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TRADE MEASURES ON PHARMACEUTICAL PRODUCTS: CAN THEY PROMOTE LOCAL PRODUCTION AND PUBLIC HEALTH?

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The rise in trade measures on pharmaceutical products has become a matter of intense debate since the start of the COVID-19 crisis. By October 2022, more than140 export restrictions had been placed on them worldwide; at least 50 directly affected vaccine production and distribution. A systematic assessment of their welfare effects offers a way to classify the plethora of trade measures in the global pharmaceutical sector with an explanation of their use in different jurisdictions worldwide. It also provides an assessment and indicates advances on ways in which such trade measures can be used in the interest of local production and public health.

Keywords: local production, trade measures, tariffs, non-tariff measures, industrial policy, access to medicines, government policy, intellectual property rights

JEL classification: I11, I15, I18, L11, L23, L52, O25, O34, O38

I. INTRODUCTION

Trade measures on pharmaceutical products have been a subject of scrutiny since the start of the COVID-19 crisis, owing to the imposition of export restrictions by many countries even amid continued shortages of medical equipment, drugs and vaccines in many regions of the world. At the peak of the crisis, in October 2022, a total of 147 export restrictions worldwide were imposed, of which fifty of them directly affected vaccine production and distribution (Gill and Ruta, 2022). This reality raises many technical trade-related and ethical questions: Primarily, what kinds of trade measures exist in the pharmaceutical sector? Are all such trade measures bad, or are there some that can be used in the interest of public health? If so, how can the nationalistic trade measures, differences in regulatory frameworks between countries and other impediments to cross-border trade that adversely affect the production and distribution of medicines be reconciled with those that may be beneficial to promote local production or health?

Broadly speaking, trade measures fall into two categories: tariff and non-tariff measures (NTMs). Tariff and quotas are more easily understood and widely studied. While on a decline worldwide, tariffs to imported medicines, or components thereof continue to be applied in several countries. For instance, a 2019 study in which a comparison of pharmaceutical tariffs was conducted indicated that Argentina, Colombia, India, the Lao People's Democratic Republic and Nepal, impose the highest tariffs on imported medicines, which eventually are passed on in the final prices of medicines (Adam Smith Center and others, 2019). NTMs, in contrast, do not have any specific definition or classification; they can refer to any measures other than tariffs that are imposed to restrict or prohibit imports (Forzely, 2007) and can be defined as those "policy measures other than ordinary customs tariffs that can potentially have an economic effect on international trade in goods, changing quantities traded, or prices or both" (UNCTAD, 2010, p. 99). These measures originate primarily in domestic regulations and create hidden costs that affect the quantity and/or price of traded goods (OECD, n.d.). In general, such NTMs can be split into (a) technical measures, which includes regulations, standards, testing and certification, primarily sanitary and phytosanitary (SPS) and technical barriers to trade (TBT) measures; and (b) non-technical measures (quantitative), which includes quantitative restrictions in commercial and industrial policies in countries, price measures, among others (OECD, n.d.).

Different arguments can be made for and against trade measures of both kinds. First, in their favour, tariffs and quota restrictions can be used by countries that produce specific medical products to ensure adequate prioritized domestic access to the products produced nationally in a manner similar to what was witnessed during

the pandemic (OECD, 2020). Second, some tariff measures, also called contingent measures, can be used to restrict imported quantities either as a matter of commercial regulations or industrial policy in favour of advancing domestic pharmaceutical production. In these instances, the cap on imports helps ensure that local firms that produce relevant pharmaceutical products can rely on local demand as an incentive for expanding their production. Third, export restrictions can help prevent price gauging and a "winner-takes-all" dynamic in cases in which normal market forces have failed (Paulwelyn, 2020, p.4). Finally, quantitative restrictions on imports can also prevent a dependency on imports of the kind that has now left many regions of the world – particularly Africa – very exposed to the fallouts of the pandemic and other health crises.

At the same time, a tariff can end up redistributing wealth by forcing consumers who may have to pay more for the locally produced products to the local producers of those products if it continues for an extended time period without the creation of a more competitive production landscape under which prices are closer to marginal costs. There is also the possibility that markets might look substantially different if such export restrictions and quantitative import restrictions are not in place to limit supplies or artificially increase prices in the global pharmaceutical market.[1] The proponents of low or zero tariffs, therefore argue that even the lowest of import tariffs affects the final end price of medicines with implications for access and affordability (Bauer, 2017), or that tariffs can undermine differential pricing by firms simply because the price reductions offered by the manufacturer are not reflected in end-patient prices for consumers and patients (Yadav, 2010).

Globally, approximately 3,000 new or changed NTMs have been reported to World Trade Organization (WTO) since 2013. In 2018, a total of 95 per cent of all notifications were technical measures (SPS and TBT) while the remaining 5 per cent were considered as contingent measures (ESCAP, 2019, p.9). OECD (2018, p. 26) estimates that already in 2018, the *ad valorem* equivalents of NTMs in countries (across all sectors) are more than twice as high as tariffs. In this overall picture, the use of NTMs in the pharmaceutical sector is also rising, but the use of them and their impact remain an understudied empirical issue because there is no readily available classification of NTMs on health-related products. This makes it difficult to assess how and in what ways they can help or undermine global health or assist in balancing domestic considerations with international trade.

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[1] 34 members of WTO agreed to reciprocally eliminate import duties on approximately 7,000 pharma products under the WTO Pharmaceutical Tariff Elimination Agreement (known as the "Zero for Zero Initiative") in 1995. By and large, the Agreement has not expanded in reach, and the total global trade in pharmaceuticals in countries that are non-parties to the Zero-for-Zero Initiative has been increasing.

The present paper contributes to this discussion in two ways. Starting off with a summary of general trends in tariffs for pharmaceutical products (section 2), the focus of the paper is primarily to create a classification structure for NTMs in use in the global pharmaceutical sector in section 3. It also presents examples – to the extent possible from a review of literature and country-level studies – on how they are structured in different countries worldwide. Section 4 concludes with an assessment of the cumulative effects of tariff and non-tariff barriers on access, and the identification of future areas for research.

II. GENERAL TRENDS IN TARIFFS ON PHARMACEUTICAL PRODUCTS

Sifting through trade statistics and tariffs on health-related products to segregate impacts remains a difficult task, given the absence of a precise classification of health products in WTO and its agreements. Broadly speaking, health products are identified under 207 subheadings (comprising 334 tariff lines) of the Harmonized Commodity Description and Coding System (HS) of tariff nomenclature (used to monitor international trade). The main categories that relate to the pharmaceutical sector within this nomenclature are contained in HS29 (labelled as Organic Chemicals, 57 tariff subheadings covering inputs specific to the pharmaceutical industry, such as antibiotics, hormones and vitamins) and in HS30 (labelled as pharmaceutical products with six tariff subheadings covering medicaments not put up in measured doses for retail sale, namely sold in bulk).[2] These categories also are not supported by data that could form the basis of any exhaustive empirical analysis, but the categorization provides a useful basis to understand the evolution and directionality of pharmaceutical trade between countries. This section contains a summary of the key results available in this regard.

2.1 Changes in pharmaceutical tariffs since the onset of the COVID-19 pandemic

In general, tariffs on pharmaceuticals have declined steadily since the 2000s, down from a global average of 4.9 per cent in 2001 to 3.4 per cent in 2018. Banik and Stevens (2018) note that a large share of the overall decline in tariffs is attributable to changes in tariff regimes in low-and middle-income countries. Many of these countries, such as Bahrain, Ghana, Israel, Mongolia and Nigeria, have eliminated pharmaceutical tariffs altogether.

[2] https://www.wto.org/english/tratop_e/trips_e/trilatweb_e/ch4d_trilat_web_13_e.htm. Similarly, the dataset generated from UNCTAD TRAINS shows 500 lines of measures, but this only means that certain requirements are imposed – whether those requirements are unnecessarily burdensome, since they constitute a barrier to trade, or whether they deviate from international standards, cannot be inferred from these data.

The situation has changed drastically since the onset of the COVID 19 pandemic. At least 106 jurisdictions worldwide have executed over 234 trade policy measures to either restrict export of COVID-19-related medical products or to relax tariffs on imports of COVID-19 medical products supposedly to increase accessibility. On a closer look, trade policy during the pandemic appears to be closely correlated with trade imbalances of countries in essential medical equipment. Leibovici and Santacreu (2020) use data on trade policy for essential medical equipment starting in March 2020 and data on imports and exports of these goods for 109 countries during 2018 to draw comparisons. They conclude that approximately 86 per cent of countries with a medical equipment surplus in 2018 restricted exports, but only 46 per cent of the countries running deficits in these goods imposed restrictions. On the other end of the spectrum, regarding relaxation of tariffs, only 18 per cent of countries with a surplus in these goods reduced tariffs in these categories, in contrast with almost 30 per cent of the net importers. These trends indicate that inflationary trade barriers[3] have posed unnecessary barriers to access to medicines during the pandemic and raise the question whether such measures are justified when countries have production surpluses in medical products that are needed globally to save lives.

2.2 Country-and region-specific tariff differences

Several country-specific or regional tariff differences exist. The European Union, for instance, has practically no tariff measures for medicine imports, but pre-COVID figures in 2019 show that total European Union (EU) trade (imports plus exports) in medical products represented 9.3 per cent of total EU trade and that it remained a net exporter of medical products overall (World Bank, 2022),[4] with net exports totalling 123 billion euro (€) ($121 billion), or 0.9 per cent of EU gross domestic product (GDP) in 2019 (Hallak, 2020). Of these, pharmaceuticals accounted for 66 per cent of total exports in 2019. Data on trade in medicinal products of the 27 EU countries show that global exports from the trade bloc have increased steadily from $50 billion in 2002 to $203 billion in 2019. During the same time period, the 27 EU countries imports have risen from $32.3 billion in 2002 to $93.5 billion in 2019 (Eurostat, 2019).

Other countries impose differential tariff regimes, such as the Russian Federation (10.2 per cent), India (10 per cent), Uruguay (9.9 per cent), Argentina (9.8 per cent), Brazil (9.8 per cent) and Thailand (9.3 per cent) (Banik and Stevens, 2015). Primarily, tariffs are used in several countries in this category – such as by Argentina, Brazil,

[3] When trade barriers create shortages which domestic suppliers cannot meet, especially in the face of rapidly rising demand, such as due to the pandemic response, then such trade barriers can become inflationary.

[4] Including the HS categories of pharmaceutical products, medical equipment, medical supplies and personal protection.

India and Thailand – as an incentive to promote and maintain markets for the local pharmaceutical sector, which has come under increased competition since the global trading regime was instituted by WTO in 1995. Tariffs on imported goods almost always help competing domestic producers to protect their market share if they already have been producing and supplying the domestic market, or to gain access to the market if they are new producers. In general, tariffs ensure that local demand remains an incentive for local production, leading often to lower prices, and thus contributing to increased health security and access to medicines. However, the observed trend on increases in tariffs in some countries has been accompanied by a decline in tariffs in other countries and is mostly aimed at promoting access to medicines. The most notable changes have occurred in Chile, Israel and Türkiye, where tariffs have been cut altogether (Bauer, 2017). Other countries, such as Mexico, have lowered their tariffs to a weighted average of 2.6 per cent (Bauer, 2017), but continue to apply numerous tariff lines (78 in the case of Mexico).

III. THE COMPLEXITY OF NON-TRADE MEASURES IN THE PHARMACEUTICAL SECTOR

In the pharmaceutical sector, there has been an exponential increase in the kinds of NTMs in use. To understand their scope and impact, the following classification is proposed for this paper:

(a) Technical measures, which include regulations, standards, testing and certification, primarily SPS measures.

(b) Non-technical measures (quantitative), which include quantitative restrictions in commercial and industrial policies in countries.

(c) Non-technical measures (pricing and distribution), which include parallel imports, price controls, and forced distribution channels.

These three categories of NTMs essentially cover the areas that shape competition in the pharmaceutical market, namely manufacturing regulations, drug regulatory processes and pricing regulations. Consequently, they have large implications for how trade in pharmaceutical products unfold, and how local production of pharmaceutical products is facilitated.

3.1 Non-technical measures (quantitative) in favour of local production

Non-technical measures are quantitative restrictions in commercial and industrial policy that apply to imported and exported goods. Commercial restrictions include contingent trade protective measures (anti-dumping and countervailing duties), which are used for trade defence. On the industrial policy side, quotas and preferences

(based on local content), subsidies, localization requirements, managed technology transfer and licensing measures are used to maximize public health objectives.

3.1.1 Contingent trade protective measures

These measures are implemented to counteract potential adverse effects of imports on the domestic market of the importing country (UNCTAD, 2019). Anti-dumping measures are common in this category, charging import duties on a good exported by a foreign producer for "dumping" that product at a price below what is charged in the foreign producer's home market and causing market losses to the domestic producer of the product in the importing country (Wu, 2012). Such price differentials can emerge when the exporting country offers specific tax rebates to firms that create price advantages, or when firms explore certain price advantages in outside markets in an effort to gain shares abroad. Countervailing duties are similarly imposed as a trade remedy when a country feels that importers are engaging in "unfair" trade practices by seeking to sell goods that undercut the market price. These measures are referred to as "contingent" protection because WTO calls for a link between the trade volume and the imposition of trade protection. India, for instance, offered the Merchandise Exports from India Scheme, 2015, under which pharmaceutical products exported to specific countries received a 3 per cent reward from the government.

3.1.2 Import licences and quotas

Different licensing requirements – such as licensing of imports only when there is on local production of the product, and in the interest of public health – fall under this category. Countries can also impose import quotas on active pharmaceutical ingredients or drugs not produced locally, or in extreme cases, impose full prohibitions on imports entirely.

(i) Import licenses only in categories in which there is no local production

Market constraints of many kinds have been imposed by several lower middle-income countries to protect and nurture local pharmaceutical firms. Import licensing only in categories where local firms do not manufacture is one such constraint. For example, to assist the Bangladesh pharmaceutical sector, the national policy explicitly reserves the national market for local firms in product categories in which they have the competencies. Importers are allowed to conduct business only in those categories in which local products are unavailable (Gehl Sampath, 2020). Currently, many countries provide for such import restrictions, including Algeria, which prohibits imports of virtually all pharmaceutical and biopharmaceutical products that compete with similar products that are manufactured domestically. The country also imposes annual quotas on those products and active

pharmaceutical ingredients that are not manufactured locally to contain costs.

(ii) Quotas for local producers in government procurement processes

Enhanced use of quotas for local producers is becoming increasing prevalent. In the Russian Federation, preferences can be given to locally produced finished dosage forms through the government procurement system. The regulations provide for restrictions on imports of drugs when at least two local producers are able to source them domestically.[5] In addition, local producers receive a 15 per cent price preference in all domestic tenders.[6] In South Africa, pharmaceuticals are similarly earmarked as a sector requiring domestic content in government procurement processes of between 35 to 90 per cent.[7]

3.1.3 Market access incumbent on localization

Another form of market constraint is when countries specifically deny access to firms that do not produce locally. This requirement to "work" a patent, widely prevalent in many national patent laws prior to the Trade Related Aspects of Intellectual Property Rights (TRIPS) Agreement, is imposed from the perspective of promoting local manufacturing capacity and technology transfer in several national laws. For example, in Indonesia, the local manufacturing and technology transfer requirements of Decree 1010, and the recent Patent Law stipulate a forced localization requirement, without which multinational corporations cannot receive market authorization for their products.[8] Since December 2015, the Government of Türkiye has enacted a scheme that promotes localization by offering preferential reimbursement arrangements for

[5] Resolution 1289 (30 November 2015) provides for what is widely known as the "three is a crowd" approach. According to the resolution, the presence of two or more Eurasian Economic Community pharmaceutical manufacturers to bid on a tender related to any product on the Essential Drugs List in the Russian Federation automatically leads to rejections of foreign bids on the matter. All medicines not covered by the resolution were granted a 15 per cent price preference by a preference system established by the Ministry of Economic Development. Resolution 572 of 12 May 2018 amends the earlier Resolution 1289 by introducing a new regulatory framework that came into force from 1 January 2019 and provided additional preferences in state procurement for essential medicinal products that use active pharmaceutical ingredients that are locally manufactured. The earlier "three is a crowd" procurement system no longer applies.

[6] Order of the Ministry of Economic Development No.155 dated 25 March 2014.

[7] See South African Regulation Gazette No. 9544 – Regulasiekoerant, volume. 552 – Number 34350 (8 June 2011), under which preferential procurement regulations granting preferences for local products and Broad-Based Black Economic Empowerment "B-BBEE" scheme were revised, effective December 2011.

[8] Ministry of Health (Decree 1010/ MENKES/PER/XI/2008 ("Decree 1010').

health-care products produced domestically, and delisting imported products from the national reimbursement list.[9] In the Russian Federation, as of 1 January 2017, local production of the finished dosage form was made a prerequisite in order to qualify as a Russian manufacturer,[10] and several kinds of medical products/devices not originating from the Eurasian Economic Union were entirely banned from state and municipal level procurements in the Russian Federation to promote local production.[11] The Government has been, in parallel, encouraging foreign manufacturers to switch to full cycle production in the country by providing a number of financial and other incentives to foreign producers.[12] Other countries imposing localization barriers are Argentina, China, India and Viet Nam.

3.1.4 Compulsory licensing to promote public health

Compulsory licensing is a widely recognized flexibility under the TRIPS Agreement, the use of it as a public health tool was clarified and upheld by the Doha Declaration on Public Health in 2001. Since then, it has been used by many countries to promote access to medicines, and in the presence of a local manufacturing sector, can also contribute towards strengthening local production capacity in so far as it facilitates the transfer of licences with new product/process technologies to local firms. In the very least, the willingness of governments to engage in compulsory licensing can promote investments in local production, given that it acts as a signal of a country's commitment to promote cheap, and efficacious access to medicines through local firms.

A review of licences issued between 2001 and 2018 shows two main trends. First, the highest application of compulsory licensing was limited to the HIV/AIDS crises and applied to antiretrovirals (ARVs) between 2001 (spiking immediately after the 2001 Doha decision), and then tapering down by 2008.[13] Starting in 2012, a new trend emerged. Thanks to rising drug prices, compulsory licences had begun to be issued across different disease categories, most notably hepatitis C and cancer. Emphasizing the wider use of the mechanism, the United Nations High-Level Panel on Access to Medicines has recently recommended the use of TRIPS flexibilities and the implementation of legislation that facilitates the issuance of compulsory licenses

[9] Article 46 of the sixty-fourth Government Action Plan (released on 10 December 2015).

[10] Regulation of the Government of Russia, No.719 dated 17 July 2015.

[11] Resolution of the Government of Russia No.102 dated 5 February 2015.

[12] Federal programme for development of pharmaceutical and medical industry for the period until 2020 and subsequently approved by the Regulation of the Russian Government No.91 dated 17 February 2011.

[13] T'Hoen and others (2018) report a similar trend in their study on compulsory licences.

"designed to effectuate quick, fair, predictable, and implementable compulsory licenses for legitimate public health needs" (United Nations, 2016).

3.1.5 Managed technology transfer

Managed or "forced" technology transfer, where market access is coupled with a condition to engage in technology transfer has received much attention in recent years. The 301 findings in 2018[14] of the United States Trade Representative argued that Chinese laws effectively compel foreign investors in China to transfer technology to domestic joint venture partners as a condition for approving inward investments, or for conditioning regulatory approvals (Abbott, 2020). Other provisions in Chinese domestic laws, such as Article 27 of the Technology Import-Export Regulation. require that follow-on improvements made to technology in contractual relations be owned by the party making these changes (Prud'Homme, 2019). The United States-China conflict on this issue has brought back attention to efforts by countries – particularly developing countries – to target the transfer of technology by making market access, or investment, conditional (Andrenelli, Gourdon and Moïsé, 2019), which remains an essential arsenal in the industrial policy toolkit for building industrial capacity.

In the pharmaceutical sector, such managed technology transfer stipulations are not common, but some countries couple market access with technology transfer. In Indonesia, for instance, a biopharmaceutical company is allowed to import drugs into the country only when it partners with a local company and ensures technology transfer in a manner that allows the local counterpart to produce the drug within Indonesia in five years from the start of the partnership (PhRMA, 2018).

3.2 Technical measures: procedural and regulatory

Technical objectives frequently serve the legitimate purpose of drug safety. There are numerous such regulations in this regard, ranging from those that relate to drug approval to patent protection and enforcement.

3.2.1 Drug regulatory approval processes

In general, importers are required to apply for authorization to the national drug regulatory authority in each importing country before products can be introduced in the market. If the drug is new and innovative, the regulatory process calls for clinical trials data (and dossiers) to demonstrate its safety and efficacy profile. The approval process for generic drugs is simpler, but generally requires proof of bioequivalence. In turn, bioequivalence typically requires a clinical trial that shows the generic delivers the

[14] See USTR. Findings of the Investigation into China's Acts, Policies, and Practices Related to Technology Transfer, Intellectual Property, and Innovation Under Section 301 of the Trade Act Of 1974, 22 March 2018.

same quantity of active ingredients into a patient's bloodstream in the same amount of time as the original drug. In this process, normally, in addition to the demonstration of substantive equivalence (namely that the generic is substantively the same as the originator drug), the manufacturer must prove compliance with production quality standards and show that the generic is identical in terms of dosage form, strength, route of administration and intended use.

A common step in the process is the inspection of the manufacturing plant to check compliance with production quality standards. However, given the globalized nature of manufacturing, it is hard for national governments to ensure this step as a large share of the medicines may be produced abroad. In the case of the United States, for instance, more than 40 per cent of finished pharmaceutical products and more than 80 per cent of all active pharmaceutical ingredients in use in the local market are manufactured abroad (GAO, 2016). The Food and Drug Administration (FDA) conducts routine inspections of these plants through its foreign offices, but estimates suggest that as of 2016, approximately 1,000 plants may not have been inspected for reasons of resource constraints (GAO, 2016). Several Organisation of Economic Co-operation and Development (OECD) countries – especially EU member countries, along with Australia, Canada, and New Zealand – have reciprocal arrangements for inspection to ameliorate these delays and promote product entry. FDA has now begun a new reciprocal inspection agreement with the EU which began to be implemented in 2019 (European Medicines Agency,2018). But more widely, the lack of such reciprocal inspection agreements and an agreement on general standards continues to cause delays for the authorization of new manufacturers in these countries.

In a wider, global context, the multiplicity of drug approval agencies and drug regulatory standards and protocols adds to the costs of drug registrations for pharmaceutical companies. Many studies have highlighted how drug regulatory approval systems in lower middle-income countries, either due to a lack of transparent registration procedures or by virtue of their extremely divergent requirements across countries for bioequivalence, act as barriers to entry of pharmaceutical products in several markets (Barton and others, 2019, p. 2). There are not, however, many studies on how delays in inspection agreements involving the EU, the United States and other countries act as a barrier to local producers seeking to export to regulated markets, although these matter equally.

Delays in processing applications and high costs of drug approval also persist. In Latin America, for instance, estimates suggest an increase in overall regulatory approval times in recent years, with Brazil and Columbia taking two years each to grant approval (Adam Smith Center, and others, 2019, p. 5). The time lag from the date of application of a drug or vaccine dossier for approval and the receipt of regulatory approval varies, but it is equally large or larger in other countries. It can

take between one and two years in India, more than three years in Indonesia, more than two years in China, and anywhere between four and seven years in sub-Saharan Africa countries (Adam Smith Center, and others, 2019; Ahonkhai and others, 2016. Efficiency increases and cost reductions can be achieved if regulatory authorities harmonize their review processes in addition to sharing inspection formalities of clinical or manufacturing sites for similar purposes (Zerhouni and Hamburg, 2016).

3.2.2 Other obligations to manufacturers

Local manufacturers also face other obligations in exporting countries. An EU directive of 2001[15] lists the many obligations that need to be met by pharmaceutical companies before and after market entry. It establishes an obligation for a firm obtaining market authorization to inform the competent authority of the actual date when marketing of the said product will begin,[16] and sets a time limit of three years to market the product, otherwise, market authorization can be withdrawn.[17] Other obligations begin to take effect if the manufacturer plans to withdraw the product from the market, temporarily or permanently. In such an eventuality, manufacturers must notify the competent authorities at least two months prior to withdrawal.[18] The notice period is to allow the health-care providers to ensure alternate treatments are available. National authorities in the EU countries have different variations of these obligations, with France providing for a full one-year notice before product withdrawal (de Weert and others, 2015). Such other obligations frequently act as barriers, particularly to producers from lower middle-income countries seeking to introduce products in the EU market.

3.2.3 Mark-ups, taxes and organization of supply chains

As a pharmaceutical product moves along the supply chain from the point of entry to the market, several taxes, levies and other charges are imposed by different regulatory agencies, which changes the final price of the medicines (Cameron and others, 2009). These include taxes (general sales tax, value added tax), port charges, warehouse costs, local government levies, distribution costs and retailer mark-ups, among others, depending on the regulatory context. There is little comparative data on the topic, even though such charges have a significant impact on the end price of pharmaceuticals (Ball, 2011). The variations in the in the mark-ups can be wide, not

[15] The European Parliament and the Council of the European Union, 2011a. DIRECTIVE 2001/83/EC OF THE European Parliament and of the council of 6 November 2001 on the Community code relating to medicinal products for human use (EU Dir 2001/83/EC).

[16] See Art 23a, EU Dir 2001/83/EC.

[17] Article 24, EU Dir 2001/83/EC.

[18] See Art 23a, EU Dir 2001/83/EC.

just between countries but also within countries. One study suggests that generics in Thailand, for instance, can be subject to pharmacy mark-ups anywhere in the range of 20 to 150 per cent (Kanavos, 2014, p. 9). On the question of taxes, once again, the paucity of data limits the ability to create a clear picture. Country-level comparisons, however, show extreme variances. In Brazil, taxes alone amount to 35 per cent of the total retail price, whereas in many other countries they can account for no more than 6 per cent of the retail price (PhRMA, 2018, p.50).

Mark-ups are affected mostly by the way in which medicine distribution channels are organized within countries. In general, however, when tariffs on pharmaceutical products seem low, products are accompanied by multiple mark-ups along the supply chain, which add to the end price of the medicine. For example, in several lower middle-income countries, there is a reliance on subdistributors given that they have local knowledge of rural areas. However, in the absence of strong regulatory frameworks that promote cooperative dynamics, this reliance often adds to inefficiencies and costs. The International Finance Corporation (IFC) estimates that in lower middle-income countries, these mark-ups along supply chains add up in the following manner: 25 to 30 per cent (importer mark-up), 25 to 50 per cent (wholesaler mark-up and 25 to 75 per cent (when subwholesalers are involved), thus leading to a total approximate mark-up that is between 50 and 80 per cent of the product price when the generics are eventually sold to the consumer. (Barham and others, 2017, p. 11). High mark-ups also are prevalent in several high-income countries. Many European countries also charge high pharmacy margins, which, according to Kanavos (2014, p. 7), in the case of generics were quite high in Germany, Greece, and Ireland, while pharmaceutical distributor mark-ups in the United Kingdom, Denmark, Sweden, Finland and the Netherlands were in the range of 2 to 24 per cent (Barham and others, 2017, p. 10).

3.2.4 Restrictive patenting criteria, pre-grant, and post-grant oppositions

Article 27 of the TRIPS Agreement offers the flexibility to national governments to determine the criteria for patentability: novelty, inventive step and industrial application (see Correa, 2016). Several countries, consequently, have adopted national laws that seek to interpret these in the light of public health considerations, or patent offices determine these standards during the course of their work.

In many countries, laws on the more stringent interpretation of patentability criteria have been a reaction to the concern that publicly traded pharmaceutical companies seek to safeguard their profits by sustaining market dominance through the following:

(a) Patenting all active compounds, formulations, processes and methods, modifications and combinations or delivery systems related thereto to continue “product hopping” (Kumar and Nanda, 2017).

(b) Use of life-cycle management to delay the entry of generic substitution through differentiated branding, dosing, or other tactics that prevent the entry of competitors Cunningham and Ederer, 2018.

The earliest effort of its kind, Section 3(d) of the Patents Act of 2005 of India prohibits patents on known substances, unless the applicants can show that they meet an additional requirement ("the enhanced therapeutic efficiency" test). Section 3(d) along with detailed pre – grant and post-grant opposition proceedings are in place to protect public health considerations. But similar patent legislations are now in place in many countries, such as in Argentina, Ecuador, Indonesia and the Philippines. These laws contain provisions that specify patentability standards with the intent of avoiding the grant of patents that extend monopoly of the patent holder without an explicit demonstration of an "inventive step". In Argentina, a regulation enacted in 2012 prevents any applicant from securing patents on certain types of inventions, including new dosage forms and combinations. The new patent law of 2016 of Indonesia prohibits patents on new forms and new uses of existing medicines. Particular provisions of these laws – such as pre-grant opposition procedures in the Indian patent law, may imply additional hurdles for inventors seeking patents in these jurisdictions but they allow for public interest to be upheld (PhRMA, 2018).

3.3 Technical measures (pricing and availability) in the interest of local production

Trends in competitive drug entry, health spending, the role of public authorities in regulating prices through coverage-and-spending decisions or off-the-counter generics when a large share of health spending is privately incurred all affect the pricing and availability of medicines. The main technical measures that seek to promote local production in this regard are as follows.

3.3.1 Regulations aimed at promoting the entry of generics

National regimes often seek to ensure allowing generics without time delays upon the expiry of patents. Indian law is the most explicit in this context, by allowing the granting of manufacturing approval for a generic version of any drug under patent four years after the original product was approved in the local market.[19] The patent

[19] Rule 122 E of the Indian Drugs and Cosmetic Rules provides that a new drug shall be considered as new for a period of four years from the date of its first approval or its inclusion in the Indian Pharmacopoeia, whichever is earlier. The Indian Drugs and Cosmetics Act further specifies: "Where an application under this Rule is for the manufacture of drug formulations falling under the purview of new drugs as defined in Rule 122E, such application shall also be accompanied with approval, in writing in favour of the applicant, from the licensing authority."

holder is allowed to seek addressal only through the Indian judicial system, adding uncertainty to how the provisions are interpreted, often also leading to costly litigation.[20]

3.3.2 Parallel importation

Parallel trade refers to the sale of medicines outside the formal import-export channels of pharmaceutical companies. Whether a country allows parallel importation depends on the regime it chooses for the "exhaustion" of rights of the intellectual property holder. In a regime of national exhaustion, such as in the United States, the exclusive rights of the intellectual property rights holder are "exhausted" upon first sale within that country alone. This allows the firm to control/exclude parallel imports from other countries into the local market. However, several countries allow for international exhaustion, implying that the patent holder company loses his or her right to dictate the channels through which the products flow after a first sale into the territory. The EU has a regional exhaustion principle, namely that, products once sold anywhere in the EU lead to an exhaustion of rights for the intellectual property holder.

Countries choose international exhaustion regimes to undercut the opportunities to price discriminate in different markets to the detriment of consumers. The results of a recent study on the share of parallel imports in total pharmacy sales in the EU indicated that the fragmentation of the EU pharmaceutical market had led to lucrative parallel trade within European countries, which neither benefits patients nor secures additional resources for research and development (R&D) (EFPIA, 2018, p. 4). Estimating parallel trade to be at €5.2 billion (at ex-factory prices) in 2016, the study showed that products from parallel trade constituted final pharmacy sales from 1.5 per cent (Austria, Belgium) to 25 per cent (Denmark) (EFPIA, 2018). Several authors note that undercutting the opportunity of pharmaceutical firms to price discriminately also undermines their ability to recover the high pharmaceutical R&D costs (Lichtenburg, 2011) and reduces their incentives to offer lower prices in lower middle-income countries (see next section).

3.3.3 Pricing approaches: external reference pricing and international price referencing bases

Countries also impose a variety of pricing restrictions given the relevance of pharmaceutical prices on national health spending, public budgets and public health. For patented drugs, these include cost-plus pricing, pharmaceutical price regulation schemes, price negotiations, external reference pricing and international

[20] This refers to the fact that the patent holder only can take any legal recourse within the Indian judicial system.

price referencing bases in various countries (Kanavos and others, 2011). For generics, the most popularly used pricing approaches are tendering (to reduce costs per unit by offering large contracts), price capping (setting a ceiling on the price after the expiry of the patent) and internal or external reference pricing (De Weert and others, 2015). Such pricing approaches can, generally, lead to price differentials in different jurisdictions. In the presence of parallel trade, added concerns by firms that products priced low in some markets make their way to others may cause them to reduce trade in certain jurisdictions or completely delay product introduction altogether (De Weert and others, 2015).

IV. PROMOTING TARIFF AND NON-TARIFF MEASURES THAT HELP LOCAL PRODUCTION: A DISCUSSION

The overview of tariffs and NTMs, and the classification thereof, as provided by this paper suggests a wide variety of such measures are in force in the pharmaceutical sector. A few relevant findings on their impact on trade and access follows from the discussion, which are presented below under two headings.

4.1 Tariffs, trade and access

Although tariffs on pharmaceutical products are generally low, and there have been many efforts to bring tariffs down further, several countries continue to impose tariffs on them. An underlying motivation to impose tariffs on pharmaceuticals appears to not be primarily to generate revenue, but to protect domestic firms. Studies comparing tariffs in recent years show that the tariff lines applied by several countries, such as Brazil, India and Mexico, have not changed since 2007, while the number of tariff lines applied by China have increased significantly from 30 in 2007 to 125 by 2016 (Bauer 2017). This is in keeping with other studies that note a rise in protectionism in certain sectors in emerging economies, in particular in China (Wu, 2012; Lee, 2020).

However, in countries that impose tariffs to protect local firms, a distinction between different product categories of products is not evident. This could hurt consumers and prevent access. For example, India imposes a steady tariff of 10 per cent on all pharmaceutical imports regardless of the public health need for those products locally. Bauer (2017), similarly, studies import tariff levels across several pharmaceutical product categories and concludes that half of tariff lines of Brazil set import tariffs at levels of at least 8 per cent and that 50 per cent of pharmaceutical products' tariff lines show import duties that exceed 5 per cent, whereas 75 per cent of the tariff lines of Indonesia are set at 5 per cent. If imposed to protect the local pharmaceutical sector and promote access to medicines, a more cautious and calibrated approach to tariffs is advisable, tailoring them accurately to local

production portfolios of local companies and access to the priority medicines of countries. By failing to do this, the tariffs can impose unnecessary trade costs and affect access to medicines adversely by shifting the rents accrued by the production of cheaper medicines away from consumers to local companies in certain product categories. A more granular approach to tariffs per product category, however, may even incentivise local companies to master new techniques faster, thereby promoting domestic manufacturing.

4.2 Non-trade measures, trade and access

An important point made in this paper is that evaluating NTMs is not so straightforward. NTMs can have several positive effects on international trade and global health, and therefore present serious trade-offs for policymakers. For example, drug regulations aimed at promoting quality and efficacy of pharmaceutical products assist in increasing good quality production and boost consumer confidence in foreign products. Similarly, NTMs that promote local production of pharmaceuticals can help increase competition and reduce prices across all product categories thereby benefiting consumers worldwide. Despite these benefits, NTMs remain quite complex, less transparent and difficult to monitor (ESCAP, 2019; Helble and Shepherd, 2017). There still remains, however, certain venues to reduce trade costs while still meeting national objectives, as identified here.

4.2.1 Non-technical measures

Contingent trade measures require closer scrutiny, given that they can be used as a tool to protect domestic industries as opposed to their original intent of preventing predatory pricing (Banik and Singh, 2017, p. 12). In many instances, contingent measures are used along with other instruments – such as quotas on imports – to nurture domestic pharmaceutical sectors. As countries embark on ways to respond to national and regional health security issues in the aftermath of the COVID-19 pandemic, there is a need to address them more systematically. In many instances, contingent trade measures appear to be in place in what seems to the expectation of the emergence of a local sector, rather than to actively support local firms that are engaged in producing drugs, vaccines and other medical products. In instances of the former, there needs to be a clearer assessment of the health costs associated with enforcing the contingent trade measures given that the consumer and the public health-care system bear the brunt of the costs of promoting local production at least in the initial stages. So, enhancing transparency and monitoring progress of these measures as applicable, from an access point of view, is needed to ensure that not too many measures are in place at the expense of pricing and access.

Patent laws that promote new and different standards of an inventive step, such as those in India, have been effective in promoting access to cheaper, good quality

locally produced medicines. For instance, two anti-cancer products and a schizophrenia product were denied patent protection in 2017, as India claimed they had shown no enhanced efficacy and thus were not patentable under Section 3(d) (Correa, 2016). It remains important, however, that countries carefully consider the benefits offered by such provisions and maintain them to promote access and increase transparency of non-technical measures.

More generally, NTMs should be more closely reviewed and streamlined with the aim to promote local production and access. This is especially the case for NTMs that are applied on the imports of pharmaceutical products, as they can simply add to costs without any direct bearing on local production, competition, or drug quality. Banik and Singh (2017, p 13) note for instance that of a total of 3,958 measures used in India for the import of pharmaceutical products, the most common ones are related to labelling (21.4 per cent), packaging (13 packaging), authorization (9.9 per cent) and registration (8.4 per cent), apart from those that are related to inefficient customs procedures and other processes. Customs procedures, cumbersome import/export processes, packaging and labelling requirements, licences, levies and permits for infrastructure or transport and port processes, and other bureaucratic costs that more generally result from a suboptimal trade infrastructure continue to be critical barriers for local production and access to medicines. In fact, although not considered at length in this paper due to their generic nature, these kinds of non-tariff barriers at a border, or "behind the border" not only hinder cross-border trade by simply imposing higher costs, but they also prevent local companies from being able to produce medicines effectively and at lower costs in many countries (Gehl Sampath and Vallejo, 2022).

4.2.2 Technical measures

Regulatory approval processes and delays in granting market approval can be traced to difficulties in inspection of manufacturing plants or to inefficient frameworks for safety and efficacy of skills, expertise or resources with the national drug regulatory authorities, among others. In general, there is a need to promote information-sharing, which may be useful for countries as they process regulatory approval of pharmaceutical products. Augmenting of skills and expertise is also needed in many lower middle-income countries, apart from consideration of regional drug harmonization procedures, such as an ongoing effort in Africa. This can cut costs and time lags in drug approval processes, enhance transparency, and promote product entry from local companies from lower middle-income countries just as it can enhance product entry from elsewhere.

It would also appear, based on the analysis conducted for this paper, that concentrating on the share of total imports of pharmaceutical products in any market

would not be a helpful method to study how non-tariff measures can pose barriers for access to medicines. Instead, the focus should be on the following:

(a) Degree of harmonization between approval procedures to speed up market entry;

(b) Degree of information-sharing to promote and support regulatory approval;

(c) Regulatory barriers for the use of generics, namely barriers for competitive off-patent markets;

(d) Other laws and regulations (or absence thereof) that certainly play a role in shaping competition in on-patent markets;

(e) The efficiency of health spending and pricing approaches on access.

A review of mark-ups along product chains, and the ways in which pricing affects availability is another topic that requires further consideration. The underlying results of such empirical studies, while not entirely promoting harmonization at the expense of national objectives, can raise awareness on the kinds of trade-offs that are inherent to certain measures in the pharmaceutical sector.

NOTE ON CONTRIBUTOR

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