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The effects of trade agreements on imports of biologics: evidence from Chile

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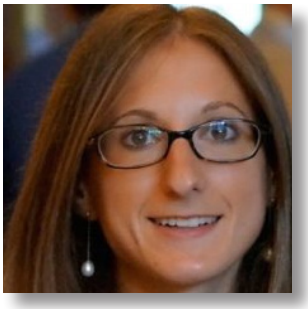
ABSTRACT:

This paper develops new indicators that measure the strength of intellectual property rights (IPRs) provisions in Chile's free trade agreements (FTAs). We use these new indicators to examine the extent to which FTAs with strong IPR provisions impact the volume, unit value and overall value of imported biologic medicines into Chile. We find that FTAs with more stringent IPR provisions increase both the volume and the unit value of imported biologics. Further research is necessary to determine whether this increase in volume and unit prices of imports has led to greater universal access to biologics in Chile or greater inequity in access of these medicines.

Keywords: International Trade, Access to Medicines, Economic Impacts of Globalization, Empirical studies of Trade, International Trade Law



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Introduction

Intellectual property rights (IPR) provisions have become a staple of modern free trade agreements since the 1995 Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS), which set minimum standards for IPR protection for World Trade Organization (WTO) members. TRIPS requires members to provide a legal structure encompassing patents, trademarks, copyrights, other provisions such as geographical indications and enforcement and dispute resolution.[1] Because implementing an IPR regime- including supporting robust patent protection- may reduce the number of generic medicines available and increase the price of medicines, compliance with the TRIPS requirements has been controversial in low and middle income countries concerned about ensuring access to medicines, particularly those countries with small domestic pharmaceutical industries or a large need for essential medicines (Smith, Correa and Oh, 2009).

Many recent bilateral or multilateral trade agreements increase the scope and coverage of IPR provisions (so-called TRIPS-Plus agreements). More stringent IPR provisions ensure profits and investments remain stable for pharmaceutical producers. Additionally, pharmaceutical producers have greater incentives to undertake R&D for new medicines (Barton (2004)). On the other hand, the potential for increased market power of pharmaceutical producers has implications for prices and availability of medicines, including generics (Correa, 2006).

The debate over the impact of trade agreements on access to medicines falls at the intersection of trade, health and IPR policy.[2] Now that TRIPS and TRIPS-Plus agreements have been in place for a significant period, there is a considerable literature in all three fields examining the impact of such provisions on access to medicines, generally using price or consumption as an indicator of access. As we note in our literature review, the empirical evidence on the impact of TRIPS and TRIPS-Plus regimes on prices and consumption is mixed. Additionally, several limitations exist that prevent analysts from making definitive conclusions.

This paper builds on the literature using a gravity model to estimate the impact of the strength of the IPR provisions in Chile's free trade agreements (FTAs) on the value, volume and price of imported biologic medicines in Chile. We improve upon the existing literature and address some of the limitations in previous analyses in three ways. First, we develop new indicators for the strength of the IPR provisions in Chile's FTAs by classifying and coding the IPR provisions in Chile's FTAs. Second, we estimate the impact of IPR protection on biological medicines, which we argue are important pharmaceuticals more likely to be impacted by IPR provisions in FTAs than other medicines. Third, we estimate the impact of the strength of IPR provisions on three dimensions of trade data – the nominal value of imports, the quantity imported in kilograms and the unit value of imports – to better understand how imported biologic medicines are affected.

We find that FTAs with stronger IPR provisions raise unit prices of imported biologics into Chile. However, we also find that the imported volume of biologics increases. Further research is necessary to determine whether the increase in the volume and unit prices of imports has led to greater universal access to biologics in Chile or greater inequity in access of these medicines.

Literature Review

There are two large sets of relevant literature, the effects of IPR protection on international trade and the impact of trade agreements on access to medicines. The literature examining the effect of the strength of patents or other intellectual property rights on international trade includes cross-country studies (Maskus and Penubarti (1995), Park and Lippoldt (2008)) and country-specific studies (Smith (1999), Co (2004), Awokuse and Yin (2010), USITC (2011) and Koff et al. (2011)). The majority of papers make use of gravity models to estimate the impact of IPR protection on trade, finding that increased IPR protection is associated with larger nominal values of imports.

1 The text of the TRIPS agreement is available at https://www.wto.org/english/docs_e/legal_e/27-trips_01_e.htm

2 The interaction between trade, health and IPR policy is well-covered in two policy reports, (WHO, WIPO and WTO (2012) and WHO (2015).

Maskus and Penubarti (1995) frame the impact of IPR protection on international trade as the sum of two competing effects, market expansion and market power. When market expansion dominates, IPR protection increases international trade by reducing the potential for infringement in importing markets. Conversely, market power can decrease international trade when temporary monopolies to patent and other intellectual property right holders result in increased prices and restricted quantities sold in importing markets. The examples in the empirical trade policy literature generally find in favor of market expansion. Park and Lippoldt (2008) examine the impact of IPR protection on trade and technology transfer, finding in favor of market expansion in both value of imports and foreign direct investment (FDI) flows of high-tech products such as chemicals, pharmaceuticals and telecommunications equipment, which they argue suggests import and investment flows contain technology that exporters and investors want to protect.

Maskus and Penubarti (1995) note that the market power effect is more likely to dominate in smaller countries without imitative capacity, i.e. countries that do not have the resources and knowledge to innovate and produce domestically and therefore rely on imports. The potential for reduced access to imported medicines is a major concern for low and middle income countries, especially those that rely on imports (Smith, Correa and Oh (2009)).

The second body of literature examines the potential for trade agreements to reduce the affordability and availability of medicines. Several *ex-ante* studies meant to evaluate the impact of potential policy changes find large negative expected effects from the implementation of TRIPS or TRIPS-Plus agreements. Akaleephan et al. (2009) and Kessomboon et al. (2012) analyze the impact of the implementation of TRIPS-Plus provisions in a proposed US-Thailand FTA, predicting a significant increase in medicine prices in Thailand after implementation of the more stringent IPR requirements in the FTA. IFARMA (2009) assesses the impact of IPR provisions in the EU-Andean Community FTA in Peru, estimating that an increase in the number of protected medicines would lead to price increases and declines in consumption. Chauduri, Goldberg and Gia (2006) analyze the impact of the implementation of a TRIPS-compliant patent regime in India and find a substantial consumer welfare loss for Indian consumers of quinolones, even with price intervention tools available. Moir et al. (2014) assess the impact of the proposed patent provisions in the Trans-Pacific Partnership (TPP) on the cost of HIV medicines in Vietnam, finding the TPP will reduce the number of eligible patients treated due to higher costs.

Ex-post empirical evidence is mixed. Several studies find harmful impacts from the implementation of TRIPS or TRIPS-Plus FTAs. Abbott et al. (2012) and OXFAM (2007) analyze the impact of the US-Jordan FTA, finding large price increases for brand name medicines in Jordan. Shaffer and Brenner (2009) find the data exclusivity provision in the Central America Free Trade Agreement (CAFTA), a TRIPS-Plus provision, limited availability for some lower cost generics in one member country, Guatemala.

A number of studies, however, find neutral effects of IPR regimes on prices and neutral or higher consumption and highlight the importance of pricing intervention mechanisms designed to lessen the burden on low and middle income countries implementing IPR regimes. Duggan et al. (2016) examine the implementation of a patent system in India and find new patents caused only a small average price increase of 3 to 6 percent, did not decrease the number of firms making molecules and did not change the quantity sold. The authors attribute their neutral findings to India's ability to implement price controls and patent licensing, which they note could influence pricing decisions on the part of patent-holding firms. Results from Kyle and Qian (2014) also suggest policies meant to counter expected medicine price increases are effective. Kyle and Qian (2014) examine how patents affect new medicine launches, prices and sales in 59 countries and find that patents are associated with earlier launch of a product, higher sales but lower medicine prices, which they argue could be the result of price control and licensing mechanisms.

In reviewing the literature on access to medicines, it is clear that there are several challenges in undertaking a comprehensive analysis of the effects of trade agreements on price, consumption and other indicators of access to medicines, which might explain why results are mixed and few studies can be generalized to other environments. Shadlen (2018) outlines the conceptual and methodological challenges, including the choice of outcome variables, the context of negotiation and implementation of the agreement and the framing of analytical questions. Shadlen notes that not all TRIPS-Plus provisions are likely to affect the various domains of access; the provisions with the highest potential to

do so are related to patents, data exclusivity and limiting the use of compulsory licensing. Similarly, not all medicines are equally likely to be affected by IPR protections; new medicines are more likely to be affected by data exclusivity and new patents, while older medicines might be affected by patent term extension (Shadlen (2018)). Shadlen also notes the timing of the implementation of the agreement or of the expiration of patents should be carefully considered when constructing an analytical framework.

The analytical framework in our analysis addresses these concerns in three ways. First, we develop new indicators of the strength of the IPR provisions in Chile's FTAs that allow us to focus on the effects of provisions most likely to affect availability and affordability of medicines. Additionally, we can use our indicators to compare which types of provisions have larger impacts on pharmaceutical imports. Second, we focus on biological medicines or "biologics," which we argue are more likely to be impacted by IPR provisions in FTAs than other medicines. The manufacturing of biologics is R&D intensive and done in countries with well-developed IPR and innovation regimes that negotiate strong protections into trade agreements. Third, we estimate the impact of the strength of IPR provisions on three dimensions of trade data – the nominal value of imports, the quantity imported in kilograms and the unit value of imports. Our use of three dimensions of trade data as outcome variables goes beyond the usual focus on price and consumption, allowing us to dissect the impact on the value of imports into the components coming from changes in volume and a proxy for price. Our approach also provides intuition on the impact of Chile's FTAs on the availability (imported volume) and affordability (unit price of imports) of imported biologics, two key dimensions of the concept of access to medicines.3

Dataset construction and analysis

Trade data

We construct a dataset of Chile's imports of pharmaceutical products by exporting country and product for the years 1997 to 2016. Data on Chile's imports of Harmonized System (HS) 6 digit products comes from UN Comtrade.[4] We focus on trade in the HS-6 products falling under Chapter 30, i.e. Pharmaceutical Products of the Harmonized System.[5] Chapter 30 is divided into six subheadings – 3001, 3002, 3003, 3004, 3005 and 3006 – with approximately 30 HS-6 products classified under the six subheadings.[6] Although we focus on products in Chapter 30, it is possible relevant products exist in other chapters of the Harmonized System, e.g. chemicals used in the manufacturing of medicines that are classified under Chapter 28 (Inorganic Chemicals) or Chapter 29 (Organic Chemicals).

Our econometric analysis uses data on the reported value (in dollars) and volume (in kilograms) of imports and the unit value of imports. We calculate the unit value as the value of imports of a HS-6 code divided by the number of kilograms imported under the HS-6 code. We use the unit value as a proxy for the price of the HS-6 product; however, we note that the unit value may not accurately capture prices of the potentially hundreds of individual pharmaceutical products imported under a HS-6 code. The unit value also will not capture any markups or taxes within Chile. Additionally, it is important to remember the mechanical relationship between the unit value and the two components used in its calculation, the value and volume of imports.

Additional data on bilateral tariffs and the distance between Chile and its trading partners for our gravity dataset comes from the UNCTAD TRAINS database and the CEPII gravity dataset, respectively.[7]

3 Management Sciences for Health. Chapter 1. Towards sustainable access to medicines. Washington, D.C.: MSH, 2012. Available at: http://apps.who.int/medicinedocs/documents/s19577en/s19577en.pdf

4 https://comtrade.un.org

5 https://unstats.un.org/unsd/tradekb/Knowledgebase/50018/Harmonized-Commodity-Description-and-Coding-Systems-HS

6 Chapter 30 products are divided into the following subheadings: 3001 Glands and other organs for organo-therapeutic uses, 3002 Human blood; animal blood prepared for therapeutic, prophylactic or diagnostic uses; antisera and other blood fractions and modified immunological products, 3003 Medicaments (excluding goods of heading No. 3002, 3005 or 3006) consisting of two or more constituents which have been mixed together for therapeutic or prophylactic uses, 3004 Medicaments (excluding goods of heading No. 30.02, 30.05 or 30.06) consisting of mixed or unmixed products for therapeutic or prophylactic uses, 3005 Wadding, gauze, bandages and similar articles (for example, dressings, adhesive plasters, poultices), impregnated or coated with pharmaceutical substances or put up in forms or packings for retail sale and 3006 Pharmaceutical goods specified in Note 4 to this Chapter.

7 TRAINS tariff data accessed via WITS (https://wits.worldbank.org). CEPII gravity database available at http://www.cepii.fr/

Creating measures of the strength of IPR protection

We review the language used in the IPR provisions in each FTA and categorize each provision as TRIPS-Plus, TRIPS neutral or not explicitly mentioned in the treaty's IPR chapter, according to the literature on the commonly accepted definition of TRIPS-Plus provisions.[8] We accessed the text of all of Chile's bilateral and multilateral FTAs in force from the Foreign Trade Information System of the Organization of American States.[9] Agreements only available in Spanish (Panama, Peru, Colombia and Vietnam) were not translated. We used the analytical framework found in Roffe (2004) to divide the IPR provisions into the following domains: objectives, temporal scope of application and general principles, including minimum standards, non-derogation clause, national treatment, most favored nation, substantive IP provisions, e.g., patentable subject matter and exceptions, regulatory exemptions, patent revocation, delays in patent granting, protection of "undisclosed information."

We then categorized all provisions relating to IPR in Chile's trade agreements as falling **into one or more of these above-referenced domains**, noting when no such 'domain' language existed in an agreement. We did not review enforcement and dispute settlement provisions in any of these agreements, nor did we review authors' copyright and related rights (i.e., rights of a creative work not connected with the work's actual author).

Appendix Tables A1 and A2 shows the eleven provisions and our assessment of whether the language in each provision indicates the provision is TRIPS-Plus, TRIPS neutral or compliant or there is no specific language relevant to the provision in the FTA.

From Tables A1 and A2, we construct three measures of the strength of the IPR provisions in a treaty. *TRIPSPlus* is a dummy variable indicating whether the FTA contains any provisions considered to be TRIPS Plus. The *TRIPSPlus* variable is equal to one only for the United States, Australia and the four EFTA countries, Iceland, Liechtenstein, Norway and Switzerland. *IPRScore* scores the IPR chapter of each FTA by assigning each of the eleven provisions in Tables A1 and A2 a score (0 if there is no specific language in the FTA for that provision, 1 if the language if TRIPS compliant or TRIPS neutral and 2 if the language indicates the provision is TRIPS Plus) and summing up over all provisions to calculate *IPRScore. IPRScore* ranges from 1-15 for Chile's FTA partners. *PatentScore* scores the FTA on four of the eleven provisions, those four provisions related to patents, by assigning a score of 1 to each provision if it is mentioned in the FTA and summing over all four provisions. The *PatentScore* variable takes values of 0 to 4. For the four countries whose FTAs with Chile were only available in Spanish, we assigned values of *TRIPSPlus, IPRScore* and *PatentScore* from the most similar country among Chile's FTA partners.

*TRIPSPlus, IPRScore and PatentScore a*re measures of the strength of the IPR provisions in each of Chile's FTAs. We use these measures to estimate whether treaties with stronger IPR provisions result in larger impacts on unit value, volume and value of imported biologic medicines.

Identifying pharmaceutical products impacted by IPR provisions

As noted in Shadlen (2018), not all medicines are equally impacted by IPR provisions in FTAs. We believe the IPR provisions in Chile's FTAs are more likely to impact biological medicines than other medicines. Biological medicines are those that are produced through a biotechnological process and are made using a variety of genetically engineered source materials—human, animal, and microorganism. They act in the body by replicating natural substances such as enzymes, antibodies, or hormones in contrast to "small molecule" medicines whose structures are well characterized and made using relatively well-developed organic chemical methods.[10] Examples of biological medicines are vaccines, insulin and monoclonal antibodies used to treat cancer or rheumatoid arthritis.

8 See Mercurio (2006), El Said (2010) and Clift (2007).

9 http://www.sice.oas.org/ctyindex/CHL/CHLagreements_e.asp

10 Food and Drug Administration. Available at: https://www.fda.gov/ForConsumers/ConsumerUpdates/ucm048341.htm [accessed June 30 2018]

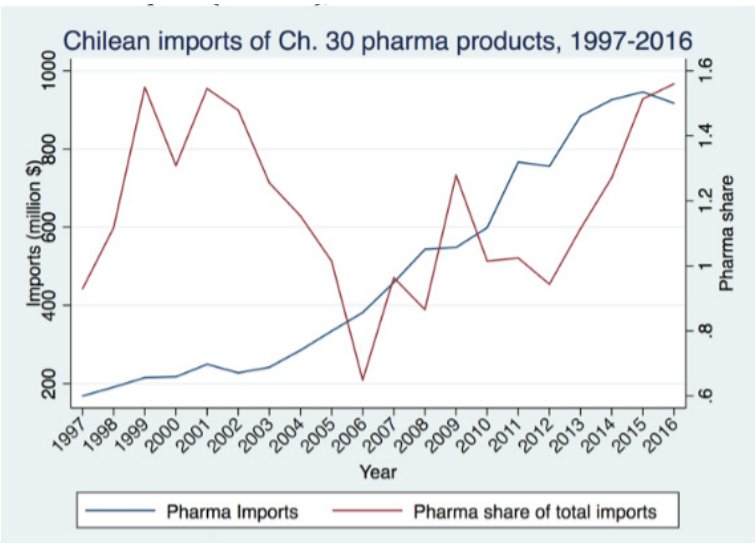
The manufacturing of biologics is more complex than that of small molecules with many technological advances made in the last 20 years, making the use of IPR provisions especially relevant to protect the technology and research embedded in these medicines.[11] Manufacturing and marketing of biologics is currently dominated by pharmaceutical companies from countries in Europe and North America with well-developed IPR legislation and powerful lobbies for strong IPR provisions in trade agreements. The proposed Trans-Pacific Partnership (TPP) agreement that included the U.S. contained several provisions related to biologics. During the TPP negotiations, U.S. pharmaceutical companies lobbied for protection of biological medicines and the clinical data used in their development while other TPP countries felt such strong provisions protection would reduce availability and affordability of new medicines (Branstetter, 2016).

In our analysis, we focus on the impact of Chile's FTAs on imported biological medicines. Appendix Table 4 lists the HS-6 codes in Chapter 30 of the Harmonized Schedule we classify as biological medicines. We did not have access to a detailed tariff schedule for Chilean imports, so we examined the more detailed HTS-10 codes in the 2016 U.S. Harmonized Tariff Schedule to construct our classification.[12] We used descriptions of the HTS-10 codes classified under a HS-6 code in the U.S. as an indication of the types of medicines imported under each HS-6 code in Chile to label the HS-6 code as a biological medicine or not.[13]

Data analysis

Figure 1 shows the value of Chapter 30 pharmaceutical imports (blue line) and the share of pharmaceutical imports in Chile's total imports (red line) from 1997 to 2016. Imports of Chapter 30 pharmaceutical products increase nearly five times over this period, from $170 million in 1997 to $920 million in 2016, greatly outpacing the 66 percent growth in GDP per capita from $9,000 to $15,000 over the same period. The share of pharmaceutical products in Chile's total imports increased in the late 1990s to 1.6 percent and dropped down to 0.6 percent in the mid-2000s before rising again to a total of 1.6 percent of total imports in 2016.

FIGURE 1: CHILEAN PHARMACEUTICAL IMPORTS (MILLION $), 1997 TO 2016



Source: UN Comtrade

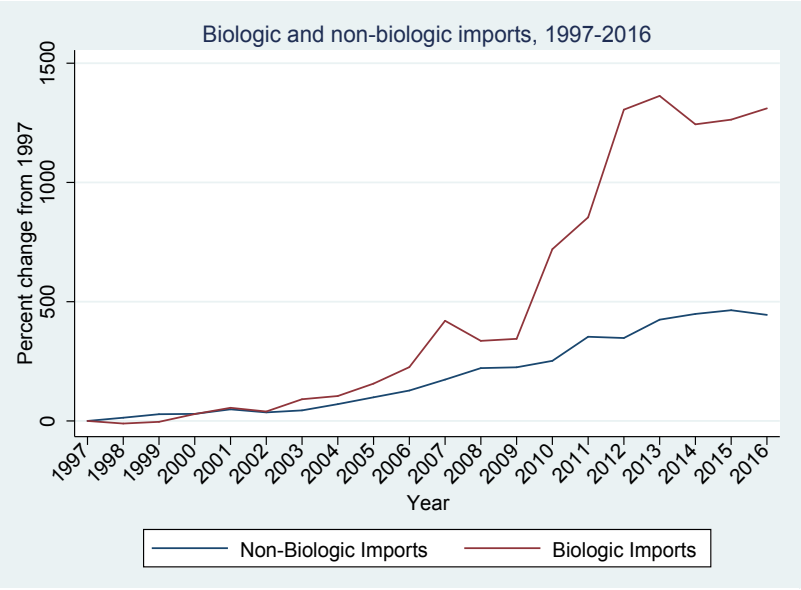
11 http://www.gabionline.net/Biosimilars/Research/Small-molecule-versus-biological-drugs

12 The 2016 U.S. Harmonized Tariff Schedule is available at https://hts.usitc.gov/view/release?release=chapter98

13 Because the most disaggregated level at which tariff schedules are harmonized internationally is the HS-6 level of aggregation, the composition of the HTS-10 products comprising a HS-6 code may be different for the U.S. and Chile and our examination of U.S. HTS-10 codes may not be an exact representation of what is imported at a disaggregated level in Chile. The econometric analysis in this paper is at the more aggregated HS-6 level at which product categories are harmonized internationally and should not be greatly affected by our examination of U.S. HTS-10 codes conducted to classify the contents of a HS-6 code.

The steady rise in the value of Chile's imports of pharmaceutical products could be related to the increase in the number of FTAs Chile signed in the late 1990s and 2000s. Although Chile negotiated a handful of preferential trade agreement in the early 1990s with Bolivia, Venezuela and Argentina, the majority of its trade agreements came into force in the late 1990s and 2000s, including MERCOSUR (1996), Canada (1997), Mexico (1999), EU (2003), USA (2004), South Korea (2004), China (2006), Japan (2007), India (2007) and Australia (2009).14

FIGURE 2: BIOLOGIC AND NON-BIOLOGIC IMPORTS, 1997 TO 2016

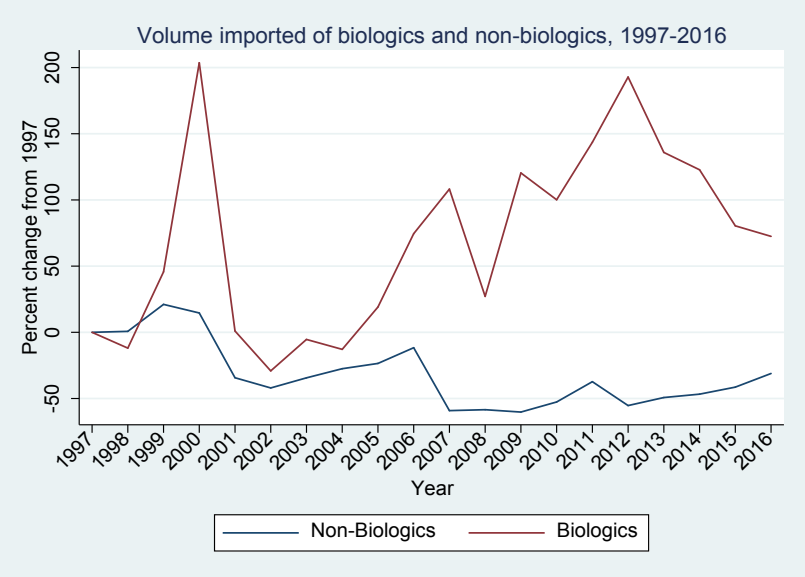


Source: UN Comtrade

In Figures 2 through 4, we divide pharmaceutical imports into imports of biologic and non-biologic medicines. Figure 2 shows the change since 1997 in the value of Chilean imports of biologics (red line) and non-biologics (blue line). Although imports of biologics are smaller in value—in 1997 (2016), imports of biologics were $20 million ($274 million) compared to $166 million ($907 million) for non-biologics—, the value of imports of biologics increased at a higher rate relative to its 1997 value than that of non-biologics. Figure 2 shows an increase in the value of biologic imports of over 1000 percent from its 1997 value while imports of non-biological medicines increased by less than 500 percent.

14 http://www.sice.oas.org/ctyindex/CHL/CHLagreements_e.asp

FIGURE 3: VOLUME OF IMPORTS OF BIOLOGICS AND NON-BIOLOGICS, 1997 TO 2016

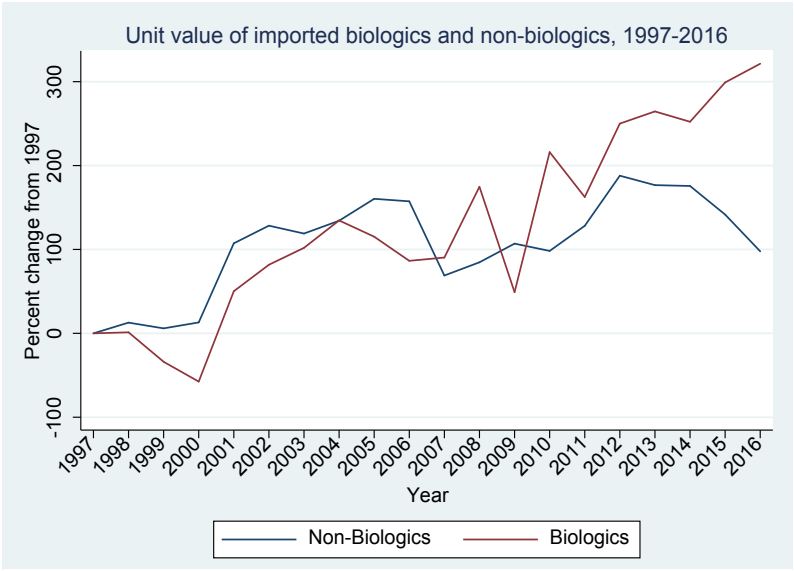


Source: UN Comtrade

Although import volumes of both biologics and non-biologics vary from year to year, absolute volumes of imported biologics remain substantially below those of non-biologics throughout the period. In 1997, Chile imported 275,000 kilograms of biologics compared to 8.6 million kilograms of non-biologics. Biologics, however, were imported at much higher unit values than non-biologics, an average of $162 per kilogram over the period 1997-2016 compared to $40 per kilogram.

Figures 3 and 4 show the changes from 1997 in the volume and unit value of imported biologics (red line) and non-biologic medicines (blue line). Despite being imported in a lower volume, Figure 3 shows biologic imports increased well above their 1997 volume for most of the period, while the change in volume of non-biologics has been effectively negative since 1997. The percent change in the average unit values of imported biologics and non-biologics since 1997 trended together for most of the period, seen in Figure 4. After 2012, however, changes in the average unit value of biologics and non-biologics diverged, with unit prices increasing for biologics, medicines with already higher unit values, and declining for non-biologics relative to 1997.

FIGURE 4: UNIT VALUE OF IMPORTS OF BIOLOGICS AND NON-BIOLOGICS, 1997 TO 2016



Source: UN Comtrade

Figures 3 and 4 show that the steep annual increase in the value of biologic imports relative to their 1997 values (as seen in Figure 2 after 2005) is due to a more moderate increase in volume and large increase in import unit value over the last 20 years. In contrast, the volume of imported non-biologics has declined since 1997 and the import unit value is on a downward trend in recent years. Even though biologics are a small share of pharmaceutical imports, the volume and unit value of imports of these IP-sensitive products is increasing.

Econometric analysis

Our econometric analysis examines whether the strength of the IPR provisions in Chile's FTAs can account for the trends in the value, volume and unit value of imports seen in Figures 2 through 4. Our analysis focuses on imports of biologics, the group of medicines we believe is most affected by IPR provisions in trade agreements.

We use a gravity model to estimate the impact of FTAs containing strong IPR provisions on biologic imports, controlling for other factors potentially driving pharmaceutical imports in Chile. We use a standard gravity specification with the natural log of the volume of a HS-6 product imported in kilograms from exporting country n in year t as the dependent variable. Our independent variables include IPR, which is one of the three calculated measures described above (TRIPSPlus, IPRScore, PatentScore) representing the strength of the IPR provisions in a treaty, and Biologic, a dummy variable for the HS-6 codes we classify as biologics. The three IPR measures vary by partner country n and year t (before the entry into force of an FTA, all IPR measures are 0).

We interact each IPR measure with the Biologic dummy to estimate the impact of strong IPR provisions in a treaty on the volume of imports of biologics. FTA is a dummy variable equal to one in the years following the entry into force of an FTA between Chile and exporting country n. We also include an interaction term between FTA and Biologic to capture the effect of the FTA on the imported volume of biologics. Our gravity dataset covers all imported HS-6 codes in Chapter 30 from 1997 to 2015 in Chile.

Exporter, year and HS-6 product fixed effects are included to control for any unobserved and omitted trends specific to an exporter, year or product that may be influencing the volume of Chile's imports. We also include as control variables the applied bilateral tariff on the HS-6 product and the natural log of the distance between the exporting country and Chile as proxies for trade costs. We repeat our regressions with two additional dependent variables, the unit value of imports of an HS-6 code and the value of imports in dollars. Our coefficient of interest in all regressions is , which gives the effect of treaties with strong IPR provisions on imports of biologics.

If the market expansion effect of Maskus and Penubarti (1995) dominates and strong IPR treaties are associated with a higher volume imported, we expect to be positive for specifications with volume as the dependent variable. On the other hand, if the market power effect dominates, we expect higher unit values of imported biologics (for specifications with unit value as the dependent variable) and smaller volumes of imported biologics (for specifications estimating the impact on volume). The effect of strong IPR provisions on the value of imports under either effect is ambiguous *a priori*.

Table 1 presents the results from regressions of the volume of imports in kilograms on our three IPR measures, the dummy variable for biologics and interaction and control terms. Column (1) uses PatentScore as our measure of treaty IPR strength, column (2) uses IPRScore and column (3) uses *TRIPSPlus*. Our coefficient of interest appears in all columns as the interaction term between Biologic and each measure of treaty IPR strength. In each case, it is positive and significant. Treaties with stronger IPR provisions are associated with larger volumes of imported biologics.

The coefficient of 0.18 on the interaction between Biologic and PatentScore in column (1) implies that a one unit increase in PatentScore, which is equivalent to adding one patent-related provision to the IPR chapter of an FTA, results in an approximately 20 percent (increase in the imported volume of biologics in Chile. The coefficient of 0.10 on the interaction term between Biologic and IPRScore in column (2) implies that a one unit increase in IPRScore, equivalent to adding an IPR provision with TRIPS-neutral or TRIPS-compliant language to an FTA, results in an 11 percent increase in imported volume of biologics. Adding a provision with TRIPS-Plus language to an FTA is a two unit increase in IPRScore and results in a 22 percent increase in the imported volume of biologics. The coefficient of 0.79 on interaction between Biologic and TRIPSPlus is presented in column (3). Having any TRIPS-Plus provisions in an FTA, i.e. TRIPSPlus equal to one, increases imported volume of biologics by 120 percent relative to an FTA with no TRIPS-Plus provisions.

In contrast, the coefficient on the interaction term between the FTA and Biologic dummy variables is negative, indicating the mere presence of an FTA is not sufficient to increase the volume of biologic imports. The content of the IPR chapter in the FTA does matter for imports of biologics, as seen by the impacts of various measures of IPR strength on the volume of imported biologics discussed above. The difference between the impact of FTAs on imported biologics and other medicines is further highlighted by the positive and significant coefficient on the FTA dummy variable. FTAs increase the imported volume of all pharmaceutical imports when we do not distinguish between biologics and non-biologics, but the imported volume of biologics is larger only under FTAs with strong IPR provisions. The negative coefficient on the biologic dummy reflects the fact that the imported volume and value of biologics is lower than non-biologic medicines in Chapter 30.

TABLE 1: THE EFFECT OF IPR TREATY STRENGTH ON THE VOLUME OF IMPORTS

	(1) PatentScore	(2) IPRScore	(3) TRIPSPlus
	ln(KG)	ln(KG)	ln(KG)
Biologic	-4.06***	-4.04***	-4.01***
	(1.18)	(1.18)	(1.18)
PatentScore	0.09		
	(0.07)		
Biologic*PatentScore	0.18***		
	(0.09)		
IPRScore		-0.01	
		(0.02)	
Biologic*IPRScore		0.10***	
		(0.03)	
TRIPSPlus			-0.25
			(0.20)
Biologic*TRIPSPlus			0.79***
			(0.29)
FTA	0.28**	0.34**	0.35**
	(0.11)	(0.14)	(0.12)
Biologic*FTA	-0.30*	-0.58***	-0.32*
	(0.18)	(0.20)	(0.18)
ln(Distance)	-0.88	-0.86	-0.84
	(3.91)	(3.90)	(3.91)
Tariff	-0.15***	-0.15***	-0.15***
	(0.02)	(0.02)	(0.02)
Exporter FE	Yes	Yes	Yes
Year FE	Yes	Yes	Yes
HS6 FE	Yes	Yes	Yes
Observations	6727	6727	6727

Standard errors in parentheses * p < 0.10, ** p < 0.05, *** p < 0.01

Table 2 presents results using the unit value of imports, a proxy for prices, as the dependent variable. As in Table 1, our coefficient of interest on the interaction between *Biologic* and one of our three measures of IPR strength is positive and significant, suggesting prices of biologics increase when imported under FTAs with strong IPR provisions. The coefficient of 0.14 in column (1) suggests that adding one patent-related provision to an FTA increases prices by approximately 15 percent. Results in column (2) show that adding any IPR provision with TRIPS compliant language increases prices by 4 percent (or 8 percent for adding one provision with TRIPS Plus language to an FTA). The coefficient of 0.52 in column (3) implies an FTA with any TRIPS-Plus language increases prices of biologics by 68 percent relative to an FTA with no TRIPS-Plus language.

Again, the coefficient on the interaction between *Biologic and FTA* is negative, demonstrating the mere presence of an FTA is not sufficient to impact unit values of imported biologics. What matters for biologics is the strength of the IPR language in an FTA. This is not the case for non-biologic medicines; the negative coefficients on the FTA dummy indicate that the presence of an FTA lowers unit values of all imported pharmaceutical products, again highlighting the difference between the impact on biologics and non-biologics from an FTA.

TABLE 2: THE EFFECT OF TREATY IPR STRENGTH ON THE UNIT VALUE OF IMPORTS

	(1) PatentScore	(2) IPRScore	(3) TRIPSPlus
	ln(ValKG)	ln(ValKG)	ln(ValKG)
Biologic	-1.05**	-1.06**	-1.07**
	(0.51)	(0.51)	(0.51)
PatentScore	-0.05*		
	(0.03)		
Biologic*PatentScore	0.14***		
	(0.04)		
IPRScore		-0.01	
		(0.01)	
Biologic*IPRScore		0.04***	
		(0.01)	
TRIPSPlus			-0.04
			(0.09)
Biologic*TRIPSPlus			0.52***
			(0.12)
FTA	-0.11**	-0.09	-0.13**
	(0.05)	(0.06)	(0.05)
Biologic*FTA	0.05	-0.07	0.02
	(0.08)	(0.09)	(0.08)
ln(Distance)	0.31	0.31	0.30
	(1.69)	(1.69)	(1.69)
Tariff	0.00	0.00	0.00
	(0.01)	(0.01)	(0.01)
Exporter FE	Yes	Yes	Yes
Year FE	Yes	Yes	Yes
HS6 FE	Yes	Yes	Yes
Observations	6727	6727	6727
	(1)	(2)	(3)
	ln(KG)	ln(KG)	ln(KG)
Standard errors in parentheses * p < 0.10, ** p < 0.05, *** p < 0.01			

Table 3 presents results for regressions of the value of imports on our key independent variables and controls. It is no surprise that our coefficients of interest on the interaction between Biologic and the three measures of IPR strength are positive, as we know from Tables 1 and 2 that the volume and price of imported biologics increase when biologics are imported under FTAs with strong IPR provisions. Adding a patent provision to an FTA increases the value of imports of biologics by approximately 38 percent. Adding any IPR provision with TRIPS compliant language increases the value of imports of biologics by 15 percent, implying that adding one provision with TRIPS-Plus language to an FTA increases the value of imports by 30 percent. The value of imports of biologics is 271 percent higher for FTAs containing any TRIPS-Plus language relative to FTAs with no TRIPS-Plus language.

TABLE 3: THE EFFECT OF TREATY IPR STRENGTH ON THE VALUE OF IMPORTS

	(1) PatentScore	(2) IPRScore	(3) TRIPSPlus
	ln(Imports)	ln(Imports)	ln(Imports)
Biologic	-5.11***	-5.09***	-5.08***
	(1.09)	(1.09)	(1.09)
PatentScore	0.04		
	(0.06)		
Biologic*PatentScore	0.32***		
	(0.09)		
IPRScore		-0.02	
		(0.02)	
Biologic*IPRScore		0.14***	
		(0.02)	
TRIPSPlus			-0.29
			(0.19)
Biologic*TRIPSPlus			1.31***
			(0.27)
FTA	0.17	0.25**	0.22**
	(0.11)	(0.13)	(0.11)
Biologic*FTA	-0.25	-0.64***	-0.30*
	(0.16)	(0.18)	(0.16)
ln(Distance)	-0.57	-0.55	-0.54
	(3.61)	(3.60)	(3.61)
Tariff	-0.15***	-0.14***	-0.14***
	(0.02)	(0.02)	(0.02)
Exporter FE	Yes	Yes	Yes
Year FE	Yes	Yes	Yes
HS6 FE	Yes	Yes	Yes
Observations	6727	6727	6727

Standard errors in parentheses * p < 0.10, ** p < 0.05, *** p < 0.01

Conclusions and Future Research

We examined the impact of the strength of the IPR provisions using new indicators we developed from the text of Chile's FTAs. We find the strength of the IPR provisions in an FTA matters for the imported volume and unit value of imports of biologics and, by extension, the total value of imports of these products. FTAs with strong IPR provisions increase both the volume and unit value of imported biologics, indicating both the market expansion and market power effects are present. Comparing the magnitude of our results in Tables (1) and (2) shows that the quantity imported in kilograms is more affected by all three measures of treaty IPR strength than the unit value of imports, our proxy for price, suggesting the market expansion effect may be larger.

Comparing the impacts of the three measure of IPR strength on all three measures of imports (value, volume and unit value), the largest impact on imports comes from implementing an FTA with at least one TRIPS-Plus provision. This result is intuitive, as FTAs with deeper integration have the potential to significantly stimulate bilateral trade by removing non-pecuniary barriers to trading IP-intensive goods in addition to pecuniary barriers. By comparing the impacts of *PatentScore and IPRScore*, we see that the impacts on imports of adding a patent-related provision to an FTA are consistently larger than for any other type of IPR provision. In the case of Chile, patents, therefore, are important drivers of imports of IP-intensive biologics.

Our paper contributes to the literature by developing new indicators of treaty IPR strength, focusing on one group of pharmaceuticals that is highly affected by IPR provisions and increasingly important to public health and using the gravity model to estimate the impacts on the value, volume and unit value of imports. Our work, however, has an important limitation. Our results suggest that IPR-intensive FTAs may raise the unit value and volume of imported biologics, but our work cannot answer whether Chile's FTAs have expanded or limited universal access to medicines in general and biologics in particular. Optimistically, increased imports could have led to more access to biologics across the Chilean population. However, increased imports could be due to losses in domestic production or diversion of government purchases away from spending on other health or necessary investments. Even if Chile's IPR-intensive FTAs result in trade creation related to biologics, it is possible additional imports are distributed upwards toward those patients that can afford the higher prices, increasing inequity in access (Wirtz et al, 2017). It is beyond the scope of this paper to conduct a corollary analysis on domestic factors affecting Chile's imports and the distributional aspects related to pharmaceuticals. We plan to conduct follow-up research on how the implementation of an FTA affects Chilean health care, insurance and government institutions and the ways in which those changes are passed on to consumers of medicines.

On its own, this paper adds to the literature and debate over the effect of trade agreements on the imports of medicines. Moreover, our findings raise interesting questions and provide new avenues for further research.

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Appendix Tables

Appendix Table 1: Assessment of Chile's Bilateral FTAs

Partner Country	**United States**	**Japan**	**India**	**European Union**	**EFTA**	**Mexico**	**China**	**Canada**
Specific Incorporation of DOHA Agreement	TRIPS-compliant	NO specific language	NO specific language	NO specific language- incorporation of UN Dec'l Human Rights : TRIPS compliant	NO specific language	NO specific language	TRIPS compliant	NO specific language
non-derogation of TRIPS/affirm TRIPS obligations	TRIPS- compliant	TRIPS-compliant	NO specific language	TRIPS-compliant	TRIPS- compliant	TRIPS-compliant	NO specific language	NO specific language
National Treatment (non discrimination)	TRIPS-compliant	TRIPS-compliant	TRIPS-compliant	TRIPS-compliant	TRIPS-compliant	TRIPS-compliant	TRIPS-compliant	TRIPS-compliant
Patentable subject matter	None Potentially TRIPS plus	NO specific language	NO specific language	NO specific language	NO specific language	NO specific language	NO specific language	NO specific language
Revocation or cancellation of patents	Potentially TRIPS plus	NO specific language	NO specific language	NO specific language	NO specific language	NO specific language	NO specific language	NO specific language
Patent term restoration due to administrative delays	Potentially TRIPS plus	NO specific language	NO specific language	NO specific language	Potentially TRIPS plus	NO specific language	NO specific language	NO specific language
Patent term extension due to marketing/regulatory process	Potentially TRIPS plus	NO specific language	NO specific language	NO specific language	Potentially TRIPS plus	NO specific language	NO specific language	NO specific language
Protection of 'undisclosed data" language	TRIPS plus	NO specific language	NO specific language	NO specific language	TRIPS plus	NO specific language	NO specific language	NO specific language
Government procurement: may discriminate against open tendering if goods are protected by patent	TRIPS-compliant	TRIPS-compliant	NO specific language	TRIPS-compliant	TRIPS-compliant	NO specific language: negotiations supposed to start ONE year after this FTA goes into force Potentially TRIPS-plus	NO specific language	TRIPS-compliant
government provision of goods and services to persons or to a regional or local level of government are NOT obliged to be open tendering	TRIPS-compliant	NO specific language	NO specific language	NO specific language	NO specific language	NO specific language-see above Potentially TRIPS plus	NO specific language	NO specific language
Compulsory licensing only under TRIPS terms/ DOHA Declaration	NO specific language	NO specific language	NO specific language	NO specific language	TRIPS-compliant	NO specific language	NO specific language	NO specific language

Appendix Table 1 (continued): Assessment of Chile's Bilateral FTAs

Partner Country	Thailand	Hong Kong	Malaysia	Turkey	Australia	Korea	Panama, Peru, Colombia, Vietnam
							IN SPANISH
Specific Incorporation of DOHA Agreement	No specific language	No specific language	No specific language	No specific language	No specific language	No specific language	
Non-derogation of TRIPS/affirm TRIPS obligations	Affirm: TRIPS compliant	Affirm: TRIPS compliant	Affirm: TRIPS compliant	Affirm: TRIPS compliant	Affirm: TRIPS compliant	Specific non-derogation: TRIPS-compliant	
National Treatment (non discrimination)	No specific language	TRIPS-compliant	TRIPS-compliant	TRIPS-compliant	TRIPS-compliant Either Party can implement MORE "extensive" IP protection than required under FTA	TRIPS-compliant Either Party can implement MORE "extensive" IP protection than required under FTA	
Patentable subject matter	No specific language	No specific language	No specific language	No specific language	No specific language (one year grace period for novelty/non-obvious)	No specific language	
Revocation or cancellation of patents	No specific language	No specific language	No specific language	No specific language	Potentially TRIPS-plus	No specific language	
Patent term restoration due to administrative delays	No specific language	No specific language	No specific language	No specific language	No specific language	No specific language	
Patent term extension due to marketing/regulatory process	No specific language	No specific language	No specific language	No specific language	No specific language	No specific language	
Protection of 'undisclosed data" language	No specific language	No specific language	No specific language	No specific language	No specific language	No specific language	
Government procurement: may discriminate against open tendering if goods are protected by patent	No specific language	TRIPS-compliant	No specific language	No specific language	TRIPS-compliant	TRIPS-compliant	
government provision of goods and services to persons or to a regional or local level of government are NOT obliged to be open tendering	No specific language	No specific language	No specific language	No specific language	No specific language	No specific language	
Compulsory licensing only under TRIPS terms/DOHA Declaration	No specific language	No specific language	No specific language	No specific language	No specific language	No specific language	

Appendix Table 2: Assessment of Chile's multilateral FTAs

Multilateral agreements	Pacific Alliance (Colombia, Mexico, Peru)	P4 (New Zealand, Singapore and Brunei Darussalam),	Chile-Central America	Chile-Mercosur
Specific Incorporation of DOHA Agreement	No specific language	No specific language	No specific language	No specific language
non-derogation of TRIPS/affirm TRIPS obligations	No specific language	Non-derogation and affirmation	No specific affirmation of TRIPS	Affirmation of TRIPS
National Treatment (non discrimination)	TRIPS compliant	TRIPS compliant	TRIPS compliant	??
Patentable subject matter	No specific language	No specific language	No specific language	No specific language
Revocation or cancellation of patents	No specific language	No specific language	No specific language	No specific language
Patent term restoration due to administrative delays	No specific language	No specific language	No specific language	No specific language
Patent term extension due to marketing/regulatory process	No specific language	No specific language	No specific language	No specific language
Protection of 'undisclosed data" language	No specific language	No specific language	No specific language	No specific language
Government procurement: may discriminate against open tendering if goods are protected by patent	TRIPS compliant	TRIPS compliant	No specific language	No specific language
government provision of goods and services to persons or to a regional or local level of government are NOT obliged to be open tendering	No specific language	TRIPS compliant	No specific language	No specific language
Compulsory licensing only under TRIPS terms/ DOHA Declaration	TRIPS-neutral	No specific language	No specific language	No specific language

Appendix Table 3: Classification of Ch. 30 HS-6 codes into Biologic or Non-Biologic

3001	Glands and other organs for organo-therapeutic uses, dried, whether or not powdered; extracts of glands or other organs or of their secretions for organo-therapeutic uses; heparin and its salts; other human or animal substances prepared for therapeutic or prophylactic uses, not elsewhere specified or included.		
	300110	Glands and other organs, dried, whether or not powdered	Biologic
	300120	Extracts of glands or other organs or of their secretions	Biologic
	300190	Other under heading 3001	Biologic
3002	**Human blood; animal blood prepared for therapeutic, prophylactic or diagnostic uses; antisera and other blood fractions and modified immunological products, whether or not obtained by means of biotechnological processes; vaccines, toxins, cultures of micro-organisms (excluding yeasts) and similar products.**		
	300210	Antisera and other blood fractions and modified immunological products, whether or not obtained by means of biotechnological processes	Biologic
	300220	Vaccines for human medicine	Biologic
	300230	Vaccines for veterinary medicine	Biologic
	300290	Other other heading 3002	Biologic
3003	**Medicaments (excluding goods of heading 30.02, 30.05 or 30.06) consisting of two or more constituents which have been mixed together for therapeutic or prophylactic uses, not put up in measured doses or in forms or packings for retail sale.**		
	300310	Containing penicillins or derivatives thereof, with a penicillanic acid structure, or streptomycins or their derivatives	No
	300320	Containing other antibiotics	No
	300331	Containing hormones or other products of heading No. 29.37 but not containing antibiotics :-- Containing insulin	Biologic
	300339	Containing hormones or other products of heading No. 29.37 but not containing antibiotics :-- Other	No
	300340	Containing alkaloids or derivatives thereof but not containing hormones or other products of heading 29.37 or antibiotics	No
	300390	Other under heading 3003	No
3004	**Medicaments (excluding goods of heading 30.02, 30.05 or 30.06) consisting of mixed or unmixed products for therapeutic or prophylactic uses, put up in measured doses (including those in the form of transdermal administration systems) or in forms or packings for retail sale.**		
	300410	Containing penicillins or derivatives thereof, with a penicillanic acid structure, or streptomycins or their derivatives	No
	300420	Containing other antibiotics	No
	300431	Containing hormones or other products of heading No 29.37 but not containing antibiotics :-- Containing insulin	Biologic
	300432	Containing hormones or other products of heading No 29.37 but not containing antibiotics :-- Containing adrenal cortical hormones	No
	300439	Containing hormones or other products of heading No 29.37 but not containing antibiotics :-- Other	No
	300440	Containing alkaloids or derivatives thereof but not containing hormones, other products of heading No. 29.37 or antibiotics	No
	300450	Other medicaments containing vitamins or other products of heading No. 29.36	No
	300490	Other under heading 3004	No
3005	**Wadding, gauze, bandages and similar articles (for example, dressings, adhesive plasters, poultices), impregnated or coated with pharmaceutical substances or put up in forms or packings for retail sale for medical, surgical, dental or veterinary purposes.**		
	300510	Adhesive dressings and other articles having an adhesive layer	No
	300590	Other under heading 3005	No
3006	**Pharmaceutical goods specified in Note 4 to this Chapter**.		
	300610	Sterile surgical catgut, similar sterile suture materials and sterile tissue adhesives for surgical wound closure; sterile laminaria and sterile laminaria tents; sterile absorbable surgical or dental haemostatics	No
	300620	Blood-grouping reagents	No
	300630	Opacifying preparations for X-ray examinations; diagnostic reagents designed to be administered to the patient	No
	300640	Dental cements and other dental fillings; bone reconstruction cements	No
	300650	First-aid boxes and kits	No
	300660	Chemical contraceptive preparations based on hormones or spermicides	No

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