Strategies to Support Intra-Country Tiered Pricing  
Can it Promote Access to Medicines to Those Who Need it Most?

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I. Introduction

Access to essential medicines and vaccines remains an uphill battle for approximately eighty percent of the two billion people living in low- and middle-income countries today (Dube, 2017). Despite significant efforts to shoulder the burden by the international community, the challenges continue in light of growing disease burden and ever-increasing prices for both infectious diseases and non-communicable diseases across countries. Tiered pricing - a strategy that offers drugs and vaccines at more affordable prices to those that have less/ no ability to pay - has been proposed as a potential solution to this problem, with a number of studies proposing this mechanism to promote access while also allowing pharmaceutical firms to allocate returns on investment (Lang and Hill, 2004; Danzon and Towse, 2003; Reich and Bery, 2005).

The merits to the argument are evident. Firstly, it will help mainstream the private sector into the folds of the access to medicines debate, which remains an imperative if we are to seriously engage all stakeholders in finding solutions to the monumental challenge that lies ahead of us. Pharmaceutical firms have already been partnering in many ways to shoulder the burden despite the political controversies surrounding tiered pricing. In the global vaccines market, for instance, a tiered pricing structure has emerged with the help of the Global Alliance for Vaccines and Immunization (GAVI) that charges systematically differentiated prices for low-income countries. Furthermore, in the past decade, the top 20 pharmaceutical companies have significantly intensified their efforts to promote access to medicines (Access to Medicines Foundation, 2018; Stevens and Huy, 2017). A study conducted by Hogerziel et al. (2014) finds that 20 of the world’s largest pharmaceutical companies ranked positively on six of the core indicators of the global access to medicines index for products relevant for the treatment of diseases that were covered by the index.

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2 According to the WHO, 80% of deaths due to chronic disease occurred in low and middle-income countries, but the availability of medicines for communicable and non-communicable diseases are below 50% of what is required on average (WHO, 2018a). In the case of vaccines, in 2017, 19.9 million infants did not receive routine immunization services, 60% of which are in just ten low and middle-income countries (WHO, 2018b).

3 The recent Lancet Commission on Essential Medicines for Universal Health Coverage highlights high pricing of medicines as one of the major barriers to equitable access for all income groups, due to the dynamics of patenting and pricing in the pharmaceutical market. Affordability challenges are exacerbated for all diseases including cancer and diabetes, which are typically more expensive, and continue to persist for communicable disease (particularly chronic infections such as HIV/AIDS and tuberculosis) despite a historical emphasis on funding in this area (Wirtz et al., 2016).

4 The 2012 index focuses on 33 high-burden communicable, non-communicable, and neglected tropical diseases, as well as a range of maternal and neonatal disorders (Access to Medicine Foundation, 2012).
Tiered pricing draws on the economic theory of price discrimination, which suggests that a profit-maximizing firm can sell the same product to different consumers at different prices. The price differences in such a scenario do not result from varying production costs but are rather a reflection of the differences in the willingness/ability of consumers to pay in the different markets. In order to engage in tiered pricing, firms require certain pre-conditions to fall into place. Firstly, the selling firm should have a degree of market power to segment its markets. The idea being that in the absence of such market power, there would be a competitive market, and tiered prices would get further undercut by other suppliers, leaving no incentives for the selling firm to engage in such a strategy. Secondly, the selling firm should be able to discriminate amongst consumers based on price sensitivities. Finally, the selling firm must be able to control resale opportunities from the low-priced markets to the higher priced markets (Watal, 2001; Fisher and Syed, 2006).

When these three conditions are met, economic theory dictates that it would be more profitable for the firm to charge lower prices in highly price-sensitive markets (with low ability to pay) and higher prices in the less price-sensitive markets (with higher ability to pay). The firm can then continue its sales in each of these segmented markets to the point where the cost of production and distribution of additional units do not exceed the revenues from the sale in that market. This would result in a ‘win-win’ scenario because consumers who could otherwise not afford the drugs can have access, and the selling firm would still benefit from the sale of its products in the more price sensitive market because the increased volume of sales in the less-price sensitive markets would offset the lower prices it charges. This paper seeks to explore the conditions under which potential ‘win-win’ outcomes can be established for price discrimination. This paper uses the term ‘tiered pricing’ to denote the explicit shift in pricing strategy to create a balance between firm level profits and social benefits by expanding access. In a scenario of tiered pricing, rather than using a uniform price for the global market as a whole, firms will tier prices based on the economic reality and access constraints faced by consumers with lower income, and not just for increased profits or convenience.

In the pharmaceutical sector, the past two decades have seen a rise in inter-country tiered pricing where firms have sought to differentiate between ability of users to pay depending on whether they are located in high-income, middle-income or low-income countries. Particularly, a number of global pharmaceutical companies have introduced a category 1 price (offering certain products on lower prices for consumers in low-income countries using the World Bank classification or least developed countries using the UN classification) for several drugs that have a public health relevance. Reviews of existing inter-country pricing experiences, in the antiretrovirals (ARVs) market and some other sectors, highlight the complexity of economic, legal and regulatory considerations involved, with a number of tensions emerging between national governments, international agencies, pharmaceutical companies and non-governmental organizations (Yadav, 2010; other references).

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5 Tiered pricing is often also termed as differential pricing, referring simply to the ability of firms to differentially price for different groups of consumers, or equity pricing, referring to the need for firms to price as per equity considerations.

6 Demand is said to be highly price elastic when the demand of the product varies hugely with small changes in price. In general, demand in LMICs, where between 50-90% of the drugs are privately funded and medical insurance is not common, exhibits functions that are highly price elastic, since the people are very sensitive to price rises.

7 The World Bank assigns income groupings by gross national income (GNI). In the 2019 fiscal year, low-income (LIC) countries are defined as having a GNI of $995 or less, low-middle income (LMIC) countries have a GNI between $996 and $3,895, upper middle-income (UMIC) countries have a GNI between $3896 and $12,055 and high-income countries (HIC) possess a GNI above $12,055 (World Bank, 2019).
To date, empirical data do not support the conclusion that inter-country tiered pricing approaches increase access to medicines in a systematic way, leaving open the discussion on how and under which circumstances such a strategy may be desirable, in which form, and whether it should be pursued in conjunction with other mechanisms (such as compulsory licensing and reference pricing) to increase access to medicines to those who need it most (Danzon, 2018; Beall et al, 2015). Pharmaceutical firms, on their part, have stated their inability to control arbitrage between countries as an impediment that makes the costs of control and oversight associated with tiered pricing much higher than the profits of potentially expanding their customer base. There is also a concern amongst industry that lowering prices in one/some markets can create a contagion effect through external reference pricing, thus impeding their ability to recoup R&D investments. Viewing the problem from a different lens, access to medicines proponents argue that the voluntary nature of tiered pricing risks placing too little regulatory control and oversight on the firms, leading to fears that firm-driven inter-country tiered pricing strategies could lead to anti-competitive outcomes in the long run (Equal Access Initiative, 2016; Médecins Sans Frontières, 2013; Baker, 2014).

To attenuate some of these market failures and balance the demands of firms, countries and consumers better, a different kind of tiered pricing that does not discriminate prices on the basis of countries but offers segregates consumers within any particular country depending on the economic ability to pay has been suggested as a solution. Offering different price categories within a given country - namely, intra-country tiered pricing - although complex, might be a feasible solution given that people of differing economic categories often seek treatment and obtain medicines differently owing to a variety of factors such as the cost of treatment, insurance coverage (private, public, hybrid or the lack thereof), transportation costs, time spent, and location of the household, among others. Previous work by Berkman Klein Center’s Global Access in Action Program has argued that such intra-country tiered pricing can offer a way to expand access and promote innovation for medicines (Palfrey, 2017).

This study aims to conduct an objective assessment of tiered pricing strategies to explore and assess whether intra-country tiered pricing can be an option to enhance price transparency and global access to medicines in the current context. Section 2 begins with an assessment of the key issues in designing tiered pricing strategies with a particular consideration of the difficulties encountered in inter-country tiered pricing strategies up until now. It presents evidence from HIV/AIDS, cancer and Hepatitis C segments to highlight the various market failures. The best case for intra-country tiered pricing comes from the market failures of inter-country tiered pricing policies, as Section 3 analyses, with a wider discussion on the merits of the pricing strategy and its wider applicability. Section 4 offers some insights on how this could be enabled in countries along with some thoughts on questions of institutional design. Section 5 briefly concludes.

2. The Theoretical Case for Intra-Country Tiered Pricing

In a perfectly competitive market where price is equal to the marginal cost, the aggregate producer surplus and consumer surplus is the value created through the exchange of the goods, and the total surplus of consumers and producers is as large as possible. The global

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8 Studies have, in the past, noted that international agencies like PEPFAR saved $323 million from 2005-2008 by purchasing generics rather than tiered-priced HIV drugs (Holmes et al., 2010), and also concluded that it might not be as potent an option as generic competition to increase access to medicines (Moon et al, 2011).
pharmaceutical market not only fails to fit this description, but also, in the case of many patented drugs, directly contrasts this scenario by being a monopoly where the total surplus shrinks due to the deadweight losses created by exercise of monopoly power. In these cases, price discrimination could be an effective solution only if policy can enable the shift in firm level strategies to the ‘win-win’ outcomes associated with tiered pricing.

2.1. Price Discrimination and Inter-Country Tiered Pricing: Comparing the Welfare Effects

To clearly demarcate between price discrimination and welfare enhancing tiered pricing, pharmaceutical firms engage regularly in price discrimination voluntarily by offering the same/ similar drugs at different prices in different markets. This kind of price discrimination is guided by business considerations such as competition, profits, and the capacity to dictate prices with governments, and has little to do with creating equitable outcomes. Morel et al (2011), for example, analyze average prices of pharmaceutical products across fourteen countries and find several instances where high income countries had lower average prices when compared to low income countries.

Importantly, when a monopolist firm moves from uniform pricing (one price for the global market) to charging different prices in exogenously identifiable markets, whether such price discrimination is better than a simple monopoly and results in social welfare on the whole depends entirely on the kind of price discrimination in question. Theory suggests that in a discriminatory monopoly (a monopolist who price discriminates), resources are allocated efficiently than under a simple monopoly only in the case of first and second-degree discrimination. In these two forms of discrimination, either the same amount of surplus is created as in a perfectly competitive market or at least a higher surplus than in a simple monopoly because the firm can set the prices exactly according to the preferences of its consumers. This meets all the conditions for a welfare increase (measured as the sum of consumer surplus and profits) because the total output of the selling firm (measured for instance, in terms of volumes of sales) increases on the whole (Schwartz, 1990; Schmalensee, 1981) and all groups of consumers across all market categories have greater access to the products.

In the pharmaceutical market, given that it is difficult for firms to identify and perfectly discriminate consumers on a one-on-one basis (first degree discrimination) or in the form of neater groups with revealed preferences (second degree discrimination) that determines their ability to pay, firms have chosen the option of offering differential prices in different countries based on pre-existing national economic classifications (i.e., GDP-based). This makes it far from a textbook case of welfare enhancing tiered pricing at the outset itself. It also ignores the fact that as countries develop, the distribution of income in many low- and middle-income countries tends to become highly skewed, with large intra-country differentials between the rich and the poor. Thus, the pricing mechanism provides ample scope and incentives for originator companies that hold monopoly positions in certain product categories to set prices that target to the wealthy minority in each of the country categories rather than simply set low prices based on average per capita income.

Given that the pricing strategy does not make pricing more accountable to income status (and the ability to pay) in neater categories other than GDP (as would be possible in the case of intra-country pricing), there remains ample scope for firms to skim off the most high pricing customers across different markets instead of allowing swathes of new consumers who had

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9 First-degree price discrimination is when a firm sets its prices with the knowledge of ability to pay of each of its customers. Second-degree price discrimination is when a firm can induce its customers to reveal their preferences.
no access to the drugs in a single price context to gain access under the tiered price setting, with the result that it is detrimental to social welfare (Schmalensee, 1981; Varian, 1985; 1989). Flynn et al (2009) document this phenomenon in practice and conclude that in many instances, prices of life-saving drugs have been set at exorbitantly higher costs than anticipated even in a tiered-pricing setting. Similarly, Moon et al. studied the global ACT market to find that the presence of competition in fact helped reduce tiered prices (2011, p. 15). Their study, looking at several drug categories shows how in sizeable markets with a number of competitors, tiered pricing performed poorly when compared to competitive production of drugs to achieve sustained price reductions and affordable access to medicines.

2.2. Market Failures and Alignment Issues in Existing Inter-Country Tiered Pricing Strategies

Existing evidence in inter-country pricing approaches help demonstrate some of the shortcomings of the approach. For the firms, there are at least three impediments for firms to engage actively and more widely in the mechanism: (a) the inability to control arbitrage (i.e. restrict the flow of products between the lower priced groups back to the high-income groups), (b) the generalized concern that a reduction of prices in some markets may lead to a contagion effect where the parent firm is forced to provide reduced prices in others too (due to external reference pricing),10 and (c) the presence of national supply side constraints/leakages and inefficiencies.11

To address these shortcomings, industry proponents have suggested that firms might need policy support to prevent leakage of products from one market to another, enabling them to control arbitrage, and effectively segregate markets, ensuring that the costs of control and oversight of tiered pricing are not much higher than the profits that a firm can potentially count on by expanding its customer base. If this is the goal, and essentially, if one were to focus on tiered pricing from the lens of creating sufficient incentives for firms, a central question would revolve around the practice of parallel importation, i.e., the practice of importing drugs that are available much cheaper elsewhere to increase access to medicines within national boundaries. This would also require action from national governments to prevent leakage within the country to increasing arbitrage, and to curb retail chain margins, which can often be really high due to the presence of supply-side inefficiencies in countries.

But the possibility of parallel importation and arbitrage is an essential mechanism that governments use to bring down the threat of unduly high prices set by pharmaceutical firms. In fact, parallel importation is lucrative only pharmaceutical firms engage regularly in price discrimination to maximize their profits. Taking this into account, national regimes resort to allowing parallel importation to curb the capacity of firms to engage in profit-enhancing arbitrage at the expense of consumers.12 For instance, both the United States of America and

10 Countries use external reference pricing—the practice of comparing international prices of the same pharmaceutical product—in order to determine pricing parameters for negotiation with pharmaceutical companies (Danzon, 2012; Maniadakis et al., 2017). Although governments usually reference prices for countries of a comparable income level, this is not always the case (Danzon, 2012). External reference pricing can undermine a pharmaceutical firm’s ability to differentially price because countries are aware of lower prices offered on other markets and are less willing to accept higher prices for their own (Maniadakis et al., 2017).

11 In many countries, there are specific characteristics of the health systems that do not guard against leakages of the lower priced drugs into private sales (where they are sold for an additional profit), or the presence of wholesale and retail chain margins add up costs along the distribution chain thereby negating the access effects of the original lower price offered by the manufacturer.

12 Article 6 of the TRIPS Agreement excludes the question of exhaustion of intellectual property rights from the purview of the Agreement by stating: "For purposes of dispute settlement under this Agreement, subject to the provisions of Articles 3 and 4, nothing in this Agreement shall be used to address the issue of exhaustion of
the European Union apply the first sale principle within their territories as an effective way of controlling market power and abuse of consumers that can arise from privately contracted exclusive territories. Based on studies of the positive impacts that these measures have on creating better prices for consumers in these markets, the access literature often proposes parallel importation as a tool to promote competition and reduce prices more widely, especially in low income countries (Correa, 2002; Maskus, 2001).

Given these advantages of parallel importation in bringing prices down, as opposed to the shortcomings witnessed in inter-country tiered pricing approaches, proponents of access have previously argued against it. Other general trends in the pharmaceutical sector, such as the inability of R&D to yield drugs in recent times than in years past (van der Gronde et al, 2017), alongside the growing reliance of firms on intellectual property rights (especially patents, but also trade markets, trade secrets, among others) to maintain critical advantages (Nealey et al., 2015; Kyle, 2016; Ni et al., 2015) have acted as red herrings, raising questions of anti-competitive conduct. There are also expanding instances of evergreening, i.e., the practice of applying for new patents over minor or incremental versions of existing drugs (see Collier, 2013); also known as ‘product-hopping’ or ‘forced switching’, whereby a parent company takes on patents on new formulations of the same product to preserve its profits by switching the market (or market antics) ever so slightly (Jones et al, 2016). These practices have both caused a flurry that the benefits of such intellectual property in fostering innovation might no longer be balanced by the welfare losses of monopoly profits and diminished outputs (Fischer and Syed, 2006; Leslie et al., 2011).

Typically, when firms engage in price discrimination in the presence of strong (and broad) intellectual property protection with little anti-trust oversight, this increases the market power of the monopolist firm to such an extent that high prices for all countries become an imminent reality leading to above-competitive returns on investment for a long time (Cragier, 2014; Kesselheim et al., 2016; Danzon, 2012). Such market power can also be used by incumbent firms to lower prices with the intent of discouraging new market entry by competitors, or even worse, with the intent of explicitly encouraging market exit of competitors. In so doing, although tiered pricing can benefit consumers at first, its effects will wane over time due to the lack of existence of competition. This coupled with efforts to retain intellectual property monopoly through instruments such as reverse buyout, patent evergreening, and other intellectual property abuse poses the threat of longer term in-transparent pricing for society as a whole. Preventing parallel importation or curbing generic competition to promote tiered pricing without an accountable framework that addresses its shortcomings will, in such cases, more likely than not result in reinforcing monopoly pricing without restraints, thus leaving all markets worse off with the patent owner firm benefiting from an abnormally high return on investment (ROI) at the expense of consumers everywhere (Maskus, 2001; Danzon, 2018).

intellectual property rights. As a result, regulating parallel imports remains a question of national jurisdiction and countries have varied approaches to this question.

13 Evergreening refers to possibilities through which the patent holder can artfully apply for new patents just before the end of its existing term, thus ‘evergreening’ its protection. Kumar and Nanda (2017) identify the following common strategies of evergreening: (a) combinations of two or more drugs; dosing rage and dosing route; (c) biological targets for old molecule, (d) delivery profiles, mechanism of action; (e) derivatives and isomeric forms; (f) screening methods, dosing regimen; (g) packaging; and (h) different methods of treatment.

14 The literature on intellectual property and competition assumes that while IPRs grant a monopoly for a specific amount of time, they do not automatically confer significant market power on holders of the rights. But to the extent that broader patent scope leads to increasing market power, such patents could be responsible for anti-competitive effects that result from the exercise of this power by firms.

15 Danzon (2018, p. 3) notes in this context: “Thus, economic theory concludes that, even without regulatory constraints, the profit motive leads a monopolist to charge prices across market segments inversely related to price elasticity, and this enhances social welfare compared with charging a uniform price. However, the absolute price levels charged by an unregulated, profit-maximizing monopolist may yield above-competitive return on
2.3. Inter-Country Tiered Pricing in Practice: Evidence from HIV/AIDS, Hep C and Cancer Segments

In this section, three different experiences in inter-country tiered pricing are assessed to highlight the ensuing welfare effects. The therapeutic categories are chosen on the basis of the fact that they offer significantly different market structures, both globally and within countries. The HIV/AIDS medicines market offers interesting evidence on the interplay between tiered pricing, patents and competition for several reasons. Firstly, antiretrovirals (ARVs) are highly relevant for the global access to medicines debate given the historical scale of the crisis. Secondly, the scale of the HIV/AIDS epidemic has been such that tiered pricing, generic competition and international procurement (by agencies such as Global Fund for AIDS, Tuberculosis and Malaria (GFATM), the President’s Emergency Program for AIDS Relied (PEPFAR) and the Clinton Aids Initiative (CHAI)) have all been used as instruments in parallel, thus offering a good basis for comparison. As a result, ARVs is the therapeutic category with the most available data on tiered pricing. Finally, differentiated impacts have been obtained by countries while combining these supply mechanisms with other policy options, such as the use of TRIPS flexibilities (including compulsory licensing), and voluntary licensing by large firms through the Medicines Patent Pool (MPP). The study of these helps flesh out certain critical interdependencies. Two other sectors - Hep C, where a single patented drug has been the main treatment available globally, and cancer treatments, which are now a large part of the growing health burden in all countries - are discussed for their varied implications for access.

2.3.1. HIV/AIDS

Despite rigorous interventions, HIV/AIDS remains a serious public health issue globally as also evident by the 90-90-90 target of the UNAIDS Fast Track Initiative for treatment (see UNAIDS, 2016). Data on global antiretroviral coverage suggests that treatment options remain insufficient, and only an estimated 59% of people worldwide living with HIV/AIDS are covered by antiretroviral therapy (figure 1).16

Figure 1: Global Antiretroviral Coverage: 2000 and 2016

investment (ROI) unless pricing power is constrained by the potential entry of differentiated substitute products and robust consumer price sensitivity, such that the market approximates monopolistic competition rather than pure monopoly.7

16 http://apps.who.int/gho/data/view.main.23300REGION?lang=en
(a) Supply, Demand and Price Reductions in the ARVs Market

In the ARVs market, access to generic options have been historically instrumental for steep reductions of prices (MSF, 2013). Beck et al (2019) note that as a result of generic competition, costs of first-line ARV therapies dropped form USD 10,000-15,000 per year to just US$64–102 per year. Figure 2 below maps the relationship between originator prices and price reductions using data available with the WHO’s Global Price Reporting Mechanism (GPRM), to show that the price decreases are most evident in the case of those ARVs when there was utmost generics competition when compared to those other categories of drugs (such as Raltegravir or Ertravirine) where the number of generic suppliers are limited.

Figure 2: The role of competition in reduction of prices

Source: Reproduced using the Global Price Reporting Mechanism Database.
Note: X-axis lists the main ARVs. Y axis plots the treatment cost per year and the number of generic competitors respectively. Moon et al (2011) present a similar chart using MSF data.

As Figure 2 shows, fierce competition by Indian generic companies for drugs was critically important in bringing down the prices and increasing the access to ARVs in a large number of countries around the world. This is evident in trends for several drugs assessed therein, but applies especially to Lamivudine, Efavirenz and Tenofovir. The option of securing these drugs at a cheaper price resulted in the number of countries purchasing generic ARVs from Indian companies expand from 11 to 96 between 2003 and 2008 globally (Waning et al., 2010).

(b) Tiered Pricing by Originator Companies and Generic Competition: Price Comparisons
Generic competition had two impacts on restructuring the HIV/AIDS market. On the one hand, it prompted direct price competition with originator companies thus bringing prices of drugs down drastically and enhancing access to medicines as figures 3-11 show. On the other, it also compelled originator companies to offer price reductions to avert the threat of compulsory licensing in many countries. In particular, studies on the topic find that until the introduction of competition, tiered pricing offered by companies tends to remain relatively high even in the low-income markets, and in some cases, even after the introduction of cheaper generics, originator companies continue to offer higher tiered prices for the same products in countries that were obliged to procure the patented versions. Waning et al (2009) conduct a review of 7,000 developing-country purchase transactions from 2002-2007 and find that the tiered prices for 15 of 18 antiretroviral (ARV) drugs were anywhere between 23-498% higher than the prices offered by the generic companies. Holmes et al (2010) find similarly that international agencies like PEPFAR saved $323 million from 2005-2008 by purchasing generics rather than using tiered-priced HIV drugs. Studying the relationship between generic competition and the fall in the prices of originator drugs through tiered pricing in ARVs, artemisinin-combination therapy for malaria, treatments for drug-resistant tuberculosis, drugs for visceral leishmaniasis, and the pneumococcal vaccine, Moon et al ((2011) conclude that generic competition plays an important role in securing reduction of prices from originator companies. They discuss the case of Lopinavir/ Ritonavir, on which Abbott Laboratories holds the patents. From an initial tier price of USD 650 offered to several African countries and other least developed countries, Abbott announced a drop to USD 500 in 2002, which remained steady until 2009. In 2009, as Moon et al (2011, p. 4) note, when CHAI announced that the same combination would be available at USD 470, Abbott brought down its price to USD 440.

To break down the data particularly into middle income countries and low-income countries to assess the benefits for low-income countries, Table 1 compares prices offered through generic competition and tiered pricing across all first and second line ARVs for the year - 2014 - using data from the GPRM database and MSF. In table 1, the first column (GPRM Originator) shows the price of the originator drug, without tier pricing, whereas the third column (MSF originator) shows the tier priced offer of the originator company for category 1 countries (mainly LICs, or least developed countries, which are offered the lowest price). Columns 2 and 4 show the available generic price, offered by generic companies across all the ARV therapies. A comparison of columns 2, 3 and 4 shows the differences between the tier price and the generic price. For example, for the NVP+(TDF+3TC) combination, the tier price is at USD 501 for the treatment per year, whereas the generic price would be anywhere between USD 96 and USD 106 for the same regimen.

Table 1: Tiered Prices Versus Generic Prices Across All First Line and Second Line Drugs, 2014.

<table>
<thead>
<tr>
<th>WHO Regimen</th>
<th>Treatment Cost Per Year (2014)</th>
</tr>
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<tbody>
<tr>
<td></td>
<td>GPRM</td>
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<td>GPRM</td>
<td>GPRM</td>
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17 Some fluctuations in the prices can be seen, which may be accounted by erratic pricing of active pharmaceutical ingredients and other market shocks. See for example, Beck et al (2011).

18 Year 2014 has been chosen because of the maximum availability of data points.

19 Companies do not have a standard list of what countries fall into category 1, but generally it is based on the World Bank classification of low-income categories, or the UN classification of Least Developed Countries. Some companies offer the category 1 price to all sub-Saharan African countries, and some other Asian LDCs.
### First Line

<table>
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<tr>
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<th>Generic</th>
<th>Originator</th>
<th>Generic</th>
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</thead>
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<tr>
<td>NVP+AZT+3TC</td>
<td>452*</td>
<td>120</td>
<td>N/A</td>
<td>134</td>
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<tr>
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<td>1538*</td>
<td>96</td>
<td>501</td>
<td>106</td>
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<tr>
<td>NVP+ (TDF+FTC)</td>
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<td>N/A</td>
<td>138</td>
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<tr>
<td>EFV+(AZT+3TC)</td>
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<td>153</td>
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<tr>
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<td>519</td>
<td>125</td>
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<tr>
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<td>N/A</td>
<td>157</td>
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<tr>
<td>DTG+TDF+3TC</td>
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### Second Line

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<th>Generic</th>
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<tr>
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<tr>
<td>LPV/r+(TDF+3TC)</td>
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<td>304</td>
<td>532</td>
<td>355</td>
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<tr>
<td>LPV/r+(TDF+FTC)</td>
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<td>N/A</td>
<td>387</td>
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<td>N/A</td>
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<td>337*</td>
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<td>N/A</td>
<td>357</td>
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<td>N/A</td>
<td>N/A</td>
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<td>DRV/r+(AZT+3TC)</td>
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<td>DTG+(DRV/r)</td>
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<td>N/A</td>
<td>N/A</td>
<td>1332*</td>
</tr>
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</table>

### Third Line

<table>
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<tr>
<th>Combination</th>
<th>Originator</th>
<th>Generic</th>
<th>Originator</th>
<th>Generic</th>
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</thead>
<tbody>
<tr>
<td>Raltegravir</td>
<td>675</td>
<td>372</td>
<td>675</td>
<td>1752</td>
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</tbody>
</table>

*Asterix indicates alternate year used for: GPRM Originator – AZT (2013), NVP (2013), ATV/r (2012), DTG (2015); MSF Originator – DTG (2017); MSF Generic – DTG (2017). Category 1 pricing is used for MSF Originator cost. MSF Generic prices are averaged across available data. All numbers are rounded to the nearest whole number.

(c) Patents, Evergreening and Bundling Issues

The ARVs sector also exhibits several of the other market imperfections discussed in sections 2.1 and 2.2 of this paper and evidence shows that these that come in the way of effective, and welfare maximizing tiered pricing.

**Bundling:** An important ARV therapy that has been at the heart of most ARV disputes is Lopinavir/ Ritonavir, a combination therapy, of which Ritonavir (trade name Norvir) deserves special mention. Originally patented by Abbott Pharmaceuticals (now AbbVie) in 1989, the drug is frequently used as a booster in highly active anti-retroviral (HAART) combination therapies. The stand-alone ritonavir is most often used as a booster for protease inhibitor-based therapies such as Bristol-Myers Squibb’s Reyataz and Merck’s Crixivan. However, by the end of 2003, when these drugs began to appear in the market, Abbott hiked the price of stand-alone ritonavir by 400%, from $1.71 for the 100mg dosage to $8.57 per daily dose. Abbott did not, however, modify the price of its other product Kaletra — a combination

20 [https://www.keionline.org/prices/ritonavir](https://www.keionline.org/prices/ritonavir)
therapy of ritonavir and lopinavir - thus ensuring that its own product remained the most cost-effective (Lancet, 2004). This decision drove a large price discrepancy between Kaletra and other ARV therapies that use ritonavir as a booster. Prior to ritonavir’s price increase, two of Kaletra’s main competitors, atazanavir (Bristol-Myers Squibb’s Reyataz) and fosamprenavir (GlaxoSmithKline’s Lexiva) were sold at USD 684 and USD 480 respectively, when compared to Kaletra’s USD 580 (Huff, 2004). Abbot’s pricing decision did not just raise the cost of drugs already on the market, but it also threatened the marketability of new drugs being developed in combination with ritonavir (Fuhrmans, 2003).

In addition to the inconsistent pricing, Ritonavir has experienced excessive patenting that has delayed generic entry. The patent on Ritonavir was set to expire in 2014 but secondary patenting has extended its coverage to 2028, pushing back generic entry (Amin and Kesselheim, 2012; Marshall, 2010). The patents filed for ritonavir address elements such as combination therapies, liquid and solid dosage formulations, chemical synthesis of the core compound and intermediates, as well as polymorphs and crystalline forms as Table 4 below shows.

Evergreening: Table 2 below shows the number of secondary patents that have been issued on all essential ARV therapies. A total of 12 secondary patents exist on Ritonavir, pushing the patent extension on the drug from 2013 to late 2020s or 2032. Similarly, Lopinavir/ Ritonavir has seven additional patents that push the patent expiration up to 2027 from the original expiration date of 2015.

Table 4: Secondary Patents on ARVs

<table>
<thead>
<tr>
<th>Drug Name</th>
<th>Patent Holder</th>
<th>Compound patent expiration</th>
<th>New patent</th>
<th>New patent holder</th>
<th>patent</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Merck &amp; Co Inc.</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>2020 [US7141593B1]</td>
<td>AbbVie Inc</td>
<td>Improved solubilized pharmaceutical composition</td>
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</tbody>
</table>


2027 [US8377952B2 — solid solution or solid dispersion of lopinavir and ritonavir in a matrix] AbbVie Inc

Nelfinavir (NFV) Viracept

<table>
<thead>
<tr>
<th>Year</th>
<th>Patent Number</th>
<th>Description</th>
</tr>
</thead>
</table>

Atazanavir (ATV)

<table>
<thead>
<tr>
<th>Year</th>
<th>Patent Number</th>
<th>Description</th>
</tr>
</thead>
</table>

Saquinavir (SQV)

<table>
<thead>
<tr>
<th>Year</th>
<th>Patent Number</th>
<th>Description</th>
</tr>
</thead>
</table>

Ritonavir

<table>
<thead>
<tr>
<th>Year</th>
<th>Patent Number</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Year</td>
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<td>Issuer(s)</td>
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<tr>
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<td>---------------</td>
<td>-----------</td>
</tr>
<tr>
<td>2022</td>
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<td>AbbVie Inc</td>
</tr>
<tr>
<td>2027</td>
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<tr>
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<td>AbbVie Inc</td>
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<td>2033</td>
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<td>AbbVie Inc</td>
</tr>
<tr>
<td>2027</td>
<td>[US8129385B2]</td>
<td>Shinogi, Licensed to ViiV Healthcare</td>
</tr>
<tr>
<td>2016</td>
<td>[US6417191B1]</td>
<td>KSB SE and Co KGaA Wellcome Foundation Ltd</td>
</tr>
<tr>
<td>2018</td>
<td>[US6294540B1]</td>
<td>SmithKline Beecham Corp</td>
</tr>
</tbody>
</table>
Efforts by Abbot to tier price Lopinavir/ Ritonavir for category 1 countries as presented in Table 1, for instance, when considered in conjunction with these evergreening realities presents an entirely different scenario. The combination therapy for people starting HIV treatment: TDF (tenofovir) with 3TC (lamivudine) or FTC (emtricitabine is available from the parent holder companies for an original price of 1538 USD, with a category 1 price of 501 USD. But if the secondary patent on solid forms of Tenofovir had not been issued extending its monopoly from 2017 to 2035, the drug could have been made available at the generic price of 108 USD all over the world. Similarly, for Tenofovir (TDF) the category 1 price is USD 183, whereas the lowest generic price is USD 30, which could have been secured but for the patent on the solid form extending its monopoly until 2035 (MSF data, 2017).

2.3.2. Hepatitis C Virus and Sofosbavir

As opposed to ARVs where a number of suppliers exist, Sofosbavir has been the main drug to cure the Hepatitis C Virus (HCV) worldwide. High costs of the disease have implied that over 90% of the 71 million people affected worldwide remain without treatment. Gilead, the patent holder of the main drug Harvoni (sofosbuvir and ledipasvir), prices the drug at USD 84,000 in high income markets, 48,000 USD in middle income markets and has issued a voluntary licensing at a 7% royalty rate allowing some Indian manufacturers to produce the drug cheaply to 91 LICs (Van der Gronde, 2017). Despite this effort by the originator company to engage in price discrimination, the positive welfare effects of tiered pricing are not to be observed. Estimates suggest that of the 71 million people infected with the disease,

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75% live in both low and middle income countries (DNDi, 2018), but since Gilead continued to charge its regular price of 48,000 USD for a treatment course in middle-income countries where the disease is highly prevalent, this excluded a large number of poor people from accessing the treatment. This prompted, most recently, Malaysia to issue a compulsory license on the product in 2017 and Chile to embark on a similar effort.\footnote{The Chilean government came under pressure in 2018 to weaken national resolution 399/2018 that enables for the issuing of compulsory licenses in the interest of public health in the country in the context of this particular drug (IP Watch, Sept. 2018).}

Competition for the drug has been slow to develop. Although AbbVie launched a competing product, Mavyret in 2017 at 26,400 USD, the company is yet to announce a tiered pricing program for the drug. Thus, to resolve the crisis in this market with just two main producers, DNDi has recently licensed the rights for a new combination treatment (Sofosbuvir/Ravidasvir)\footnote{DNDi has licensed the rights to Ravidasvir from Presidio Pharmaceuticals, California, which has developed the drug.} from another company and plans to make it available in several low- and middle-income countries at 500 USD per treatment.

### 2.3.3. Cancer Treatment

Cancer drugs have always been more expensive than many other therapeutic categories, but in recent years, their prices have skyrocketed exponentially. In countries that reference price, while the price ceilings offer greater access to all patients, a large number of studies find that it deters market entry of drugs on the whole, with originator companies opting to introduce the drugs only in those markets where price ceilings do not apply (Ingram, 2011). Parker-Lue et al. (2015, p.194) conclude that for some cancer drugs, price controls can eliminate introduction of products to entire countries/regions. They find that European cancer survival rates are lower than in the USA because reference pricing reduces the availability of some kinds of life-saving treatments in the EU market.

Systematic evidence on inter-country tiered pricing of cancer drugs is not available, but the World Health Organization (WHO, 2018c) estimates that a course of standard treatment for early stage HER2 positive breast cancer (doxorubicin, cyclophosphamide, docetaxel, trastuzumab) would cost about 10 years of average annual wages in India and South Africa and 1.7 years in the USA. Imatinib, for example, is a cancer drug developed by Novartis (brand name Gleevec), whose price almost tripled between the time it was first introduced (in 2001) and the time its patent was set to expire (in 2013). Despite Novartis’s initial admission that the original price would allow its R&D costs to be recovered in two years (Kushnick, 2015),\footnote{Although Gleevec was priced at USD 26,000 in 2001 upon introduction, by the time its patent expired, its price had soared to over USD 120,000 per year (Cohen, 2018).} price of the medication continues to rise. Chen and Kesselheim (2017, p. 353) trace the journey of entry of generic Imatinib in the USA, and note the following developments that helped the company preserve monopoly profits for six extra years from 2013 until 2019:

(a) Novartis filed to have its patent term restored for a period of time equal to the length of time the drug is under FDA review plus one half its clinical trial testing period (to a maximum of 14 years).

(b) Novartis also secured a pediatric exclusivity extension for Imatinib’s patent, which had the effect of extending the patent from May 2013 to July 2015 (with the patent term restoration of 586 days and the pediatric exclusivity of 180 days).
Novartis applied for a number of secondary patents covering incremental changes to the active pharmaceutical ingredient. This extended its market exclusivity from July 2015 until Nov 2019 without offering any new benefits to US consumers.

In one of the few studies that examine whether the pricing of cancer drugs corresponds to the income status of countries, Goldstein et al (2015) conduct an empirical assessment of the prices of cancer drugs across seven countries in the high income category (USA, Australia, United Kingdom and Israel), upper-middle income category (China and South Africa) and lower-middle income country (India) to capture both retail and discounted prices of these drugs. They conclude that while all the seven drugs were most expensive in the USA, they were more affordable in the other high income countries in the study (Australia, Israel and the United Kingdom) than in China and South Africa, where they were still priced in such a way that they were less affordable than all the high income countries. The drugs were least affordable in India by a large margin when compared to all other countries in the study.

2.4. Drawing Lessons

The review of existing evidence on international price discrimination by pharmaceutical firms and inter-country tiered pricing across the different therapeutic segments of HIV/AIDS, Hep C and cancer medicines discussed here highlight three kinds of issues: the relationship between tiered pricing and competition, the inadequacy of the country-based classification as a means to guide pricing, and the limitations of voluntary approaches.

2.4.1. The Relationship between Tiered Pricing and Competition

The case study of the ARVs market shows how despite its partial success, there are a number of shortcomings that continue to affect the effectiveness of tiered pricing.

Firstly, the evidence proves the conclusion of some other studies in this regard (Moon et al, 2011; Darrow, 2011), showing that competition is a more reliable and sustainable mechanism when compared to voluntary price discounts offered by firms for reducing prices. Secondly, in the case of the ARVs market, voluntary tiered pricing did not really work in ensuring price reductions on its own. The evidence underscores the effect that when firms are monopolistic suppliers of the market (that is, only one firm producing/owning the patent on the drug in question globally), there does not seem to be sufficient incentives for them to tier price as theory would suggest for capturing greater market shares on their own. In the HIV/AIDS market, originator firms moved from a uniform price to tiered pricing, and only acted to do so in most instances after competitors entered, or because there was threat of compulsory license.

Thirdly, the data and evidence presented in section 2.3. highlights that competition and tiered pricing have a virtuous relationship that is poorly understood. In the ARVs market, it was competition that created incentives for originator companies to introduce tiered pricing that increased access in all markets. It also helped create a contagion effect, working alongside the threat of compulsory licensing, inducing originator firms to identify and create lower prices for specific groups of countries that now belong to ‘category 1’. These results on competition, compulsory licensing and tiered pricing are also confirmed by T’Hoen et al (2018) who conduct a detailed review of the use of TRIPS flexibilities by countries. In their study, by collecting information on 176 instances of the possible use of TRIPS flexibilities by 89 countries between 2011 and 2016, they conclude that of the 100 instances of compulsory licensing, only 81 were implemented and 19 resulted in price reduction by patent holder firm (or donation in 6 cases), or a voluntary license allowing the purchase of the generic drugs from other
producers (5 cases). What stands out from their study, once again, is that without the threat of compulsory licensing, and the presence of other generic suppliers, the reductions in prices would not have been made available.

Fourthly, analyzing the pricing data with the patents data on the same drugs as conducted for ARVs in section 2.3 shows how firms on the one hand, use the patent system to extend monopolistic rents through secondary patents or other marketing arrangements, and then offer the same medications through tiered pricing/ price discrimination in an inefficient but monopolistic/ monopsonist manner. This results in an overall reduction of social welfare, where firms benefit unnecessarily for longer periods of time by “tacitly maintaining high prices over extended periods of time despite competitive markets” (Kushnick, 2015). In other words, tiered pricing can only work to enhance access when the backdoor option of extending monopolies through secondary patenting of life saving medicines and the substantive welfare losses that it causes to society are in check.  

2.4.2. The Inadequacy of Country Classifications

GDP based country classifications offer a poor basis for discriminating prices, since it does not account for this skewed distribution of income within developing countries. According to the WHO (2018b), over seventy percent of the world’s poorest live in what are classified as developing countries or middle-income countries. But voluntary pricing programs of companies until now use the nomenclatures of least developed countries or low-income countries, to define which countries could belong to Category 1 to offer preferential prices. This implies that they end up excluding a large share of the people who are the poorest world-wide but reside in middle income countries such as India and Brazil. Thus, although the Access to Medicines Index 2018 shows that pharmaceutical companies are expanding their portfolios to engage more and more in African countries, in reality, these expanded efforts still might end up missing out on a large number of people who need it most.

Industry advocates argue that price discrimination persists effectively only when markets can be effectively segregated, and that the internet (and internet sales) are a new form of leakage that firms have to contend with in addition to traditional health systems leakages in middle income countries, thereby precluding them from offering lower prices in such countries, this simply points to the shortcomings of the mechanism in general. The evidence from both Hep C and cancer, as section 2.3 shows, confirms that in general, firms are more resistant to oversight across all markets in a landscape of voluntary price discrimination, and the justification of promoting (or recovering) R&D investments do not offer much grounds to support these tiered pricing strategies. In the case of Imitanib and Gleevec, Novartis increased the price of the drug for all years that the product was under patent protection in a relatively transparent manner. Moving beyond Gleevec and Imitanib, the detailed analysis of over 150 US FDA approved cancer drugs by the World Health Organization shows that the sales

26 Downing et al (2012) analyze the case of Abbott’s Fenofibrilate, a cholesterol drug that was repeatedly issued new formulation patents. They note that while there is no evidence that Abbott’s successive reformulations of fenofibrate improved patient outcomes, the annual cost savings from switching all branded fenofibrate users to generic formulations, could exceed $700 million per year to the US healthcare system (at p.727). Chen and Kesselheim (2017) note at a general level that secondary patents are now so widely used by originator companies to extend the life cycle products with expiring patents that branded manufacturers had an average of 10 patents per drug in the late 200s, when compared with an average of two patents per drug in the 1990s.

27 Companies also define category 1 according to product/ therapeutic category, and some companies use a combination of countries that do not necessarily confirm to low income or least developed on a one-to-one basis. For example, in the case of HIV/AIDS, https://accesstomedicinefoundation.org/news/2018-access-to-medicine-index-finds-that-pharmaceutical-companies-are-deepeening-their-focus-on-africa

28
revenues of a majority of cancer medicines are significantly above the risk-adjusted costs of R&D as estimated in the wider literature (WHO, 2018c, p.10). In the case of Hep C, similarly, reviews conclude that Gilead’s prices have little recourse on grounds of R&D given that Gilead Sciences bought out the drug, sofosbuvir (Sovaldi) from Pharmasset, a start-up, and marketed the drug at double the cost that Pharmasset had intended to charge (Van der Gronde, 2017; Cunningham et al, 2019).

These reasons account for why previous efforts to establish an international tiered pricing initiative were eschewed by access to medicines proponents in 2013 (Médecins Sans Frontières, 2013, Baker, 2014). Civil society organizations, first voicing support for the initiative, withdrew amid concerns that pharmaceutical companies were using tiered pricing to thwart generic competition with longer term consequences for the global pharmaceutical market. Other critiques emphasized that such an initiative promoted the pricing of drugs in terms of income categories of countries - into high, middle and low-income - thus vitiating the objective of increased access given that MICs house over three quarters of the world’s poorest (Médecins Sans Frontières, 2013).

2.4.3. Voluntary Programs and the Lack of Oversight

So long as tiered pricing continues on a voluntary basis, there will always be open questions on its efficacy as an instrument of access to medicines. There will always be a tendency and continued misevaluation between price discrimination of any kind and welfare enhancing tiered pricing (as in the case of Hep C). More importantly, it will continue to vitiate the consideration of tiered pricing as an alternative within a larger basket of options for increasing access to medicines.

3. Intra-Country Tiered Pricing as an Option

Despite the various shortcomings of tiered pricing as a strategy that have been identified in this study, what is missing until now is a comparative perspective from which to understand tiered pricing within a competitive market scenario. Most previous studies, while comparing or evaluating the effectiveness of tiered pricing with other options, often juxtapose these as mutually exclusive solutions for enhancing access to medicines.

The reality of the situation globally and in the developing world is more complex. Not only do many data-related inconsistencies persist in accounts that uphold one or the other option, but also, from a wider systemic perspective, even taking into account the relative disadvantages of tiered pricing, it remains important to see how various actors, including pharmaceutical firms (both originator and generic) can be brought together to resolve issues of access. Underscoring this point, Beall et al. (2015) note that previous accounts of the effects of compulsory licensing as a threat or a real option to reduce prices do not compare these outcomes with other alternatives such as the prices procured by the Global Fund to Fight AIDS, Tuberculosis, and Malaria; UNICEF; and other international channels through collective bargaining, or the voluntary prices offered by companies. Similarly, the Medicines Patent Pool (MPP), established in 2010, has been actively negotiating voluntary licenses for HIV/AIDS drugs, but comparing the price differentials between drugs obtained through the MPP and other channels has not been common practice.

29 A number of civil society organisations came forth with the concern that such a tiered pricing initiative could strategically enable firms to exclude generic competition in global markets. See Open Letter by Civil Society to Mark Dybul, Executive Director of the Global Fund to Fight AIDS, Tuberculosis and Malaria: Abandon the “Blue-Ribbon Task Force to Develop a Global Framework on Tiered-Pricing” 13 May 2014.
In the past, pharmaceutical firms have been partnering in many ways globally to shoulder the burden despite the political controversies surrounding tiered pricing, but as the previous sections highlight, there is a need to consider a wider framework to structure these interactions. In the global vaccines market, for instance where this has been tried, a tiered pricing structure has emerged with the help of the Global Alliance for Vaccines and Immunization (GAVI) that charges systematically differentiated prices for low-income countries.

All markets do not work in the same way, and given that there are a number of therapeutic categories where drugs are patent protected and options for generic competition are limited, intra-country tiered pricing, with its option of segmenting consumers within countries may offer a significant way to integrate and work with pharmaceutical firms in promoting access to medicines in such therapeutic categories. Other economic and market-related advantages of intra-country tiered pricing are discussed below.

3.1. Welfare Enhancing Price Discrimination Effects of Intra-country tiered pricing

As highlighted by section 2 effectively, the wider issue with tiered pricing policies in the pharmaceutical sector is that while currently operating as voluntary programs of pharmaceutical companies, it still allows for price discrimination in markets with linear demand functions. Through this, the monopolist firm caters to the marginal consumers in both markets (middle- and high-income countries in this instance) but has no increase in the total surplus created, thereby reducing allocative efficiency, and offers greater reductions in prices in low income countries on a voluntary basis. While this guarantees some reductions in prices in low income countries, it does not cater to efficiently reducing the price for all who need it from an access to medicines perspective especially in those categories where sufficient generic competition is not available. What is needed, effectively, from an access to medicines perspective is the opposite of this: namely, to cater to poor people that are segregated on more effective ‘means to pay’ basis across all countries with a strategy that is more tailored to public-interest oriented tiered pricing.

Moving away from inter-country tiered pricing to intra-country tiered pricing, where discrete groups of consumers are offered different prices within countries, would imply that resources are allocated more efficiently because it would amount to either first or second-degree discrimination.30 In these two forms of discrimination, either the same amount of surplus is created as in a perfectly competitive market or at least a higher surplus than in a simple monopoly is created leading to lesser deadweight losses and increased allocative efficiency. This of course, would depend on how firms separate their customers based on demand elasticities and choose profit-maximizing prices for each category and administer their sales.

3.2. Higher Drug Prices and Rising Health Inequality Across All Countries

Two other factors that support the consideration of intra-country tiered pricing are rising drug prices and rising inequality across all countries, which is gradually making access to medicines a wider global problem. Estimates show that drug spending on the global level has prematurely surpassed all projections. For instance, the U.S. Center for Medicare and Medicaid forecasts that prescription drug spending in the USA is expected to increase by 6.1% each year through 2027 in the United States due to rising costs and use, particularly for chronic disease (CMS, 2017). Patented drugs account for much of these costs, but there has been a

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30 First-degree price discrimination is when a firm sets its prices with the knowledge of ability to pay of each of its customers. Second-degree price discrimination is when a firm can induce its customers to reveal their preferences.
steady pushback against high prices all over the world in recent times.\textsuperscript{31} Governments are increasingly substituting branded drugs with generics, and also finding other ways to curb costs but the market dynamics are often highly complex. In 2018, for example, generic drugs represented 90\% of all drugs prescribed in the USA, demonstrating a 75\% rise from 2009, making 2018 the first year of declining drug prices in the USA in 46 years (Tempest, 2019).\textsuperscript{32} An important illustrative category is that of cancer medication. The IMS’s prediction that spending on cancer drugs would reach $100 billion in 2018 had already been crossed by the end of 2014 (IMS, 2015). Although the situation varies somewhat from country to country, the general trends persist. Oncologists have since 2013, sought to focus attention on skyrocketing prices of cancer medications in several categories (’t Hoen, 2014). Sanofi for instance, lowered the price of its colon cancer drug Zaltrap by from 11,000 to 5,000 USD when criticized by oncologists in 2012 (Hernandez, 2012; Boltz, 2013). Such erratic drug price differences have been observed in other categories as well.

Rising drug costs alongside rising inequality have had drastic consequences for public spending and access. In the USA, for example, existing estimates suggest that one of every two US families diagnosed with cancer file end up in bankruptcy due to the costs of health care (Goldstein et al, 2017). In the case of Hep C, Gilead’s USD 84,000 price tag for sofosbuvir (Sovaldi) and has caused health plans to refuse routine coverage of this drug (Radhakrishnan, 2015; van der Gronde, 2017), also leading to a Congressional investigation in the USA (DNDi, 2016). Other high-income countries such as those in the Europe, struggling to formulate a response to rising drug prices, have also begun to consider the implementation of TRIPS flexibilities, including compulsory licensing as plausible options (’t Hoen et al, 2017). Some recent developments in this regard include: a recent resolution of the European Parliament on options for improving access to medicines in the European Union, including compulsory licensing in 2017;\textsuperscript{33} and a decision of the Council of the European Union in 2016 to find ways to “strengthen the balance in the pharmaceutical system in the EU and its Member States.”\textsuperscript{34} Boulet et al (2018) note that in light of patents and related exclusive rights including data exclusivity and market exclusivity, the decision aims to offer the members of the European Union the option of introducing changes to their regulations to balance innovation incentives with the right of all European citizens for affordable access. A number of national initiatives are also underway, such as for example, a pharmacy exception introduced by the Netherlands in February 2019 to patent law to curb the excessive drug prices (’t Hoen, 2019).

3.3. Lack of Competition in Several Segments

If explored within a good basket of options that seek to promote access to medicines, and guided by a wider ethical framework, intra-country tiered pricing might offer a distinct and important strategy particularly in the case of medicines where there is no generic competition in sight to even out the market immediately in favour of access to medicines. This is especially true in the case of more R&D intensive drugs, like biosimilars for example, where the market looks substantially different with just one or two companies ruling the market with no generic suppliers in sight. Bringing generic drugs to the market might be costly, time consuming, and

\textsuperscript{31} Even the United States, which has few price controls set within its “free market” has increased pushback against high prices set by pharmaceutical firms. U.S. congressional committees have issued warning reports and opened inquiries into pricing practices of companies (Van der Gronde et al., 2017).

\textsuperscript{32} Unfortunately, at the same time, the USFDA also approved 62 new novel medicines in 2018. So, in terms of value, these large number of new product introductions (and high prices) overshadowed to compensate for the fall in overall US drug prices that were obtained through greater generic use (Tempest, 2019).

\textsuperscript{33} European Parliament Resolution of 2 March EU options for improving access to medicines. 2017; 2016/2057(INI).

fraught with economic, research and legal complications, leading to substantial delays in introduction of alternatives. In such cases, it remains important to consider tiered pricing to enhance access to medicines, even as we think of other options to enhance competition.

4. Strategies to Enhance Intra-Country Tiered Pricing

The previous sections of this study show that intra-country tiered pricing can indeed be more welfare enhancing than the current spate of inter-country pricing (or simply price discriminatory) strategies. The analysis also highlights how it could offer a win-win outcome in the cases of drugs where there is no competition especially in the presence of a wider framework that holds firms more widely accountable to an ethical conduct with some level of oversight. This section explores strategies to enhance intra-country tiered pricing, which remain few and far between up until now, despite the prevalence of evidence that price differentials between market segments within a country can be preserved (Yadav, 2010).

4.1. Segregating consumers more effectively: Channels in the developing and developed countries

In low- and middle-income countries, there are at least two important ways to segregate consumers. In a large number of these countries, given the shortcomings in public insurance systems and out of pocket expenses, healthcare is segregated into two kinds of channels: the publicly financed government health care delivery channel and large privately funded out of pocket private channel. There remain national and disease level differences in how patients use these systems. Evidence from countries like Bangladesh, India and Tanzania, shows that there remains an overlap in disease categories treated in both public and private channels, but people from different socio-economic segments of the population seek treatment in each of these (Gehl Sampath, 2018; UNCTAD, 2014). While the poorest and the most vulnerable still try to access the public health care system to the extent possible, the more well-to-do segments of the population resort to out-of-pocket private treatments that are costlier (but often associated with better medical professional advice and infrastructure). A second possible venue of distinction for price discrimination is the location: on an urban and rural basis, but the distinction between urban and peri-urban locations can also offer an effective basis for offering intra-country differential pricing.

Ideally, firms could use a combination of the two - i.e., offer cheaper prices to those who access public healthcare channels in rural or peri-urban areas in all countries, to increase access to medicines. From a governmental side, this would require some effort to put in place adequate safeguards to prevent the diversion of the product or patients from one channel to another (Yadav, 2010). Firms can also rely on a more effective system of medical representatives (which are already widely prevalent in a large number of countries), offering them additional incentives to oversee as an additional private safeguard, and offer separate packaging of products (including branding). Hospitals, in public distribution channels, and health care suppliers, will need additional incentives and monitoring mechanisms that offer a better system of accounting for firms.

Despite all this, there will be some switching between private and public channels, especially amongst those consumers who will now find it easier to save and access cheaper medicines that is more in line with their income and savings capacity in the intra-country tiered pricing scenario. These cases will still qualify overall for a better outcome from an access to medicines perspective but will not result in lower income for the firms since they will continue to increase volumes of sales, while keeping a wider channel of higher price category sales intact.
in all countries. Given that all countries in the developing world will gradually exhibit skewed income differentials as they embark on stronger development trajectories, moving firms from a system of voluntary tiered pricing of the third-degree to the more socially useful intra-country tiered pricing, several of the ills of the current system can be averted.

In the developed world, evidence from the USA similarly indicates that the kind of health care facilities and the location offer serve as a basis to delineate those who have little ability to pay. But there are other complexities in the health care market, where current price differentials are based on a more complex system of discounts that are determined by negotiated volume-rate contracts between manufacturers, pharmacy benefit managers (PBMs), wholesale distributors, pharmacies, and health insurance companies. Thus, as opposed to segregating prices between the rich and the poor, or the insured or the uninsured, the current system is one where the price is dependent on the ability to sell specific volumes of certain drugs or achieve a certain share of a specified market. As a result, although this system shows how the market can effectively be segregated without much leakage, it is currently structured around an ineffective system whereby those actors (PBMs in particular) with the ability to offer large purchases and thereby help firms increase their markets shares by enabling the favouring of one drug over another - are able to negotiate the cheapest prices. These usually end up favouring the rich, or the well-insured, leaving those who need it to deal with the highest prices. Offering intra-country differential pricing in this regard can really work in favour of increasing access to medicines within a wider accountable policy framework.

4.2. Policy Support and the Role of the Government

To enable the separation at the intra-country level, the following national regulatory provisions are suggested for enactment by governments as part of a national tool kit:

(a) Enact regulations that mandate patient-based background information that can certifiably declare their income status to avail of cheaper priced drugs. This could be done for example, by using the newly available digital identity system in many countries that contains repositories of individuals’ socio-economic status.
(b) Enact national regulatory frameworks on tiered pricing (see next section) which should identify/allow for the voluntary enlisting of health care institutions that can offer differentially priced health care.
(c) Enlisted health care facilities should by requiring a thorough vetting of the economic background of users.
(d) Enable the tracking of such institutions, with rules for auditing and accountability to the government, with penalties for any arbitrage.

In some particular cases of public health importance, to increase generic access, governments could also consider:

(c) In return for the ‘best price’ assurance from pharmaceutical companies, the waiving of national exhaustion on a product-by-product basis, to be reviewed annually.
(d) National regulators should work with companies’ hand-selected for the exercise, assisting them to directly also monitor the effectiveness of their programs, and also allowing companies to choose, where applicable new and competing channels for the distribution of their drugs, such as health care workers in rural areas.

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35 Yadav (2010) models some of these results, showing how the system will not adversely affect pharmaceutical companies.
4.3. A Wider National Framework to Enforce Intra-Country Differential Pricing

Given the difficulties in tiered pricing approaches identified in this study, and the importance of ensuring the development of competition not just for access, but also to promote research in all therapeutic categories, a wider policy framework is suggested for the promotion of intra-country differential pricing. Such a national tiered pricing framework should ideally set out the broad parameters for tiered pricing, moving it away from a voluntary mechanism, to one where firms work alongside governments to ensure greater access. In the past, suggestions have been made by Paul Hunt, the UN Special Rapporteur on the Right to Health, on a similar basis, suggesting the application of human rights principles to the pharmaceutical sector in two separate reports (United Nations Secretary-General 2008, paragraph 5; and United Nations Secretary-General 2009, paragraph 41). These suggestions, widely known as the ‘Hunt Guidelines’ describe a duty by pharmaceutical firms to take all reasonable steps necessary to make life saving medicines available as much and as soon as possible in line with a viable business model. This study proposes intra-country differential pricing to be such a model, but clearly places the onus of ascribing responsibilities to businesses to national governments (Moon 2013; Coleman and Loon Ho, 2017) with the following principles.

Principle 1: Promote intra-country tiered pricing in the context of a broader competitive market scenario

There is not only no substitute for competition in the long run for innovation and access, but also, in light of the fundamental differences between what firms are prone to engage in, and what society actually needs. It would therefore be logical to conclude that tiered pricing might only work effectively in a regulated environment, in the presence of competition and other regulatory mechanisms that discipline the behavior of the firms in the interest of welfare gains to all.

National tiered pricing strategies should focus on those categories where sufficient market competition is yet to develop - as monitored by a national health agency (such as the drug regulatory authority). It should be time limited and accompanied by all other efforts to enhance competition including a regular review of the patents issued, because they also help discipline the behavior of originator companies even in sectors where only a few options exist. Ideally, they also need to be supplemented with increased competition coordination and surveillance between governments, the consideration of which, while relevant to curb monopolistic pricing strategies is outside of the core focus of this study.

Principle 2: Tiered prices should be set on the basis of competitive or ‘pseudo’ competitive bids

This important issue has already been raised in the context of the proposed global tiered pricing framework discussions in 2014 (Owain et al, 2014). In light of the issues discussed in this study, it is highly relevant not just to enable firms to price discriminate, but to infact ascertain and negotiate that these price discounts are aligned with social objectives. This necessitates that tiered prices should ideally be negotiated by the national agencies tasked with these objectives in a fair and free manner. Where firms do not have sufficient incentives to come forward, the following two incentives can be considered:

(a) a demand pooling giving the originator firm/s incentives to engage;
(b) an assurance of the purchase commitment duration;

Providing these two assurances upfront is essential signalling the expansion of market and assurance of profits for the pharmaceutical industry. In order to be able to set the right price
for tiered pricing, the central authority requires to start off from a competitive producer’s price (or a ‘pseudo’ competitor price, if a generic firm to produce the said product is unavailable) and work to include some sort of an additional premium on the originator firm’s investment costs, thus making it lucrative for the company to engage in the said exercise, while respecting its original investments. There is also a need for oversight in this instance on whether the said product has already benefited from patent protection and market exclusivity and is under a secondary patent protection, or whether there are other extenuating factors that should affect the pricing process.

*Principle 3: Creating fair pricing outcomes*

There are a number of actions that can be taken to promote this. First and foremost, there should be a elimination of all voluntary tiered pricing, thereby mandating firms willing to tier price to engage within the broader contours of the national tiered pricing framework. But at the same time, the same kind of fair pricing should apply transparently to the companies’ costs of R&D and production, in order to retain incentives for future R&D (Owain et al, 2015). In this context, there are real difficulties posed by information asymmetries to determine what a fair price for any product could be. Solutions proposed to address this question up until now include separating R&D from pricing, and value-based pricing. Value based pricing is based on the logic that instead of prices being set by the pharmaceutical firms on the basis of their R&D costs, they should instead be determined on the basis of their expected benefit to the consumers (Levaggi, 2016). This process shifts the pricing power from the firms to the regulators who specifies the maximum willingness to pay for a unit of any particular drug based on its effectiveness.

While the suitability of these proposals is still contested, it appears that designing effective tiered pricing that allows firms to cater to differential markets in an effective way across low, middle and high income markets will be sufficient to preserve enough space for profits given the rising middle class in the emerging economies, the converging disease profiles which will all contribute to expansion of markets to pharmaceutical companies.

5. References


Hernandez, R. (n.d.) “Sanofi Halves the Price of Zaltrap in Response to Criticism from Oncologists.”


