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QUALITY REGULATION AND COMPETITION: EVIDENCE FROM PHARMACEUTICAL MARKETS

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ABSTRACT

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Quality Regulation and Competition: Evidence from Pharmaceutical Markets*

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Keywords: quality regulation, disclosure, competition, bioequivalence, generics
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1 Introduction

When consumers cannot verify product quality, the risk of purchasing a low-quality product reduces their willingness to pay. Moreover, the inability of firms to signal quality harms competition, affecting the set of products offered and their prices. Quality regulation—often in the form of minimum quality standards—is widely used to address the market failures caused by a lack of information about quality. However, despite its widespread adoption, empirical evidence on the equilibrium effects of quality regulation and its mechanisms is limited.

The effects of quality regulation are theoretically ambiguous. On the one hand, it removes products below the minimum quality standard, which reduces asymmetric information, increases perceived quality, and lowers vertical differentiation. However, if complying with the standard is costly, quality regulation can lead to exit and harm price competition. Overall, the equilibrium effects of quality regulation result from an interplay between increased quality, reduced vertical differentiation, and changes in market structure due to costly compliance.

In this paper, we study quality regulation in pharmaceutical markets, where issues of quality, asymmetric information, and quality misperceptions are a central part of the academic and policy debate (WHO, 2000; Bate *et al.*, 2011; Bronnenberg *et al.*, 2015). Specifically, we study the impacts of bioequivalence requirements, the main quality regulation for generic pharmaceuticals in the U.S. and Europe, and increasingly adopted elsewhere, including China in 2016 and India in 2017. We leverage a bioequivalence reform in Chile. The policy required generic drug manufacturers—copies of the innovator drug first marketed to treat a given condition—to provide evidence that their products are therapeutically equivalent to a reference drug, often the innovator. Products that failed to provide such evidence by a set deadline had to exit the market. This paper provides the first study of this form of quality regulation on market outcomes and welfare.

Before the introduction of quality regulation, the Chilean market displayed low generic penetration. Specifically, *unbranded generics* (those generics marketed by the molecule name) accounted for less than 30 percent of sales, even though they were on average 6 and 10 times cheaper than *branded generics* (those marketed under a trading name) and innovator drugs, respectively. In this context, the government introduced quality regulation to increase the perceived quality of unbranded generics and enhance price competition.

We start by estimating the effects of quality regulation on market outcomes. We exploit the staggered implementation of the reform, along with features of its enforcement, to compare outcomes across and within markets (molecules) exposed to the policy. Stronger quality regulation affected market structure by decreasing the number of drugs by 21 percent and led to a 13 percent increase in average paid prices, most of which was due to within-drug price increases. These effects were larger among small markets—with baseline revenue below the median—for which the number of drugs decreased by 30 percent, and average paid prices increased by 26 percent.

To quantify the main mechanisms through which quality regulation operates and to study counterfactuals and their welfare implications, we develop and estimate a model for this market. On the demand side, consumers choose drugs that belong to one of three segments: innovators, branded generics, or unbranded generics. Demand for these products is subject to two frictions. First, due to asymmetric information, consumers cannot distinguish between high- and low-quality generics prior to the regulation. As a consequence, consumers may be harmed by the presence of low-quality drugs. Second, consumers might be averse to generics, even if they could observe product quality. Asymmetric information and aversion lower the relative willingness to pay for generics. From the demand side, we recover willingness to pay for drugs. On the supply side, firms have private information about their quality and play a two-stage game. In the first stage, firms choose whether to participate in the market in an incomplete information entry game, which requires incurring an entry cost and, once quality regulation is introduced, a certification cost. In the second stage, entrants compete on prices. From the supply side, we recover entry costs, certification costs, marginal costs, and the prevalence of low-quality drugs before the reform.

Our estimates imply that the regulation substantially increased the valuation of unbranded generics but did not impact the valuation of branded generics. We also estimate that 31 percent of unbranded generics and 3 percent of branded generics were below the standard. Our estimates imply that 80 percent of the increase in the estimated valuation of unbranded generics stemmed from resolving asymmetric information and the rest from decreasing aversion to generics.

In the model, quality regulation affects outcomes by resolving asymmetric information, eliminating low-quality generics from the market, changing the extent of consumer aversion to generics, and increasing fixed costs through certification costs. We quantify the overall welfare effects of quality regulation and the relative contribution of each mechanism by combining model estimates and a welfare metric that properly accounts for choice frictions.

Quality regulation leads to higher welfare despite losses in product variety and higher prices. Resolving asymmetric information is the main channel through which the regulation impacts welfare, by improving consumer choices and inducing entry of high-quality generics. By imposing a minimum quality standard, quality regulation further forces low-quality generics to exit. However, its impacts are limited since their market share is negligible without information frictions. By affecting aversion to generics, the regulation further decreases vertical differentiation, leading to more intense competition and higher welfare. Finally, certification costs induce product exit and large price increases. However, these adverse effects are not large enough to offset the welfare gains from the other mechanisms. Overall, welfare increases by between $40 and $78 million USD per year (3.7 and 6.1 percent). In sum, the effects of the regulation through improved quality of consumed drugs dominate its adverse competitive effects from a welfare perspective.

While quality regulation increases welfare in the aggregate, its effects are heterogeneous across markets. Welfare decreases in 25 percent of the markets. These welfare losses are concentrated

among small markets, consistent with our descriptive evidence. Moreover, we use the model to show that quality regulation would be more beneficial in counterfactual environments with low baseline drug quality, where resolving asymmetric information has stronger impacts.

We depart from the observed policy change and use our model to study alternative policy designs. First, we consider certification subsidies as a policy to limit the adverse competitive effects of quality regulation while still resolving asymmetric information. We show that subsidizing certification counteracts the weakening of competition due to quality regulation, particularly in small markets where adverse impacts from exit are more severe. Second, we consider quality disclosure as a policy to deal with asymmetric information about product quality (Dranove and Jin, 2010; Barahona *et al.*, 2023; Vatter, 2024). Contrary to quality regulation, low-quality products can still be sold under this policy. We find that quality disclosure leads to less unbranded generic exit and weaker price increases than quality regulation, hence to slightly higher consumer welfare. However, quality regulation leads to higher overall welfare than disclosure by inducing less net entry and better selection of drugs. Finally, we consider policies that complement quality regulation by impacting aversion to generics. We find that quality regulation improves consumer welfare even if it does not impact aversion to generics at all. When quality regulation also induces a moderate decrease in aversion to generics, vertical differentiation decreases, and quality regulation becomes more effective. However, significant reductions in aversion to generics intensify competition to the point where exit harms consumers beyond the benefits of better decision-making.

The main contribution of our paper is to study the equilibrium effects of quality regulation in a setting where consumers lack information on product quality. Previous research includes a well-established theoretical literature (Leland, 1979; Shapiro, 1983; Ronnen, 1991), along with empirical work on childcare input regulation (Currie and Hotz, 2004; Hotz and Xiao, 2011), occupational licensing (Kleiner, 2000; Farronato *et al.*, 2024; Kleiner and Soltas, 2023), seller certification in e-commerce (Hui *et al.*, 2023; Jin *et al.*, 2022), and testing of medical devices (Grennan and Town, 2020). Relative to this literature, we are the first to estimate a structural model to quantify the main mechanisms at play, develop welfare analysis, and evaluate policy counterfactuals. The model is novel in combining a supply side with entry and price competition where firms face quality regulation, with a demand side with choice frictions that respond endogenously to the policy. This framework also enables us to provide an empirical comparison between quality regulation and quality disclosure, the main alternative policy in the literature (Dranove and Jin, 2010).

Second, we contribute to the literature on pharmaceutical market regulation. Most previous work focuses on price regulation (Danzon and Chao, 2000; Brekke *et al.*, 2009; Dubois and Lasio, 2018; Dubois and Sæthre, 2020; Mohapatra and Chatterjee, 2020; Dubois *et al.*, 2022; Maini and Pammolli, 2023; Cao and Gupta, 2024), off-label prescription regulation (Tunçel, 2024), public competition (Atal *et al.*, 2024), and patent protection (Chaudhuri *et al.*, 2006). In contrast, to our knowledge, ours is the first paper to study the equilibrium effects of quality regulation for generics.

Finally, we contribute to a better understanding of aversion to generics and brand preferences (Ching, 2010; Bronnenberg *et al.*, 2015; Colgan *et al.*, 2015; Bairoliya *et al.*, 2017; Carrera and Villas-Boas, 2023; Cao and Gupta, 2024) by estimating how quality regulation affects information asymmetries and aversion to generics, and how those determine equilibrium outcomes. Accounting for the value that consumers place on higher quality allows us to conclude that bioequivalence led to an overall increase in welfare despite price increases due to less competition.

The remainder of the paper is organized as follows. Section 2 describes the Chilean pharmaceutical market, the policy change, and the data we use. Section 3 provides descriptive evidence for the effects of quality regulation on market structure and market outcomes. Section 4 provides survey evidence on perceived quality gaps across drug segments and how they relate to bioequivalence. Section 5 describes the model and its estimates. Based on the model estimates, Section 7 shows our analysis of the equilibrium impacts of quality regulation, and Section 8 discusses our counterfactual policy analysis. Finally, Section 9 concludes.

2 Setting

2.1 Institutional Framework

We study the retail pharmaceutical market in Chile, which provides around 40 percent of prescription drugs in the country according to the 2016 National Health Survey.[1] In this setting, insurance coverage is limited. Around 80 percent of purchases are paid fully out-of-pocket, the exception being public insurance enrollees with a particular subset of diseases (Osorio, 2020). Moreover, there is no price regulation. Hence, prices play a key role in consumer choice and drug affordability.

Three features of our setting influence the workings of the quality regulation policy. First, direct-to-consumer advertising of prescription drugs is forbidden, which could make consumers more price-sensitive since expensive branded drugs cannot use advertising to boost demand. Second, the retail pharmacy market is highly concentrated, which may affect supply-side reactions to regulation. Three large pharmacy chains account for over 80 percent of the market, with the remainder shared by small local chains. Third, physician prescription behavior and pharmacists' ability to offer alternatives to prescribed drugs affect consumer choice. In Chile, pharmacists can only offer generic substitution when prescriptions specify the generic name and a bioequivalent substitute is available. Despite recent policy efforts to constrain prescribing discretion, physicians still occasionally prescribe by brand name, limiting substitution towards generics.[2]

[1]The remaining 60 percent are provided free (or almost free) in primary care clinics to public insurance enrollees.

[2]In February 2014, Law 20,724 was passed to require physicians to prescribe by the generic name to allow for substitution towards bioequivalent generics upon patient request. However, industry actors concede that there has not been any enforcement, which motivated subsequent policy discussions in Congress.

2.2 Quality Regulation

Bioequivalence certification demonstrates the therapeutic equivalence between a generic drug and a reference drug, often the innovator drug.[3] The Chilean government introduced bioequivalence requirements to complement the existing quality regulation that focused solely on minimum production standards and safety based on International Pharmacopeia books' guidelines (WHO, 2017), but not on therapeutic efficacy. A main stated goal of the regulation was to increase competition and reduce prices through increasing the perceived quality of generics.[4]

The first list of molecules subject to bioequivalence was published in 2005 by the Chilean Ministry of Health (MINSAL). This list consisted of molecules included in a major reform to the public health insurance system called AUGE (Bitrán *et al.*, 2010). However, it was not until 2009 that the regulator established technical norms for bioequivalence testing (Balmaceda *et al.*, 2015). Bioequivalence requirements were phased in since then, with 167 molecules covered as of March 2018. All new drugs containing the molecules listed in each decree were mandated to certify bioequivalence before obtaining a marketing license.[5] Each decree specified the deadline for bioequivalence testing among incumbent drugs. However, enforcement of the requirements occurred mostly at the time of the drug's marketing license renewal, which happens every five years. A drug without bioequivalence approval at the time it was due for renewal lost its marketing license and had to exit (Vasallo, 2010)—we exploit this feature of enforcement for our empirical strategy below. Drugs with bioequivalence certification could stay in the market, and started to carry a distinctive label to inform the consumer that they are bioequivalent to the innovator.[6]

The certification deadlines were often extended due to slow uptake and capacity constraints in testing facilities. The combination of the staggered introduction of the regulation and subsequent deadline extensions generates substantial policy variation.[7] Figure 2-b summarizes this variation.

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[3]Two drugs are bioequivalent if the rate and extent of absorption of the tested and reference drugs do not significantly differ when administered at the same molar dose of the therapeutic ingredient under similar conditions (Davit *et al.*, 2013). These parameters are influenced by, for example, pharmacokinetic properties of the active ingredient and secondary ingredients combined with features of the production process (Pramod *et al.*, 2016). Bioequivalent drugs can be substituted expecting them to yield the same clinical effect and safety profile as the reference drug (FDA, 2017). Therefore, bioequivalence allows bridging pre-clinical and clinical data associated with the reference drug to the generic.

[4]For example, the Head of the National Drug Agency (ANAMED) stated: "We have no doubts that drug prices will decrease because the population will have access to a wider and more competitive drug market" (La Tercera, 2012).

[5]Bioequivalence requirements were only imposed on orally administered drugs, i.e., the requirements do not apply to topical medications, vaccines, or any other drug that is not orally administered.

[6]In practice, the label could affect demand through quality disclosure. However, drugs without bioequivalence approval must exit the market so that, if consumers are aware of the policy, the label does not carry any additional informational content in our setting. We show an example of this label in Figure A.1.

[7]Among the molecules with bioequivalence requirements, there are nine unique combinations of policy dates, namely the date of the first decree, date of extensions if any, and corresponding deadlines established in the first decree and the extensions. Table A.1 shows the dates of the first decree (when a bioequivalence requirement was announced), the last decree (when the last extension to the original deadline was announced), and the corresponding deadlines for each group, as well as the number of molecules in each group. For example, Group 1 includes four molecules with

We exploit this variation to estimate policy effects later.

Bioequivalence certification is provided after the manufacturer presents successful studies done at private certified laboratories. For imported drugs, this certification is often validated in Chile if obtained in countries with high certification standards (e.g., Canada, the U.S., and the European Union, among others).[8] The price of bioequivalence testing at licensed laboratories is reported to range between $48 to $240 thousand per drug and is fully covered by the manufacturer (La Tercera, 2012; CIPER, 2015).[9] To put this number in context, the median drug in our sample had an annual revenue of $99 thousand in 2010. Moreover, 35 and 71 percent of drugs had annual revenue lower than $48 and $240 thousand, respectively. Though these amounts only cover the retail market, they suggest that the financial burden imposed by bioequivalence testing was non-negligible.

2.3 Data

We employ three data sources. First, a drug registry maintained by the Public Health Institute (ISP), which collects marketing license data for the universe of drugs (equivalent to the Orange Book in the U.S.). The registry provides information on the manufacturer, the date of a drug's first license in Chile, and the dates of subsequent license renewals. It also includes information on drug dosage, presentation (tablet, capsule, injectable, or other), and marketing status (prescription or over-the-counter). Second, we combine the drug registry with data on bioequivalence certification, also available from ISP. These data contain a list of all drugs with bioequivalence certification, including the certification date and the corresponding reference drug.

We measure market outcomes using IQVIA data on monthly retail prices and sales between January 2010 and December 2017.[10] For branded drugs, the IQVIA data provide price and sales at the product level, identifying each drug's laboratory, dosage, and presentation. For unbranded drugs, the data provide prices and sales at the dosage and presentation level, aggregated across laboratories. We focus on prescription drugs, which account for more than 90 percent of drugs in the molecules we study.

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their first decree announced in January 2011, with a deadline in February 2012. However, the original deadline was extended, and its final decree was announced in June 2013, with a deadline in December 2013.

[8] Although the certification is awarded *ad eternum* for a given formula and production technology, any change requires a new certification. Generally, bioequivalence is determined through *in vivo* clinical studies for each drug presentation. However, under certain conditions, only *in vitro* studies are required for different dosages of the same drug.

[9] All monetary values are inflation-adjusted to December 2017, when the exchange rate was 636 CLP per USD.

[10] IQVIA collects data from pharmacy chains and distributors. The data cover 83 local markets, which account for most of the country. To aggregate the data to the national level, we compute monthly sales by adding across local markets and monthly prices as sales-weighted averages across local markets. We adjust prices in two ways. First, we adjust for inflation using the health CPI from the National Institute of Statistics (INE). Second, we calculate prices per defined daily dose of the drug to normalize prices across presentations by their dosage.

We define markets at the ATC-5 (molecule) level, following Duggan *et al.* (2016).[11] For our analysis, we focus on 115 markets. [12] The resulting dataset includes 1,780 unique drugs defined as unique combinations of drug name, dosage, and presentation, and 101 different manufacturers.

2.4 Descriptive Statistics

The number of bioequivalence certifications increased throughout our study period, as shown by Figure 1-a. Certification started slowly in 2010 but increased steadily since mid-2012. By December 2017, there were 972 bioequivalent drugs, of which 631 were branded generics. The timing of bioequivalent certification relates to the policy roll-out. Figure 1-b displays the number of certifications around the first deadline, showing that (i) bioequivalence approval was rare before mandated, and (ii) bioequivalence approval increased substantially after the policy.[13]

The data also suggest that quality regulation affected drug entry and exit. We measure entry and exit using the ISP data on licensing and renewals. For a drug, we record an entry as obtaining a license for the first time and an exit as not renewing a license upon expiration. Figure 1-c displays the number of drugs that entered and exited during our sample. Drug exit was stable up to late 2014 and increased after. On the other hand, we do not find noticeable changes in entry patterns over time. Figure 1-d displays the number of drugs that entered and exited the market over time relative to the policy and shows that the increase in exit occurred after the policy roll-out.

Regarding market outcomes, the average innovator drug is more than twice as expensive as the average branded generic, and more than seven times as expensive as the average unbranded generic. These price differences across segments reveal large premiums for innovator and branded generics within molecules before the policy change.[14] Price premiums are positive and large on average, with innovators and branded generics charging average price premiums of 10 and 6 times

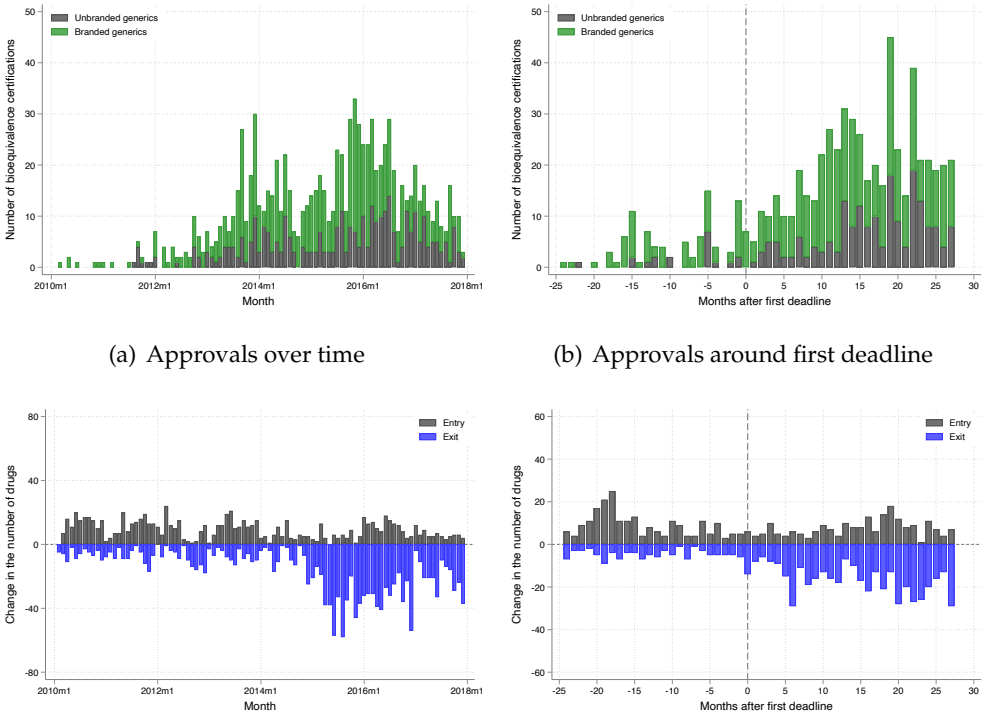
[11]This choice is motivated by the fact that the policy we study was assigned at that level. Other studies define markets at the ATC-4 level (e.g., Dubois and Lasio 2018; Dubois *et al.* 2022) to account for the potential substitution across molecules. Our results for the market effects of the policy in Section 3 are robust to using either definition.

[12]We construct our sample as follows. We start with the 134 molecules exposed to the policy after 2010. We drop those treated before 2010 since, as noted, technical norms for bioequivalence testing were not developed until 2009 and, in addition, our sample starts in 2010. Second, we drop 19 markets featuring sporadic sales. We thus focus on markets that are active throughout the sample so that we can study the effects of the policy. In particular, we drop all ATC-4 groups containing a molecule with a difference between its sales' maximum and minimum above the 95th percentile.

[13]In a context where quality is heterogeneous and unobservable to consumers, voluntary quality disclosure may take place and lead to information unraveling. In that case, consumers become aware of quality differences, and low-quality drugs might exit (Dranove and Jin, 2010). However, this prediction does not hold if disclosure is costly enough (Jovanovic, 1982). Also, consumers in our setting were likely unfamiliar with the concept of bioequivalence before the policy change, which could limit the returns to disclosure and explain the lack of voluntary quality disclosure.

[14]We estimate premiums by estimating regressions of log real prices per daily defined dose in 2010 and 2011 on indicators for innovator and branded generics separately for each market. The exponentiated coefficients on the drug segment indicators measure each segment's average price premiums relative to unbranded generics (the omitted category). We restrict the sample to molecules with price data for at least one innovator drug, branded drug, and unbranded drug during the periods. See the distribution of price premiums in Figure A.2.

Figure 1: Quality certification, entry, and exit around policy events



(a) Approvals over time

(b) Approvals around first deadline

(c) Entry and exit over time

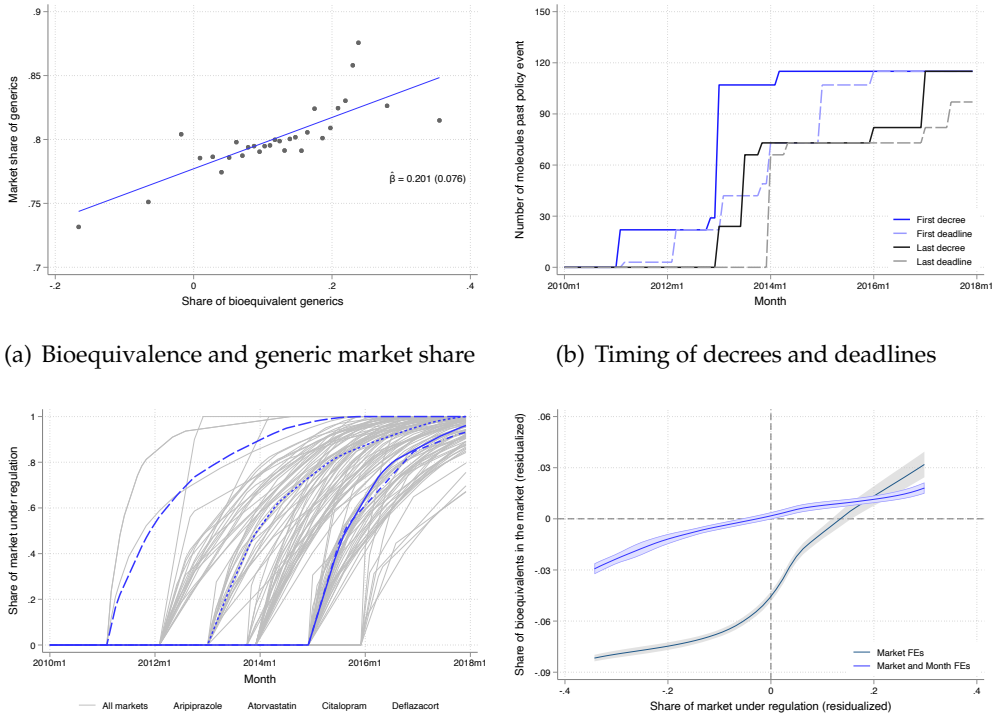
(d) Entry and exit around first deadline

Notes: The top row displays trends in quality certification. Panel (a) displays the evolution of the number of drugs with bioequivalence approval over time, split by unbranded (gray) and branded generics (green). Panel (b) displays the approvals around the first bioequivalence deadline. The bottom row displays the trends in drug entry and exit. Panel (c) displays the evolution of drug entry (gray) and exit (blue) over time. Panel (d) displays the evolution of entry and exit relative to the first bioequivalence deadline.

relative to unbranded generics, respectively. There is substantial heterogeneity across molecules, as many molecules display price premiums of around 3 to 5 times, while several others display price premiums higher than 10 times. See Table A.2 for additional descriptive statistics.

Innovator drugs and branded generics hold substantial market shares despite charging higher prices. In 2010, branded generics had an average market share of 41 percent, followed by innovator drugs and unbranded generics with 34 and 25 percent, respectively. However, innovator drugs lost market share throughout our sample period, whereas branded and unbranded generics reached 45 and 38 percent average market shares by 2017. These increases coincide with an increase in the average market share of bioequivalent drugs from 0.03 percent in 2010 to 30 percent in 2017. These trends seem to be related: a regression of the market share of generics on the share of generics with bioequivalence certification in a market shows a positive correlation, even after controlling for market and time fixed effects. In particular, an increase of 10 percentage points in the share of generics that is bioequivalent is associated with a statistically significant increase of 2 percentage points in market share, as shown by Figure 2-a. We further examine this relationship in the remainder of the paper, estimating market effects in Section 3 and using a model in Section 5.

Figure 2: Evolution of quality regulation



(a) Bioequivalence and generic market share

(b) Timing of decrees and deadlines

(c) Evolution of quality regulation by market

(d) Regulation and share of bioequivalent drugs

Notes: Panel (a) displays a binned scatter plot of the generic market share on the share of bioequivalent generics in a given market, controlling for market and month fixed effects. Panel (b) displays the number of markets affected by different bioequivalence policy events, from first decree to last deadline. Panel (c) displays the evolution over time of the treatment variable in equation (1) across markets. We highlight particular examples in blue, displayed in more detail in Figure A.3. Panel (d) displays the non-parametric relationship between the residualized policy intensity variable and the share of bioequivalent drugs in the market, controlling for market fixed effects (gray) and market and month fixed effects (blue). The bottom and top centiles of the data are not included.

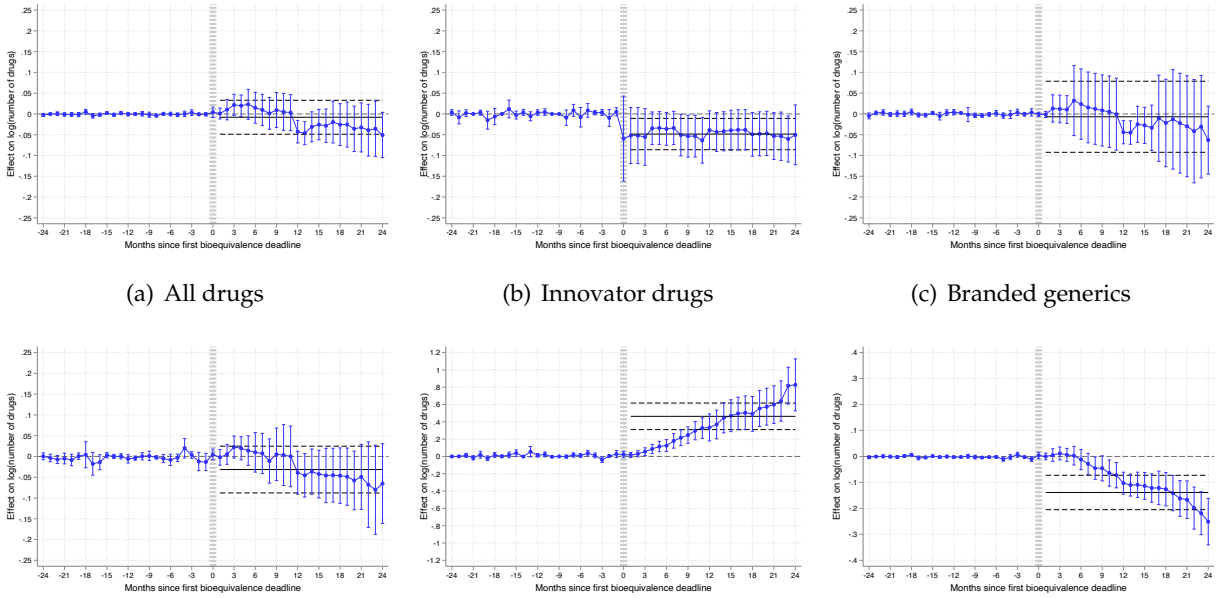
3 Effects of Quality Regulation on Market Outcomes

3.1 Event Study Evidence

We exploit the staggered roll-out of the regulation to study its effects on market outcomes. We start by implementing an event study analysis to (i) assess the assumption of parallel trends across groups of molecules treated by the policy at different moments, and (ii) provide visual evidence of the effects of quality regulation on market outcomes. To accommodate potentially heterogeneous treatment effects, we use the doubly-robust difference-in-differences methods in Sant'Anna and Zhao (2020) and Callaway and Sant'Anna (2021). We consider the first bioequivalence deadline as the policy event and report results for two years before and after that event.

The results suggest the policy strongly affected market structure, as Figure 3 shows. Our estimates show that the total number of drugs decreased, which seems to be largely driven by the exit of unbranded generics. The results also show a large increase (decrease) in the number

Figure 3: Event study results for market structure



(a) All drugs (b) Innovator drugs (c) Branded generics

(d) Unbranded generics (e) Bioequivalent generics (f) Non-bioequivalent generics

Notes: This figure displays the results from event study specifications described in Section 3.1, using the first deadline as policy event. Dots indicate point estimates and lines indicate 95 percent confidence intervals based on standard errors clustered at the market level. Coefficients are displayed for 24 months before and 24 months after the policy event. The solid horizontal lines indicate the estimated average treatment effect. The dashed horizontal lines represent the 95 percent confidence interval for the average treatment effect. The coefficient on the month previous to the event is normalized to zero.

of bioequivalent (non-bioequivalent) generics after the policy change. Similarly, Figure 4 displays results related to drug prices, market shares, and sales.[15] We find that prices increased after the policy change, particularly among unbranded generics. In terms of quantities, we find no clear evidence of effects on total sales or market shares by segment. We provide a more detailed discussion of effects along all these margins in Section 3.2 below.

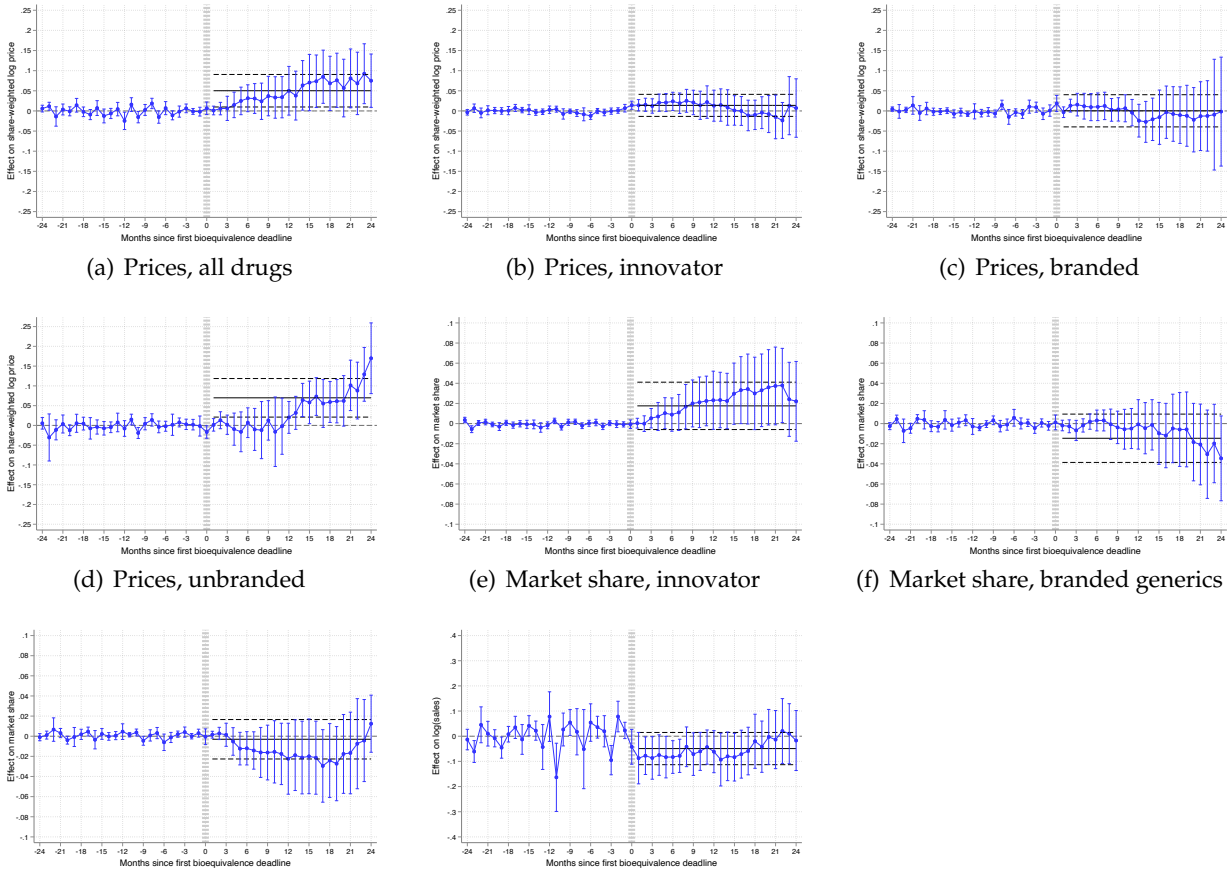
Overall, the event studies suggest that stronger quality regulation decreased the number of drugs in the market and increased drug prices. In addition, the trends in outcomes before the first bioequivalence deadline are well-behaved for all outcomes, validating the use of the differential timing of bioequivalence requirements across markets as identifying variation in our setting.

[15]We use a price index constructed as the share-weighted average of log prices in a market (e.g., Chevalier *et al.* 2003):

$$\hat{P}_{mt} \equiv \sum_{i \in \mathcal{I}_{mt}} w_{it} P_{it},$$

where $\mathcal{I}_{mt}$, is the set of drugs in market m in period t, P_{it} is the logarithm of price per daily defined dose of drug i in period t and w_{it} denotes the share of sales of drug i in market m in period t.

Figure 4: Event study results for prices, sales and market shares



(a) Prices, all drugs (b) Prices, innovator (c) Prices, branded

(d) Prices, unbranded (e) Market share, innovator (f) Market share, branded generics

(g) Market share, unbranded generics (h) Total sales

Notes: This figure displays the results from event study specifications described in Section 3.1 for price and quantity outcomes, using the first deadline as policy event. Dots indicate point estimates and lines indicate 95 percent confidence intervals based on standard errors clustered at the market level. Coefficients are displayed for 24 months before and 24 months after the policy event. The solid horizontal lines indicate the estimated average treatment effect. The dashed horizontal lines represent the 95 percent confidence interval for the average treatment effect. The coefficient on the month previous to the event is normalized to zero.

3.2 Regression Analysis

Our primary empirical strategy exploits policy variation across and within markets. The first source of variation is the staggered roll-out of the reform we exploited in the event study analysis. The second source of variation comes from a particular institutional feature. In practice, deadlines for incumbent drugs become binding when a drug must renew its marketing license every five years. At that point, ISP denies license renewal to drugs without bioequivalence approval (Vasallo, 2010). Thus, the first license renewal after the policy deadline marks the effective deadline for each drug. License renewal dates are arguably exogenous for drugs that were in the registry before the deadline was known. Moreover, renewal dates vary across drugs within markets due to the variation in licensing dates. Differences in renewal dates across drugs generate variation in the share of drugs for which the policy is effectively binding, both across markets with a common

deadline and within markets over time.

We combine these sources of variation in a variable that measures the evolution of the policy roll-out for each market. This variable captures three features of the policy. First, the policy becomes relevant for a market only after its first decree. Second, the policy becomes increasingly relevant for each drug as its license renewal date approaches. Finally, the policy is fully in place for a market when the license renewal date of all drugs has passed. Formally, denote the policy date for market m by t^d_m and renewal date of drug i in m by t^r_{im}. For a drug i, the share of time between the decree and the next renewal date that has passed by time t is:

$$T_{imt} = \begin{cases} 0 & \text{if } t \leq t^d_m \\ \frac{t - t^d_m}{t^r_{im} - t^d_m} & \text{if } t^d_m < t \leq t^r_{im} \\ 1 & \text{if } t^r_{im} < t \end{cases}$$

For each market m, we define the *share of market under regulation* by month t as the average of T_{imt} across the set of generic drugs in market m in the baseline period t^d_m, $\mathcal{G}_m$:

$$T_{mt} = \frac{1}{|\mathcal{G}_m|} \sum_{i \in \mathcal{G}_m} T_{imt}, \tag{1}$$

where $|\mathcal{G}_m|$ is the number of branded and unbranded generics in market m in month t^d_m. Our analysis uses T_{mt} as a treatment variable. T_{mt} is a weakly increasing function of time relative to the policy date t^d_m: it is equal to 0 before t^d_m and is equal to 1 after the last renewal date across drugs in $\mathcal{G}_m$. Figure 2-c displays the evolution of T_{mt} over time for all markets in the sample, showing substantial variation both across markets and within markets over time.[16] Finally, Figure 2-d shows that this variable is indeed correlated with the share of bioequivalent drugs in the market.

Our main specification to estimate policy effects on market-level outcomes y_{mt} is:

$$y_{mt} = \beta T_{mt} + \theta_m + \delta_t + \varepsilon_{mt}, \tag{2}$$

where the coefficient of interest is β; θ_m are market fixed effects that control for permanent differences across markets; and δ_t are month fixed effects that control for common time shocks across markets. When discussing results, we focus on the impact of moving from not having regulation to having it entirely in place, which is captured by increasing T_{mt} from zero to one.

The key identifying assumption in (2) is that there are no unobserved market-specific trends driving both the timing of the policy roll-out and the outcomes of interest. This assumption

[16]For illustration, Figure A.3 shows examples of the evolution of T_{mt} over time for four markets, along with the evolution in the number of bioequivalent drugs. These plots show how bioequivalence certification increases as bioequivalence requirements become relevant for a market. We highlight these examples in Figure 2-c.

requires that policy deadlines and renewal dates were not set as a function of unobserved shocks not captured by market and time fixed effects. A violation of this assumption would happen if, for example, decrees and deadlines were set earlier for markets expected to have earlier price increases. We cannot directly test this assumption, but the fact that decree extensions were mostly set based on capacity constraints of testing facilities makes it unlikely that they were driven by unobserved future demand or supply shocks. Moreover, market-level observables do not show a clear correlation with the policy timing, which supports this identifying assumption.[17] Finally, the evidence of parallel pre-trends in the event study analysis supports our identifying assumption.

We focus on market size as a dimension for heterogeneity analysis. This exercise is motivated by the intuition that when compliance is costly, quality regulation should have stronger effects among small markets because it would induce more drug exit. We test this prediction by estimating differential effects by market size. Specifically, we divide markets according to whether their total market revenue in 2010 was above or below the median.

Effects on market structure. We start by estimating equation (2) for the number of drugs in the market using a Poisson regression (Chen and Roth, 2023). Column 1 in Table 1-A shows that the policy decreased the total number of drugs by 20 percent. Columns 2–8 split this result across drug segments. The exit of branded and unbranded generics drives this overall reduction. While the number of bioequivalent generics increases, it does not compensate for the exit of non-bioequivalent generics. We do not find significant changes in the number of innovator drugs.

The adverse effects on the number of drugs are larger in small markets, as shown by Table 1-B. We estimate that the number of drugs decreased by 34 percent in small markets and 13 percent in large markets, which is also driven mainly by the exit of branded and unbranded generics.

Effects on drug prices. Price effects of quality regulation are theoretically ambiguous. On the one hand, a lower number of firms may weaken competition and lead to price increases. However, changes in perceived quality may reduce vertical differentiation and enhance competition. We find that average prices across all drugs increased by 13 percent due to the regulation, as shown in Table 2-A. The increase in average paid prices comes from increases among unbranded generics, while we find no statistically significant effects for innovators and branded generics.[18]

As shown above, the decrease in the number of drugs is concentrated among small markets, and hence these are the markets where we expect to find the strongest price effects, which the results in Table 2-B confirm. The increase in prices across all drugs is driven largely by a 26 percent

[17] Table A.1-B shows statistics for market outcomes in 2010 across markets affected by the policy at different points in time. There is substantial heterogeneity across these groups in terms of the number of drugs, market size, and market outcomes, but no clear pattern related to the policy timing.

[18] We construct the same price index for each drug segment but define the weights as shares within the corresponding segment. We estimate the effect of the regulation for the segment-specific price indices for the subset of markets for which there is at least one drug of that segment in the baseline period.

Table 1: Effects of quality regulation on number of drugs

	(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)
	Dep. var.: Number of Drugs							
	All	Innovator	Branded generics			Unbranded generics		
			All	BE	Non-BE	All	BE	Non-BE
A - Average effects								
Regulation	-0.20***	-0.02	-0.21***	1.55***	-0.38***	-0.20***	2.78***	-0.37***
	(0.05)	(0.06)	(0.05)	(0.26)	(0.06)	(0.06)	(0.42)	(0.06)
B - Heterogeneity by market size								
Regulation × Low Revenue	-0.34***	-0.12	-0.30***	1.42***	-0.31***	-0.40***	3.29***	-0.28***
	(0.07)	(0.09)	(0.08)	(0.30)	(0.09)	(0.09)	(0.70)	(0.09)
Regulation × High Revenue	-0.13**	0.03	-0.17***	1.62***	-0.40***	-0.08	2.58***	-0.42***
	(0.05)	(0.07)	(0.06)	(0.34)	(0.06)	(0.08)	(0.43)	(0.08)
Pre-regulation average	22.06	2.40	12.32	0.09	12.23	7.34	0.01	7.33
Observations	11,040	9,600	10,272	8,064	10,272	10,560	7,008	10,560
Market FE	Y	Y	Y	Y	Y	Y	Y	Y
Month FE	Y	Y	Y	Y	Y	Y	Y	Y

Notes: Each column in this table is a Poisson regression of the number of drugs in a segment on the policy roll-out variable constructed using the first decree deadline. Panel B provides results by baseline revenue. Markets are classified as having low or high revenue according to the total revenue in the market in 2010 relative to the median across markets in that year. Standard errors clustered at the market level in parentheses. ***p<0.01, **p<0.05, *p<0.1.

increase in small markets, again concentrated among unbranded generics.[19]

Effects on market shares and sales. Changes in market structure driven by generic drug exit may shift drug consumption away from generics and potentially reduce overall consumption. Price increases may, in turn, exacerbate these effects. However, changes in perceived quality may increase demand for generics. We find limited effects of quality regulation on segment market shares, as shown by columns 5-9 in Table 2-A. If anything, we find a marginally statistically significant decrease in the market share of branded generics, which translates into slight increases in the innovator's and unbranded generics' market share. As expected, we find a significant increase in the market share of bioequivalent generics and a decrease for non-bioequivalent generics. In terms of heterogeneity, we find that the extent to which unbranded generics increase their market share due to quality regulation is greater in large markets—where adverse effects on the number of firms and on prices were weaker—although these results are not statistically significant.

Theoretically, quality regulation can increase or decrease the market share of the outside option

[19] In Appendix A, we develop a novel decomposition of price effects into changes in prices of individual drugs and changes in market shares, which we further decompose into changes in market shares conditional on being in the market as well as entry and exit. We find that price increases have two main sources. The most important are price increases of incumbent drugs, accounting for two-thirds of the price increase. This result is consistent with competition weakening due to exit. Incumbents may also increase their price if consumers' valuation for them increases with the policy since it reveals their high quality. For the same reason, new entrants are able to set prices higher than pre-reform average prices. Indeed, our decomposition shows that around a third of the price increase comes from the entry of more expensive drugs. Changes in valuations are a key component in the model we develop in Section 5.

Table 2: Effects of quality regulation on drug prices and quantities

	(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)	(9)	(10)
	Drug price index ($\hat{P}_{mt}$)				Quantity outcomes					
					Market shares					log(Sales)
			Branded	Unbranded	Innovator	Branded generics			Unbranded	All
	All	Innovator	generics	generics		All	BE	Non-BE	generics	
A - Average effects										
Regulation	0.12**	0.04	-0.01	0.16***	0.09**	-0.07*	0.05	-0.12***	-0.02	-0.04
	(0.06)	(0.03)	(0.05)	(0.06)	(0.04)	(0.04)	(0.04)	(0.05)	(0.03)	(0.08)
R^2	0.99	0.99	0.99	0.99	0.86	0.94	0.53	0.87	0.95	0.98
B - Heterogeneity by market size										
Regulation × Low revenue	0.23***	0.05	0.00	0.16**	0.13***	-0.06	0.01	-0.07	-0.08	-0.08
	(0.08)	(0.04)	(0.05)	(0.07)	(0.05)	(0.03)	(0.05)	(0.05)	(0.05)	(0.13)
Regulation × High revenue	0.048	0.033	-0.013	0.17**	0.05	-0.08*	0.10*	-0.18***	0.03	(0.00)
	(0.06)	(0.03)	(0.05)	(0.07)	(0.05)	(0.05)	(0.05)	(0.06)	(0.03)	(0.09)
R^2	0.99	0.99	0.99	0.99	0.86	0.94	0.54	0.88	0.95	0.98
Observations	11,040	8,141	8,707	5,238	11,040	11,040	11,040	11,040	11,040	11,040
Market FE	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y
Month-Segment FE	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y

Notes: Columns 1-4 display results from regressions of share-weighted log prices by molecule on the policy roll-out variable constructed using the first decree deadline. Columns 5-9 display results from regressions of segment market shares on the policy roll-out variable. Column 10 displays a regression of total log sales on the policy roll-out variable. Panel B provides results by baseline market size. Markets are classified as having low or high revenue according to the total revenue in the market in 2010 relative to the median across markets in that year. The sample size in column 1 is equal to the number of markets in the sample (115) multiplied by the number of months (96). The sample size in columns 2–4 is the number of market-month observations for which there is at least one product in the segment. We also drop markets for which there is no product in the segment at baseline (January 2010). Standard errors clustered at the market level in parentheses. ***p<0.01, **p<0.05, *p<0.1.

due to the interplay between changes in market structure, price effects, and perceived quality. We do not find statistically significant effects of quality regulation on total drug sales, as shown by column 10 in Table 2.

Summary of the descriptive evidence. Stronger quality regulation may have reduced vertical differentiation, increased willingness to pay for generics, and enhanced price competition. However, our results suggest that these positive effects were at least partially overturned by the adverse competitive effects of drug exit. Most of the adverse effects of stronger regulation on drug exit and higher prices are concentrated among small markets. This pattern suggests that drugs exit when the certification cost is large relative to market profitability.[20,21]

[20] As an additional set of results, in Appendix B, we provide evidence that neither the incidence of drug recalls nor the incidence of adverse health events associated with drug consumption increased after the reform. Although we find these results informative, these measures of quality are mostly related to drug safety and not to drug efficacy. Hence, they are not directly associated with bioequivalence, so we interpret this result cautiously. Using our model, we are able to indirectly infer the improvement in drug quality as measured by bioequivalence.

[21] In Appendix C, we expand the heterogeneity analysis. We study heterogeneity by classifying drugs according to whether they treat a chronic condition and whether they have high mortality impacts. We find stronger effects on prices and quantities among markets for non-chronic conditions. This result is consistent with information frictions playing a role in the effects of the reform, as captured by our model in Section 6. On the other hand, we find large price effects among drugs with high mortality impacts, suggesting potentially large welfare impacts. Our welfare analysis in Section 7.2 computes the overall welfare of the reform using estimates of market (and segment)-specific drug valuations.

While lower variety and higher prices often suggest welfare decreases, that implication is not immediate in this context. If the distribution of drug quality improved due to the regulation, then consumers may be better off despite lower variety and higher prices. The model we develop and estimate in Section 5 allows us to quantify the welfare effects of quality regulation, unpack its equilibrium effects, and study alternative policy designs.

4 Evidence on Perceived Quality from a Consumer Survey

Our findings suggest that quality regulation had unexpected consequences. The estimated price increases hint that the adverse competitive effects of drug exit more than compensated for those from reductions in vertical differentiation. However, the welfare effects of the regulation depend critically on whether consumers perceive drug quality accurately at baseline and how regulation may impact those perceptions. We administer a consumer survey to shed light on quality perceptions and how bioequivalence shapes them.

We conducted in-person surveys to frequent consumers recruited outside pharmacies. We focused on Atorvastatin, a common anti-cholesterol drug. We asked consumers for their quality perceptions over four different products: the innovator drug (Lipitor, by Pfizer), a bioequivalent branded generic (Lipoten, by Pharmavita), and bioequivalent and non-bioequivalent unbranded generics (Atorvastatina, by Mintlab). We surveyed 401 consumers, of which 58 percent reported having a household member with a chronic disease, and 34 percent reported buying Atorvastatin for a household member. See Appendix D for more details and Table A.5 for summary statistics.

Consumers display substantial variation in perceived drug quality. We collect data on perceived quality on a numerical scale and compute the innovator's perceived quality premium relative to the three generic alternatives. On average, the innovator has a higher perceived quality than each of the generic alternatives.[22] Also, consumers perceive branded generics to be of higher quality than unbranded generics, suggesting consumers attach a quality premium to brands. Finally, consumers perceive bioequivalent drugs to be of higher quality than non-bioequivalent drugs. Consumers thus attribute a quality premium to bioequivalence, large enough to close the brand premium but not the innovator's perceived quality premium. These insights guide our demand model in Section 5, where drug valuations may vary by segment and with bioequivalence certification. Moreover, we note that other factors, such as biased beliefs regarding quality, lack of understanding about bioequivalence, or detailing, may also affect perceived valuations of generics. We refer to these factors as aversion to generics and also account for them in our model.

[22] Figure A.4 displays the distribution of the three perceived quality premiums. Relative to innovator drugs, perceived quality is 10 percent ($0.62\sigma_I$) lower for branded generics, 11 percent ($0.68\sigma_I$) lower for unbranded bioequivalent generics, and 26 percent ($1.62\sigma_I$) lower for branded generics, where σ_I is the standard deviation of the innovator's perceived quality. The $p-$value of a test of difference in means is zero for each of the three perceived quality premiums.

5 A Model of Entry, Certification and Demand

In this section, we develop a model that captures the main channels through which quality regulation impacts market outcomes: resolving asymmetric information, eliminating low-quality drugs, changing aversion to generics, and imposing costly certification. With this model, we aim to quantify the importance of these mechanisms in driving the effects documented in Section 3. In addition, we are interested in developing a welfare analysis to determine whether decreased asymmetric information and quality assurance compensate for the adverse effects of reduced variety and higher prices. Finally, we are interested in studying counterfactual policy designs.

5.1 Environment

Market structure and drug quality. In each market m, there is a set of drugs $\mathcal{P}_m$ that treat a particular health condition that may decide to enter the market. Each drug $j \in \mathcal{P}_m$ is either an innovator (I), a branded generic (B) or an unbranded generic (U). These segments are indexed by k. Before entering the market, each drug draws its quality $\psi_j \in \{\psi_L, \psi_H\}$ from a Bernoulli distribution with parameter π_H^k. We define high quality as being bioequivalent and normalize ψ_L and ψ_H to 0 and 1, respectively. The distribution of drug quality may differ across segments. All innovator drugs are of high quality by definition since bioequivalence is defined relative to them, so $\pi_H^I = 1$. The parameter π_H^k measures the share of bioequivalent drugs among branded and unbranded generics in the absence of quality regulation. We do not make any assumptions on the relative share of bioequivalent drugs between the two generic segments.

Timing. The model has two stages. In the first stage, potential entrants in $\mathcal{P}_m$ decide whether to enter based on expected profits net of sunk entry costs. At this stage, all relevant characteristics of demand and costs of potential entrants are observed up to quality and idiosyncratic shocks to demand, marginal cost, and profits. Quality and profit shocks are firms' private information, but their distributions are common knowledge, leading to an incomplete information entry game (e.g., Seim 2006; Sweeting 2009). Before regulation, firms base their entry decisions solely on expected profits net of entry costs. After regulation, however, firms face additional certification costs, and low-quality firms are barred from entry.These entry decisions determine the market structure, $\mathcal{J}_m$. Once firms have entered, demand and marginal cost shocks are realized. In the second stage, firms set prices in a Bertrand-Nash equilibrium, and demand is realized.

Demand. When choosing drugs, consumers trade off perceived quality, prices, and other attributes. Consumers choose a drug in market m at time t, or the outside option $j = 0$ of no drug. The indirect utility of consumer i for drug j in segment k, market m, and period t is:

$$u_{ijmt}^k = v_{jmt}^k + \frac{\alpha}{\varphi_{mt}} \ln y_{it} - \alpha \ln p_{jmt} + x'_{jmt}\beta + \xi_{jmt} + \zeta_{imt}^k + (1-\sigma)\epsilon_{ijmt}, \tag{3}$$

where v^k_{jmt} is the perceived value of the drug, y_{it} is consumer income, p_{jmt} is the drug price, x_{jmt} are drug attributes, ξ_{jmt} is a utility shock that is unobserved by the econometrician, and $\zeta^k_{imt} + (1-\sigma)\epsilon_{ijmt}$ is an idiosyncratic preference shock with a nested structure that allows for asymmetric substitution patterns within and between drug segments (Berry, 1994). The parameter σ measures the correlation of idiosyncratic taste shocks within segments. A higher σ implies greater within-segment substitution, leading to more severe business stealing and making excessive entry more likely (Berry *et al.*, 2016). The specification is a special case of the discrete-continuous choice framework of Hanemann (1984), and is described as the constant expenditure model by Bjornerstedt and Verboven (2016).[23,24] We provide more details in Appendix E.1.

A key object of interest is perceived value v^k_{jmt}. We consider two frictions that generate a gap between the perceived value of generics and that of the innovator. First, there is asymmetric information regarding the quality of generics. Consumers cannot discern the quality of any given drug j but base their assessment on its segment and whether it has certified bioequivalence, as denoted by the indicator b_{jmt}. We write the expected quality of generics as $\mathrm{E}[\psi_j \,|\, k, \mathrm{b}_{jmt}]$. Second, consumers may display aversion to generics, even if a generic is bioequivalent. This aversion could arise from several sources, including biased beliefs over quality, differences in side effects, and detailing, among others. We do not attempt to distinguish these and rather let $\tau^k_m(\mathrm{b}_{jmt})$ capture aversion to generics broadly. We allow aversion to depend on whether the generic is branded or unbranded and on certification status. For welfare analysis, we consider different assumptions regarding the welfare relevance of aversion to generics.

Letting μ^I_m be the valuation of drug quality, the perceived value of a drug is:

$$v^k_{jmt} \equiv \underbrace{\mu^I_m}_{\substack{\text{Valuation of} \\ \text{drug quality}}} \cdot \underbrace{(\mathrm{E}[\psi_j \,|\, k, \mathrm{b}_{jmt}]}_{\substack{\text{Expected} \\ \text{drug quality}}} - \underbrace{\tau^k_m(\mathrm{b}_{jmt}))}_{\substack{\text{Generic} \\ \text{aversion in } k}}, \tag{4}$$

so positive values of $\tau^k_m(\mathrm{b}_{jmt})$ increase perceived vertical differentiation between innovator drugs and generics in segment k relative to an environment without aversion to generics.

Consumers have rational expectations about quality ψ_j. Given that only high-quality drugs

[23]The functional form in income and price implies that the consumer allocates a constant income share φ_{mt} to the market, which is spent on a single preferred alternative. Hence, this specification allows for differences in drug purchases between consumers with different incomes, which is realistic in the Chilean setting, where consumers pay close-to-full drug prices in the retail market. In Appendix E.1, we use auxiliary survey data to show that drug expenditures are indeed approximately proportional to income in Chile. Note that the additive utility from income does not vary across alternatives and, therefore, does not affect choice behavior, though it matters for welfare evaluation.

[24]A log price specification fits our data better than including price in levels due to the large heterogeneity in prices across markets. Related work has also adopted this specification for the same reasons (Dubois *et al.*, 2022). In addition, we note that having prices in logs in a standard discrete choice model with (assumed) unit demand is not an economically consistent model and, therefore, does not allow for a welfare analysis consistent with utility maximization. In contrast, our model allows for both having prices in logs and a well-founded welfare analysis.

can be certified, bioequivalence is a certain signal of high quality. The expected quality of drug j given its segment and certification status is then:

$$\mathrm{E}[\psi_j \,|\, k, \mathrm{b}_{jmt}] = \pi_H^k(1 - \mathrm{b}_{jmt}) + 1 \cdot \mathrm{b}_{jmt},$$

such that for generics without bioequivalence certification, their expected quality is equal to the baseline share of high-quality drugs, $\mathrm{E}[\psi_j \,|\, k \in \{B, U\}, \mathrm{b}_{jmt} = 0] = \pi_H^k$. For generics with certification, $\mathrm{E}[\psi_j \,|\, k \in \{B, U\}, \mathrm{b}_{jmt} = 1] = 1$, which is equal to $\mathrm{E}[\psi_j \,|\, k = I, \mathrm{b}_{jmt} = 1]$ by definition.

We define τ_{m0}^k and τ_{m1}^k as the levels of aversion to generics in segment k and market m before and after bioequivalence certification, respectively. We can then write aversion to generics as:

$$\tau_m^k(\mathrm{b}_{jmt}) = \tau_{m0}^k(1 - \mathrm{b}_{jmt}) + \tau_{m1}^k \mathrm{b}_{jmt},$$

and impose by definition that there is no aversion against innovator drugs, such that $\tau_m^I = 0$.

Under this structure, perceived quality depends only on the segment and bioequivalence certification of a drug j. Therefore, we can define $v_{jmt}^k = v_{m0}^k(1 - \mathrm{b}_{jmt}) + v_{m1}^k \mathrm{b}_{jmt}$. Then we get, for example, that $v_{m0}^B = \mu_m^I(\pi^B - \tau_{m0}^B)$ is the perceived quality valuation of branded generics in market m without bioequivalence certification, and $v_{m1}^U = \mu_m^I(1 - \tau_{m1}^U)$ is the perceived quality valuation of unbranded generics in market m with bioequivalence certification.

Supply. The supply side of the model consists of two stages. In the first stage, firms in a set $\mathcal{P}_m$ of potential entrants simultaneously decide whether to enter market m. In the second stage, entrants maximize profits by competing on prices. Each potential entrant j draws drug attributes x_j, marginal cost c_j, an entry cost F_j, a certification cost κ_j, and quality ψ_j. We assume that marginal costs and fixed costs are unrelated to quality within a segment. This assumption allows for differences in these costs across segments but implies that high- and low-quality drugs within a segment share the same systematic components of them.

Upon entry, the variable profits of firm j under a market structure $\mathcal{J}_m$ are given by:

$$\widetilde{\Pi}_j(\mathcal{J}) = \max_{p_j} \quad (p_j - c_j) q_j(p, x; \mathcal{J}_m),$$

where $q_j(p, x; \mathcal{J}_m)$ is the demand for firm j given prices p and attributes x of all firms in $\mathcal{J}_m$. If the firm enters, it also gets an idiosyncratic profit shock ε_j^1, whereas if it does not enter, it gets an idiosyncratic profit shock ε_j^0 from an outside option.

Firms hold incomplete information about their rivals (Seim, 2006; Sweeting, 2009). Firm attributes, marginal costs, entry costs, and certification costs $\{x_j, c_j, F_j, \kappa_j\}$, and the set of potential entrants $\mathcal{P}_m$ are common knowledge to all potential entrants. In contrast, firms only know the distributions of profit shocks $(\varepsilon_j^1, \varepsilon_j^0)$ and quality ψ_j (i.e., they know π_H^k and π_L^k), while their realizations

are private information.

Quality regulation. Under quality regulation, branded and unbranded generics decide whether to sink a cost κ_j to test for bioequivalence or to exit the market. Regulation may affect outcomes through three channels. First, only high-quality firms stay in the market under regulation, and hence expected quality will be $\mathrm{E}[\psi_j | k, \mathrm{b}_j = 1] = \psi_H \quad \forall k$. Second, the regulation may affect perceived drug valuations by reducing aversion to generics, such that τ_m^k may adjust. Finally, the regulation imposes certification costs κ_j that affect equilibrium market structure and prices.

5.2 Equilibrium

An equilibrium without quality regulation is such that all firms in the market make non-negative expected profits net of entry costs while maximizing profits given the realized market structure. An equilibrium with quality regulation is defined similarly, but expected profits are net of entry and certification costs for new entrants, and net of certification costs for incumbent firms.

Because of private information, firm j does not know the realized market structure $\mathcal{J}_m$ when considering entering the market. Let $\mathcal{S}_m$ be the set of potential market structures and $\mathcal{J}_s$ be an element of $\mathcal{S}_m$. Then, the expected profits net of fixed costs χ_j are:

$$\mathrm{E}_\phi[\Pi_j(\mathcal{J})] = \underbrace{\sum_{\mathcal{J}_s \in \mathcal{S}_m} \widetilde{\Pi}_j(\mathcal{J}_s) P_j^S(\mathcal{J}_s; \phi)}_{\equiv E_\phi[\widetilde{\Pi}_j(\mathcal{J})]} - \chi_j + \varepsilon_j^1,$$

where the expectation is taken over a vector of entry probabilities of all potential entrants, ϕ, $P_j^S(\mathcal{J}_s; \phi)$ is the probability that firm j assigns to market structure $\mathcal{J}_s$ given entry probabilities ϕ, and χ_j includes entry and possibly certification costs. This probability $P_j^S(\mathcal{J}_s; \phi)$ takes the form:

$$P_j^S(\mathcal{J}_s; \phi) = \frac{1}{\phi_j} \prod_{l \in \mathcal{J}_s, l \in \mathcal{P}_m} \phi_l \prod_{h \notin \mathcal{J}_s, h \in \mathcal{P}_m} (1 - \phi_h). \tag{5}$$

A firm enters whenever the expected profits from entering exceed those from not entering. Therefore, the probability that firm j enters the market is:

$$\phi_j = \Pr(\mathrm{E}_\phi[\widetilde{\Pi}_j(\mathcal{J})] - \chi_j + \varepsilon_j^1 > \varepsilon_j^0).$$

Equilibrium without quality regulation. In the absence of quality regulation, an equilibrium market structure is such that all entrants make non-negative expected profits and all non-entrants make negative expected profits, for an entry cost $\chi_j = F_j$.

Let ϕ^{NQ} be the vector of equilibrium entry probabilities for all potential entrants, which induces

probabilities $P_j^S(\mathcal{J}_s; \phi^{NQ})$ in equation (5). Then, the expected total profits for firm j are:

$$\mathrm{E}_{\phi^{NQ}}[\Pi_j(\mathcal{J})] = \mathrm{E}_{\phi^{NQ}}[\widetilde{\Pi}_j(\mathcal{J})] - F_j + \varepsilon_j^1 \qquad \forall j \in \mathcal{P}_m,$$

which implies entry probabilities:

$$\phi_j^{NQ} = \Pr(\mathrm{E}_{\phi^{NQ}}[\widetilde{\Pi}_j(\mathcal{J})] - F_j + \varepsilon_j^1 > \varepsilon_j^0) \qquad \forall j \in \mathcal{P}_m, \tag{6}$$

which is a system of equations on ϕ^{NQ} that describes the equilibrium of the entry model, with one equation for each of the P_m potential entrants.

Equilibrium with quality regulation. The basic structure of equilibrium changes in two dimensions when considering the case with quality certification. First, entry costs change because of certification costs. In particular, innovators only incur a fixed cost to enter, and thus $\chi_j = F_j$ for $k_j = I$. In contrast, branded and unbranded generics incur both fixed and certification costs to enter, and thus $\chi_j = F_j + \kappa_j$ for $k_j \in \{B, U\}$. Second, entry probabilities change due to the selection of low-quality drugs out of the market. We define entry probabilities under quality regulation as $\phi_{j|L}$ and $\phi_{j|H}$ for low- and high-quality drugs, respectively.

Under quality regulation, the probability that firm j assigns to market structure $\mathcal{J}_s$ depends on the likelihood that branded and unbranded generics are of high quality, π_H^k, and is given by:

$$P_j^S(\mathcal{J}_s; \phi, \pi_H) = \frac{1}{\phi_{j|H}\pi_H^k} \prod_{l \in \mathcal{J}_s, l \in \mathcal{P}_m} \phi_{l|H}\pi_H^k \prod_{h \notin \mathcal{J}_s, h \in \mathcal{P}_m} (1 - \phi_{h|H}\pi_H^k) \qquad \forall j \in \mathcal{P}_m,$$

which reflects that only high-quality firms remain in the market under quality regulation. Expected profits are calculated using these probabilities.

The equilibrium market structure under quality regulation is described by the following set of equations on entry probabilities:

$$\begin{aligned} \phi_{j|L}^Q &= 0 && \forall j \in \mathcal{P}_m, \psi_j = \psi_L \\ \phi_{j|H}^Q &= \Pr(\mathrm{E}_{\phi^Q}[\widetilde{\Pi}_j(\mathcal{J})] - \chi_j + \varepsilon_j^1 > \varepsilon_j^0) && \forall j \in \mathcal{P}_m, \psi_j = \psi_H, \end{aligned} \tag{7}$$

which is a system of P_m equations on ϕ^Q.

Pricing. In the second stage of the game, the set of entrants compete by setting prices in a Nash-Bertrand game. Equilibrium prices are the solution to the following first order conditions:

$$p_j = c_j - \frac{q_j(p)}{\frac{\partial q_j(p)}{\partial p_j}} \qquad \forall j \in \mathcal{J}_m, \tag{8}$$

such that firms charge a mark-up over marginal cost that depends on consumer price sensitivity.

5.3 Model Discussion

While our model captures several key features of the environment, it also has some limitations.

Exogenous drug quality. We assume that drug quality is exogenous. This assumption limits the extent to which firms could react to quality regulation by investing in quality. Regarding timing, this assumption implies that regulation happens after production technology is set up. Although this is a reasonable assumption in the short run, the long-run effects of quality regulation may include endogenous responses along this margin or, more broadly, in terms of R&D by pharmaceutical companies.

The role of physicians. We do not formally model the role of physicians in consumer decision-making. Given that we do not observe prescriptions in our data, we cannot disentangle such influence. Any misalignment between physicians and consumers or barriers to generic substitution will load on our estimates of aversion to generics.[25]

Risk aversion. Though risk aversion could play a role in drug choice, we do not explicitly include it in our utility specification. In principle, our estimates of aversion to generics could be driven by risk aversion, but our results in Section 6.3 below are mostly inconsistent with that possibility. First, we estimate substantial aversion to both branded and unbranded generics, even though the average quality of the former is close to that of innovator drugs. Second, aversion to unbranded generics remains high after the reform, when uncertainty about quality is fully resolved.

Dynamics and belief updating. We abstract from dynamic considerations. First, the model does not allow for learning about drug quality through consumption. Since quality discovery most likely would operate through physicians (Crawford and Shum, 2005), learning should play a limited role for unbranded generics where prescriptions cannot specify a manufacturer. It is plausible that branding of generics plays a role as a quality signal. This could explain the differences we estimate between branded and unbranded generics in their distributions of quality (most branded generics are high-quality) and entry costs (which are higher for branded generics) in Section 6.1 below.

Second, by assuming that expected quality is equal to the share of high-quality drugs, we rule out that consumers update their beliefs about drug quality based on bioequivalence certification by other drugs. This assumption rules out that the timing of bioequivalence certification is informative for consumers, e.g., an equilibrium where high-quality drugs are more likely to obtain certification early. The fact that the clear majority of certifications take place at the last possible time (the first

[25] A recent report by the antitrust authority (*Fiscalía Nacional Económica*, FNE) shows that retail pharmacies pay 70 percent more than the public sector, and 60 percent more than institutional private entities (mostly, private hospitals) for the same drug. It associates this price gap with individuals having higher brand preferences than institutional buyers.

marketing license renewal after the bioequivalence deadline) suggests that the strategic value of early certification is limited, making this assumption reasonable.

6 Econometric Model

6.1 Demand estimation

A key object of interest in the demand model is the perceived valuation of a drug, v^k_{jmt}, which we parameterize as:

$$v^k_{jmt} = v^I_m - \Delta^k_m + \eta^k \mathrm{b}_{jmt}, \tag{9}$$

where v^I_m, Δ^k_m and η^k are parameters to be estimated. This parameterization allows the value of innovators and generics to be market-specific through the terms v^I_m and $v^I_m - \Delta^k_m$, which are market-segment fixed effects.[26] The parameter Δ^k_m captures the gap in valuation between the innovator and the generic in segment k before bioequivalence certification. Finally, bioequivalence certification reduces the gap between the valuation of generics and innovators by a segment-specific factor η^k.

These parameters map to the structural parameters of demand in equation (4) as follows:

$$v^I_m = \mu^I_m, \qquad \Delta^k_m = \mu^I_m(1 - \pi^k_H + \tau^k_{m0}), \qquad \eta^k = \mu^I_m(1 - \pi^k_H + \tau^k_{m0} - \tau^k_{m1}), \tag{10}$$

such that v^I_m is equal to the valuation of innovator drugs, and Δ^k_m and η^k are functions of parameters governing aversion to generics τ^k_m and asymmetric information π^k_H. Specifically, the gap in valuation between innovators and generics before bioequivalence approval, Δ^K_m, is due to a combination of quality differences captured by $1 - \pi^k_H$ and aversion to generics τ^k_{m0}. Changes in the valuation of generics, η^k, stem from the update of expected quality captured by 1- π^K_H and changes in aversion to generics induced by the policy, $\tau^k_{m0} - \tau^k_{m1}$.

Following Bjornerstedt and Verboven (2016), the discrete-continuous nested logit model in equation (3) implies the estimating equation:

$$\ln s_{jmt} - \ln s_{0mt} = v^I_m - \Delta^k_m + \eta^k \mathrm{b}_{jmt} - \alpha \ln p_{jmt} + x'_{jmt}\beta + \lambda_t + \sigma \ln s_{jmt|k} + \xi_{jmt}, \tag{11}$$

where the shares are expenditure shares rather than quantity shares as in the unit-demand models (Berry, 1994). The expenditure share of a drug j is $s_{jmt} \equiv p_{jmt}q_{jmt}/B_{mt}$, where B_{mt} is the total budget allocated by consumers to the market including the outside option.[27] The dependent variable is

[26] Allowing market-segment fixed effects in valuations will allow us to parsimoniously evaluate the welfare effects of a quality regulation that impacts 115 different markets. When combined with further assumptions on how choice frictions enter demand, this demand model accommodates substantial heterogeneity in the underlying consumer drug valuations. We provide more details on the welfare evaluation in Section 7.2.

[27] We do not observe the total market budget B_{mt} directly, which motivates a calibration based on Huang and Rojas (2013, 2014) to recover it from data and be able to calculate expenditure shares. Recent work estimating drug demand

the difference between the log expenditure shares of drug j and the outside option, λ_t is a vector of time fixed effects, $s_{jmt|k}$ is the expenditure share of drug j among the drugs in segment k, and ξ_{jmt} is an unobserved demand shock.

We use annual data on market shares, prices, and drug attributes to estimate equation (11). We define a drug as a combination of ATC-5, segment, and producer. While a firm can offer each drug in multiple presentations, we treat all of them as a single product and include the number of presentations as a product attribute, as in Dubois and Lasio (2018). For each product, we measure prices p_{jmt} as the volume-weighted average price per daily defined dose of each drug, and b_{jmt} as the share of presentations with bioequivalence certification—we allow for heterogeneous effects of this variable on demand for branded and unbranded generics. Besides the number of presentations, drug attributes x_{jmt} include the share of presentations that have been 5 years or more in the market as a measure of product age. Finally, we include year fixed effects in λ_t to capture changes in the relative attractiveness of the outside option over time.[28]

Identification. The main identification concern in equation (11) is that pricing and certification may be driven by unobserved preference shocks ξ_{jmt}. Moreover, the conditional market share $s_{jmt|k}$ is correlated with ξ_{jmt} by construction. We employ instrumental variables to obtain consistent estimates and use GMM for estimation. We instrument prices using average prices in Norway within an ATC-5. Norwegian prices are regulated based on a basket of prices in 9 European countries (Brekke *et al.*, 2015) and capture overall changes in production costs by ATC-5 over time. We instrument bioequivalence certification with the share of presentations past their marketing license renewal deadline after the certification deadline, separately for branded and unbranded generics. Finally, we instrument within-segment shares with the average age of competing drugs, which captures variation in the relative appeal of alternatives within a segment.

Results. We summarize our demand estimates in Table 3-A. We estimate substantially higher price elasticities for generics than for innovators. Own price elasticities are, on average, 2.4 for innovators, 4.6 for branded generics, and 4.9 for unbranded generics, which are in line with recent estimates in the literature (e.g., Dubois and Lasio, 2018). Moreover, our nesting parameter estimate $\hat{\sigma} = 0.58$ indicates substantially stronger substitution within a segment than across segments.[29]

To describe the baseline gaps in perceived drug valuation between segments, we fit our demand model to an environment prior to quality regulation, $\mathrm{b}_{jmt} = 0$, to obtain estimates of perceived quality valuation for each market and segment, $\hat{v}^k_{m0}$. Before the regulation, the average perceived

using similar data also uses this method (Dubois and Lasio, 2018; Dubois *et al.*, 2022). See Appendix E.2 for details.

[28] A limitation of the sales data from IQVIA is that it reports unbranded generics as a bundle, and laboratories are not identified. We describe how we deal with this issue in Appendix E.3.

[29] Table A.3 shows auxiliary linear regressions of the endogenous variables on the instruments separately. As expected, our instrument for prices based on prices in Norway is associated with higher drug prices in Chile. Moreover, as expected, license renewals have strong effects on drug certification.

Table 3: Model estimates

	(1)	(2)	(3)	(4)	(5)
A - Demand side estimates	GMM				
log Price (α)	1.85				
	(0.71)				
Bio, branded (η^B)	-0.33				
	(0.33)				
Bio, unbranded (η^U)	1.22				
	(0.50)				
Nesting parameter (σ)	0.58				
	(0.10)				
Observations	4,514				
B - Supply side estimates	Marginal cost (γ_c)	Entry cost (\$1,000s)	Certification cost (\$1,000s)	Profit shock (γ_{σ_ϵ})	Drug quality (π_H)
Innovator		0.00			1.00
		(0.01)			-
Branded	-0.24	432.00			0.97
	(0.02)	(35.82)			(0.02)
Unbranded	-1.49	334.84			0.69
	(0.03)	(29.29)			(0.03)
Developing country origin			182.85		
			(38.37)		
Developed country origin			0.00		
			(0.00)		
log(Market size)				0.34	
				(0.03)	
Constant				8.53	
				(0.38)	
Observations	4,514	3,934	3,934	3,934	3,934
C - Aversion to generics	Before regulation (τ_0^k)		After regulation (τ_1^k)		
	Mean	SD	Mean	SD	
Branded	0.24	0.43	0.38	0.43	
	(0.06)		(0.12)		
Unbranded	0.99	0.93	0.95	0.91	
	(0.15)		(0.20)		

Notes: Panel A shows demand estimates. The specification includes market and year fixed effects. Panel B shows estimates of the supply model. Marginal cost is estimated on a panel of yearly observations for 2010–2017, and the specification includes market and year fixed effects. The remaining parameters are estimated on the cross sections of 2010 and 2017. Entry and certification costs are reported in USD 1,000s, and the distribution of drug quality is reported as the probability that a drug is of high quality. Panel C shows the mean and standard deviation of estimated aversion to generics before and after the regulation. Standard errors in parentheses.

valuation of innovator drugs was 2.3 times higher than that of unbranded generics, which helps explain the low unbranded generic market share despite of their low prices. In contrast, the average perceived valuation of innovator drugs was only 1.3 times higher than that of branded generics, which helps explain the high branded generic market share despite of their high prices.

Quality regulation affected demand differently across segments. Our estimate of η^U is large and positive, implying the relative valuation of unbranded generics increased after the reform. In particular, the average valuation of innovator drugs under regulation is 0.94 times higher than that of unbranded generics, as shown by Figure 5. These increases in valuations help rationalize the finding from Section 3 that unbranded generic market shares did not decrease after the reform

despite their price increases. In contrast, our estimate of η^B is not significantly different from zero and negative, such that the relative valuation of branded generics decreased after the reform if anything. This slight decrease helps rationalize that branded generic market shares decreased after the reform despite their prices not increasing.

Together, these results imply that quality regulation decreased vertical differentiation across generic segments, intensifying competition among them. Note that valuations depend on both expected quality and aversion to generics. From equation (4), it is easy to see that we cannot disentangle the contribution of each of them from demand-side estimates alone. However, recovering the share of high-quality drugs from the supply side will allow us to make such decomposition.

6.2 Supply estimation

The objects of interest are marginal costs c_j, entry costs F_j, certification costs κ_j, the share of high-quality drugs π_H, and the variance of profit shocks σ_ε. We parameterize them as follows:

$$\begin{aligned} c_{jmt} &= \exp(x'_{cjm}\gamma_c + \omega_{jmt}) \\ F_{jm} &= \exp(x'_{Fjm}\gamma_F) \\ \kappa_{jm} &= \exp(x'_{\kappa jm}\gamma_\kappa) \\ \pi_{Hj} &= \Lambda(x'_{\pi jm}\gamma_\pi) \\ \sigma_{\varepsilon j} &= \exp(x'_{\sigma_\varepsilon jm}\gamma_{\sigma_\varepsilon}), \end{aligned}$$

such that the parameters of interest are γ_c, γ_F, γ_κ, γ_π and $\gamma_{\sigma_\varepsilon}$. The covariates included in the specification differ across these equations. Marginal costs c_{jmt} are specified as a combination of a vector of observables x_{cjm} that includes indicators for drug segments, markets, and years, and cost shocks ω_{jmt}. Entry costs are allowed to vary across drug segments, and certification costs are allowed to differ depending on whether the drug was manufactured in a developing or developed country, given the latter were granted waivers. The probability of being of high quality is specified as constant by segment, and Λ is the logistic function, which we adopt to ensure that $\pi_{Hj} \in [0, 1]$. Finally, the profit shocks ε^1_{jmt} and ε^0_{jmt} are iid T1EV with scale parameter σ_ε, which we specify as a function of a constant and the log of market size.

The first step in estimation consists of recovering marginal costs. Using our demand estimates, we invert the optimal pricing condition in equation (8) to recover marginal costs for each product in the market for each year. Assuming that cost shocks ω_{jmt} are independent of the observable determinants of costs, we recover γ_c from a linear regression of $\log \hat{c}_{jmt}$ on x_{cjm}.

To estimate the remaining parameters of the model, we exploit firm entry choices in environments with and without quality regulation. We start by computing entry probabilities. A common concern related to entry models with incomplete information is the potential for multiple

equilibria, which complicates both estimation and counterfactuals (Seim, 2006). To avoid this issue in the estimation stage, we follow Sweeting (2009) and compute these probabilities directly from the data. Specifically, we estimate logit regressions of entry and certification choices on their determinants as predicted by the model, namely own and rival drivers of variable profits, fixed costs, and certification costs. We denote the implied probabilities by $\hat{\phi}^{NQ}$ and $\hat{\phi}^{Q}$.

We then proceed to simulate variable profits under every potential market structure, using estimates of preferences and marginal costs. We compute optimal pricing, implied demand, and variable profits for each potential entrant and potential market structure, market by market. Combining those results with fitted entry probabilities from the previous step, we then compute expected variable profits by integrating over potential market structures. We assume demand and cost shocks are realized after entry and certification choices. In particular, we assume that ξ_{jmt} and ω_{jmt} are iid conditional on the information sets held by firms when deciding about entry and certification. This assumption rules out selection into the market based on knowledge of those unobservables by potential entrants.

Finally, we exploit these inputs and the equilibrium conditions on entry probabilities to recover entry costs, certification costs, and the share of high-quality generic drugs among potential entrants.[30] The distributional assumption on ε^1_{jmt} and ε^0_{jmt} yields entry probabilities in equations (6) and (7) with the usual logit form. In particular, entry probabilities for environments without and with quality regulation respectively are:

$$\begin{aligned}
\phi^{NQ}_{jmt} &= \frac{\exp(\frac{1}{\sigma_\varepsilon}[\mathrm{E}_{\hat{\phi}^{NQ}}[\widetilde{\Pi}_{jmt}(\mathcal{J})] - x'_{Fj}\gamma_F])}{1+\exp(\frac{1}{\sigma_\varepsilon}[\mathrm{E}_{\hat{\phi}^{NQ}}[\widetilde{\Pi}_{jmt}(\mathcal{J})] - x'_{Fj}\gamma_F])} \\
\phi^{Q}_{jmt} &= \frac{\exp(\frac{1}{\sigma_\varepsilon}[\mathrm{E}_{\hat{\phi}^{Q}}[\widetilde{\Pi}_{jmt}(\mathcal{J})] - x'_{Fjm}\gamma_F - (1-d^I_j)x'_{\kappa jm}\gamma_\kappa])}{1+\exp(\frac{1}{\sigma_\varepsilon}[\mathrm{E}_{\hat{\phi}^{Q}}[\widetilde{\Pi}_{jmt}(\mathcal{J})] - x'_{Fjm}\gamma_F - (1-d^I_j)x'_{\kappa jm}\gamma_\kappa])}\left[\frac{\exp(x'_{\pi jm}\gamma_\pi)}{1+\exp(x'_{\pi jm}\gamma_\pi)}\right]^{1-d^I_j},
\end{aligned}$$

where d^I_j indicates that j is an innovator drug. We use these probabilities to estimate the remaining parameters of the model by maximum likelihood. We provide further details in Appendix E.5.

We estimate the model using two cross-sections of markets. We use 2010 to capture the pre-reform period and 2017 to capture an environment where the reform had been rolled out extensively. We use past market participation data to take into account that, once quality regulation is introduced, incumbent firms must not cover the entry cost but only the certification cost. Estimation requires taking a stance on the set of potential entrants. For each market, we include all the firms that ever participated in the market during our sample period, along with the five firms with the highest participation in each segment across markets at the national level.

[30] To put variable profits, entry costs, and certification costs on the same scale, we use an annual discount rate of 0.05 to take the present value of a stream of variable profits.

Identification. Formally, identification follows the framework of Aradillas-López (2020). The static entry game with incomplete information is guaranteed to have an equilibrium, though it may not be unique. We assume that the equilibrium selection mechanism is degenerate, meaning a unique equilibrium is selected in the data. Under this assumption, the payoff function is identified from the data, as in Seim (2006), Pesendorfer and Schmidt-Dengler (2008), and Bajari *et al.* (2010).[31]

Having estimates of demand, marginal costs, and entry probabilities, we can predict expected variable profits for any market structure. The remaining parameters to identify in the payoff function are the scale of profit shocks σ_ε, entry costs F, certification costs κ, and the share of high-quality drugs π_H^k. Before regulation, only entry costs and the scale of profit shocks are relevant, and these can be identified in the pre-regulation data alone. Segment-specific entry costs are identified from observed entry rates, conditional on expected variable profits within each segment. The scale of profit shocks is identified from the sensitivity of entry rates to variations in expected profits, which we estimate as a parametric function of market size for statistical precision.

After regulation, given F and σ_ε, the parameters π_H and κ are identified from differences in entry and exit across firms and markets with varying profitability levels. A lower π_H implies more excess exit of high-profit drugs since low-quality drugs exit regardless of profitability. Conversely, higher certification costs κ lead to more excess exit of marginally profitable firms, as these firms are more sensitive to cost increases.[32] These mechanisms are captured in the entry probability function under regulation, ϕ_{jmt}^Q, where the marginal impact of π_H on entry increases with profitability, while the marginal impact of κ decreases.[33] Variation in π_H by segment and κ by country of origin is estimated by leveraging differences in entry and exit rates, such as the relative exit of high- versus low-profitability drugs in each segment after regulation.

Results. Our supply-side estimates are displayed in Table 3-B. The marginal cost estimates imply average markups of 21 percent for unbranded generics, 22 percent for branded generics, and 44 percent for innovators. We estimate an average entry cost of $353 thousand. In our model, this cost does not have the interpretation of the cost of developing a drug but rather the cost of marketing it. Entry costs vary across segments, and branded generics incur entry costs 29 percent higher than unbranded generics, possibly reflecting investments the former incur to establish their brand. In contrast, we estimate that innovator drugs face essentially no entry costs. This is somewhat mechanical since only one firm in each market is an innovator and is almost always active. Finally, we estimate a certification cost of $183 thousand for drugs from developing countries—within the range of certification costs reported in Section 2.2—and of essentially zero for drugs from

[31] Including rich product and market features in estimation of entry probabilities accommodates equilibrium variation across markets, provided the same equilibrium is played within each market (Sweeting, 2009; Bajari *et al.*, 2010).

[32] Figure A.5 displays the relationship between post-regulation exit rates and baseline revenues to show this pattern.

[33] This pattern holds under standard distributional assumptions for profit shocks, including the extreme value distribution used in our estimation.

developed countries, as expected. To put these numbers in context, our estimates imply that the average generic gets annual variable profits of $45 thousand and that 47 percent of generics had variable profits below the annualized certification cost before the policy change.

Baseline quality is high, but not all drugs are of high quality. In particular, the shares of high-quality branded and unbranded generics before the reform are $\hat{\pi}_H^B = 0.97$ and $\hat{\pi}_H^U = 0.69$, respectively. These results are consistent with some of the drug exit we documented earlier being driven by generics being of lower quality than the innovator. As we discuss below, this finding implies that quality regulation impacts the pool of drugs in the market and shifts the perceived quality of generics upwards by resolving asymmetric information about drug quality.

6.3 Disentangling Aversion to Generics and Quality Differences

By combining demand estimates with estimates for the share of low-quality drugs from the supply model, we recover the parameters governing aversion to generics. Specifically, plugging our estimates in equation (10), we recover aversion to generics before and after the regulation as:

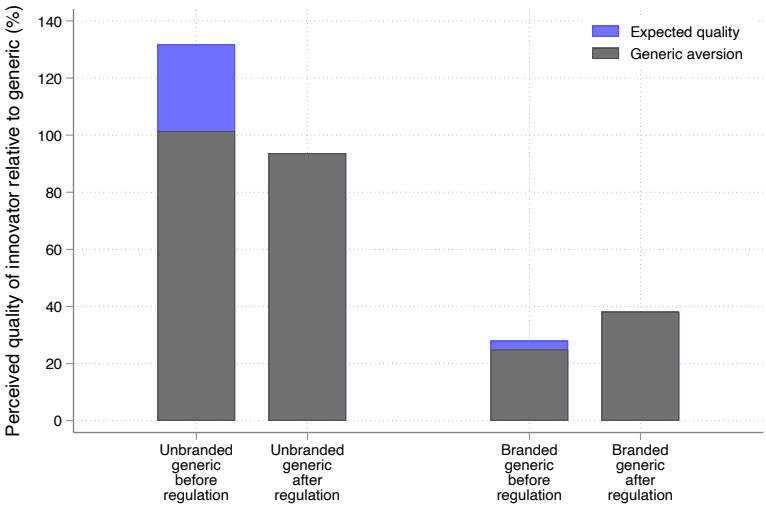
$$\tau_{m0}^k = \pi_H^k - \frac{v_{m0}^k}{v_m^I}, \qquad \tau_{m1}^k = 1 - \frac{v_{m1}^k}{v_m^I}, \tag{12}$$

with which we quantify the contributions of expected quality differences and aversion to generics to the lower valuation of generics before the reform and the extent to which quality regulation impacted aversion.

Our estimates imply substantial aversion against unbranded generics and, to some extent, against branded generics. Before quality regulation, aversion to generics was on average $\overline{\hat{\tau}_0^U} = 0.99$ and $\overline{\hat{\tau}_0^B} = 0.24$. These estimates are qualitatively in line with previous research showing that aversion to generics contributes to brand premiums (e.g., Bronnenberg *et al.*, 2015). The estimated magnitude of aversion to generics is particularly large for unbranded generics. These large differences in perceived valuation are necessary to rationalize that innovator drugs and branded generics hold large market shares despite charging much higher prices than unbranded generics.

Quality regulation had different effects on aversion to generics across segments. Aversion against unbranded generics decreased to $\overline{\hat{\tau}_1^U} = 0.95$. This decrease comes from the fact that their perceived valuation increased more than the increase in average quality. This finding implies that, on top of the direct effects on drug quality, the regulation further decreased vertical differentiation by reducing aversion against unbranded generics. Conversely, aversion against branded generics increased after the policy, with $\overline{\hat{\tau}_1^B} = 0.38$. This result comes from finding no increase in the valuation of branded generics along with an increase in their average quality. This finding suggests the policy revealed to consumers that branded generics are indeed generics and separated them more from innovator drugs relative to baseline. This may be related to all bioequivalent generics

Figure 5: Perceived quality gaps and quality regulation



Notes: This figure displays the perceived valuation of innovators relative to unbranded and branded generics. Each bar is decomposed into the components of perceived valuation gaps related to aversion to generics (gray) and drug quality (blue).

getting the same distinctive yellow label, shown in Figure A.1. This interpretation is consistent with the high baseline branded generic market share despite their high relative prices.

Figure 5 displays a decomposition of perceived innovator quality premiums.[34] Around 80 percent of the increase in the relative perceived valuation of unbranded generics was due to resolving asymmetric information, whereas the remainder was due to decreases in aversion to generics. These results are consistent with our survey evidence, also pointing towards large baseline gaps in perceived quality and a partial reduction in them due to the regulation.

7 Equilibrium Effects of Quality Regulation

Quality regulation affects market outcomes through four channels. First, it resolves asymmetric information by making drug quality observable to consumers, increasing willingness to pay for generics. Second, it changes the distribution of drug quality by mechanically removing low-quality drugs through a minimum quality standard. Third, the regulation affects outcomes by reducing consumer aversion to generics. Finally, it induces drug exit by imposing certification costs.

[34] We decompose differences in valuations between innovator and generic drugs as:

$$\hat{v}^I_m - \hat{v}^k_{mt} = (\hat{v}^I_m - \dot{v}^k_{mt}) + (\dot{v}^k_{mt} - \hat{v}^k_{mt}),$$

where $t = 0$ and $t = 1$ denote environments without and with quality regulation; $\hat{v}^I_m$ and $\hat{v}^k_{mt}$ are the estimated valuations for drugs in market m among innovators and generics in segment k; and $\dot{v}^k_{mt}$ is the valuation of generics in segment k if they were of high quality ($\pi^k_H = 1$) but at the estimated aversion to generics ($\tau^k_{mt} = \hat{\tau}^k_{mt}$). The first term captures the part of the gap due to expected quality differences, and the second term captures the part due to aversion to generics. With quality regulation, the first term is mechanically zero since there are no remaining differences in expected quality.

The model structure allows us to decompose the overall effects into these different channels. Specifically, let an equilibrium outcome be summarized by $y = y(E[\psi], \underline{\psi}, \tau, \kappa)$. In this expression, $E[\psi]$ captures consumer expectations of drug quality, namely π and ψ at baseline and after quality regulation, respectively. Moreover, $\underline{\psi}$ is the minimum quality standard, which rises to ψ_H once the standard is in place. We decompose the effects of quality regulation on y as:

$$\begin{aligned}\Delta y \;=\; & \underbrace{y(\psi, \psi_L, \tau_0, 0) - y(\pi_H, \psi_L, \tau_0, 0)}_{\substack{\Delta \text{ due to} \\ \text{no asymmetric information}}} + \underbrace{y(\psi, \psi_H, \tau_0, 0) - y(\psi, \psi_L, \tau_0, 0)}_{\substack{\Delta \text{ due to} \\ \text{minimum quality standard}}} \\ & + \underbrace{y(\psi, \psi_H, \tau_1, 0) - y(\psi, \psi_H, \tau_0, 0)}_{\substack{\Delta \text{ due to} \\ \text{changes in aversion to generics}}} + \underbrace{y(\psi, \psi_H, \tau_1, \kappa) - y(\psi, \psi_H, \tau_1, 0)}_{\substack{\Delta \text{ due to} \\ \text{certification cost}}}. \end{aligned} \tag{13}$$

We first simulate equilibrium outcomes without quality regulation, $y(\pi_H, \psi_L, \tau_0, 0)$. Using the resulting market structure as a baseline, we simulate equilibrium outcomes under each environment up to the full policy, $y(\psi, \psi_H, \tau_1, \kappa)$. See Appendix E.6 for simulation details.

7.1 Effects on Market Outcomes

We start by simulating market outcomes for an environment without quality regulation, where there is asymmetric information and the share of high-quality drugs is the estimated π_H^k, aversion to generics is given by $\tau_{mt}^k = \tau_{m0}^k$, and certification costs are $\kappa = 0$. The results for this baseline environment are shown in column 1 of Table 4-A. The simulated model matches the main industry patterns documented in Section 2.4 regarding market structure, market shares, and prices across segments. Starting from this baseline, we compute each of the terms in equation 13 to decompose the impacts of quality regulation.

In the first step, we isolate the effect of resolving asymmetric information about drug quality by setting $E[\psi_j] = \psi_j$. Columns 2 and 3 of Table 4-A show the results. Resolving asymmetric information leads to an increase in willingness to pay for high-quality generics. This demand shift is most substantial for unbranded generics since their average quality at baseline is the lowest. Higher demand lures high-quality generic entry and induces low-quality generic exit, taking the average quality of the generic drug pool close to the level of the innovator.

In the second step, we add the effect of a minimum quality standard $\underline{\psi} = \psi_H$, by forcing the remaining low-quality drugs with $\psi_j = \psi_L$ to exit. Columns 4 and 5 of Table 4-A show the results. There is net exit among branded and unbranded generics. The number of firms in each segment is 3.5 and 20.3 percent lower, respectively.[35] Coupled with drug exit, the increase in willingness to

[35]The net exit rate due to the quality standard is higher than the share of low-quality drugs among branded generics (3.5 percent as opposed to 3 percent), and lower than the share of low-quality drugs among unbranded generics (20.3 percent as opposed to 31 percent). Evaluating this policy without accounting for this margin would have led to incorrect

Table 4: Decomposition of the effects of quality regulation

		(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)	(9)
		Baseline	+Δ Due to no asymmetric information		+Δ Due to quality standard		+Δ Due to generic aversion		+Δ Due to certification cost	
	Segment	y	Δy	$\Delta\%y$	Δy	$\Delta\%y$	Δy	$\Delta\%y$	Δy	$\Delta\%y$
A - Market outcomes										
Number of firms	Innovator	0.87	-0.01	-0.48	-0.01	-0.48	-0.01	-0.30	-0.01	-0.30
	Branded	7.75	-0.06	-0.86	-0.31	-3.55	-0.50	-5.87	-0.88	-12.70
	Unbranded	6.72	0.42	7.32	-1.75	-20.31	-1.66	-18.55	-2.05	-25.69
Average price	Innovator	3.57	-0.05	-2.06	-0.06	-2.00	0.01	-0.38	0.03	1.17
	Branded	2.00	-0.00	-0.01	0.01	0.55	0.01	0.26	0.06	2.67
	Unbranded	0.57	0.02	3.97	0.03	8.93	0.03	10.13	0.07	22.63
Market share	Innovator	0.25	-0.03	-2.32	-0.03	-2.51	-0.01	-0.37	0.00	0.31
	Branded	0.48	-0.08	-5.34	-0.04	-2.62	-0.12	-7.78	-0.12	-7.59
	Unbranded	0.26	0.11	8.80	0.07	5.75	0.12	10.21	0.11	9.53
Share-weighted quality		0.92	0.08		0.08		0.08		0.08	
B - Welfare effects (MM/year)										
Compensating variation (A1)		1,019.40	48.52	4.76	48.12	4.72	47.16	4.63	45.09	4.42
Compensating variation (A2)		1,213.55	84.23	6.94	83.77	6.90	85.70	7.06	83.27	6.86
Variable profits		102.10	-2.63	-2.58	-3.11	-3.04	-1.09	-1.07	-0.71	-0.70
Certification costs		0.00	0.00		0.00		0.00		9.73	
Fixed costs		29.41	0.60	2.03	-3.77	-12.82	-4.04	-13.75	-5.60	-19.05
Total profits		72.69	-3.23	-4.44	0.67	0.92	2.95	4.06	-4.84	-6.66
Welfare (A1)		1,092.09	45.29	4.15	48.79	4.47	50.12	4.59	40.25	3.69
Welfare (A2)		1,286.24	81.00	6.30	84.43	6.56	88.65	6.89	78.43	6.10

Notes: Column 1 shows baseline outcomes without the reform. The rest of the table decomposes the effect of quality regulation. Columns 2 and 3 show changes in outcomes relative to column 1 coming from resolving asymmetric information about drug quality, but without imposing a minimum quality standard. Columns 4 and 5 display changes relative to column 1 after imposing the minimum quality standard. Columns 6 and 7 display changes relative to column 1 after also accounting for changes to aversion to generics. Columns 8 and 9 display the changes relative to column 1 after also accounting for certification costs. This is the full effect of quality regulation. Compensating variation and total welfare are reported according to assumptions A1 and A2 in Section 7.2. To compute baseline consumer welfare, we calculate the compensating variation between the baseline equilibrium and an environment in which only the outside option is available. Fixed and certification costs are reported in annualized terms. Results for market outcomes report average across markets. In particular, Δy is the average level change in an outcome relative to baseline across markets, and $\Delta\%y$ is the average percentage change outcome y relative to baseline across markets. Welfare results aggregate across all markets.

pay for generics induces price increases among generics. At this point, the market is characterized by high-quality drugs, higher prices, and a demand shift towards unbranded generics.

In the third step, we quantify the additional effects of decreasing aversion to generics. In particular, we set $\tau^k_{mt} = \tau^k_{m1}$. Columns 6 and 7 of Table 4-A show the changes in equilibrium outcomes from the effects of quality regulation on top of imposing a quality standard. Setting aversion to generics to its post-regulation level makes unbranded generics more competitive and branded generics less competitive, resulting in the entry of the former and exit of the latter. Along the same line, unbranded generics gain substantial market share and increase their prices.

conclusions about the distribution of drug quality. These results underscore the relevance of accounting for endogenous firm entry and exit margins responses to regulation, as recent work has also pointed out (Fan, 2013; Wollmann, 2018).

Finally, in the fourth step, we introduce the certification cost κ to get the full effect of quality regulation. Columns 8 and 9 of Table 4-A shows the results. Adding certification costs reduces the number of branded and unbranded generics in the market, making the negative effect of the policy on the total number of drugs in the market 46 percent larger. As a result, price increases among generics more than double relative to an environment without certification costs.

These are the full effects of quality regulation. Overall, our model predicts reductions in the number of drugs for all segments, coupled with price increases among generic drugs. The magnitudes of these simulated effects are close to those in our descriptive evidence. We find that resolving asymmetric information is the main driver of the effects of quality regulation: higher demand for unbranded generics leads to higher prices and net entry of drugs in this segment. The quality standard removes all remaining low-quality drugs from the market, relaxing competition and increasing prices. Changes in aversion to generics amplify the substitution towards unbranded generics because of the increased aversion against branded generics coupled with a small decrease in aversion against unbranded generics. Finally, certification costs induce further exit, amplifying the adverse effects on market structure and prices.[36]

7.2 Welfare Analysis

There are two main frictions in consumer choice that shape the welfare effects of quality regulation. First, asymmetric information about product quality implies that consumers who purchase a non-bioequivalent generic would have been better off with a different product. Therefore, eliminating non-bioequivalent generics from the choice set may improve consumer welfare. Second, the policy may improve consumer choices by decreasing biases against generics (e.g., biased beliefs about drug quality). Biases decrease welfare by inducing suboptimal choices.

These demand-side frictions provide two reasons not to adopt a revealed preference approach to welfare analysis in this setting. More precisely, these frictions introduce two wedges between choice utility v^k_{jmk} and experienced utility $\tilde{v}^k_{jmk}$, which determine choices and welfare, respectively. First, choice utility is based on expected quality $E[\psi_j]$, whereas experienced utility is based on actual quality ψ_j. Second, choice utility is based on a degree of aversion to generics τ^k_m that might be only partially welfare-relevant. We evaluate the welfare effects of the regulation under two different assumptions for experienced utility:

$$\text{A1:} \quad \tilde{v}^k_{jmt} = \mu^I_m \cdot (\psi_j - \tau^k_m(1))$$
$$\text{A2:} \quad \tilde{v}^k_{jmt} = \mu^I_m \cdot (\psi_j - 0),$$

[36]Note that whereas the decomposition relies on the assumed structure of the perceived value of drugs in equation (4)—how expected quality and aversion to generics enter utility along with their respective estimates—the overall effects are independent of those and only depend on demand estimates in equation (11).

both of which treat actual quality rather than expected quality as welfare-relevant, and take different stances for the part of the aversion to generics that is welfare-relevant.[37]

Under assumption A1, the welfare-relevant aversion to generics is what we estimated for the post-reform period, $\tau_m^k(1)$. That is, consumers are not biased against generics after the reform, hence their aversion to generics at that point reflects lower experienced utility (in the pre- and post-reform environments). This assumption corresponds to an environment where the regulation removes all the welfare-irrelevant components of aversion to generics.[38] Alternatively, under assumption A2, none of the estimated aversion to generics is welfare-relevant, so bioequivalent generics provide the same benefits as innovator drugs. Assumption A2 would be preferred over A1 if, for instance, consumers still hold biased beliefs about quality after the regulation, or if demand is still affected by detailing efforts from manufacturers. However, it rules out the possibility that bioequivalent generics have worse side effects than innovators.[39]

We calculate the total welfare effect of counterfactual policies as:

$$\Delta W = \sum_{i,m} CV_{im} + \sum_{j,m} \Delta\widetilde{\Pi}_{jm} - \sum_{j,m} \Delta F_{jm} - \sum_{j,m} \Delta\kappa_{jm},$$

which includes consumer compensating variation CV, the change in firm variable profits $\Delta\widetilde{\Pi}$, changes in the amount of fixed costs incurred by entrants ΔF, and changes in the amount of certification costs paid by generics $\Delta\kappa$. Appendix E.4 provides more details.

The results of our welfare analysis of quality regulation are shown in Table 4-B. Overall, welfare increases by between \$40 and \$78 million per year due to the regulation, depending on the welfare metric. As expected, welfare increases more under assumption A2, under which aversion to generics is not welfare-relevant, since there is a net increase in the market share of generics. Increases in consumer welfare drive the bulk of the overall welfare increase. On the other hand, firms are worse off under the regulation since their variable profits decrease by \$0.7 million and they must incur \$9.7 million in certification costs, albeit lower entry saves \$5.6 million in fixed costs. Taken together, these results indicate that the increase in drug quality and the reduction in incurred entry costs more than compensate for the lower variety and higher prices associated with the adverse competitive effects of certification costs.[40]

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[37] See e.g., Handel (2013) for a similar approach in the context of consumer inertia in insurance choice, and Grennan *et al.* (2024) for a welfare analysis of the effects of physician payments on demand for drugs.

[38] In other words, under this assumption, quality regulation turns consumers into "experts". This way to uncover the welfare-relevant part of aversion is similar to that in Bronnenberg *et al.* (2015), who use demand from experts, with the added assumption that individuals become experts after quality regulation.

[39] This possibility is not ruled out by bioequivalence tests, which only ensure equivalent therapeutical efficacy.

[40] The results of our welfare analysis depend on the value of low-quality drugs. We note that our main specification of the demand model normalizes this value to zero. In Appendix E.7, we discuss this normalization at length and show that our results are robust to other plausible normalizations. In particular, Figure A.6 shows that the impacts of

Resolving asymmetric information is the main driver of the positive welfare impacts of quality regulation. Using the decomposition in equation 13, we find that such component of the policy on its own increases welfare by between $45 and $81 million. Accounting for the impacts of the quality standard and effects on aversion to generics increases those welfare effects by around 10 percent. Conversely, the negative impacts of certification costs on market structure and competition decrease welfare, limiting the overall welfare gains from the regulation.

Connection to descriptive patterns. It is worth discussing how the findings from our welfare analysis connect to the main descriptive patterns of the industry in terms of market outcomes. Quality regulation may impact consumer welfare by affecting market outcomes along three channels: (i) exit of low-quality generics in response to the quality standard, implying consumers cannot draw a low-quality drug, (ii) changes in market shares, and (iii) changes in prices.

On the first, the data show that unbranded generics have a baseline market share as high as 26 percent, even though we estimate that 31 percent were non-bioequivalent. The quality standard eliminates the welfare losses from purchasing low-quality generics. Through the lens of the model, we infer that the welfare loss of buying a low-quality generic instead of a bioequivalent generic is large from the low market share of unbranded generics despite their low prices. On the second, we find that quality regulation induces net substitution towards high-quality unbranded generics. This shift leads to consumer welfare gains to the extent lower expenditures more than compensate for losses from aversion to generics. On the third, quality regulation led to higher prices of unbranded generics, as documented in Section 3.2. Whereas these price effects are detrimental to welfare per se, our model allows us to establish they are not large enough to overturn the gains from improving the pool of unbranded generics.

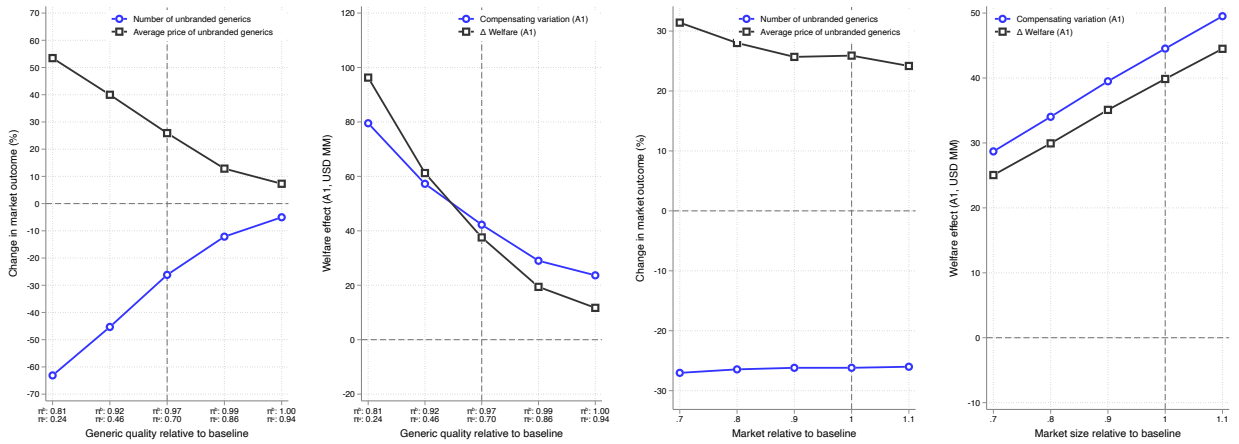
7.3 The Drivers of the Equilibrium Effects of Quality Regulation

Our welfare analysis shows that quality regulation was welfare-enhancing in aggregate. However, the trade-offs in place suggest that this regulation could also be detrimental to welfare. Indeed, quality regulation leads to lower welfare for 25 percent of markets in our sample. Market size is a relevant correlate of this heterogeneity since this fraction is 48 (2) percent for markets below (above) the median market size. This pattern is consistent with the descriptive evidence in Section 3.2, which showed stronger impacts of the regulation on market structure among small markets.

We further explore the determinants of the effects of quality regulation by implementing the same analysis under alternative market configurations. In particular, we explore changes along two key dimensions: the distribution of drug quality at baseline and market size. In practice, we simulate baseline outcomes without quality regulation for a range of alternative configurations

quality regulation on consumer and total welfare remain positive for a broad range of assumptions regarding the value of low-quality drugs and for both assumptions A1 and A2.

Figure 6: Quality regulation under counterfactual baseline quality and market size



(a) Quality, outcomes (b) Quality, welfare (c) Market size, outcomes (d) Market size, welfare

Notes: Each dot indicates the full effect of quality regulation relative to a baseline without quality regulation for a range of industry primitives. For each configuration, we simulate the model for both environments. Panels (a) and (b) report results for a range of distributions of baseline quality of generics, where we vary π_H^k. Panels (c) and (d) report results for a range of market sizes relative to baseline. Panels (a) and (c) display effects on the number (blue) and price (black) of unbranded generics as a subset of market outcomes. Panels (b) and (d) display effects on consumer (blue) and total (black) welfare as a subset of welfare outcomes. Vertical dotted lines indicate baseline industry primitives, namely estimates of average drug quality by segment and observed market size.

and then evaluate the impacts of quality regulation starting from each such baseline. Figure 6 displays the results from this analysis. First, Figures 6-a and 6-b show that quality regulation would have substantially stronger welfare effects in markets with lower baseline expected quality, where resolving asymmetric information and removing low-quality drugs from the market would be most impactful. Second, Figures 6-c and 6-d show that quality regulation would be more welfare-enhancing for large markets, among which certification costs would have less incidence.

8 Policy Counterfactuals

Certification cost subsidies. Certification costs limit the welfare gains from quality regulation by inducing exit and price increases. In this section, we study whether certification subsidies could limit these unintended consequences. Table 5-A shows results for an environment where certification costs are subsidized at 50 percent. Compared to the environment with quality regulation but no subsidies in columns 8–9 of Table 4, this equilibrium features more firms and lower prices. Fully eliminating certification costs further limits drug exit and price increases.

Subsidizing certification would be more impactful in small markets, consistent with the results in Section 7.3. In particular, when firms incur the full certification cost, quality regulation leads to decreases in the number of firms by 29.5 and 14.2 percent in small and large markets, respectively. When subsidizing certification costs, these adverse effects are 13.8 and 2.5 percentage points lower

in small and large markets, respectively. Similarly, the positive impact of quality regulation on average prices of unbranded generics is 4.3 percentage points lower with certification cost subsidies in small markets, as opposed to only 0.2 percentage points in large markets.[41] These results suggest that subsidizing certification may enhance the impacts of quality regulation, particularly among small markets, possibly justifying targeted subsidies.

Quality disclosure. An alternative to a minimum quality standard is quality disclosure. This policy involves informing consumers about each product's quality while still allowing products below the quality standard to sell. To the extent these products compete with high-quality products, keeping them in the market may reduce the adverse competitive effects of minimum quality standards while still resolving asymmetric information. We compare these policies by implementing a disclosure policy in our model whereby firms must pay the same certification cost κ to verify their quality but can stay in the market even if their drug is not bioequivalent.[42] After a firm tests for bioequivalence, its quality ψ_j becomes observable.

Quality disclosure outperforms minimum quality standards in terms of market outcomes, as shown by Table 5-B. Because low-quality firms are allowed to sell under quality disclosure, the number of firms falls less than under quality regulation (in columns 8 and 9 of Table 4). The number of unbranded generics decreases by less than one percent, which comes from more entry of high-quality drugs and less exit of low-quality drugs than under minimum quality standards—low-quality incumbents are not forced to exit and must pay only the certification cost but not the entry cost to remain in the market, which gives them an advantage relative to potential entrants and limits turnover.[43] The weaker effects of quality disclosure on market structure lead to smaller price increases than under minimum quality standards.

Quality disclosure has a slightly stronger effect on consumer welfare than minimum quality standards. Like minimum quality standards, quality disclosure eliminates the welfare losses from consumers buying a low-quality drug by resolving asymmetric information and has less adverse competitive effects. However, minimum quality standards dominate in terms of total welfare. By not allowing low-quality drugs to be sold, this policy reduces the total fixed and certification costs incurred, leading to higher overall welfare despite the weaker competition.

[41] To further explore this comparison, Figure A.7 shows the effects of quality regulation with and without certification subsidies across markets. While quality regulation decreases the number of firms and increases unbranded generic prices in most markets, these effects are weaker with certification subsidies, particularly among smaller markets.

[42] In terms of the effect of disclosure on aversion to generics, we impose that once the policy is in place, consumers have aversion $\tau_m^k(1)$ to all drugs in a segment, regardless of their quality.

[43] Figure A.8 shows how quality regulation and disclosure impact variable profits for low- and high-quality firms relative to baseline. While profitability is the same for both sets of firms at baseline, they separate under both policies since quality can be priced once asymmetric information is resolved. Several incumbent low-quality firms remain profitable, though those can only operate under disclosure.

Table 5: Counterfactual analysis: certification costs, quality disclosure, and aversion to generics

		(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)	(9)	(10)	(11)	(12)	(13)
			A - Role of certification costs				*B - Disclosure*		*C - The role of aversion to generics*					
			Amount of subsidy				Quality		Share of aversion to generics corrected by regulation					
		Baseline	50%		100%		disclosure		s = 0%		s = 50%		s = 100%	
	Segment	y	Δy	$\Delta\%y$	Δy	$\Delta\%y$	Δy	$\Delta\%y$	Δy	$\Delta\%y$	Δy	$\Delta\%y$	Δy	$\Delta\%y$
Market outcomes														
Number of firms	Innovator	0.87	-0.01	-0.30	-0.01	-0.30	-0.01	-0.30	-0.01	-0.48	-0.03	-1.65	-0.10	-4.97
	Branded	7.75	-0.72	-9.74	-0.50	-5.88	-0.66	-10.38	-0.68	-10.30	-0.69	-10.65	-0.86	-12.57
	Unbranded	6.72	-1.86	-22.41	-1.66	-18.55	-0.01	-0.45	-2.17	-27.68	-1.56	-15.62	-1.24	-8.62
Average price	Innovator	3.57	0.02	0.31	0.01	-0.38	0.02	0.72	-0.03	-0.48	-0.19	-6.91	-0.35	-9.83
	Branded	2.00	0.03	1.13	0.01	0.26	0.05	1.93	0.06	3.09	0.05	3.30	0.04	3.26
	Unbranded	0.57	0.05	14.88	0.03	10.13	0.05	11.11	0.06	18.93	0.05	15.75	0.06	17.75
Market share	Innovator	0.25	-0.00	-0.04	-0.01	-0.37	0.00	0.21	-0.02	-1.87	-0.13	-10.07	-0.21	-16.57
	Branded	0.48	-0.12	-7.72	-0.12	-7.79	-0.12	-7.93	-0.04	-2.50	-0.14	-8.11	-0.33	-19.61
	Unbranded	0.26	0.12	9.90	0.12	10.21	0.12	9.79	0.06	5.22	0.27	24.00	0.55	50.48
Share-weighted quality		0.92	0.08		0.08		0.08		0.08		0.08		0.08	
Welfare effects (MM/year)														
Compensating variation (A1)		1,019.40	46.21	4.53	47.23	4.63	45.37	4.45	46.06	4.52	53.98	5.30	57.15	5.61
Compensating variation (A2)		1,213.55	84.45	6.96	85.79	7.07	83.53	6.88	81.11	6.68	81.78	6.74	64.34	5.30
Variable profits		102.10	-0.90	-0.89	-1.09	-1.07	-0.76	-0.74	-2.74	-2.69	-9.93	-9.72	-11.97	-11.72
Certification costs		0.00	11.43		11.83		11.81		9.78		10.34		10.51	
Cost of public funds (20%)		0.00	1.14		2.37		0.00		0.00		0.00		0.00	
Fixed costs		29.41	-4.89	-16.64	-4.05	-13.76	-1.51	-5.14	-5.36	-18.21	-4.31	-14.65	-4.14	-14.09
Total profits		72.69	-7.44	-10.23	-8.88	-12.21	-11.06	-15.21	-7.17	-9.86	-15.96	-21.95	-18.33	-25.22
Welfare (A1)		1,092.09	37.63	3.45	35.99	3.30	34.31	3.14	38.89	3.56	38.02	3.48	38.82	3.55
Welfare (A2)		1,286.24	75.87	5.90	74.55	5.80	72.47	5.63	73.94	5.75	65.82	5.12	46.01	3.58

Notes: Column 1 shows outcomes in the baseline without the reform. Panel A displays results for equilibria under regulation with subsidies to certification costs. Columns 2 and 3 display the changes relative to column 1 under a 50 percent subsidy. Columns 4 and 5 show changes relative to column 1 under a full subsidy. Panel C displays results for equilibria under quality disclosure relative to column 1. Panel C describes how aversion to generics mediates the effects of quality regulation on market outcomes. Columns 8-13 display the effect of the regulation on market outcomes relative to that baseline for different degrees of correction of aversion to generics. We define aversion to generics as a linear combination between the baseline aversion to generics and that of a consumer with no aversion towards generics, which is $\check{\tau}^k_{m1}(s) = (1-s)\cdot\hat{\tau}^k_{m0} + s\cdot 0$, where s measures the effect of quality regulation on aversion to generics. Compensating variation and total welfare are reported according to assumptions A1 and A2 in Section 7.2. To compute baseline consumer welfare, we calculate the compensating variation between the baseline equilibrium and an environment in which only the outside option is available. Fixed and certification costs are reported in annualized terms. Results for market outcomes report average across markets. In particular, Δy is the average level change in an outcome relative to baseline across markets, and $\Delta\%y$ is the average percentage change outcome y relative to baseline across markets. Results for welfare aggregate across all markets.

Lowering aversion to generics. Quality regulation attempts to foster the use of generics by increasing their expected quality as well as decreasing aversion. Our estimates reveal baseline aversion to unbranded generics, as well as policy impacts along this margin. However, policymakers could adopt complementary policies to regulating quality that target aversion directly, such as information campaigns, regulating prescription behavior, or generic substitution, among others. We study how the impacts of quality regulation depend on its effects on aversion to generics, by simulating the regulation for a range of post-reform aversion levels defined by $\check{\tau}^k_{m1}(s) = (1-s)\cdot\hat{\tau}^k_{m0} + s\cdot 0$, where s is the share of aversion towards generics corrected by the policy.

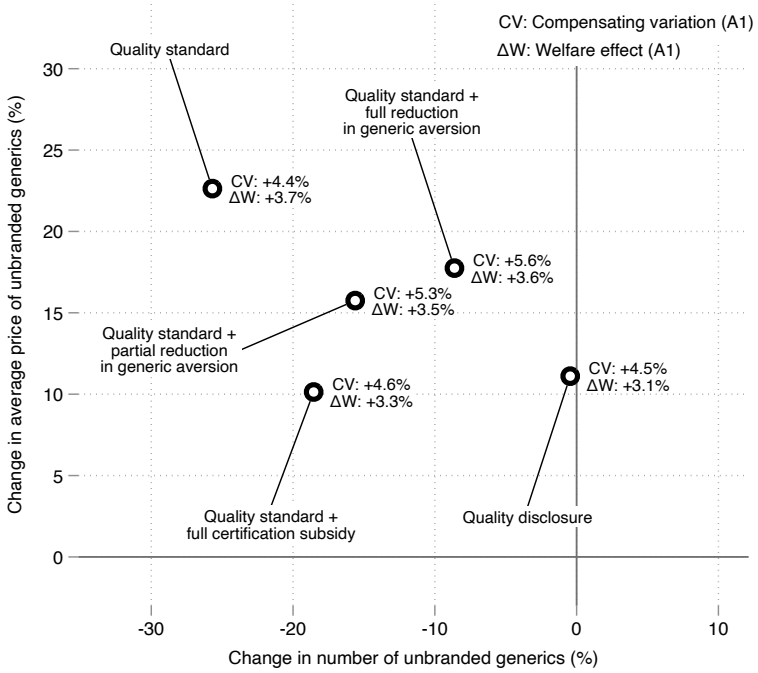
Whether quality regulation affects aversion to generics is an important determinant of its effects on market outcomes. Table 5-C shows the results. When quality regulation has no effect on aversion to generics, it has a limited effect on vertical differentiation and limited competitive effects. Quality regulation has stronger effects in terms of reducing vertical differentiation when it decreases aversion to generics more, as shown to the right of Table 5-C. As aversion to unbranded generics decreases, competition towards innovators and branded generics intensifies. This leads to more branded generic exit and stronger price decreases by innovator drugs.

The welfare effects of quality regulation depend on how it affects perceived quality, and whether choice and experienced utility become more aligned. Small decreases in aversion to generics improve consumer welfare. However, when the effects on aversion to generics are larger, competition becomes intense enough that the adverse effects of drug exit more than compensate for the benefits of better consumer choices. This result leads to inverse U-shaped effects on consumer welfare under assumption A2. Moreover, quality regulation has smaller overall welfare effects when it has a stronger impact on aversion to generics, partly driven by a decrease in profits due to more intense competition by generics. These results suggest that complementary strategies that close perceived quality gaps across segments may influence the effectiveness of quality regulation.

Comparison of counterfactual policies. In Figure 7, we compare the policies we study in terms of their effects on market outcomes and welfare. A simple quality standard has the strongest adverse effect on the number of unbranded generics and unbranded generic prices. That partly explains why the other policies deliver mostly larger consumer welfare increases. Still, given drug exit saves on certification and fixed costs, the simple quality standard dominates the alternative policies in overall welfare effects.[44] In addition, quality disclosure is the policy for which the number of unbranded generics decreases the least. While this helps limit the price effects of the regulation, the policy is dominated in terms of welfare because some low-quality drugs remain in the market, which requires sinking additional fixed and certification costs. These results suggest that quality standards induce a stronger and better selection of products in the market. Finally,

[44]This result is partly driven by the strong within-segment substitution patterns we estimate. A market with more substitutable products is more likely to feature inefficiently high entry (Mankiw and Whinston, 1986). In a setting with weaker substitutability, quality standards would be less likely to dominate quality disclosure in terms of welfare effects.

Figure 7: Comparison of counterfactual policies



Notes: Each dot indicates the effect of a counterfactual policy relative to a baseline without quality regulation on the number of unbranded generics (x-axis) and their average price (y-axis). Five different policies are considered: (i) baseline quality regulation as a minimum quality standard in columns 8 and 9 of Table 4, (ii) quality regulation with fully subsidized certification costs in columns 4 and 5 of Table 5-A, (iii) quality disclosure in columns 6 and 7 of Table 5-B, (iv) quality regulation with partial reduction in aversion to generics in columns 10 and 11 of Table 5-C, and (v) quality regulation with a full reduction in aversion to generics in columns 12 and 13 of Table 5-C. For each policy, the figure also reports the compensating variation and welfare effect under assumption A1.

note that all these designs of quality regulation increase welfare, as their main impact is to resolve asymmetric information and improve the quality of the pool of drugs in the market.

9 Conclusion

Quality regulation in markets with asymmetric information may ensure product quality, improve consumer product quality perceptions, and foster price competition by reducing vertical differentiation. However, costly compliance may also have unintended consequences on the market structure by inducing product exit and thus harming price competition. We study this trade-off in the context of pharmaceutical markets, where drug quality and asymmetric information are primary concerns. We leverage the introduction of bioequivalence requirements in Chile, a market characterized where unbranded generics display low penetration despite charging much lower prices than branded substitutes. Contrary to the goal of reducing prices by increasing competition, we find that quality regulation induced drug exit and price increases, particularly in small markets.

We develop and estimate a model to quantify the contribution of the main mechanisms at play,

evaluate the welfare effects of quality regulation, and study alternative policy designs. We find that quality regulation improves welfare despite its adverse effects on market structure and prices. Using the model, we decompose the overall impacts into four mechanisms: resolving asymmetric information, removing low-quality products, changing aversion to generics, and imposing certification costs. We find that resolving asymmetric information is the main driver of the positive welfare effects of quality regulation in our setting.

Our analysis provides lessons for the design of quality regulation. First, this regulation is more likely to enhance welfare when product quality is relatively low. Moreover, the extent to which quality regulation affects consumer quality perceptions interacts with the effects of the policy. Hence, knowledge about the distribution of product quality in the market and consumer quality perceptions quality should be key inputs for policy design. In addition, compliance costs are a key driver of the unintended consequences of quality regulation on market outcomes. Subsidizing certification is a powerful tool to counteract these adverse effects, particularly in small markets. Finally, we compare regulation to information policies and show that minimum quality standards induce a stronger and better selection of products into the market than quality disclosure. However, the latter leads to slightly higher welfare in our context. While our quantitative results are specific to our context, the same economic forces are likely present in other settings. Our model provides a rich framework for studying the design of quality regulation in different contexts.

While this paper addresses several aspects of how quality regulation affects equilibrium outcomes, some questions remain unanswered. First, we do not account for potential firm responses in terms of quality investments. Although this is a plausible assumption in our context, long-run evaluations of quality regulation—particularly in markets where quality is easier to adjust—should incorporate endogenous quality adjustments. Second, it is important to stress that quality regulation in pharmaceutical markets is a precondition for more aggressive policies that foster generic substitution and reduce physician agency (WHO, 2000). We do not account for the extent to which this regulation facilitates the introduction of such policies. Finally, measuring the long-run effects of quality regulation on health outcomes would be a natural complement to our welfare analysis.

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Online Appendix

Quality Regulation and Competition: Evidence from Pharmaceutical Markets

Juan Pablo Atal, José Ignacio Cuesta and Morten Sæthre

A Decomposition of Price Effects

The effects on average prices combine drug-specific price changes, changes in shares, and changes in the composition of drugs in each market. To understand the drivers of price effects, we develop a decomposition for the evolution the price index into such components.[45]

We define $\hat{P}_{mt} \equiv \sum_{i \in \mathcal{I}_{mt}} w_{it} P_{it}$ as the share-weighted average of log prices in market m and month t. Denote the set of drugs in the market in t that were also in the market in the baseline period as $\mathcal{S}_{m,t} \equiv \mathcal{I}_{mt} \cap \mathcal{I}_{m0}$; the set of drugs that entered market m after the baseline period and remain in the market in t as $\mathcal{E}_{mt} \equiv \mathcal{I}_{mt} \setminus \mathcal{I}_{m0}$; and the set of drugs that exited between the baseline period and t as $\mathcal{X}_{mt} \equiv \mathcal{I}_{m0} \setminus \mathcal{I}_{mt}$. We then decompose the change in the share-weighted average of log prices between a baseline period $t = 0$ and any period $t > 0$ as:

$$\begin{aligned}\hat{P}_{mt} - \hat{P}_{m0} \quad = \quad & \underbrace{\sum_{i \in \mathcal{S}_{mt}} w_{i0}(P_{it} - P_{i0})}_{\Delta P_{mt,C}} + \underbrace{\sum_{i \in \mathcal{S}_{mt}} (P_{i0} - \hat{P}_{m0})(w_{it} - w_{i0})}_{\Delta P_{mt,RW}} \\ & + \underbrace{\sum_{i \in \mathcal{S}_{mt}} (w_{it} - w_{i0})(P_{it} - P_{i0})}_{\Delta P_{mt,CS}} + \underbrace{\sum_{i \in \mathcal{E}_{mt}} w_{it}(P_{it} - \hat{P}_{m0})}_{\Delta P_{mt,E}} - \underbrace{\sum_{i \in \mathcal{X}_{mt}} w_{i0}(P_{i0} - \hat{P}_{m0})}_{\Delta P_{mt,X}}.\end{aligned}$$

The first term, $\Delta P_{mt,C}$, is the change in the share-weighted average price due to price changes among incumbent drugs, holding weights fixed at their baseline level. The second term, $\Delta P_{mt,RW}$, is the change in the share-weighted average due to changes in market shares, holding prices fixed. This term is positive when relatively expensive incumbent drugs increase their market share. The third term, $\Delta P_{mt,CS}$, is the change in share-weighted prices due to the correlation between price changes and changes in market shares. This term is positive when drugs that increase their prices also increase their market shares. The fourth term, $\Delta P_{mt,E}$, captures price changes due to the entry of drugs into the market. This component is positive whenever drugs that enter the market

[45] Nevo and Hatzitaskos (2006) use the same price index (a weighted average of log prices) and study the extent to which changes in the composition (changes in weights) can explain changes in average prices between high- and low-demand periods. However, they do not provide an explicit decomposition, nor include explicitly the role of entry and exit. Moreover, we are not aware of other papers that use the same or a similar strategy to decompose the effects of a variable of an event of interest (e.g., a reform or changes in demand) into its different sources. This decomposition is analogous to decompositions of productivity changes over time into within-plant changes and changes in the composition of plants over time, including entry and exit (Foster *et al.*, 2001).

are more expensive than the average drug in the baseline period. Finally, the fifth term, $\Delta P_{mt,X}$, measures price change due to the exit of drugs. This component is positive whenever drugs that exit the market are less expensive than the average drug in the baseline period. Therefore, the price index can be decomposed as:

$$\hat{P}_{mt} = \hat{P}_{m0} + \Delta P_{mt,C} + \Delta P_{mt,RW} + \Delta P_{mt,CS} + \Delta P_{mt,E} + \Delta P_{mt,X}. \tag{14}$$

To estimate the effect of quality regulation on each component, we estimate equation (2) using $\hat{P}_{mt,C} \equiv \hat{P}_{m0} + \Delta P_{mt,C}$, $\hat{P}_{mt,RW} \equiv \hat{P}_{m0} + \Delta P_{mt,RW}$, $\hat{P}_{mt,CS} \equiv \hat{P}_{m0} + \Delta P_{mt,CS}$, $\hat{P}_{mt,E} \equiv \hat{P}_{m0} + \Delta P_{mt,E}$ and $\hat{P}_{mt,X} \equiv \hat{P}_{m0} + \Delta P_{mt,X}$ as dependent variables. The sum of the OLS coefficients on T_{mt} from these regressions equals the coefficient on T_{mt} when estimating equation (2) for $\hat{P}_{mt}$.

Table A.6 displays estimates of effects on each component of our price index, across and within drug segment. Overall, the results reveal that more than half of the price increases come from price changes among incumbents, which supports the interpretation that drug exit reduced the intensity of price competition. For the same reason, when quality is revealed, new entrants are expected to have prices that are higher than pre-reform average prices. Our decomposition confirms this, as around a third of the increase is due to compositional changes, in particular to the entry of more expensive drugs.

B Effects on Drug Quality

We study whether the bioequivalence regulation affected observable quality of drugs in the market. The effects of the reform on quality are key to understand its welfare consequences. Unfortunately, direct measures of quality (e.g., results from drug testing) are not available in our setting, so we use adverse health events associated with specific drugs and drug recalls as indirect measures. Note that both outcome variables are mostly related to drug safety—which was already covered by the quality standards in place before the reform we study—whereas bioequivalence certification mostly targets drug efficacy. We see this analysis as a complement to our main empirical strategy in Section 5, where we estimate changes in quality due to the regulation using a structural model.

Let the quality outcome for market m at time t be $y_{mt} = \mu_{mt} sales_{mt}$, where μ_{mt} is the probability of an adverse effect associated with drugs in market m, and $sales_{mt}$ are sales of drugs in m. Similar to Jin and Leslie (2003), we model the probability of an adverse outcome—either an adverse health event or a drug recall—as $\mu_{mt} = \mu_{m0} + \gamma_t + \theta T_{mt} + \varepsilon_{mt}$, which combines a baseline probability μ_{m0}, with time shocks common to all markets γ_t, a shifter related to quality regulation θT_{mt}, and a random shock ε_{mt}. This simple framework motivates the estimating equation:

$$\frac{y_{mt}}{sales_{mt}} = \mu_{m0} + \gamma_t + \theta T_{mt} + \varepsilon_{mt} \tag{15}$$

where θ measures the effect of stronger quality regulation on the number of adverse outcomes per unit of sales, whereas μ_{m0} and γ_t are captured by market and time fixed effects.

B.1 Evidence from Adverse Health Events

A first set of outcomes related to quality are the adverse health events associated with drug consumption. We collect data on yearly clinical outcomes between 2010 and 2017 for ICD-10 diagnosis codes associated with molecules in our sample. We exploit public records collected by DEIS (2019), which cover admissions, days of hospitalization, and the number of surgeries across all hospitals in Chile. We link diagnoses to molecules using a crosswalk between American Hospital Formulary Service (AHFS) and ICD codes that tracks adverse health events associated with the consumption of drugs (WHO, 2007).[46,47] We focus on the 71 molecules with at least one listed adverse effect.[48] In our setting, these events are rare. In 2010, there were on average 7.3 admissions, 13.2 hospital days, and 0.002 surgeries per 100,000 daily doses sold across all markets.

We estimate equation (15) for these outcomes. Columns 1–3 in Table A.4-A display the results across all markets. We find no evidence suggesting that stronger quality regulation decreased the number of discharges and the number of days associated with them. Moreover, we find no evidence of heterogeneous effects on these outcomes across small and large markets in Table A.4-B. These results suggest that stronger quality regulation was not able to reduce the adverse health effects of drugs.

B.2 Evidence from Drug Recalls

To study the effects on drug recalls, we collect data on the 209 recalls for prescription drugs that occurred during our period of study. Recalls are implemented by ISP as preventative sanitary measures upon notice of adverse events linked to licensed drugs.[49] In the period we cover, there is an average of 1.9 recalls per month, of which 1.4 relate to molecules without bioequivalence requirements and 0.5 relate to molecules with bioequivalence requirements.[50]

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[46] When several ICD codes capture adverse effects associated with the same molecule, we assign outcomes to molecules using weights for sales volume across molecules within each ICD code.

[47] As an example, admissions coded under "T455 - Poisoning by, adverse effect of and underdosing of anticoagulants and antithrombotic drugs" are attributed to the consumption of Acenocoumarol, an anticoagulant.

[48] The results from the regressions on market outcomes are very similar when restricted to this sample. The results are available from authors upon request.

[49] The reasons for these recalls can be categorized broadly into manufacturing defects including chemical defects and contamination (71 percent); efficacy concerns or side effects (19 percent); or others, which mostly correspond to counterfeit drugs or mislabeling (20 percent). Due to the small number of recall events, we use all data irrespective of the specific reason.

[50] Figure A.9 shows the monthly frequency of recalls, split into drugs with bioequivalence requirements in our sample and drugs without a bioequivalence requirement. We cannot reject the hypothesis of a common trend in recalls over time across these two groups. We estimate an OLS regression for recall rates on an indicator for requirements and its

Our estimates of equation (15) in the sample of molecules with bioequivalence requirements provide no evidence suggesting that stronger quality regulation improved drug quality as measured by recalls. Columns 4 and 5 in Table A.4-A display the results across all markets, while Table A.4-B does so by market size. Our point estimates are close to zero across both specifications. These results suggest that imposing bioequivalence requirements was unable to decrease drug recalls relative to the quality standards previously in place in our setting.

C Additional Heterogeneity Analysis by Drug Characteristics

In this section, we expand on the analysis of the effects of the reform by investigating further dimensions of heterogeneity. Specifically, we are interested in evaluating the impact of the reform on different types of drugs. We split markets along two dimensions of interest: whether they treat a chronic condition, following the classification in Huber *et al.* (2013), and whether they are classified as having a high impact on mortality, following the classification in Chandra *et al.* (2024).

The analysis consists of estimating equation (1) taking into account the two proposed dimensions of heterogeneity. In our sample, there are 115 markets, of which there are 50 that treat a chronic condition, and 19 that are classified as having a high impact on mortality according to this classification. The results of the heterogeneity analysis are shown in Tables A.7 and A.8 for the effects of the policy change on the number of drugs and prices, respectively.

Considering heterogeneity by whether drugs treat a chronic condition has a direct link to our modeling framework: A key aspect of quality regulation is to provide information, and consumers in markets for drugs targeting chronic conditions are likely more informed about the quality of generics at baseline. Therefore, we should expect stronger effects of the regulation in markets for non-chronic diseases. Reassuringly, our results are in line with this prediction. Overall, we find that the effects on the number of drugs are more pronounced for generics treating non-chronic diseases. Conversely, we find statistically significant differences in price effects among unbranded generics.

In contrast, considering heterogeneity by whether a drug has high mortality impacts is not directly linked to our model. However, estimating heterogeneous impacts along this dimension is relevant in its own right. Overall, we find that quality regulation had similar effects on the number of drugs for markets with high and low mortality effects. Conversely, we find that the price increases are more pronounced for markets with high-mortality effects. These results suggest that the negative consequences of the reform in terms of price increases for generics concentrated among markets for drugs with high mortality impacts.

interaction with a time trend and find that the coefficient on the latter is not statistically different to zero.

D Description of Consumer Survey

D.1 Methodology and Results

To aid the interpretation of our descriptive evidence and guide our model assumptions, we collect additional survey data in which we interview consumers and gather information on perceived quality, perceived price differences, the relationship between physician prescription behavior and consumer choices, and some additional characterization variables. The questionnaire is displayed in Section D.2 below.

A surveying team composed of six members conducted surveys in four counties in the city of Santiago, namely Ñuñoa, Providencia, Puente Alto and Santiago. Surveyors recruited consumers outside pharmacies within such counties, where consumers were purchasing drugs. This recruiting strategy aimed at constructing a sample of consumers familiar with the pharmaceutical market. Recruited participants were asked to participate in a survey with a duration of between 5 and 10 minutes, and were offered no compensation.

To collect data on perceived quality and price differences, we focus on a particular market, Atorvastatin, a molecule commonly prescribed as a treatment to high cholesterol. Within that market, we focus on four drugs that are relevant products in this market. In particular, we work with (i) a popular innovator drug called Lipitor, which is produced by Pfizer, (ii) a bioequivalent branded generic called Lipoten, produced by Pharmavita, (iii) a bioequivalent unbranded generic called simply Atorvastatina, produced by Mintlab, and (iv) and a non-bioequivalent unbranded generic also called Atorvastatina and produced by Mintlab. For reference, the prices of these drugs in the market are around \$50,000 CLP, \$10,000 CLP, \$2,500 CLP, and \$2,500 CLP, respectively (\$77.5, \$15.5 and \$7.8 USD, respectively). Perceived quality and price differences are elicited using a paper sheet that showed the four drugs, which is displayed in Figure A.10. For these questions, we use a 1-7 scale. This is a natural scale for Chileans as it is used as the standard scale for exam scores at schools.

The final sample includes $N = 401$ consumers. Table A.5 provides summary statistics for the main variables in the survey. Among consumers in the sample, 62 percent report having a household member with a chronic disease, and 36 percent report purchasing Atorvastatin for a household member. In terms of purchase behavior, 41 percent often purchase innovator drugs, 21 percent often purchase branded generics, and the remaining 38 percent often purchase unbranded generics. The results of the survey and their relationship to our main analysis are discussed in Section 4. We code observations in which a consumer answered "I don't know" or "I don't recall" as missing.

D.2 Questionnaire

We are conducting a survey about the quality perception of drugs sold in pharmacies. We will ask you a few questions regarding the quality and prices of drugs. In all examples, we will focus in a drug called Atorvastatin, which is commonly used to control cholesterol levels. While we understand that it may be that no one in your household takes Atorvastatin, we ask that you consider it as an example and think as if you had to acquire it for a family member.

> (Show pictures of four drugs) Consider a scale of 1 to 7, where 1 is a drug of the minimum quality and that does not have the desired therapeutic effects and 7 is a drug of the highest quality that has exactly the expected therapeutic effects. What level of quality do you think the following drug has?
>
> - Innovator
> - Bioequivalent unbranded generic
> - Unbranded generic
> - Bioequivalent branded generic

E Empirical Model Details

E.1 The Constant Expenditure Model

Consider the direct utility function for consumer i over quantities q_{ij} of products indexed by j with quality index ψ_{ij} and the amount z_i of the numeraire:

$$u(\textstyle\sum_j \psi_{ij} q_{ij}, z_i) = \varphi \ln(\sum_j \psi_{ij} q_{ij}) + (1-\varphi) \ln z_i,$$

where the quality index is specified as:

$$\psi_{ij} = e^{\frac{\delta_j + \epsilon_{ij}}{\theta}},$$

with δ_j being a utility term common across consumers for product j, while ϵ_{ij} is an individual-specific random utility term. This utility function implies that the goods indexed by j are perfect substitutes, where the one with the highest ratio of quality over price ψ_{ij}/p_j will be chosen by the consumer. The consumer has Cobb-Douglas preferences over z_i and $\sum_j \psi_{ij} q_{ij}$, implying constant budget shares $1-\varphi$ and φ allocated to z_i and the products indexed by j. The form of the quality index implies that θ governs the relative importance of quantities z_i and q_{ij} compared with determinants of quality (δ and ϵ in the consumer's preferences).

The conditional direct utility function when choosing product j—which implies $q_{ij} > 0$ and

$q_{i,k\neq j} = 0$—can be written as:

$$u_{ij} = u(\psi_{ij} q_{ij}, z_i) = (1-\varphi)\ln z_i + \varphi \ln q_{ij} + \ln \psi_{ij},$$

which implies that quantity q_{ij} and the quality components—δ_j and ϵ_{ij} from $\ln \psi_{ij}$—are additively separable in utility for a given choice j. Maximizing the conditional direct utility subject to a budget constraint $p_j q_{ij} + z_i = y_i$ gives the conditional ordinary demand functions:

$$\begin{aligned} q_{ij}(p_j, y_i) &= \frac{\varphi y_i}{p_j} \\ z_i(p_j, y_i) &= (1-\varphi) y_i. \end{aligned}$$

Inserting into the conditional direct utility, we obtain the conditional indirect utility function:

$$\tilde{v}_{ij} = \ln y_i - \varphi \ln p_j + \frac{\delta_j + \epsilon_{ij}}{\theta},$$

which after rescaling by θ becomes:

$$v_{ij} = \theta \ln y_i - \theta\varphi \ln p_j + \delta_j + \epsilon_{ij},$$

where the consumer chooses the product j as $\max_j v_{ij}$, while quantities demanded conditional on this choice are given by the conditional ordinary demand functions above and zero for all non-chosen products.[51] Defining $\alpha = \theta\varphi$ and substituting out θ in the conditional indirect utility function, specifying δ_j as a function of observed and unobserved product characteristics, and appropriately redefining the random utility term, we obtain the utility function from equation (3) in Section 5.1.

Relationship between income and expenditures. As noted in Section 5.1, the functional form in income and price of this demand model implies that consumers allocate a constant income share φ_{mt} to the market, which is spent on a single preferred alternative. We test this model prediction using auxiliary data from the 2016 National Household Spending Survey (*Encuesta de Presupuestos Familiares*, EPF). For each household h we construct income per capita y_h as well as drug expenditure e_h. Figure A.11 shows a binned scatter plot relating the two variables as well as a histogram of e_h. We find that the relationship between income and expenditures is almost linear along most of the distribution of per-capita income.

[51] Note that we ignore the constant $\varphi \ln \varphi + (1-\varphi)\ln(1-\varphi)$, which is common across all alternatives in the conditional indirect utility function.

E.2 Market Size Approximation

In our demand model, we normalize the utility of the outside good to zero and model the expenditure share of each product as a function of observable characteristics. From observed data on quantities and prices, one needs to take a stance on the market size in terms of total potential budget spent in market m at time t, $B_{mt} \equiv \varphi_{mt} Y_t$. This variable plays a fully analogous role in our discrete-continuous demand model to quantity-based market size in the commonly used unit-demand models.

Since the potential budget is not observed and we do not have any measures that would allow us to directly infer it, such as the number of individuals with a diagnosis for which a given drug would be relevant, we approximate B_{mt} for each ATC-5 code m and year t using the insights of Huang and Rojas (2013, 2014). Specifically, we adapt the procedure used by Dubois and Lasio (2018) to the specific model we use. We start by specifying a simple logit version of our model, where we use the expenditure share equations:

$$\ln s_{jmt} - \ln s_{0mt} = v_{jmt} - \alpha \ln p_{jmt} + x'_{jmt}\beta + \xi_{jmt}, \qquad s_{jmt} = \frac{p_{jmt} q_{jmt}}{B_{mt}},$$

for two observed, distinct goods j and j' to derive:

$$\ln p_{jmt} q_{jmt} - \ln p_{j'mt} q_{j'mt} = v_{jmt} - v_{j'mt} + -\alpha(\ln p_{jmt} - \ln p_{j'mt}) + (x_{jmt} - x_{j'mt})'\beta + \xi_{jmt} - \xi_{j'mt}, \quad (16)$$

which does not depend on the potential budget. The parameters of this equation can be consistently estimated by 2SLS using similar instruments to those introduced in Section 6.1. In a second step, we use the equation:

$$\ln p_{jmt} q_{jmt} - \ln p_{0mt} q_{0mt} = \hat{v}_{jmt} - \hat{\alpha} \ln p_{jmt} + x'_{jmt}\hat{\beta} + \xi_{jmt}, \quad (17)$$

where we take the parameters estimated from equation (16) as given, and $\ln p_{0mt} q_{0mt}$ is the log of the expenditure allocated to the outside good, which is common for all products j in market m in year t. Note that the potential budget by definition is equal to the expenditure on all observed alternatives in addition to the expenditure on the outside good, therefore knowing the latter is equivalent to knowing the potential budget with typical price-quantity data.[52] We specify expenditures on the outside good as:

$$\ln p_{0mt} q_{0mt} = \sum_{r=0}^{4} \varsigma_{rm} t^r + \varsigma_p \overline{\ln p}_{mt} + \overline{x}'_{mt} \varsigma_x, \quad (18)$$

where the first sum is a fourth-degree polynomial in time (including a constant) that is allowed to differ across markets, and $\overline{\ln p}_{mt}$ and $\overline{x}_{mt}$ are the average log price and average characteristics

[52] It can be noted that only the aggregate expenditure on the outside good is important in this model, meaning that no assumptions on p_{0mt} is necessary.

in market m and year t. The average terms capture the effect of the attractiveness of the inside goods in competition with the outside good. This equation is estimated using a modified GMM-IV procedure, minimizing:

$$O(\varsigma) = G(\varsigma)'WG(\varsigma) + \varsigma'\mathbf{\Lambda}\varsigma,$$

where $G(\varsigma) = Z'\xi(\varsigma)$ is the vector of moments, Z is a matrix of the exogenous variables in equation (18) including price in Norway for the corresponding ATC and year, and W is the weighting matrix for the moments. The quadratic form in the parameter vector ς is a regularization term, with $\mathbf{\Lambda}$ as a diagonal matrix of regularization parameters. We allow for two different regularization parameters, one for parameters controlling the market-time polynomials, and one for the parameters controlling the effect of average characteristics. We add regularization due to the large number of parameters in equation (18), and calibrate the regularization parameters to minimize RMSE using cross-validation.

E.3 Aggregation of Unbranded Drugs for Demand Estimation

Since the data on sales from IQVIA only contain sales for unbranded generics at the aggregate level, we use the average expenditure share $s_{ut} \equiv \frac{1}{N_{ut}} \sum_{j \in \mathcal{J}_u} s_{jt}$ for this segment as the observed expenditure share, implicitly utilizing only the information in the choice of the segment for estimation, and not of particular products within the segment. Note that the expenditure share of a product $j \in \mathcal{J}_g$ (omitting the subscript m for market) can be written as:

$$s_{jt} = \frac{e^{\frac{\delta_{jt}}{1-\sigma}}}{e^{I_{gt}}} \frac{e^{(1-\sigma)I_{gt}}}{e^{I_t}},$$

where $I_{gt} \equiv \ln \sum_{j \in \mathcal{J}_g} e^{\frac{\delta_{jt}}{1-\sigma}}$ and $I_t \equiv \ln \sum_g e^{(1-\sigma)I_{gt}}$. Note that δ is here defined as the average utility *including* price, as opposed to the exposition in E.1. Define $\delta_{jt} \equiv \delta_{gt} + v_{jt}$, which decomposes δ_{jt} into a group average and deviation from this average, where the first term is:

$$\delta_{gt} = v_{gt} - \alpha \ln p_{gt} + x'_{gt}\beta + \lambda_t + \xi_{gt},$$

where any variable with subscript gt, say z_{gt}, is the average of z_{jt} across products in group g, and the second term is:

$$v_{jt} = \tilde{v}^g_{jt} - \alpha \widetilde{\ln p}^g_{jt} + \tilde{x}'_{gt}\beta + \tilde{\xi}^g_{jt},$$

where $\tilde{z}^g_{jt} = z_{jt} - z_{gt}$ measure deviation of the value of variable z_{jt} for a firm relative to the group average. We can then write:

$$I_{gt} = \frac{\delta_{gt}}{1-\sigma} + \ln N_{gt} + \ln\left(\frac{1}{N_{gt}} \sum_{j \in \mathcal{J}_g} e^{\frac{v_{jt}}{1-\sigma}}\right),$$

where N_{gt} is the number of products in group g at t. Note that the last term is zero if $v_{jt} = 0 \quad \forall j \in \mathcal{J}_g$, and that it is positive in any other case. We can then write:

$$\begin{aligned}
\ln N_{ut} s_{ut} &= \ln \sum_{j \in \mathcal{J}_u} s_{jt} \\
&= (1-\sigma) I_{ut} - I_t \\
&= \delta_{ut} + (1-\sigma) \ln N_{ut} + (1-\sigma) \ln \left(\frac{1}{N_{ut}} \sum_{j \in \mathcal{J}_u} e^{\frac{v_{jt}}{1-\sigma}} \right) - I_t.
\end{aligned}$$

This expression leads to the following estimating equation for the unbranded segment:

$$\ln s_{ut} - \ln s_{0t} = v_{ut} - \alpha \ln p_{ut} + x'_{ut}\beta + \lambda_t - \sigma \ln N_{ut} + \nu_{ut},$$

with the term $-\sigma \ln N_{ut}$ reflecting the average conditional market share $1/N_{ut}$ among unbranded generics, and the composite error term

$$\nu_{ut} = \xi_{ut} + (1-\sigma) \ln \left(\frac{1}{N_{ut}} \sum_{j \in \mathcal{J}_u} e^{\frac{v_{jt}}{1-\sigma}} \right).$$

E.4 Compensating Variation

Denote $u_{ij} \equiv u(y_i, \delta_j, \xi_j, \nu_{ij})$, where the dependence on market m and t is omitted for notational convenience, and $\nu_{ij} = \zeta_i^k + (1-\sigma)\epsilon_{ij}$. Consider a policy that changes the initial $\boldsymbol{\delta} = (\delta_1, \delta_2, \ldots, \delta_J)$ to $\boldsymbol{\delta}'$ while ξ, y and the distribution of ν stays fixed. The compensating variation for individual i is defined as CV_i such that:

$$\max_j u(y_i, \delta_j, \xi_j, \nu_{ij}) = \max_{j'} u(y_i - CV_i, \delta'_{j'}, \xi_{j'}, \nu_{ij'}),$$

such that the compensating variation is the income reduction in the post-policy environment necessary for the consumer to equate her maximum utility before and after the policy change. With the preferences given above, (log of) income is additively separable, and we can write:

$$\begin{aligned}
\alpha\varphi^{-1}[\ln y_i - \ln(y_i - CV_i)] &= \max_{j'}\{\delta'_{j'} + \nu_{ij'}\} - \max_j\{\delta_j + \nu_{ij}\} \equiv \Delta_i \\
CV_i &= y_i(1 - e^{-\varphi\alpha^{-1}\Delta_i}).
\end{aligned}$$

The expected compensating variation in the market can be obtained by integrating over y and

ν. Assuming that y and ν are independently distributed and thus $F_{y,\nu}(y,\nu) = F_y(y)F_\nu(\nu)$, we get:

$$\mathrm{E}[CV] = \int y \, \mathrm{d}F_y(y) \int (1 - e^{-\varphi\alpha^{-1}\Delta_i}) \, \mathrm{d}F_\nu(\nu) = \bar{y} \int (1 - e^{-\varphi\alpha^{-1}\Delta_i}) \, \mathrm{d}F_\nu(\nu),$$

where $\bar{y}$ is the average income and the integral over the random utility components can be approximated using the procedure suggested by McFadden (1996), which can be simplified for this case as follows:

1. Draw a sequence of vectors ν^t for $t = 1, \ldots, T$, which empirical distribution approximates F_ν as $T \to \infty$.

2. For each draw, compute the maximum indirect utility for the baseline and counterfactual policy scenarios to obtain:

$$\Delta(\nu^t) \equiv \max_j \{\delta_j + \nu_j^t\} - \max_{j'} \{\delta'_{j'} + \nu_{j'}^t\}$$

3. Approximate $\mathrm{E}[CV]$ as:

$$\overline{CV} = \bar{y} \frac{1}{T} \sum_{t=1}^{T} (1 - e^{-\varphi\alpha^{-1}\Delta(\nu^t)})$$

E.5 Supply Model Estimation Details

The parameters of interest on the supply side of the model are γ_c, γ_F, γ_κ, γ_π and $\gamma_{\sigma_\varepsilon}$, as discussed in Section 6.2. These parameters govern marginal costs, entry costs, certification costs, and profit shocks, respectively. In this appendix, we provide further details about the estimation procedure of these parameters. Throughout this procedure, demand is known to the econometrician.

The first step consists of recovering marginal costs by inverting the first order condition in equation (8) as follows:

$$\hat{c}_{jmt} = p_{jmt} + \frac{q_{jmt}(p)}{\frac{\partial q_{jmt}(p)}{\partial p_{jmt}}} \qquad \forall j \in \mathcal{J}_{mt},$$

where the right-hand side depends on prices, drug attributes, and demand parameters, all of which are either observed or estimated at this point. To estimate γ_c, we use these fitted values for marginal costs to estimate the following regression:

$$\log \hat{c}_{jmt} = x'_{cjmt}\gamma_c + \omega_{jmt}$$

where x_{cjm} includes indicators for drug segments, markets, and years. This regression is estimated on the sample of drugs that sell in market m and year t. Assuming that all potential entrants share the same structure of marginal costs, that cost shocks ω_{jmt} are iid and only observed after entry, we

can use these estimates to construct marginal costs and calculate variable profits for all potential entrants. We store the distribution of residuals from this regression to take draws of marginal cost shocks below, and call this distribution $\hat{G}_\omega$.

The second step recovers the remaining parameters relying on the entry and certification choices of manufacturers. We assume that profit shocks ε^1_{jmt} and ε^0_{jmt} are iid T1EV. Given this distributional assumption, the entry probabilities in equations (6) and (7) have the usual logit form. In particular, the entry probabilities for environments without and with quality regulation Q and NQ are respectively:

$$\begin{aligned}
\phi^{NQ}_{jmt} &= \frac{\exp(\frac{1}{\sigma_\varepsilon}[\mathrm{E}_{\hat{\phi}^{NQ}}[\widetilde{\Pi}_{jmt}(\mathcal{J})] - x'_{Fj}\gamma_F])}{1+\exp(\frac{1}{\sigma_\varepsilon}[\mathrm{E}_{\hat{\phi}^{NQ}}[\widetilde{\Pi}_{jmt}(\mathcal{J})] - x'_{Fj}\gamma_F])} \\
\phi^{Q}_{jmt} &= \frac{\exp(\frac{1}{\sigma_\varepsilon}[\mathrm{E}_{\hat{\phi}^{Q}}[\widetilde{\Pi}_{jmt}(\mathcal{J})] - x'_{Fjm}\gamma_F - (1-d^I_j)x'_{\kappa jm}\gamma_\kappa])}{1+\exp(\frac{1}{\sigma_\varepsilon}[\mathrm{E}_{\hat{\phi}^{Q}}[\widetilde{\Pi}_{jmt}(\mathcal{J})] - x'_{Fjm}\gamma_F - (1-d^I_j)x'_{\kappa jm}\gamma_\kappa])}\left[\frac{\exp(x'_{\pi jm}\gamma_\pi)}{1+\exp(x'_{\pi jm}\gamma_\pi)}\right]^{1-d^I_j},
\end{aligned}$$

where d^I_j indicates that j is an innovator drug.

We then use the probabilities to estimate the remaining parameters of the model by maximum likelihood. The log-likelihood of the observed market structure for environments without and with quality regulation are respectively:

$$\begin{aligned}
\log \ell^{NQ}_{jmt} &= y_{jmt}\log\phi^{NQ}_{jmt} + (1-y_{jmt})\log(1-\phi^{NQ}_{jmt}) \\
\log \ell^{Q}_{jmt} &= y_{jmt}\log\phi^{Q}_{jmt} + (1-y_{jmt})\log(1-\phi^{Q}_{jmt}),
\end{aligned} \tag{19}$$

To compute the likelihood, we need several inputs. The first input are variable profits $\widetilde{\Pi}_{jmt}(\mathcal{J})$ for any potential market structure $\mathcal{J}$. For a given $\mathcal{J}$ and vector of draws of marginal cost shocks from $\hat{G}_\omega$, it is straightforward compute variable profits by solving the second-stage pricing for a vector of cost shocks. Taking the expectation over variable profits requires integrating over the distribution of market structures since this is a private information game. However, these probabilities are an endogenous outcome in the model, as discussed in Section 5.2. To deal with this issue, Seim (2006) develops a nested likelihood estimator that exploits the equilibrium entry conditions from the model. This would be extremely computationally costly given the number of markets and potential market structures in our data. Instead, we follow Sweeting (2009) and compute these probabilities directly from the data. In particular, we estimate logit regressions of entry and certification choices on all their determinants as predicted by the model, namely own and rival drivers of variable profits, fixed costs, and certification costs. This is:

$$P(y_{jmt}=1) = \Lambda(x'_{jmt}\eta),$$

where y_{jmt} is an indicator for entry of firm j in market m in year t, x_{jmt} is a vector of firm and market characteristics that includes segment dummies, the segment shares of rival potential entrants per segment, a dummy for being previously in the market, the number of rival firms previously in the market, market fixed effects, and log market size. We estimate this model using data from the first and last years of our sample, 2010 and 2017, to approximate environments without and with quality regulation, respectively. We use the fitted values from this regression as estimates of firm entry probabilities, $\hat{\phi}^{NQ}_{jmt}$ and $\hat{\phi}^{Q}_{jmt}$.

The number of potential market structures is remarkably large at $2^{P_{mt}}$, where P_{mt} is the number of potential entrants in a given market and year. Having entry probabilities, we take $N_{MS} = 200$ Halton draws of market structures. Denoting each drawn market structure $\mathcal{J}^{(s),NQ}_{mt}$ and $\mathcal{J}^{(s),Q}_{mt}$ for environments, we approximate expected variable profits as:

$$\begin{aligned} \mathrm{E}_{\hat{\phi}^{NQ}}[\widetilde{\Pi}_{jmt}(\mathcal{J})] &\approx \frac{1}{N_{MS}} \sum_{s=1}^{N_{MS}} \widetilde{\Pi}_{jmt}(\mathcal{J}^{(s),NQ}_{mt}) \\ \mathrm{E}_{\hat{\phi}^{Q}}[\widetilde{\Pi}_{jmt}(\mathcal{J})] &\approx \frac{1}{N_{MS}} \sum_{s=1}^{N_{MS}} \widetilde{\Pi}_{jmt}(\mathcal{J}^{(s),Q}_{mt}). \end{aligned}$$

Having expected variable profits, estimation proceeds directly by maximum likelihood, following equation (19). We obtain standard errors following the standard procedure based on the inverse of the Hessian matrix.

There are three practical details in this estimation procedure. First, we must take a stance on the set of potential entrants in the entry model. For each market, we include all the firms that ever participate in the market during our sample period, along with the five firms with the highest participation in each segment across markets at the national level. Second, in terms of the estimating sample, we focus on the first and last year in our data. By focusing on those two cross sections, we aim at letting our estimates be mostly informed by environments without and with quality regulation rather than by the intermediate transition period. Finally, to ease interpretation, we use an annual discount rate of 0.05 to take the present value of a stream of variable profits. By doing this, we put variable profits in the same units as fixed and certification costs.

E.6 Model Simulation Details

To implement our counterfactual analysis in Section 7, we simulate equilibrium outcomes using our estimated model. We start from a dataset that includes all potential entrants to a market, their segments, and product attributes, along with estimates of demand, marginal costs, entry costs, certification costs, the distribution of drug quality, and the scale of profit shocks. For each market in this dataset, we proceed as follows:

1. To start simulation s, take $N_{MS} = 50$ draws of potential market structures from the distribution of market structures.

2. Take a draw of profit shocks $(\tilde{\varepsilon}_{0j}^{(s)}, \tilde{\varepsilon}_{1j}^{(s)})$ for each potential entrant. Take a draw of quality $\tilde{\psi}_j^{(s)}$ for each potential entrant.

3. For each market structure simulated in step 1, solve for optimal pricing and compute variable profits for all entrants using our demand and marginal cost estimates. Compute expected variable profits for each potential entrant across all draws of potential market structures.

4. Using expected variable profits from step 3, estimates of fixed costs and certification costs (when considering environments with quality regulation), draws of drug quality $\tilde{\psi}_j^{(s)}$ from step 2, and an initial guess for entry probabilities as inputs, solve for a fixed point in entry probabilities.

5. Using equilibrium entry probabilities from step 4 and draws of profit shocks $(\tilde{\varepsilon}_{0j}^{(s)}, \tilde{\varepsilon}_{1j}^{(s)})$ from step 2, compute realized equilibrium market structure, solve for optimal price and compute demand given that market structure.

6. Repeat this procedure from 1 to 5 for $s = 1, \ldots, N_S$ runs, so we can then average across simulations to smooth the realizations of shocks. The results in the paper average across $N_S = 50$ runs of this procedure.

To obtain the results in the paper, we use this procedure to generate a baseline market structure over which to develop our counterfactual analysis. We proceed as follows:

1. We start from an environment without quality regulation to simulate a baseline market structure. This market structure essentially accounts for the fact that when the regulation is imposed, there is already a particular market structure in place, generated by the same underlying parameters for demand, marginal costs, quality, and entry costs.

2. Taking the baseline market structure as given and known to all firms, we simulate market outcomes again under different environments ranging from no regulation to particular forms of regulation. Depending on the counterfactual, we adjust various parameters of the model for each simulation. The results we report in the paper correspond to equilibrium outcomes from this second simulation.

E.7 Robustness of Welfare Analysis

The welfare consequences of the reform depend on the value of low-quality generics *vis a vis* high-quality generics. In our baseline welfare calculations, we normalize this value to zero. Here, we discuss the need for a normalization and the robustness of our estimates regarding the welfare effects of the reform on alternative assumptions.

A more general version of the utility function we use in the main text can be written as follows:

$$v_m^k = \mu_m^I \cdot \left(E[\psi^k | b_t^k] + (1 - E[\psi^k | b_t^k]) \cdot \frac{\mu_m^k}{\mu_m^I} - \tau_m^k \right),$$

which differs from equation (4) in the paper by including the term $(1 - E[\psi^k | b_t^k]) \cdot \frac{\mu_m^k}{\mu_m^I}$, which reflects that non-bioequivalent drugs could in principle have a value μ_m^k different than zero. In this case, the relationship between the structural parameters and the estimated parameters is:

$$\begin{aligned} v_m^I &= \mu_m^I \\ \Delta_m^k &= \mu_m^I(1 - \pi_H^k + \tau_{m0}^k) - \mu_m^k(1 - \pi_H^k) \\ \eta^k &= \mu_m^I(1 - \pi_H^k + \tau_{m0}^k - \tau_{m1}^k) - \mu_m^k(1 - \pi_H^k). \end{aligned}$$

These expressions highlight that a normalization is needed, because there are three equations and four unknown parameters. Intuitively, it is not possible to separately identify the value of generics and the level of bias against them.

In the text, we normalize the value of non-bioequivalent generics μ_m^k to 0, and the previous expressions simplify to those in equation (10). This normalization is consequential for our estimates of the welfare effects of quality regulation. The lower the value of μ^k, the higher the welfare losses from purchasing low-quality drugs in the pre-reform period and, therefore, the higher welfare gains from the reform.

To analyze the robustness of our welfare results in a parsimonious way, we consider cases where:

$$\mu_m^k = \rho \mu_m^I \qquad \text{for} \qquad \rho \in [0, 1), \tag{20}$$

such that we set the value of non-bioequivalent generics equal to a fraction ρ of the value of the innovator and recompute our welfare results for different levels of ρ. The value of ρ parameterizes the medical value of bioequivalence. The case of $\rho = 0$ is the benchmark case in the main text and assumes there is no medical value in consuming a drug that is not therapeutically equivalent to the innovator. Conversely, the case of $\rho = 1$ corresponds to assuming that therapeutical equivalence is inconsequential for welfare; i.e., that non-bioequivalent generics provide the same medical value to patients as the innovator. This is, evidently, an inconvenient assumption, as it would not be possible to justify the widespread adoption of quality regulation based on bioequivalence if this were the case.

Although we believe that the case of $\rho = 0$ is a natural benchmark, it is ultimately an untestable assumption, and it could be the case that non-bioequivalent drugs provide *some* value to patients. Let us note that the value of ρ only affects the calculation of consumer welfare. The effect of the reform on market shares, prices, market structure, and profits depend only on how *choice utility*

changes with the reform and on the supply-side parameter, which is invariant to ρ.

Figure A.6 shows the welfare results for different assumptions on ρ. The figure shows the impacts of quality regulation on consumer welfare and total welfare under both assumptions regarding the part of the aversion to generics that is welfare-relevant (assumptions A1 and A2). As discussed above, the welfare effect of the reform decreases with ρ. However, even for very high values of ρ, the welfare effects of the reform are positive. In other words, the reform produces welfare gains even with small welfare losses from buying a non-bioequivalent drug.

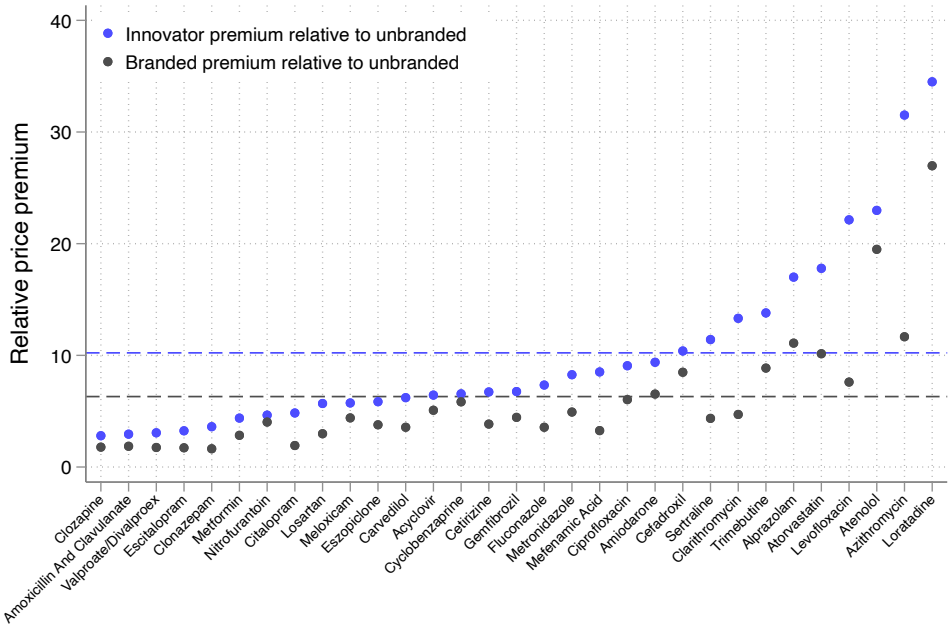
Figure A.1: Labeling of bioequivalent drugs

(a) Instructions for bioequivalent drugs labeling

(b) Examples of labeled bioequivalent drugs

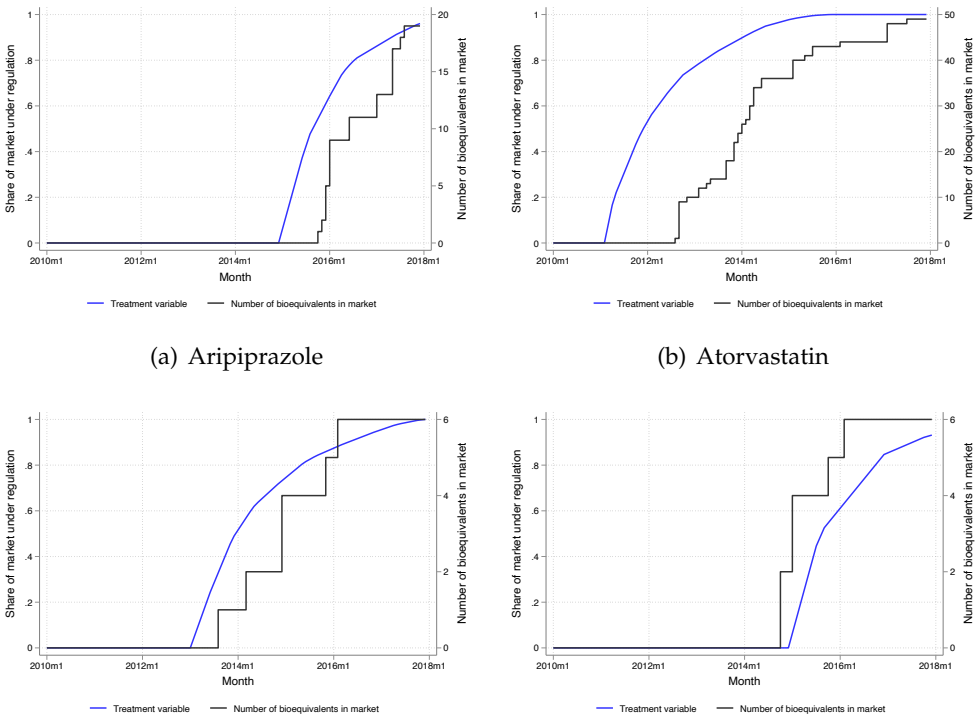
Notes: These figures display both instructions and examples of required labeling of bioequivalent drugs. The objective of this labeling was to highlight drugs with bioequivalence approval.

Figure A.2: Innovator and branded generics price premiums relative to unbranded generics



Notes: This figure displays the estimated price premium for innovator and branded generic drugs relative to unbranded generic drugs. Each dot in the figure corresponds to an exponentiated coefficient from a regression of log prices on innovator and branded drug dummies, estimated separately for each molecule using data for 2010-2011. The sample includes all markets with price information for at least one innovator, one branded, and one unbranded drug during that period. Dashed lines indicate the average price premium across this set of molecules.

Figure A.3: Policy variation induced by bioequivalence requirements

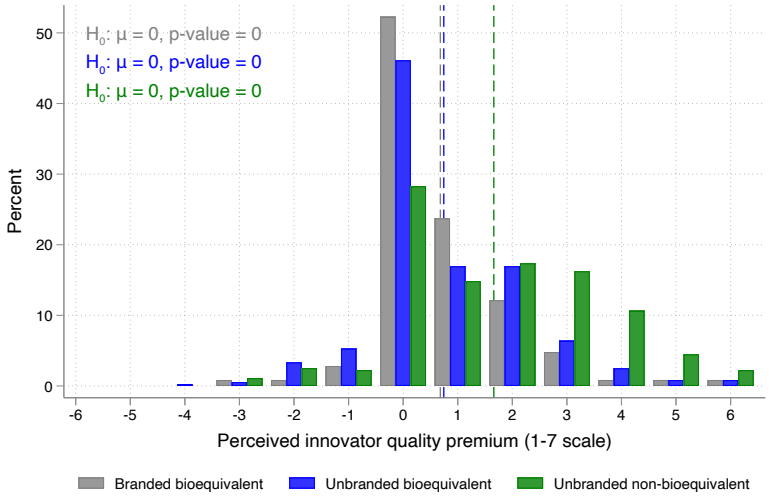


(a) Aripiprazole (b) Atorvastatin

(c) Citalopram (d) Deflazacort

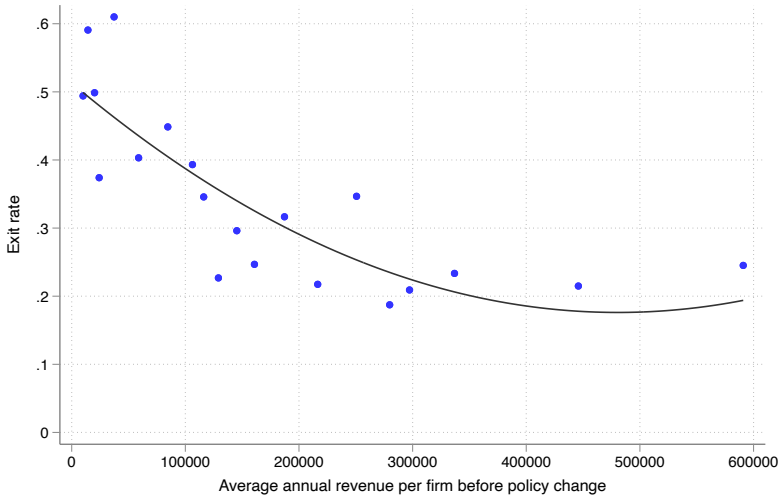
Notes: Each figure displays the values of the treatment variable and the number of bioequivalent drugs in a different market. This version of the treatment variable uses the first deadline as the relevant date. The instrument is displayed in blue and takes a value of 0 before the first decree, and then increases as renewal dates of drugs in the molecule approach. The number of bioequivalent drugs in the molecule is displayed in gray. These four examples are plotted along all other markets in our sample in Figure 2-c.

Figure A.4: Survey results for perceived quality



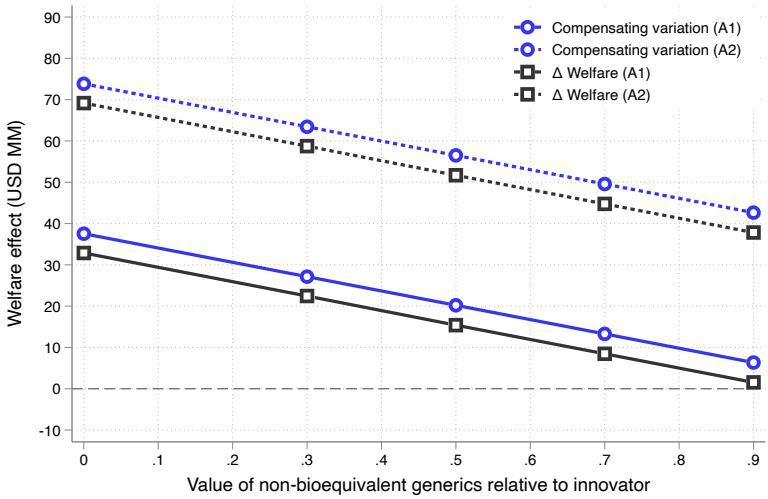
Notes: This figure displays the distribution of perceived quality premiums for different drug segments relative to the innovator drug, namely a branded bioequivalent generic (gray), an unbranded bioequivalent generic (blue), and an unbranded non-bioequivalent generic (green). The premium is calculated as the difference between the perceived quality of the innovator drug and the perceived quality for each drug segment, where the premium is recorded in a 1-7 scale. Dashed lines indicate the average for each drug segment in the figure.

Figure A.5: Correlation between drug exit after regulation and baseline revenue



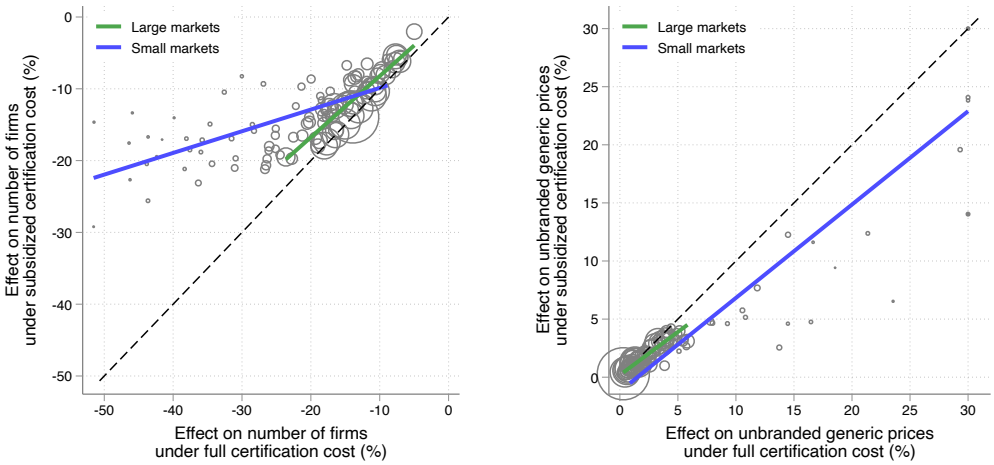
Notes: This figure shows a binned scatter plot for the relationship between exit rate after the policy change. The black line indicates a quadratic fit of this relationship.

Figure A.6: Quality regulation under alternative assumptions about valuation of non-bioequivalent drugs



Notes: This figure shows the impact of quality regulation on consumer welfare (blue) and total welfare (black) for different assumptions regarding the ratio between the value of non-bioequivalent generics and the value of innovators, denoted by ρ in equation (20). The results for $\rho = 0$ correspond to the benchmark case we focus on throughout the paper. We report results for welfare assumptions A1 (solid) and A2 (dashed).

Figure A.7: Heterogeneity in simulated effects and the role of certification costs

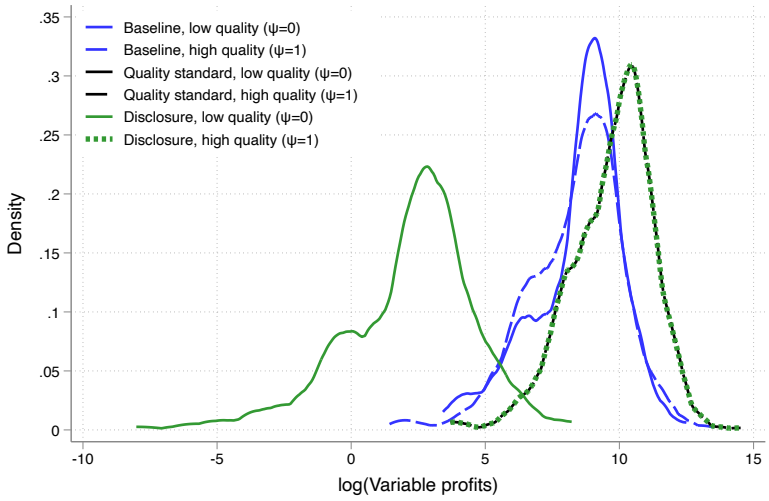


(a) Number of firms

(b) Price of unbranded generics

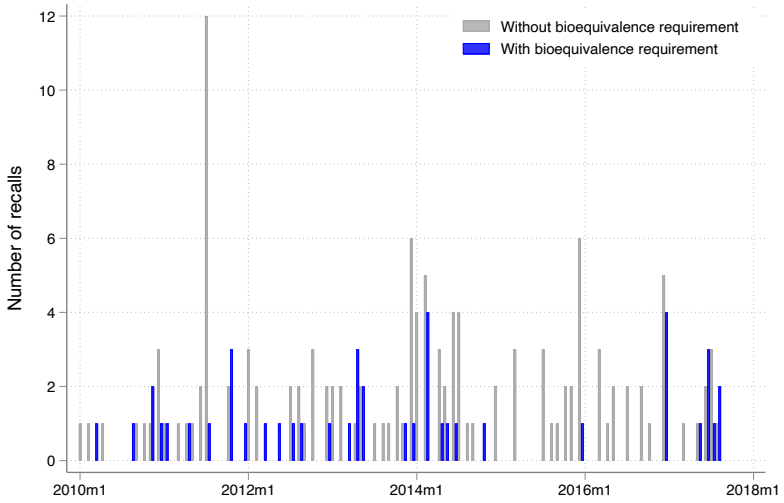
Notes: These figures compare simulated effects of quality regulation across environments where firms must pay the full certification cost (x-axis), and where the certification cost is fully subsidized (y-axis). Each circle is a market, and the size of each circle indicates market size. The green (blue) line is a linear fit for large (small) markets, defined around the median market size. The dashed line is a 45-degree line. Panel (a) displays results for the effect of quality regulation on the number of firms in the market, Panel (b) displays results for the effect of quality regulation on the average price of unbranded generics in the market.

Figure A.8: The impact of a quality standard and quality disclosure on variable profits



Notes: This figure displays the density of log variable profits among firms that enter the market in three environments: a baseline without regulation (blue), a quality standard (black), and quality disclosure (green). Solid line indicate variable profits for low-quality drugs, whereas dashed lines indicate profits for high-quality firms.

Figure A.9: Number of recalls per month

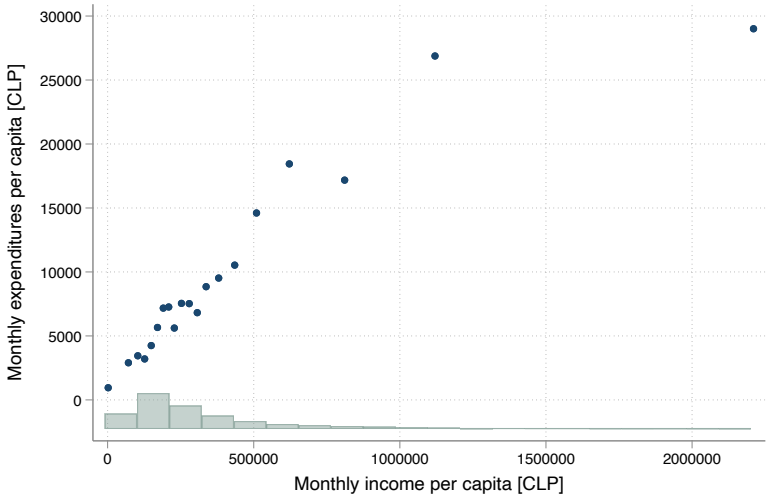


Notes: The figure shows the number of product recalls over time split into markets with bioequivalence requirements and markets without bioequivalence requirements.

Figure A.10: Consumer survey elicitation of perceived quality and price

Notes: This figure displays the sheet surveyors provided consumers in our survey sample. This sheet displays the 4 drugs we used as an example to elicit perceived quality and price differences. While observing this sheet, surveyors asked consumers first to assign a score in a 1-7 scale to each drug regarding their quality, and then to estimate the price of each drug given that the innovator had a price of $50,000 CLP ($77.5 USD).

Figure A.11: Drug expenditures and income



Notes: This figure displays a binned scatterplot of monthly income per capita and monthly drug expenditures per capita at the household level using data from the 2016 National Household Spending Survey (Encuesta de Presupuesto Familiares). The graph also includes a histogram of monthly per-capita household income.

Table A.1: Timing of reform to quality regulation

		A - Relevant policy dates				*B - Market characteristics*					
	Number of	First decree		Last decree		Number of	Average	Average	Share of drugs by segment		
Group	molecules	Decree	Deadline	Decree	Deadline	drugs	price	revenue	Innovator	Branded	Unbranded
1	3	2011-01	2011-02	2013-06	2013-12	60	1.75	22,232	0.18	0.74	0.08
2	19	2011-01	2012-02	2013-06	2013-12	158	4.27	21,909	0.27	0.62	0.11
3	7	2012-10	2013-10	2013-10	2014-04	54	0.76	14,589	0.13	0.67	0.20
4	24	2012-12	2013-12	2012-12	2013-12	264	4.86	14,226	0.21	0.69	0.10
5	20	2012-12	2013-01	2013-06	2013-12	282	2.70	17,551	0.18	0.77	0.05
6	9	2012-12	2014-12	2015-12	2016-12	101	5.38	15,135	0.17	0.79	0.05
7	15	2012-12	2014-12	2016-12	2017-06	210	4.59	14,889	0.19	0.76	0.05
8	10	2012-12	2014-12	2016-12	2017-12	82	2.60	14,812	0.18	0.77	0.05
9	8	2014-02	2015-12	2016-12	2017-12	18	3.83	5,496	0.00	0.41	0.59

Notes: Panel A in this table displays the dates of announcement and deadlines of BE requirements for different groups of molecules included in our sample. The groups are defined as a unique combination of decrees and deadlines. Panel B in this table displays average product characteristics in 2011, by molecule groups. Prices per defined daily dose and revenues are measured in 2017 USD.

Table A.2: Descriptive statistics for IQVIA data

Variable	N	Mean	SD	p10	p50	p90
A - Price per DDD						
Innovators	24,808	6.86	8.99	0.88	3.81	16.22
Branded generics	79,141	2.96	3.87	0.44	1.77	6.54
Unbranded generics	9,792	0.85	1.70	0.04	0.27	2.20
Bioequivalents	16,997	2.78	3.75	0.40	1.65	6.10
B - Market shares						
Innovators	11,040	0.29	0.29	0.00	0.23	0.75
Branded generics	11,040	0.44	0.33	0.00	0.44	0.88
Unbranded generics	11,040	0.27	0.37	0.00	0.00	1.00
Bioequivalents	11,040	0.09	0.19	0.00	0.00	0.37
C - Number of drugs						
Innovators	11,040	2.34	2.17	0.00	2.00	5.00
Branded generics	11,040	12.78	13.18	1.00	9.00	29.00
Unbranded generics	11,040	6.74	6.34	1.00	5.00	16.00
Bioequivalents	11,040	2.85	6.49	0.00	0.00	9.00
D - Number of laboratories						
Innovators	11,040	0.88	0.42	0.00	1.00	1.00
Branded generics	11,040	6.52	4.48	1.00	6.00	12.00
Unbranded generics	11,040	4.28	3.30	1.00	4.00	9.00
Bioequivalents	11,040	1.78	3.49	0.00	0.00	6.00

Notes: This table displays descriptive statistics from the IQVIA data and the ISP registry data. Statistics for prices come from IQVIA and are displayed in 2017 USD and calculated at the drug level, while the remainder are calculated at the market level. Statistics for market shares come from IQVIA and are only observed for markets in which at least one drug is sold in the period. Statistics for the number of drugs and laboratories come from the ISP registry, are computed using only observations with a valid marketing license.

Table A.3: First stage of demand estimation

	(1)	(2)	(3)	(4)
	Dependent variable			
	$\ln s_{jmt\|k}$	$\ln p_{jmt}$	b^{B}_{jmt}	b^{U}_{jmt}
log Price, Norway	0.01	0.19	-0.16	0.02
	(0.18)	(0.03)	(0.02)	(0.00)
Average age of competitors	-1.95	-0.20	0.05	-0.01
	(0.21)	(0.04)	(0.03)	(0.00)
Past renewal, branded	-0.27	-0.07	0.37	-0.01
	(0.14)	(0.03)	(0.02)	(0.00)
Past renewal, unbranded	-0.64	0.20	-0.67	1.08
	(0.76)	(0.14)	(0.10)	(0.02)
Observations	4,514	4,514	4,514	4,514
R^2	0.44	0.92	0.51	0.76
F-stat IV	23.41	16.88	142.56	922.97

Notes: This Table displays first stage regressions of each endogenous variable in the model on the instrumental variables. The specification includes market and year fixed effects. Standard errors in parentheses.

Table A.4: Effects of quality regulation on proxies of drug quality

	(1)	(2)	(3)	(4)
	Drug adverse effects			Drug
	Admissions	Hospital days	Surgeries	recalls
A - Average effects				
Regulation	-0.023	-0.120	-0.000	-0.002
	(0.023)	(0.112)	(0.000)	(0.002)
R^2	0.849	0.869	0.142	0.170
B - Heterogeneity by market size				
Regulation × Low revenue	-0.072	-0.235	-0.000	-0.000
	(0.071)	(0.224)	(0.000)	(0.002)
Regulation × High revenue	0.022	-0.016	-0.000	-0.003
	(0.024)	(0.014)	(0.000)	(0.003)
R^2	0.850	0.871	0.142	0.170
Pre-regulation average	0.073	0.132	0.000	0.000
Observations	568	568	568	867
Market FE	Y	Y	Y	Y
Month FE	Y	Y	Y	Y

Notes: Each column in this table is an outcome related to drug quality on the policy roll-out variable constructed using the first decree deadline, as in equation (15). Outcomes are constructed as the ratio of the variable of interest over drug sales measured in thousands of daily doses. Columns 1-3 are related to adverse health effects, whereas column 4 is related to drug recalls, and includes all recalls. Panel B provides results by baseline revenue. Markets are classified as having a low or high revenue according to the total revenue in the market in 2010 relative to the median across markets in that year. Clustered standard errors in parentheses. ***p<0.01, **p<0.05, *p<0.1.

Table A.5: Summary statistics from consumer survey data

Variable	N	Mean	SD	p10	p50	p90
Perceived quality of innovator drug (1-7)	361	6.32	1.01	5.00	7.00	7.00
Perceived quality of bioequivalent branded drug (1-7)	378	5.69	1.31	4.00	6.00	7.00
Perceived quality of bioequivalent unbranded drug (1-7)	386	5.63	1.28	4.00	6.00	7.00
Perceived quality of non-bioequivalent unbranded drug (1-7)	381	4.68	1.65	3.00	5.00	7.00
Perceived price of bioequivalent branded drug (CLP 1,000s)	398	25.37	14.13	6.00	25.00	45.00
Perceived price of bioequivalent unbranded drug (CLP 1,000s)	401	15.69	10.98	3.00	15.00	30.00
Perceived price of non-bioequivalent unbranded drug (CLP 1,000s)	399	12.60	9.97	2.00	10.00	25.00
Recognizes bioequivalent drug label	401	0.84	0.37	0.00	1.00	1.00
Understanding about bioequivalence (1-5)	401	2.91	1.47	1.00	3.00	5.00
=1 if physicians specify brand in prescriptions	299	0.65	0.48	0.00	1.00	1.00
=1 if always purchases physician recommendation	310	0.15	0.36	0.00	0.00	1.00
=1 if sometimes deviate from physician recommendation	310	0.52	0.50	0.00	1.00	1.00
=1 if always chooses cheapest available drug	310	0.34	0.47	0.00	0.00	1.00
Purchases innovator drugs	338	0.41	0.49	0.00	0.00	1.00
Purchases bioequivalent branded drugs	338	0.20	0.40	0.00	0.00	1.00
Purchases bioequivalent unbranded drugs	338	0.28	0.45	0.00	0.00	1.00
Purchases non-bioequivalent unbranded drugs	338	0.11	0.31	0.00	0.00	1.00
Chronic illness by household member	401	0.58	0.49	0.00	1.00	1.00
Atorvastatin consumption by household member	401	0.34	0.48	0.00	0.00	1.00

Notes: This table displays summary statistics from our consumer survey. The total number of surveys is $N = 401$. Whenever the number of observations is smaller, is due to the consumer not answering the question, except for the case of questions regarding physician prescription behavior, which were added to the survey with a lag and are therefore not available for around a fourth of the sample.

Table A.6: Decomposition of the effects of quality regulation on drug prices

	(1)	(2)	(3)	(4)
	All drugs	Innovator	Branded generics	Unbranded generics
Dep. var.: Contribution of changes in prices ($\hat{P}_{PC}$)	0.069**	0.015	0.002	0.152***
	(0.028)	(0.025)	(0.024)	(0.056)
R^2	0.63	0.70	0.67	0.65
Dep. var.: Contribution of changes in shares ($\hat{P}_{RW}$)	0.026	0.048*	-0.002	0.010
	(0.035)	(0.025)	(0.018)	(0.011)
R^2	0.53	0.65	0.53	0.49
Dep. var.: Contribution of correlation between shares and prices ($\hat{P}_{CS}$)	-0.000	-0.005	-0.046	0.008
	(0.012)	(0.016)	(0.034)	(0.010)
R^2	0.49	0.63	0.48	0.29
Dep. var.: Contribution of drug entry ($\hat{P}_{E}$)	0.034**	0.001	0.041**	-0.007
	(0.016)	(0.014)	(0.020)	(0.007)
R^2	0.52	0.61	0.61	0.44
Dep. var.: Contribution of drug exit ($\hat{P}_{X}$)	-0.005*	-0.019**	-0.004	0.001
	(0.003)	(0.008)	(0.006)	(0.001)
R^2	0.38	0.28	0.31	0.06
Observations	11,040	8,141	8,707	5,238
Market FE	Y	Y	Y	Y
Month-Segment FE	Y	Y	Y	Y

Notes: The table displays results for each component of the decomposition of price changes in equation (14). Each coefficient comes from a separate regression of the component indicated in the left for the drug segment indicated in the top row on the policy roll-out variable constructed using the first decree deadline. The sample size in column 1 is equal to the number of markets in the sample (115) multiplied by the number of months (96). The sample size in columns 2–4 corresponds to the number of market-month observations for which there is at least one product in the corresponding segment. We also drop markets for which there is no product of the corresponding segment at baseline (January 2010). Standard errors clustered at the market level in parentheses. ***p<0.01, **p<0.05, *p<0.1.

Table A.7: Effects of quality regulation on number of drugs by drug attributes

	(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)
	Dep. var.: Number of drugs							
	All	Innovator	Branded generics			Unbranded generics		
			All	BE	Non-BE	All	BE	Non-BE
A - Heterogeneity by chronic condition								
Regulation × Non-chronic	-0.26***	0.01	-0.28***	2.12***	-0.41***	-0.26***	2.64***	-0.45***
	(0.07)	(0.08)	(0.07)	(0.25)	(0.08)	(0.08)	(0.42)	(0.08)
Regulation × Chronic	-0.11**	-0.08	-0.10*	1.31***	-0.32***	-0.11	2.90***	-0.26***
	(0.05)	(0.07)	(0.06)	(0.28)	(0.07)	(0.09)	(0.55)	(0.08)
p-value	.051	.316	.02	.008	.399	.178	.628	.065
B - Heterogeneity by mortality effects								
Regulation × Low mortality effect	-0.20***	-0.03	-0.21***	1.52***	-0.38***	-0.19***	2.83***	-0.31***
	(0.05)	(0.06)	(0.05)	(0.27)	(0.07)	(0.07)	(0.43)	(0.08)
Regulation × High mortality effect	-0.20**	0.02	-0.19*	1.97***	-0.37**	-0.21**	2.51***	-0.52***
	(0.10)	(0.11)	(0.10)	(0.28)	(0.15)	(0.10)	(0.55)	(0.11)
p-value	.954	.555	.78	.157	.954	.84	.517	.077
Pre-regulation average	22.06	2.40	12.32	0.09	12.23	7.34	0.01	7.33
Observations	11,040	11,040	11,040	11,040	11,040	11,040	11,040	11,040
Market FE	Y	Y	Y	Y	Y	Y	Y	Y
Month FE	Y	Y	Y	Y	Y	Y	Y	Y

Notes: Each column in this table is a Poisson regression for the number of drugs in a segment on the policy roll-out variable constructed using the first decree deadline. Panel A provides heterogeneity results by whether the drugs treats a chronic condition. Panel B provides heterogeneity results by whether the drugs is classified as having high mortality impacts. Standard errors clustered at the market level in parentheses. ***p<0.01, **p<0.05, *p<0.1.

Table A.8: Effects of quality regulation on drug prices by drug attributes

	(1)	(2)	(3)	(4)
	Dep. var.: Drug Price Index ($\hat{P}_{mt}$)			
	All drugs	Innovator	Branded generics	Unbranded generics
A - Heterogeneity by chronic condition				
Regulation × Non-chronic	0.151**	0.062*	-0.020	0.233***
	(0.058)	(0.034)	(0.052)	(0.067)
Regulation × Chronic	0.083	0.006	0.011	0.071
	(0.082)	(0.043)	(0.053)	(0.070)
p-value	0.431	0.183	0.569	0.090
R^2	0.986	0.992	0.987	0.986
B - Heterogeneity by mortality effects				
Regulation × Low mortality effect	0.103*	0.022	-0.041	0.143**
	(0.058)	(0.031)	(0.048)	(0.060)
Regulation × High mortality effect	0.235**	0.146***	0.163*	0.231**
	(0.090)	(0.052)	(0.091)	(0.113)
p-value	0.166	0.017	0.019	0.481
R^2	0.986	0.992	0.987	0.985
Observations	11,040	8,141	8,707	5,238
Market FE	Y	Y	Y	Y
Month-Segment FE	Y	Y	Y	Y

Notes: This table displays regressions of share-weighted log prices for each molecule on the policy roll-out variable constructed using the first decree deadline. The average is taken over all drugs within each market. Panel A shows results by whether the drug treats a chronic condition. Panel B shows results by whether the drug treats has high mortality impacts. The sample size in columns 2–4 corresponds to the number of market-month observations for which there is at least one product in the corresponding segment. We also drop markets for which there is no product of the corresponding segment at baseline (January 2010). Standard errors clustered at the market level in parentheses. ***p<0.01, **p<0.05, *p<0.1.