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PHARMACEUTICAL PRICING IN EMERGING MARKETS: EFFECTS OF INCOME, COMPETITION AND PROCUREMENT

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ABSTRACT

This paper analyzes determinants of ex-manufacturer prices for originator and generic drugs across a large sample of countries. We focus on drugs to treat HIV/AIDS, TB and malaria in middle and low income countries (MLICs), with robustness checks to other therapeutic categories and other countries. We examine effects of per capita income, income dispersion, number and type of therapeutic and generic competitors, and whether the drugs are sold to retail pharmacies vs. tendered procurement by NGOs.

The cross-national income elasticity of prices is 0.4 across high and low income countries, but is only 0.15 between MLICs, implying that drugs are least affordable relative to income in the lowest income countries. Within-country income inequality contributes to relatively high prices in MLICs. Number of therapeutic and generic competitors only weakly affects prices to retail pharmacies, plausibly because uncertain quality leads to competition on brand rather than price. Tendered procurement attracts multi-national generic suppliers and significantly reduces prices for originators and generics, compared to prices to retail pharmacies.

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I. Introduction

Pharmaceutical pricing in middle and low income countries (MLICs) is an important and contentious issue. Since most patients lack insurance coverage and pay out-of-pocket for drugs, pricing commensurate with income is critical to affordability. The requirement that all countries adopt the World Trade Organization (WTO)'s patent regime as a condition of membership prompted concerns that patents would make drugs unaffordable in MLICs. However, patents need not imply high prices if originator firms price discriminate across countries based on per capita income (for example, Malueg and Schwarz, 1994; Danzon and Towse, 2003). Moreover, generic copies are available for most originator drugs. Thus whether drug prices are affordable in MLICs is an empirical question.

This paper examines determinants of ex-manufacturer prices for originator and generic drugs across countries at all income levels, with more detailed evidence on MLICs, focusing on effects of mean per capita income (PCI), income dispersion, and number of competitor products. For drugs to treat HIV/AIDS, TB and malaria, we also compare ex-manufacturer prices charged to the retail pharmacy channel vs. to large NGO purchasers, such as the Global Fund and the Clinton Foundation, which purchase only from qualified suppliers and use tendering to stimulate price competition. The retail channel data from IMS Health include a broad range of therapeutic categories and countries. The procurement channel data from the WHO's Global Price Reporting Mechanism (GPRM) are just for HIV/AIDS, TB and malaria drugs.

For drugs sold to the retail channel, we estimate the price elasticity with respect to PCI across the full range of countries at 0.4 for originators and 0.6 for generics, but

insignificantly different from zero across MLICs (Appendix Table II). Income dispersion further contributes to relatively high prices in MLICs. Although generics are priced on average 47 percent below originators in the retail channel, the generic/originator price ratios are widely dispersed and some exceed one. The estimated price reduction due to an additional retail generic competitor is significant but small. Additional originator competitors have no effect on prices. The procurement channel lowers originator and generic prices by 44 percent and 28 percent, respectively, compared to their retail channel prices. Overall, the evidence suggests that retail customers in MLICs face high originator and generic prices, relative to their PCIs, and that price discrimination by originators and price competition by generics are relatively weak. Compared to the retail channel, the tendering process reduces quality uncertainty; focuses competition on price, not brand; and attracts multinational generic suppliers that have scale and other advantages relative to the local branded generics that dominate the retail channel.

In the remainder of this paper, section II reviews relevant theory and previous literature; section III describes data and empirical methods; section IV reports results of the multivariate regression analysis; and section V concludes.

II. Theory and Previous Literature

Price Discrimination and Income Previous theoretical analysis of cross-national pharmaceutical pricing has examined welfare effects of price discrimination vs. uniform prices, assuming that on-patent producers are monopolists. For example, Malueg and Schwartz (1994) conclude that price discrimination is both profit-maximizing and welfare-superior to uniform pricing, if demand dispersion across countries is significant, discrimination increases aggregate consumption and all markets continue to be served,

which is plausible for pharmaceuticals. Szymanski and Valetti (2005) and Valetti and Szymanski (2006) show that price discrimination also leads to more R&D and higher quality products than does uniform pricing. Applying Ramsey pricing principles to paying for pharmaceutical R&D implies that varying prices inversely with demand elasticities is the second-best optimal way to pay for the global joint costs of R&D (Danzon, 1997; Danzon and Towse, 2003; Jack and Lanjouw, 2005). These theoretical results suggest that manufacturers' profit-maximizing strategies may lead to prices that vary across countries roughly with PCI and that this would be welfare superior to uniform prices, assuming that price elasticities vary inversely with PCI and that differential pricing leads to higher utilization. An inverse relation between income and uncompensated price elasticities is plausible if health is a normal good, although strict proportionality of price elasticities and income is not necessarily predicted (Danzon et al. 2011). Increased utilization under differential pricing is also plausible and supported by the limited data (for example, Danzon and Furukawa, 2008).

In practice, however, several factors may undermine the potential relationship between prices and PCI. First, all high income countries (HICs) have comprehensive health insurance that pays for drugs. Insurance reduces consumer price elasticities and hence would lead to higher prices if payers were passive. But payers in most countries must manage pharmaceutical prices and access within constrained budgets that reflect their citizens' willingness-to-pay for health. If these insurance mechanisms reflect consumer preferences, the resulting price levels may still vary with income, if average consumer price elasticities vary inversely with income.[1]

[1] Baros and Martinez-Giralt (2006) discusses the effects of insurance on Ramsey pricing.

Second, parallel trade and regulation based on external referencing undermine manufacturers' ability to price discriminate across countries (Danzon, Wang and Wang, 2005; Kyle, 2006, 2007; Danzon and Epstein, 2009). In particular, within the EU parallel trade is legal and external referencing is common. Such policies create incentives for firms to seek higher prices in low income countries than would occur under perfect segmentation. Moreover, some regulators may seek to pay only their incremental cost, free riding on other countries' contributions to R&D. However, since external referencing and parallel trade occur mostly between HICs, it is unlikely that these policies could explain high prices in MLICs.

Third, Flynn et al. (2009) show that in theory the highly skewed income distributions in MLICs create incentives for a single price monopolist to set higher prices, relative to PCI, than would occur with more equal income distribution. No empirical evidence is presented. Moreover, this effect might be mitigated if manufacturers could price discriminate within countries, offering lower prices to outlets that serve low income populations. Within-country price discrimination is feasible in countries with pluralistic payers or insurers, such that manufacturers can pay different rebates to different payers, as occurs in the US and Brazil.[2] However, in MLICs most consumers pay cash for drugs in retail outlets served by common distribution networks. If manufacturers were to offer discounts to distributors who serve poor populations, these distributors could simply divert the drugs to higher income outlets with larger mark-ups. Thus if price discrimination

[2] In the US, firms give voluntary rebates to private health plans for preferred formulary placement and are mandated to give discounts to public payers. Brazil regulates prices to the private sector and mandates a rebate to the public sector.

within cash-paying MLIC markets is infeasible, firms may rationally set higher prices in countries with a highly skewed income distribution, conditional on mean PCI.

Previous empirical evidence on cross-national price differences focuses mainly on originator prices and high income countries (for example, Danzon and Chao 2000, 2004). Danzon and Furukawa (2003, 2008) found that average drug prices vary roughly in proportion to income across HICs, but for Brazil, Mexico and Chile drug prices are 2-3 fold higher relative to PCI. Empirical evidence on drug prices in MLICs is limited. Maskus' (2001) analysis of 20 drugs in 14 countries in 1998 found a correlation between average list price and PCI of roughly 0.5. Scherer and Watal (2001) found that for 15 antiretroviral drugs in 18 countries for the period 1995-9 the average price was 85% of the US list price, and a fifth of prices were above the US level. Per capita income weakly contributed to price differences, and the relationship declined over time as companies began offering discounts that were unrelated to PCI.

Competition Most previous literature assumes that originators are monopolists, due to patents, and that competition forces generics to price at marginal cost. In fact originators compete with other originators in the same class ("therapeutic substitutes") and with generic producers of the same molecule ("generic substitutes"). Most generics in MLICs are branded generics that claim equivalence to the originator but have not passed regulatory tests of bioequivalence, as required in HICs. Generic quality is thus uncertain, but most consumers (or their physician/pharmacy agents) know that originator brands have met strict safety and efficacy requirements of the US FDA or European EMA. In such imperfectly competitive markets with uncertain quality, originator and generic copies may rationally use brand marketing and pricing to signal quality. Originators may optimally

follow a segmentation strategy, optimizing price for the most quality-inelastic, price-inelastic segment, while more quality and price-elastic consumers shift to generics.[3] This strategy predicts that originators would charge higher prices if faced with branded generic competitors than would occur with no generic competitors.

Procurement of Drugs for HIV/AIDS, TB and Malaria Prior to 2000, most HIV/AIDS drugs were originator brands purchased through standard distribution channels. Annual treatment cost for the standard 3-drug cocktail cost up to $10,000, or 10 times average PCI in the poorest countries (Kapstein and Busby, 2009). In 2001 the WTO Doha round elaborated the rights of poor countries to issue compulsory licenses for either domestic production or imported generics in the event of public health emergencies. Around the same time, donors increased resources for purchasing through NGOs such as the Global Fund to Fight AIDS, TB and Malaria in 2002 and the Clinton Foundation's HIV/AIDS Initiative (CHAI). These NGOs purchase only from WHO-qualified suppliers and use tendering to stimulate price competition. Expanded demand in turn enabled Indian generics and other suppliers to achieve greater scale economies. Originator firms may also have incentives to offer discounts to NGOs, if their demand is more elastic than retail channel purchasers and/or their procurement channels reduce the risk of parallel export and external referencing. Waning et al. (2009) examined prices for 24 generic anti-retroviral drugs (ARVs) procured July 2002-October 2007, as reported to the World Health Organization (WHO) Global Price Reporting Mechanism (GPRM). They found CHAI

[3] Frank and Salkever (1996) present a similar rationale for originator price increases following generic entry in the US. Szymanski and Valetti (2005) consider the option for the originator company of introducing a "fighting brand" when facing a generic competitor of uncertain quality but find it unlikely to be profitable.

eligibility significantly lowered price, but volume had no consistent effect.[4] They did not analyze originator prices to CHAI, GPRM purchasers other than CHAI or any retail channel prices.

Our analysis extends existing literature by estimating price elasticities with respect to both mean PCI and a GINI measure of income skewness for a large range of countries and for both originator and generic products; we estimate effects of competition, distinguishing number of originators, local generic firms and large multinational generic suppliers; and for HIV/AIDS, TB and malaria drugs we compare these determinants of prices in the retail channel vs. the procurement channel.

III. Data and Methods

Data

Retail Pharmacy Channel (IMS): Our IMS MIDAS database reports sales for all drugs in the J (anti-infectives) class and the C (cardiovascular) class for most major industrialized countries and a subset of MLIC countries. IMS reports quarterly ex-manufacturer sales and volume data for each product, in current US dollars, converted from local currencies at quarterly exchange rates.[5] We include year indicators to control for inflation, exchange rate changes and other unmeasured year-specific effects.[6] We converted the IMS price per

[4] The reported magnitudes may be biased because the log price regression coefficients were apparently exponentiated without variance adjustment.
[5] For most MLICs IMS reports a single aggregate channel. When IMS reports separate data for retail and hospital channels we aggregate to a single channel.
[6] Producer price indexes (PPIs) were available for some but not all countries. We estimated equations for countries with PPIs available, and results were similar to those reported here.

standard unit to annual treatment cost using the WHO defined daily dose (DDD) for each drug presentation.[7]

GPRM: We use prices for all drugs procured by NGOs such as UNICEF, the Global Fund, Mission Pharma, the IDA Foundation etc. as reported in the WHO's GPRM database. Each GPRM contract records the purchaser, recipient country, purchase date, manufacturer, total contract cost in current US dollars, and quantity of units and packs.[8] The GPRM data include about 23,000 contracts for 115 countries. The majority of these contracts are for ARVs (21,344 for ARVs vs. 2,066 others).[9]

Dataset structure and country groups For our comparison of IMS vs. GPRM prices, our IMS sample is limited to those HIV/AIDS, TB, or malaria drugs that are also sold through GPRM in at least one country. We use January 2004-June 2008 IMS and GPRM data, aggregating over multiple contracts in GPRM and multiple packs in IMS. Thus our unit of analysis is average annual treatment price for the molecule-country-year, with separate observations for generic and originator and by IMS (retail) vs. GPRM (tendered) channel where available.[10] Combination drugs are treated as unique products.[11]

Ten countries (Algeria, Brazil, China, Egypt, India, Indonesia, Morocco, the Philippines, South Africa, and Thailand) are in both IMS and the GPRM datasets. A group of ten Sub-Saharan Africa countries (Benin, Burkina Faso, Cameroon, Congo, Cote d'Ivoire,

[7] When WHO DDDs were unavailable, we used recommended daily doses published in the medical literature.
[8] We calculate annual treatment cost by dividing the GPRM contract price and quantity after adjusting quantity by the WHO defined daily dose (DDD) to arrive at the number of annual treatment courses per contract. Our calculated annual treatment cost data closely match an estimate provided in the GPRM data for oral solid formulations. For other formulations GPRM does not provide annual treatment cost.
[9] Appendix Table I shows countries in the GPRM and IMS databases.
[10] A few molecules have two observations, due to a non-oral solid form in addition to the oral solid form.
[11] Most combination drugs are ARVs which include component ARVs of the same or different classes. These combinations were generally produced only by generic manufacturers selling to GPRM and are not available in the IMS data.

Gabon, Guinea, Mali, Senegal, and Togo) are reported aggregated in IMS as "French West Africa." We therefore created a comparable, GPRM French West Africa aggregate, defined as the population-weighted average of the country-specific data in GPRM for these individual countries.

We report regression estimates for three country groups: (a) all countries for which we have data; (b) the eleven matched MLIC countries in both IMS and GPRM; and (c) all MLICs in the same income range as the matched country sample. This matched income sample includes GRPM data for more low income countries and has very similar summary statistics (see Table 1). We therefore base most conclusions on this sample, which provides more robust evidence on GPRM prices.

Methodology

We estimate a quasi difference-in-differences model of log prices, using the pooled sample with indicator variables to test for differential effects for each license-channel category (IMS generics, GPRM originators and GPRM generics, designated by the vector Z below) compared to the referent IMS originator category:

$$\ln(P_{ijt}) = a_0 + a_1 \text{IMS*GEN} + a_2 \text{GPRM*ORIG} + a_3 \text{GPRM*GEN} + b_0 lnY_{jt} + b_1 Z^* lnY_{jt} + c_0 COMP_{ijt} + c_1 Z^* COMP_{ijt} + d_1 GINI_{jt} + d_2 HIV_{jt} + u_i + u_t + v_{ijt}$$

In this pooled equation, a_1, a_2, and a_3 measure the mean price differential of IMS generics, GPRM originators and GPRM generics, respectively, relative to IMS originators; b_0 is the income elasticity for IMS originators in the retail channel and b_1 is the vector of differential income effects for generics and the GPRM channel; c_0 and c_1 are the coefficients on the vector of competition variables COMP; d_1 and d_2, respectively, measure effects of income

dispersion and HIV prevalence; u_i and u_t are molecule and year fixed effects and v_{ijt} is a random disturbance term. We also estimate separate equations for each of the four license-channel categories (originator brands and generics in the retail pharmacy and the procurement channels), to permit all coefficients to differ across categories. The GPRM regressions include purchaser indicators, to test for variation in prices paid by different GPRM purchasers, due to scale, bargaining power or other factors.

Per capita income, income dispersion and HIV Prevalence Per capita income is measured by (log) per capita gross national income (GNI) in international dollars. Originator drug prices are expected to be positively related to PCI under the joint hypothesis that originators can price discriminate between countries and face price elasticities that vary directly with mean PCI. By contrast, if generic markets are competitive, generic firms would lack the market power necessary to price discriminate across countries and generic prices should be invariant with PCI, reflecting marginal production cost which is largely uniform across countries.

The GINI measure of income equality ranges from 0 (perfectly equal distribution) to 100. The coefficient is expected to be positive if greater income inequality leads to higher prices due to demand convexity (Flynn et al. 2009). This effect is expected to be greater for originators than for generics, and only operative in the retail sector.

Some countries argue that disease burden should justify a lower price, and some originator companies list disease burden as a factor in their corporate responsibility and pricing strategies. If these considerations are significant, HIV prevalence is expected to be inversely related to drug prices.

Competition Therapeutic competition is measured as the number of originator products in the same therapeutic class-country-year (Originator class count). We separately count Tendering Generic and Retail Generic competitors in the class-country-year. These measure the number of generic producers in the same therapeutic class and country that, respectively, did and did not sell to the tendering process during our time period. Tendering Generics have demonstrated ability to meet quality standards and compete on price, whereas the Retail Generics have not. Both counts are at the class-country rather than the molecule level, to provide a rough measure of potential entrants as well as actual competitors. Coefficients are expected to be negative under standard price competition models. These effects are expected to be more negative for Tendering Generics than Retail Generics, and more negative in the GPRM channel than the retail channel if uncertain quality undermines price competition in the retail channel.[12]

We include an Originator Present indicator equal to one if the molecule originator is present in a country-year. The coefficient is expected to be positive if generics shadow-price the originator. Similarly, we include a Generic Present indicator in the originator price regressions; the coefficient is expected to be positive if originators follow segmentation strategies when faced with generic competition, raising price to the quality loyal customers while the price-sensitive customers switch to generics (Frank and Salkever 1996).

[12] To test for effects of potential competitors we also estimated regressions with these competition variables measured at the region rather than the country level. Results were generally similar but sometimes less significant than the country-level measures reported here.

Product Characteristics An indicator variable is included for non-oral solids such as liquids and creams, which may have higher production costs and/or fewer competitors than the tablets and capsules which are the bulk of the observations.

Purchaser Characteristics In separate GPRM regressions we include indicators for the four individual purchasers with the largest number of contracts: UNICEF, the Global Fund, IDA and Mission Pharma.[13] If their purchasing volume gives these purchasers a size advantage over other smaller purchasers, their coefficients should be negative.

Descriptive Statistics

Table I reports descriptive statistics. The all-country sample includes 37 countries with IMS data, with mean PCI of $24,318, and 112 countries in GPRM with mean PCI of $3,467. The matching country sample has 11 countries, with mean PCI of roughly $4,360-$4,610. The matched PCI range sample increases the number of observations five-fold, primarily adding countries with GPRM data, with no material differences in demographic characteristics. Our discussion therefore focuses mainly on results for the matched PCI range countries, which have PCI of $1,000-$10,000.

For these countries, the pharmacy channel (IMS) has relatively more molecules with both an originator and at least one generic available than the procurement channel (GPRM). The pharmacy channel also has more originator and generic competitors per class (means 2.97 and 25.77, respectively) than the procurement channel (means 1.23 and 1.13,

[13] The Clinton Foundation (CHAI) has played a major role in negotiating upper limits on supplier prices for countries that it deems eligible. However, CHAI itself accounts for only 4% of the GPRM contracts. It has contracted with IDA for purchase of its pediatric medicines and presumably contracts with other purchasers for adult medicines. Since the CHAI prices are a ceiling price and actual purchasers may negotiate lower prices, we use indicators for actual purchaser rather than CHAI eligibility of the recipient country, as in Waring et al (2009).

respectively).[14] Whereas most originator firms participate in both the retail and procurement channels, very few generic manufacturers serve both the pharmacy and procurement channels. Of the 370 retail generic firms and 100 tendering generic firms, only 24 sell in both, with even less overlap within each region. Why many large, multinational tendering generic firms do not sell through the retail channel is an important question for future research.

IV. Multivariate Regression Estimates

Pooled License-Channel Estimates

Table II reports pooled license-channel multivariate regression estimates for log annual treatment price for our three country groups defined above. Estimates from analogous equations with interaction terms between log PCI and the three channel/brand indicators are reported in Appendix Table II. All equations include molecule fixed effects to control for unobserved drug heterogeneity, as well as year fixed effects to control for price inflation and other unmeasured time effects. Robust standard errors are clustered at the country-level. Exponentiated coefficients (including a variance correction as in Kennedy (1981)) appear in a third row for indicator variables. Table III reports separate regressions by channel and generic status for the PCI range countries only. These estimates permit all coefficients to differ by channel and generic status, and show effects of individual

[14] The 25.7 mean for Retail generic competitors in the pharmacy channel reflects high numbers in India and China. As an alternative proxy for potential competitors, we tried measuring competitors at the region-class, rather than country-class level. This increased competitor counts for procurement (1.56 for originators and 4.57 for generics), with little change for pharmacy (3.18 for originators and 23.24 for generics). Regression results were similar but generally less significant than with the country-class measures reported here.

GPRM purchasers. Our discussion here is based mainly on the pooled regressions in Table II, with reference to the channel-specific regressions where relevant.

License-Channel effects For the all-countries sample, the average price differential, compared to retail originators, is -40.4 percent for retail generics, -68.3 percent for tendered originators, and -83.2 percent for tendered generics For the matched PCI range countries, the differentials relative to retail originators are: -47.5 for generics, -42.0 for GPRM originators, and -73.2 for GPRM generics. Thus generics do charge significantly less than originators in the retail channel in MLICs, presumably due to quality perceptions and other factors; however, these retail generic prices are still comparable to originator prices to the procurement process, while procured generic prices are an additional 25.7 percentage points lower than retail generics. This 25.7 percentage point procurement-pharmacy channel differential for generics plausibly reflects competitive tendering and standardization of quality to focus competition on price, and participation of large, multinational generic suppliers in international tenders, whereas the retail channel is served primarily by local branded generics of uncertain quality. The 42.0 percent procurement-pharmacy differential for originators in MLICs plausibly reflects originator willingness to offer lower prices for greater volume and that the procurement process offers a separate distribution channel that targets the discounted prices to mainly low income consumers, with reduced risk of price-spillover to higher income consumers within the same country or other countries.

Income The income elasticity of drug prices with respect to PCI is 0.269 for the full range of countries and drugs, or less than one third what would be required to maintain prices proportional to PCI. Within the MLICs, the income elasticity of

prices is only 0.15. For the full range of countries the GINI effect is small and negative (-0.015), contrary to the predicted positive effect if income dispersion contributes to high prices. However, for the MLIC matched countries, the GINI effect is significantly positive (0.040), consistent with the hypothesis that income inequality contributes to high prices in MLICs.[15]

Estimated coefficients for equations including interaction terms to test for differences in the income elasticity by channel and generic status are reported in Appendix Table II. Including these interactions changes the channel and generic fixed effects, so results should be interpreted with caution. Taken at face value, the all-country regressions suggest that the overall average PCI elasticity of 0.269 masks higher elasticities in the pharmacy channel of 0.40 for originators and 0.60 for generics, but no significant income elasticity in the GPRM channel. The high income elasticity of generic prices in the retail channel provides further evidence that these generics are not forced by competition to price at marginal cost, which would presumably vary little across countries.[16]

The channel-specific regressions confirm that PCI effects are small or perverse, and skewness effects are weakly positive. For the full range of countries (results not reported), income elasticities are positive and significant in all four channels, with a larger elasticity for generics (0.54) than originators (0.26) in the retail channel that is reversed in the procurement channel (0.26 for originators vs. 0.04 for generics), and the GINI coefficient is insignificant.[17] However, when we restrict the analysis to the matching PCI range countries (Table III), the retail generic income elasticity is significantly negative and the originator

[15] Estimated effects of skewness may be imprecise due to missing GINI data for several low income countries.
[16] Danzon and Furukawa (2011) shows that branded generics are less price-competitive than unbranded generics in higher income countries.
[17] Equations available from authors.

elasticity is positive only for procurement channel (0.325).[18] The GINI coefficient is significantly positive for retail originators (0.047) and retail generics (0.075), but insignificant for GPRM originators and generics.[19] Thus procurement contracting not only reduces drug prices overall but appears to eliminate perverse PCI-based price differentials for generics and permits modestly income-related pricing for originator products. Procurement also eliminates income skewness effects found in pricing to the retail channel.

Originator prices are inversely related to HIV prevalence in MLICs, but the effect is small, with larger effects in the pharmacy channel than the GPRM channel.

Competition Tendering generics consistently reduce prices more than do Retail generics. In the all-countries sample, the marginal effect of an additional Tendering generic on drug prices is -7.2 percent, compared to only -1.1 percent for an additional Retail generic. For the MLIC countries, the marginal Tendering generic reduces prices by 3.1 percent, compared to only 0.8 percent for the marginal Retail generic. Interactions to test for differential effects of competitors on originator vs. generic prices were generally not significant. The separate channel regressions (Table III) confirm that the marginal effect of a Tendering generic on originator prices is -12.6 percent in the pharmacy channel, whereas the marginal effect of a Retail generic is only -0.12 percent.

In MLIC countries, having at least one generic competitor raises prices by 27 percent, consistent with segmentation pricing by originators when faced with lower quality competitors. Prices are 29 percent higher if the originator is present in the market,

[18] Diagnostics to identify influential observations (e.g., dffits) did flag a small fraction of observations beyond a threshold of $2\sqrt{p/n}$ where p is the number of estimated parameters and n is the number of observations. Regressions omitting these observations resulted in very similar coefficients to those reported in Table 3.
[19] The correlation between log PCI and the Gini for the MLIC countries is 0.51 for IMS countries, 0.27 for GPRM countries and 0.31 for all countries combined. Tests for restricted models do not support excluding the Gini and Gini missing flag for retail generic and originator regressions.

consistent with shadow pricing by generics. The MLIC separate channel regressions (Table III) show that the presence of the originator product is associated with 16.6 percent higher generic prices in the pharmacy channel; this effect is smaller but still positive (9.5 percent) in the GPRM channel.[20] Thus taken overall, this evidence suggests that in MLICs having multiple generic competitors in the pharmacy channel has at most a small negative effect, and possibly a positive effect on originator and other generic prices, consistent with models of uncertain quality in which generics compete on brand rather than price.

The channel-specific regressions for MLICs indicate that originator prices are positively related to number of originator substitutes in the pharmacy sector channel. These effects may reflect unmeasured factors, such as higher promotional spending and other forms of non-price competition in retail channels for more crowded therapeutic classes. These estimates may also be upward biased, if entry is endogenous and responds positively to price. Such endogeneity bias should not be significant for originators, because originators usually face one or two years of regulatory delay in getting approval of a new molecule. Generic entry also faces regulatory delay, but usually less than originators. Given the potential for upward biased estimates if entry is endogenous, a safe conclusion is that in MLICs additional originators in a class do not reduce prices, retail generics have at most minimal effects, but tendering generics have significant negative effects.

Tendering purchaser effects The channel-specific regressions (Table III) show significant differences in prices obtained by different procuring NGOs. Contrary to the common assertion that purchaser volume increases leverage, our results indicate that 2 of the 4 large purchasers (Global Fund and IDA) pay 22 and 19 percent higher prices for

[20] These are the exponentiated and variance-corrected values from the coefficients in Table 3.

generic drugs, respectively , than do the smaller purchasers (the omitted category). UNICEF pays 24 percent more for originator products than small do purchasers, but 6 percent less for generics (not statistically significant). These equations include drug fixed effects, to control for differences in drugs purchased by different purchasers. It is possible that these positive size differentials reflect intentional policies of large purchaser to pay prices sufficiently high to assure that multiple suppliers, including multinational originators, continue to bid in this market. These conclusions are tentative, because it is also possible that our controls (form indicators, DDD-corrected prices and molecule fixed effects) do not adequately control the relatively high share of pediatric formulations purchased by both IDA and UNICEF.[21]

Comprehensive anti-infective and cardiovascular class results

Table IV reports regression results for the entire ATC J class (anti-infectives) and C class (cardiovascular), for retail originators and generics, respectively, in the matched PCI range countries only. There is no procurement process for these categories, and hence no GPRM data are available. The dependent variable is log price per standard unit rather than log DDD-adjusted annual treatment price as we lacked DDD data for many drugs. We include formulation indicators to control for non-oral formulations. We exclude combination products from the full J-class and C-class analysis.

Income Income elasticities in both classes are significantly negative for originator drugs, whereas GINI coefficients are significantly positive. The significant correlation between log PCI and GINI coefficients for countries in this income range may

[21] Pediatric-specific DDDs were applied for clearly pediatric formulations, but some ambiguous cases remained.

make separate effects difficult to identify. In similar regressions for originators and generics combined for the entire range of countries rather than only the matched PCI range countries the income elasticity for J and C class pharmacy drugs is around 0.3 and the GINI is insignificant.[22]

Each additional generic competitor reduces generic prices by 0.4% and originator prices by 0.2% in both the J and C classes. Competition from other originator therapeutic substitutes reduces originator prices only for cardiovascular drugs. Thus overall the conclusions appear to be robust across classes, that the (at best) weak relation between drug prices and PCI implies that prices are least affordable, relative to income, in low income countries. In these countries, despite multiple competitors, price competition does not appear to be strong in retail channels.

Conclusions

This evidence on prices for both originator and generic drugs suggests that income effects and competition alone are unlikely to achieve affordable prices in low income countries, given traditional distribution and institutional environments. Drug price elasticities with respect to mean PCI are positive but small – around 0.2 – 0.4 for originators across all countries but insignificant or negative in MLICs, implying that the poorest countries face the highest prices relative to their PCI. Generics appear to pursue similar pricing strategies. Skewed income distributions appear to exacerbate high drug prices relative to PCI in MLICs. Competition from other originator drugs is not effective at reducing prices in retail channels in MLICs. Although generic prices are roughly 40 percent

[22] Regressions available.

below originator prices in MLICs, the fact that the marginal effect of an additional Retail generic competitor is only 0.8 percent or less suggests that this average generic price differential primarily reflects the lower and/or less certain quality of generics, not price competitiveness. The tendency for branded generic to compete on brand rather than price is found in high income countries with branded generics (Danzon and Furukawa, 2011). By contrast, an additional Tendering generic (a multinational generic supplier that has met quality standards and demonstrated ability to compete on price) reduces prices by 3.21 percent, or almost fourfold greater than an additional Retail generic.

The evidence from HIV/AIDS, TB and malaria drugs shows that procurement mechanisms lower originator and generic prices by 42 percent and 28 percent, respectively, compared to their retail pharmacy prices. These large procurement effects may reflect not only price-competitive tendering but also greater willingness of originators to grant discounts to a separate distribution channel that targets lower income customers and is less prone to price spillovers to other countries. Procurement also appears to reduce price because it attracts multinational generic suppliers that meet quality standards, have lower costs and are more price competitive than the local branded generics that sell only in retail channels.

Obviously the HIV/AIDS, TB and malaria drugs are a unique category of drugs, as reflected in their special donor funding and procurement arrangements. However, our analysis of pharmacy channel prices for the entire anti-infective and cardiovascular classes shows similar modest or even negative effects of income and competition.

This evidence suggests that although price-discrimination between MLICs countries could in theory be a welfare enhancing and profit-maximizing strategy for companies, this

incentive is undermined if income distributions are skewed and/or competition focuses on brand, rather than price, due to quality uncertainty of generics. Price discrimination within MLICs is unlikely to be feasible when drugs are sold to largely self-pay patients in retail pharmacy channels served by common distribution networks. Encouraging generics of uncertain quality has limited benefit in retail channels. A protected procurement channel, with informed buyers who require minimum quality standards, encourage generic price competition and target drugs to low income subgroups, can in theory achieve within-country differential pricing and thereby provide drugs at lower prices to targeted poor populations than is possible in the retail sector. Whether public hospitals, targeted insurance programs or other mechanisms might serve as such a protected channel for a broad range of drugs in at least some MLICs is an important question for future research. More generally, finding better mechanisms to enable differential pricing between and within low and middle income countries is an important challenge for firms and policymakers.

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Table I: Summary Statistics for retail (IMS) and tendered (GPRM) samples

	All Pooled Data		Matched Countries*		Matched Income Range**	
	mean	*stddev*	*mean*	*stddev*	*mean*	*stddev*
Retail (IMS) sample						
Log per capita income	9.76	1.00	8.24	0.65	8.25	0.64
Raw per capita income	24,318	14,082	4,610	2,812	4,644	2,802
Log annual treatment cost	7.01	1.81	5.45	1.57	5.43	1.58
Raw annual treatment cost	2,974	3,858	574	827	570	822
HIV prevalence per 100K	7.93	23.70	25.41	42.42	25.02	42.17
Gini coefficient	34.37	13.12	40.17	18.37	40.17	18.22
Gini coefficient missing flag	0.07	0.25	0.13	0.33	0.12	0.33
Tender gen. manufs. in class-ctry.	0.39	1.17	1.55	1.90	1.53	1.90
Retail gen. manufs. In class-ctry.	9.70	20.53	26.18	34.05	25.77	33.92
Originator manufs. in class-ctry.	2.72	1.62	3.01	1.87	2.97	1.88
Originator present in country	0.85	0.36	0.78	0.42	0.78	0.42
Generic present in country	0.50	0.50	0.82	0.38	0.82	0.38
Form = *Not* oral solid	0.17	0.38	0.16	0.37	0.16	0.37
Observations (n)†	5,790		1,468		1,493	
Tendered (GPRM) sample						
Log per capita income	7.70	0.98	8.10	0.79	8.08	0.61
Raw per capita income	3,467	3,451	4,360	2,990	3,867	2,291
Log annual treatment cost	5.14	1.42	5.35	1.37	5.18	1.46
Raw annual treatment cost	561	2,347	547	1,178	634	2,704
HIV prevalence per 100K	29.23	49.26	31.47	42.14	26.21	55.88
Gini coefficient	37.39	19.14	43.90	14.15	38.42	17.74
Gini coefficient missing flag	0.17	0.38	0.05	0.22	0.13	0.34
Tender gen. manufs. in class-ctry.	2.11	1.88	3.18	2.55	2.11	1.90
Retail gen. manufs. In class-ctry.	0.73	6.04	5.74	16.05	1.13	7.48
Originator manufs. in class-ctry.	1.18	1.12	2.19	1.44	1.23	1.19
Originator present in country	0.52	0.50	0.72	0.45	0.52	0.50
Generic present in country	0.79	0.41	0.85	0.35	0.79	0.40
Form = *Not* oral solid	0.24	0.43	0.25	0.43	0.25	0.43
Observations (n)†	5,905		754		3,821	

*Matched countries = Brazil, China, Algeria, Egypt, India, Indonesia, Morocco, Philippines, Thailand, South Africa, and French West Africa. French West Africa aggregates ten West African countries (Ivory Coast, Cameroon, Gabon, Senegal, Congo, Benin, Guinea, Togo, Mali, Burkina Faso).

**Matched range countries include all countries with per capita income range of the precisely matched countries by year (roughly $1K-$10K).

† Observations at the molecule-country-year-brand/generic-formulation level.

Table II: Effects of per capita income, competition, and other variables on HIV/AIDS, TB, and malaria drug prices

OLS regressions of log annual treatment price on log PCI and controls, 2004-2008 GPRM and IMS data)†

	All countries	Matched countries	PCI-range countries
IMS*GENERIC indicator‡	-0.512*** [0.111] *-40.4%*	-0.572** [0.224] *-45.0%*	-0.617*** [0.230] *-47.5%*
GPRM*BRAND indicator‡	-1.128*** [0.206] *-68.3%*	-0.612** [0.247] *-47.4%*	-0.513** [0.251] *-42.0%*
GPRM*GENERIC indicator‡	-1.760*** [0.212] *-83.2%*	-1.268*** [0.270] *-72.9%*	-1.284*** [0.250] *-73.2%*
Log per capita GNI (lnPCI)	0.269*** [0.0478]	-0.00905 [0.0506]	0.150*** [0.0484]
Gini coefficient	-0.0148*** [0.00500]	0.0404** [0.0133]	0.00238 [0.00433]
Gini missing indicator‡	0.135 [0.107] *13.8%*	0.0757 [0.126] *7.0%*	0.12 [0.0977] *12.2%*
HIV prev. (/100K)	-0.000893 [0.000776]	-0.0113*** [0.00296]	-0.00184** [0.000854]
Tender generic class count	-0.0719*** [0.0207]	-0.0515** [0.0209]	-0.0311** [0.0146]
Retail generic class count	-0.0110*** [0.00122]	-0.00869*** [0.00106]	-0.00820*** [0.00129]
Originator class count	0.0332 [0.0324]	0.0859* [0.0452]	0.0517*** [0.0185]
Originator molecule flag‡	0.316*** [0.0612] *36.9%*	0.261** [0.117] *28.9%*	0.261*** [0.0658] *29.5%*
Generic molecule flag‡	0.0494 [0.0877] *4.7%*	0.0224 [0.0988] *1.8%*	0.244*** [0.0833] *27.2%*
Non-oral solid‡	0.354*** [0.0675] *42.2%*	0.769*** [0.200] *111.5%*	0.272** [0.107] *30.5%*
Molecule and year fixed effects	X	X	X
Constant	4.983*** [0.544]	4.058*** [0.806]	4.450*** [0.508]
Observations	11695	2222	5314
R-squared	0.788	0.661	0.648

† Significance levels: ***=p<0.01, **=p<0.05, *=p<0.1. Robust standard errors adjusted for 37 clusters in country in brackets.

‡ Predicted linear effects for indicator variables including variance correction (see Kennedy 1981) reported in italics.

Table III: Channel and brand-specific estimates of effects of income, competition, and other variables on HIV/AIDS, TB, and malaria drug prices

OLS regressions of log annual treatment price on log PCI and controls, matched income country data, 2004-2008†

		IMS Generic	IMS Brand	GPRM Generic	GPRM Brand
Log per capita GNI		-0.621**	0.102	0.0476	0.325***
		[0.269]	[0.345]	[0.0321]	[0.0580]
Gini coefficient		0.0750**	0.0474**	-0.00153	-0.00324
		[0.0258]	[0.0159]	[0.00326]	[0.00580]
Gini coefficient missing indicator		-0.398	0.466	0.0773	0.0607
		[0.421]	[0.490]	[0.0594]	[0.131]
HIV prevalence per 1K		-0.0114	-0.0183***	0.00024	-0.00215***
		[0.00781]	[0.00332]	[0.000386]	[0.000871]
Competition measures	Tender generic class count	-0.0477	-0.126***	0.00324	-0.0265
		[0.0291]	[0.0350]	[0.00948]	[0.0159]
	Retail generic class count	-0.0124***	-0.0125***	0.0102	0.00962
		[0.00356]	[0.00193]	[0.00986]	[0.0144]
	Originator class count	-0.00757	0.142***	0.0075	-0.0155
		[0.0839]	[0.0378]	[0.0274]	[0.0308]
	Generic molecule flag		0.028		0.144**
			[0.113]		[0.0581]
	Originator molecule flag	0.156**		0.0915*	
		[0.0693]		[0.0473]	
	Non-oral solid flag	1.700***	1.431***	0.00866	-0.285***
		[0.307]	[0.226]	[0.0476]	[0.0746]
Supplier	Supplier: UNICEF			-0.0741	0.217**
				[0.0520]	[0.0862]
	Supplier: GlobalFund			0.202***	0.239**
				[0.0578]	[0.0920]
	Supplier: IDA			0.176***	0.408***
				[0.0516]	[0.105]
	Supplier: MissionPharma			0.124	-0.0977
				[0.0762]	[0.128]
Molecule and year fixed effects		X	X	X	X
Constant		6.852**	3.071	4.272***	3.780***
		[2.850]	[3.141]	[0.346]	[0.500]
Observations		741	719	3890	2088
R-squared		0.856	0.799	0.728	0.455

† Significance levels: ***=p<0.01, **=p<0.05, *=p<0.1. Robust standard errors adjusted for 37 clusters in country in brackets.

Table IV: Effects of per capita income, competition, and other factors on drug price, all ATC J and C-class drugs†

OLS regressions of log price per standard unit on log PCI and controls, matched income range countries, 2004-2008 IMS data)

	HIV/AIDS, malaria, & TB drugs		**Entire J-class (anti-infectives)**		**Entire C-class (cardiovascular)**	
	Generics	Originators	Generics	Originators	Generics	Originators
Log per capita GNI	-0.591*	0.126	-0.274	-0.944***	-0.269	-0.940***
	[0.272]	[0.341]	[0.303]	[0.160]	[0.287]	[0.125]
Gini coefficient	0.0738**	0.0502**	0.105**	0.135***	0.107***	0.139***
	[0.0259]	[0.0185]	[0.0340]	[0.0149]	[0.0333]	[0.0119]
Gini missing indicator	-0.54	0.145	-0.825	-2.052***	-0.804	-2.055***
	[0.393]	[0.583]	[0.533]	[0.260]	[0.512]	[0.215]
HIV prevalence per 1K	-0.0108	-0.0199***	-0.0191**	-0.0242***	-0.0192**	-0.0244***
	[0.00835]	[0.00288]	[0.00762]	[0.00266]	[0.00743]	[0.00207]
Generic class count	-0.0123***	-0.0134***	-0.00405***	-0.00227***	-0.00442***	-0.00203***
	[0.00331]	[0.00284]	[0.000846]	[0.000675]	[0.000966]	[0.000585]
Originator class count	0.00177	0.179***	0.00715	-0.0362	-0.0161	-0.0566**
	[0.0944]	[0.0541]	[0.0301]	[0.0290]	[0.0235]	[0.0232]
Originator mol. flag	0.165	N/A	-0.11	N/A	-0.0698	N/A
	[0.117]	N/A	[0.126]	N/A	[0.129]	N/A
Generic molecule flag	N/A	-0.0657	N/A	-0.113	0	-0.106
	N/A	[0.150]	N/A	[0.0921]	[0]	[0.0801]
Non-oral solid flag	1.685***	1.501***	0.689***	0.621***	-0.488**	-0.166
	[0.294]	[0.227]	[0.169]	[0.100]	[0.161]	[0.148]
OTC flag	1.057*	0.887	0.505	0.631***	0.513	0.774***
	[0.526]	[0.510]	[0.620]	[0.167]	[0.608]	[0.126]
Molecule and year FE	X	X	X	X	X	X
Constant	6.591*	2.722	-3.036	2.288*	-2.147	2.611***
	[3.004]	[2.935]	[2.828]	[1.090]	[2.668]	[0.715]
Observations	766	743	9207	4600	7597	3942
R-squared	0.847	0.773	0.764	0.804	0.76	0.793

†Significance levels: ***=p<0.01, **=p<0.05, *=p<0.1. Robust standard errors adjusted for 37 clusters in country in brackets.

Appendix Table I: Countries in IMS and matched samples

Countries in both IMS and GPRM data (Matched sample)	**Countries in IMS but not GPRM data** (*denotes country is in matched range sample)	**Countries in GPRM but not IMS data**‡ (*denotes country is in matched range sample)
Algeria	Australia	Moldova*
Brazil	Austria	Haiti
China	Belgium	Georgia*
Egypt	Canada	Nigeria
French West Africa†	Finland	Cambodia
India	France	Rwanda
Indonesia	Germany	Uganda
Morocco	Greece	Central African Republic
Philippines	Italy	Mozambique
South Africa	Japan	Sudan
Thailand	South Korea	Zambia
	Malaysia	Ethiopia
	Mexico	Kenya
	Netherlands	Peru*
	Poland	Tanzania
	Portugal	Liberia
	Saudi Arabia	Burundi
	Singapore	Namibia*
	Spain	Honduras*
	Sweden	El Salvador*
	Switzerland	Angola*
	Thailand	Nepal
	Tunisia*	Swaziland*
	United Kingdom	Dominican Republic*
	United States	Ukraine*
		Armenia*
		Malawi
		Nicaragua*
		Niger
		Vietnam*

† "French West Africa" is a population-weighted aggregate of ten West African countries (Ivory Coast, Cameroon, Gabon, Senegal, Congo, Benin, Guinea, Togo, Mali, Burkina Faso).

‡ There are a total of 96 countries in GPRM and not IMS, of which 53 are in the matched income range sample, 13 have greater per capita income than the matched income range sample, and 30 have lower per capita income than the matched income range sample. This table lists the thirty GPRM countries with the most drug-year observations. Asterisks denote those in the matched income range sample.

Appendix Table II: Effects of per capita income, competition, channel/brand interaction terms, and other variables on HIV/AIDS, TB, and malaria drug prices
OLS regressions of log annual treatment price on log PCI and controls, 2004-2008 data)†

	All countries	Matched countries	PCI-range countries
IMS*GENERIC indicator‡	-2.353** [1.032] *-94.4%*	-1.677 [2.039] *-97.7%*	-1.628 [2.029] *-97.5%*
GPRM*BRAND indicator‡	-0.044 [1.273] *-57.4%*	-3.074* [1.401] *-98.3%*	-3.829** [1.735] *-99.5%*
GPRM*GENERIC indicator‡	1.132 [1.194] *52.1%*	-2.129 [2.141] *-98.8%*	-2.28 [1.983] *-98.6%*
Log per capita GNI (lnPCI)	0.401*** [0.116]	-0.17 [0.195]	-0.0493 [0.221]
lnPCI* IMSGENERIC	0.200* [0.105]	0.133 [0.242]	0.122 [0.249]
lnPCI* GPRMBRAND	-0.111 [0.127]	0.294* [0.157]	0.400** [0.199]
lnPCI* GPRMGENERIC	-0.344*** [0.118]	0.1 [0.264]	0.115 [0.241]
Gini coefficient	-0.0106** [0.00499]	0.0432*** [0.0131]	0.00398 [0.00397]
Gini missing indicator‡	0.130 [0.127] *13.0%*	-0.0659 [0.213] *-8.5%*	0.0761 [0.0863] *7.5%*
HIV prev. (/100K)	-0.00124 [0.000771]	-0.0116*** [0.00305]	-0.00192** [0.000842]
Tender generic class count	-0.0542*** [0.0188]	-0.0479** [0.0212]	-0.0321** [0.0149]
Retail generic class count	-0.00563*** [0.00201]	-0.00910*** [0.00115]	-0.00877*** [0.00121]
Originator class count	0.0164 [0.0331]	0.0880* [0.0473]	0.0469** [0.0183]
Originator molecule flag‡	0.318*** [0.0568] *37.2%*	0.261** [0.115] *29.0%*	0.262*** [0.0729] *29.6%*
Generic molecule flag‡	0.0467 [0.0684] *4.5%*	0.00647 [0.0758] *0.4%*	0.236*** [0.0849] *26.2%*
Non-oral solid‡	0.355*** [0.0686] *42.3%*	0.776*** [0.200] *113.0%*	0.274** [0.108] *30.8%*
Molecule and year fixed effects	X	X	X
Constant	3.539*** [1.237]	5.296*** [1.650]	6.070*** [1.913]
Observations	11695	2222	5314
R-squared	0.797	0.663	0.651

† Significance levels: ***=p<0.01, **=p<0.05, *=p<0.1. Robust standard errors adjusted for 37 clusters in country in brackets.
‡ Implied effects for indicator variables including variance correction (see Kennedy 1981) reported in bottom line.