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Tamara Hafner
David Popp

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ABSTRACT

As countries reform their patent laws to be in compliance with the Trade Related Intellectual Property Rights Agreement, an important question is how increased patent protection will affect drug prices in low-income countries. Using pharmaceutical trade data from 1996 to 2005, we examine the role of China and India as suppliers of medicines to other middle- and low-income countries and evaluate the competitive effect of medicine imports from these countries on the price of medicines from high-income countries. We find that imports of antibiotics and unspecified medicaments from India and China significantly depress the average price of these commodities imported from high-income trading partners, suggesting that India and China are not only important sources of inexpensive medicines but also have an indirect effect by lowering prices through competition. As India is the leading supplier of medicines in Sub-Saharan Africa, this region will likely be affected most adversely.

Tamara Hafner
Assistant Professor
Department of Public Administration and Policy
School of Public Affairs, American University
4400 Massachusetts Ave. NW
Ward Circle Building, Room 345
Washington, DC 20016
hafner@american.edu

David Popp
Associate Professor of Public Administration
Syracuse University
The Maxwell School
426 Eggers Hall
Syracuse, NY 13244-1020
and NBER
dcpopp@maxwell.syr.edu

Introduction

The World Health Organization (WHO) cites high medicine prices and the underuse of generics as a major inefficiency in national health systems (WHO, 2010). High prices can be particularly burdensome to the poor in developing countries, many of who live on less than 1 USD per day and pay for medicines and health services out-of-pocket. Approximately one third of the global population lacks reliable access to medicines because they cannot afford to purchase them (WHO, 2004). A recent study has shown that purchasing selected medicines out-of-pocket has the potential to push a significant proportion of the population into poverty (Niëns et al., 2010). High medicine prices are also a burden on government budgets, with medicines accounting for about 25% of national health care budgets in developing countries as a whole (WHO, 2003).

Generic medicines have proven to be a cost-saving alternative to more expensive branded equivalents (Lexchin, 2004). Developing countries, such as Brazil and India, have developed drug manufacturing capacity and have emerged in the last decade as important sources of inexpensive generic medicines for their domestic and regional consumers. India, for example, is often cited as the lead source of inexpensive antiretroviral medicines that have helped to revolutionize HIV/AIDS treatment in Sub-Saharan Africa. Given the anecdotal evidence regarding the importance of some of these countries as suppliers of cheaper medicines, this paper attempts a systematic evaluation of the importance of middle-income countries as suppliers of affordable medicines to other developing countries.

The issue of access to affordable medicines is particularly salient given the implementation of the Trade Related Intellectual Property Rights Agreement (TRIPS), which requires all members of the World Trade Organization to guarantee intellectual property rights protection for pharmaceuticals. Prior to the ratification of the TRIPS, many developing countries allowed very little, if any, intellectual property rights protection for pharmaceutical products (Barton, 2004).

Many countries have since reformed their patent laws to be in compliance with the TRIPS and now grant patents for new medicines (Arvind, 2004; Scherer & Watal, 2002). One possible implication of this change in patent policy is that developing countries with an active generic drug industry will be unable to continue copying innovative drugs from the developed world. This may decrease the availability of affordable drugs for poor consumers in developing countries. However, in order to fully assess the impact of such policy changes, we need to know the extent to which these countries matter as a source of medicines for developing countries.

The purpose of this paper is two-fold: it explores the role of middle-income countries, particularly China and India, as suppliers of medicines to other middle- and low-income countries; and it examines the competitive effect of drug imports from these countries on the price of medicines imported from high-income trading partners. Using the assumption that firms in developing countries are primarily involved in imitative drug production, we exploit the variation in trade with developing countries across time and pharmaceutical commodity classes to determine the price impact of pharmaceutical products exported by China and India.

The Global Pharmaceutical Market

Developing countries tend to run a trade deficit on pharmaceuticals because most countries lack manufacturing and innovative capability. They therefore depend on imports for their domestic supply of medicines. Local pharmaceutical industries in developing countries, when they exist, tend to be small and focused on the production of traditional medicines or generic medicines for domestic consumption. Some middle-income countries are an exception to that trend. Argentina, Brazil, China, Cuba, India, Mexico and South Africa, for example, have domestic pharmaceutical industries with varying levels of innovative capability (Balance, 1992). India and China are important suppliers of medicines, particularly in products such as antibiotics and ARVs that treat diseases

prevalent in developing countries. India produces both active ingredients and final products and is among the leading suppliers of antiretrovirals to developing countries. The government Pharmaceutical Organization in Thailand, for example, sources 90% of its materials for ARV production from India and produces ARVs that are up to 25 times cheaper than their branded equivalent. The Thai Public Health Ministry acknowledges that these savings would have been impossible without the Indian supply (Grace, 2004). China is also a major supplier of ingredients for antibiotics and has been ranked as the leading producer of penicillin, doxycyclin hydrochloride, cephalosporin and teramycin, producing more than 50% of the global supply (Grace, 2004). Brazil is regarded as a leader in its successful response to the HIV/AIDS epidemic which was partially facilitated by domestic production of generic antiretrovirals (Flynn, 2008). Pharmaceutical production capabilities in Africa are far less developed but the situation is likely to improve with recent initiatives by the African Union and the United Nations Industrial Development Organization (UNIDO) to strengthen local production (Berger et al., 2010). South Africa is the only country with the ability to manufacture active pharmaceutical ingredients and account for 70% of the estimated $1 billion in annual pharmaceutical production in Sub-Sahara Africa. Ghana, Nigeria and Kenya are also regional players but to a lesser extent.

The ability of these countries to develop their generic industry has been facilitated by their patent laws that, prior to TRIPS, did not allow patent protection for pharmaceuticals. India's weak intellectual property protection, for example, helped to facilitate the development of its local pharmaceutical industry (Grace, 2004; Lanjouw, 1998; Kettler & Modi, 2001; Watal, 2000). After India's 1970 patent law reforms, the government allowed patents for the manufacturing process but not the final product. This allowed companies to legally reverse engineer patented products developed in high-income countries and provide cheaper generic copies produced using a different process.

TRIPS, which was signed at the Uruguay Round of the World Trade Organization (WTO) negotiations in 1995, establishes the framework for the protection of intellectual property protection. Article 27 requires that all WTO members guarantee at least 20 years of market exclusivity for patented medicines. Brazil amended its patent laws to become TRIPS-compliant in 1996. China and India took similar steps in 1999 and 2005 respectively. The public health implications of TRIPS have been extensively discussed in the literature (see for example: Barton, 2004; Commission on Intellectual Property Rights Innovation and Public Health, 2006; Shadlen, 2007; Smith, Correa, & Oh, 2009; Trouiller et al., 2002). The issue of access to affordable medicines has gained particular attention with the primary concern being TRIPS-compliance will eliminate the supply of affordable generic medicines, in particular copies of drugs still on patent, for poor consumers in low- and middle-income countries. It is also likely that enhanced intellectual property protection will incentivize domestic firms to invest in R&D, as preliminary evidence in India suggests (Lanjouw & Cockburn, 2001). However, it is not clear whether these firms are likely to invest in products that target the health problems of the developing world or those of high-income countries. Emerging evidence suggests that TRIPS compliance has changed the incentives for Indian firms who are shifting their focus to R&D and high-income markets (Chaudhuri et al., 2010; Shadlen, 2007). The emergence of TRIPS-plus, which tends to have even more stringent requirements for intellectual property rights protection embedded in bilateral free-trade agreements, has made the potential effects of TRIPS on access to medicines even more unclear and contentious (Smith, Correa, & Oh, 2009). As such, a systematic evaluation of the role of middle-income countries as medicine suppliers is a necessary precursor in studying the impact of TRIPS on access to medicines.

Patents, Generic Competition and Medicine Prices

For most commodities, one of the most important determinants of price is the marginal cost of production. In the case of pharmaceuticals, however, variations in marginal costs are unlikely to affect the prices of drugs, particularly patent-protected branded drugs (Scherer, 2004). There are very high fixed costs associated with the discovery and development of new a new drug but the marginal costs of production are very low. The high fixed costs, which need to be recovered, dictate the price of the drug more so than the marginal costs. Danzon (1998), for example, estimated that fixed costs comprised 70% of pharmaceutical costs while manufacturing and short-run costs accounted for the remaining 30%. The fixed costs for generic drug production are much lower than those for innovative drugs because the high fixed costs associated with R&D are reduced as the innovation has already been achieved. Marginal costs are also reduced because of lower production costs for generic firms in developing countries. Generics are therefore expected to be cheaper than branded drugs, but the price for any given drug will be more strongly determined by fixed costs instead of marginal costs.

International reference pricing, a practice in which the price of a 'basket' of pharmaceutical products in one or more countries is used to set a benchmark price for the same product in a given country, is often a key determinant of medicine prices (Epsin et al., 2011). However, the method for calculating prices varies across countries depending on regulatory capabilities, the reference countries chosen and the basket of goods chosen for comparison. So even with this price benchmarking, price differentials exist both across countries and across different groups of consumers in a given country. Further, firms usually engage in price discrimination, an important factor that affects the price differences. Drug firms face two markets, one (typically in low-income countries) where consumers are price sensitive and seek the lowest cost possible, and another (typically in high-income countries) where consumers are fairly price insensitive and are willing to

pay more. While the firm may choose setting a high, uniform price to target the price insensitive consumers, more commonly, firms choose to price discriminate to capture as much of each market as possible (Ridley, 2005). Therefore prices of pharmaceuticals are expected to vary with the ability to pay across countries. There is evidence of this in the preferential pricing practices among multinational pharmaceutical firms (Lichtenberg, 2010). The least developed countries are usually sold medicines at lower prices compared to richer countries.

Intellectual property rights protection is a major incentive for innovation in the pharmaceutical industry and is a key determinant in medicine pricing. Innovative medicines with patent protection are granted limited market exclusivity within the jurisdiction of the patent, which limits the legal competition to therapeutic equivalents in a different brand. For products with no therapeutic equivalent and that are protected by a patent, the manufacturer can price the drug as high as the market will bear. Upon patent expiration, these medicines usually face competition from generic versions, which are therapeutically equivalent.

Copies of on-patented innovative drugs may also be marketed before patent expiration but the legality of these generics will vary depending on patent jurisdiction. Prior to the ratification of the TRIPS, many developing countries allowed very little, if any, intellectual property rights protection for pharmaceutical products (Barton, 2004). Many countries have since reformed their patent laws to be in compliance with the TRIPS and now grant patents for new medicines (Arvind, 2004; Scherer & Watal, 2002). Least developed countries have until 2016 to implement these changes. Given this gradual reform of the patent laws across countries, it is expected that the same drug may face different competition from generics depending on whether or not patents are allowed in a given jurisdiction. This competition is limited to the extent that the given country has local manufacturing capability and/or allows importation of generics from other countries with such capability. The local industry, where it exists, can respond to local and regional health needs to the

extent that the trade and patent laws allow the legal copying of innovative drugs. In Brazil, for example, local generic manufacturers have decreased the cost of anti-retroviral drugs by more than 70% (Samb, 2003).

The entry of generics will follow one of two price trajectories (Scherer, Anthony, & Newhouse, 2000). Initial generic entry will lead to the price of generics being slightly less than average of the brand name drugs. As more generic brands enter the market, competition develops from just generics versus branded drugs to include competition among generic brands, which may cause the average price of generics to decrease more substantially. In a developed country where consumers can afford to pay or rely on insurance coverage, the branded drug firm may find it more profitable to serve the market preferring the branded drug and maintain their high prices instead of decreasing prices to compete with generics. In the developing world, however, where there is such a high inability to pay, the branded drug firm may find it more profitable to decrease prices to compete with the generics (Danzon & Towse, 2003; Ridley, 2005).

In developing countries, concerns over TRIPS are often with drugs that are still on patent, meaning that western generic versions for those drugs are unavailable. The generic version of branded on-patent drugs are therefore likely to only be sourced from middle-income countries like India and Brazil, which up until recently did not grant patents for pharmaceutical products. The presence of generic drugs competition from these middle-income countries is therefore likely to be a chief determinant of pharmaceutical prices in developing countries. Thus, in addition to evaluating the importance of select middle-income countries as sources of medicines, another primary objective of this paper is to investigate the effect of the share of pharmaceutical imports from these countries on the price of pharmaceutical imports from high-income trading partners. A key assumption here is that the drugs marketed by developed countries are either patented branded drugs or generic copies of drugs that have gone off patent (WHO, 2004). Developing countries on the other hand may

market generics of two kinds: those that are copies of drugs that are still on patent and generics that are copies of branded drugs that have gone off patent.

On average, it is expected that generics of off-patent drugs are likely to be the same in terms of price whether the drug is being marketed by firms from developed or developing countries. Ideally, the focus should be on the other type of generics, those that are copies of drugs that are still on patent, as they will present the biggest cost differential between generics and branded versions. Further, it is for this group of generics that trade from developing countries with manufacturing capability are expected to be different and most relevant to the implication of TRIPS on the affordability of medicines. Unfortunately, the available data do not allow for differentiation between these two types of generics.[1] We therefore assume that, on average, drugs marketed by developing country firms are generic copies of branded drugs while drugs offered by firms from developed countries are innovator brands. If this is the case, it is expected that the importation of generics from Brazil, China and India will depress the prices of drugs sold by firms from high-income countries.[2]

Data

Three different types of data were used in this study: patent, trade, and economic development indicators. Patent data were obtained from Delphion, a fee-based patent search service, and the free-access database of the European Patent Office. The patent data were used for two purposes: to identify the innovative developing countries to be used in the regressions for evaluating the effect of trade; and to examine the patenting trends of innovators from high-income countries in developing countries for which data are available.[3] The International Patent Classification (IPC) provides a hierarchical system in which technologies are divided into various groups. There are two major subclasses of patents that classify pharmaceuticals, A61K and A61P. Subclass A61K classifies

pharmaceutical compounds based on their chemical structure while A61P classifies compounds according to their therapeutic activity. Patent data were downloaded with the search restricted to subclass A61K excluding the patent groups that relate to veterinary medicine, cosmetics and dentistry (A61K 5/00, 6/00, 7/00, 8/00).[4] These data were used to generate patent counts based on the inventor's country. Inventors need to file patent applications in each jurisdiction where they desire patent protection. We examine the patenting activity of pharmaceutical innovators, particularly from high-income countries.

The data on trade in pharmaceuticals are from the United Nations Statistical Division Commodity Trade database (ComTrade) and the analysis is limited to the years 1995 to 2005. They were used to examine trends in pharmaceutical trade. These trade data were also used along with variables derived from the World Bank's Development Indicators (WDI) in the regression analyses. The ComTrade database uses the Harmonized Systems (HS), which is a six-digit internationally standardized nomenclature used for classifying traded commodities. The trade values of exports and imports between participating countries are recorded for different commodities in US dollars and various quantity measures. Chapter 30, which deals specifically with pharmaceuticals, has six headings at the 4-digit level. Only subheadings (six-digit level) under headings 3002, 3003 and 3004 are considered for the purposes of this research as they classify medicinal preparations for prophylactic or therapeutic uses. This results in 15 different commodity classes that codify active ingredients and finished products at the 6-digit level. We combined these 15 classes into 7 commodity groups for analysis as shown in Table 1.

[Table 1 about here]

For each trade event, both the exporter and the importer provide a report of the trade. We used the importer-reported values because we use trade value and quantity to calculate price per kilogram as a proxy for base market price in the importing country. The importer-reported trade is therefore more suitable. The importer-reported value includes the transaction value of the goods, the quantity of goods in kilograms, the value of services performed to deliver the goods to the border of the exporting country and to the border of the importing country.[5] The data do not allow us to identify specific manufacturer brands, nor do they allow us to identify specific medicines and their therapeutic classes. Second, the reported trade values do not represent the final purchase price of the drug for a consumer. Additional taxes, local distribution costs and other retail markups also help to determine the final purchase price. However, it is reasonable to treat the import value as an indicator of aggregate base price before additional markups. The mean price per kilogram for a pharmaceutical commodity from a given country can therefore be assessed based on the recorded trade value and quantity. A primary advantage of using the trade data is that they allow us to associate an approximated cost of pharmaceutical commodities with their country of production.

Trends in Patents and Trade

The trends in the patent data show that innovative capacity for pharmaceuticals has increased tremendously since the 1990s for some developing countries (Fig. 1). While there is no clear threshold indicating the point where the industry becomes innovative, it is clear from Figure 1 that there is an increasing trend among these countries in the number of US-granted pharmaceutical patents.[6] There are two apparent groups of countries with India and China as the clear leaders. Both India and China show a similar trend of explosive growth after 1993 with India surpassing China and leading in total patent count in 1997 and thereafter (Fig. 1). The second group includes South

Africa, Argentina, Brazil, Mexico and Cuba which showed an increase in patent applications starting in 1994 and which has remained constant on average but higher than their respective counts in the 1980s. These trends are consistent with the typology described by Ballance and colleagues (1992), which cites these developing countries among those that have a pharmaceutical industry with some level of innovative and reproductive capability.

[Figure 1 about here]

Of the seven countries included in Figure 1, we only have a close to full panel of data for patents granted domestically in Brazil and India.[7] As Figure 2 shows, pharmaceutical patents granted in Brazil increased exponentially starting in 1997. This increase coincides with the introduction of Brazil's new TRIPS-compliant patent law, which allows patenting of pharmaceutical products. Note that inventors need to file separate patent applications in each patent jurisdiction where they need intellectual property protection. The increases in granted patents in Brazil are not surprising but note that patents to US inventors increased exponentially relative to the other leading innovators. The introduction of the new law changed patenting behavior among the leading inventors and allowed innovators from countries like the US to strengthen the intellectual property protection of their products in Brazil.

[Figure 2 about here]

The trends in India are different from those observed for Brazil. Unlike Brazil, India did not make its patent laws TRIPS-compliant until 2005. As Figure 3 shows, pharmaceutical patent grants started to increase in India in 1992. Domestic patents account for much of the increase and the number of patents granted to the leading pharmaceutical innovating countries remain fairly constant

for much of the period. While there was a slight increase in the patent counts for the US, its counts remained relatively low and stable compared to that of the domestic patents granted in India. So while producers from the innovative high-income countries account for much of the increase in granted patents in Brazil, much of the increase in granted patents in India were to local producers. Note that this increase in patents in India started before TRIPS-compliance and therefore likely indicates the growth of the local generic industry.

[Figure 3 about here]

Much of the trade activity in pharmaceuticals is attributable to just two commodity groups, antibiotics and unspecified medicaments. Unspecified medicaments account for 85% of exports from high-income countries, antibiotics account for 6% and vitamins account for 5%. On average unspecified medicaments account for 75% and antibiotics account for 15% of exports from Argentina, Brazil, China, India and Mexico. This is not surprising as these two groups include the broadest classes of medicines for both chronic and infectious diseases. They also include antiinfectives such as antibiotics and antiretrovirals, which are particularly relevant in some developing country markets.

The polarization of the global pharmaceutical market is reflected in Figure 4, which shows that high-income countries tend to trade among themselves with 77% of pharmaceutical export volume for the period 1996 to 2005 going to other high-income countries. Europe and Central Asia represented only 9% of the trade volume for that same period with the remaining volume almost equally divided between the other regions. This pattern aligns with income-level and is consistent with what is known about the global pharmaceutical market. High-income countries have a higher purchasing power and pharmaceutical consumption rates and therefore account for the bulk of the global pharmaceutical market.

[Figure 4 about here]

There is also some notable variation in the destination of the pharmaceutical exports from Argentina, Brazil, China, India and Mexico. The majority of the exports from Argentina and Brazil—95% and 96% respectively—were traded with other countries in the Latin American region (Fig. 4). Thirty nine percent of the exports from Mexico are traded with high-income countries, primarily the US, but the majority of its export is also traded within the region. The export trends for the Latin American countries are in contrast to those of India and China, which have more diverse regional markets (Fig. 5 & 6). What is most notable about the case of China is that exports to high-income countries remained relatively stable between 1996 and 2005 while exports to both Sub-Saharan Africa and Asia Pacific increased during that period from 3 to 15 and 10 to 18 million kilograms respectively (Fig. 5). India also had increases in its exports to all regions during that period but particularly to Sub-Saharan Africa and high-income trading partners (Fig. 6). Much of the increase began in 1999 with exports to Sub-Saharan Africa increasing from approximately 20 to 50 million kilograms between 1999 and 2006. On average, only 26% of India's pharmaceutical exports were traded with high-income countries, 35% was traded with Sub-Saharan African countries, 16% with Asia and Pacific countries and 14% with Eastern and Central Europe (Fig. 4). Since 2000, India's share of exports to Sub-Saharan Africa has exceeded the amount traded with all other regions.

We also examined the import trends across the different regions to see whether there is variation in the reliance on Argentina, Brazil, China, India and Mexico as sources of pharmaceutical products. Figure 7 shows the patterns in regional imports. With the exception of the Sub-Saharan Africa region, high-income countries are the major source of pharmaceutical imports for developing

countries between 1996 and 2005. This is particularly evident in the Middle East and North Africa Region which received an average of 88% of its imports from high-income countries for the entire period. The lowest averages were in Latin America and Sub-Saharan Africa where imports from high-income countries represented only an average share of 53% and 33% respectively for the period 1996 to 2005 (Fig. 7). The group of five countries is a major source of imports for Sub-Saharan Africa providing more than 50% of import volume for that period. Much of that trend is driven by India, which on average supplies 40% of the region's imports each year.

If we consider the percentage of imports based on trade value, the findings are similar. However, while high-income countries on average account for 43% of import volume, they account for almost 80% of imports in terms of trade value. Interestingly, for Latin America and the Caribbean, and Sub-Saharan Africa regions the percent of import value coming from high income countries is almost 8 times the percentage of imports coming from the group of five countries or other developing countries. This is despite the import quantity being almost the same. This is consistent with the expectation that imports from high-income countries are more expensive than those from developing countries.

[Figure 7 about here]

These trade trends provide evidence that China and India have become increasingly more important as sources of pharmaceutical imports for other low- and middle-income countries. While Argentina, Brazil and Mexico also demonstrate a relatively high level of trade activity, they tend to be active only in their regional market. There are two preliminary conclusions we can draw from these trade trends. If middle-income countries do have a competitive effect on trade from high income countries, we would expect the greatest effect in Sub-Saharan Africa given that India is the

largest supplier of pharmaceuticals on average. Second, of the five innovative developing countries India is likely to have the most pronounced effect because it is the only country with a leading market share relative to high-income countries as a trading block. We will therefore do a regression analysis focusing on the effect of imports from India and China on the average price of imports from high-income trading partners in the Sub-Saharan Africa region. We discuss our analysis in the proceeding sections.

Model Estimation

Given that Argentina, Brazil and Mexico export, on average, 1% or less of their pharmaceutical commodities to Sub-Saharan Africa, and trade the majority of their commodities within the regions, we have chosen to focus on India and China. Specifically, the regression analysis focuses on the effect of the share of pharmaceutical imports from China and India on the price of pharmaceutical imports from high-income trading partners. We employ the following model to estimate the effect:

$$P_{itc} = \beta + \delta CI_{itc} + \gamma X_{it} + \Psi_i + \Omega_c + T_t + \xi_{itc}$$

P_{itc} is the average price per kilogram of commodity c imported from high-income trading partners by developing country i in year t, with t ranging from 1996-2005. CI_{itc} is the percent of drug imports from China and India by developing country i in year t; X_{it} is a vector of country-level controls; Ψ_i represents country fixed effects; Ω_c represents commodity fixed effects and T_t represents year fixed effects.

The dependent variable, P_{itc} is the mean annual price per kilogram of a given commodity imported by country i from high-income countries as a group. Appendix I provides a list of the

country groups based on economy and region. The dependent variable is constructed by aggregating the trade value (2000 US$) and trade quantity as reported by the importing country across related commodity classes:

$$P_{itc} = \frac{\sum_j value_{ijtc}}{\sum_j volume_{ijtc}},$$ where j is each high-income exporter.

Table 1 shows the grouping for the commodities and Table 2 shows the descriptive statistics for the variables used in the regression models. Note that the commodity groups are very general and do not allow us to compare medicines that fall into specific therapeutic classes. As such each group contains a mix of both innovative, and hence expensive, drugs along with older and less expensive medicines. For example, the 'other medicaments' group will contain aspirin, a relatively non-expensive and ubiquitous commodity, as well as more innovative medicines such as cancer and HIV/AIDS therapeutics.

We need to address an endogeniety issue that is inherent in the model. The same variables that help to determine the price of pharmaceutical imports from high-income countries may also influence the share of imports from China and India, *CI*, so that *CI* may be correlated with ξ_{itc}. We instrument for the share of imports from China and India to address this endogeneity issue. A reasonable instrument will be correlated with *CI* but not with the mean price of pharmaceutical imports from high-income countries. In order to identify a suitable instrument we note that there are two factors that help to determine *CI*: (i) the existence of pharmaceuticals produced by China and India on the global market; (ii) and the existence of a trade relationship between these two countries and the importing country. The availability of medicines produced by China or India in a given country is conditional on the production of that medicine and its availability on the global market. A reasonable instrument for the supply of medicines from China or India is therefore the

percentage of medical imports worldwide from these countries to all countries excluding the country of interest. We construct such a variable called *PerGenElse*. Existence of a trade relationship between two countries will also determine the extent to which they trade a particular commodity. We therefore lag *CI* as CI_{t-1} and CI_{t-2} and include them as an instrument. The reasoning is that CI_{t-1} and CI_{t-2} are measures of an existing relationship between the trading partners. We therefore expect the lagged variable to be correlated with *CI* but not directly correlated with the dependent variable in year *t*.[8] So the first stage model was estimated using the following equation:

$$CI_{itc} = \gamma_0 + \gamma_1 PerGenElse_{itc} + \gamma_2 CI_{ic(t-1)} + \gamma_3 CI_{ic(t-2)} + v_{icrt}$$

One other variable related to the commodities is *bulk*, which represents the percent of imports for a particular commodity group that is imported in bulk form. There are two types of pharmaceutical products, finished products which are packaged in dosage formulation and coded under the 3004 heading. The second type is active ingredients which are intended to be used in the manufacture of a pharmaceutical product and as such packaged in bulk and not for retail sale and coded under the 3003 heading. Vaccines are not differentiated between finished and active ingredient formulation as shown in Table 1. Vitamins are also coded only under the 3004 heading. It is expected that bulk products will be cheaper than the finished product which has gone through full production and dosage formulation. It is therefore important to account for the amount of the imported commodity group that is imported as active ingredient. We accomplish this by including *bulk*, which represents the percent of imports for a particular commodity group as active ingredient (or traded under the 3003 heading).

The model also includes a vector of control variables that attempt to account for the other factors that affect the prices of medicines. National GDP per capita is included as a measure of ability to pay. GDP is often used as a criterion in preferential pricing schemes in which countries

with a lower GDP are usually offered lower prices. Life expectancy (*life*), tuberculosis incidence (*tb*), infant mortality (*infmort*) and physicians-population ratio (*physi*) are included as indicators of the national disease profile and the demand for medicines. The model also includes country dummies to account for time-invariant country specific effects. These variables control for other factors such as tariffs and procurement practices, which will affect the price of imports but are unlikely to vary over time. Year dummies are included to account for year-specific effects such as the licensing dispute in South Africa in 2001, which may have impacted medicine pricing negotiations and pharmaceutical procurement decisions across developing countries.

Results and Discussion

Column 1 of Table 3 presents the estimates for the effect of percentage imports from China and India (*CI*) on the average price of antibiotics and unspecified medicaments imported from high-income trading partners. Columns 2 and 3 show the same regression with the sample restricted to countries from the Asia and Pacific, Latin America and the Caribbean, and Sub-Saharan Africa regions. All the pharmaceutical commodities are included in column 3. As shown in columns 1 and 2, the effect of the percentage imports from China and India is statistically significant and in the expected direction. This effect is no longer significant when we include the full sample of pharmaceutical commodities (Table 3, Column 3). This is not surprising because we know from examining the trends in the trade data that antibiotics and other medicaments account for approximately 90% of the pharmaceutical export volume for India and China.

In terms of magnitude, the effect of the *CI* variable is strongest when the model is applied to the full sample of countries (Table 3, Column 1). On average, a one unit increase in the percent of imports from India and China will result in a 87-cents decrease in the average price of a pharmaceutical commodity imported from the high-income trading partners. While this may not seem like a substantial effect, it is important to put these numbers in context. Since the average price

of antibiotics and unspecified medicaments from high income countries is around $40 (Table 2), on average prices fall by over 2 percent for each one percentage point increase in imports from China and India. Emphasizing the importance of such savings, Niëns and colleagues (2010) have estimated the impoverishing effects of purchasing medicines out-of-pocket across 16 low- and middle-income countries. In Uganda, for example, where 73% of the population subsists on less than US$2 per day, purchasing generic amoxicillin (a common antibiotic) has the potential to increase the proportion of the population below the poverty line (US$2 per day) to 74% compared to 86% if the originator brand is purchased (Niëns et al., 2010).

[Table 3 about here]

In terms of country characteristics, GDP and TB incidence are generally insignificant. This is not surprising given that both GDP and TB incidence do not show much variation from year to year. The effect of life expectancy is positive and significant in all three models (Table 3).[9] This suggests that countries with higher life expectancy tend to pay higher prices for their medicines. It is also possible that there is some collinearity between life expectancy and GDP in our model specification. Countries with higher life expectancy also have a higher ability to pay because of higher incomes. Further, income levels are one of the criteria used in preferential pricing to set lower prices for the least developed countries. Countries with lower income levels, and hence lower life expectancy, may therefore pay lower prices for their pharmaceutical imports.

We also tested the effect of the percentage of imports from all five innovative middle-income countries as an alternate key independent variable. The results for this model are presented in Table 4, columns 1 and 2. While the sign on the coefficient is in the expected direction, the variable is insignificant and the magnitude smaller whether for the full panel of commodities (Column 1) or just antibiotics and medicaments (Column 2). The dummy variables for commodity

type are also strongly significant with unspecified medicaments being cheaper than antibiotics, and antisera, vaccines and insulin being the most expensive commodity groups. However, note that our instruments do not perform as well in the full panel (column 1), as the p-value for Hansen's J test is small, suggesting our instruments are not exogenous. Given that Argentina, Brazil and Mexico trade the majority of their pharmaceutical commodities within the region and that antibiotics and medicaments account for the bulk of export volume for all five countries, our instruments appear to be picking up endogenous links between countries and commodities, rather than exogenous shifts in supply.[10] This is not a concern in column 2, however, where we once again limit the sample to those commodities most likely to be traded. Here, the p-value for Hansen's J test is greater than 0.1, and the F-statistic testing for weak instruments is large.

We also tested the effect of imports from Argentina, Brazil and Mexico on the average prices of pharmaceutical imports from high-income trading partners in Latin American countries only. The results are shown in Table 4, columns 3 and 4. Again we fail to observe a significant effect of import share.[11] Another possible explanation for the lack of significance is that the US dominated as the leading source of imports for much of the period under study and accounted for as much as 60% of the import volume in 2002 before its annual market share started to decrease. The dominance of the market by one high-income producer suggests that the middle-income country producers are likely to have little effect at the regional level especially if the focus is on their domestic market. The patenting trends in Brazil, particularly if similar to those in other countries like Argentina, may also explain the lack of significance observed for all three alternate key independent variables for Latin America. As shown in Figure 2, all the high-income producers increased patenting after Brazil introduced its new patent laws in 1997. However, the US, which dominated as a source of regional imports, had a disproportionate amount of patents granted relative to the other innovators. This suggests that much of the regional trade is for generics of drugs off-patent or

branded medicines produced by multinational subsidiaries or licensees, who can legally produce patented medicines. Therefore, the group of medicines for which we would expect the biggest cost differences, generics of patented medicines, do not comprise a substantial portion of the market.

The observations for the Latin American exporters are in contrast to the significant effect of imports from China and India in the Sub-Saharan Africa region (Table 3). Again, both the patent and trade trends are consistent with this finding. When we consider the regional imports, note that India is the lead source of imports for Sub-Saharan, albeit not to the levels that the US was for Latin America and Caribbean region. So India has a greater potential to compete with high-income producers. It is also clear from the patent counts (Fig. 3) that domestic patents dominate the increasing trend in patents granted in India. Note that India did not become TRIPS-compliant until 2005, so pharmaceutical patents on products were not allowed until 2005. The increase in patent counts for India is therefore most likely from process patents. This suggests that India pharmaceutical manufacturers could therefore legally produce generics for both off- and on-patent medicines for much of the period being studied. This may therefore help to explain the significant effect we observe for imports from India and China. Indian manufacturers are able to trade in both on- and off-patent medicines therefore providing larger cost savings for consumers in that region.

The regression results suggest that only pharmaceutical imports from China and India—and not all five innovative middle-income countries—have a significant effect on the average cost of pharmaceutical imports from high-income trading partners in developing countries. However, this effect is only observed for the antibiotics and unspecified medicaments and not the other commodity groups. This is not surprising as antibiotics and unspecified medicaments together account for 90% of the exports from China and India for the study period 1996 to 2005 and the bulk of overall pharmaceutical trade. The findings are also consistent with the trade data that show that China and India are the leading suppliers of medicines among the innovative middle-income

countries, with Argentina, Brazil, Mexico only playing a regional role. It is likely therefore, that only China and India have a big enough market share to compete with high-income producers of medicines.

Conclusions

The study provides evidence to support existing anecdotal evidence for the importance of China and India as suppliers of inexpensive medicines to other developing countries. While Latin America depends heavily on intraregional trade and imports from the U.S., Sub-Saharan Africa relies on India for 45% of its imports. As such, the enforcement of TRIPS is likely to have differing implications for the two regions. In Latin America where countries rely on domestic production and regional trade, they are likely to more easily invoke compulsory licenses and negotiate cheaper medicine prices as they can use their innovative capability as a bargaining tool. However, this will be countered by the effect of more stringent intellectual property protection, which may limit the export market for pharmaceutical products from these countries and reduce potential cost savings regionally.

The effect in the Sub-Saharan Africa region is likely to be more adverse. Most countries have until 2016 to become TRIPS-compliant but that is unlikely to have a direct effect on medicine prices as most countries in the region lack the innovative capability to reverse engineer innovative medicines for their domestic market. However, given the importance of India as a supplier of inexpensive medicines, TRIPS is likely to negatively affect the availability of affordable medicines not only from India but also high-income trading partners through reduced competition from some generics.

Endnotes

[1] There are existing studies that use private datasets but they tend to focus on prices in industrialized countries (Danzon & Furukawa, 2008; Danzon & Kim, 1998). There is also the Health Action International drug price survey in collaboration with the WHO but they do not take the source of imports into account and focus on another important aspect of the issue, the differences at the point-of-purchase across select countries (Cameron, Ewen, Ross-Degnan, Ball, & Laing, 2009; WHO & HAI, 2003).

[2] As, of course, not all medicines imported from developing countries are generic copies of patented drugs, and not all imports from developed countries are branded drugs, our estimates provide a lower bound of the effect of generics on branded drugs.

[3] The term *innovative developing countries* refers to those countries that have the capability to reverse engineer innovative drugs. We hope to draw a distinction between such countries and others that merely manufacture or repackage bulk formulations through local subsidiaries.

[4] A61P would allow us to find patents that are related to specific diseases. For example, A61P 31/06 for drugs that treat tuberculosis or A61P 33/06 for drugs that treat malaria. Unfortunately, this subclass was introduced in the 7th and 8th (January 1, 2006) version of IPC and is therefore unavailable for earlier patents. We therefore use only subclass A61K to generate the patent counts, which does not allow for distinction between innovations for different illnesses without reading the bibliography of each patent.

[5] This is because the importer-reported trade values are recorded as cost, insurance and freight (CIF-type) value—includes the transaction value of the goods, the value of services performed to deliver the goods to the border of the exporting country and top the border of the importing country. The exporter-reported values on the other hand, are free-on-board (FOB-type) and only include the value of services performed to deliver the goods to the border of the exporting country (United Nations, 2004).

[6] We focus on patents granted in the US here because patent data from many individual developing country patent offices is incomplete. Using the US data gives us complete coverage and focuses on patents applied for under a common set of patent laws.

[7] Unfortunately there are several noticeable gaps in the patent data, some of which have been documented by Inpadoc. Argentina for example, granted 35 patents in 1992 but none thereafter or in the preceding 1985-1991 period.

[8] Note that we also ran models based on imports from different combinations of the six middle-income countries. In such cases we reconstruct our instruments using the correct combination of countries.

[9] For all the regressions presented in Tables 3 and 4, both infant mortality and physicians per capita were included together or separately as a measure of demand in other regressions (not shown). However, their inclusion did not substantively change the estimates observed with life expectancy as a measure of demand. We therefore chose to use life expectancy for which we had a more complete panel of countries and years.

[10] In particular, *pergenelse*, which is intended to identify supply shifts, has almost no explanatory power in this model, with a t-statistic of just 0.08.

[11] Note that in column 4, where we only focus on antibiotics and medicaments, our instruments again perform poorly. We thus have less confidence in this result, but are comforted by the fact that import share is also insignificant in the full sample under column 3, where the instruments are valid.

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Table 1. A description of the commodity classes from the Harmonized Classification System used to construct the seven commodity groups for analysis.

Commodity Group	Commodity code	Commodity description
Antibiotics	300310	Medicaments containing penicillins, streptomycins or derivatives thereof, in bulk formulation
	300320	Medicaments containing antibiotics not elsewhere specified, in bulk formulation
	300410	Medicaments containing penicillins, streptomycins or derivatives thereof, in dosage formulation
	300420	Medicaments containing antibiotics not elsewhere specified, in dosage formulation
Antisera	300210	Antisera and other blood fractions and modified immunological products
Hormones	300339	Medicaments containing hormones not elsewhere specified, formulated in bulk
	300439	Medicaments containing hormones not elsewhere specified, in dosage formulation
Insulin	300331	Medicaments containing insulin, formulated in bulk
	300431	Medicaments containing insulin, in dosage formulation
Other Medicaments	300340	Medicaments containing alkaloids or derivatives thereof but not containing hormones or antibiotics
	300390	Medicaments not elsewhere specified, formulated, in bulk
	300440	Medicaments containing alkaloids or derivatives thereof but not containing hormones or antibiotics, measured doses or packings for retail sale
	300490	Medicaments not elsewhere specified, in dosage
Vaccines	300220	Vaccines, human use
Vitamins	300450	Vitamins, derivatives, in dosage

Table 2. Descriptive statistics for the full sample of countries.

Variable	Description	N	Mean	Std. Dev.	Min	Max
Dependent Variable:						
Average Price	Average price of imports sourced from high income countries (Constant 2000 US$)	5884	$110.37	$203.91	$0.01	$4,965.64
	Antibiotics	868	$43.31	$62.50	$0.01	$1,060.95
	Antisera	803	$213.40	$329.86	$0.01	$4,158.51
	Hormones	853	$85.98	$136.76	$0.01	$2,127.72
	Insulin	779	$197.90	$248.90	$0.01	$4,965.64
	Unspecified medicaments	877	$35.36	$37.08	$0.01	$607.54
	Vaccines	847	$186.72	$210.63	$0.01	$3,600.89
	Vitamins	557	$27.78	$138.66	$0.01	$3,709.11
Import Share	% of imports from China and India	5884	9.30%	19.08%	0%	100%
% Generics Elsewhere (PerGenElse)	% of imports from China and India elsewhere	5884	12.59%	11.43%	0.05%	61.16%
% Bulk	% of imports in bulk formulation	5884	8.77%	20.65%	0.01%	100%
Antibiotics	Dummy variables for each commodity group	5884	0.15	0.35	0	1
Antisera		5884	0.14	0.34	0	1
Hormones		5884	0.14	0.35	0	1
Insulin		5884	0.13	0.34	0	1
Medicaments		5884	0.15	0.36	0	1
Vaccines		5884	0.14	0.35	0	1
Vitamins		5884	0.15	0.35	0	1
GDP	GDP per capita (constant 2000 US$)	5847	$2,097.97	$1,941.93	$104.64	$8,961.25
TB Incidence	Incidence of tuberculosis (per 100,000 people)	5884	152.65	164.09	4.87	1261.93
Life Expectancy	Life expectancy at birth (total years)	5849	64.12	11.09	34.97	78.95

Table 3. Estimation results for the effect of imports from China and India on the average price of pharmaceutical commodities imported from high-income trading partners.

Dependent Variable: Average price of pharmaceutical commodities from high-income trading partners			
Excluded Instruments: Pergenelse, Percent of imports from China and India lagged t-1 and t-2			
Explanatory Variables	(1)	(2)	(3)
Import Share (CI)	-0.867*	-0.689*	0.347
	(0.353)	(0.279)	(0.419)
% Bulk	-0.073	-0.050	-0.360**
	(0.091)	(0.095)	(0.110)
GDP	0.004	0.003	0.038***
	(0.005)	(0.007)	(0.008)
TB Incidence	0.075	0.028	0.060
	(0.062)	(0.054)	(0.106)
Life Expectancy	4.539*	2.335*	-2.742
	(1.810)	(1.064)	(2.212)
Medicaments	-7.849***	-4.876**	-5.535
	(2.250)	(1.693)	(3.560)
Antisera			115.138***
			(11.942)
Hormones			34.274***
			(5.688)
Insulin			128.376***
			(8.121)
Vaccines			121.406***
			(7.135)
Vitamins			-10.091
			(8.082)
Constant	-292.504*	-111.797	103.163
	(127.682)	(92.310)	(146.246)
N	1525	1075	3575
R^2	0.345	0.416	0.269
Hansen J	4.274	2.865	3.386
Hansen J p-value	0.118	0.239	0.184
Kleibergen-Paap Wald F	10.939	8.984	42.275

Standard errors in parentheses. Significance: *p<0.05; **p<0.01; ***p<0.001

Notes: Column 1 includes the full sample of countries; Columns 2 and 3 are limited to countries from the Asia and Pacific, Latin America and the Caribbean, and Sub-Saharan Africa regions, Column 3 includes all seven commodity groups. All models included year and country fixed effects.

Table 4. Estimation results for the effect of imports from Argentina, Brazil and Mexico on the average price of pharmaceutical commodities imported by countries in the Latin America and Caribbean region.

Dependent Variable: Average price of pharmaceutical commodities from high-income trading partners				
Excluded Instruments	*Pergenelse, Percent of imports from Argentina, Brazil, China, India and Mexico lagged t-1 and t-2*		*Pergenelse, Percent of imports from Argentina, Brazil and Mexico lagged t-1 and t-2*	
Explanatory Variables	(1)	(2)	(3)	(4)
Import Share (ABM)	-0.106	-0.312	-0.535	0.239
	(0.407)	(0.200)	(0.668)	(0.150)
% Bulk	-0.312	-0.069	-0.333	-0.224*
	(0.182)	(0.090)	(0.189)	(0.103)
GDP	0.021*	0.004	-0.002	-0.012
	(0.011)	(0.005)	(0.019)	(0.008)
TB Incidence	0.036	0.054	-0.174	-0.125
	(0.114)	(0.060)	(0.198)	(0.068)
Life Expectancy	-3.208	3.743*	-11.713	-1.302
	(3.714)	(1.645)	(15.697)	(1.739)
medicaments	-9.362*	-7.718***	-6.966	-6.070**
	(4.218)	(2.091)	(5.421)	(2.127)
antisera	164.586***		110.101***	
	(14.018)		(21.435)	
hormones	42.481***		35.095***	
	(6.242)		(6.608)	
insulin	155.010***		155.894***	
	(7.629)		(9.641)	
vaccines	140.125***		116.918***	
	(10.399)		(13.799)	
vitamins	-21.086*		-5.199	
	(8.330)		(19.890)	
Constant	188.297	-248.715*	871.153	154.796
	(272.410)	(118.245)	(1118.373)	(133.991)
N	4856	1457	1408	415
R^2	0.273	0.344	0.218	0.505
Hansen J	8.580	4.409	4.060	7.850
Hansen J p-value	0.014	0.110	0.131	0.020
Kleibergen-Paap Wald F	90.924	18.570	61.206	36.007

Standard errors in parentheses. Significance: *p<0.05; **p<0.01; ***p<0.001

Notes: Column 1 includes the full sample of countries; Column 2 is limited to countries from the Asia and Pacific, Latin America and the Caribbean, and Sub-Saharan Africa regions. Columns 3 & 4 are restricted to just Latin America and Caribbean countries but differ in the commodity groups included in the model. All models included year and country fixed effects.

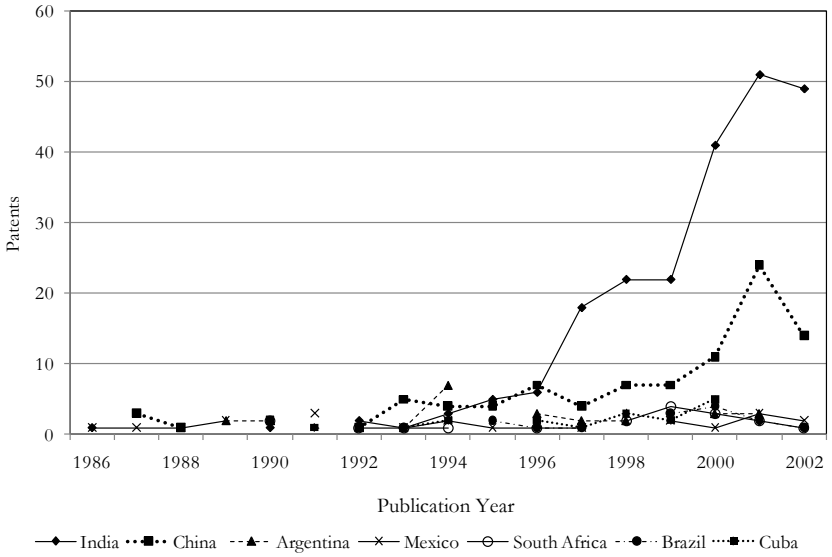

Figure 1. Trends in patenting in the US among innovators from leading developing countries in the US, 1986-2002. Only the top seven countries are included.

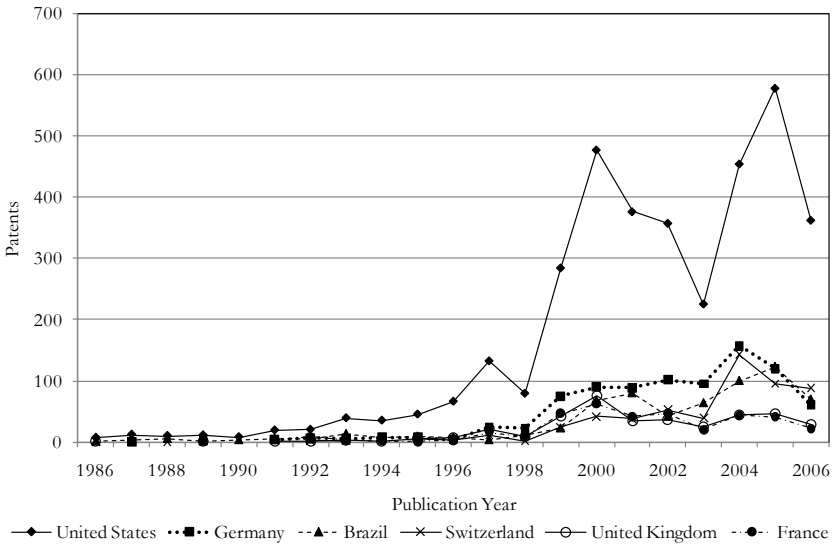

Figure 2. Trends in patents granted in Brazil to foreign inventors, 1986-2006. Only the top six countries are included.

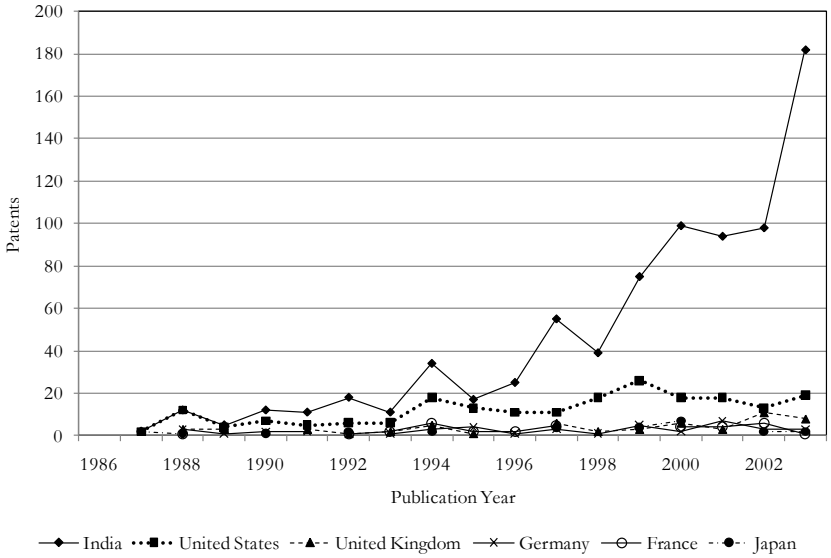

Figure 3. Trends in patents granted in India to foreign inventors, 1987-2003. Only the top six countries are included.

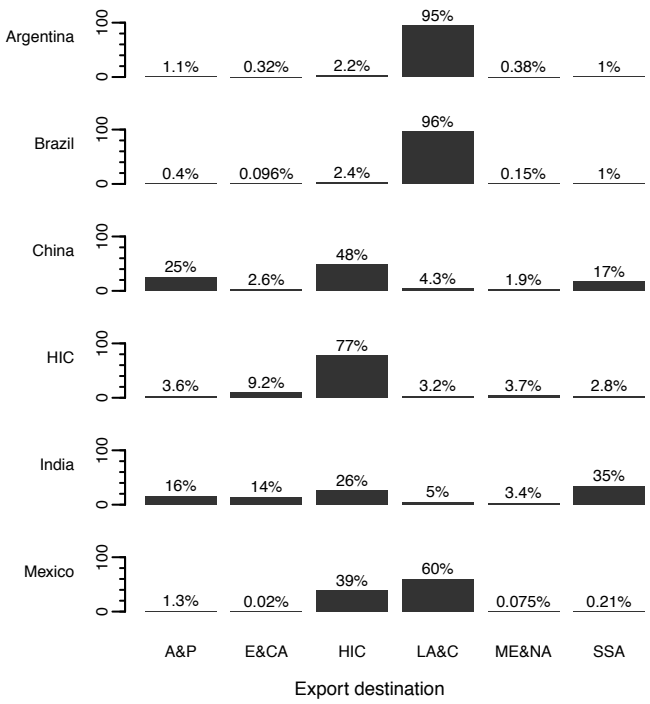

Figure 4. The regional markets for pharmaceutical exports from high-income countries (as a group), Argentina, Brazil, China, India and Mexico, 1996 to 2005.

(NOTE: A&P = Asia & Pacific; E&CA = Europe and Central Asia; HIC = High income countries; LA&C = Latin America & Caribbean; ME&NA = Middle East and North Africa; SSA = Sub-Saharan Africa)

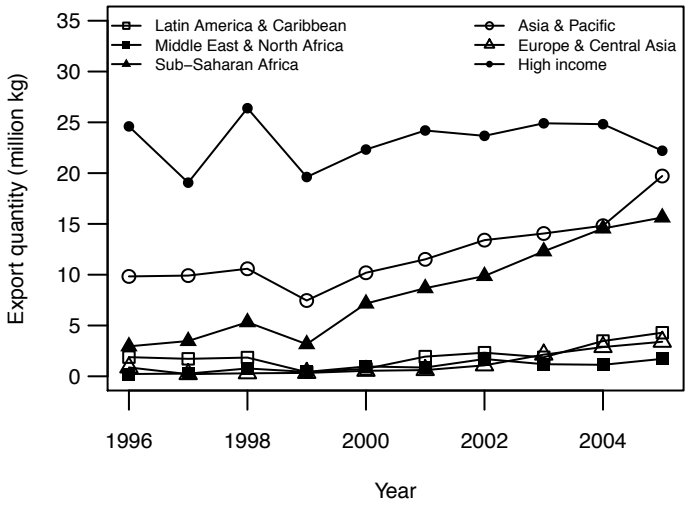

Figure 5. Trends in pharmaceutical exports from China to regional markets, 1996 to 2005.

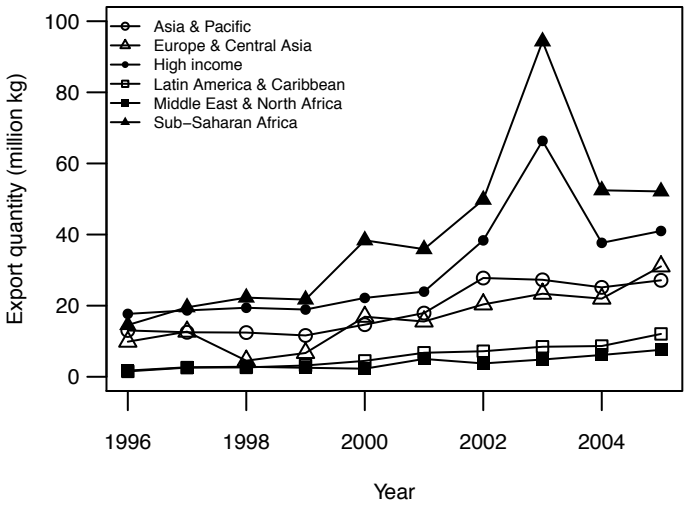

Figure 6. Trends in pharmaceutical exports from India to regional markets, 1996-2005.

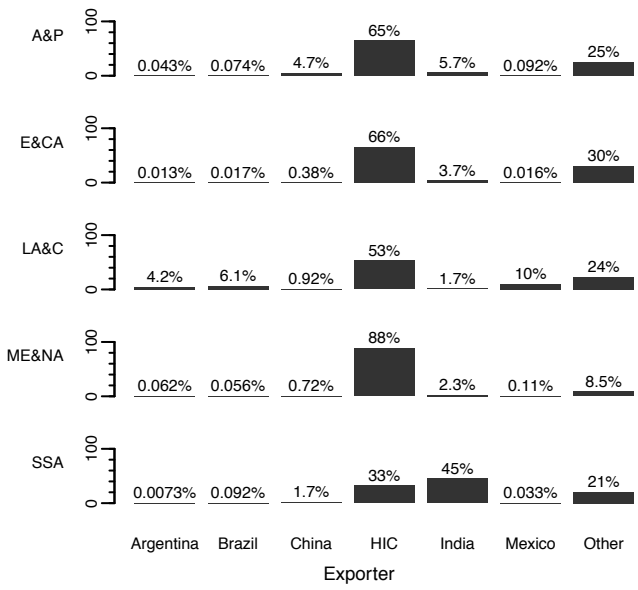

Figure 7. The source of pharmaceutical imports for each region, 1996-2005.

(NOTE: A&P = Asia & Pacific; E&CA = Europe and Central Asia; HIC = High income countries; LA&C = Latin America & Caribbean; ME&NA = Middle East and North Africa; SSA = Sub-Saharan Africa)

Appendix I. Country groups based on region and economy.

High Income			
Andorra	China, Macao SAR	Israel	Qatar
Anguilla	Cyprus	Italy	Rep. of Korea
Antigua and Barbuda	Denmark	Japan	Saudi Arabia
Australia	Finland	Kuwait	Singapore
Austria	France	Luxembourg	Slovenia
Bahamas	French Polynesia	Malta	Spain
Bahrain	Germany	Netherlands	Sweden
Belgium	Greece	New Caledonia	Switzerland
Bermuda	Greenland	New Zealand	USA
Brunei Darussalam	Iceland	Norway	United Arab Emirates
Canada	Ireland	Portugal	United Kingdom
China, Hong Kong SAR			
Asia and Pacific Region			
Bangladesh	Indonesia	Nepal	Thailand
Bhutan	Kiribati	Pakistan	Timor-Leste
Cambodia	Malaysia	Philippines	
Fiji	Mongolia	Sri Lanka	
Middle East & North Africa			
Algeria	Jordan	Oman	Yemen
Egypt	Lebanon	Syria	
Iran	Morocco	Tunisia	
Latin America & the Caribbean			
Argentina	Ecuador	Jamaica	Saint Kitts and Nevis
Belize	El Salvador	Mexico	Saint Lucia
Bolivia	Grenada	Nicaragua	Vincent and the Grenadines
Chile	Guatemala	Panama	Suriname
Colombia	Guyana	Paraguay	Uruguay
Costa Rica	Honduras	Peru	Venezuela
Dominica			
Sub-Saharan Africa			
Benin	Ethiopia	Mauritius	Sierra Leone
Botswana	Gabon	Mozambique	South Africa
Burkina Faso	Gambia	Namibia	Sudan
Burundi	Ghana	Niger	Swaziland
Cameroon	Guinea	Nigeria	Tanzania
Cape Verde	Kenya	Rwanda	Togo

Central African Rep.	Madagascar	Sao Tome and Principe	Uganda
Comoros	Malawi	Senegal	Zambia
Cote d'Ivoire	Mali	Seychelles	Zimbabwe
Eritrea	Mauritania		

Note: Based on the World Bank's Country Classification available at http://go.worldbank.org/K2CKM78CC0.