

Understanding the Relationship  
between NTMs and FDI in Asia and  
the Pacific: A Case Study Analysis



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# Trade, Investment and Innovation

## Working Paper Series

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### Understanding the Relationship between NTMs and FDI in Asia and the Pacific: A Case Study Analysis

Heather Taylor-Strauss and Jiaxin Chen<sup>1</sup>

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## Abstract

A growing body of research has developed since the global economic and financial crisis analyzing the relationship between NTMs and trade. However, much less attention has been dedicated to investigating the relationship between NTMs and foreign direct investment (FDI). Nonetheless, as trade and investment are intrinsically linked to each other, either as complements or substitutes, it stands to reason that NTMs can also either directly or indirectly influence the decision of firms to invest abroad and this should also be reflected in aggregate investment patterns. The following paper conceptually outlines the effects NTMs may have on FDI, and then explores these effects in three qualitative case studies in the Asia-Pacific region. The general conclusions that can be drawn from the case studies is that NTMs do indeed have an effect on FDI, and the extent to which that effect is positive or negative largely depends on the type and scope of the NTM, the industry and political economic context in which it is implemented, and the procedures followed for implementation. Therefore, NTMs need to be carefully crafted, and continuously monitored and evaluated. Furthermore, because some NTMs may have the capacity to encourage FDI levels, this could prove increasingly relevant to policy makers aiming to generate investment in key SDG sectors.

**JEL:** F21, F23, O10, O20, O30, O31, O34, O53, P45

**Keywords:** Non-tariff measures, Foreign Direct Investment, Asia-Pacific, intellectual property rights, local content requirements, technical barriers to trade, pharmaceutical industry

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# 1. Introduction

The proliferation of non-tariff measures (NTMs) since the global financial crisis of 2008 has been a worrying trend globally. NTMs can restrict trade volumes by non-transparently increasing the cost for traders, and as a result can cause more economic distortion than tariffs. The growing implementation of NTMs has pushed forward research aimed at understanding and assessing the impacts of NTMs on trade, economic growth and sustainable development (as trade is one of the key means of implementation of the 2030 Agenda for Sustainable Development).

Nonetheless, estimating the amount and impact of NTMs has proven challenging for economists. Among other things, unlike tariffs, NTMs are difficult to quantify; they are often regulatory in nature and therefore do not have a number attached to them that can be readily used to assess their economic impact. In fact, the definition and classification of NTMs is recent (see ESCAP and UNCTAD, 2019). Furthermore, because they are often found in complex legislation with numerous overlapping rules, their impacts are difficult to measure and highly case-specific. Complicating matters further, there is a lack of comprehensive and reliable data on the scale of existing NTMs or on the introduction of new NTMs. This is particularly challenging for country or sector level analyses because no single repository on existing or new NTMs exists in most countries, despite the fact that the WTO is supposed to receive notification from all of its member States on the implementation of any NTMS and to make this information public. Overall, the lack of information or transparency on the existence and scope of NTMs poses problems for businesses and investors alike, as well as for researchers and policymakers aiming to assess and understand NTMs.

While considerable attention has been paid to understanding the relationship between NTMs and trade, less has been dedicated to investigating the relationship between NTMs and FDI. This is largely because by definition NTMs regulate trade,<sup>2</sup> and consequentially economists have concentrated on studying their impacts on trade. Nonetheless, as trade and investment are intrinsically linked to each other, either as complements or substitutes, it stands to reason that NTMs can also either directly or indirectly influence the decision of firms to invest abroad and this should also be reflected in aggregate foreign direct investment (FDI) patterns.

The purpose of this paper is to explore the relationship between NTMs and FDI. Given the case specific nature of NTMs, this paper focuses on exploring this link through a set of case studies. The general conclusions that can be drawn from the case studies is that NTMs do indeed have an effect on FDI, and the extent to which that effect is positive or negative largely depends on the type and scope of the NTM, the industry and political economic context in which it is implemented, and the procedures followed for implementation.

The paper is structured as follows: Section 2 provides a conceptual discussion of the likely effects of select NTMs on FDI. Section 3 provides an exhaustive overview of the literature on the relationship between NTMs and FDI. As that section shows, that the little research that has been done for developed countries. Nonetheless, the majority of new NTMs enacted since the global financial crisis have been in developing countries, particularly in Asia and the Pacific. In light of this, the paper analyzes the NTM-FDI relationship in Asian and Pacific countries in case studies of three types of NTMs, namely intellectual property rights, local content requirements, and technical barriers to trade. These NTMs were selected based on the conceptual discussion in

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<sup>2</sup> By definition, NTMs regulate trade and should not unnecessarily restrict trade, otherwise they are considered a non-tariff barrier. See more in ESCAP 2019.

section 2 which identifies those NTMs which are most likely to influence firms' decisions to invest abroad, and the availability of data to analyze the impact of NTMs on FDI. These case studies focus on home countries and the impact of NTMs on their inward FDI. Section 4 provides in-depth qualitative case studies on the impact of three types of NTMs on inward FDI highlighted in the conceptual discussion (IPR, LCRs, and technical barriers) in three NTM implementing or home countries (China, India and Indonesia). These case studies were chosen based on the availability of data, and also based on availability of information on the NTM itself. In each case study, aggregate figures are used to illustrate the link between the NTM and FDI. The case studies do not contain econometric findings but rather focus on providing context, which is often lacking from the literature on NTMs and FDI and making use of descriptive metrics to understand and draw conclusions on the relationship under study. Finally, the paper concludes by highlighting the policy relevance of the case studies and providing areas for future research.

## 2. NTMS and FDI: Introduction of Concepts and their Linkages

Conventional FDI theories<sup>3</sup> presuppose that a firm will prefer FDI to exporting when faced with things like market, public sector or other failures. NTMs can for instance represent on type of such failures. The type and size of the NTM, as well as the strategic choice constraints facing the firm will collectively determine a firm's response to the NTM. It is expected that a firm will choose to circumvent an NTM through FDI when the costs of doing so are lower than the costs for trading as a result of the NTM. It could also be assumed that, to the extent that tariffs may trigger tariff-jumping, i.e. attempts by firms to bypass tariffs by setting up shop locally, NTMs may generate similar behaviour because they increase market access barriers.<sup>4</sup>

Different types of NTMs<sup>5</sup> may have different cost implications for firms; consequently, certain types of NTMs may be more likely to motivate a firm to pursue FDI instead of exporting, or vice versa. For the purposes of this paper, the conceptual discussion in this section is not an exhaustive discussion of all NTMs and their possible impacts on FDI, but is rather a focused discussion on a select set of NTMs. Indeed, many other types of NTMs are likely to affect FDI. However, as this paper is an initial exploration into identifying those links and whether they even exist, it is warranted to first focus on a select few NTMs before broadening the scope to all NTMs. Should these links be clearly visible conceptually and empirically, future work can then build off this paper and extend the analysis to other types of NTMs.

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<sup>3</sup> Including *inter alia* Kindleberger(1969), Hymer (1976), Buckley and Casson (1976) and Dunning (1977 and 1979). For a review of these works and more see Nayal and Choudhury (2014).

<sup>4</sup> Of course, the extent to which an NTM may incentivize FDI by increasing market barriers is also directly linked to the investment climate in the host country. Investment barriers in the host country can create a substandard investment climate which would then deter FDI, even if an NTM is present which may have otherwise induced inward FDI.

<sup>5</sup> For the purposes of this paper, UNCTAD taxonomy of NTMs is being used as a reference for the classification of the types of NTMs. UNCTAD's taxonomy is coded according to 16 chapters (A-P), and each chapter has further sub-groups within them. The taxonomy "comprises of technical measures, such as sanitary or environmental protection measures, as well as" non-technical measures such as "quotas, price control, export restrictions or contingent trade protective measures, and also other behind-the-border measures, such as competition, trade-related investment measures, government procurement or distribution restrictions."

[https://unctad.org/en/PublicationsLibrary/ditctab20122\\_en.pdf](https://unctad.org/en/PublicationsLibrary/ditctab20122_en.pdf)



Government procurement restrictions and local content requirements<sup>6</sup> are, perhaps, most likely to sway a firm towards FDI. Both types of NTMs could exclude or reject foreign firms from trading because of their nationality. In such instances, firms would be faced with the choice between market entry through FDI or market exclusion, and therefore the cost of the NTM for the firm is the profit foregone from not operating in the market. Furthermore, the nature of these types of NTMs could determine the type of FDI a firm pursues, e.g. establishment of a wholly-owned subsidiary or a joint-venture partnership. For example, if the policy gives preference to indigenously-owned firms, then pursuing a joint-venture may be the only way that a foreign firm can access the market. Measures which discriminate on the basis of nationality may also prevent FDI if they restrict investment in certain sectors in order to reserve the sector for indigenous firms.

Both technical barriers, such as standards and other measures, and intellectual property rights (IPRs) increase the costs for firms regardless of whether firms choose to export or pursue FDI. Differences in technical standards among countries, for instance, may force firms to produce different models of their products to meet varying market requirements, consequently increasing expenditures and reducing any economies of scale for batch production that a firm may have. Firms in sectors most affected by such technical standards may pursue FDI instead of exporting to circumvent the NTMs. The option of FDI will most likely only be chosen when the cost of establishing production abroad is lower than the cost of technical duplications to service a market through exporting. However, the extent and scope of the technical barriers may also serve to discourage both exports and FDI.

Strongly enforced IPR regimes may also serve to both encourage FDI and exporting, the opposite would be true when IPRs are weakly enforced in importing countries, especially in high-tech and fast-paced industries such as pharmaceuticals and ICT. In other words, lack of or poorly enforced IPRs would deter both exports and FDI, especially in high-tech industries, because it may imply a greater risk for patent or copyright infringements. This is particularly relevant for developing countries, where implementation of stronger IPR regimes may not only serve to incentivize inward FDI, but also help their indigenous firms learn how to comply with IPRs and thereby enable them to better pursue outward FDI in countries with stronger IPR regimes. Of course, stronger IPR regimes in a host country may act as a barrier to inward FDI from firms with weaker IPR regimes in their home countries. This is most likely to affect the investment patterns of firms from developing countries into developed countries. In such situations, the required know-how and compliance costs would deter FDI from developing country firms in developed countries.

These above-mentioned considerations illustrate several ways that the selected NTMs can motivate firms to pursue FDI and are summarized in Figure 1 below. At an aggregate level, the considerations in this section should translate into positive effects on incoming FDI to the NTM implementing country (home country).

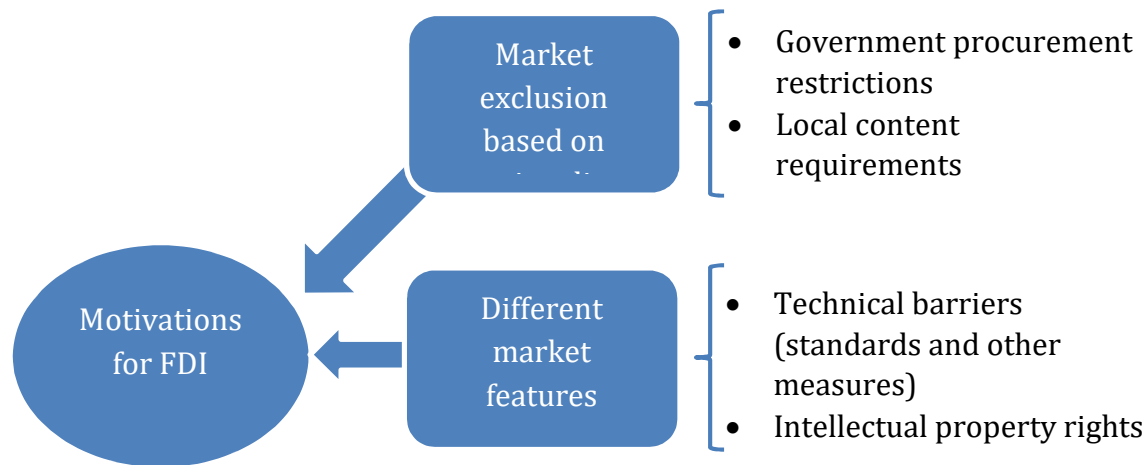
Indeed, Nicoletti et. al. (2003) confirmed such a positive relationship between NTMs and FDI in their study of trade and FDI policies in OECD countries. Yet, in the 15 years since that study there have been no follow-up to confirm this relationship – neither in OECD nor non-OECD countries. This working paper is therefore the first attempt at doing so. For researchers and policymakers to fully assess and understand the implications of the proliferation and substantive evolution of NTMs since the global economic and financial crisis, they must also begin to focus attention on how NTMs affect FDI. Recognizing the complex and highly case-specific nature of NTMs, the paper illustrates the relationship between selected NTMs and FDI through three qualitative case

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<sup>6</sup> LCRs put in place in host countries on (imported) goods are specifically being focused on here. As discussed further below, although LCRs are prohibited by the WTO TRIMS agreement, there has been a quiet proliferation in LCRs in both developed and developing countries since the global financial crisis.

studies on the NTMS discussed above, and in doing so provides relevant new empirical evidence to existing literature on the impact of NTMs.

**Figure 1: Relationship between selected NTMs and FDI motivations**



Source: Authors.

### 3. A Review of the Literature on NTM-FDI Relationship<sup>7</sup>

As noted in the introduction, there is a growing body of research on non-tariff measures and their impacts on trade; yet, the impact of NTMs on FDI has remained a relatively underexplored area. The literature that is available can be separated into two categories: (a) literature primarily focused on NTMs more broadly and their impact on trade, with a secondary focus on FDI; and (b) literature on one or more specific types of NTMs which may also address FDI either as primary or secondary focus. The literature review that follows below is thus structured according to these two categories.

The literature at the broader level is mostly based on quantitative analysis, and most commonly uses gravity modelling. For instance, Duval and Utotham (2014) find that 1% reduction in comprehensive international trade costs (excluding tariffs) between source and host country leads to a 0.8% increase in FDI inflows on average. Looking at tariffs, non-tariff barriers<sup>8</sup> and exchange rate variability, Di Mauro (2000) demonstrates that empirical evidence does not lend support to the theoretical claim of tariff jumping FDI, Di Mauro further illustrates that non-tariff barriers negatively impact FDI because of the sunk costs for foreign investors incur.<sup>9</sup> Francois (2013) demonstrates that, on average, a 10% increase in the NTM index leads to a 5.06% reduction in

<sup>7</sup> Although the conceptual and case study discussion in this paper focus on selected NTMs only, the literature review in this section provides an extensive discussion of all work related the NTMs and FDI. This detailed discussion, including of NTMs that are not addressed in the conceptual or case study sections, is important for justifying the need to produce more research to understand what the relationship is specifically between NTMs and FDI.

<sup>8</sup> As described in footnote 1, non-tariff barriers, as compared to non-tariff measures, are those which restrict trade whereas non-tariff measures are those that regulate trade and should not unnecessarily

<sup>9</sup> Such sunk costs refer to those that foreign firms may incur when setting up an affiliate; “if foreign firms then cannot access a larger market, not because of tariffs, but because of non-tariff barriers, their losses can be even greater than for the exporters” (Di Mauro 2000).

observed income from foreign investment. Nicoletti et al (2003) considered NTMs as an indicator of openness of a country to FDI. They find that border barriers have a direct depressing effect on FDI, but there is also evidence that MNEs may be able to bypass non-tariff barriers.

A few studies which have investigated the relationship of multiple NTMs, trade and FDI have focused their analysis at the country level. For instance, several studies have been done on China given the large volumes of inward FDI flows it receives. Yang (2005) concludes that Chinese firms experience more NTMs when exporting abroad than foreign firms encounter when investing in China. Yang notes that while China has lowered investment thresholds to attract FDI, its exporters do not receive equal treatment from the EU, the USA, Japan or Republic of Korea.<sup>10</sup> Turning the analysis to developed countries, the Ciuriak Consulting report (2018) studies the impacts of the European Union-Canada Comprehensive Economic and Trade Agreement (CETA) on the United Kingdom and Canada. The agreement removes 98% of customs tariffs between the parties and lowers barriers to trade in services FDI. The report finds that the greatest positive impact of NTM reduction on investment was in the recreational, water transport and business service sectors in the United Kingdom, but that reduction of NTMs in the goods sectors has not occurred in either country.

Regarding the second category of the NTM-FDI literature, several different NTMs feature prominently in the literature. For instance, focusing on technical measures, Charalambides (2005) analyzes pre-shipment inspections and their impact on value chains. The author finds that shipping processes in the Southern African Development Community differ widely, with the clearing process in Zambia taking up to four days compared to two weeks in Tanzania. Long clearing processes and large difference within the community hinder value chain integration and negatively affect FDI.

Turning to non-technical measures, a number of studies have been done on the impacts of anti-dumping measures and their effect on Japanese FDI in particular. For instance, Wakasugi (1997), Sourafel Girma et al. (1999), Sourafel Girma et al. (2002), Blonigen (2002) and Belderbos (2003) analyze the impact of anti-dumping measures on Japanese investment. According to Wakasugi (1997), anti-dumping measures were an important determinant of Japanese FDI during 1990s. However, Sourafel Girma et al. (2002) juxtapose Wakasugi's conclusions by demonstrating that the overall impact of anti-dumping on employment and investment from Japanese firms in the United Kingdom manufacturing sector is relatively small. These results lend weight to the argument that other factors, for instance, the specific advantages of Japanese firms and the locational advantages of the United Kingdom play a more important role than the growth in contingency protection. Blonigen (2002) also finds that Japanese FDI responded modestly to anti-dumping protection and suggests that tariff-jumping is only a realistic option for multinational firms from developed countries. Girma et al. (1999) and Belderbos (2003) both examine the potential benefits of anti-dumping for host countries. Girma et al. (1999) finds that in fact increased Japanese FDI in the United Kingdom is related to tariff jumping and anti-dumping cases raised against Japanese firms. However, they also find that anti-dumping cases made against other countries negatively impacted Japanese FDI. Looking at the European market, Belderbos (2003) demonstrates that the potential indirect contribution of "anti-dumping jumping" FDI from Japan to the EU economy in the form of inducing or maintaining inward investment are in many cases short-lived and weaker than perceived.

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<sup>10</sup> Nonetheless, it should be noted that this situation has dramatically changed since the publication of Yang's work and while this may no longer hold true, there has been no follow up work that could be found to verify this.

Government procurement policies is another type of NTM that has received some attention in the literature on NTMs and FDI.<sup>11</sup> Such public purchasing policies can be utilized as means to discriminate in favor of locally based firms and “buy national” policies, therefore acting as an NTM against foreign suppliers. Through a retrospective cross-country (France, Germany, Italy, and the United Kingdom) analysis of 30 industries, Madras et. al. (2008) finds that public procurement<sup>12</sup> in the sectors under analyzes was a strong positive determinant of FDI. Coudé and Bernard (2014) also find that government procurement policies in China have positively impacted FDI.

A few studies have also focused on rules of origin (RoO) and FDI. Córdova et al. (2006) indicates that under the North American Free Trade Agreement, RoO played a central role in foreign investors’ cost assessments of locating production in Mexico, and that FDI in post-NAFTA Mexico has been attracted to sectors with flexible RoO. Both Mukonoki (2013) and Jinji and Mizoguchi (2015) investigate the effect of RoO on FDI under free trade agreements (FTA). Jinji and Mizoguchi illustrate that to comply with the RoO, foreign enterprises must undertake FDI in FTA countries and manage part of or all their production within the FTA. Mukonoki (2013) further discusses the potential effects of the presence of RoO and concludes it can induce export-oriented FDI of a less efficient firm to replace market-oriented FDI of an efficient firm.

Two kinds of NTMs in particular have received the most attention recently, intellectual property rights and local content requirements. As each of these NTMs are dealt with in the case studies that follow, the following two subsections provide a more detailed review of each below.

### **3.1 Intellectual Property Rights**

Intellectual property rights (IPRs) have received increasing attention in the trade and investment literature. IPRs include copyrights, trademarks and patents. Largely due to the conclusion of the World Trade Organization (WTO) Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPS) (discussed in detail below),<sup>13</sup> there has been a considerable strengthening of IPR globally over the last few decades. Strong IPR protection is often expected to foster investments in research and development and contribute to the development of a technology-driven and knowledge-based economy since proper IPR protection can encourage innovation by raising the difficulty of imitation.

While IPRs are often considered a key determinant of investment decisions, the exact relationship between IPR and FDI is ambiguous and as a result there has been a considerable amount of controversy in the literature on the extent to which IPR protection affects FDI. It must also be recognized that IPRs affect investment decisions only in certain industry, for instance the pharmaceuticals, and only in certain parts of the value chain. For instance, IPRs are not a concern for Apple when it outsources assembly of iPhones to Foxconn in China, but it does worry about IPR violations in the USA when coding is done. Some literature has developed theoretical models to examine the relationship between IPR protection and FDI. For instance, Sun and Kang (2008)

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<sup>11</sup> Illustrating the increasing relevance of government procurement measures in Asia and the Pacific, a recent study by Trivedi et. al. (2019) the extent to which RTAs in Asia and the Pacific address three types of NTMs, including government procurement. It finds that the number of RTAs with government procurement provisions was 80% in 2019, up from 50% in 2014.

<sup>12</sup>Data on public procurement was based on an extensive study from the EU Commission on public purchases at the sectoral level for the year of 1991.

<sup>13</sup> For TRIPS specific literature on developing countries, see for instance: Correa, 2000; Su et al., 2000; Samuelson, 1999. The pharmaceutical industry in developing countries has been one of the main focus of the TRIPS literature in developing countries; see for instance Braga, 1995; Supakankunti et al., 2001; Abrol, 2004; Mathur and Shapiro, 2014; Linton and Corrado, 2008; Khatri and Sahu, 2009; Rai, 2009.

developed a theoretical model which focused on how IPR protection influences investment decisions made by technology-seeking enterprises from developed countries in developing countries. The results indicate that strong IPR protection in less developed countries stimulates technology-seeking FDI from technology-intensive firms. Furthermore, Glass and Saggi (2002), using a product-cycle model, noted that while strong IPR protection lowers the probability of imitation in the South it may lead to resource distortion to the extent that developing countries may allocate more resources, both monetary and manpower, towards increasing the probability of successively imitating. (WIPO 2007; WIPO 2009; WIPO 2019; Verna and Rao 2009). However, as these resources are scarce in most developing countries, such attempts leave fewer resources available for production and as a result may serve to deter FDI.

Some empirical literature investigates the relationship between IPR protection and FDI in aggregated terms. For instance, Zhang and Yang (2016) evaluated whether TRIPS has caused a surge in inward FDI in developing countries by using panel data for 23 developing countries from 1985 to 2012. Their empirical result suggests that TRIPS enforcement has played a key role in attracting FDI in most developing countries since 1994 although the relation varies across countries. Similarly, Rai (2009) and Mathur and Shapiro (2014) concluded that TRIPS in itself led to increased FDI into the Indian pharmaceutical industry.<sup>14</sup> Furthermore, Hsu and Tiao (2014) and Awokuse and Yin (2010) both show that strengthening IPRs leads to a significant rise in FDI inflows in host countries. Seyoum (1996), however, found patents hardly influence FDI into less developed countries, and this was later confirmed by Kashcheeva (2013), who finds that a weak IPR protection regime does not deter inward FDI in some countries. Nicholson (2007) argued that MNEs in capital-intensive industries are more likely to choose FDI as their mode of market entry in countries with weak IPR protection in order to maintaining control over production knowledge. In comparison, firms with research and development intensive industries with significant intangible assets are most likely to pursue licensing to an unaffiliated firm in the host country as their mode of market entry where IPR protection is weak. This conclusion stands at odds with a several studies demonstrating that the extent to which a firm is likely to pursue licensing agreements in industries dependent on IPRs, such as pharmaceuticals and chemicals, is significantly related to the strength of the IPR system, i.e. the stronger the IPR system the more likely a firm would be to enter into a licensing agreement (Kanwar 2012; World Bank 2002).

Aside from TRIPS laying down the minimum standards for the enforcement of IPRs, a large number of International investments agreements (IIAs) and Regional trade agreements (RTAs) also contain IPRs provisions<sup>15</sup> that are possibly viewed as undermining TRIPS flexibilities and reaching further than TRIPS standards, thus giving rise to a TRIPS-plus impact. Some literature analyses and questions the TRIPS-plus dimension of IIAs and RTAs. Liberti (2010) examined the extent to which and how IIAs and RTAs expand the scope of IPRs protection beyond TRIPS minimum standards, finding that IPR provisions contained in RTAs signed by the US, the European Union and Japan embody more detailed or even additional obligations regarding TRIPS, while IIAs strengthen IPR protection through unqualified treatment protection provisions. However, Farley (2014) argued that constant increases in the quantity and complexity of IPR provisions contained in free trade agreements and bilateral investment agreements render a host state's legal framework unknowable and highly unpredictable. This trend may also result in the incompetence of investment arbitration tribunals when difficult substantive questions of IP rights

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<sup>14</sup> In juxtaposition to this, one could also argue that not TRIPs but the fact that the developmental state of the pharmaceutical industry within India at the time of TRIPS implementation was also a key factor helped increased FDI.

<sup>15</sup> According to Puutio and Parisotto 2016, as of 2015 "there were 165 FTAs in force involving Asia-Pacific economies, of which 97 agreements include IPR provisions. This amounts to approximately 59 percent of all FTAs in force".

are involved. Mittal (2016) pointed out that the TRIPS-plus provisions contained in trade agreements may have negative effects on public health, particularly restricting access to essential medicines to people in developing and least developed countries. Mercurio (2014) also noted the threat to public health posed by IIAs, showing the danger of compulsory licenses issued in conformity with TRIPS but deemed an illegal expropriation under IIAs, and further arguing that IIAs should be carefully drafted to ensure the implementation of legitimate health measures. Furthermore, Boie (2010) concluded that the argument for a TRIPS-plus dimension of BITs is unnecessary since the discussion does not reach the heart of the matter. Instead, Boie argues that there are considerable overlaps and incongruences between IIAs and TRIPS due to their distinct character, different regulatory intents and fragmented growth over the past decades, therefore removing inconsistencies and providing better interaction between two legal regimes are the most paramount tasks.

A number of studies have also investigated the role of IPRs on inward FDI at the firm level. These studies show that there is a positive relationship between the strength of IPR and FDI flows into IPR-sensitive sectors (Lee and Mansfield, 1996; Javorcik, 2002; Du et al., 2008). Javorcik (2002) compiled a dataset from companies that made investments in Eastern Europe and the former Soviet Union and found that foreign investors tend to establish distribution outlets instead of local manufacturing production in countries with weak IPR protection. Mansfield and Mundial (1994), using firm-level data, asserted that weak IPR protection deters FDI from research-intensive MNEs. In addition, the strength of IPR protection impacts firms' decisions concerning technology transfer more significantly than investments, in particular in the chemicals and pharmaceutical industries. The empirical results also indicate that firms tend to transfer advanced technologies to countries with strong IPR protection.

In conclusion, the relationship between IPR protection and FDI is still ambiguous, largely because both theoretical claims and empirical studies provide mixed evidence. While a number of studies have focused on the impact of TRIPS on FDI, their empirical results are often limited by a lack of comprehensive and reliable data which would allow for a full evaluation of the effect of TRIPS in many developing countries. Furthermore, many of these studies tend to be very narrowly focused and only consider the impact of TRIPS implementation, without due regard for the political economic and sectoral developments in which TRIPS were implemented in many developing countries. The variety of motivational factors behind FDI make it virtually impossible to establish a causal link between TRIPS implementation and FDI. However, when TRIPS implementation is considered in the political economic and sectoral contexts, a more convincing correlation between TRIPS and FDI can be established.

### **3.2 Local Content Requirements**

Local content requirements (LCRs) are typically regulations stipulating that a certain amount of goods or parts of a final product must be produced by or sourced from domestic firms, and often applies to both domestic and foreign firms producing the good. Foreign firms can achieve this either by sourcing components from local firms or by manufacturing their goods locally. In recent years, there has been a well-documented wave of newer generation local content requirements. These requirements include provisions such "as tax, tariff or price concessions on local procurement; condition bailouts, government contracts, and export financing for local sourcing; tailored import licensing procedures to encourage domestic purchases" (Evenett and Fritz 2016) reservation of certain business functions for indigenous firms only; local data storage and analysis

requirements; and local product testing requirements. Despite being prohibited by the WTO, traditional and newer versions of LCRs have proliferated since the global financial crisis in both developed and developing countries across the globe and they have been applied in a wide range of industries, including agriculture, automobiles, healthcare, information technology, natural resources, renewable energy, and telecommunications.

Several recent studies have documented the quiet proliferation of LCRs since 2008. For instance, based on their classification of LCRs, Hufbauer et. al. (2013) found that 117 new LCRs were introduced between 2008 and 2013 globally, and caused a \$93 billion reduction in international trade. Meanwhile, Stone et. al. (2015) found that between 2008 and 2015, governments in 39 countries imposed 146 new LCRs between 2008 and 2015 to boost employment and industrial performance. Using the OECD METRO trade model,<sup>16</sup> that study concluded that LCRs “have caused a decline in global imports and exports in every region” and have been significantly damaging to global value chains as 80% of reduced trade caused by LCRs has been in intermediates. In yet another study, the Global Trade Alert documented the implementation of over 340 new localization measures, mostly in “electrical machinery and equipment including telecommunications equipment, and vehicles” and “another 371 state purchasing regulations or decisions...requir[ing] some form of local sourcing” since 2008 (Evenett and Fritz 2016).

Three WTO agreements attempt to discipline a country's ability to impose LCRs: the Trade and Investment Related Measures agreement (TRIMs), the General Agreement on Tariffs and Trade (GATT) and the General Agreement on Trade in Services (GATS). TRIMs provisions limit a country's ability to impose LCRs that affect trade in goods, while GATS does the same for services. However, GATS is only applicable to the sectors that the respective country includes in its Schedule of Commitments<sup>17</sup>. The most important provisions related to LCRs under the GATT is Article III which indicates that imported products may not be discriminated against *vis-à-vis* their domestic counterparts., this is otherwise known as the principle of national treatment. TRIMs covers the following types of LCRs: requirements to buy or utilize products with a domestic origin – TRIMs prohibits discrimination between goods of domestic and imported origin; limits to the number of imported products firms purchase or use depending on the volume or value of local products that the enterprise exports; restrictions on foreign exchange necessary to import; and export restrictions. GATS, on the other hand, contains the follow prohibitions relevant for LCRs: forced use of local service suppliers; service supplier limits; service transactions or assets value limits; service operations or service output limitations; restrictions on or requirements for certain legal entities; domestic equity requirements.

While both the GATS and TRIMs Agreement attempt to “discipline the use of LCRs,” the rules are neither comprehensive nor effectively enforced” (Cimino et. al., 2014). Since both Agreements have been in force, only three cases have been brought to the WTO regarding the use of LCRs. Moreover, several forms of LCRs remain WTO-legal, including those that mandate requirements for local training, technology transfer, joint-ventures, and exports (Sauvé, 2016). Furthermore, some newer forms of LCRs, such as those related to data storage and analysis, are not governed by either agreement and therefore escape WTO discipline. With little WTO jurisprudence, it is unsurprising that both more traditional and newer forms of LCRs have proliferated in the aftermath of the global financial crisis which have profoundly impacted international trade and investment.

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<sup>16</sup> This model is a computable general equilibrium model that uses data to explore the economic impact of changes in policy, technology and other factors.

<sup>17</sup> Indonesia's commitments are in business services, construction and related services, financial services and telecommunication services.

International Investment Agreements (IIAs), however, have become one option to restrict LCRs beyond what is possible through the WTO (see Table 1 below). In fact, IIAs are where some of the strongest regulations against the use of LCRs are found. LCRs can be restricted in IIAs in four ways. First, IIAs can restrict LCRs through non-discrimination provisions which bar discrimination at pre-establishment phases; secondly through standards of protection provisions, such as the fair and equitable treatment obligation; thirdly, through explicit restrictions on performance requirements<sup>18</sup>; and finally through provisions on the nationality of corporate board members and senior managers (Johnson 2016). Each have been on the rise in IIAs in recent years, and while “there is some overlap between national treatment obligations under IIAs and those under the WTO agreements, important distinctions between the two systems are (1) their different dispute settlement mechanisms, and (2) that IIAs cover all sectors and activities (whether related to goods or services)” (Johnson 2016). The proliferation of IIAs and their broadening of scope to increasingly include provisions which restrict local content measures in recent years receded the policy space and tools available to governments for using local content measures which both aim to build up a domestic industry and force the linkages of that domestic industry with foreign investors.

**Table 1: International Law Restrictions on Local Content Requirements**

TRIMs	<ul style="list-style-type: none"> <li>• prevents local measures mandating or making incentives contingent upon use of local goods</li> <li>• prevents quantitative restrictions on imports that can be used to favor local goods</li> </ul>
GATS	<ul style="list-style-type: none"> <li>• prevents requirements that would favor use of domestically owned service providers over foreign-owned service providers</li> </ul>
IIAs	<ul style="list-style-type: none"> <li>• prevent mandatory and incentive-based measures requiring foreign investors to achieve a level or percentage of domestic content through expenditures on domestic labor, goods, and services</li> <li>• prevent states from requiring or, in some cases incentivizing, investors to use or accord a preference to local providers of goods or services</li> <li>• prevent states from requiring use of domestic labor</li> <li>• prevent states from requiring investors to make in-country expenditures (including intra-firm expenditures) on services such as company expenditures on R&amp;D or education and training</li> <li>• bar enforcement of contractual provisions containing commitments by investors to comply with any of these requirements</li> <li>• result in liability for any measure that has the effect of discriminating against the operation or, in some cases, establishment of foreign-owned investments in the host country, or that otherwise negatively affects the operations or establishment of foreign-owned investments</li> </ul>

Source: Johnson (2016).

A survey of the literature on LCRs reveals a long-standing debate on the advantages and disadvantages of LCRs with mixed evidence of their implications. Opponents of LCRs have suggested that they often come with high costs and uncertain outcomes, and they have often pushed up the costs of production for foreign firms given the lower quality and higher costs of local components and inferior technology. Several studies have demonstrated that LCRs are anti-

<sup>18</sup> Performance requirement provisions have historically been found in IIAs concluded by Japan, the USA and Canada with developing countries and groups of states and a wider range of countries are also now employing them. For instance, the Comprehensive and Progressive Trans-Pacific Partnership (CPTPP) includes restrictions on a number of flat and incentive based performance requirements; performance requirement restrictions were also found in an IIA concluded between the European Union and Vietnam in 2015.



competitive and welfare reducing. For instance, Belderbos and Sleuwaegen (1997) demonstrated that the European Community's LCR for Japanese firms led to anti-competitive welfare reducing effects. Using a general equilibrium model to analyze the effects of an LCR on the automotive industry in North America, Lopez-de-Silanes et. al. (1996) showed that the LCR resulted in reducing industry output and shifting rents to local producers. Kwon and Chun (2009) analyzed the effects of LCRs on technology transfer and conclude that LCRs may discourage technology diffusion in the less developed countries that employ them as foreign firms may instead choose to establish their own supplier in the local market rather than work with indigenous suppliers.

Meanwhile, more recently Hufbauer et. al. (2015) concluded that LCRs provide fickle support to domestic producers because the effective rates of protection are often misunderstood by the policymakers putting them in place. They also find that LCRs tend to limit the availability of new technology and therefore also prevent higher tech industries from developing; LCRs tend to adversely affect downstream producers; they often result in increased roadblocks for infrastructure projects; and often have long lasting market distorting effects because they rarely include sunset clauses (Cimino et. al. 2014). Both Hufbauer et. al. (2015) and Stone et. al. (2015) also demonstrate that LCRs have significantly distorted global trade.

On the other end of the spectrum, proponents of LCRs show that such requirements can increase foreign investment and help developing countries protect and strengthen their indigenous industries that are otherwise unable to compete in world markets. They further contend that LCRs are important for expanding local production and employment and encouraging technology transfers. Richardson (1993) employed a two-stage general equilibrium model of foreign capital flows and concluded that LCRs induce inward FDI because foreign firms are encouraged to increase their local production. Using a partial equilibrium model to analyze the optimal LCR-profit tax policy mix to attract FDI, Lahiri and Ono (1998) concluded that LCRs may positively impact employment and price levels. However, they also noted that the optimal policy mix to attract FDI is very much dependent on "the number of domestic firms in the host country and their relative efficiency" (Lahiri and Ono, 1998). Veloso (2006) finds LCRs, if reasonably formulated to induce favourable economies of scale and promote local competition, can be welfare enhancing. Taking the case of the automotive sector, Veloso demonstrates that LCRs can be effective if they meet two conditions: (1) there is only a small gap in the manufacturing conditions for those components which are required to be produced locally; and, (2) localization is linked to learning processes (Veloso 2006).

Johnson (2016) argued in a more recent study that LCRs may in fact have a role to play in achieving the Sustainable Development Goals. In particular, the author analyzed the extent to which LCRs may potentially contribute to the attainment of Goal 8 on inclusive and sustainable growth and productive employment; Goal 9 on infrastructure, industrialization and innovation, and Goal 10 on reducing inequalities. Recognizing the complexity and depth of the arguments for and against LCRs, the author concluded that if "properly designed and implemented and complemented by an appropriate domestic enabling environment and absorptive capacity, local content policies can form an important part of governments' strategies to achieve their sustainable development objectives" (Johnson 2016).

This literature review illustrates that LCRs have been hotly debated for several decades. And while LCRs are a tool aimed at generating investment, relatively little work has actually been done to assess the impact of LCRs on FDI specifically. Instead, the work that has been done in this area (see for instance Qui and Tao, 2001) has very narrowly focused on the optimal policy design. Thus, questions about whether LCRs really do generate increased investment and whether these increases are sustainable are often left unanswered. The lack of focus on FDI specifically is in part because LCRs have much broader impacts on local economies than just on investment. This

is further complicated by the fact that assessing and quantifying the “impact” of an LCR on investment is challenging, as not only the availability of consistent and reliable FDI data is an issue, but there is also no one-to-one ratio between an LCR and a reduction or improvement in investment (Hufbauer et. al. 2015).

### 3.3 Literature Review Summary

The conceptual discussion in section 2 outlined several NTMs which are most likely to affect FDI and is summarized in Table 2 below. Among these were intellectual property rights, local content requirements, and technical barriers. The literature review as presented in this section gave a broad overview of the existing, albeit limited work that has been done on the impact of NTMs on FDI. This research has either focused more broadly on NTMs and their impact on trade, with a secondary focus on FDI, or has been NTM-specific with a primary or secondary focus on FDI. It is important to recognize that the conclusions of the studies presented versus those that will be drawn in the case studies below may differ and this is related to the type of study being undertaken (qualitative) and the types of NTMs being studied. While there have been a number of studies on both accounts, they lack a focus on the Asia-Pacific region, and none provide a case analysis of a specific NTM to understand the relationship between the NTM and its potential effect on FDI. Given the highly complex and often case-specific nature of NTMs, a case study analysis to understand the NTM-FDI relationship is warranted.

**Table 2: Summary of NTM-FDI literature**

NTM Topic	Author(s)	Main conclusions
Pre-shipment inspections	Charalambides (2005)	The difference in shipping processes, as well as the long clearing process, have negatively affected FDI in South Africa.
Anti-dumping measures	Wakasugi (1997); Girma et al. (1999); Sourafel Girma et al. (2002); Blonigen (2002); Belderbos (2003)	Several studies have been done on the impacts of anti-dumping measures and their effect on Japanese FDI in particular. Most authors agreed on the empirical evidence that the overall impact of anti-dumping on investment from Japanese firms is relatively modest.
Competition-affecting measures	Sunsen et. al. (2009); The European Commission (2014)	Lack of transparency of state support, high entry barriers, one-sided state aid schemes (that has been observed in Russian Federation), etc. can reduce the competitive pressure from foreign competitors through FDI, although the impact can be relatively weak (e.g. in the case of Japan’s service sector).
Public procurement	Madras et. al. (2008); Coudé and Bernard (2014)	Public procurement is proven to have a strong positive impact on FDI in Europe and China.
Rules of origin	Córdova et al. (2006); Mukonoki (2013); Jinji and Mizoguchi (2015)	FDI can be attracted to sectors with flexible rules of origin. There have been some demonstrated potential effects from the presence of rules of origin, e.g. inducing export-oriented FDI while replacing market-oriented FDI of a more efficient firm.

<b>Intellectual property rights (IPR)</b>	Mansfield and Mundial (1994); Seyoum (1996); Glass and Saggi (2002); Javorcik (2002); Sun and Kang (2008); Rai (2009); Awokuse and Yin (2010); Kashcheeva (2013); Mathur and Shapiro (2014); Hsu and Tiao (2014); Zhang and Yang (2016)	The relationship between IPR protection and FDI is ambiguous, largely due to the mixed evidence and theoretical claims. While some researchers demonstrated that strengthening IPRs leads to a significant rise in FDI inflows in host countries, other authors found a weak IPR regime hardly influence FDI into some countries.
<b>Local content requirements (LCR)</b>	Richardson (1993); Lopez-de-Silanes et. al. (1996); Belderbos and Sleuwaegen (1997); Lahiri and Ono (1998); Velooso (2006); Kwon and Chun (2009); Hufbauer et. al. (2013, 2015); Stone et. al. (2015); Johnson (2016)	A long-standing debate on the impact of LCRs on FDI has produced mixed evidence. Several studies have suggested that LCRs push up the costs of production for foreign firms and force them to produce more locally, henceforth reducing inward FDI. Other research found that if reasonably formulated, such requirements can increase foreign investment and help protect and strengthen domestic infant industries.

Source: Authors.

## 4. Case Studies

### 4.1 Intellectual Property Rights in India's Pharmaceutical Industry

#### 4.1.1 Background and overview

TRIPS has had a substantial effect on regulations in the pharmaceutical sector in developing countries. Prior to TRIPS, there were no global conventions that specified any minimum standards for IP protection for pharmaceutical products specifically. TRIPS introduced several key concepts to the regulation of the pharmaceutical sector; the most significant have been the introduction of product patents and regulations on generic medicines, compulsory and voluntary licensing, and parallel importation (see Taylor, 2015 for an elaboration on each of these concepts). These new regulatory concepts have altered the competitive structure of the sector most prominently in developing countries such as India. For example, TRIPS has not only had a significant impact on how countries can ensure that their populations have access to essential medicines,<sup>19</sup> but also ensured a certain degree of harmonization of competitive standards in the sector globally through the introduction of a minimum standard for product patents and detailed obligations to be enforced. For the purpose of this paper, the introduction of product patents is most relevant because it may have the potential to both force local firms to augment their capabilities and encourage foreign firms to invest and operate in TRIPS compliant countries.

<sup>19</sup> In particular the Doha Declaration on TRIPS and Public Health (2001).

India serves as an interesting case study to understand the effects of an increase in IPRs (through TRIPS implementation) on investment flows in an intellectual property driven sector such as the pharmaceutical sector. Over the last two decades, low cost production advantages and drug manufacturing expertise have helped it become a hub of global generic drug manufacturing. This has also supported the internationalization efforts of its firms and penetration into generic markets in developed countries. Furthermore, the high incidence of infectious and chronic diseases in India, combined with a large and growing middle class population that is demanding and can afford pharmaceutical drugs, has made India an increasingly attractive market for multinationals firms.

With this background in mind, the following case study explores the extent to which the introduction of product patents through TRIPS has catalyzed increased inward FDI. Nonetheless, to fully understand the impact of TRIPS on inward FDI in the Indian pharmaceutical sector, the introduction of product patents needs to be seen within the broader context of economic and FDI policy, developments in the pharmaceutical sector, as well as broader economic and political developments at the time in India. Thus, an overview of the political economic context at the time the TRIPS Agreement started implementation is provided first and followed by an analysis of the effects of TRIPS implementation on aggregate FDI inflows.

#### 4.1.2 India's political economic context

Shortly before the adoption of the TRIPS Agreement, India had embarked on a path towards economic liberalization. Liberalization reforms were the result of a consistent eleven-year expansion in fiscal deficits, which peaked in 1990-91. In brief, a depletion of foreign reserves had prevented the Indian Government's ability to repay loans which negatively affected its credit rating. This, combined with political instability, galvanized a new era of economic reform. The reforms were aimed at, *inter alia*, disciplining government spending and alleviating external debt that had been accrued by the Government since 1979. The latter goal entailed the liberalization of inward FDI in 1991, as well as an opening up of equity markets to foreign portfolio investors, and this was shortly followed by outward FDI liberalization. Other changes during this period included the reduction over time of price controls, mandating good manufacturing practices, and a lowering of protective trade barriers.

Several new policies were also enacted during this time in the pharmaceutical sector, including the New Drug Policy of 1994 and 2002; the National Pharmaceutical Policy of 2002 and 2006; changes to the FDI regime; and the enforcement of a new patent system. Together these policies mutually reinforced each other to create a more favourable environment for inward FDI to the pharmaceutical sector.

Changes to the New Drug Policy in 1994 and 2002 completely de-licensed the sector. Next, through the National Pharmaceutical Policy, the first round of quality control systems (Global Clinical Practice, Global Laboratory Practice, and Global Manufacturing Practice guidelines) to ensure the availability of good and affordable quality drugs were introduced. The National Pharmaceutical Policy of 2002 also aimed at stimulating R&D through actively encouraging new investment, including foreign investment, in novel drug discovery, research and development.

The New Pharmaceutical Policy of 2006 was geared towards the enforcement and quality assurance of the new patent system that had come into effect in 2005. It focused on strengthening the Drug Regulatory System and patent offices throughout the country as well as on quality assurances in research and drug development through clinical trials. The enforcement of these quality assurance systems pushed the sector to comply with global industry standards which in

turn served to support rapid increases in both inward and outward FDI in the sector. The policy also rationalized excise duty on drugs and pharmaceuticals and streamlined government bulk drug procurement while also promoting the production and distribution of generic drugs.

Regarding the changes to the FDI regime, while inward FDI in the drugs and pharmaceutical sector was not prohibited before 1991, the unfavourable patent environment was a major obstacle as foreign firms feared that a local firm would reverse engineer their patented product and market it as a generic drug, and thereby “steal” the patented product. As a first step towards encouraging inward FDI, as of 1994 automatic approval by the Reserve Bank of India (RBI) for 100% inward FDI investment was granted and automatic approval for technological collaboration was permitted (Mazumdar, 2013). Moreover, imports of intermediates, bulk drugs, and formulations were exempt from import duties.<sup>20</sup>

At the same time of the implementation of the above policy changes, the patent regime was also dramatically revamped to comply with TRIPS. Before TRIPS, and since 1970, India had only recognized process patenting in the pharmaceutical sector. For the pharmaceutical sector this meant that the final product, i.e. the ‘drug’, could not be patented, but only the process to produce the final formulation could be patented. The term of patent protection for pharmaceutical process patents was the lesser of 7 years from initial patent application or 5 years from the sealing of the patent.<sup>21</sup> In an attempt to prevent any one firm from holding a monopoly on the production of one drug, firms were only allowed to patent one process per drug. Furthermore, Indian patent law prior to TRIPS had a compulsory licensing provision which established that a process was considered a license of right only for the 3 years directly after a patent was granted. After the 3 years, the process could be used by anyone as long as a royalty was paid to the patent holding firm. The process patent system in place between 1970 and 2005 meant that numerous versions of foreign-patented drugs were not under patent in the Indian market before TRIPS implementation, which in turn opened up an avenue for a generics industry to grow with comparative advantages in reverse engineering.

As a founding developing country member of the WTO in 1995, India was obliged to become fully TRIPS compliant by 2005, which consequently required a complete overhaul of its IP law and process patent regime. In the time between signing TRIPS and its full enforcement, India enacted the Patents Act of 1999, which was subsequently amended in 2002 and again in 2005. The 2002 amendment created 20-year product patent protection in the pharmaceutical sector as of 2005; while the 2005 amendment introduced two avenues for compulsory licensing. In the first, it recognizes that a compulsory license can be applied for three years after the patent on the drug has been granted if either the product is not available at a reasonable price, not produced in India, or if the supply does not meet “the reasonable requirements of the public” (Indian Patents Act, 2005). In the second instance, a compulsory license can be issued to address a public health emergency or if the firm applying for the license intends to produce and export the patented drug to another country in a state of public health emergency if that other country lacks the domestic manufacturing capacity to produce the drug.

#### 4.1.3 Inward FDI in India’s pharmaceutical sector pre- and post-TRIPS

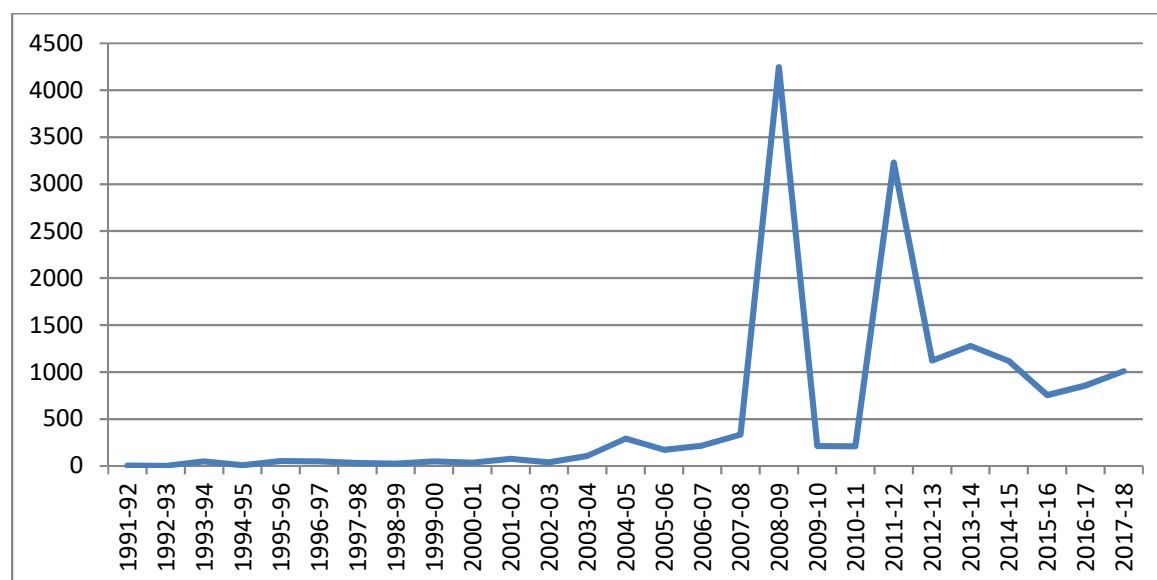
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<sup>20</sup> For policy changes related to OFDI see Taylor, 2015.

<sup>21</sup> For all other sectors, patents were granted for 14 years.

As previously discussed, since 1991 India has implemented several policy changes that together opened the pharmaceutical sector to inward foreign direct investment.<sup>22</sup> The introduction of product patents has had the most far reaching implications, both in terms of the changing competitive environment of the sector and in creating an attractive environment for foreign investment in the sector. Both table 3 and figure 2 show that of the policy changes that took place between 1991 and 2005, the sharpest increases in inward FDI during that period coincided with India's entrance into the WTO in 1995 and the full implementation of product patents in 2005. Moreover, these increases have generally continued on an accelerated pace upwards since the full introduction of product patents in 2005.

**Figure 2: Inward FDI to the Indian Pharmaceutical Sector, 1991-2018 (\$US millions)**



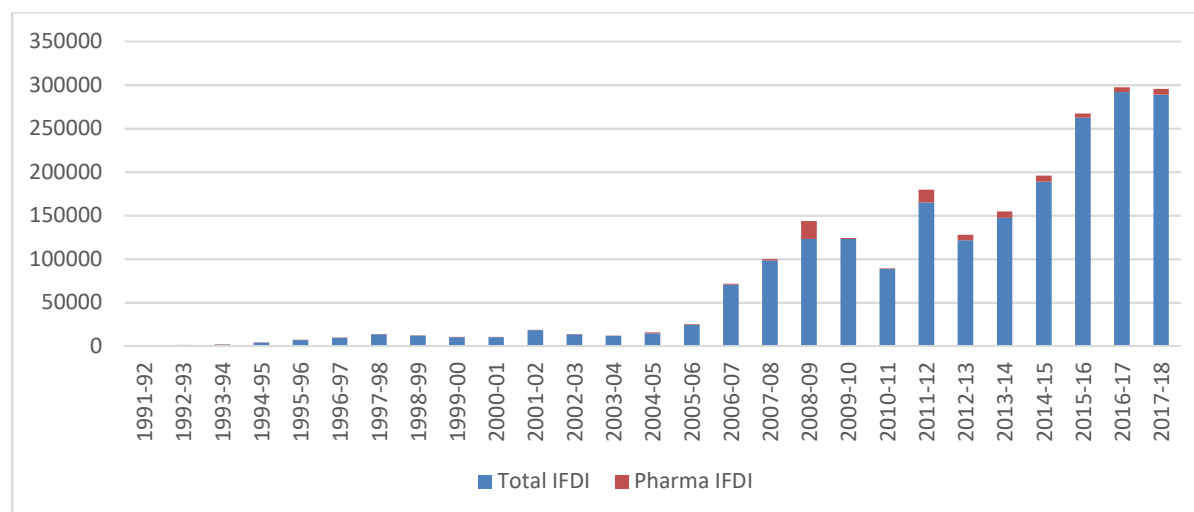
Source: Authors' calculations based on Department of Industry Policy and Promotion, FDI Statistics (various years).

\*Data based on total equity flows, minus reinvested earnings and portfolio investments.

In the 1991-95 period, FDI inflows in the pharmaceutical sector averaged a moderate \$17 million and totaled a \$68.7 million. In comparison, during the TRIPS transition period (1995-2005), inward FDI averaged roughly \$73 million annually, with the largest year-on-year increases occurring in the years closest to full implementation of TRIPS in 2005. During the 1995-2005 transition period, the largest jumps in inward FDI came in 2003-2004 in anticipation of TRIPS and then again in 2004-2005 once implementation had begun. Furthermore, inward FDI into pharmaceuticals as a percentage of total FDI inflows has also increased since TRIPS implementation (figure 3). Illustrating this, between 1991 and 2003 pharmaceutical inward FDI in India averaged about 2% of total FDI inflows, however, since then it has doubled and averaged at about 5% of total FDI inflows annually. In summary, these data confirm that the introduction of product patent rights and the TRIPS Agreement more broadly catalyzed inward FDI increases in the Indian pharmaceutical sector.

<sup>22</sup> In addition to these policy changes and among other things, a large and growing population combined with projected growth in the chronic disease segment of the sector served to attract foreign companies to the market.

**Figure 3: Pharmaceutical inward FDI as portion of total inward FDI in India (Rupees in crores)**



Source: Authors' calculations based on Department of Industry Policy and Promotion, FDI Statistics (various years).

Nonetheless, in the post TRIPS implementation era, there has indeed been a degree of volatility in FDI inflows, particularly during the period 2007-2013. These fluctuations have largely been due to one or a combination of the following factors: the global financial crisis, broader structural transformations within the pharmaceutical sector globally and, a series of IP rulings in India against foreign pharmaceutical firms along with concerns over India's TRIPS compliance. Sharp decreases in inward FDI all coincided with landmark IPR decisions in India against multinational pharmaceutical firms on issues related to patent linkages, evergreening and compulsory licensing (see Taylor, 2015 for further elaboration).

#### 4.1.4 Conclusions

The evidence presented in this case study illustrates that implementation of a stricter IPR regime associated with TRIPS rules and regulations encouraged increases in inward FDI in the pharmaceuticals sector in India. The aggregate data that was presented linked the greatest increases in inward FDI with years in which stronger IPRs that were particularly relevant for the sector were introduced. Nonetheless, uncertainties particularly related to the enforcement of IPRs since full implementation of TRIPS in 2005 have held back great FDI. As the data that was presented also suggests, these enforcement issues also correlate to the years in which there was the greatest fluctuations in inward FDI in the sector. Thus, while the introduction of a legal framework for IPRs has facilitated greater FDI flows, the lack of a stable and consistent enforcement mechanisms have hindered further growth in FDI flows from occurring. Enforcement challenges in the Indian pharmaceutical IPR context are largely driven by priority India has consistently placed on ensuring the availability and affordability of life saving drugs. This priority drove the development of the IPR framework pre-TRIPS, and has come to the forefront again through the multiple IP court cases in India since TRIPS on issues related to patent linkages, evergreening and compulsory licensing.

Going forward, stimulating further and consistent inward FDI into the sector critically requires that India strike a delicate balance between moving towards a stricter IPR regime with consistent

enforcement mechanisms and enabling the affordability and availability of life saving medicines for its population. If such a delicate balance can be struck it has the potential to not only generate more inward and outward FDI, but to also positively spillover into output, employment, and increased R&D activities that could support industrial upgrading in the sector towards as innovative drug research and development. To support such a delicate balance, among other things priority should be placed on educating companies, entrepreneurs, and the future skilled workforce in the sector on IPR; streamlining IPR registration processes; and facilitating IPR licensing arrangements. Such priorities would help alleviate many of the bottlenecks within the patent system and improve the IPR environment for the sector. Achieving these priorities, however, is dependent upon both government and private sector efforts. In particular, local firms with the capacity to innovate and that are already integrated into global value chains are essential to steering the achievement of all of these priorities.

## **4.2 Local Content Requirement on 4G Enabled Smartphones in Indonesia**

### **4.2.1 Background and overview**

In mid-2015, the Government of Indonesia announced that a 30% local content requirement (LCR) for all 4G enabled smartphones would come into effect on 1 January 2017. Local content rules had been already in place in the mobile handset sector since 2012 and reports had been circulating as early as 2014 that the Government would eventually be issuing 4G device-specific localization measures. After this announcement, the LCR was progressively phased in, with a 20% local content implemented in 2016 and 30% taking effect in 2017. Since 2017, there have been reports that the LCR may be upped to 40% in 2019. Phased implementation of the LCR was expected to give companies enough time to comply with the new measures. Once in effect, companies would be issued certificates to verify that the devices they sell meet the LCR requirements. If, however, any device is found incompliant with the LCR, it will be banned from being sold the market.

The LCR on 4G devices was the result of joint efforts from the Ministry of Industry, Ministry of Trade and the Ministry of Communications and Information. It was formally set out in the Regulation of Communication and Information Ministry No. 27/2015 on the Technical Requirements for Long Term Evolution Technology Standard Based Telecommunication Tool and Equipment. The timing of the Reg. 27/2015 announcement and subsequent implementation was no coincidence. The first long term evolution or commonly referred to as LTE service in the 900 MHz frequency spectrum was launched in December 2014, and the 1,800 MHz frequency band was opened for LTE services shortly thereafter. By July 2015, five telecom operators were offering 4G/LTE service on 900 and 1800 spectrums. Despite the introduction of 4G/LTE services, last-mile 4G coverage had however only reached 23 % and 4G penetration was only 7.6% by the end of 2015. (Das et. al., 2016)

Low 4G penetration at the time meant there was ample room for growth in a largely untapped market. The smartphone market in Indonesia, including 2G, 3G and 4G devices, is expected to boom between 2015 and 2020 with estimates forecasting the number of users to grow from 54 million in 2016 to nearly 82 million by 2020 (table 3 below) and sales of smartphones devices to double in that same period (BMI, 2016). By 2016, mobile devices had already overtaken fixed-line devices and become the main portal for accessing the Internet, with 73% of internet users in Indonesia accessing it through mobile devices (Das et. al., 2016). Currently, 2G and 3G connections account for 69% of mobile connections. However, increased government



investments in 4G infrastructure is expected to accelerate migration to 4G services. By 2025, 4G is expected to account for 74% total connections or 361 million connections (Gomez, 2018).

**Table 3: Smartphone users and sales**

	2016	2017	2018 (forecasted)	2019 (forecasted)	2020 (forecasted)
<b>Millions of users (a)</b>	54	63	70	77	82
<b>Smartphone penetration as share of population (b)</b>	21	24	26	28	30
<b>Millions of Dollars (c)</b>	4,564.74	6,166.97	7357.19	8,284.20	9,087.77

Sources: (a) Statista 2017a; (b) Statista 2017b; (c) Fitch Solutions Consumer Electronics 2018.

A fast-growing smartphone market with expanding 4G coverage and penetration combined with inexpensive mobile services, a large and growing population, including a rising middle-class, and an expanding GDP, have made Indonesia an attractive market for smartphone device manufacturers. Foreign firms have increasingly grown to dominate the market over the last 5 years, and Chinese and Japanese firms have invested the largest volumes in the market during this period. In terms of market players, in 2018 Samsung held the largest market share (27%), followed by Oppo (10%), Vivo (9%), Advan (6%), and Xiaomi (5%) (Statista 2018). Recognizing the attractiveness of the market for international players, the Government introduced the LCR in the 4G segment to both stimulate a local industry and strengthen the ability of indigenous manufacturing firms in the sector “to move up...the value chain by requiring companies investing in Indonesia to develop domestic manufacturing, which [would subsequently] further integrate Indonesia into global value chains” (WTO, 2016).

The smartphone market really began to take off after 2010. As a result, both the demand and imports of smartphone devices sharply rose. In 2010, 43 million mobile device units (incl. smartphones) were imported. By 2014, this figured jumped to 54 million (Soela, 2013; Ministry of Communication and Information Technology, 2015). The value of imported smartphones in 2014 was estimated to be \$3.3 billion. However, the actual figure could have been as close to \$5 billion if illegally imported phones were also included in the total value (Soela, 2013; Ministry of Communication and Information Technology, 2015). Localization measures were therefore introduced into the 4G device segment in an attempt to preemptively thwart an overreliance on 4G device imports before migration to 4G begun and to stimulate indigenous industry development.

It should also be noted that as imports of smartphones grew, Indonesia also had and continues to grapple with a structural current account deficit (CAD) that has persistently been around 3% of the country’s GDP since 2011. The CAD has been fueled by sluggish export performance related to the drop in demand and prices for global commodity and growing imports. While oil imports to uphold a decades-old fuel subsidy programme have been the key problem, the Government has also pursued curbing imports in other sectors to contain the CAD. Thus, while the primary objective of the local content requirements was to in the mobile and smartphone segment from 2012 onwards was to stimulate local industry growth and value added, and secondary, and related, objective was to curb ease deficits through curbing imports.

#### 4.2.2 Reactions to the LCR in the context of the WTO and from foreign investors

WTO member States have utilized the meetings of the Committee on Trade Related Investment Agreements (hereinafter referred to as the Committee on TRIMs) to voice their opposition to the LCR. The three most common concerns raised have been related to the LCR's inconsistency with WTO regulations, the adverse trade impacts of the LCR, and vague guidelines on how firms could comply with the LCR.

Regarding the first issue, WTO members have asserted that the LCR is inconsistent with GATT Article III:4 on General National Treatment Obligation and Article 2.1 of the TRIMs Agreement on National Treatment and Quantitative Restrictions. The latter prohibits "any TRIM that is inconsistent with the provisions of Article III or Article XI of GATT 1994" (WTO Analytical Index). In 2015, Indonesia responded to this concern for the first time and since then has consistently repeated the same response each time the matter was raised (WTO 2016):

"The policy was not an investment measure as it only set technical standards and minimum local content requirements. It was consistent with Article III:4 of GATT 1994 as it applied to domestic and imported products. The 20% local content requirement meant that 80% of the contents of the products could be imported, and almost all local brands of 4G LTE contained more than 80% foreign inputs. Thus, the policy did not treat foreign products less favorably than imported products".

Nonetheless, some WTO members have continued to point out that because the measure is related to investment it is in effect an investment measure and regardless of how it was applied, the LCR was by its very "nature discriminatory and inconsistent with Article III:4 of GATT 1994 as stipulated in paragraph 1(a) of the Annex to the TRIMs Agreement" (WTO 2016c). Although these concerns continue to be discussed in the context of TRIMs meetings, no formal complaint or further action has been taken against Indonesia on this specific LCR.

Regarding the LCR's impact on trade, Japan asserted that already after the first year of implementation the policy had adversely impacted trade. As evidence, Japan cited declining exports of smartphones to Indonesia by Japanese firms directly as a result of the LCR. (WTO 2016c)

The third and final concern frequently raised by multiple countries in the context of the WTO is the lack of clarity on how the LCRs are calculated (WTO 2016, 2016a, 2016b). In its original form in 2015, the LCR required firms to set up manufacturing facilities and to conduct 20% research and development in Indonesia. However, the LCR was subsequently changed in 2016 through the release of the Regulation of Ministry of Industry No. 65/2016 on the Provision for Calculating Local Content in Cell Phone, Handheld, and Tablet Computer Products. Regulation 65/2016 outlined three schemes by which firms could meet the LCR: hardware; software; and, investment schemes. Furthermore, each scheme consists of 3 components: manufacturing, research and development, and applications ("apps"). Table 4 below outlines each scheme and its components.

**Table 4: Tracks to meet 4G smartphone LCRs**

No	Scheme	Description
1	Hardware	<ul style="list-style-type: none"> <li>• Manufacturing of 70%, consisting of 95% material, 2% labour, 3% production machinery</li> <li>• 20% R&amp;D consisting of 10% license, 40% firmware, 20% industrial design, 30% integrated circuit layout design</li> <li>• Apps of 10%, with minimum of 2 embedded local apps or 4 embedded local games which are actively being used by 250,000 users, the software injection process is done in the country, use of domestic server, and own local online app store</li> </ul>
2	Software	<ul style="list-style-type: none"> <li>• Manufacturing of 10%, consisting of 95% material, 2% labour, 3% production machinery</li> <li>• 20% R&amp;D consisting of 10% license, 40% firmware, 20% industrial design, 30% integrated circuit layout design</li> <li>• Apps of 70%, with minimum of 7 preload local apps or 14 preload local games which are actively being used by 1,000,000 users, the software injection process is done in the country, use of domestic server, own local online app store, and the cost, insurance, and freight (CIF) price of a minimum of 6 million IDR</li> </ul>
3	Investment	<ul style="list-style-type: none"> <li>• Investment of 400 billion IDR to 550 bn IDR is equal to 25% local content</li> <li>• Investment of 550 billion IDR to 700 bn IDR is equal to 30% local content</li> <li>• Investment of 700 billion IDR to 1 trillion IDR is equal to 35% local content</li> <li>• Investment over 1 trillion IDR is equal to 40% local content</li> <li>• This applies to investment only and the investment must be completed within 3 years. Vendors must realize 40% of investment during the first year and provide details on its annual investment</li> </ul>

Source: Global Business Guide 2017.

The most notable change that came into effect for calculating the LCR through Regulation 65/2016 was that it established an avenue for smartphone manufacturers to only pursue software localization measures. This change reflected the Government's shift in priority towards stimulating both a local manufacturing *and* software industry that could cater not only to the Indonesian market but also international markets.

The introduction of a software component into the local content calculation sparked considerable uproar among industry players due to the inconsistent way the calculation of the LCR had been developed overtime. For instance, after the initial announcement of the LCR many firms had already increased their investments in physical capital assets, including factories, machinery, tools, etc., because this was the main way that they could meet the content requirements. The delayed introduction of a software component to the LCR was unsettling to first-LCR-responders because software development requires less investment in fixed assets and people. In other words, the cost of investing in software is nowhere near as expensive as investing in physical plants.

Beyond the context of the WTO, governments and firms alike have also complained about the shortsightedness of the LCR. Such grievances have been rooted in the fact that an indigenous industry to meet the demands of the LCR did not exist prior to or at the time of LCR implementation. Additionally, high logistics costs stemming from the lack of hard infrastructure, both in quantity and quality terms, have undermined and will continue to undermine the development of a strong manufacturing base to meet the LCR requirements. Confirming the high burden of transit costs in Indonesia, logistics accounted for 17% of company expenditures, with land and sea transport absorbing the most significant amount of expenditures, in 2017 compared

to 10% or lower in other Asia and Pacific economies (Worldfolio, 2018). Lack of an indigenous industry combined with high logistics costs would thus stifle local industry growth and development.

Finally, industry analysts have expressed two interrelated concerns, namely that the LCR would impact the migration to 4G devices and promote the black market for smartphones. Regarding the former, as the research on LCRs has consistently demonstrated, they tend to increase the prices of the goods on which they are implemented while simultaneously providing consumers with a lower selection of choices. A limited selection of products combined with lowered affordability may consequentially lead to slower or stunted migration to 4G devices. Moreover, limited selection might also fuel growth in the black market as demand for new 4G devices grows. Already in 2017, one in five smartphones sold in Indonesia was sold illegally (Nian 2017). This number could grow if customers are forced to choose between inferior technology or illegally buying devices with newer technology.

#### 4.2.3 Impact on investment<sup>23</sup>

A big challenge preventing causal conclusions on the LCR's impact on inward FDI is the lack of reliable aggregate data on FDI flows for smartphone manufacturing and assembly in Indonesia. However, aggregate FDI figures supplemented with qualitative evidence on the investment projects of firms in the smartphone segment can provide an initial assessment which confirms that the LCR's can be correlated with an immediate increase in FDI inflows in the short run. The immediate increase in FDI in the short run is directly related to the growth potential of the 4G smartphone market in Indonesia. As discussed in the above, while growth in the smartphone market has reached maturity in most countries across the globe and in Asia-Pacific in particular, it has only just begun to boom in Indonesia and is forecasted to continue grow in the years to come. As a result, the LCR did not discourage foreign investors because of the market potential in the short run.

Starting at an aggregate level, inward FDI in the manufacturing sector rapidly expanded in both 2015 (Rp 236 million) and 2016 (Rp 335 million) before tapering off in 2017. The largest contributor, both in terms of number of projects and volume of investments, to the rise in inward FDI in the manufacturing sector came from the metal, machinery and electronic sub-sector, which includes the smartphone segment (tables 5 and 6). Although the smartphone segment was not solely responsible for the upward trend in FDI projects, it did contribute to it. As shown in Table 5 below, since 2012, at least 14 out of 16 investment projects by foreign firms were initiated to meet the precise requirements of the LCR on 4G smartphones in 2015. Of the 2 investments made prior to the introduction of the LCR, one was initiated in anticipation of the LCR being introduced and the other was made in relation to the predecessor LCR on smartphones that came into effect in 2012. The LCR not only caused foreign firms to increase their investments, but it also pushed local smartphone manufacturers to repatriate their investments from abroad (table 6 below).

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<sup>23</sup> As the focus of this paper is on investment, only the LCR's impact on investment is discussed. Nonetheless, it should be noted that the LCR also caused a marked shift in the composition of the country's consumer electronic trade flows. The value of finished smartphone device imports declined, while the value of device component imports increased. While the overall trade value remained the same as component parts has offset finished good parts (BMI Consumer electronics Q4, 2017). Indonesia's consumer electronics trade deficit peaked in 2017, with the import of smartphone devices contributing the most to the widening deficit. Thus, while the LCR was expected to slow imports of both smartphone devices and parts, especially from China, imports from China have continued to grow reaching 2.2 billion in 2017 compared to 300 million in 2014 (Fitch Solutions, 2018).

Tables 5 and 6 below confirm that the immediate response of firms to the LCR was to increase their investments in the local market. The tables further show that most of the FDI projects took place in 2015, with a few announced in 2015 but only realized in 2016 or 2017. Most of these investments were made to rapidly meet the requirements of the LCR. Since 2015, FDI has waned as most brands with the largest market share are now capable of meeting the LCR requirements and are catering to the local market. As a result, in its current form the LCR is unlikely to stimulate commensurate levels of FDI in the smartphone segment going forward.

**Table 5: Investments of foreign firms since 4G LCR announcement in 2015**

Brand	Source	Year	Indonesia market (% market share)	Estimated Jobs Created	Investments Details
PT Celxpert Indonesia	Taiwan Province of China	2018	N/A	151	Through its subsidiary, Celxpert Energy Corporation is investing \$20 million to open a new cellphone battery manufacturing plant in Subhang. The plant will produce 5,000 cellphone battery units daily.
Apple	United States	2018	4.16	104	\$3.9 million to open a developer academy in Jakarta to train local students in developing apps for IOS system. Apple plans to open 2 more academies by 2019 in Indonesia.
Apple	United States	2016	4.16	210	\$15.9 million invested in opening a research and development center.
Asus	China	2016	5.05		Entered into a joint venture with Panggung Electronic Citrabuana.
Oppo	China	2015	13.18	544	Invested \$30 million in an assembly plant in Tangerang with a production capacity of 500,000 smartphones.
ZTE	China	2015	0.1	163	Invested \$33.10 million to build manufacturing factory to supply white-label smartphones to Indonesian brands, such as Smartfren Andromax series and Bolt Power phone.
Samsung	Republic of Korea	2015	29		Invested \$23 million to build a factory in West Java at the existing Samsung complex to assemble smartphones. The new facility has a production capacity of 1.3 million devices monthly.
Lenovo	China	2015	N/A		Joint venture with PT Tri Dharma Kencana to operate factory in Serang.
Lenovo	China	2015	3.66	787	Invested \$59.10 million a smartphone manufacturing facility in Serang with capacity to produce 75,000-150,000 devices monthly.
Asus	China	2015	5.05	787	Invested \$59.10 million in a smartphone manufacturing plant which opened in 2016.

Huawei	China	2015	1.22	94	Signed a Memorandum of Understanding with the Ministry of Communications and Information Technology to invest \$7 million in establishing an ICT innovation center in Indonesia to develop human resource capacity in ICT and function as a training center for Huawei.
Huawei	China	2015	1.22	787	Invested \$59.10 million in a new smartphone manufacturing plant by first quarter of 2016.
Huawei	China	2015	1.22		Entered into a joint venture with PT Sat Nusapersada.
Arima-Asus-HTC	Taiwan Province of China	2015	N/A		Entered into a joint venture with Tiphone Mobile Indonesia for local handset assembly (\$50m), production capacity of 300,000 units per month.
Xiaomi	China	2015	17.28	787	Invested \$59.1 million in a smartphone manufacturing plant which opened in 2016, by 2017 100% of phones in Indonesia were produced locally.
Haier	China	2014	N/A		Invested \$1 million to expand production line of phones for local brand Smartfren Andromax. The investment was made in anticipation of the LCR on 4G devices.
Axioo	Singapore	2013	N/A		Invested in 2 manufacturing facilities in 2013.

Source: Authors based on fDi Intelligence

**Table 6: Repatriation of investments by Indonesian phone manufacturers to since the LCR**

Evercoss	2015	N/A	As of 2015 it was still sourcing parts of phone manufacturing abroad. In 2015, it began to develop another factory in Indonesia to repatriate production.
Advan	2015	N/A	Expanded production to include smartphones and tablets (investment of \$8.1 million) to repatriate production from China by 2016.
Mito	2015	N/A	Repatriation of parts of production from China to meet LCR at home.
Polytron	2012	N/A	Repatriated production from China in 2012 to comply with LCR at home.

Source: Authors based on fDi Intelligence

While the LCR provided an immediate increase in the quantity of FDI in the short term, the bigger question is whether the LCR has helped attract quality FDI. Quality FDI contributes “to the creation of decent and value-adding jobs, enhancing the skill base of host economies, facilitating transfer of technology, knowledge and know-how, boosting competitiveness of domestic firms and enabling their access to markets, as well as operating in a socially and environmentally responsible manner” (Goerg et. al., 2017). The lack of reliable aggregate data on the sector and empirical evidence at the firm level on inward investments make it difficult to gauge the extent to which the investments initiated in response to the LCR were quality investments.

However, the selective targeting of the 4G smartphone segment and adjustment of the LCR’s calculation through Regulation 65/2016 to incorporate an investment scheme on software development represent a shift, albeit a minor one, towards integrating a qualitative approach to FDI in the LCR. Compared to a strictly quantitative approach which focuses solely on stimulating

FDI inflows and job creation, a qualitative approach targets attracting FDI which will lead to technological upgrading and knowledge spillovers (Guimon and Filippov, 2017), Apple's recent investment to open a training academy in cooperation with an Indonesian university to train students to develop apps for the IOS system is the first reported investment that matches these requirements.

Considering that the smartphone market will soon reach maturity and since most companies have already met the LCR requirements, the quantity of investments in the smartphone segment is expected to continue to decrease in the medium and long-term. The aim of the LCR, as set by the Indonesian representative at the WTO, was to stimulate an indigenous industry and help firms integrate and move up in the global and regional smartphone value chains (WTO, 2016). The LCR may have helped increase investments in physical capital to build an indigenous industry to cater to the local market. However, for the next steps to occur, the Government in cooperation with the investment promotion agency must take measures to attract more quality FDI. This includes addressing high logistics costs which deter value chain linked investments and evaluating and carefully redesigning the LCR to seize the benefits it may offer for attracting quality FDI. Most recently, the Government of Indonesia has set up a task force, the P3DN, to monitor the extent to which all LCRs currently in place in Indonesia are actually being met. This task force could, however, also be used in the future to evaluate and redesign LCRs to ensure that they are effective in attracting quality FDI. For instance, one area that such a task force might take under consideration is the arbitrary construct of 20% R&D requirements in the hardware and software investment schemes for the 4G smartphone LCR. Such mandatory requirements are challenging because they preclude the availability of local talent to absorb, adapt and develop capacity that a foreign firm might bring in through an R&D facility. In carefully redesigning the LCR, it would therefore be important to include, for instance, a capacity building element that focuses on improving the absorptive capacities of new and existing firms. Another area that should be considered is the introduction of a sunset clause to curtail any longer-lasting market distortions or rent-seeking behaviour that may have been introduced into the smartphone manufacturing segment because of the LCR.

#### 4.2.4 Conclusions

In conclusion, smartphone manufacturers have increased their investments in Indonesia in order to meet LCR criteria as laid out in Regulation 65/2016. These investments have helped promote local assembly, but they have not led to Indonesia developing sufficient capacity to challenge any of the major exporter countries for consumer electronics in South East Asia. The growth potential for 4G smartphone devices market has been the primary driver of increased investments since the introduction of the LCR. However, while the LCR may have increased the quantity of FDI in the short-term, it is unlikely to lead to any further increases in FDI as the smartphone market reaches maturation and as most brands have already made investments to enable them to meet the requirements of the LCR. To effectively develop an indigenous industry that can cater to both local and international markets, infrastructure must be improved to lower logistics costs, the LCR must be revamped to more effectively promote quality FDI, and a sunset clause should be included into the LCR.

### 4.3. Technical Barriers to Trade in Pharmaceutical Products in China

#### 4.3.1 Background overview

Pharmaceutical products, including both drugs and medical devices, are among the most heavily regulated products globally. To ensure both their safety and efficacy, many governments have applied a variety of NTMs to regulate the trade in pharmaceutical products, mostly involving technical standards. These standards are often quoted as important barriers to trade. While the WTO Agreement on Technical Barriers to Trade (TBT) permits WTO members to use technical standards to protect the health of humans, animals and plants as long as these measures are non-discriminatory and do not create any unnecessary obstacles to trade, it is a horizontal agreement and not sector-specific. As such, the Agreement does not have specific provisions directed at enhancing transparency and reducing the complexity of technical standards in the pharmaceutical sector. While a number of sector-specific initiatives have been undertaken to harmonize regulations of pharmaceutical products in developed countries, especially those identified as TBT, only a few countries in the Asia and Pacific region have taken part in these initiatives to date. As a result, many countries of the region continue to have complex technical regulations and standards in place hampering cross-border trade in pharmaceutical products.

China, in particular, has extensively used NTMs, especially TBT, to restrict foreign firms from entering the drug and medical device market and to encourage indigenous firm development in both segments of the industry. A survey of NTMS applied in the pharmaceutical industry in China over the last ten years using the UNCTAD NTMs classification confirms that TBT measures related to product registration (B81), inspection requirement (B84) and product-quality or performance (B7) have been the most frequent measure applied to both pharmaceuticals and medical devices imports to China (tables 7 and 8).

**Table 7: Non-tariff measures applied to imports of all pharmaceuticals (medicines, drugs) from trade partners enforced by China from 2008 to 2018**

Type of NTM	Category <sup>24</sup>	Total number of NTMs Applied to Pharmaceutical Imports
Technical Barriers to Trade [TBT] [B]	B7 B14 B31 B81 B82 B83 B84 B852	B7 (Listed 2 times) B14 (4 times) B31 (1 time) B81 (9times) B82(6 times) B83(3 times) B84(8 times) B852(1 time)
Pre-shipment inspection [INSP] [C]	C3	C3 (listed 5 times)
Quantity control measures [QC] [E]	E119 E329	E119 (listed 1 time) E329(1 time)
Other measures [OTH] [G,H,I,J,K,L,M,N,O]	H19 O	H19 (listed 1 time) O (2 times)
Price control measures [PC] [F]	F61	F61 (1 time)

Source: Authors based on UNCTAD TRAINS database.

<sup>24</sup> For further information on each of these categories please refer to UNCTAD 2012 <https://unctad.org/en/Pages/DITC/Trade-Analysis/Non-Tariff-Measures/NTMs-Classification.aspx>



**Table 8: Non-tariff measures applied to all import of all medical devices from trade partners enforced by China from 2008 to 2018**

Type of NTM	Category	Total number of NTMs Applied to Medical Devices
Technical Barriers to Trade [TBT] [B]	B7 B11 B32 B33 B81 B82 B83 B84	B7 (listed 5 times) B11 (1 time) B32 (1 time) B33(1 time) B81 (4 times) B82 (2 times) B83 (2 times) B84(1 time)
Export-related measures [EXP] [P]	P14 P62 P69	P14 (listed 2 times) P62 (3 times) P69 (2 times)

Source: Authors based on UNCTAD TRAINS database.

China is the second largest pharmaceutical market in the world and fastest growing emerging market for pharmaceutical products (Tan, 2018). In 2017, it was worth \$122.6 billion and is expected to reach up to \$175 billion by 2022 (IQVIA, 2018). As the growing middle class in China is ageing, the healthcare industry and associated pharmaceutical industry are poised to witness significant growth. Unlike the global market where ten global pharmaceutical companies accounted for approximately 40% of the market share, the pharmaceutical industry in China is highly fragmented and competitive with no truly dominant leading firms (Igeahub, 2017). Sizable domestic pharmaceutical firms are mostly state-owned enterprises and MNCs, and a those that are privately owned firms are SMEs finding which have difficulty competing with larger domestic and foreign firms in the market. In 2018, the five top domestic pharmaceutical companies were Sinopharm Group, Jiangsu Hengrui Medicine, Kangmei Pharmaceutical, Yunnan Baiyao Group and Shanghai Fosun Pharmaceutical, with the market value of approximately \$11.7 billion, \$39.8 billion, \$19.4 billion, \$17.3 billion and \$14.5 billion respectively (Forbes, 2018). Among the foreign pharmaceutical companies active in China, Pfizer, AstraZeneca, Bayer and Sanofi lead the pack and hold 2.3%, 2.0%, 1.8% and 1.5% market shares respectively (Sinohealth CMH's data & Deloitte, 2017). Over the past decade, the Government has strongly encouraged FDI in the pharmaceutical industry, covering both production and R&D activities. Multinational pharmaceutical companies have contributed sizable investments in drug manufacturing and distribution in China, and a number have also recently begun to invest in drug development and discovery activities in China, including Pfizer, Roche, GSK, Bayer and Novartis. FDI is generally considered to be beneficial in the sector because of the potential it has to spur innovation in the indigenous sector through spill over effects.

In recognition of the growth potential of the sector and the need to meet the demands of a rapidly growing middle class and ageing population, the Government of China has been implementing reforms to revamp the healthcare system and expand access to health insurance as well as the availability and affordability of pharmaceutical products, including both drugs and medical devices, since 2009. These reforms have included a reduction in TBT measures applied to the pharmaceutical industry which has, in turn, gradually opened the market to foreign pharmaceutical firms and their products. For instance, in 2015, technical barriers to business registration and clinical trial testing for pharmaceutical products were reduced. In theory, the reduction of these barriers should have led to an increase in both imports of and FDI in pharmaceutical products, and this case study explores to what extent this has indeed occurred. This case study thus explores the impact of TBT removals on investment to understand whether it positively impacted FDI in the sector.

#### 4.3.2 Context: registration requirements for clinical trial testing of medical devices

Until 2015, foreign pharmaceutical drug and device firms were required to apply for licenses to manufacture and/or distribute their products with the China Food and Drug Administration (CFDA) before obtaining a standard business license. In 2015, however, the Drug Administration Law was

amended in two significant ways. First, pharmaceutical drug companies were no longer required to have manufacturing and distribution licenses before operation licenses, instead they could obtain them after getting their operation licenses and setting up their firms in China. Second, price controls were lifted on most medicines. Both amendments were implemented to address a number of shortages in critical lifesaving drugs across the country to treat hyperthyroidism and other ailments in 2014. The changes were expected to help ensure a steady supply of vital medicines and of pharmaceutical drugs more broadly, by easing market entry requirements for foreign firms while simultaneously allowing the trading price of pharmaceutical products to be determined by market competition.

Shortly after the registration and price controls were relaxed, the CFDA also began to simplify the clinical trial testing requirements for pharmaceutical drugs to further expand the availability and accessibility of medicines in China. Prior to 2017, only evidence from clinical trials conducted in China demonstrating the safety and efficacy of imported pharmaceutical products were accepted by the CFDA. Indeed, this often meant that firms were required to duplicate the clinical trials they had conducted abroad in order to obtain approval to manufacture and/or distribute their drugs in China. Consequently, this limited both access to and availability of drugs in the market. To remedy this, in March 2017 the CFDA began accepting clinical data generated abroad as long as the trial design fit with China's technical guidelines for clinical trial drug testing.

At the same time, the CFDA also initiated several changes to the registration and testing of medical devices. Registration requirements and the length of the approval process to distribute medical devices in China are linked to a class which categorizes the device. Devices are categorized into three distinct classes based on the risk level of the device: class I devices pose the lowest risk level and need only routine administration for their safety and efficacy; class II devices pose moderate risk level and need greater control to ensure their safety and efficacy; and, class III devices pose the highest risk that need the strictest controls. Average registration time ranges from ten months for class I devices and up to 24 months for class II and class III devices. Additionally, all imported medical devices were required to conduct clinical trial testing of the devices in China. In other words, clinical trial evidence for devices conducted abroad was not accepted by the CFDA. Starting in 2014, the CFDA began to reform the registration and approval process in a number of ways.

Three changes are particularly relevant for this case study: First, imported class I devices no longer required registration, but only a filing notification for approval with the CFDA, which thereby eased the filing requirements and time to market for class 1 devices. Second, the CFDA released a batch of 488 categories of class II products and 79 categories of class III products which were exempt from the local clinical trial requirement. Thirdly, the length of imported product registration licenses was extended from 4 years to 5 years. In August 2018, simplification of the registration process was further attempted through the release of the revised Medical Device Classification Catalogue which, *inter alia*, downgraded the risk level of an additional 40 types of devices, thereby opening them up to faster time to market (Shobert, 2016). Most recently, in 2018 China revised the guidance catalogue for foreign investment industries to encourage foreign investment in the manufacture and distribution of all types of medical devices in China, particularly in high-end devices.

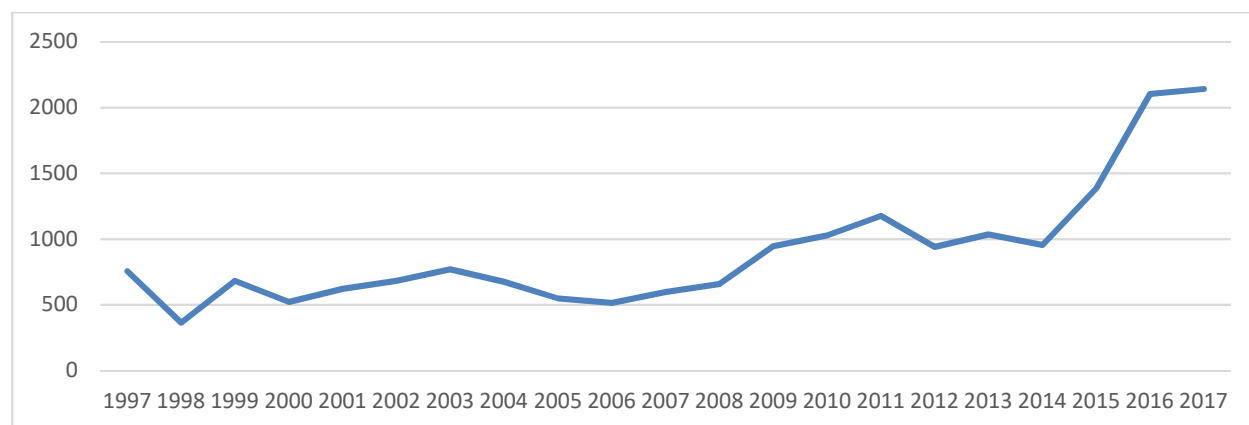
#### 4.3.3 Impact on investment

Eased registration and clinical trial testing for both pharmaceutical drugs and medical devices were aimed at increasing the availability and accessibility of both while also decreasing their prices. These reforms were particularly targeted at gradually relaxing the market entry and

operating barriers for foreign firms and imported pharmaceutical products, and therefore should have led to increase in import associated inward FDI.<sup>25</sup>

As Figure 4 below illustrates, while FDI had been growing steadily prior to regulatory reform in 2015, there were considerable fluctuations. However, inward FDI in both segments of the industry have skyrocketed since the implementation of the reforms of both the registration and clinical trial requirements. Between 2014 and 2017, inward FDI jumped from \$956 million to \$2.1 billion. The largest year-on-year increase in FDI between 1997-2017 occurred in the 2015-2016 period, when inward FDI increased by 52%. Indeed, the large jump in FDI corresponds with the year in which reforms were loosened on both pharmaceutical drugs and devices, suggesting a positive correlation between the removal of the complex requirements and inward FDI and that reforms to registration requirements and additional trials for products already approved outside of China has had a positively impacted inward FDI by removing some of the upfront risk and investment that is required to enter the Chinese market.<sup>26</sup> As with imports, foreign investors were also most likely attracted to the untapped market potential in China, and with loosened restrictions had more of an opportunity to invest. A number of factors can explain why both imports and investment increased. For instance, while there has been some loosening of the sector through these regulations, the sector still remains heavily regulated, with high entry barriers and is significant price controls. Moreover, risks related to intellectual property and drug development and production may make a firm more inclined to choose importing over investing.

**Figure 4: Inward FDI flows to China in pharmaceutical products (drugs and devices), 1997-2017 (US\$ millions)**



Source: Authors' calculations based on data retrieved from CEIC.

Firms from the United States have been the largest investors in the industry, and most investments have been directed to Jiangsu, Zhejiang and Shanghai. Indeed, the Yangtze River Delta has become a growing hotbed of foreign pharmaceutical companies (Deloitte, 2017). As

<sup>25</sup> Regarding trade impacts, import values between 2010 and 2017 suggest that eased requirements for registration and clinical trial testing for both pharmaceutical drugs and medical devices positively affected imports. Imports of pharmaceutical drugs nearly doubled between 2010 and 2017, growing from nearly \$4.5 billion to \$7.4 billion, while imports of medical devices jumped from \$4.6 billion to \$9.7 billion. The continuous increase in imports of both drugs and devices suggest, however, that the gradual loosening of registration and testing requirements were not solely responsible for an increase in imports over time and especially between 2015-17. Instead, it is likely that both loosened TBT measures combined with growing untapped market potential were both responsible.

<sup>26</sup> In this instance, the upfront risk and investment referred to here is associated with the cost of registration requirements and often duplicated local clinical trials that were previously required.

the sector continues to develop, FDI will play a critical role in meeting the healthcare needs of the population and in helping the local manufacturing sector to upgrade skills into both the generics and R&D segments of the sector.

#### 4.3.4 Conclusions

The rapid expansion of an ageing middle class population that demands better access, affordability and availability of pharmaceutical products has significantly influenced the growth of imports and investment in pharmaceutical drugs and devices. Nonetheless, access to the pharmaceutical market has been and remains extremely regulated. High entry barriers have long discouraged and at times prevented foreign players from manufacturing and distributing their drugs and medical devices in China. These entry barriers, particularly in the form of TBT measures, were put in place to favor domestic industry growth. However, population growth, a growing middle class and a steady and growing increase in disease profiles in China, has led to some of the barriers being removed in order to ensure increased access to affordable and *quality* drugs and devices. This case study has showed that the removal and simplification of some of these barriers has indeed encouraged growth in both imports and FDI in the sector. The removal and simplification of these barrier has helped reduce the time and cost of distributing drugs and devices in China and encouraged imports and FDI. Furthermore, quicker approval processes for drugs and devices with clinical trials from abroad have further supported imports and investments. Despite this, further growth in FDI has been hampered not only by the stringent TBT measures that continue to guard the sector from foreign investors, but also from strict price controls that have forced many firms, especially foreign firms, to slash the cost of their drugs and devices being sold in China. At the same time, China has also been encouraging domestic and foreign firms to increase their innovative drug development work in China. Such a dual priority, i.e. ensuring availability and affordability of drugs and devices and promoting a transition to more innovative drug development activities, require delicate and well-crafted long-term strategy for the industry that allows generics produced both at home and abroad to flourish but also supports R&D activities at home. Foreign investors are critical to supporting more R&D activities in China, however, investments from these firms are like to remain hampered until further market entry barriers are reduced and stricter IPR regime in the sector is enforced.

## 5. Lessons Learned

This paper provided a detailed assessment of the work that has been done thus far related to NTMS and FDI and a conceptual discussion with initial assumptions on the links between selected NTMs and FDI. This conceptual discussion was used as a basis to explore and verify the impacts of 3 specific types of NTMs in concrete real-world examples. Qualitative case studies on NTMs that have been deployed and also removed in three Asia-Pacific countries were studied. The case studies utilized descriptive metrics and aggregate data to understand and draw conclusions on the impact of the implementation or removal of a specific NTM on FDI. The case studies also placed emphasis on understanding the context in which the NTMs were deployed or removed. An analysis of the contextual environment in which NTMs are employed is often lacking from the literature on their impacts, however, as these case studies have shown context was critical to understanding not only how but also to what extent the NTM under study impacted FDI.

The analysis of both strengthened IPRs in the pharmaceutical sector in India and implementation of an LCR on 4G enabled smartphones demonstrated the extent to which these types of NTMs

can positively impact FDI; while the case study on TBT measures illustrated how complex and overly stringent TBT measures can be negatively associated with inward FDI. These results are in line with the assumptions put forth in section 2 of this paper on how these NTMs might affect FDI.

Specifically, in section 2 the assumption was put forth that strengthened IPRs may incentivize inward FDI. The study on IPRs in the Indian pharmaceutical industry illustrated that inward FDI increased after the introduction of stronger patent protection and remained much higher than previous levels in the years that followed implementation. However, despite higher overall levels of FDI flows, significant volatilities were still apparent following IPR implementation. The most volatile years for FDI were also years in which there were a series of IP rulings in India against foreign pharmaceutical firms on violating TRIPS Agreement provisions. These cases of TRIPS Agreement violations corresponded with dramatic declines in inward FDI, however, inward FDI quickly recovered after each decline, largely due to massive market potential. Maximizing the potential gains in FDI that can come through strengthened IPRs, however, critically requires that going forward more efforts are made to strike a delicate balance between moving towards a stricter IPR regime with consistent enforcement mechanisms and enabling the affordability and availability of life saving medicines for its population. Striking such a delicate balance will be essential to achieving consistent and increased inward FDI, and it also has the potential to spillover and lead to increased outward FDI.

With regard to local content NTMs, the paper started off with the intuition that an LCR may lead to increased inward FDI in the country implementing the LCR because they would rule out the possibility of firms being able to trade or compete based on nationality. The case study confirmed this initial assumption, however, FDI only spiked in the year of LCR implementation and then it tapered off significantly. Thus, while inward FDI expanded in the year the LCR was announced, 2015, since then inward FDI has dramatically declined. The LCR has been unable to stimulate commensurate levels of FDI because the firms with the largest market share became capable of meeting the LCR requirements and catering to the local market. The principal recommendation coming from this case study was that a performance evaluation of LCR in its current form is urgently needed as it only resulted in a one-time spike in inward FDI and has since then discouraged FDI. Such a performance evaluation should focus on determining if and how the LCR could be redesigned or removed to better achieve its stated aims and support indigenous industry growth and value chain integration of indigenous firms in the smartphone sector.

A word of caution should be given at this point – there is large and growing evidence on the harmful impacts of LCR to trade and investment.<sup>27</sup> The case study in this paper does not veer far from this evidence. Although the immediate impact of the LCR was positive for inward FDI, this positive impact was short-lived and context-specific. Short-lived because it was a one-time immediate increase, whereas over the medium-term the LCR has actually resulted in dramatically reducing FDI to levels almost below that before the LCR. Context-specific because it was only able to persuade firms to continue to invest given the smartphone market potential in Indonesia over the 2015-2022 period. While the LCR may have the potential to contribute to short-term gains in FDI, they are more likely to be FDI-reducing in the long-term.<sup>28</sup> In the instances when they are applied for short-term gains, it is critical that they are properly designed and implemented, *and* continuously monitored and evaluated to determine whether they are indeed achieving their intended purpose or if they need to be redesigned or removed.

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<sup>27</sup> For example see Evenett and Fritz 2016; Hufbauer et. al. 2015; Kwon and Chon 2009; Stone et. al. 2016.

<sup>28</sup> Unless domestic suppliers can provide high quality inputs, in which case, a mandatory LCR would no longer be necessary.

Finally, and returning to the case study analyses, the paper assumed the extent and scope of certain TBTs, which may be very sector specific, may discourage FDI. To validate this, the paper focused on the extent to which removal of sector-specific TBTs encouraged FDI. As a case study, the paper analyzed the removal of several TBTs which have acted as entry barriers in the pharmaceutical drug and medical device sector in China. The case study demonstrated that removal and simplification of these barriers reduced the time and cost of distributing drugs and devices in China and encouraged FDI. Nonetheless, meeting the medicinal needs of its growing and aging population while also building an innovative and competitive pharmaceutical sector critically depends on developing a well-crafted long-term strategy for the industry that allows generics produced both at home and abroad to flourish but also supports R&D activities at home. Removal of further TBTs that continue to hamper investment, and a loosening of the strict drug and device price controls in the sector must be critical components of such a strategy.

These case studies initially illustrate the impact that NTMs can have on FDI. However, they are limited – one case study on one type of NTM in one country cannot broadly confirm that the causal link between one specific NTM and its impact on FDI. Indeed, extension and verification are needed. In other words, more case studies on these types of NTMs in more countries, and also on other NTMs in these and other countries are needed. Furthermore, *both* qualitative and quantitative work is needed, as only informed conclusions on the impact of NTMs on FDI can be drawn if we have both. It is critical that these case studies also focus on the contextual factors that influence the impact of the NTM on FDI, for only then can we truly begin to understand when and to what extent an NTM may positively or negatively impact FDI. Of course, a core challenge in undertaking such research and analysis is identifying the NTMs in each country and also obtaining data to assess their impact on FDI. One potential way to navigate this challenge would be to take the analysis down to the firm level. In this case, the Non-Tariff Measures Business Surveys undertaken by the International Trade Centre (ITC) would be a particularly relevant starting point as they are extended to cover more of the Asia and Pacific region. They would of course also need to be extended and supplemented with additional questionnaires to understand how NTMs affect the investment decision of firms. Such information would be particularly relevant for policymakers to design, monitor, and evaluate NTMs.

The main takeaway from this paper for policy makers is that NTMs do impact FDI. Putting the size limitations of this analysis aside, the initial and clearly demonstrated links between NTMs and FDI patterns emphasizes the need for NTMs to be carefully designed and monitored. Furthermore, because some NTMs may have the capacity to encourage FDI levels, this could prove increasingly relevant to policy makers aiming to generate investment in key SDG sectors. As countries are currently involved in establishing policies for implementing the SDGs, the ability to design targeted NTMs to build a base of quality FDI in key SDG sectors is particularly relevant. Just as the ability to understand how NTMs may prevent or hamper FDI in key SDG sectors, such as TBT measures in the health sector, is also important. Furthermore, the effects of any NTM on FDI will certainly be tied to the political and economic context in which they are implementing and therefore they need to be carefully designed and based on an effective assessment of country and sector needs. By better understanding trends and developments in existing and potential future industries based on current capacity, governments can gain a better understanding of how NTMs can effectively hinder or support these industries.

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