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## Determinants of Drug Prices in Middle Income Countries: How important are intellectual property rights?

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# Determinants of Drug Prices in Middle Income Countries:

## How important are intellectual property rights?

Ingmar Schustereder and Johannes Jütting\*

### Abstract

This paper analyzes the impact of trade related intellectual property rights (TRIPS) on drug prices in seven middle income countries. Applying both an econometric as well as an explorative analysis we find three key messages: First, the introduction of TRIPS in the selected countries tends to have no major impact on the development of drug prices. Country specific factors like excessive procurement and marketing costs seem to be more important determinants for the observed high price levels. Second, the application of TRIPS safeguards which allow countries to override TRIPS requirements appears to be an important lever to contain drug prices by encouraging competition. There seems, however, scope for improvement in the efficient use of these safeguards. Third, with respect to policy implications, middle income countries should in particular address inefficiencies in local marketing and procurement costs whereas OECD countries need to improve the coherence between trade and aid policies.

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# 1 Introduction<sup>1</sup>

Diseases are one of the major obstacles to economic and human development in large parts of the world. Among them, HIV/AIDS and Malaria are particularly considered to create a severe damage. According to World Health Organisation (WHO) sources 3 million and more than 1 million people died of the two respective diseases worldwide last year (WHO, 2002a). While the death toll and the rate of infections have been steadily increasing, one third of the global population still lacks regular access to essential medicines. Improving access to drugs in developing countries remains, therefore, a crucial challenge for the entire global community in the years to come.

In line with the Millennium Development Goals the WHO (2004) has developed a framework how to improve access to essential medicines. According to this “Access Framework” policymakers are urged to put policies and action plans in place in order to achieve the following four goals in a coherent way: Affordable prices, rational selection and use of essential medicines, sustainable financing, and reliable supply systems.

This paper focuses on the first policy goal namely on drug prices and its determinants. It contributes hereby to the ongoing debate on patents and medicines which has intensified since trade-related intellectual property rights (TRIPS) had been incorporated in the multilateral trading system in 1994 (Roffe et al., 2006). In a very simplified and stylised way, the “TRIPS and Public Health” debate can be divided into two different camps: On the one hand, civil society and non-governmental organisations (NGOs) argue that multinational research-based pharmaceutical companies misuse trade-related intellectual property rights in order to charge higher prices for their patented products (Baker, 2007; MSF, 2001; Myhr, 2000; Oxfam, 2002). According to this view, TRIPS impose a severe barrier to accessing essential drugs. Proponents of TRIPS such as leading pharmaceutical and biotechnology companies, on the other hand, claim that a globally respected patent system for pharmaceuticals is a vital precondition for drug producers to undertake research and development on medicine in the first place (Bale, 2000). Furthermore, they argue that TRIPS do not have a major influence on local drug prices in contrast to country-

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specific factors (such as tariffs, non-tariff barriers, taxes, excessive wholesale and retail mark-ups). Latter are considered to have the strongest impact on local drug prices and the level of accessibility to essential medicines (Bale, 2001; Bate et al., 2005; Bate et al., 2006; Levison, 2003).

Against this background, the main objective of this paper is to analyze the potential impact of trade related intellectual property rights on prices for essential drugs in middle income countries. The scope of the analysis will hereby include drug products in two devastating disease areas (HIV/ AIDS and Malaria) across seven countries dispersed over Africa (Morocco, Tunisia, and South Africa) and Asia (Jordan, Philippines, Thailand, and Malaysia). This paper - being one of the first in this research area to use both qualitative as well as quantitative approaches in its analysis - gives a comprehensive picture of what determines local drug prices in middle-income countries.

The structure of the paper is as follows: Section 2 has a brief introduction of the specific characteristics of the pharmaceutical industry. Subsequently, a conceptual framework is developed, separating drug price determinants into the following two groups: TRIPS on the one hand and country-specific factors on the other hand. In Section 3 explanations are given why the two disease areas and the seven countries have been selected for this analysis. Subsequently, in Section 4 the methodology and the data, including its limitations, are presented. Section 5 concludes.

## **2 Patents, Prices and Access to Medicines**

### **2.1 Specific Characteristics of the Pharmaceutical Industry**

Drug pricing is determined by market forces and a set of government policies. Like any other business, pharmaceutical companies pursue to maximize profit and shareholder value in the market. Still, two major industry-specific characteristics make this business very special: First, pharmaceutical companies “supply products that affect human welfare in a way that most other products do not: antiretroviral drugs are not coca cola” (Saggi, 2006: 3). Secondly, pharmaceutical companies are among the most research-intensive corporations in the world and are therefore highly dependent on intellectual property right

systems (IPRs) in order to recuperate the high research and development (R&D) expenditures. Heavy R&D investment induces high fixed costs whereas the marginal cost of production is relatively low (Kremer, 2002; Saggi, 2006).

In this discrepancy lies the crux of the problem: Economic efficiency implies that a product is supplied to all consumers at marginal cost. Pharmaceutical companies, however, have to earn more than the marginal cost in order to recover the high fixed costs. To resolve this market failure governments intervene by enforcing product patent legislation which grants innovator firms a temporary monopoly status. However, if drug prices are the same around the globe, large parts of the world will not be able to afford urgently needed medicaments. To avoid such a scenario governments of the OECD countries have accepted that pharmaceutical companies can charge their consumers a higher price for the same medicaments than their counterparts in the developing world. While price discrimination between the developed and the developing world is appropriate for drugs against diseases prevailing in both high and low income countries it can not be considered as a feasible strategy for drugs against diseases afflicting only developing countries. In the latter case the costs of researching and developing drugs will have to be entirely born by low income countries. Given the lower purchasing power of the developing world pharmaceutical companies anticipate lower prices and are therefore less willing to invest in R&D. Additionally they are confronted with a time-inconsistency problem: In contrast to the OECD world developing countries often lack well developed and respected IPRs. As a result, once a drug is developed national governments pursue to force prices down to the market efficient level while generic producers start to imitate the product (Kremer, 2002; Saggi, 2006).

## **2.2 Determinants of Drug Pricing in Developing Countries**

While trade-related intellectual property rights are a necessary prerequisite for pharmaceutical companies to do research the incorporation of TRIPS into the multilateral trading system has raised significant protests from NGOs and civic society organisations. The “TRIPS and Public Health” debate centres hereby around the question if TRIPS or country-specific factors such as tariffs, taxes or excessive mark-ups on pharmaceuticals have rendered drug prices unaffordable throughout the developing world.

### **2.2.1 The TRIPS Controversy**

The relationship between patents and medicines has been controversial ever since the signing of the Paris Convention of 1883. This first major international treaty on the protection of industrial property acted as a catalyst leaving “countries with the freedom to legislate in the industrial sectors that they considered appropriate for granting exclusive production and marketing rights. As a result, medicine was an area that many countries generally excluded from patentability” (Roffe et al., 2006: 9). The rationale for this exclusion was two-fold: on the one hand, policymakers wanted to keep prices down thereby assuring full affordability of essential medicines; on the other hand, policymakers were interested in nurturing the infantile national pharmaceutical industry. Consequently, patent protection only included processes instead of products in most developing and developed countries until the mid 1970s. With the emergence of the multinational pharmaceutical industry, policymakers in OECD countries came increasingly under pressure to extend patentability from pharmaceutical processes to products. Low income countries such as India and Pakistan, on the contrary, held on to their existing patent protection legislation which exclusively focused on industrial processes (Maria/ Ramani, 2005; Commission on Intellectual Property Rights, 2002; Roffe et al., 2006).

In this context, the incorporation of intellectual property rights into the multilateral trading system is considered as a fundamental break from past developments. The TRIPS Agreement obliged each member state of the World Trade Organisation (WTO) to align its patent legislation with the multilaterally accepted intellectual property rules. Amongst others, latter implied full product patentability for medicines for a minimum duration of twenty years (WHO, 2002b). While the 1994 enforcement of the TRIPS Agreement was welcomed as a milestone in the history of international trade by the WTO and other inter-governmental organisations as well as policymakers of high income countries it received a growing level of criticism from both civil society organisations as well as policymakers in the developing world. More precisely, a multitude of different objections was raised against the TRIPS Agreement: First, critics argued that trade-related intellectual property rights were not going to improve, but rather aggravate the health situation in low-income countries. According to this view multinational pharmaceutical companies did not consider TRIPS as an incentive system to invest in research and development of medicines against diseases afflicting poorer nations, but rather misused TRIPS to charge higher prices for already existing patented medicaments. This argument was substantiated by the fact that

prices of patented drugs have been increasing throughout the developing world while at the same time only one percent of almost 1400 new drugs approved for sale in 1975-1999 were oriented at tropical diseases (The Economist, 2003). Secondly, industrialised countries were accused of having imposed a legal framework that would not only have a negative welfare effect for low income countries, but also for the world as a whole (Chaudhuri et al., 2003; Deardorff, 1992). Moreover, proponents of this view did not only fear that the local generic pharmaceutical industry was doomed to exit the market, but that the overall technological gap would widen undermining any development process of the low income countries (Barton, 1999; Correa, 1999; Sachs, 1999).

With mounting pressure to resolve the “TRIPS and Public Health” debate WTO member states entered into negotiations to readjust the 1994 TRIPS Agreement. As a result, the 2001 Doha Declaration on the TRIPS Agreement and Public Health was born. Considered by the WTO as a final breakthrough for the relationships between OECD and developing countries the declaration recognized “the gravity of the public health problems afflicting many developing countries [...], especially those resulting from HIV/AIDS, tuberculosis, malaria” and stressed the need for the TRIPS Agreement “to be part of the wider national and international action to address these problems” (WTO, 2001: 1). As a result, it was agreed upon “that the TRIPS Agreement does not and should not prevent Members from taking measures to protect public health” (WTO, 2001: 1). More precisely, the refined TRIPS Agreement provides today important flexibilities – TRIPS safeguards – that enable “governments [in developing countries] to make exceptions to patent holders’ rights such as in national emergencies, anti-competitive practices, or if the right-holder does not supply the invention, provided certain conditions are fulfilled” (WTO, 2006a: 2). Amongst others, three safeguards play a very prominent role in the public health area of developing countries: Compulsory licensing, parallel importation, and bolar provision.

Compulsory licensing refers to an authorization granted by the government to use an invention without the consent of the patent holder.<sup>2</sup> Parallel importation can be defined as importation (without the permission of the patent holder) of a patented product that is marketed in another country. Bolar provision facilitates the entry of generic competitors by

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<sup>2</sup> Besides allowing members to authorize (without the consent of the patent holder) use by third parties (compulsory licensing) the TRIPS Agreement also permits members to use an invention for public non-commercial use (government use) without the consent of the patent holder (TRIPS, 2006b; Oh, 2005).

permitting testing and regulatory approval in advance of the patent expiration date (WHO, 2002b). Recently, the declaration has been temporarily (in 2003) and then permanently (in 2005) modified in order to allow countries that do not have feasible production capacities in place to import pharmaceuticals under compulsory licensing. Furthermore, granting additional time in order to bring national legislation in conformity with TRIPS rules WTO member states have agreed to extend the existing transition period (1995-2000) for two kinds of developing countries: Developing countries that provided only process patents before the signing of the TRIPS Agreement could delay their compliance until 1<sup>st</sup> January 2005<sup>3</sup> while the least-developed countries are still excluded from patent enforcement until 1<sup>st</sup> January 2016 (WTO, 2006b). Figure 1 summarises the milestones of TRIPS legislation on a time-line.

**Figure 1: Milestones of TRIPS legislation**

1994	2000	2001	2003	2005	2016
<i>TRIPS Agreement (GATT, Uruguay)</i>	<i>Enforcement of TRIPS by first transition status countries</i>	<i>Doha Declaration on TRIPS and Public Health</i>	<i>30 August 2003 Decision - Temporary waiver: compulsory licence not restricted anymore to domestic market</i>	<i>Permanent Waiver of the 30 August 2003 Decision</i>  <i>Enforcement of TRIPS Agreement by second transition status countries</i>	<i>Enforcement of TRIPS by least developed countries</i>

Despite these recent achievements to strike a balance between the interests of the global pharmaceutical industry and the social needs of developing countries, the “TRIPS and Public Health” debate is still far from being resolved. In 2002 prominent trade economists such as Bhagwati still considered the policy of “getting IPR into the WTO, in shape of the TRIPS [...] regime, [...] a bad mistake” (Bhagwati, 2002: 14). In 2003, a number of influential non-governmental organisations published a joint statement denouncing the Doha Declaration and its temporary waiver to be a gift to the poor “bound tightly in red tape” (Act Up Paris et al., 2003). In 2006, one year after the signing of the permanent

<sup>3</sup> During the transition period, these countries are required to accept patent applications from 1995 onwards and to keep such applications pending, in a patent “mailbox” until the mailbox is opened in 2005 when the applications will be assessed (WTO, 2006b).



waiver, Pascal Lamy, Director General of the WTO, considered the fact that his organisation “had not received a single notification of a developing country issuing a compulsory licence [...] a problem, [...] arguing that it was cited by some as proof that the current flexibilities were too complex to be used in practice” (Jack, 2006: 8). Moreover, criticism has also been targeted at recent attempts by the USA and other OECD countries to sign free trade agreements (including TRIPS+ provisions) with developing countries such as Thailand. According to NGOs and civic society organisations these provisions undermine the use of TRIPS flexibilities and as a result make drugs unaffordable.

The above statements are at odds with the pharmaceutical industry’s point of view, which considers the fact that no compulsory licence has been issued so far rather as a proof that the industry has sufficiently reduced drug prices in developing countries (Jack, 2006). Unsurprisingly, the International Federation of Pharmaceutical Manufacturers & Associations (IFPMA), therefore, does not see any need for action with respect to TRIPS safeguards, but rather continues to postulate stronger intellectual property rights enforcement throughout the developing world. More precisely, private pharmaceutical companies – being more innovative than public institutions regarding medicines against AIDS and Malaria (Ito/ Yamagata, 2005) – criticize both the “lack of intellectual property protection and the tendency for governments to force prices down after firms have sunk their research and development costs” (Kremer, 2002: 10). By referring to the fact that 95 percent of products on the WHO Model Essential Drug List (EDL)<sup>4</sup> are off-patent, they further emphasize their disagreement with NGOs and policymakers of developing countries (Attaran, 2004; Bale, 2001). However, this argument is highly problematic since essential medicines are not only selected by the WHO on the basis of public health relevance, efficacy or safety, but also based on comparative cost-effectiveness (WHO, 2006a). Latter implies that patent products are often deemed unaffordable according to the criteria set by the WHO and therefore are not put on the EDL despite their potential efficacy to satisfy serious health care needs (Love, 2004).

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<sup>4</sup> The EDL concept was developed by the WHO in 1977 and constitutes one of the eight pillars of the multilateral organisation’s “Primary Health Care” strategy (also see [www.essentialdrugs.org](http://www.essentialdrugs.org)). Essential drugs or now called essential medicines “are those that satisfy the priority health care needs of the population. They are selected with due regard to public health relevance, evidence on efficacy and safety, and comparative cost-effectiveness” (WHOa, 2006: 54).

## **2.2.2 Country-specific Determinants of Drug Pricing**

Proponents of TRIPS hold the view that innovator brand pharmaceutical producers cannot be held responsible for the increase of drug prices in developing countries since these companies face increasing market pressure from therapeutic competitors and therefore cannot afford to augment their prices in the first place (Bale, 2000). As a result, the main determinants of drug prices in developing countries are assumed to be of country-specific nature: state-imposed price inflators of pharmaceuticals such as tariff and non-tariff barriers, duties and sales taxes; local procurement and distribution costs related to storage, transportation and distribution including mark-ups for wholesaler and retail level (Bale, 2000; Bate et al., 2006).

In line with the above stated view Harvey Bale (2001: 12), Director-General of IFPMA, points out that drug prices as a potential barrier to access should not just reflect “the cost of the drug itself, [but also] the costs of effectively distributing, administering and monitoring its use; and the financing to pay for” both cost components. Import tariffs, port charges, sales tax as well as other local charges (wholesale/ retail mark-ups) sometimes amount to a mark-up of more than 80 percent on the ex-manufacturing selling price (Bate et al., 2006).

Recently, various cross-country studies such as Bale (2001) and European Commission (2003) have provided further evidence in favour of a negative correlation between tariffs on pharmaceuticals and access to drugs. Yet, as Laing/ Olcay (2005) pointed out tariffs do not have a major impact (relative to other country-specific factors) on drug prices anymore. While tariffs on active pharmaceutical ingredients and finished pharmaceutical products are levied respectively by fifty-nine and sixty-one percent of countries under analysis both authors emphasise that ninety percent of these countries apply tariff rates lower than ten percent. Besides tariffs non-tariff barriers such as bureaucratic hurdles to register a drug product or clear the customs can also increase the price of a drug. Sales taxes as well as port charges are additional drug price inflators. Some countries even tax life-saving medicaments that are donated for free (Bate et al., 2006).

Besides the above mentioned state-imposed drug price inflators, governments in developing countries are also increasingly held accountable for inefficient procurement activities related to domestic healthcare issues. According to Bale (2001: 12) procurement

with regards to pharmaceuticals can be defined as “the sum total of processes involved in the purchase and delivery of drugs”. It is deemed efficient if it is in accordance with the EDL concept; latter implying that “the most cost-effective drugs are bought in the most appropriate quantities from reputable suppliers, delivered where and when required, at the lowest possible total cost” (Bale, 2001: 12) So far most developing countries lack efficient drug procurement systems. It is not rare to see mark-ups as high as 40 to 60 percent above the import price of pharmaceuticals paid by end-customers to wholesalers and retailers along the pharmaceutical supply chain (Bate et al., 2006).

The root of these inefficiencies can be traced back to a number of traits typical for health care systems in the developing world: First, health care expenditures are characterised by relatively high rates of out-of-pocket expenditures and rather low rates of expenditures paid by public and private insurance firms. Consumers negotiate on an individual level and therefore are faced with problems of asymmetric information. This situation stands in sharp contrast to the health care markets of the developed world where public or private institutions pool customers in order to dispose monopsony power when bargaining with pharmaceutical companies (Hellerstein, 2003). Secondly, alongside the appropriate health expenditure system the degree of local generic and therapeutic competition also plays a vital role in keeping drug prices in developing countries low (Hellerstein, 2003; Lucchini et al., 2003; Oxfam, 2002). Thirdly, the efficiency of transportation and distribution systems as well as the degree of competition in the wholesale and retail markets have a major influence on drug prices too. For instance, Woodward (2001: 7) estimates that “variations in local costs may result in prices being roughly doubled in the highest-cost countries relative to the lowest.” Finally fourth, governments are accused of taking on a lax attitude to enforcing an optimal drug policy. NGOs encourage policymakers to maximize the use of TRIPS safeguards in order to intensify competition and thereby bring drug prices down (MSF, 2001; Oxfam, 2002).

To sum up, it is very much an empirical question whether or not TRIPS has a major influence on drug prices in developing countries.

## **3 Methodology**

### **3.1 Selection of Illnesses and Countries**

To assess the impact of TRIPS on drug prices in developing countries the following procedure has been applied: First, disease areas have been chosen. Secondly, seven emerging and developing countries in Africa and Asia have been selected. Thirdly, a balanced empirical approach combining various research techniques has been conducted.

Selecting HIV/ AIDS and Malaria as disease areas for our empirical investigation can be reasoned by the fact that these two illnesses pose a severe burden for the socio-economic development of local populations in developing countries. From a more practical point of view, the decision to focus on drug prices related to these two disease areas can be explained by the following reasons: First, as the research on treatment of these illnesses has been ongoing enough patent and off-patent drug products exist to measure the relative impact of TRIPS vis-à-vis other price determinants. Secondly, comprehensive price data (dating back until 1994) of medicaments against the two illnesses is available.

Seven emerging and developing countries in Africa and Asia have been chosen to conduct the empirical investigation: Jordan, Malaysia, Morocco, Philippines, South Africa, Thailand, and Tunisia. The selection of these countries was based on the following criteria: First, the TRIPS Agreement has been successfully implemented during the first transition period or in an early stage of the second transition period. South Africa enforced TRIPS in 1997. Following the TRIPS provisions for developing and emerging countries Jordan, Malaysia, the Philippines and Thailand brought their national IPR legislation in line with WTO rules until 2000. The North-African countries Morocco<sup>5</sup> and Tunisia<sup>6</sup> belonging to the second transition country group updated their legislation to meet TRIPS requirements as early as 2004 (EIU Country Commerce Reports, 2005/ 2006; Strategis, 2004; Teljeur, 2002; USTR 2006; WTO, 2006b). Secondly, all countries dispose local pharmaceutical capacity in order to produce generic drug products, inducing domestic competition for patent protected western products. Thirdly, a national health system exists that can deliver the requested

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<sup>5</sup> Morocco signed a free trade agreement (including TRIPS+ provisions) with the USA in 2004.

<sup>6</sup> According to Strategis (2004) Tunisia's national legislation was brought in line with TRIPS rules in 2004. However, comprehensive IPR enforcement was still not fully ensured by then.

medication. Fourthly, data for drug prices is available for both disease areas in all seven countries.

### **3.2 Estimating the “TRIPS-Effect”**

The first challenge in the endeavour to measure the relative impact of TRIPS vis-à-vis country-specific determinants on drug prices in developing countries has been to establish an appropriate price index for each disease area (HIV/ AIDS and Malaria) in each country for the time period 1994-2004. The index comprising of patent, off-patent and generic drug products which are measured as retail drug prices in international dollars per standard unit changes its composition over time according to the drug products' annual country-specific sales.<sup>7</sup>

This paper takes two empirical approaches to measure the relative impact of TRIPS vis-à-vis country-specific determinants on drug prices in developing countries. The first method is a simple exploration of the trend of real public (also known as retail) drug prices in international dollars (purchasing power parity (PPP)) per standard unit for every disease area in each of the seven countries for the period 1994-2004. The aim of visualizing these country-specific price indices is to inspect the data series for any obvious structural breaks in the price trend or any rapid changes in the price level due to the implementation of the TRIPS Agreement. The hypothesis is hereby the following: If TRIPS has an impact on drug prices the increase of the price index should take the form of a structural break at the moment of TRIPS implementation for two reasons: First, cheap generic competitors will exit the market and as a result patented products will have more weight in the index. Secondly, it is assumed that TRIPS will increase the prices of patented drugs. Furthermore, country-specific mark-ups are presented for all seven countries. In theory, the overall mark-up is defined as the difference between retail and manufacturing prices. It encompasses all costs, legal and illegal, as well as retail profits to get the product from the manufacturer to the final consumer.<sup>8</sup> Hence, the lower the mark-up on a product the more effective is the country-specific distribution of the given product. Taking both the trend of

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<sup>7</sup> See Appendix A for a more comprehensive analysis of how the price indices for each disease area have been constructed. A.1 gives insights into the methodological procedure of the index construction. Furthermore, A.2 provides as an example a detailed list of all medicaments included in the HIV/ AIDS antiretrovirals price index for South Africa.

<sup>8</sup> See Appendix B for a summary of the theoretical composition of a retail price mark-up.

real public drug prices as well the mark-up structure for each country into account first conclusions can be drawn that are further tested in the quantitative analysis.

As a second method an econometric analysis is conducted in order to measure the relative effect of TRIPS on real public drug prices in the seven countries under inspection. More precise, a technique of ordinary least squares (OLS) regression is applied. It takes the following equation:

$$P_{ijt} = \beta_0 + \beta_1 GDP_{pc\ it} + \beta_2 CPI_{it} + \beta_3 TRIPS_{it} + \beta_4 HealthGDP_{it} + \beta_5 MarkSize_{ijt} + \sum_n \beta_n Time_{it} + \sum_n \beta_n Cty_{it} + u_{ijt}$$

Where  $P_{ijt}$ , the real public price in international dollars (PPP) per standard unit in country  $i$ , anatomical therapy class (ATC)<sup>9</sup>  $j$  and at time  $t$ , is a function of the following independent variables: First,  $GDP_{pc}$  (real constant gross domestic product per capita PPP in country  $i$  at time  $t$ ) is a control variable for real income. Following Engel's law a positive correlation between real income and demand for medication is assumed (Engel, 1857). As the demand for drugs increases with growing income per capita, drug prices are also assumed to augment. Secondly,  $CPI$  (consumer price index in country  $i$  at time  $t$ ) is incorporated in the model to control for general price level effects on the real public prices of drugs. Thirdly,  $TRIPS$  is a simple time dummy taking the value one for all years since the TRIPS Agreement has been enforced. In case the TRIPS Agreement has rendered drug prices unaffordable the coefficient of the control variable should have a significant positive value. Fourthly,  $HealthGDP$  (ratio of total health expenditure relative to GDP in country  $i$  at time  $t$ ) is a proxy for the development of the national health system in country  $i$ . As mentioned in Part I one of the main characteristics of the health care markets in the developed world is that public or private institutions pool customers in order to dispose monopsony power when bargaining with pharmaceutical companies (Hellerstein, 2003). Thus, it is assumed that the more developed a country  $i$ 's health care market is the lower will be the prices for the procurement of drugs due to the buyer's monopsony power. Fifthly,  $MarkSize$  (market size in standard units of ATC  $j$  in country  $i$  at time  $t$ ) refers to the hypothesis that larger market size is negatively correlated with drug prices due to two reasons: fiercer

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<sup>9</sup> The anatomical therapeutic class (ATC) is a system of classifying drugs into classes according to the intended treatment of the drug. For instance, ATC J05 stands for HIV antiviral drugs.

competition for the higher sales volume on the supplier side; potential formation of bigger monopsony power on the consumer side (Levison, 2003). Finally, the pooled estimation equation also includes country and time dummies and an error term to control for the cross-country and time dimensions as well as any stochastic variation. Table 3 summarises the hypothesised determinants of drug prices with expected direction of impact.

<b>Table 3: Hypothesised Determinants of Real Public Drug Prices</b>		
Dependent Variable:	Real Public Drug Prices in US \$ (PPP) per standard unit	
		Expected impact on Real Public Drug Prices
Independent Variables:	GDPpc/100	+
	CPI	+ or -
	TRIPS	+
	Health/GDP	-
	MarkSize/1,000,000	-

### 3.3 Data

Two datasets are utilised for the subsequent analyses: Drug price data and market size data are retrieved from the IMS Health MIDAS Quantum Database. Data for all other variables comes from the World Development Indicators (WDI) 2006 Database provided by the World Bank on an annual basis.

In order to make drug prices in a cross-country analysis framework comparable this paper uses average real public prices per standard unit in US dollars PPP as dependent variable. A calculation is required to retrieve this data: Nominal public drug prices per standard unit provided by IMS are converted according to PPP exchange rates supplied by the WDI 2006 database into international dollars (PPP). This method, in contrast to official exchange rates, has the advantage that the cross-country variation of public prices per standard unit is now comparable in terms of local purchasing power affordability. For

Malaria drug price data is available for all seven countries for all years. Concerning HIV/AIDS there is only data for Malaysia, the Philippines and South Africa; additionally, some price data is provided for Thailand, but not for all years. Thus, for Malaria there are in total seventy-seven observations for drug prices encompassing the seven countries and eleven years. In the case of HIV/AIDS there are thirty-nine observations for drug prices in four countries for eleven years, with one and four missing observations for the Philippines and Thailand respectively. Furthermore, quarterly market size data measured in sales of standard units per ATC is available for both disease areas, except for the same missing country observations as already stated above. Data provided by WDI is complete, with exception of total health expenditures as percentage of GDP. Latter is only available for the period 1997 to 2003; hence, it was decided to extrapolate the existing data using a simple OLS regression technique to expand the data to range from 1994 to 2004. Moreover, since data for all WDI variables is provided on an annual basis, the quarterly IMS data was transformed using simple yearly averages.

Finding comparable price data in order to conduct a cross-country paper on drug pricing in developing and emerging countries is highly complex for three reasons: First, statistical data on historical drug prices is rare in the developing world. Secondly, package size and dosage of medicaments do not only vary across countries, but also across pharmaceutical companies competing in the same therapy. Thirdly, prices charged at each level in the distribution chain are the result of a multitude of different pricing issues as explained above. To our knowledge, IMS Health is the only company offering complete data on a range of local pharmaceutical prices and market shares in the developing world. Using sources such as manufacturer, wholesaler and government price lists as well as industry publications IMS Health collects sales and price data on the level within the pharmaceutical market supply and distribution chain that will provide the most accurate information for the specific country. In general, data is collected for one of the following three levels: manufacturing, wholesaler and pharmacy selling price. Subsequently, using a predefined country-specific mark-up factor IMS Health converts the price and sales information collected for one level to the other two levels (IMS Health, 2006). According to IMS Health the mark-up factors are continually updated based on information derived from the supplier as well as the consumer side. Moreover, since drugs of different firms come in various sizes and forms IMS Health also provides prices per standard unit in order to make a meaningful comparison of drug prices within an ATC possible. The price per standard



unit is calculated by equating “the price of all preparations to the standard solid dosage of one tablet, which means the dose equivalent is being compared independent of preparation” (IMS Health, 2006: 11). Overall, the data reporting procedure of the IMS Health MIDAS Quantum Database, however, can involve three potential complications for the empirical cross-country analysis conducted in the subsequent chapter: First, the predefined country-specific average conversion factors can distort actual sales and price values. Secondly, the calculations applied to retrieve the price per standard unit can also lead to biased results if the price and the sales volume data have been collected at different levels (IMS Health, 2006).<sup>10</sup> Thirdly, price and sales volume data can also become distorted if the value added tax (VAT) is included in one level or country, but not in the other. When considering the dataset of this study in light of these data gathering problems the first complication can pose the only true problem for the empirical analysis of this study.<sup>11</sup> However, country-specific conversion factors are continuously updated by IMS Health and the risk of biased results is therefore minimised.

## **4 Results**

### **4.1 Explorative Analysis**

The first part of the explorative analysis is directed at the mark-up factors defined by IMS Health for each country. Figure 2 presents the mark-up as a percentage of the manufacturing selling price of drug products. It is reported as a constant across ATC and only displays small variations over time for each country. The highest mark-up, as calculated by IMS Health, exists in South Africa. It hereby amounts to eighty-two percent of the manufacturing selling price. The other countries follow with an average mark-up range of forty to fifty-nine percent of the manufacturing selling price.<sup>12</sup>

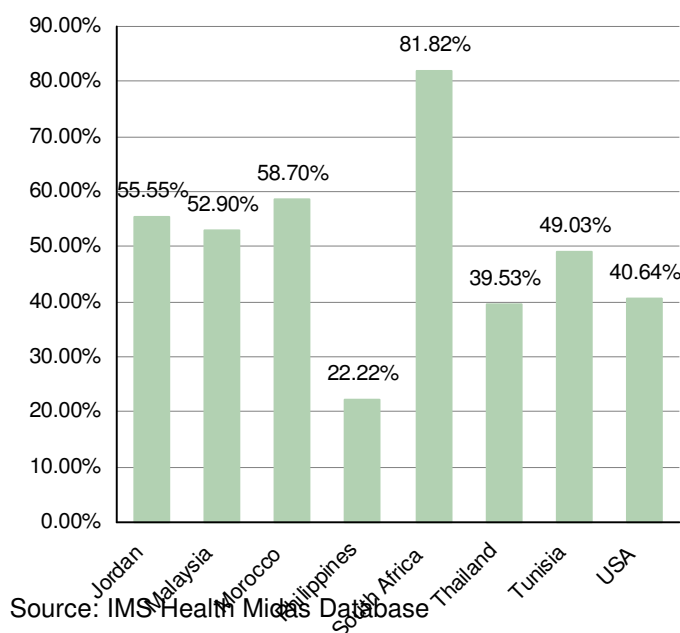
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<sup>10</sup> This complication can be explained for “example in Switzerland where prices are held at the Public level [pharmacy selling price] but volume is held at the Ex-manufacturer level. The prices are converted to Trade and Ex-manufacturer, however SHP is based on volume and so conversions are then required to come back up from the Ex-manufacturer level to Trade and then Public” (IMS Health, 2006: 11).

<sup>11</sup> With exception of Morocco, price and sales volume data is collected on the same level for all countries. Furthermore, price and sales volume data for each country either include or exclude the VAT simultaneously.

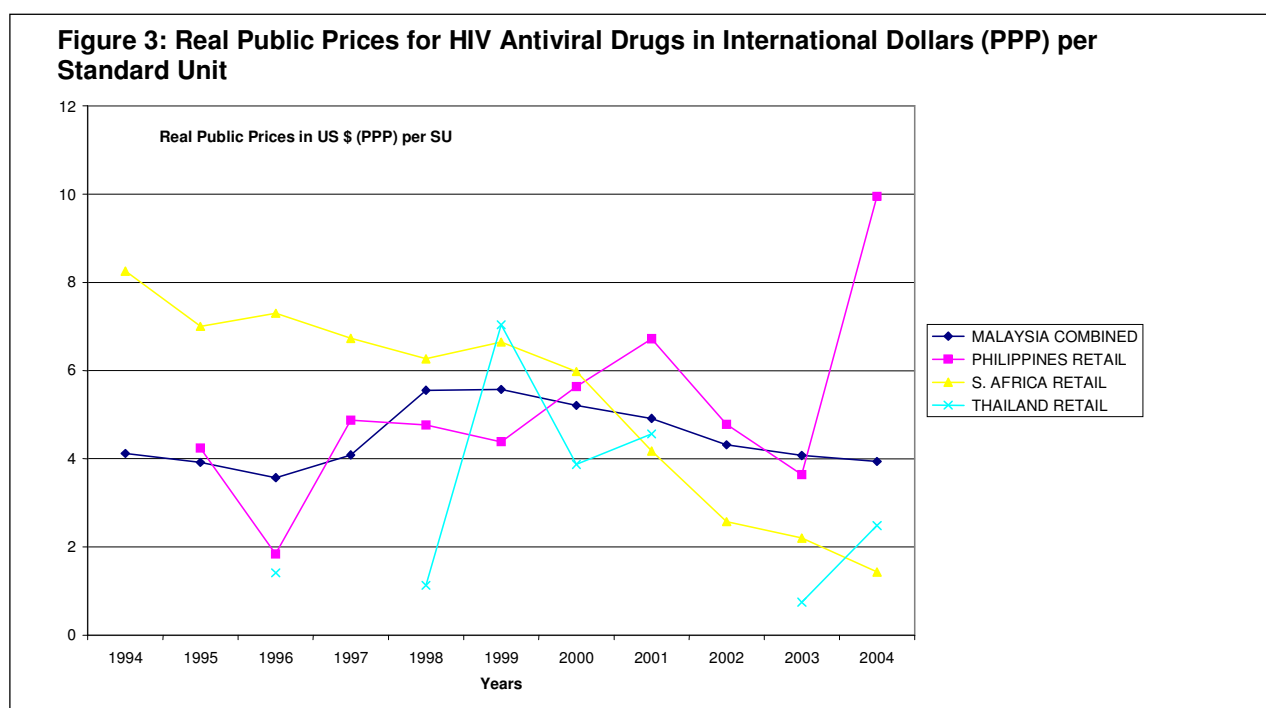
<sup>12</sup> In this context, the Philippines, with a mark-up of only eighteen percent, are considered to be an outlier. More research on the country has to be conducted since this figure seems to be remarkably low.

**Figure 2: Mark-Up as Percentage of Manufacturing Selling Price, 2006**



As indicated in Figure 2, wholesalers and retailers in the USA dispose an average mark-up of forty percent in total. With the exception of New Zealand (twenty-three percent) and Austria (one hundred fifty percent) most OECD countries dispose an average mark-up in the range of forty to sixty percent of the manufacturing selling price. However, although latter is similar with the results retrieved earlier for the seven countries under inspection, it cannot be concluded that the procurement and distribution activities in the developing and emerging countries are as efficient as in the OECD world. This controversy can be explained in the following way: Critics of the TRIPS Agreement state that the local population in developing countries cannot afford medicaments, because innovator brand companies impose excessive drug prices. According to this view inefficiencies along the procurement chain only have a minor impact, if at all, on local drug prices. If this argument is valid, wholesale and retail mark-ups as percentage of seemingly excessive manufacturing selling prices should be by far lower in the developing countries than in OECD countries due to much lower labour and transport costs. However, this is not the case in reality. The seven countries under inspection have similar or sometimes even higher local mark-ups than OECD member states. Inefficient procurement and distribution activities as well as state-imposed price drivers, therefore, appear to be still a big problem.

In the second part of the explorative analysis public price trends are inspected for structural breaks related to the implementation of TRIPS in the various countries. Figure 3 displays the time trends of real public prices in international dollars (PPP) per standard unit for HIV/ AIDS related drugs. Most remarkable is hereby the decline of real public drug prices by more than eighty percent for South Africa and almost thirty percent for Malaysia. It was most likely caused by the massive political pressure that global AIDS activist groups put on the pharmaceutical industry to lower the prices and thereby make HIV antivirals affordable for the local population.<sup>13</sup> Furthermore, Thailand had a short term price hike from 1999-2001 before prices declined to the initial low prices. However, the data series is not complete; hence, one can only infer the overall price development. The drug price data related to HIV antivirals clearly shows that none of the countries above experienced a rapid change in the real public price trend or even price increases due to TRIPS implementation.<sup>14</sup>



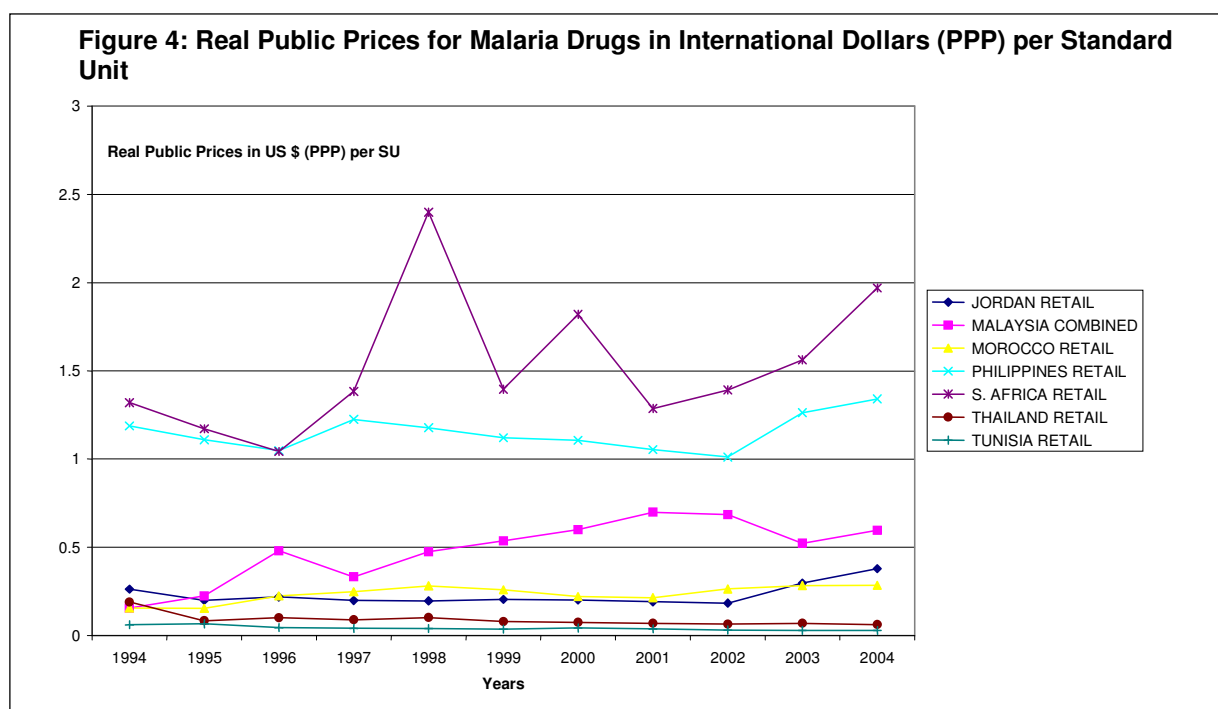
Finally, Figure 4 displays the time trend of real public prices in international dollars (PPP) per standard unit for Malaria related drugs. While Malaysia<sup>15</sup> and the Philippines

<sup>13</sup> More information on South Africa will be provided in the case paper. See section 4.

<sup>14</sup> The Philippines are the only exception with major price increases over the observation period. Given the low HIV/ AIDS prevalence rate in the country results are not really meaningful.

<sup>15</sup> The dramatic price increase took place before TRIPS was implemented in Malaysia. See section 4 for more information on Malaysia.

experienced a dramatic (almost three hundred percent) and a slight (15 percent) increase in real public prices respectively for the period 1994-2004 prices in Thailand, by contrast, fell to one third of their original level.<sup>16</sup> Overall, no clear structural break in the real public price trends can be observed for any country for the period of TRIPS implementation.



In conclusion, the explorative analysis reveals that none of the observed trends in real public prices of medicaments against HIV/ AIDS or Malaria exhibits a dramatic structural break or an overall increase in price levels due to the implementation of the TRIPS Agreement in the countries under inspection. The implication is that TRIPS has, if at all, only a minor impact on drug price development and hence on the affordability of drugs in the seven countries. Other factors are most likely more important which is reflected in the overall falling price trend for many drugs in a multitude of countries. Furthermore, despite remaining differences in prices across countries one can observe an overall convergence pattern towards generally lower prices, except for Malaria related drugs that tend to diverge slightly over time. Another striking fact is the dramatic decline of HIV antiviral prices in South Africa which has most likely been caused by supply side changes, but also by intensive campaigning of global AIDS activist groups.

<sup>16</sup> In the remaining countries the real public price trends were rather stable, with the exception of South Africa. However, results for these four countries can be neglected since they are hardly affected by Malaria.

## 4.2 Econometric Analysis

Against the background of the general results obtained in the graphical depiction of price trends a quantitative paper is conducted. As specified in section 2.1 a pooled OLS regression technique is applied in order to test the hypothesised determinants of real public drug prices. The results are displayed in Table 5. Regressions (1) and (2) show the results for annual real public drug prices in international dollars (PPP) per standard unit for HIV/ AIDS and Malaria respectively. The variable GDP pc has been divided by 100 and the variable MarkSize has been divided by 1,000,000 in order to give meaningfully interpretable coefficients. All regressions control for country and time effects.

**Table 4: Pooled OLS Regression Results for Yearly Real Public Prices for HIV and Malaria (1994-2004)**

	Real Public Prices in US \$ (PPP) per SU	
	(1) HIV	(2) MAL
Constant	8.716 (0.35)	-0.446 (-0.57)
GDPpc/100	-0.144 (-1.01)	0.011 (1.34)
CPI	0.127 (0.82)	0.016 (3.23)***
Health/GDP	-0.170 (-0.01)	-0.597 (-0.93)
MarkSize/1,000,000	-0.267 (-3.41)***	-0.021 (-2.28)**
TRIPS	-1.056 (-0.78)	0.083 (1.05)
Observations	39	77
R-squared	0.71	0.94

Absolute value of t statistics in parentheses  
 \* significant at 10%; \*\* significant at 5%; \*\*\* significant at 1%

The results of regressions (1) and (2) reported in Table 5 show that TRIPS do not have a positive significant effect on local drug prices. GDPpc behaves negative in regression (1) and positive in regression (2). The negative, but statistically insignificant coefficient for GDPpc in regression (1) is driven by the rapid real public price decline of HIV antivirals in South Africa which is the richest of the four countries under investigation. The covariate CPI implies a positive relationship between general price level increases and real public drug prices for both regressions. The control variable Health/ GDP is characterised by very

low t-statistics. No impact whatsoever can be inferred. Furthermore, MarkSize is highly negative and significant in both regression specifications and behaves as expected. For example, an increase by 10,000,000 standard units in market size for Malaria related products would lower the real public price by 0.21 US \$ PPP per standard unit due to fiercer competition for higher sales volumes on the supplier side and potential formation of monopsony power on the consumer side. This result strengthens the argument that larger drug markets or increased procurement size by any single agent, whether a state, an international organisation or a global initiative, allows the buyer to lower drug prices significantly.

Given the explorative analysis above, the results of the regressions concerning the TRIPS time dummy are not surprising. It can be now concluded with greater confidence that the implementation of TRIPS has not led to a real public drug price increase for HIV/AIDS or Malaria products in the seven countries under inspection. If TRIPS had a dominating impact on prices in most countries the regressions would certainly identify a structural break. Summarizing, the results of the explorative analysis have all been confirmed in the econometric paper. In the seven countries under empirical investigation, country-specific price determinants have a more important impact on local drug prices in the two analysed disease areas than TRIPS.

## **5 Conclusion**

In the seven selected middle income countries the introduction of TRIPS had no major long lasting impact on local drug price development in the area of HIV/ AIDS and Malaria. Both the explorative as well as the econometric analysis do not find any structural break or any positive correlation between the date of TRIPS enforcement and an increase in real public drug prices. From the presented findings, two policy conclusions emerge: First, reducing the high mark-up costs for drugs is a main area for policy intervention in developing and emerging economies. Secondly, policy coherence is essential for avoiding negative effects of existing IP regulations.

Efficient procurement activities are key to affordable drug prices. Minimising inefficiencies requires a combined governmental policy that takes both the supplier's as well as the consumer's side into account. On the supplier side governments should define mark-ups

and price caps for drugs throughout the supply chain from manufacturer or importer to end-buyer. On the consumer side governments should aim at pooling patients in order to create monopsony power when bargaining with pharmaceutical companies. Besides these measures all pharmaceuticals should be exempt from tariffs, non-tariff barriers and taxes. Although governments in the developing world have begun to realise that tariffs and taxes on medicaments aggravate the public health situation in their countries, some still consider them as a much needed source of state revenue. Finally, governments should also optimise the use of TRIPS safeguards in order to enhance generic competition. As the case paper Malaysia has shown, if TRIPS safeguards are not used, pharmaceutical companies will be keen on charging higher prices.

OECD countries can also make a significant contribution to render drugs in developing countries more affordable. In this context, Cecilia Oh proposes a “formula for fairness” consisting of the following three components: “Advocacy for effective use of TRIPS safeguards; Balance in patent, trade and development policies; Cooperation and coherence between national governments, international organisations and civil society” (Oh, 2005: 27). Striking a balance between asserting own strategic economic interests (primarily in the areas of patent and trade policy) and strengthening aid effectiveness in the health sector of developing countries poses a great challenge for policymakers in the OECD world. However, while the damage of infectious diseases has been disproportionately shared in the developing world, “it is worth bearing in mind that in this age of air-travel, diseases that have been wiped out in the rich countries could be reintroduced in them rather quickly. Thus, even if one were to ignore the urgent morale case [...], a narrowly perceived notion of self-interest on the part of richer countries calls for them” to support efforts to make drugs affordable (Saggi, 2006: 5).

Against this background OECD countries should advise developing countries how to effectively use TRIPS safeguards. More precise, capacity building guidance should be given in order to make the administrative and legal infrastructure adequate for the use of TRIPS safeguards. As long as existing deficiencies in the institutional setting prevail developing countries will not be able to use TRIPS flexibilities in practice. In this context, recent attempts to tighten TRIPS rules by applying a carrot and stick policy approach with respect to free trade agreements and TRIPS+ provisions have not been beneficial for achieving this goal.

Besides acting as advisors OECD countries should also strengthen their financial contribution (for instance “tax on airline ticket initiative”) in order to make drugs more affordable. Encouraging stronger collaboration and harmonisation between all stakeholders in the development aid arena is a necessary prerequisite to make foreign assistance in the health sector of developing countries effective. A particular emphasis should hereby be devoted to public-private partnerships. In this context, pull programs play a prominent role. One kind of pull program is the “purchase commitment in which sponsors would commit to purchase a specified number of doses at a specified price if a vaccine meeting certain specifications were developed” (Kremer, 2002: 83). Such a pull program creates a win-win situation for both the supplier as well as the sponsor of the requested drugs: Pharmaceutical companies do not face any problem of time-inconsistency when researching and producing the drug while donors pay lower prices due to monopsony power. Overall, local populations in developing countries would benefit from both affordable as well as state of the art drug products.

While these results are considered to be valid for middle income countries that have a capacity to produce drugs themselves one has to act with caution when generalising these findings with regards to least developed countries. On the medium- to long-term horizon TRIPS can have a negative effect on the public health situation in these countries in case of two specific circumstances: First, generic companies in middle income countries (such as India or Brazil) can be forced to exit the market due to TRIPS enforcement; secondly, as a reaction to the latter generic companies might aim to upgrade their business to become innovator drug manufacturers. In such scenarios developing countries which do not dispose pharmaceutical production know-how will face a severe health crisis in the future since they are not able to import any cheap generic drugs of patented medicaments anymore.

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## **Appendix**

### **A Construction of the Price Indices for the Cross-Country Analysis**

#### **A.1 Methodological Procedure**

Patent, off-patent and generic drug products make up the price index (for each disease area and each country) which is weighted according to their annual country-specific sales. Close attention has hereby been paid that drugs under patent protection have a significant share in the price index in order to measure potential effects of TRIPS. Since drugs of

different firms come in various sizes and forms the prices per standard unit are incorporated in order to make a meaningful comparison of drug prices within an anatomical therapy class (ATC) possible. The price per standard unit provided by IMS Health is calculated by equating “the price of all preparations to the standard solid dosage of one tablet, which means the dose equivalent is being compared independent of preparation” (IMS Health, 2006: 11).

## **A.2 List of HIV/ AIDS antiretrovirals included in the price index for South Africa in 2004**

<b>Medicament</b>	<b>Patent Expiry Date</b>
Trizivar	04/2011
Ziagen	12/2010
Viramune	11/2010
Combivir	04/2011
Duovir	04/2011
Forto-Vase	12/2010
Aspen Lamzid	04/2011
Avocomb	04/2011
Stocrin	08/2013
Nevran	11/2010

Aspen Zidovudine	No patent protection
Aspen Nevirapine	11/2010
Retrovir	No patent protection
Zidaid	No patent protection
Hivid	No patent protection
Videx	No patent protection
Invi-rase	12/2010
Vira-cept	No patent protection
Crixivan	11/2012
3TC	04/2011
Aspen Didanosine	No patent protection
Kaletra	12/2016
Cipla-Lamivudine	04/2011
Zidovir	No patent protection
Lamaid	04/2011
Aspen Lamivudine	04/2011
Norvir	No patent protection
Zerit	05/2009
Aspen Stavudine	05/2009
Stavir	05/2009

Source: IMS Health MIDAS Database (2006).

As explained in A.1 close attention has been paid that drugs under patent protection have a significant share in the price index. A.2 provides as an example the list of all HIV/ AIDS antiretrovirals included in the price index (for disease area HIV/ AIDS) for South Africa in the year 2004.

## **B Theoretical Components of a Public Price Mark-up**



