Does Price Reveal Poor-Quality Drugs?

Evidence from 17 countries

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Abstract

Focusing on 8 drug types on the WHO-approved medicine list, we constructed an original dataset of 899 drug samples from 17 low- and median-income countries and tested them for visual appearance, disintegration, and analyzed their ingredients by chromatography and spectrometry. Fifteen percent of the samples fail at least one test and can be considered substandard. After controlling for local factors, we find that failing drugs are priced 13.6-18.7% lower than non-failing drugs but the signaling effect of price is far from complete, especially for non-innovator brands. The look of the pharmacy, as assessed by our covert shoppers, is weakly correlated with the results of quality tests. These findings suggest that consumers are likely to suspect low quality from market price, non-innovator brand and the look of the pharmacy, but none of these signals can perfectly identify substandard and counterfeit drugs.

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I. Introduction

Poor-quality medicine is a global public health problem. Not only do counterfeit drugs prevail, some legitimate manufacturers make substandard drugs due to inappropriate production and some genuine drugs could degrade and become substandard through inappropriate distribution. According to the World Health Organization (WHO 2003), substandard and counterfeit drugs have been found in both developed and developing countries[1], accounting for more than 10% of the global medicines market and over US$32 billion in annual earnings. Even medicines sold for deadly diseases such as malaria are faked or poorly manufactured (Dondorp et al. 2004; WHO 2009). Poor-quality drugs are dangerous: they may be wrongly labeled, contain the wrong type of ingredient, formulate the active ingredients incorrectly, or be contaminated with pathogens, leading to ineffectiveness, direct harm, or even death (WHO 2003; 2010).

Surprisingly, there is little economic analysis on this topic although the policy efforts to stem the flow of counterfeit and substandard medicines have begun. One policy tool is to strengthen the enforcement of intellectual property (e.g. the Anti-Counterfeiting Trade Agreement) while others argue that trademark protection does not necessarily lead to better quality control and could hurt access to quality generic drugs (Oxfam 2011).[2]

From the economic point of view, the harm of substandard or counterfeit drugs depends on whether consumers can tell drug quality from direct or indirect information. If poor-quality drugs can always pretend to be of high quality, consumers are deceived and manufacturers are discouraged to produce high-quality in the long run (Grossman and Shapiro 1988a). Regulatory enforcement of trademarks and quality standards could curb the proliferation of poor-quality

1 In an operation targeting online sale of counterfeit and illegal medicines, the World Customs Organization seized 1,014,043 counterfeit pills worth approximately 2,598,163 US$ in one week of October 2010. The types of drugs seized (life-style drugs, antimalarials, sleeping pills, antibiotics, and heart medications, amongst others) show that the problem now affects all countries, developed and emerging.

2 There is academic evidence that better intellectual property protection is associated with more R&D investment in pharmaceuticals or related diseases (Pazderka 1999, Lanjouw and Cockburn 2001) but none of these studies consider substandard drugs.

drugs and reduce consumer fraud.[3] In contrast, a poor consumer may suspect low quality from the package or market cues, but still choose to purchase low price drugs in hope that low-price drugs will work sometimes and that is better than no treatment in expectation. In this case, the welfare consequence of a ban on low quality products is not so clear: on one hand, it may deprive the extremely poor of a treatment that sometimes works; on the other hand, consumer belief on the efficacy of substandard or counterfeit drugs is likely wrong and a misinformed choice could be worse than no purchase.

More importantly, the issue of poor-quality drugs is not independent of drug affordability. According to WHO (2008), over 50 surveys have shown that drug prices are high in many low- and middle-income countries, with some treatments requiring over 15 days' wages to purchase 30 day supply. Public policies – for example tariff reduction, price ceiling, and compulsory licensing of patented drugs – have tried to lower drug price, but buying potentially low-quality drugs is another way to fight against drug unaffordability, especially for the poor.

This paper provides the first empirical study on the economics of poor-quality drugs with an emphasis on (1) the prevalence of poor-quality drugs in association with local regulation, income and literacy rate, and (2) the extent to which consumers can infer the likelihood of poor quality from market price and appearance of pharmacy. Drawing insights from economic theories, we show that price and quality are fundamentally linked and the fight against poor-quality drugs cannot be isolated from drug affordability.

3 It is important to note that not all counterfeits will breach a trademark. A drug that claims to be Ciprofloxacin on the package but contains chalk is "falsified" but breaks no intellectual property rules since it does not infringe a competitor's trademark.

One reason for the limited literature on this topic is the lack of systematic data on poor quality medicines. To overcome this difficulty, we compiled original data on the price and quality of 899 drug samples across 17 developing and mid-income countries. In particular, our network of covert shoppers purchased 8 types of drugs from 185 private pharmacies and each collected drug sample went through three progressive tests ranging from visual inspection, disintegration and ingredient test, to Raman spectrometry test for the spectra of ingredients. We find that 15% of the drug samples fail the most stringent test (spectrometry).

It is more difficult to read consumers' mind on their knowledge of drug quality. According to Cockburn et al. (2005), many pharmaceutical companies and governments are reluctant to publicize the problem of substandard and counterfeit drugs, fearing that the publicity will prevent patients from taking genuine medicines. Under such secrecy, consumer knowledge of drug quality is limited to self-inspection, word-of-mouth, and market cues. It is often difficult if not impossible to tell poor-quality drugs from packaging. In our data, only 3% of drug samples fail the visual test. Full information may not be available after consumption either, because drug effectiveness varies from person to person and even authentic drugs may not work well if the patient does not follow doctor's instruction. However, consumers may not be completely in the dark either: some quality information may be inferred from a large number of idiosyncratic cases and tied to observable attributes such as price and distributional channels.

In our data, covert shoppers report their subjective assessment of whether the pharmacy looks “good” or “poor.” This assessment turns out to be correlated with our objective test results, but the correlation is low (with correlation coefficients ranging from 0.14 to 0.27 all with p-value<0.001). In comparison, drug price is another way to reveal drug quality. After controlling for drug type, local regulations, income and literacy rate, we find that drugs that fail the most stringent spectrometry test are priced 13.6-18.7% lower. The absolute price differential, on

average US$ 0.59 to 0.80 (per treatment course), could mean a big difference in local currencies. This suggests that buyers are likely to suspect low-quality when they pay less.

Why is there a demand for likely inferior medicines? One possibility is that patients derive benefit from them because some inferior drugs work or give the impression of working due to a placebo effect without being harmful. Ignorance of pharmacology is another reason: less educated patients might buy cheap medicines because they incorrectly believe that if expensive medicines treat one quickly cheap low-quality medicines just take longer to work. Alternatively, a family living in extreme poverty may decide that buying cheap medicines is a risk worth taking rather than not taking any medicine at all.

While poor-quality drugs are on average sold at a cheaper price, the price signal is far from complete. In our data, a large overlap exists between the price distributions of drugs that passed all the three quality tests and drugs that failed at least one test. Even after we control for drug type and local factors, the standard deviation of unexplained log price is 0.43 for non-failing drugs and 0.37 for failing drugs, both larger than the average 0.17 difference between the two groups. Further calculation suggests that drugs sold at 37% lower than the average price are only 9.51 percentage points more likely to fail any test (25.66% vs. 14.14%), while drugs sold at 36% higher than the average price are only 7.89 percentage points less likely to fail any test (6.25% vs. 14.14%). This suggests that the signaling effect of price is not as clear as the theory suggests: high price does not always guarantee high quality, and the existing price dispersion is likely to reflect market frictions in addition to the imperfect information of drug quality.

For example, some non-failing drugs in our data are not innovator brands and they are priced more than 30% lower than innovator brands. As a result, the prices of these presumably true “generics” (act identically to innovator brands) overlap significantly with those of failing drugs. The inability to distinguish generics from inferior copies leaves some patients with the

incorrect impression that all cheap drugs will probably work. Such impression will invite cheaters and further blur the signaling effect of price on quality. This raises a concern that isolated efforts to lower drug price (e.g. by encouraging genuine generics) could worsen the fight against counterfeit and substandard drugs because they undermine the role of price in signaling.

Even when price is able to signal quality, the difficulty to detect poor-quality products from genuine drugs (from non-price information) will push up the price of genuine drugs because the expected price premium from high quality must exceed the temptation to cut corners (Wolinsky 1983, Shapiro 1982). To support this argument, we find that the price discount for failing drugs is greater in countries with lower-than-median literacy rate (25.8%) than in those of higher literacy rate (12.3%), after controlling for local factors and city fixed effects. These findings highlight the fundamental links between price and quality, suggesting that public policies on price and quality must be coordinated.

The rest of the paper is organized as follows. In Section II, we review the relatively limited economic literature on counterfeit/substandard goods and a separate medical literature on the prevalence of poor-quality drugs. To help readers understand the economics behind theoretical predictions, we sketch the framework of Wolinsky (1983) and elaborate intuition behind each prediction. Section III describes the data. Section IV presents empirical models and results. Section VI concludes with a short discussion on our findings.

II. Literature

Economists have provided two theories about counterfeit goods depending on whether consumers know they are counterfeits before purchase (Grossman and Shapiro 1988a, 1988b). In the first theory, consumers are imperfectly informed of product quality and are unable to distinguish genuine products from counterfeits. In this case, counterfeits are sold at the same

price as authentic ones and a tougher policy against counterfeits enhances the total welfare, as consumers are less likely defrauded and honest producers are encouraged to produce quality products according to consumer demand (Grossman and Shapiro 1988a).

In other markets, however, it is not clear that information asymmetry exists. Consumers may buy a product that they know, or at least strongly suspect, to be a fake. The sale of fake Gucci handbags, Samsonite luggage, and Pierre Cardin accessories at a fraction of the cost of legitimate products and from outlets that are clearly not official distribution outlets suggests that the buyer is likely aware that she is not buying an authentic product. In a separate equilibrium, Grossman and Shapiro (1988b) show that consumers may choose to pay for counterfeits at a price lower than that of brand-names but higher than that of outside options because they enjoy the "status" conveyed by a counterfeit of brand name. Clearly, the psychological benefit of "status" does not apply to counterfeit drugs. However, Grossman and Shapiro's analysis can be extended to a patient buying a cheaper (and on average less efficacious) product as long as consumers believe such products can be effective with a positive probability. Why such a belief exists in equilibrium is another question that we will return to later on.

A broader theoretical literature considers low- and high-quality products even if the low-quality ones do not appear in the form of counterfeits. The analogy to our context is that some low quality drugs are substandard because legitimate manufacturers secretly cut corners or the well-manufactured drugs were inappropriately stored in the distribution process. Wolinsky (1983) shows a unique equilibrium where price completely reveals product quality although the exact quality chosen by a firm is known only to the firm itself initially. Below we recast Wolinsky's model in the context of substandard drugs. Interested readers should refer to Wolinsky (1983) for proof.

Consider a competitive drug market where the drug can be produced at different quality levels, all consumers prefer high to low quality, consumers differ in their willingness to pay for quality, and it is more costly to produce better quality. The actual quality of a drug is only known to the manufacturer, but some noisy information about drug quality such as the look of the package is available to some consumers with zero cost.

In this setting, it is possible to have a separate equilibrium where every price reveals a unique quality level but price must exceed the marginal cost of the signaled quality (except for the lowest quality). Otherwise, a manufacturer will have incentive to secretly cut quality and earn positive profit from cheating. Another necessary condition is that some consumers must have free access to some (imperfect) information about product quality other than price. When a firm charges price p but provides quality lower than what p signals in equilibrium, some consumers will shy away from the product because they have access to (imperfect) information of drug quality. The expected sales reduction discourages cheating as profit from honest production exceeds the potential profit of cheating. In other words, a signaling equilibrium must entail some negative consequence of cheating and consumer access to (imperfect) information is the mechanism to generate such negative consequence in Wolinsky's model. Other researchers have shown the same insight in different settings where the negative consequence of cheating may arise from lower reputation and fewer repeat sales (Shapiro 1982, Klein and Leffler 1981).

More importantly, the extent to which price exceeds marginal cost depends on the nature of consumer information. The poorer the information is, the less negative consequence there is for cheating. To counter the increased temptation to cheat, there must be higher profit from honest production, which implies higher mark up in the signaling equilibrium. Note that this insight is different from the observation that price is higher for higher quality when consumers have perfect information about product quality (without inference from price). In that case, price

difference only reflects cost difference (assuming the market is competitive and every one has equal access to production technology). But when consumer information is imperfect, price difference includes not only the cost difference but also the mark up difference, the latter of which increases with the imperfection of consumer information.

Above all, we have two theoretical predictions in a signaling equilibrium: (1) if consumers can infer product quality from price, price is a monotone function of quality; and (2) if price signals quality, the price difference between high and low qualities is smaller when consumers have access to better information about quality (besides price).

The reality of medicines is more complicated than theory. On the one hand, consumers may not be completely fooled because they may inspect the packaging of a drug and observe drug performance from personal experience or comments from friends and colleagues. This has already been captured in the above theory. On the other hand, price may not have a one-to-one correspondence to drug quality because many other reasons lead to price dispersion: search cost on price information alone may generate price dispersion (Stigler 1961), so do cost differences in production or distribution. To the extent that consumers cannot differentiate these confounding factors from price, they may form a rational belief that low price signals a high probability of low quality but low (high) price does not confirm low (high) quality. In this sense, providing quality information directly may complement the imperfect function of price signals, reduce the price-cost markup for authentic drugs, and facilitate consumer shopping for affordable medicines.

Another factor that is not considered in Wolinsky (1983) but may affect equilibrium price and quality is price control regulation. Atella, Bhattacharya and Carbonari (2008) examine drug price and quality outcomes under minimum quality standard and price control regulations. Although they do not consider counterfeit drugs and assume consumers have perfect information

about drug quality, their model predicts that price control reduces the price difference between high and low quality drugs, reduces the average drug quality available on the market, and weakens the positive correlation between price and quality. The second and third predictions are further confirmed using data from US and Italy. Like in Wolinsky (1983), these findings suggest that price and quality must be considered jointly in the drug market.

Existing medical studies focus on detecting the existence of substandard or counterfeit drugs. Given the difficulty in obtaining cooperation from local manufacturers and regulators, medical researchers often acquire a small sample of drugs and have them tested in the lab for quality (not trademark violation). For example, Dondorp et al. (2004) find that 53% of the 188 tablet packs purchased in Southeast Asia under the label of artesunate (an antimalarial drug) did not contain any artesunate. This quality problem, caused primarily by counterfeits, has increased significantly as compared to an earlier survey in the same area (38% of 108 drug samples, Newton et al. 2001). A more recent study (WHO 2009) acquired a larger sample of 491 antimalarials from Africa, adopted more comprehensive laboratory test procedures, and found high failure rates (10-54%) in all of the three sample countries.

Our data generation process follows the same rationale as in the medical literature, but we cover a broader range of drugs (8 including antimalarials, antibiotics and anti-mycobacterials), more source countries (17 including low- and mid-income ones), and three levels of quality tests. Greater regional variations in our data allow a better understanding as to how the presence of substandard and counterfeit drug associates with local regulations, income and literacy rate. We also restrict sampling to regular pharmacies excluding kiosks, bus vendors, or other types of drug sellers, so our estimate of failure rate is not directly comparable to that in the literature.

More importantly, our data include purchase price for 899 drug samples. These prices, combined with the objective lab test results on drug quality, help measure the extent to which

consumers can infer poor quality from cheap price. Although economic theories highlight the importance of market price in quality revelation, most existing studies on price-quality relationship are not specific to substandard or counterfeit drugs. Studies have shown that generic drugs are significantly cheaper than innovator brands but both types are authentic and bio-equivalent. For instance, Rizzo and Zeckhauser (2005) show that the first generic entrant is priced roughly 25% lower than its brand-name competitor. With subsequent generics entrants, the price of generics declines rapidly. However, brand-name producers do not necessarily lower their price in response to generic entry (Caves, Whinston and Hurwitz 1991; Grabowski and Vernon 1992; Frank and Salkever 1997). We are aware of three economic studies on counterfeits, but none of them focus on drugs. Based on a field experiment on eBay, Jin and Kato (2006) show that price and quality of sportscards can be negatively related if consumers are misled by high quality claims from low-quality sellers. It turned out that such high-claim cards are more likely to be counterfeits. Using a natural experiment in Chinese shoe market, Qian (2008; 2011) presents evidence that brands with less government protection differentiate their products from counterfeits by innovation, self-enforcement, vertical integration of downstream retailers, and subtle high-price signals.

Above all, we believe this paper is the first effort to study price-quality relationship for substandard and counterfeit drugs. Although policy makers have emphasized drug affordability and quality control separately, we show that these two dimensions are fundamentally linked and must be considered together.

III. Data

III.1 Data description

Over the past three years (2008-2010), we created networks of covert shoppers across cities and countries to help collect medicines.[4] In the study sample, medicines were procured by these local covert shoppers from 185 private pharmacies across 17 developing and mid-income countries. In particular, covert shoppers helped identify non-slum, middle class areas of their city and then took a random walk through those areas collecting samples from regular pharmacies excluding kiosks, bus vendors and other types of drug sellers where quality may be lower. On entering the pharmacy they asked the pharmacist or shop assistant to show them all the drugs sold to treat malaria, TB and bacterial infections, which they required for their family. The primary aim was to act as any other shopper[5], they therefore would listen to the advice of the pharmacist if it was given, and then randomly select products if a significant choice was available, buying three products (or fewer if only one or two were available) of each drug type in each location.[6] It is not uncommon for people to home treat without prescription, particularly in Africa where visiting a doctor is difficult and expensive, so ensuring a supply of antimalarials and antibiotics is normal. Following this protocol we believe we can compare one city with another but a more precise stratification would have required far greater knowledge of each city than we had.

Samplings took place in eleven African cities, three Indian cities, and five cities from mid-income countries. All of the eight drug types were from the World Health Organization's essential medicines list, including antimalarials, antibiotics and anti-mycobacterials (for the

4 Covert shoppers were selected based on their citizenship and knowledge of the cities chosen for study. All were compensated financially for helping collect samples.

5 There was not a single incidence where a pharmacist balked at the request, although it is of course possible they were suspicious and changed the products sold as a result. This implies that the failure rate found in our sample may be an underestimate of the actual failure rate.

6 Note that all the drugs were purchased without a prescription. In no case did the lack of a prescription prevent a drug sale. It is not clear whether there are laws requiring pharmacists to only sell drugs if a prescription is available in the sampled countries and cities. If there are such laws, they were not being followed by pharmacies or enforced by regulators.

treatment of tuberculosis).[7] With the exception of ciprofloxacin, a widely used antibiotic, no other drug was available in every location. Indeed, no antimalarials were available for purchase from the cities of Istanbul, Sao Paolo and Moscow. To ensure comparability, we bought the most standard formulations. All of the samples were tablets, most in blister packages, which are the easiest products to store and hence proliferate in emerging markets.[8]

All medicines were assessed in three types of tests. The first is a visual inspection of packaging and pills for correctness. The second type of tests, referred to as minilab tests, includes disintegration test for basic solubility and semi-quantitative thin-layer chromatography (TLC) for the presence and relative concentration of active ingredients. Both visual and minilab tests follow the Global Pharma Health Fund e.V. Minilab® protocol to identify substandard, degraded or counterfeit medicines.

The third type of test is a Raman spectrometry test for product authentication. Unlike the Minilab tests, which test for a specific attribute of a drug, a spectrometer provides a spectra of the entire treatment, including active ingredients, binding agents, dyes and other "excipients". The spectra can be compared against a known genuine version of the drug (like comparing fingerprints), or for analyzing the presence of specific ingredients, since each ingredient will likely have its own unique peak in the spectra. In this sense, it is more stringent than visual and minilab tests. All the tests were conducted with the Africa Fighting Malaria Minilab in the United Kingdom within 60 days of purchase.

7 Our aim was to pick essential drugs to combat serious infections and for diseases that are generally home treated in poor nations. It may be tempting to classify the eight drug types into the categories of acute or chronic drugs, but the distinction is not as easy as it seems. Malaria can be an acute condition, so is TB at the margin. Even if we could classify drugs by acute and chronic, it is not clear the difference is driven by acute versus chronic rather than some other attributes that differ across the eight drug types. For this reason, in the regression we use drug fixed effects as pure controls.

8 Many of the sampled drugs were imported, fewer were locally made. However, since some of them may be counterfeits, it is difficult to assess whether the labeled manufacturer source is the actual source.

Minilab tests were run in duplicate, with the generous assumption that the result more consistent with the reference was recorded. Quality control of the Minilab was performed daily prior to testing and consisted of performing TLC on Minilab-reference samples for the medicine classes being analyzed. In addition, Minilab reagents were quality control tested using reference samples when a new lot was introduced. The Minilab protocol awards medicines a "pass" for active ingredient (by TLC) if they have 80% or more of the labeled active ingredient(s). For fixed-dose combinations and sulphadoxine–pyrimethamine, a "pass" was awarded only if both active ingredients met this standard. The spectrometry tests were conducted with a Raman Spectrometer, to assess sample spectra against approved versions of the medicines, or at the least to check that the spectra of the active ingredient was present.

Some of these pharmacological data have been previously published in the literature (Bate et al. 2008, 2009a, 2009b, 2010a; Bate and Hess 2010). We do not have access to a compendial laboratory to assess all possible problems with medicines, hence some medicines could pass all of the above tests but still fail certain tests for solubility, permeability, product degradation, trace element contamination and pathogenic contamination. In other words if a drug fails one of the above tests it is definitely substandard, but if it passes it may be a higher quality, but still far from perfect medicine.

While we can establish whether the drug fails the tests or not, we cannot control for all the causes for why the drug may fail. As mentioned earlier, some products are counterfeits, but other causes for drug failures include quality control failures at a legitimate manufacturer or poor storage along the distribution chain. As such, our measure of drug failure may capture some cases of genuine drugs being identified as inferior products. That being said, by buying from real pharmacies instead of rural traders, kiosks or bus vendors, the sampled drugs were more

likely to be stored well. Another reason for storage not being a major issue for our sample is that a few well-known brands have no quality problems in any of the sample locations.[9]

The price information is less comprehensive than the quality data. Given the initial aim of the drug quality project was to establish quality, not all of the initial covert buyers (residents of each city) kept all of the receipts they received. In some instances receipts were illegible, and in some, they were simply not given by the medicine seller. Nevertheless price data are available for 899 drugs that went through all the quality tests. All prices are nominal and converted to US dollars according to the exchange rate as of the purchase date. For malaria and bacterial infections, price is reported per treatment pack, i.e. the dose presumed to cure the disease. For TB, price is reported for one uniform package. In the sampling process, we ensured that the packs procured were directly comparable in terms of treatment course. Since most cities only appear in our data for one year, city fixed effects will absorb most of the unobserved inflation. In addition to price and quality data, we also collect covert shoppers' subjective assessment of pharmacy appearance. By definition, this assessment is binary (good or poor) and subjective, but it provides direct evidence on consumer knowledge about product quality, which is an important factor in the signaling equilibrium as discussed above.

The main data described above are supplemented with data on local drug regulations, income and literacy rate. We believe local regulations are related to the price and cost of substandard and counterfeit drugs, while income and literacy rate are likely to affect both demand and cost of supply. Specifically, we obtain male and female adult literacy rates for ages 15 and over from the 2009 UNDP Human Development Report (UNDP 2009). They are country-specific and were compiled by UNESCO from censuses and surveys conducted between 1999 and 2007. We take the average of female and male literacy rates as they are highly correlated

[9] For example, one of the prominent brands of ACT for which we had 43 samples, showed no quality problems across locations.

(correlation coefficient = 0.89). One may argue that females are more likely to purchase drugs for the family and therefore female literacy rate may matter more than male literacy rate. Unfortunately, we do not have systematic measure on city-specific gender composition in drug purchase, but robustness checks find that using male, female or average literacy rate generates similar results. Literacy rate is available for all countries except for Ethiopia and Turkey.

The year- and city-specific GDP per capita data are denominated in US$ according to the exchange rate as of the purchase time. Another way to measure price and GDP per capita is by purchase power parity (PPP). Since the regression results are similar when we switch both measures to PPP, we only report results for which price and GDP are measured by exchange rate. The GDP per capita data were constructed using the 2008 city GDP estimates by PricewaterhouseCoopers (PWC 2009) and the 2009 and 2010 city population estimates from the 2009 revision of the UN's World Urbanization Prospects Report (UN 2009). We extended the 2008 GDP estimates to 2009 and 2010 using country level GDP growth rates from the International Monetary Fund (IMF). We extended the city population estimates backwards to 2008 using the UN report's 2005–2010 average population growth figure. For Istanbul, Lubumbashi, Kigali, Kampala, and Lusaka, city-level data was not available and we used country-level GDP per capita from the IMF World Economic Outlook Database as of October 2010 (IMF 2010). After these procedures, GDP per capita data are available for all countries.

We include four variables to capture local drug regulations: one is whether a drug has been registered in the purchase country or not. As shown in Oxfam (2011) and Bate et al. (2010b), drug registration is the most primitive regulation on legitimate drugs but its availability and implementation vary greatly across countries. Using drug registration data collected in Bate et al. (2010a and 2010b), we created a dummy variable equal to one if a drug has been registered in the purchase country at the purchase time. To the extent that drug registration represents

minimum quality requirement, the model of Atella, Bhattacharya and Carbonari (2008) predicts higher quality in countries with drug registration.

Some countries impose import tariff, sales taxes and other duties on ethical drugs, we borrow country-specific tax and duties from Bate, Tren and Urbach (2006). They are the average Taxes and Duties applied to Chapter 29 (active pharmaceutical ingredients) and Chapter 30 (finished pharmaceutical) products in 2006, by country. This variable is available for 10 countries, accounting for 735 of the 899 drug samples.[10] By definition, we expect higher price in countries with higher tariff and taxes but it is difficult to predict how these duties affect drug quality: on one hand, tariff and other duties may prompt government officials to take a closer look at the drugs; on the other hand, high price may invite counterfeit and substandard production.

The third regulatory variable is the number of months a person will be sentenced in prison if he is found guilty for counterfeiting drugs. We hand collected minimum and maximum penalty from the latest legal documents we can find in each country. For example, Egyptian IP Law sets down a number of penalties, including prison terms, for persons making or selling counterfeit goods. Monetary penalties range from $90 to $9,000, and terms of imprisonment range from 2 months to 3 years. Prison terms are mandatory only for repeat offenses.[11] In July 2008, the Indian cabinet approved a bill that increases fines for convicted counterfeiters from USD$250 to a minimum of USD$22,550 or three times the value of the drugs confiscated. They also increased the jail sentences for those convicted of counterfeiting from 5 years to a minimum of 10 years to life.[12] To accommodate diverse sentencing guidelines, monetary fines are coded as

9 Please refer to Bate, Tren and Urbach (2006) for detailed data description, as different types of tax duties come from different data sources.

10 Available at: http://www.notofakes.com/Resources/TravelAdvisory/Africa/Egypt/tabid/495/Default.aspx.

11 Available at: http://cdsco.nic.in/Guidelines%20under%20new%20penal%20provisions.pdf.

zero month and death penalty is coded as 360 months (30 years). We use maximum penalty in the data. This variable is available for 12 countries, accounting for 691 of the 899 drug samples. It is difficult to predict the correlation between penalty and the presence of poor-quality drugs: penalty should increase the negative consequence of counterfeit and substandard production, but penalty may be higher in response to serious problems in drug quality.

The last regulatory variable indicates the presence of direct price regulations such as price ceilings, mandatory retail price, and price guidance. We hand collected these regulations from each country's most recent government documents. Given the wide variety of price regulations, we define a binary variable equal to one if a country has adopted any price regulation on pharmaceuticals in the data collect year and zero otherwise. This variable is available for 10 of the 19 cities, accounting for 554 of the 899 observations. According to Atella, Bhattacharya and Carbonari (2008), price control regulations should reduce the average quality available in the market, reduce price difference between high and low qualities, and weaken the correlation between price and quality. Evidence has shown that price control regulation can lead to lower price and more drug consumption (Danzon 1997). However, Anis and Wen (1998) and Danzon and Chao (2000a, 2000b) suggest that price control regulation could raise market price in some cases.

III.2 Data Summary

Focusing on the 899 drug samples with both price and quality data, Table 1 provides a summary of key variables. Overall, the sample includes 79 observations on Artemsisin Combination Therapies (ACTs), 79 on Artemisinin monotherapies (Artmono), 69 on

Chloroquine (CQ), 185 on Ciprofloxacin, 146 on Isoniazid, 168 on Rifampicin, 78 on Sulphadoxine/Pyrimethamine (SP) and 119 on Erythromycin. The Appendix describes each type of drug, the dosages used, as well as the type of illness it treats. It also presents the definition of the three quality tests.

Visual appearance test is the first screening tool used to monitor for substandard and counterfeit products: one can spot spelling mistakes and other errors (wrong fonts, inks, pagination etc.) and where possible compare with an example of a genuine version. Nearly 97 percent of the drugs passed the visual test. Approximately 89 percent of drugs passed the minilab (disintegration and chromatography) tests, and 85 percent passed the spectrometry test. The three tests are progressive: 29 of the 31 samples that fail the visual test also fail the minilab tests; and all the drugs that fail the minlab tests fail the spectrometry test.

In short, we have approximately 15 percent of sampled drugs that failed the most stringent spectrometry test. This number approximates common perceptions about the percent of fake drugs circulating in the market (for instance, see Cockburn and Newton, 2005), but is lower than many studies for the worst areas of Africa and Southeast Asia, perhaps indicating our focus on regular pharmacies which tend to provide better quality than other vendors. The average drug price for our sample was $4.26 with a minimum value of .078 (for CQ) and a maximum of $48.9 (for ciprofloxacin).

Conditional on data availability, approximately 89 percent of the drugs were registered in the country in which they were sold, the average adult literacy rate is 81 percent, the length of the penalty for counterfeiting is 233 months, and the total tariffs and taxes are on average 12 percent. Unlike previous medical studies on a specific part of the world, our data cover a wide range of GDP per capita, from US$ 193.79 in Lubumbashi, Congo (2010) to US$ 19208.18 in Moscow, Russia (2010).

Table 2 provides a slightly more disaggregated look at the data. It shows for each city and each year, the average pass rate of drugs for different types of test. For instance, the highest pass rates for drugs were in Istanbul in 2010 where 35 drugs passed all tests successfully and Sao Paolo in 2010, with 32 drugs passing both visual and minilab tests and 97 percent passing the spectrometry result. The lowest pass rates were for Lubumbashi in 2010 where only 60 percent of the drugs passed the spectrometry test but in this case only 10 drugs were sampled. The lowest pass rate for a reasonable size sample was from Nairobi, where only 70 percent passed the spectrometry test in the 2010 sample.

Table 2 also shows the unusual structure of our data. While we observe most drugs and accordingly their prices in multiple years, most cities from which the samples are taken are only observed in a single year. The only exceptions are Delhi (observed in 2008 and 2010) and Nairobi (observed in 2009 and 2010). India is the only country from which we sampled more than one city.[13] This structure suggests that the sample is largely a pooled cross-section. If we control for city fixed effects, the effect of GDP per capita, literacy rate and local regulations will only be identified by variations within Delhi and Nairobi.

In addition to countries and cities, the data identify 185 unique pharmacies, each of which corresponds to at least two types of drugs. This structure allows us to control for unobserved pharmacy attributes by pharmacy fixed effects. Moreover, every covert shopper reported whether he/she assessed the look of the pharmacy "good" or "poor". This subjective opinion will help us measure the extent to which the "look" of a pharmacy signals drug quality to a cautious consumer. If consumers infer drug quality from the look of the pharmacies and a better-looking pharmacy is more likely to charge a higher price, a regression not accounting for pharmacy

12 To account for within-India variation, we obtain GDP data at the state level (higher than a city).

identity may mistakenly attribute the signaling effect to price. Inversely, if price remains significantly correlated with quality after we control for pharmacy fixed effects or shopper assessment, it is clear that price has a separate signaling effect in addition to the look or other attributes of pharmacies. The degree to which covert shoppers' subjective assessment predicts the actual lab results will also highlight the nature of consumer information as discussed in the theoretical literature.

Table 3 shows variable averages when we split the sample into failing and non-failing drugs, where failing is defined as failing any of the three tests. The most interesting observation is the difference in drug prices. The average price in the non-failing sample was more than 75% higher than the average price in the failing sample. The regression results in the next section will further confirm that the price difference remains statistically significant when we control for local regulations, income, literacy rate, city fixed effects or even pharmacy fixed effects. Other interesting results from the comparison are higher degree of product registration, higher fraction of innovator brands and better pharmacy assessment for non-failing drugs. Moreover, non-failing drugs are more likely to appear in countries with higher adult literacy rates, higher income levels and price regulations.

Figure 1 plots the kernel densities of log(price) for failing and non-failing drugs. Consistent with Table 3, the average price of non-failing drugs is higher than that of failing drugs, but both distributions are dispersed and have a large overlap with each other. This suggests that any signaling effect that price has on drug quality may be far from complete. We will test this more rigorously in Section IV.

IV. Empirical Analysis

Our empirical analysis consists of three parts: first, we show how local drug regulations, income and literacy rate correlate with whether a sample drug fails any quality test. This does not represent any causal relationship but could be informative to policy makers given the on-going debate on anti-counterfeit policies. The second part of the analysis focuses on price-quality relationship. To test the two predictions shown in Section II, we examine whether failing drugs are on average sold at lower prices than non-failing drugs. We also compare this price difference to the unexplained price variations, and test whether the difference in average price varies by adult literacy. The last part of this section examines whether shopper's subjective assessment on the look of pharmacies correlates with our quality test results and whether the price difference between high and low quality drugs is driven by the look of pharmacies instead of the true signaling effect of price.

IV.1 The prevalence of poor-quality drugs

Denoting i as a specific drug sample, d as drug type , c as city, and t as year, we run the following probit regression:

$$PASS_{idct} = 1$$

$$if \quad \alpha_d + \alpha_t + [\alpha_c] + \beta_1 GDPPC_{ct} + \beta_2 LiterRate_{ct} + \beta_3 Innovator_{idct}$$

$$+\beta_4 ProdRegist_{dct} + \beta_5 maxPen_{ct} + \beta_6 totalTax_{ct} + \beta_7 PriceReg_c + \varepsilon_{idct} > 0$$

where

$PASS =$ a dummy equal to one if sample i passes a specific quality test,

α_d = drug type fixed effects, total 8 dummies,

α_c = city fixed effects, total 19 dummies,

α_t = year fixed effects, total 3 dummies[14],

$logGDPPC$ = log (GDP per capita), in US$,

$LiterRate$ = adult literacy rate in percentage points,

$ProdRegist$ = a dummy equal to one if the drug that sample i intends to be has been registered in the purchase country,

$maxPen$ = max # of months in prison if caught counterfeiting drugs,

$totalTax$ = total tariff and tax for the drug that sample i intends to be, in percentage points.

$innovator$ = 1 if the drug intends to be an innovator brand,

$PriceReg$ =. 1 if the country has price regulations on pharmaceuticals in the study year.

In theory, stricter regulations on drug quality should raise the cost of substandard or counterfeit production, thus increasing the probability that our drug samples pass the quality tests. This implies $\beta_4 > 0,\ \beta_5 > 0$. Predications on β_3, β_6 and β_7 are less clear: high import tariffs, no price regulation and the status of innovator brands may imply higher drug price thus inviting counterfeits, but it is also likely that innovator brand holders devote more efforts to brand protection by hiring investigators, pursuing counterfeiters and making the package harder to imitate. It is also possible that price regulations limit the range of mark up (i.e. price – cost) thus reducing the potential reward for high quality drugs which implies more drug failures.

Table 4 reports four sets of results for the above probit regression: Column (1) focuses on whether a drug sample passes the visual appearance test, Column (2) on the combined Minilab tests (disintegration and chromatography), Column (3) on the spectrometry test; and Column (4) adds city fixed effects to Column (3). In theory, we could include pharmacy fixed effects but we

[14] Including all three full sets of fixed effects will create collinearity. Stata-implemented regressions will automatically drop two dummies in two of the three sets to avoid collinearity problem.

choose not to because pharmacy identity predicts many outcomes perfectly which leaves the estimation sample much smaller than that without pharmacy fixed effects. Note that failing any of the three tests is equivalent to failing the spectrometry test because that is the most stringent one. All results are presented as marginal effects, with robust standard errors clustered by city.

Across all columns, it is clear that registered drugs are more likely to pass any test. Moreover, drugs of innovator brands are more likely to pass minilab and spectrometry tests, and drugs with higher taxes and duties are more likely to fail these two tests. The correlations between test results and price regulations are less clear: the presence of price regulations tends to be associated with lower passing rate for visual appearance but higher passing rates for the other tests. Maximum penalty for counterfeiting drugs is significantly correlated with minilab and spectrometry tests but with a counterintuitive negative sign. This reflects the possibility that countries with severe counterfeit problems may adopt harsher penalties. Note that registered drugs and innovator brands continue to be positively related to passing the tests even after we add city fixed effects, as they are country-drug-year specific. The other regulatory variables (taxes, maximum penalty, price regulations) drop off Column (4) because they only vary by city.

Compared to Table 3, GDP per capita is not significantly correlated with test results (except for Column 4 which is identified from variations within Delhi and Nairobi) but countries with higher adult literacy rates tend to pass the tests more.

Above all, the most robust result from Table 4 is that both product registration and innovator brands are strongly correlated with better drug quality.

IV.2 Price-Quality Relationship

We examine price-quality relationship in the following specification:

$$logDrugprice_{idct}$$
$$= \alpha_d + \alpha_t + [\alpha_c] + [\alpha_s] + \beta FailAnyTest_{idct} + \gamma_1 GDPPC_{ct}$$
$$+ \gamma_2 LiterRate_{ct} + \gamma_3 Innovator_{idct} + \gamma_4 ProdRegist_{dct} + \gamma_5 maxPen_c$$
$$+ \gamma_6 totalTax_c + \gamma_7 PriceReg_c + \epsilon_{idct}$$

where

α_s = pharmacy fixed effects,

$FailAnyTest = 1$ if sample i fails any of the three tests,

and the other variables are described above. We use log of drug price instead of price itself as the dependent variable, because drug price is highly skewed and the distribution of log price is much closer to normal distributions as shown in Figure 1. If price provides an effective signal of whether a drug passes any quality test, we expect $\beta < 0$. Table 5 reports three sets of OLS results, with progressive addition of city fixed effects in column (2) and pharmacy fixed effects in column (3). All regressions allow robust standard errors clustered by city.

As expected, drugs are more expensive if consumers are richer or better educated, or if the drug is of innovator brand, registered, subject to high taxes and duties, and not directly regulated in price. Nevertheless, drugs that fail at least one of our quality tests are priced 21.4% lower in Column (1) and 13.6-18.7% lower (which corresponds to US$0.59-0.80) after the addition of city fixed effects or pharmacy fixed effects. This suggests that unobservable attributes such as city-specific regulation enforcement or pharmacy service do not explain most of the price discount for poor-quality drugs. In other words, consumers could have suspected lower quality from lower price.

Suppose the 13.6-18.7% price discount does signal poor quality drugs, how effective is the signal? This will depend on how drug price varies by other factors. These factors are likely in our error term as we cannot control for all the information that a consumer may observe in the

local market. In light of this, we use an iterated general least square (GLS) procedure to estimate the standard error of the unexplained log price variations for both failing and non-failing drugs separately. The estimates are reported in the bottom row of Table 5.[15]

Before we add city or pharmacy fixed effects, the standard error of unexplained log price variations is 0.43 for non-failing drugs and 0.37 for failing drugs, both much bigger than the 0.136-0.187 difference in the average log price between the two groups. While city heterogeneity and pharmacy heterogeneity are able to reduce the unexplained log price variations, the remaining variations are still large relative to the average price difference.

Figures 2-4 plot the kernel density of log price of non-failing and failing drugs after we exclude the price variations explained by the regressions in Table 5. The average log price of non-failing drugs is normalized as zero. All the three sets of comparisons (no city fixed effects, with city fixed effects, and with pharmacy fixed effects) show a huge overlap in the two price distributions. This suggests that the 13.6-18.7% difference in average price, though statistically significant, is not enough to ensure that consumers always infer poor quality from lower price. In fact, if we use the first set of log price distributions (i.e. no city fixed effects) to compute the probability of a drug failing any test by brackets of price, we find that drugs sold at 37% lower than the average price are only 9.51 percentage points (or 81%) more likely to fail any test (25.66% vs. 14.14%), while drugs sold at 36% higher than the average price are only 7.89 percentage points (55.8%) less likely to fail any test (6.25% vs. 14.14%).

Figures 5-6 follow the logic of Figures 2-3 (without and with city fixed effects) but we separate the price distributions of non-failing drugs into innovator brands and non-innovator brands. Assuming non-failing non-innovator brands are true generics, it is clear that the price

[15] Because GLS assumes the variance of error is the same conditional on failing on non-failing drugs, the estimated coefficients are not identical to what we reported in Table 5. However, all coefficients only differ in the third decimal points and there is no change in the statistical significance.

signal (on drug quality) is noisier for generics. The coefficient of innovator brands as reported in Table 5 indicates that innovator brands are on average 33.6-37.1% more expensive than generics. Combined with the facts that innovator brands have a tighter price distribution and are less likely to fail any test, this suggests that either the high price (hence higher future profit from high quality) discourages innovators from cheating or the innovators have more resources to seek self-policing and government protection.

Above all, we show that drugs that fail at least one of the quality tests are priced 13.6-18.7% lower on average, however the price dispersion is so large that consumers cannot ensure high quality by high price alone. In the strictest form, this rejects the first prediction as described in Section II. Now we turn to test the second prediction that in a signaling equilibrium the price difference between low- and high-quality drugs should increase with the imperfection of quality information that consumers have free access to in the local market (in addition to price).

Empirically, it is difficult to measure consumer access to quality information, so we search for rough proxies. To the extent that a literate consumer can at least read labels on a drug package, one may argue that consumers in a city with higher literacy rates have better ability to identify poor quality drugs. In light of this, Table 6 presents two sets of results: in the first two columns, we estimate two separate coefficients of failing any test depending on whether the adult literacy rate is below 67.5% (sample median); in the remaining four columns, we split the sample by above- or below-median literacy rate and rerun the price specification for the two subsamples separately. We report results with and without city fixed effects for robustness check.

As expected from the theory, Table 6 shows that the price discount for failing drugs is larger in low-literacy cities (25.3-27.8%) than in high-literacy cities (12.3-16.0%). Moreover, results in Columns (1) and (2) suggest that the average discount we have seen in Table 5 for the full sample is driven by the deep discount in low-literacy cities. This finding is largely consistent

with the theoretical argument that more information friction on the consumer side pushes up the mark up for high-quality drugs, which in turn makes good-quality drugs less affordable to consumers. When we repeat the above exercise for the observations with higher-than-median GDP per capita and the rest of the sample, we find that the discount difference between the high and low GDP groups is much smaller (20.3% in high GDP cities and 22.1% in low GDP cities). While we should be cautious in interpreting income versus literacy in our small sample of cities (the two are correlated), the above results suggest that the affordability of legitimate drugs is more likely tied with drug quality through consumer ability to detect bad quality than with GDP levels per se.

IV.3 Can consumers tell poor-quality drugs from the look of the pharmacy?

Evidence presented so far shows that poor-quality drugs are sold at significantly lower prices on average but the signaling effect of price is far from complete. A related question is whether consumers can infer drug quality from other market cues. One candidate is the type of distribution channels, as some brand-name manufacturers in other contexts have used downstream distribution outlets to fight against counterfeits (Qian 2008; 2010). The control of pharmacy fixed effects in Table 5 confirms that average price remains significantly lower for failing drugs no matter what inference a typical consumer could draw from the look of a pharmacy. However, pharmacy fixed effects could capture many unobservables in addition to consumer perception of a pharmacy, so it is still interesting to examine the perceived look of pharmacies explicitly.

Our data includes a binary variable indicating whether the covert shopper perceived the pharmacy as "good" or "poor." This measure is imperfect, as different shoppers may have different definitions of "good" looking pharmacies. Nevertheless, it is the closest measure to

consumer perception. Table 7 shows the piece-wise correlations between shopper assessment of pharmacy and the results of our quality tests. While shopper assessment is significantly and positively correlated with each of the three test outcomes, the correlations are quite low: 0.14 with visual test, 0.27 with minilab test, and 0.24 with spectrometry test. In contrast, the correlations within the three test results are much higher (0.44 to 0.82).

Table 8 reruns the above two specifications with shopper assessment of good looking pharmacies either as the dependent variable (Columns 1-2) or as an additional right hand side variable in the test result regression (Columns 3-4) and the log price regression (Columns 5-7). As before, we add city and pharmacy fixed effects in the price regression but only use city fixed effects for the determination of shopper assessment or test results due to few variations within pharmacy.[16]

In comparison with Table 4, Columns (1) to (2) of Table 8 show that shopper assessment is more closely related to literacy rate and GDP per capita than our objective measures of drug quality. This could reflect consumer trust in legal enforcement or the market in general. In the prediction of whether a drug sample passes all three tests (which is equivalent to passing the spectrometry test), we find that shopper assessment has a marginally significant positive effect with p-value between 0.1 and 0.05. This is consistent with the weak correlations between shopper assessment and test results as shown in Table 7. In the log price regressions, we continue to find significant price discount for failing drugs (13.8-17.1%), which suggests that the signaling effect of price is not confounded by consumer inference from the look of pharmacies. Nevertheless, shopper assessment is also positively correlated with drug price (Columns 5-6),

[16] Only 9 observations show variations of shopper assessment within a pharmacy. This happens if different covert shoppers bought from the same pharmacy or the same shopper had different views about the pharmacy if he/she bought drugs at different times.

suggesting that shopper assessment contains some useful information. The negative coefficient on shopper assessment in Column (7) is driven by the very few observations that show variations in shopper assessment within a specific pharmacy.

Finally, we would like to mention a number of robustness checks we have done but not reported in tables. One is measuring drug price and GDP per capita by purchase power parity (PPP) instead of exchange rate. The PPP measures are higher in absolute values, but regression results hardly change because coefficients are identified from relative comparison across observations. Another concern is about missing values in some control variables (mostly the tax, penalty and price regulations). The reported regressions include dummy variables indicating missing values for each independent variable with missing values. Alternatively, we have rerun the price regression (1) using observations with no missing value in any variable (resulting in a sample of 463 observations), or (2) excluding the variables with significant numbers of missing values and then conditional on no missing values in other variables (resulting in a sample of 821 observations). In both cases, we find the estimate of price discount for failing drugs (20.64% and 25.42%) similar to what is reported in Table 5 Column 1 (21.4%).[17] The third concern is whether female literacy rate is better than average literacy rate because women may be more likely to purchase drugs for their families. To address this concern, we have rerun the price regression with female literacy rate, male literacy rate, or both on the right hand side. In all cases, the coefficient on whether a drug fails any test is similar to that using average literacy rate (-0.193, -0.204, -0.225 versus -0.214 in Table 5 Column 1).

We also split the sample according to whether female literacy rate is above or below sample median. Similar to the results of Table 6, we find the price discount for failing drugs is much higher in low-literacy cities (20.31%) than in high-literacy cities (16.7%).

[17] Note that regressions with city or pharmacy fixed effects are not sensitive to missing values because most variables with missing values are city or country specific.

V. Conclusion

Overall, this paper uses a hand-collected data set to examine the problem of poor-quality drugs. We have five main findings: first, 15% of the collected drug samples fail at least one quality test and the failure is most significantly correlated with whether the drug tends to be an innovator brand and whether it is registered with local authority. Second, drugs that fail at least one quality test are priced on average 13.6-18.7% lower. Though statistically significant, this price difference is small relative to the unexplained variations in price, suggesting that the signaling effect of price is likely incomplete. Third, the price signaling effect is especially noisy for generics. Innovator brand is a good signal itself, as drugs with innovator brands are more likely to pass the tests, charge much higher price (30%+), and have a tighter price distribution. Fourth, price difference between failing and non-failing drugs is greater and most conspicuous in countries with lower-than-median literacy rate. Fifth, our covert shoppers are able to extract meaningful information from the look of pharmacies, but their subjective assessment is noisy and does not explain the signaling effect of price.

These findings are largely consistent with the theoretical insights that price could reveal quality and in such a revealing equilibrium the mark up on high quality products must be greater if consumers have more difficulty detecting quality problems from non-price information. However, the price-quality relationship found in our data is not as clean as the theory predicts, especially for drugs with non-innovator brands. While the high price of innovator brands motivate innovators to keep the reputation of good quality, this incentive is reduced for more affordable generic drugs. Less profit also implies fewer resources for generic manufacturers to engage in self-policing or lobby for government protection.

More generally, our work reveals a tension between drug affordability and the fight against substandard and counterfeit drugs. The 13.6-18.7% lower price for failing drugs, as well as the information contained in innovator brand and pharmacy appearance, suggests that consumers are likely to suspect lower quality when they pay less. Why do they choose to buy drugs that are likely to be of lower quality? One reason is poverty: in our data, the price differential between failing and non-failing drugs (controlling for other factors) is about $0.59-0.80, which could be substantial for a country like India where more than 40 percent of the population lives on less than $1 a day. Severe poverty, plus ignorance on the harm of poor-quality drugs, could foster demand for counterfeit and substandard drugs.

Unfortunately, public policies that aim to lower drug price may distort the price mechanism to sort out high quality drugs. In our data, failing drugs and non-failing generics overlap greatly in price, making it difficult to identify failing drugs based on price. Moreover, the existence of low-price true generics leads consumers to believe that cheap drugs work often, which could invite the entry of counterfeits and encourages legitimate producers to cut corners.

We argue that a policy in favor of generics (over innovator brands) must be accompanied by better regulation or information about product quality. This can be achieved by tighter registration requirement, stricter law enforcement against non-registered drugs, more frequent sampling and testing of existing drugs, a more transparent information system to report and track substandard manufacturers, and better consumer education on ways to identify poor drug quality. While medical researchers and non-profit organizations have tried to fulfill these functions, local regulators can have more authority and cost advantage to perform them. For example, local drug regulators can periodically test random drug samples and de-register those found to be of poor quality. They can also blacklist counterfeit manufacturers and prosecute them for legal penalty.

When consumers are equipped with better quality information, price will play a lesser role of signaling and quality drugs will become more affordable.

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Figure 1: Raw distributions of log (drug price) for failing and non-failing drugs

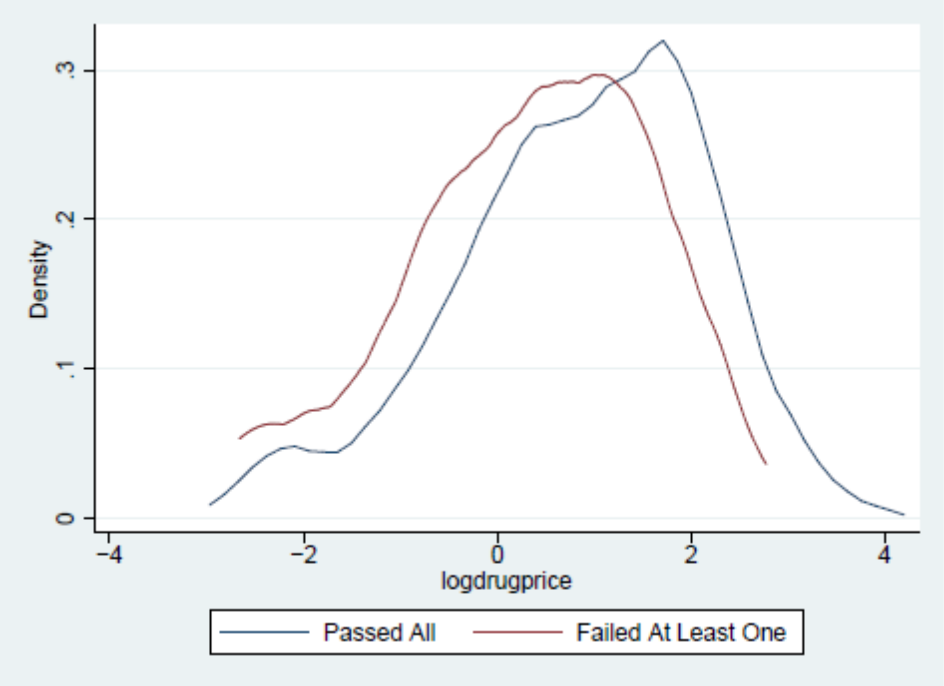

Figure 2: Distributions of log (drug price) for failing and non-failing drugs, after controlling for local regulations, income and literacy rate (without city fixed effects)

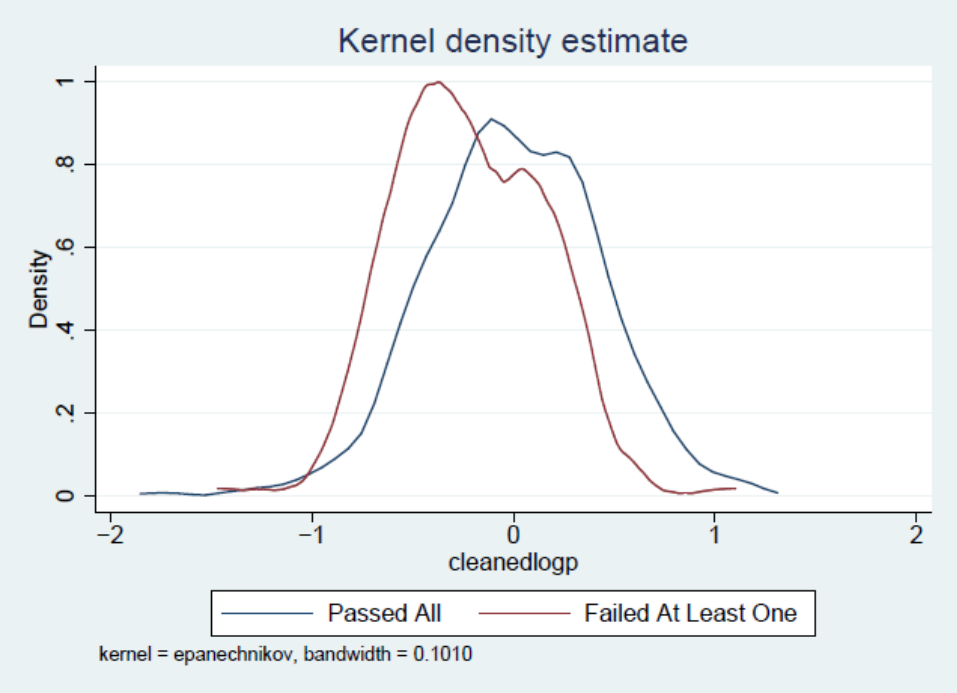

Figure 3: Distributions of log (drug price) for failing and non-failing drugs, after controlling for local regulations, income and literacy rate (with city fixed effects)

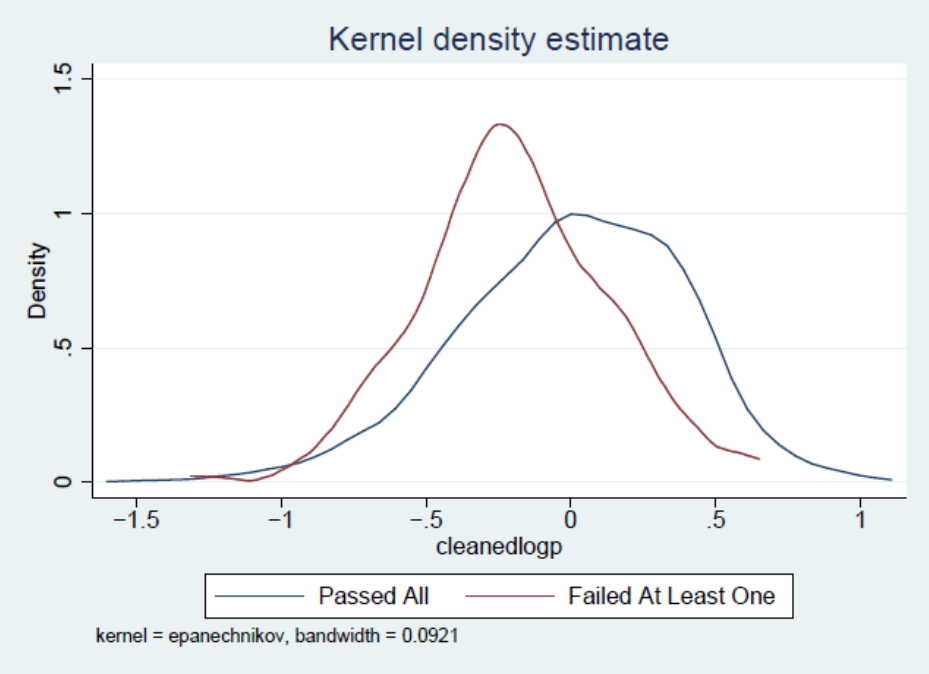

Figure 4: Distributions of log (drug price) for failing and non-failing drugs, after controlling for local regulations, income and literacy rate (with pharmacy fixed effects)

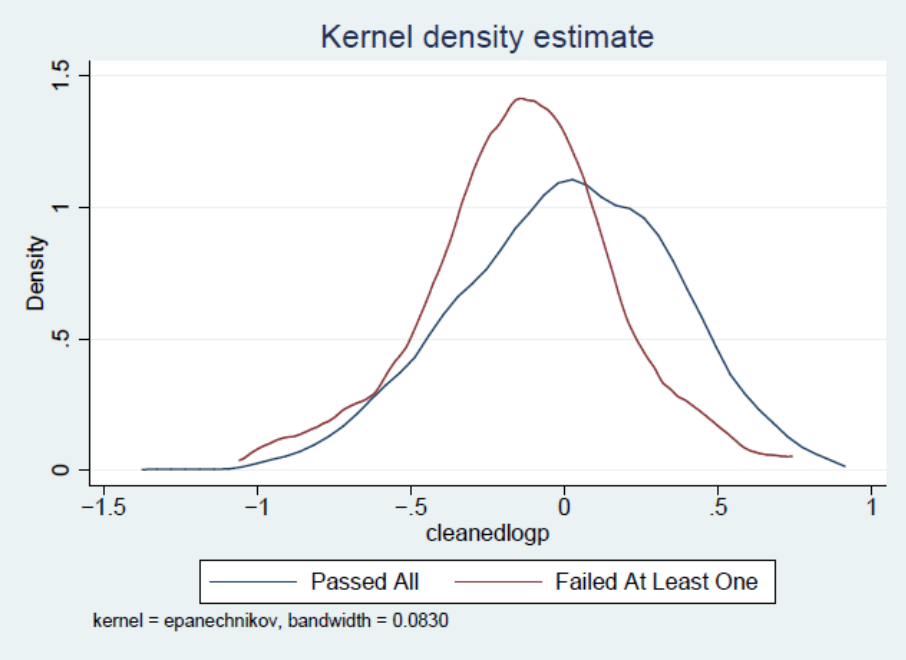

Figure 5: Distributions of log (drug price) for failing drugs, non-failing innovator brands, and non-failing generics, after controlling for local regulations, income and literacy rate (without city fixed effects)

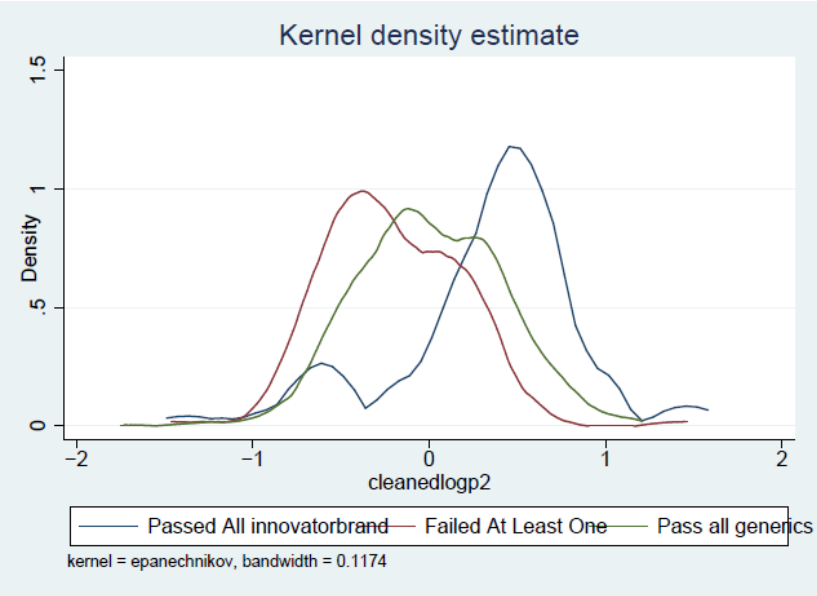

Figure 6: Distributions of log (drug price) for failing drugs, non-failing innovator brands, and non-failing generics, after controlling for local regulations, income and literacy rate (with city fixed effects)

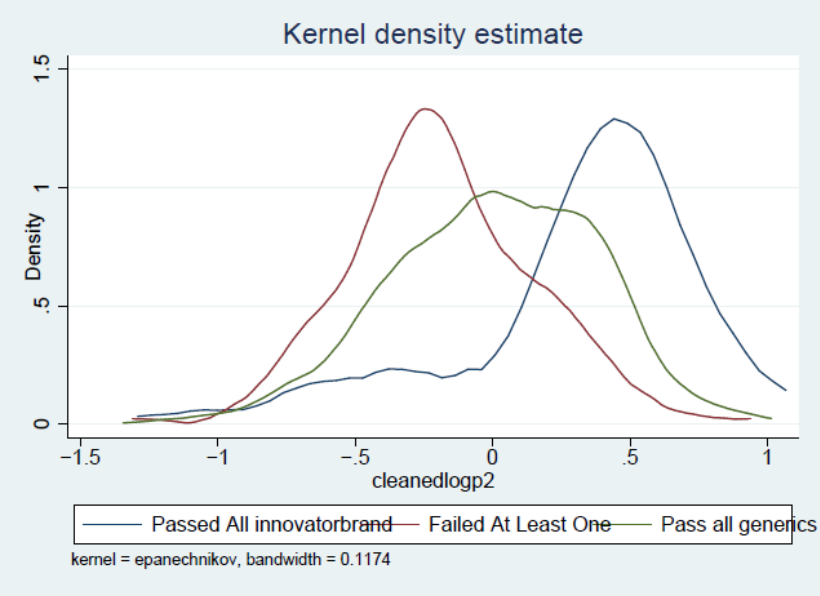

Table 1: Descriptive Statistics

	N	Mean	Std. Dev.	Min	Max
Drug Price (US$)	899	4.259	5.200	0.070	48.900
ACTs	79	5.591	1.997	2.100	9.000
Artmono	55	5.912	1.566	2.900	9.200
CQ	69	0.368	0.514	0.070	2.400
Cipro	185	8.171	8.516	0.880	48.900
Isoniazid	146	2.367	2.206	0.280	8.300
Rifampicin	168	4.056	3.838	0.380	16.200
SP	78	1.110	0.493	0.400	2.400
Erythromycin	119	3.456	3.840	0.460	15.200
=1 if Pass Visual Appearance Test	899	0.966	0.183	0	1
=1 if Pass Minilab Test	899	0.890	0.313	0	1
=1 if Pass Spectrometry Test	899	0.845	0.362	0	1
=1 if fail any test	899	0.155	0.362	0	1
=1 if the pharmacy looks “good”	899	0.249	0.433	0	1
=1 if innovator brand	899	0.080	0.272	0	1
=1 if fail any test | innovator brands	72	0.056	0.229	0	1
=1 if fail any test | non-innovator	827	0.163	0.370	0	1
=1 if Product Registered	892	0.896	0.306	0	1
Adult Literacy Rate (%)	828	73.097	10.547	65	99.55
GDP Per Capita (US$)	899	4839.51	5007.20	193.79	19759.09
Maximum Penalty (months)	691	233.52	135.80	0	360
Total Tax	623	11.705	9.447	0	31.4
=1 if price regulations exist	646	0.786	0.410	0	1

Table 2: Test-passing Rates by Country, City and Year

Country	city	year	N	% of passing all three tests
Angola	Luanda	2010	53	75.47
Brazil	San Paolo	2010	32	96.88
China	Beijing	2010	40	92.50
Congo	Lubumbashi	2010	10	60.00
Egypt	Cairo	2010	58	87.93
Ethiopia	Addis	2010	36	80.56
Ghana	Accra	2009	49	83.67
India	Chennai	2009	100	89.00
India	Delhi	2008	74	81.08
India	Delhi	2010	40	82.50
India	Kolkata	2010	39	84.62
Kenya	Nairobi	2009	8	75.00
Kenya	Nairobi	2010	40	70.00
Nigeria	Lagos	2009	53	79.25
Russia	Moscow	2010	37	94.59
Rwanda	Kigali	2010	14	92.86
Tanzania	Dar	2010	53	83.02
Thailand	Bangkok	2009	41	82.93
Turkey	Istanbul	2010	35	100.00
Uganda	Kampala	2010	44	81.82
Zambia	Lusaka	2010	43	86.05
Total			899	84.54

Table 3: Summary Statistics, by Whether the Drug Passed or Failed All the Tests

	Passing all tests			Fail at least one test		
	N	Mean	Std. Dev.	N	Mean	Std. Dev.
Drug Price (US$)	760	4.570	5.473	139	2.560	2.772
ACTs	68	5.679	2.039	11	5.049	1.698
Artmono	41	5.949	1.543	14	5.807	1.687
CQ	54	0.398	0.553	15	0.263	0.337
Cipro	167	8.596	8.728	18	4.236	4.782
Isoniazid	122	2.506	2.333	24	1.665	1.199
Rifampicin	147	4.244	3.972	21	2.741	2.409
SP	58	1.187	0.482	20	0.890	0.467
Erythromycin	103	3.766	4.031	16	1.469	0.832
=1 if Product Registered	755	0.951	0.216	137	0.591	0.473
Adult Literacy Rate (%)	696	73.41	10.89	132	71.44	8.34
GDP Per Capita (US$)	760	5100.73	5220.40	139	3411.08	3290.96
Maximum Penalty (months)	585	233.03	137.52	106	236.26	126.43
Total Tax	520	11.47	9.23	103	12.89	10.45
=1 if price regulations exist	577	0.804	0.397	89	0.674	0.471
=1 if pharmacy looks “good”	760	0.795	0.404	139	0.511	0.502
=1 if innovator brand	760	0.089	0.286	139	0.029	0.168

Table 4: Test results in correlation with local factors, Probit

	(1) Pass visual test	(2) Pass minilab tests	(3) Pass spectrometry test	(4) Pass spectrometry test
	marginal effect/t	marginal effect/t	marginal effect/t	marginal effect/t
Adult Literacy Rate (%)	0.001	0.000	0.004***	
	(1.578)	(0.075)	(2.836)	
Log GDP per capita (US$)	0.003	0.032	-0.018	0.098***
	(0.563)	(1.623)	(-1.053)	(11.903)
Maximum Legal Penalty for Drug Counterfeiting (in months)	4.07E-06	-0.0002**	-0.0003***	
	(0.124)	(-1.992)	(-3.053)	
=1 if registered with local drug authority	0.124***	0.384***	0.474***	0.489***
	(2.600)	(7.204)	(7.993)	(7.844)
Total tariffs, taxes and duties (%)	-0.001*	-0.003**	-0.003**	
	(-1.716)	(-2.262)	(-2.022)	
=1 if intends to be an innovator brand	0.002	0.063***	0.108***	0.122***
	(0.232)	(4.145)	(6.794)	(8.659)
=1 if price regulations exist	-0.018***	0.069***	0.103***	
	(-3.601)	(3.610)	(5.431)	
Year FE	Yes	Yes	Yes	Yes
Drug Type FE	Yes	Yes	Yes	Yes
City FE	No	No	No	Yes
N	828	899	899	864
Adjusted R2	0.319	0.225	0.213	0.217

Note: *** p<0.01; ** p<0.05 ; * p<0.1. T-statistics are reported in parentheses. All regressions contain missing dummies indicating missing values in included variables. Columns (1) and (4) have fewer than 899 observations because some variables included in the regressions perfectly predict the dependent variable. Literacy rate, maximum penalty, taxes and price regulations drop out of Column (4) because they are absorbed in city fixed effects.

Table 5: Price-Quality relationship

Dependent variable = log (drug price)	(1) coef/t	(2) coef/t	(3) coef/t
=1 if fails any of the quality tests	-0.214***	-0.187***	-0.136***
	(-6.119)	(-5.282)	(-2.858)
Adult Literacy Rate (%)	0.028***		
	(3.231)		
Log GDP per capita (US$)	0.452***	0.379***	0.354***
	(5.223)	(10.436)	(9.593)
Maximum Legal Penalty for Drug Counterfeiting (in months)	-0.004***		
	(-6.568)		
=1 if registered with local drug authority	0.142***	0.166***	0.088**
	(3.436)	(5.049)	(2.017)
Total tariffs, taxes and duties (%)	0.021**		
	(2.504)		
=1 if intends to be an innovator brand	0.355***	0.336***	0.371***
	(5.477)	(6.417)	(6.020)
=1 if price regulations exist	-0.511***		
	(-3.439)		
Year FE	Yes	Yes	Yes
Drug Type FE	Yes	Yes	Yes
City FE	No	Yes	No
Pharmacy FE	No	No	Yes
N / Adjusted R2	899/0.892	899/0.911	899/0.910
σ of unexplained log(drug price) for drugs passing all tests	0.426	0.385	0.347
σ of unexplained log(drug price) for drugs failing at least one test	0.372	0.326	0.311

Note: *** p<0.01; ** p<0.05 ; * p<0.1. T-statistics are reported in parentheses. All regressions contain missing dummies indicating missing values in included variables. All columns allow robust standard errors with the error term clustered by city. Column (3) does not include city fixed effects because they will be absorbed by pharmacy fixed effects. Standard deviations (σ) of unexplained log(drug price) are estimated using iterated general least squares assuming heteroscadasticity between failing and non-failing drugs. Literacy rate, maximum penalty, taxes and price regulations drop out of Columns (2) and (3) because they are absorbed in city or pharmacy fixed effects.

Table 6: Price-quality relationship by above- or below-median literacy rate

	(1)	(2)	(3)	(4)	(5)	(6)
	log(drugprice)		log(drugprice)		log(drugprice)	
	(full sample)		(if literacy >=sample median)		(if literacy <sample median)	
	coef/t	coef/t	coef/t	coef/t	coef/t	coef/t
=1 if fails any of the quality tests			-0.143***	-0.123***	-0.258***	-0.258***
			(-3.135)	(-2.640)	(-9.556)	(-9.556)
=1 if fails any of the quality tests * if literacy > sample median	-0.160***	-0.129***				
	(-3.201)	(-2.976)				
=1 if fails any of the quality tests * if literacy < sample median	-0.278***	-0.253***				
	(-6.699)	(-6.577)				
Year FE	Yes	Yes	Yes	Yes	Yes	Yes
Drug Type FE	Yes	Yes	Yes	Yes	Yes	Yes
City FE	No	Yes	No	Yes	No	Yes
N	828	828	444	444	384	384
Adjusted R2	0.901	0.919	0.801	0.807	0.942	0.942

Note: *** p<0.01; ** p<0.05 ; * p<0.1. T-statistics are reported in parentheses. All regressions contain adult literacy rate, GDP per capita, product registration, maximum penalty, taxes, price regulations, innovator brands, and missing dummies indicating missing values in included variables. All columns allow robust standard errors with the error term clustered by city. Samples conditional on countries with valid literacy rate.

Table 7: Correlations between covert shoppers' pharmacy assessment and quality test results

	Pass visual test	Pass minilab test	Pass spectrometry test	Fail any test	Pharmacy Assessed Good
Pass visual test	1				
Pass minilab test	0.4983	1			
Pass spectrometry test	0.4419	0.8226	1		
Fail any test	-0.4419	-0.8226	-1	1	
Pharmacy Assessed Good	0.1448	0.2738	0.2373	-0.2373	1

Note: all correlations are statistically significant with p-value less than 0.0001.

Table 8: Covert shoppers' pharmacy assessment

	(1)	(2)	(3)	(4)	(5)	(6)	(7)
	Pharmacy looks good		Pass all tests		Log (drug price)		
	marginal effects/t	marginal effects/t	marginal effects/t	marginal effects/t	coef/t	coef/t	coef/t
=1 if fails any of the quality tests					-0.171***	-0.165***	-0.138***
					(-5.109)	(-5.133)	(-2.901)
=1 if pharmacy looks "good"			0.131*	0.141	0.252***	0.139***	-0.073*
			(1.740)	(1.612)	(4.151)	(4.132)	(-1.754)
Adult Literacy Rate (%)	0.011**		0.003**		0.027***		
	(1.970)		(2.379)		(3.518)		
Log GDP per capita (US$)	0.020	0.151***	-0.031*	0.068***	0.413***	0.351***	0.370***
	(0.886)	(69.895)	(-1.688)	(4.396)	(5.403)	(9.577)	(9.768)
Maximum Legal Penalty	-0.000		-0.000***		-0.004***		
	(-1.469)		(-2.801)		(-8.043)		
=1 if registered	0.159	0.479***	0.406***	0.418***	0.076*	0.129***	0.087**
	(1.607)	(7.796)	(6.712)	(6.578)	(1.811)	(3.740)	(1.981)
Total tariffs, taxes and duties (%)	-0.003**		-0.004**		0.021***		
	(-2.001)		(-2.254)		(2.846)		
=1 if innovator brand	0.009	0.008	0.102***	0.117***	0.355***	0.337***	0.370***
	(0.780)	(0.112)	(6.754)	(9.296)	(5.990)	(6.588)	(6.012)
=1 if price regulations exist	0.023		0.108***		-0.475***		
	(0.878)		(4.647)		(-3.561)		
Year FE	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Drug Type FE	Yes	Yes	Yes	Yes	Yes	Yes	Yes
City FE	No	Yes	No	Yes	No	Yes	No
Pharmacy FE	No	No	No	No	No	No	Yes
N	899	632	899	864	899	899	899
Pseudo R2 / Adjusted R2	0.305	0.167	0.236	0.239	0.897	0.913	0.910

Note: *** p<0.01; ** p<0.05 ; * p<0.1. T-statistics are reported in parentheses. Columns (1)- (4) use probit; Columns (5) -(7) use OLS. All regressions contain missing dummies indicating missing values in included variables. All columns allow robust standard errors with the error term clustered by city. Literacy rate, maximum penalty, taxes and price regulations drop out of Columns (2), (4), (6) and (7) because they are absorbed in city or pharmacy fixed effects.

Appendix

A.1. Description of Drugs Sampled

Drug Name	Dosage	For Treatment Of
Ciprofloxacin	250mg, 500mg	Bacterial infections
Erythromycin	250mg , 500mg	Bacterial infections
Isoniazid	100mg	Tuberculosis
Rifampicin	300mg	Tuberculosis
Chloroquine (CQ)	250mg	Malaria
Sulphadoxine/Pyrimethamine (SP)	500mg/25mg	Malaria
Artemesinin monotherapies (ARTMono) (Artemether, artesunate, dihydrosartemesinin)	50mg 50mg,100mg 60mg	Malaria
Artemsisin Combination Therapies (ACTs) Artemether/Lumefantrine	20mg/120mg	Malaria

A.2. Description of Tests Used

Test	How it is Performed	What a Pass or Fail Implies
Visual Inspection	By comparison with a real version, or by simply noting spelling errors, or other errors	Fail implies an obvious counterfeit product
Minilab (Disintegration)	Does the drug dissolve in body temperature water within 30 minutes	Failure implies drug solubility poor
Minilab (Thin Layer Chromatography)	Assessing the active ingredient of the drug using TLC	Failure implies insufficient active ingredient
Raman Spectrometry	Assessing the Rama Spectra of the product	Failure implies incorrect drug formulation