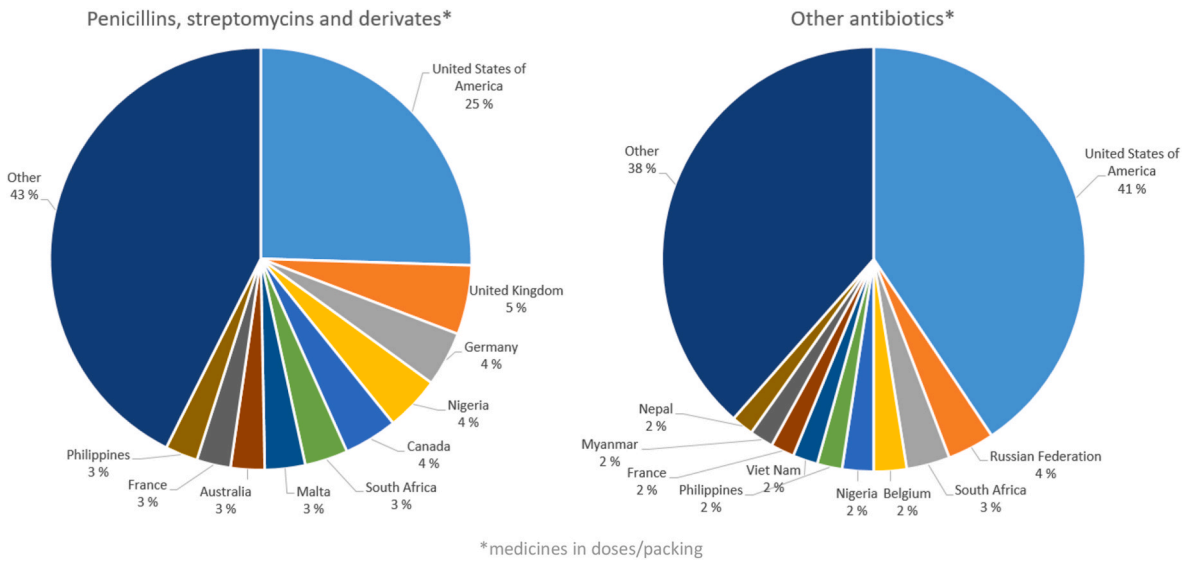

Fig. 5. Top ten importers of antibiotic medicines exported by India in 2019, in per cent of USD value. Compiled by author based on data from Trade Map, International Trade Centre, www.trademap.org.

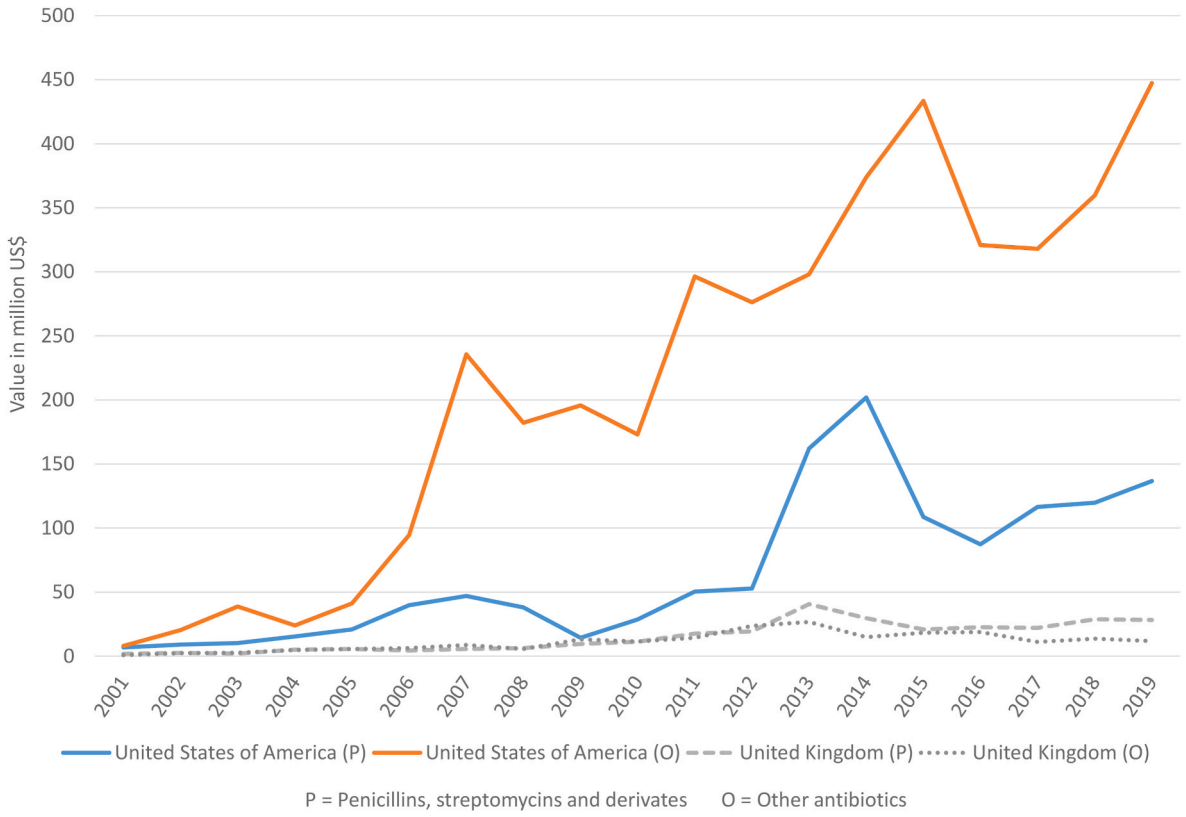

Fig. 6. Trends in India's export of antibiotic medicines in doses to the US in comparison to the UK. Compiled by author based on data from Trade Map, International Trade Centre, www.trademap.org. (For interpretation of the references to colour in this figure legend, the reader is referred to the Web version of this article.)

3.4. India's share of antibiotics imports in selected countries

To understand the role of India's pharmaceutical industry for global trade in antibiotics, I also analysed different countries' share of Indian antibiotics as part of their total antibiotic imports. For the scope of this article, I selected 9 example countries based on a list of the largest importing markets for antibiotic medicines exported by India. The list was made by sorting countries based on their total imported value of antibiotic medicines in doses from India in 2019 (see Table 4 in the Appendix). The three largest importing countries from the three major regions for Indian antibiotics exports (North America & Europe, Africa and Asia) were then selected as examples to be analysed further. Countries for which direct trade data from the ITC's Trade Map tool was unavailable or largely incomplete were skipped (Nigeria, Nepal, Myanmar, Iraq and Yemen). The countries finally selected are presented in Table 2. This does not provide a representative sample, but a few

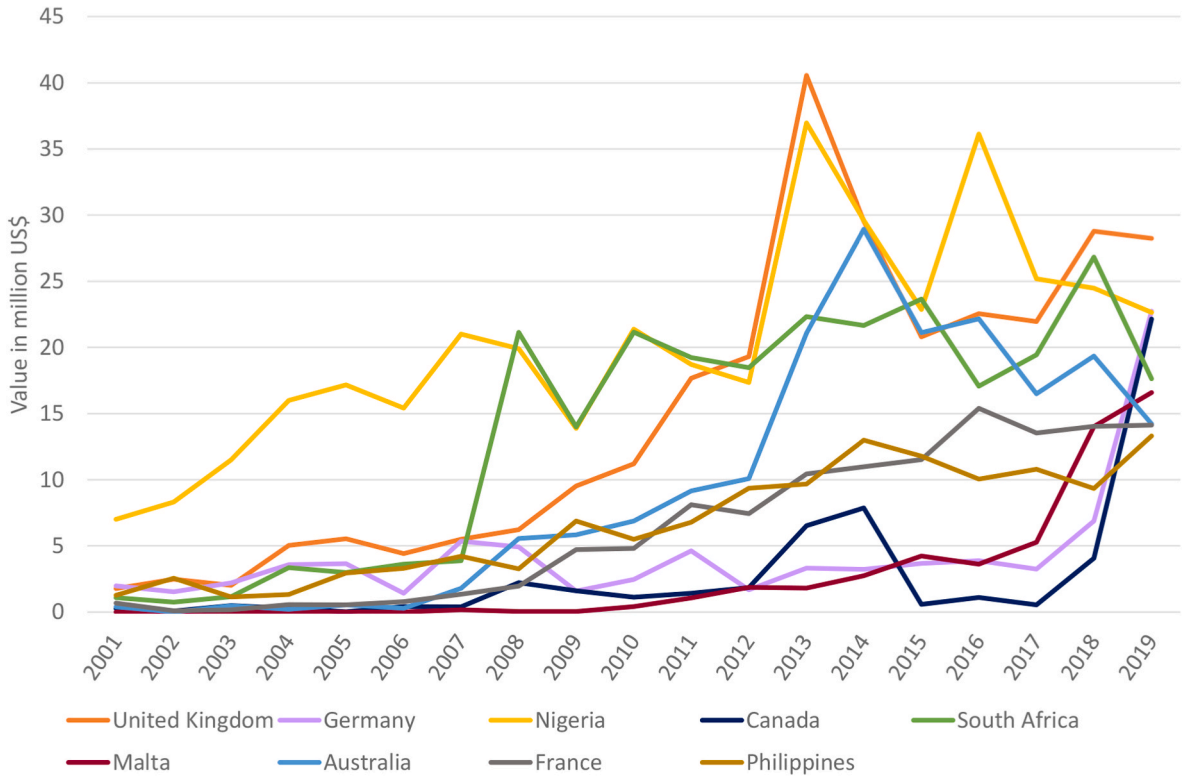

Fig. 7. Trends in India's export of antibiotic medicines to top importing countries excl. the US: Penicillins, streptomycins and derivates in doses. Compiled by author based on data from Trade Map, International Trade Centre, www.trademap.org. (For interpretation of the references to colour in this figure legend, the reader is referred to the Web version of this article.)

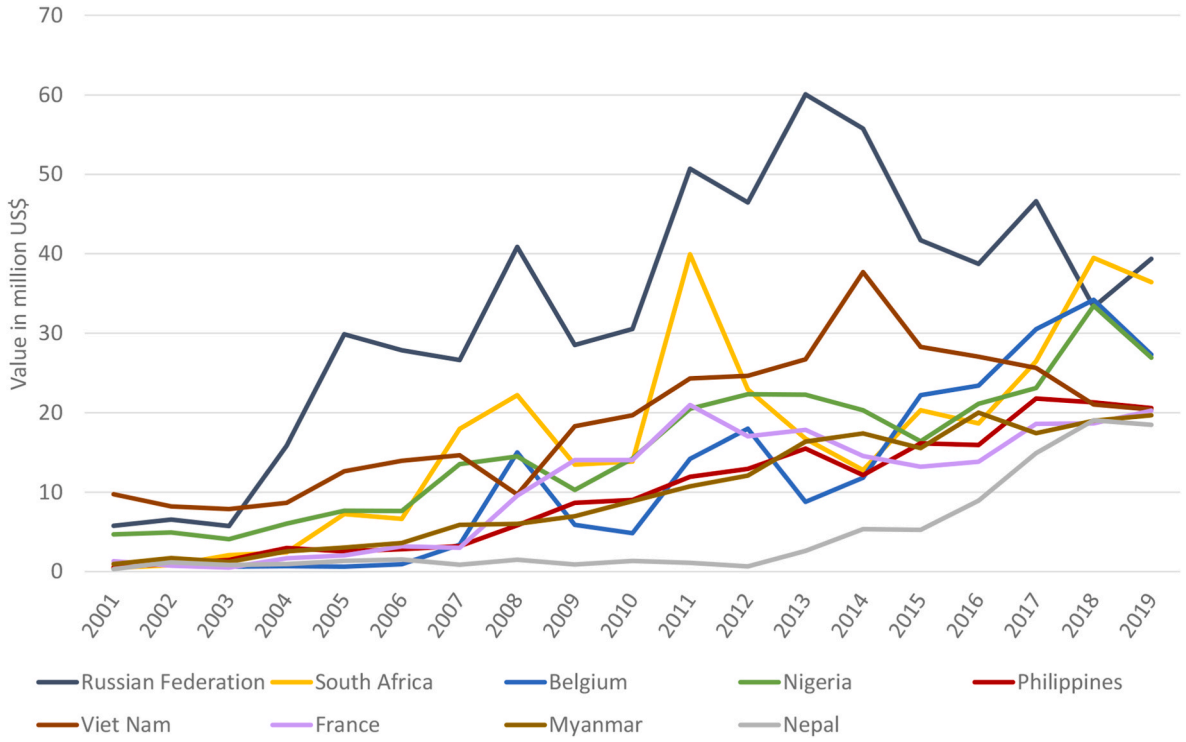

Fig. 8. Trends in India's export of antibiotic medicines to top importing countries excl. the US: Other antibiotics in doses. Compiled by author based on data from Trade Map, International Trade Centre, www.trademap.org. (For interpretation of the references to colour in this figure legend, the reader is referred to the Web version of this article.)

Table 2
Selected countries for analysis. Compiled by author based on data from Trade Map, International Trade Centre, www.trademap.org and The World Bank (income classification).

Importing country	Import of antibiotic medicines from India in 2019 (USD thousand)	Region	Direct data availability from ITC Trade Map tool, 2001–2019	Income classification 2019
United States	584,176	North America & Europe	Available	HIC
Russian Federation	43,017	North America & Europe	Available, but missing detailed trade data on imports from Belarus (2001–2011) and Kazakhstan (2010–2011)	UMIC
United Kingdom	39,985	North America & Europe	Available	HIC
South Africa	54,054	Africa	Available	UMIC
Uganda	28,490	Africa	Available	LIC
Tanzania, United Republic of	28,383	Africa	Available	LMIC
Philippines	33,890	Asia	Available	LMIC
Viet Nam	23,676	Asia	Available	LMIC
Sri Lanka	16,215	Asia	Available for 2001–2017 and 2019	LMIC

interesting examples of major trading partners of India in different locations, including both high income (HIC), upper and lower middle income (UMIC and LMIC) and low income countries (LIC).

The result from the analysis of these countries' import data is presented in Fig. 9. It shows that, of the selected top importing countries, it is the UK which throughout the period has been least reliant on imports of antibiotic medicines from India. 2% of the total value of antibiotic medicines in dosage imported to the UK in 2019 came from India. However, the other HIC included in this analysis, the US, had a much higher dependency on antibiotic medicines from India. 22% or over one fifth of the value of all antibiotic medicines in dosage form imported to the US in 2019 came from India, with the share reaching its peak in 2014 at 32%. Another interesting observation from Fig. 9 is that Sri Lanka, Uganda and Tanzania all have a very large share of their antibiotic medicines imported from India. Although there was a dip in the years around 2015, the trend now seems to be moving upwards, with Uganda importing 66% and Tanzania importing 58% of their antibiotic medicines in value from India in 2019. The other African country included in this analysis – South Africa – has throughout the period had a much lower share of their antibiotic medicines imported from India, but still reaching a 12% share of the total value in 2019.

3.5. *India's export and import of antibiotic ingredients*

What also emerges from exploring the trade data, is that the Indian antibiotic industry is a supplier of antibiotic ingredients to other pharmaceutical industries, mainly located in Asia but also in Europe. Fig. 10 shows that, in 2019, the top four destinations for antibiotic ingredients export from India were all located in Asia, i.e., Bangladesh, China, Turkey and Vietnam, and there has been a larger growth in export to

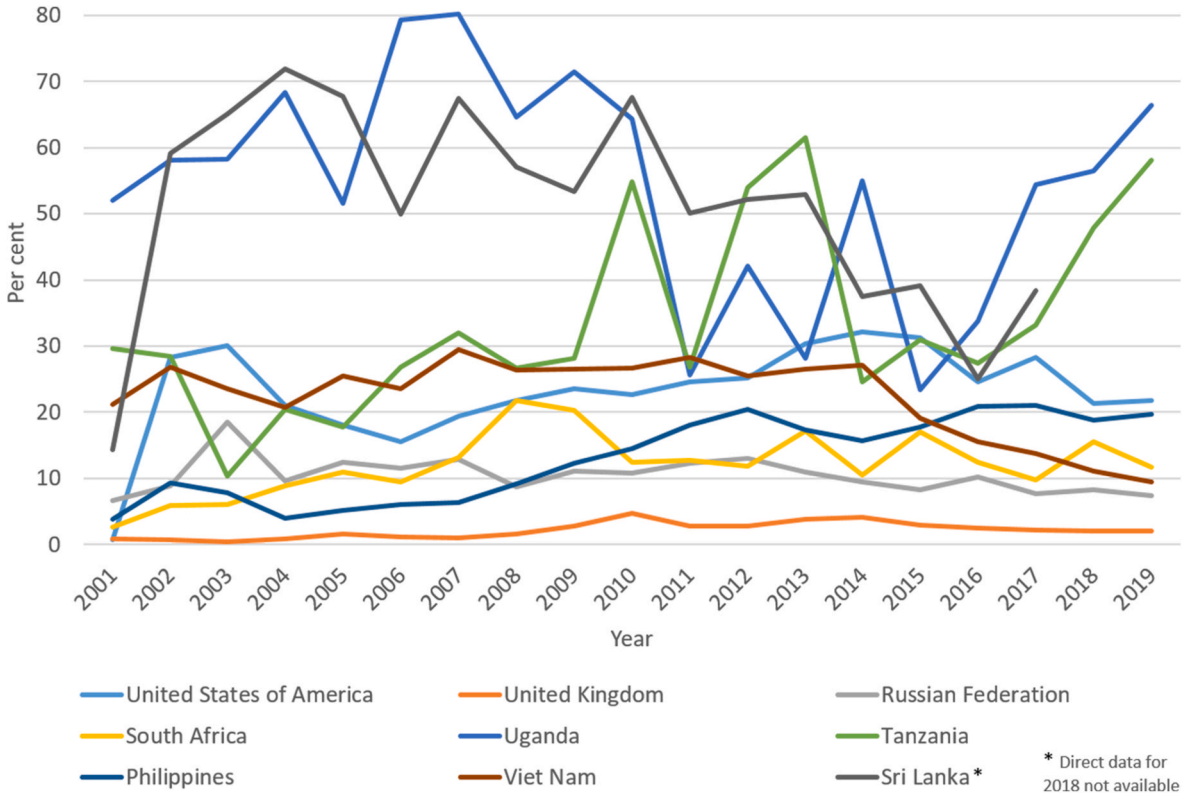

Fig. 9. Trends in Indian antibiotic imports as a share of countries' total import of antibiotic medicines in doses, per cent of USD value. Compiled by author based on data from Trade Map, International Trade Centre, www.trademap.org. (For interpretation of the references to colour in this figure legend, the reader is referred to the Web version of this article.)

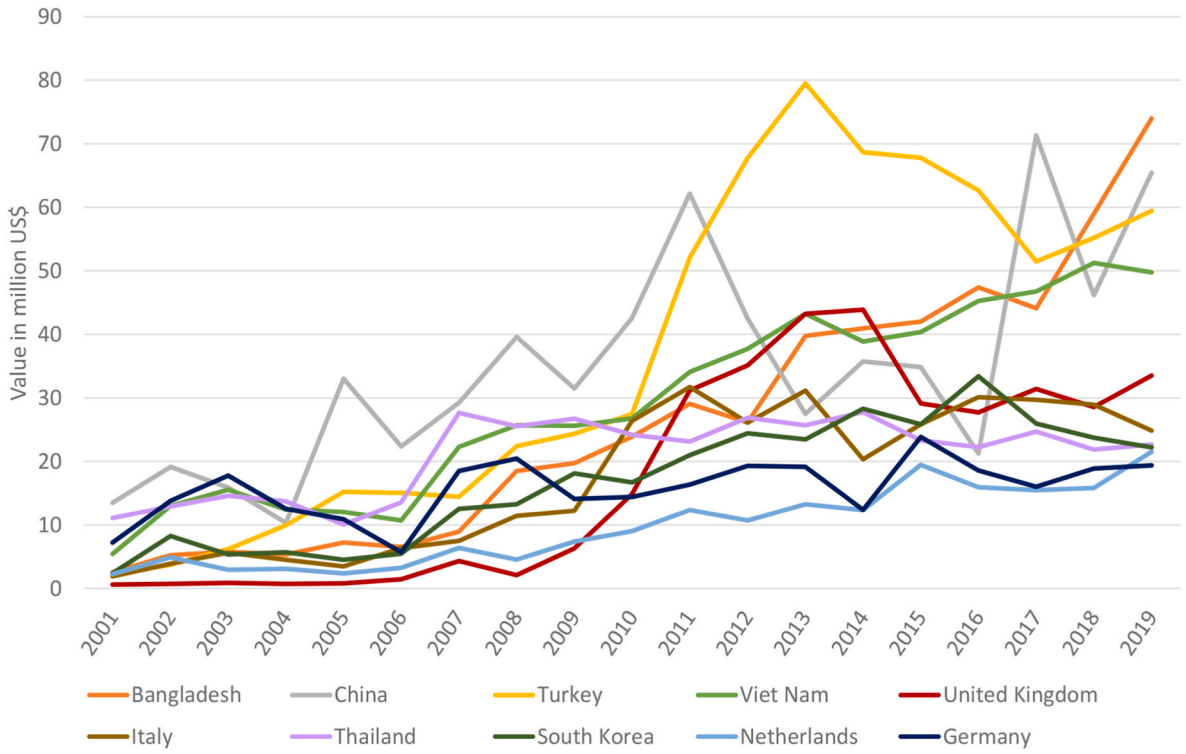

Fig. 10. Trends in India's export of antibiotic ingredients to top importing countries. Compiled by author based on data from Trade Map, International Trade Centre, www.trademap.org. (For interpretation of the references to colour in this figure legend, the reader is referred to the Web version of this article.)

these countries during the last two decades as compared to many of the European destinations for Indian antibiotic ingredients.

When observing the exported value of antibiotic ingredients from India as compared to the export from China to India, it becomes clear that it is China that today holds the leading position in this part of the global antibiotic value chain and that India today is highly dependent on import of antibiotic ingredients from China. Table 3 presents the import figures from the top 10 exporting countries of antibiotic ingredients to India in 2019, as compared to the value of imports from the same countries in 2001. It shows that there has been an enormous growth in Chinese exports of antibiotic ingredients to India during this period. The share of antibiotic ingredients imported from India to China increased from an already high share of 40% in 2001 to 80% in 2019, or from around 65 million USD in 2001 to over 1 billion USD in 2019.

Table 3
India's import of antibiotic ingredients by exporting country in 2001 and 2019. Compiled by author based on data from Trade Map, International Trade Centre, www.trademap.org.

Exporters	Imports in 2001		Imports in 2019	
	Value (USD thousand)	Share (%)	Value (USD thousand)	Share (%)
China	64,728	40	1,078,846	80
United States	10,209	6	31,491	2
Italy	7081	4	31,389	2
Hong Kong, China	194	0	27,433	2
Spain	1559	1	22,902	2
Mexico	1791	1	19,369	1
United Kingdom	8887	6	17,851	1
Denmark	1165	1	17,841	1
Korea, Republic of	4425	3	16,354	1
Slovenia	1773	1	15,816	1
World	160,894	100	1,346,570	100

Trends in India-China trade in antibiotic ingredients are illustrated in Fig. 11. It shows that the export of antibiotic ingredients from India to China accounted for the comparably low figure of around 65 million USD in 2019, recording a small upward trend since 2001.

4. Discussion and conclusion

During the last decades, the centre of gravity for the global production and export of generics has shifted towards pharmaceutical industries located in Asia. The findings outlined above have provided insights into an important part of this shift, which is the emergence of India's antibiotic industry. I have shown that India's pharmaceutical industry has achieved a key role in global antibiotic geographies as one of the world's biggest exporters of antibiotics, and particularly old types of antibiotic medicines such as penicillins and streptomycins. A major share of Indian antibiotic medicines is today exported to the global North, with the US as the single largest importer in terms of value. Countries located in Africa and Asia are also major destinations for Indian antibiotic medicines and ingredients, and some of these countries have a comparably higher dependence on imports of antibiotic medicines from India. At the same time as many countries rely on India for their supply of antibiotics, the Indian industry is today highly dependent on Chinese pharmaceutical companies for supplies of antibiotic ingredients, with a massive growth in imports from China to India over the last 20 years.

The emergence of India as a major global exporter of antibiotics must be understood in light of the more general history of India's generic industry. After India became independent from colonial rule, the domestic production of pharmaceuticals became part of a nationalist industrial strategy for economic development and self-reliance. The impact of strong government interventions and support during the 1970s for the development of the industry cannot be overstated, particularly the enactment of the Indian Patents Act in 1970 with the removal of product patents and shift to only allowing process patents on pharmaceuticals. Indian companies could now legally produce 'copied'

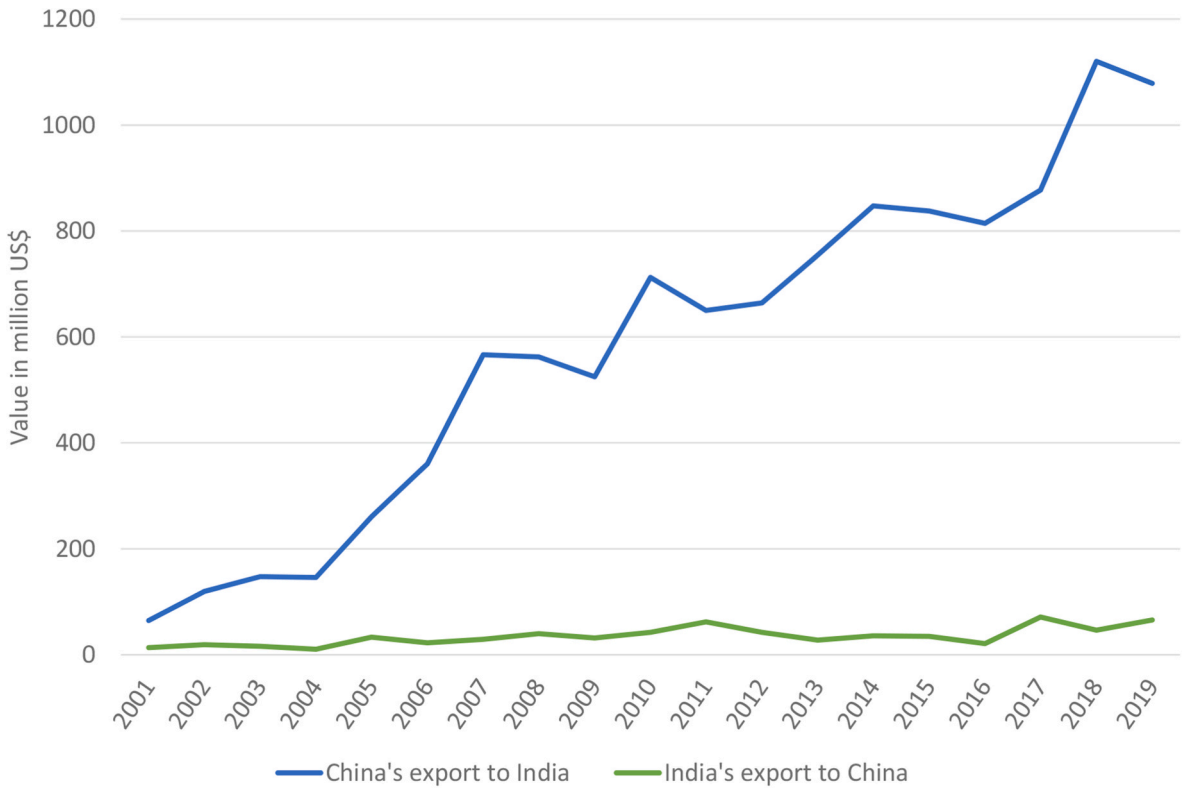

Fig. 11. Trends in China – India trade in antibiotic ingredients, 2001–2019. Compiled by author based on data from Trade Map, International Trade Centre, www.trademap.org. (For interpretation of the references to colour in this figure legend, the reader is referred to the Web version of this article.)

versions of patented drugs, as long as they developed a different process to do so. Together with the availability of public sector companies and research laboratories, private sector entrepreneurs, and a strong technological base, as well as restrictions on foreign exchange and investments, this resulted in a phase of thriving innovation and growth in the production of medicines in India (Chaudhuri, 2005).

Another important event that later facilitated the expansion of Indian generic medicines into highly profitable so-called regulated markets was the enactment of what is known as The Hatch-Waxman Act of 1984 – referred to in the US as 'the birth of the generic drug industry' (Greene, 2014, p. 86). The Act meant that producers entering the US market no longer had to repeat full clinical trials for their generics, and that they could start using the product for regulatory purposes before the patent's expiry. This greatly benefitted Indian firms who could now more easily compete with Western generic producers (Chaudhuri, 2005). Today, North America constitutes the largest market for Indian pharmaceutical exports (Pharmexcil, 2020) and India is the country with the largest number of factories approved by the United States Food & Drugs Administration (USFDA) outside the US (Joseph, 2016). It is therefore not surprising that the main destination for antibiotic medicines exported by India today is the US.

The 1990s was a period which heralded major changes in the conditions of the Indian generic industry, partly by the reversal of policies introduced in the 1970s. The liberalisation of the Indian economy from 1991 meant a turn away from public support and regulation towards market-based rules and global competition. One important reform during this period was that restrictions to limit the domestic sector's use of imported pharmaceutical ingredients were removed (ibid.). This may partly explain the enormous growth in imports of antibiotic ingredients from China to India over the last two decades. Without public policy support for the domestic Indian bulk drug industry, India was no longer in a good position to compete with China's comparative advantage in the production of low-cost antibiotic ingredients. Public subsidies and more advanced fermentation technologies are according to Joseph (2016) some of the comparative advantages of Chinese API producers.

In the 1990s and 2000s, it was feared that the implementation of WTO's TRIPS would hamper the growth of India's generics industry as well as reduce the access to vital medicines in India and other countries (Löfgren, 2017). India implemented the TRIPS amendments to its patent law in 2005, reintroducing product patents on pharmaceuticals on a twenty-year patent term. As most antibiotics were discovered before 1960, they were already off-patent by the time TRIPS was introduced. The production of antibiotics in India was therefore not directly impacted by TRIPS, but rather indirectly through the reorientation of the Indian and the international pharmaceutical industry that followed from this regulatory change. India now became a preferred outsourcing destination for foreign companies, as they no longer feared patent infringements (Dhar and Joseph, 2019; Kamiike, 2020), and since the Indian industry could produce medicines at a much lower cost and with highly developed process chemistry skills (Horner, 2014a). This development was also influenced by a crisis in the multinational pharmaceutical industry, caused by the expiry of former lucrative patents as well as the difficulty of finding new chemical entities for producing medicines. Many foreign MNCS therefore entered the generics sector through outsourcing in order to cut costs and sustain growth (Joseph, 2016).

Contrary to some expectations, the Indian pharmaceutical industry therefore experienced a steady growth post-TRIPs (Horner, 2014b; Joseph, 2016). This is also reflected in the results of this study, showing a major growth in antibiotic exports following this period. At the same time, several researchers have commented that is likely that the introduction of TRIPS led to an increased focus on high income countries' needs at the cost of access to medicines both in India and other low and middle income countries (Chaudhuri, 2012; Löfgren, 2017). Indian manufacturers were increasingly producing generics and other medicines for more profitable markets, such as the US. At the same time, it is important to note that countries located in Africa today constitute important markets for the Indian pharmaceutical industry. Africa is the

second largest region for Indian pharma exports, accounting for around 17% of total Indian pharmaceutical exports in 2019–2020 (Pharmexcil, 2020). As this article has shown, African countries are also important destinations for Indian antibiotics exports, and some of these countries are today highly reliant on India as their main source of imported antibiotics.

The role of India's pharmaceutical industry as a major global producer of antibiotics comes with both possible opportunities and important concerns for access to medicines. On the one hand, as access to antibiotics continues to be a major concern in many countries, India and its pharmaceutical industry could potentially play an important part in helping improve this situation. The history of the Indian pharmaceutical firm Cipla and its role in improving the access to HIV/AIDS medicines in the early 2000s (Zaman and Khanna, 2021), stands as an example of how Indian actors in the past have contributed to improve access to medicines in many countries through lowering prices, although of course not without self-interest (Sell and Prakash, 2004). On the other hand, the increasing dominance of Indian generics around the world, especially in Africa, may have made it even more difficult to establish or maintain robust generic domestic industries in many of these countries, as argued by Chaudhuri et al. (2010) with reference to Tanzania, and by Horner (2021) in the case of South Africa. In the new international trade regime, these countries do not have the same policy space that India had post-independence, which contributed to build a domestic pharmaceutical industry for the production of basic medicines such as antibiotics. That some countries in Africa depend on India for well over half of their imports in antibiotic medicines is potentially problematic because of risks to supply if the producer or producing country is hit by a crisis, and because prices may be inflated if only a few producers control the market – especially in countries without much drug price control.

Another major concern is India's dependency on imports of antibiotic ingredients from China. The Indian Government increasingly sees their dependence on China for APIs as a matter of national health security, also considering that China-India relations have deteriorated in recent years (Chatterjee, 2020). Recent events have also made visible how dependent global supplies of antibiotics and other generic medicines now are of well-functioning production and trade networks in Asia. When the Wuhan region of China was first affected by the COVID-19 pandemic, many factories producing APIs for export were shut down (ibid.). As a result, India reacted by restricting their own export of 26 APIs and formulations, including several antibiotics (Directorate General of Foreign Trade, 2020). Steps have recently been taken by the Indian Government to increase the country's production of APIs trough incentives for domestic manufacturing and promotion of bulk drug parks (Department of Pharmaceuticals, 2020b). It is still uncertain whether this will lead Indian producers to increase their production of antibiotic ingredients and reduce their import from Chinese suppliers, and this needs to be explored in future research.

It is also worth noting that most generic antibiotics and their ingredients, and especially the older and non-branded types, provide very low profit margins to producers because of their low market price, also causing vulnerabilities in the global supply of these medicines. Pharmaceutical companies need to have a large share of the market to be able to manufacture these medicines and ingredients with a return. This leads to market concentration that in some cases creates dependencies on only on a few producers to ensure the supply of certain antibiotics, e.g. several types of penicillin (Cogan et al., 2018). This phenomenon was illustrated in 2017, when the shutdown of a single factory in China caused a worldwide shortage of the cornerstone antibiotic piperacillin–tazobactam (Tängdén et al., 2018). More knowledge is needed to understand the functioning and effects of such dependencies in global antibiotic supply chains.

Transnational pharmaceutical industries are organisationally and technologically complex. This makes it challenging to get a comprehensive understanding of these industries without relying on long-term fieldwork. Yet, in this paper, I have offered an approach that makes it possible for health researchers to gain important insights into the globalisation of pharmaceutical industries through the use of publicly available data. This is a highly underutilised resource that makes it possible to explore trends and shifts in how various antibiotic or other pharmaceutical materials flow between countries, regions and continents – as part of what we may think of as antibiotic or pharmaceutical geographies. The approach may in future research be applied to study China's pharmaceutical industry as another important exporter of antibiotics, or to explore the global exchange of other important medicines.

There are several limitations to this paper and approach. Country-wise trade data do not always provide an accurate picture of the trade between an original country of production and a final country of consumption. As global production chains have become more complex, countries have also found it increasingly difficult to establish the origin and final destination of traded goods (Ortiz-Ospina and Beltekian, 2018). For instance, goods may be exported from country A to country B simply for (re-)packaging purposes or storage, while later being exported to country C where it is actually consumed (Athow, 2017). It is likely that this also happens with pharmaceuticals, and that certain countries work as regional distribution hubs. An additional factor that may lead to distortion in trade analysis, is that many countries do not report on re-imported or re-exported goods separately. There are also several countries that are not reporting their national trade statistics to UN Comtrade, either in periods or permanently. In such cases, 'mirror data' is created based on data reported by partner countries. These are all reason for interpreting trade data with caution, together with the possibility of recording mistakes, statistical glitches or even avoidance of recording due to tax evasions as antibiotics and trade data move across borders.

A limitation to this paper is that it does not explore in depth why some countries import more antibiotics from India compared to others. Plausible factors affecting this include epidemiological and demographic factors (e.g., population size, age and health), regulations related to the manufacturing and use of antibiotics, and factors related to geopolitics and trade. Furthermore, although volume or unit value is not found to be a relevant measure in the case of this study, a more detailed analysis of this could be useful to understand the pricing of more specific types antibiotics in different markets and how prices may be affecting trade and access. It should also be taken into account that if India's share of global antibiotic exports had been analysed using volume as a unit, the share might have been larger as compared to using value as in this article. This is because antibiotics from India are expected to be low-priced compared to for instance antibiotics produced in Europe. India's share of antibiotic exports globally and in different countries' import may therefore be underestimated. Similarly, the article does not provide data on the value of antibiotics produced and traded within the domestic market of India, and the paper can therefore only account for the role of the industry as a global exporter and importer of antibiotics. The impact of currency fluctuations on India's antibiotic trade was not systematically assesed as part of this study, but it is likely that the general depreciation of the INR against the USD since the 1990s has contributed to stimulate growth in Indian antibiotic exports.

The COVID-19 pandemic has illuminated how crucial pharmaceutical industries may be for regions or specific countries in the event of a major health crisis, and how the concentration of pharmaceutical technologies in a few companies and countries poses a major challenge to global health equity and access to vaccines and medicines. The growth of the Indian pharmaceutical industry has contributed to reduce the world's reliance on vaccines, medicines and antibiotics produced in the global North, but this has certainly not been enough to remove global inequalities in access to life-saving medical products such as antibiotics. Access to antibiotics is important because of their curative effects, but also because access to a full course of the right antibiotic can reduce the selection pressures that cause antibiotic resistance.

Accessibility of antibiotics is important both in human and animal sectors, since at least over half of all antibiotics consumed world-wide are used in livestock (O'Neill, 2015) – both to cure infections and, more problematically, to prevent infection prophylactically or to promote animal growth. More research is needed on how different markets for human and animal antibiotics function in practice and how new antibiotic geographies are shaping the access to and use of antibiotics in globalised economies and local worlds.

Data availability statement

These data were derived from the following resources available in the public domain:

- Export Import Data Bank of the Government of India, Ministry of Commerce and Industry, Department of Commerce. https://tradestat.commerce.gov.in/eidb/default.asp
- Trade Map of the International Trade Centre. Access requires registration (free). https://www.trademap.org/Index.aspx
- The Observatory of Economic Complexity (OEC). https://oec.world/en

Credit author statement

Lise Bjerke: Conceptualization, Methodology, Investigation, Writing – Original Draft and Review & Editing, Visualisation.

Funding

This work was supported by the Faculty of Medicine at the University of Oslo.

Declaration of competing interest

The author declare that there are no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

Acknowledgments

I wish to express my gratitude to Anne Kveim Lie, Heidi Fjeld and Christoph Gradmann for their comments and feedback on earlier drafts of this manuscript. This article has also benefitted from discussions with the other participants of the research project From Asia to Africa: Antibiotic trajectories across the Indian Ocean (FAR), financed by The Research Council of Norway.

Appendices

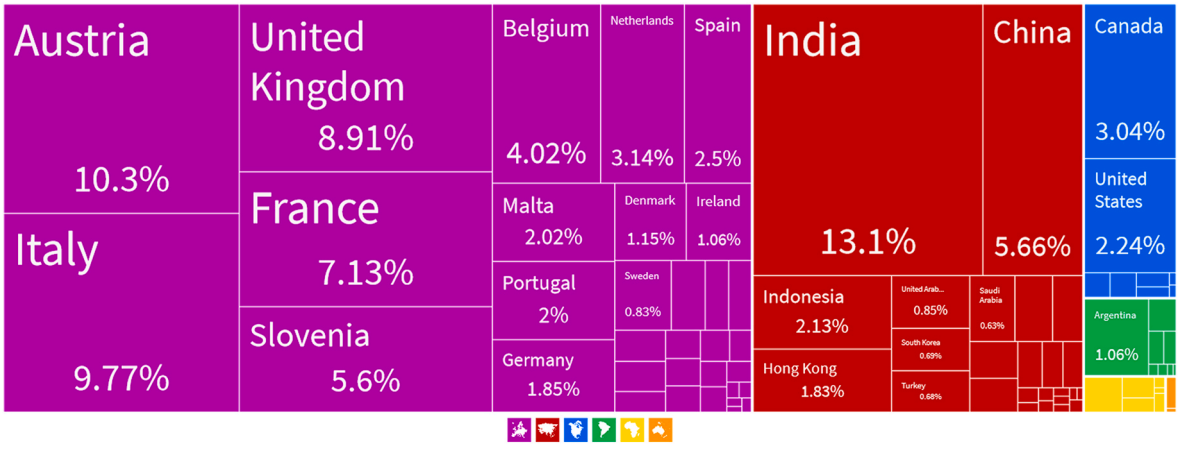

Fig. 12. Country's share of global exports in antibiotic medicines in dosage form (penicillins, streptomycins and derivates) in 2019, per cent of value in USD. Created at https://oec.world/(Simoes and Hidalgo, 2011). Used with permission. (For interpretation of the references to colour in this figure legend, the reader is referred to the Web version of this article.)

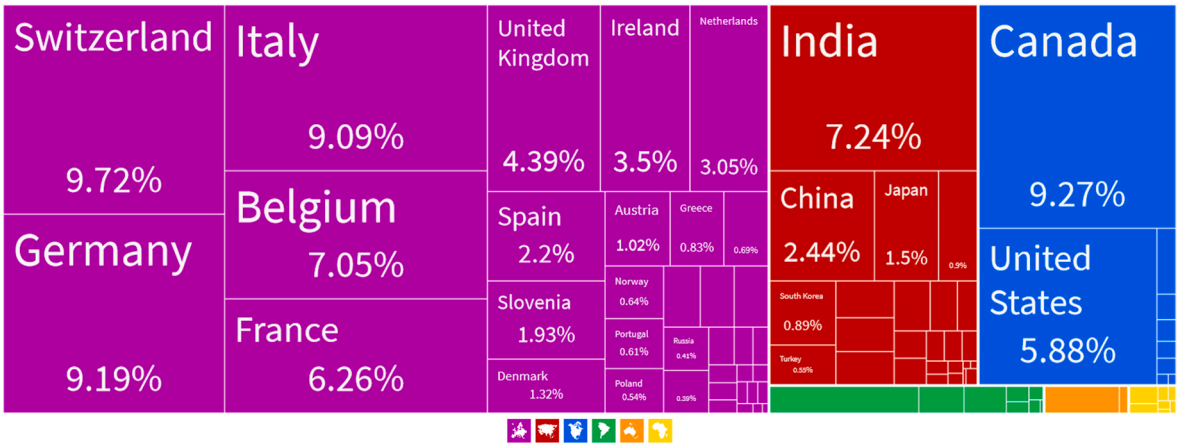

Fig. 13. Country's share of global exports in antibiotic medicines in dosage form (other antibiotics) in 2019, per cent of value in USD. Created at https://oec.world/(Simoes and Hidalgo, 2011). Used with permission. *[Print in colour]*. (For interpretation of the references to colour in this figure legend, the reader is referred to the Web version of this article.)

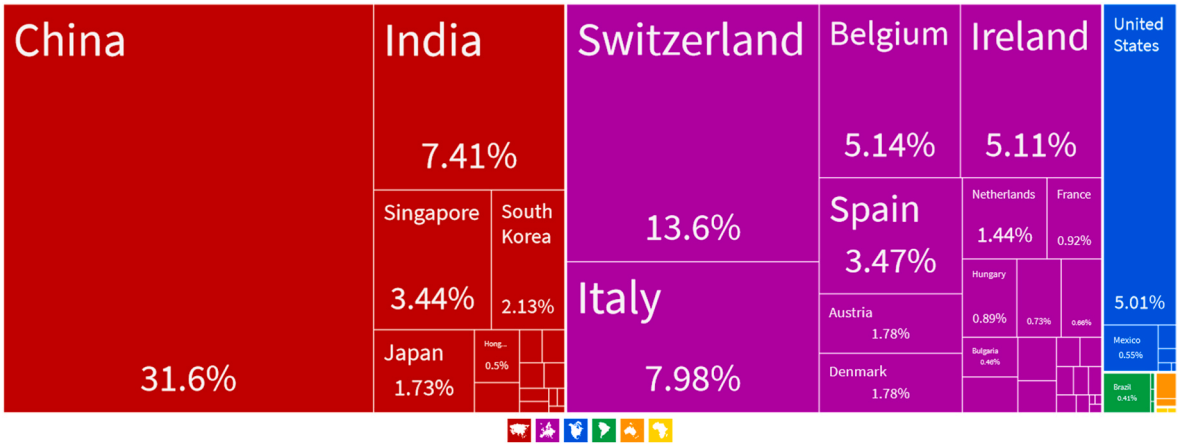

Fig. 14. Country's share of global exports of antibiotic ingredients in 2019, per cent of value in USD. Created at https://oec.world/(Simoes and Hidalgo, 2011). Used with permission. (For interpretation of the references to colour in this figure legend, the reader is referred to the Web version of this article.)

Table 4
Largest importing markets for antibiotic medicines exported by India in 2019. Compiled by author based on data from Trade Map, International Trade Centre, www.trademap.org and The World Bank (income classification).

	Importing country	Antibiotics imported from India in 2019, value in USD thousand			Region	Direct data availability from ITC Trade Map tool, 2001–2019	Income classification 2019
		HS 300410	HS 300420	Total			
1	United States	136,785	447,391	584,176	North America & Europe	Available	HIC
2	South Africa	17,628	36,426	54,054	Africa	Available	UMIC
3	Nigeria	22,650	26,928	49,578	Africa	Available, but not for download	LMIC
4	Russia	3661	39,356	43,017	North America & Europe	Available, but missing detailed trade data on imports from Belarus (2001–2011) and Kazakhstan (2010–2011)	UMIC
5	United Kingdom	28,246	11,739	39,985	North America & Europe	Available	HIC
6	France	14,135	20,250	34,385	North America & Europe	Available	HIC
7	Belgium	6658	27,308	33,966	North America & Europe	Available	HIC
8	Philippines	13,313	20,577	33,890	Asia	Available	LMIC
9	Nepal	12,272	18,480	30,752	Asia	Available for 2003 and 2009–2019	LMIC
10	Myanmar	10,643	19,686	30,329	Asia	Available for 2010–2019	LMIC
11	Uganda	10,804	17,686	28,490	Africa	Available	LIC
12	Tanzania	10,485	17,898	28,383	Africa	Available	LMIC
13	Canada	22,144	5648	27,792	North America & Europe	Available	HIC
14	Iraq	10,233	17,333	27,566	Asia	Not available	UMIC
15	Germany	22,739	2594	25,333		Available	HIC

(*continued on next page*)

Table 4 (*continued*)

	Importing country	Antibiotics imported from India in 2019, value in USD thousand			Region	Direct data availability from ITC Trade Map tool, 2001–2019	Income classification 2019
		HS 300410	HS 300420	Total			
					North America & Europe		
16	Kenya	7380	16,876	24,256	Africa	Available	LMIC
17	Vietnam	3277	20,399	23,676	Asia	Available	LMIC
18	Australia	14,220	8548	22,768	Oceania	Available	HIC
19	Brazil	7007	14,256	21,263	South America	Available	UMIC
20	Ethiopia	7800	12,776	20,576	Africa	Available	LIC
21	Malta	16,585	3828	20,413	North America & Europe	Available	HIC
22	Netherlands	4736	14,932	19,668	North America & Europe	Available	HIC
23	Yemen	4371	13,551	17,922	Asia	Available for 2004–2015	LIC
24	Sri Lanka	4926	11,289	16,215	Asia	Available for 2001–2017 and 2019	LMIC
25	Ukraine	579	13,072	13,651	North America & Europe	Available	LMIC
26	Afghanistan	3873	9463	13,336	Asia	Not available	LIC
27	Mozambique	1772	10,675	12,447	Africa	Available	LIC
28	United Arab Emirates	3101	9312	12,413	Asia	Available for 2005, 2007–2008 and 2012–2019	HIC
29	Cambodia	2989	8071	11,060	Asia	Available	LMIC
30	Thailand	7539	3471	11,010	Asia	Available	UMIC

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