Quality Regulation and Competition: Evidence from Pharmaceutical Markets*

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Abstract. We study the effects of quality regulation on market outcomes by exploiting the staggered phase-in of bioequivalence requirements for generic drugs in Chile. We estimate that the number of drugs in the market decreased by 25%, average paid prices increased by 10%, and total sales decreased by 20%. These adverse effects were concentrated among small markets. Our results suggest that the intended effects of quality regulation on price competition through increased (perceived) quality of generics—and therefore reduced vertical differentiation—were overturned by adverse competitive effects arising from the costs of complying with the regulation.

Keywords: quality regulation, competition, bioequivalence, generic pharmaceuticals
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1 Introduction

Increased penetration of generic drugs has been one of the major sources of cost savings in the U.S. health care in recent decades (Grabowski et al., 2006). A variety of policies incentivizing generic adoption, together with the expiration of several patents, led the retail market share of generics in the U.S. to rise from 34% in 1994 to 87% in 2015 (Berndt et al., 2017). However, generic penetration remains a first-order policy concern in low- and middle-income countries as a means to increase the access to affordable medicines (UN, 2010; Pinto et al., 2018).

In the context of pharmaceuticals, quality regulation is considered a key precondition for the success of policies to foster penetration of generic drugs and to pave the road for policies like generic substitution laws (WHO, 2000).

However, quality regulation in itself has ambiguous competitive effects that can either favor or decrease substitution towards generics. On the one hand, weak quality standards undermine physician and patient trust in generics, and may limit price competition due to differences in perceived quality. Quality regulation may improve the perception of generic alternatives, which increases the propensity to prescribe and choose generics, leading to increased competition. However, these regulations may also decrease substitution towards generics, as they induce the exit of affordable and yet high-quality drugs due to costly compliance. Drug exit might in turn reduce price competition, overturning positive effects of reduced (perceived) quality differences between innovators and generics brought on by the regulation. Therefore, the equilibrium market outcomes of quality regulation policies are the result of an interplay between reduced vertical differentiation and changes in market structure due to costly compliance.[1]

In this paper, we study the equilibrium effects of quality regulation policies in pharmaceutical markets by exploiting the roll-out of a requirement to certify bioequivalence for generics in Chile from 2009 to 2017. To the best of our knowledge, this is the first paper to measure the overall market effects of introducing bioequivalence requirements; which is a common policy instrument for drug quality assurance. At the onset of this policy, unbranded generics accounted for less than 30% of total retail sales on average, even though they were on average 6 and 10 times cheaper than

[1] In models of vertical differentiation, *differences* in quality are a source of market power (see, e.g., Gabszewicz and Thisse, 1979), such that a smaller difference is expected to lead to more intense price competition (conditional on market structure). Price differences between innovator and generic drugs are typically attributed to market segmentation (see, e.g., Frank and Salkever, 1992), consistent with vertical differentiation models where consumers with high willingness-to-pay for perceived quality choose a higher priced innovator drug.

branded generics and innovator drugs respectively.[2,3] The primary objectives of the reform were to increase the perceived quality of generics and enhance price competition.[4]. Bioequivalence is a central requirement in the process of approving generics in developed countries and, increasingly so, in developing countries. An innovator drug can be substituted by a bioequivalent generic with the full expectation that the generic has the same clinical effect and safety profile.[5] After the reform, generics without bioequivalence certification were no longer allowed to be sold in Chile.

We estimate the effects of quality regulation on market structure, drug prices, market shares and drug sales. For this purpose, we combine administrative data on entry and exit from the national drug registry of Chile with price and sales data from IMS Health for 2010–2017. Our empirical strategy exploits the staggered implementation of the reform, in addition to features of its enforcement, to compare outcomes across and within markets (molecules) with different levels of exposure to the regulation. This strategy provides reduced-form estimates of the overall effects of the policy on equilibrium market outcomes. We interpret our results using a model where innovator and generic drugs compete in prices in an environment where consumers only imperfectly observe the quality of generic drugs.

We start by providing evidence that stronger quality regulation induced laboratories to obtain bioequivalence certification for their drugs. We find that drugs were 12 times more likely to have bioequivalence certification after requirements were implemented. Moreover, we show that certification was more frequent in more profitable and less competitive markets.

We then turn to analyze the effects of the regulation on market structure, prices, market shares and sales. First, we find important changes in market structure, where bioequivalence requirements (when fully phased in) decreased the number of drug products by 25%. Second, we find a 10% increase in average (volume-weighted) drug prices, most of which was due to drug-specific price increases rather than changes in market shares or changes in the composition of drugs driven by entry and exit. Third, we provide evidence that stronger quality regulation shifted sales from

[2] *Innovator drugs* are the first ones containing its specific active ingredient to receive approval for use, and are often referred to as originator drugs. *Generics* are drugs with the same active ingredient as an innovator drug and can be marketed after the expiration of the patent of the innovator drug. *Unbranded generics* are marketed by molecule name and compete on prices, whereas *branded generics* are marketed under a trade name, typically advertise, and compete on brand (see, e.g., Danzon and Furukawa, 2008). In the U.S. and Europe, branded generics are predominantly marketed by (subsidiaries of) innovating pharmaceutical firms (see Grabowski and Vernon, 1992, p. 346), whereas in many Latin American and developing countries, branded generics are produced and marketed by generic manufacturers.

[3] Reported market shares for generics and price premiums are based on our own calculations from IMS Health data using the sample employed in the main analysis of the paper. See Section 4 for further details.

[4] These objectives were explicitly stated by government officials, as discussed in Section 2.2. On the other hand, to the best of our knowledge, there was no public discussion justifying this regulation on the grounds of concerns regarding the poor quality of generics

[5] More precisely, a generic drug is bioequivalent to its reference innovator counterpart when its rate and extent of absorption are not significantly different from those of its reference drug when administered under the same conditions (Davit et al., 2013). Bioequivalence became the primary means for generic drugs approval in the U.S. after the passage of the Hatch-Waxman Act in 1984, which allowed generics seeking marketing approval to submit proof of bioequivalence with the reference drugs in lieu of preclinical (animal) and clinical (human) testing on safety and efficacy.

branded generics to innovator drugs, whereas total sales volume decreased by 20%. Most of these effects are concentrated in molecules with small market size, measured by total market revenue in the pre-reform period. In small markets, we find that the number of drug products decreased by 36%, and that average prices increased by 26%. Furthermore, the market share of innovator drugs in small markets increased by 8 percentage points (p.p.) at the expense of generics, whereas total sales volume decreased by 30%. Conversely, we find a 15% decrease in drug products, but no significant effect on drug prices or the market share of generics in large markets.

Overall, our results suggest that any direct effect of increased price competition due to decreased scope for quality differentiation was overturned by indirect adverse effects to competition due to drug exit. Our results on heterogeneity of these effects across markets of different size reinforce this interpretation, and suggest that fixed costs of complying with the regulation played a significant role in driving these outcomes.

We complement our main analysis with a survey of a sample of pharmacy customers in Chile. Our survey suggests that a variety of demand-side frictions may continue to undermine the ability of the regulation to generate its intended effects. In particular, we find that our interviewees: (i) lack an appropriate understanding of what bioequivalence entails and continue to place substantial perceived quality premiums on innovator drugs, even several years after the policy change; (ii) underestimate price differences between innovators, branded generics and unbranded generics; and (iii) frequently declare that their physicians prescribe by the brand name. Although these results come from a small sample of consumers, they are suggestive of barriers that may reduce incentives for laboratories manufacturing generics to enter or remain in the market in the presence of fixed costs of complying with the regulation. The lessons from our survey suggest that policies complementary to quality regulation may be necessary to increase generic penetration and competition in this context, such as consumer information policies or the regulation of prescription behavior.

This paper is related to a large literature analyzing the effect of regulatory policies on pharmaceutical markets. Much of this research focuses on the equilibrium implications of price regulation for pharmaceutical markets in developed countries (see, e.g., Danzon and Chao, 2000; Dubois and Lasio, 2018; Dubois and Sæthre, 2018; Lakdawalla, 2018), whereas the equilibrium effects of quality regulation have yet to be studied. We contribute to this literature by analyzing the equilibrium effects of one of the most common forms of quality regulation in pharmaceutical markets.Directly related to our setting, Balmaceda et al. (2015) provide an early exploration of the reform in Chile, estimating its short-term effects on drug prices. We implement a broader analysis by evaluating effects on market structure, sales and quality outcomes after the full implementation of the policy.[6]

[6]This paper differs from Balmaceda et al. (2015) along several other dimensions. First, their sample covers until March 2014, when 75% of all bioequivalence approvals to date and several relevant policy events had not yet come into effect. Second, our empirical strategy relies on exploiting variation in the roll-out of the policy across and within markets, instead of assuming parallel-trends between markets affected and unaffected by the policy in a simpler differences-in-differences analysis. Third, we develop a conceptual framework that guides the interpretation of our results in the context of a model of competition with vertical differentiation across drugs.

Moreover, we contribute to a literature that studies the participation of generics in pharmaceutical markets. First, our study is related to previous research on the entry of generics after patent expiration in the U.S., which has highlighted the importance of market variables for entry decisions (Scott Morton, 1999, 2000). We contribute to this literature by studying a different regulatory context where generic drugs that are already in the market face the decision of whether to stay in the market under stronger quality regulation, and by focusing on a middle-income market. Our results highlight that quality regulation indeed affect drug exit decisions. Second, we build on a large empirical literature analyzing competition between innovator and generic drugs, which has primarily focused on analyzing the market responses to the entry of generics when innovator drugs go off-patent (see Caves et al. 1991; Grabowski and Vernon 1992; Frank and Salkever 1997; Grabowski et al. 2006; Knittel and Huckfeldt 2012; Branstetter et al. 2016, among others). Our paper relates to this literature by providing evidence from a regulatory change that induces generic exit, coupled with potential changes in perceived generic quality. Finally, we also contribute to a better understanding of the sources of aversion to generics that sustain brand premiums (Colgan et al., 2015; Bairoliya et al., 2017), by studying the effects of minimum quality standards that attempt to reduce information asymmetries that may bias consumers against generics.

The remainder of the paper is organized as follows: Section 2 describes the Chilean pharmaceutical market and bioequivalence regulation; Section 3 proposes a model that guides our analysis of the effects of quality regulation; Section 4 describes the data used in our analysis; Section 5 analyzes the extent of bioequivalence certification, and entry and exit choices at the drug level; Section 6 provides our main estimates of the effects on market structure and market outcomes; Section 7 provides evidence from survey data that sheds light on potential mechanisms behind our findings; and Section 8 concludes with a discussion of our findings and policy implications.

2 Pharmaceutical Market and Quality Regulation in Chile

2.1 Institutional Framework

Spending and Coverage. Chileans spend 0.9% of their GDP on pharmaceuticals, which is lower than the OECD average of 1.5% (OECD, 2013). However, expenditure on both overall health care and pharmaceuticals has grown steadily over recent years and pharmaceutical spending accounts for around 40% of all out-of-pocket health expenditures in the country (Benítez et al., 2018).

One third of Chileans pay for their prescription drugs fully out-of-pocket (Minsal, 2013). The level of financial coverage for prescription drugs depends both on whether the individual opts to enroll in the public insurance system (*Fondo Nacional de Salud*, FONASA) or in a private insurance plan, and on the specific disease to be treated.[7] FONASA enrollees who opt to receive health

[7]FONASA covers around 80% of the population. Most of the remaining 20% is covered by the private market. For a more detailed description of the health insurance market in Chile, see Duarte (2012).

care within the network of public providers face copayment rates that depend on socioeconomic variables, although outpatient claims are free of charge, including prescription drugs.[8] FONASA enrollees who instead opt for receiving care in private hospitals pay procedure-specific prices negotiated between FONASA and each provider.[9] Insurance plans in the private system do not generally include coverage for prescription drugs.

Pharmaceutical Market. The institution in charge of oversight of this market is the Public Health Institute (*Instituto de Salud Pública*, ISP). Laboratories present applications to ISP to obtain marketing licenses for distribution in Chile. These marketing licenses must be renewed every five years. ISP is also responsible for drug quality assurance and has overseen the roll-out of the bioequivalence reform.

Two additional features of the retail pharmaceutical market in Chile may influence the workings of the bioequivalence reform. First, as opposed to the U.S., direct-to-consumer advertisement of prescription drugs is forbidden, which could, in principle, make consumers more price sensitive because expensive branded drugs cannot use advertising to signal quality and boost demand. Second, the retail pharmacy sector in Chile is highly concentrated, which might affect the degree of supply-side reaction to the bioequivalence requirements. Three large pharmacy chains account for more than 90% of the market, with a fraction of their sales corresponding to private-label drugs. The remainder of the market is comprised of several small chains without national presence.[10]

Prescriptions and Generic Substitution. Prescription behavior of physicians and the ability of pharmacists to offer alternative versions of prescribed drugs to consumers are important mediators of consumer choice in the pharmaceutical market. In Chile, pharmacists may only offer generic substitution for prescriptions that specify the generic name and when a bioequivalent substitute is available. Despite recent policy efforts towards constraining discretion in prescriptions, physicians still often prescribe by brand name only, which limits substitution towards generics in practice.[11]

[8] The total level of copayment is capped for a set of 80 prioritized diseases.

[9] Enrollees receive partial coverage of claims in these cases, with the exception of the pharmacological treatment of a list of 11 high-cost diseases that are fully covered.

[10] The three large chains were involved in a collusion scandal in early 2008, almost two years before our study period. See Alé (2017) for a detail discussion of the collusion case and for a more detailed description of the retail pharmacy market in Chile.

[11] In February 2014, Law 20,724 was passed with the objective of requiring physicians to include the generic name in the prescription and allow for substitution towards bioequivalent generics if requested by the patient. However, different industry actors concede that the requirement has not been enforced in practice, and that physicians have continued to prescribe branded drugs. Our survey evidence in Section 7 is consistent with this view. The lack of enforcement of the original requirement is well known, and has motivated a new pharmaceutical law that is currently under discussion in the Congress. See, e.g., La Tercera (2015).

2.2 Bioequivalence in the Chilean Pharmaceutical Market

Bioequivalence is established to demonstrate therapeutic equivalence between a generic drug and the corresponding reference drug, that is often the innovator drug. In particular, two drugs are bioequivalent when the rate and extent of absorption of the tested drug and the reference drug do not show significant differences, when administered at the same molar dose of the therapeutic ingredient under similar experimental conditions (Davit et al., 2013). Bioequivalent drugs can be substituted with the full expectation that the generic drug yields the same clinical effect and safety profile as the reference drug (FDA, 2017). Therefore, bioequivalence allows bridging preclinical and clinical data associated with the reference drug to the generic drug. Bioequivalence is a standard requirement for commercialization of generic drugs in most high-income countries (Balmaceda et al., 2015). Moreover, many OECD countries either allow, encourage or require substitution of innovators for cheaper bioequivalent drugs (OECD, 2000). Although bioequivalence requirements were originally implemented in the developed world to foster generic entry, they have been recently adopted by developing countries as the primary tool for testing the effectiveness of the drugs allowed in their markets (Balmaceda et al., 2015). Prior to bioequivalence, quality standards in Chile required generic manufacturers to follow guidelines of the International Pharmacopeia books (WHO, 2017), which ensured minimum production standards and safety but did not ensure therapeutic efficiency. The bioequivalence requirement was introduced as an addition to the previous quality standards.

The stated goals of the bioequivalence regulation in Chile were to increase competition in the pharmaceutical market and reduce prices.[12,13] For instance, in the early years of the reform, the Head of the National Drug Agency (*Agencia Nacional de Medicamentos*, ANAMED) stated in an article published in La Tercera (2012):

> "We have no doubts that drug prices will decrease, because the population will have access to a wider and more competitive drug market"
>
> *Elizabeth Armstrong, Head of National Drug Agency*
> *May, 2012*

The first list of active ingredients subject to bioequivalence was published in 2005 by the Chilean

[12]To the best of our knowledge, there was no public discussion justifying this regulation on the grounds of concerns regarding the poor quality of generics. Arguably, the bioequivalence regulation was also meant as the first step in a series of reforms intended to increase substitution towards generics, as evidenced by the current discussions in Congress discussed in footnote 11.

[13]In a context where there is underlying heterogeneity in quality that is unobservable to consumers, it could be argued that voluntary quality disclosure might take place and lead to unravelling, by which consumers would become aware of quality differences and low quality drugs might exit the market (Dranove and Jin, 2010). However, this prediction does not hold in a setting in which disclosure is too costly (Jovanovic, 1982). In the setting we study, generic drugs were not aware of whether they were bioequivalent prior to the costly verification. Moreover, consumers were likely not familiar with the concept of bioequivalence before this regulation was implemented, which would limit the returns to disclosure. These two factors may jointly explain the lack of private quality disclosure.

Ministry of Health (*Ministerio de Salud*, MINSAL). This list consisted of active ingredients deemed to be potentially prescribed for chronic conditions 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 the technical norms for bioequivalence testing (Balmaceda et al., 2015). Bioequivalence requirements were phased in since then, with 167 molecules covered by this regulation as of March 2018. All new drugs containing the molecule listed in each law decree were mandated to certify bioequivalence before obtaining a marketing license.[14] Each decree specified the deadline for bioequivalence testing among incumbent drugs already registered. In practice, however, enforcement of the requirements occurred mostly by the time of license renewal, when ISP often denied renewal to drugs without bioequivalence approval (Vasallo, 2010). Drugs with bioequivalence certification carry a distinctive label intended to serve an as indication of bioequivalence status for the consumer.[15] We show an example of this label in Figure A.1.

The costs of bioequivalence testing are in the range of $50,000 to $240,000 U.S dollars per drug, and are covered by the manufacturer.[16] To put this number into context, the median drug in our data had a yearly revenue of $103,600 at the onset of the reform in 2010. Moreover, 35% and 71% of drugs had yearly revenues lower than $50,000 and $250,000 respectively. Although these figures only account for revenue in the retail market, they suggest that the financial burden imposed by bioequivalence compliance costs was not negligible for several drugs.[17]

In most cases, the original deadlines to provide proof of bioequivalence were extended—through a series of subsequent decrees—due to the slow uptake and capacity constraints in the laboratories performing the tests. Among the molecules with bioequivalence requirement, there are nine unique combinations of the relevant policy dates, namely the date of the first decree, date of extensions (if applicable), and corresponding deadlines established in the first decree and the extensions. Table 1-A shows the dates of the first decree (the first date when a bioequivalence requirement was announced), the last decree (the last date when an extension to the original deadline was announced) and the corresponding deadlines for each of these nine groups, as well as the number of molecules included in each group.[18] For example, Group 1 includes four molecules that had their first decree

[14] Bioequivalence requirements were only imposed for orally administered drugs, i.e. the requirements do not apply to topical medications, vaccines, or any other type of drugs that are not orally administered.

[15] In practice, one could argue that the label in itself has an effect on demand through quality disclosure (see Dranove and Jin (2010) for a review of the theoretical and empirical literature on 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.

[16] This range for certification costs is based on reports that include statements from market participants about certification costs (La Tercera, 2012; CIPER, 2015).

[17] All monetary values in the paper are inflation-adjusted to December 2013. For reference, the exchange rate at that point was of $529 CLP per U.S. dollar.

[18] We exclude from this classification all molecules that received their first decree before 2010, because they are excluded from the sample we use in our main analysis due to data limitations (our sample from IMS Health, covering sales and revenues, starts in 2010). Similarly, we exclude molecules that were not affected at all by any bioequivalence requirement.

announced in January 2011, which established a deadline for February 2012. However, the original deadline was extended, and its final decree was announced in June 2013, with a deadline for December 2013. Variation in the timing of bioequivalence regulation is summarized in Figure 6-a. We exploit this variation for estimation of policy effects later in the paper.

In practice, bioequivalence certification is provided after the manufacturer presents satisfactory studies. Generally, bioequivalence is determined through *in-vivo* clinical studies for one specific presentation of a given drug, though (under certain conditions) only *in vitro* studies are required for different dosages of the same drug. Bioequivalence certification of imported drugs is normally validated in Chile if the drug has already obtained it in countries considered to have high certification standards (e.g., Canada, USA, the European Union, New Zealand, among others). Although the certification is awarded *ad eternum* for a given formula and production technology, any change in one of these dimensions requires a new certification.

3 Conceptual Framework

We introduce an equilibrium model of pharmaceutical markets to shed light on mechanisms by which quality regulation affects market outcomes. Our model considers several important features of the market, including: (i) vertical differentiation, where generics and innovator drugs can be perceived to be of different quality either due to fundamental quality issues (e.g., lack of bioequivalence or presence of side-effects), or due to product valuation; (ii) heterogeneity in consumers' willingness-to-pay for (perceived) quality; (iii) asymmetric information on quality of generics, where consumers (and physicians) cannot observe the quality of generics; and (iv) fixed costs of operating in the market and of bioequivalence certification, which leads to entry and exit considerations among producers.

The importance of vertical differentiation follows from the general observation that innovator and generic drug prices often differ substantially (see e.g., Frank and Salkever 1997; Danzon and Furukawa 2008), which is consistent with the type of segmentation that arises in this class of models. Asymmetric information on generic quality is introduced to allow for the possibility that the perceived quality of generics is inefficiently low, such that quality regulation potentially increases both perceived quality and competition. Fixed costs allow market structure to be endogenously determined in the model. In particular, when quality regulation imposes substantial compliance costs, as in the case we study, it may lead to an unintended decrease in the number of generic drugs by deterring entry or inducing exit.

The way we model asymmetric information in this market is similar to Leland (1979), from which we differ by including vertical differentiation. Pure vertical differentiation, as introduced by Gabszewicz and Thisse (1979), has been considered by previous theoretical work on minimum

quality standards,[19] though mostly in settings with perfect information on quality and exogenous market structure.[20] The novelty of our model comes from combining asymmetric information and vertical differentiation in a setting where market structure is endogenously determined.

3.1 Model

Environment. The supply side of the market consists of an innovator drug I and N_G generic drugs indexed by g that may or may not participate in the market. Each drug has an exogenous quality level ψ. The quality of the innovator drug I is known to consumers and given by ψ_I and the unobservable quality of generic drug g is $\psi_g \leq \psi_I$. Generic quality has a (known) cumulative distribution F_ψ, so that if all generics with quality between ψ_a and ψ_b participate, the number of generic firms is given by $n_G = N_G \left(F_\psi(\psi_b) - F_\psi(\psi_a) \right)$. Drugs decide to participate in the market or not and compete in prices in a Bertrand game in which all drugs set prices simultaneously.

There is a continuum of consumers in the market, with preferences over drug quality and prices, but unable to distinguish the quality of each generic drug.[21] Instead, they treat all generic drugs as being of the average quality among market participants, denoted by $\overline{\psi}$.[22] The indirect utility that consumer i obtains from purchasing either the innovator drug I or a generic drugs g is:

$$\begin{aligned} u_{iI} &= \tau_i \psi_I - p_I + \varepsilon_{iI} \\ u_{ig} &= \tau_i \overline{\psi} - p_g + \varepsilon_{ig} \quad \forall g, \end{aligned}$$

where τ_i is the preference for quality of consumer i, and ε_{iI} and ε_{ig} are idiosyncratic preference shocks. The idiosyncratic utility terms can be interpreted as an additional, symmetric differentiation between producers, allowing prices above marginal cost among generics to be sustained in a Bertrand-Nash equilibrium.[23] Heterogeneity in preference for quality, τ, provides a role for vertical differentiation: whenever $\overline{\psi} < \psi_I$, a consumer with high τ would be more likely to purchase the innovator drug at a higher price, whereas a consumer with low τ would be more likely to buy a

[19] See, e.g., Ronnen (1991); Crampes and Hollander (1995); Scarpa (1998).

[20] An exception is Garella and Petrakis (2008), who consider imperfect information in strategic games with endogenous quality, allowing for both horizontal and vertical differentiation. Our model differs from theirs on how we model asymmetric information on quality, on which we are closer to Leland (1979), and by allowing for endogenous market structure.

[21] We assume that quality is not revealed by consumption. Lack of learning about quality may be reasonable in markets where differences in medical effects or side-effects are hard to detect or realized over a longer horizon, such that experience with any given generic can be assumed to reveal no information, neither for consumers nor physicians.

[22] This is similar to Leland (1979) and follows, e.g., from an assumption that any credible quality signal is too costly for generic producers. We note that the decision to market drugs under brand names (branded generics) may be a strategy to reduce information asymmetry in the market we study, although we do not consider this aspect in our model.

[23] Our formulation—with price entering linearly with a coefficient of one—implies that indirect utility is measured in terms of willingness-to-pay. Allowing for a utility scaling of price (αp_j) does not change the qualitative implications of the model (results available from the authors upon request).

lower priced generic. With such sorting, quality differences reduce price competition (Shaked and Sutton, 1982). Finally, a consumer may decide not to purchase any of the drugs in the market, and instead choose an outside option that yields indirect utility $u_{i0} = \varepsilon_{i0}$.

Profits of innovator and generic drugs are given by

$$\begin{aligned}\pi_I &= Ms_I p_I - C_I \\ \pi_g &= Ms_g p_g - C_G(\psi_g) - C_{QC} \quad \forall g,\end{aligned}$$

where M is market size, C_I is the fixed cost of the innovator drug, $C_G(\cdot)$ is a quality-dependent fixed cost faced by generic drugs; and C_{QC} is an additional sunk cost associated with quality certification. For simplicity, we set marginal cost to zero for all producers.[24] We assume that fixed manufacturing costs are continuous and increasing in quality ($C'_G(\cdot) > 0$). Due to asymmetric information on generic quality, this leads to adverse selection, because incentives to enter the market are higher for lower quality drugs. Finally, quality certification takes the form of a minimum quality standard denoted by $\underline{\psi}$.

Equilibrium with quality certification. Given that generic drugs are symmetric up to a quality-specific fixed cost, we focus on a symmetric equilibrium in which all generic producers set the same price p_G and obtain the same market share, denoted by s_G. In this equilibrium, generic producers choose to participate in the market as long as:

$$\pi_g \geq 0 \iff Ms_G p_G \geq C_G(\psi_g) + QC$$

which determines the set of active generic producers. Since all generics obtain the same variable profits and quality-dependent fixed costs are increasing, it follows that the marginal generic entrant is of (weakly) higher quality than inframarginal entrants.

Finally, quality certification takes the form of a minimum quality standard denoted by $\underline{\psi}$. Conditional on $\underline{\psi}$, there is a one-to-one relation between the number of generics in the market and the quality of the marginal entrant, $\hat{\psi}$, given by $n_G = N_G\left(F_\psi(\hat{\psi}) - F_\psi(\underline{\psi})\right)$. Thus, n_G is the number of generics with quality between the minimum allowable to the highest that still achieves a non-negative profit. Then, the average generic quality $\overline{\psi}$ is equal to the expected quality among the n_G active generic producers, that is, the ones with quality between $\underline{\psi}$ and $\hat{\psi}$.[25]

The market equilibrium will be determined by the conditions for a Bertrand Nash equilibrium in the prices of the generics and innovator, together with the zero-profit entry condition for the highest quality generic entrant. That is, the equilibrium is imperfectly competitive, with positive

[24] For most oral solids (tablets), this is likely a good approximation (see, e.g., Berndt and Newhouse, 2012). Otherwise, allowing for positive and asymmetric marginal costs is straightforward in our model.

[25] If generic quality was uniformly distributed, the expected quality would simply be the midpoint $(\hat{\psi} + \underline{\psi})/2$.

variable profits which covers the fixed costs for the marginal (i.e., highest quality active) generic entrant. The difference from standard entry models is selection: additional entry by generics will have a positive effect on the expected quality of all generics, possibly leading to higher generic prices and/or market shares. This could happen in cases where the perceived quality of generics is very low.[26]

3.2 Comparative Statics: The Equilibrium Effects of Quality Regulation

In this section, we discuss the equilibrium effects of stronger quality regulation implied by our model. Consider an increase in the minimum quality standard from $\underline{\psi}_0$ to $\underline{\psi}_1$, with $\underline{\psi}_0 < \underline{\psi}_1$. Stronger quality regulation has a direct effect on the willingness-to-pay for generics. Keeping the set of active producers fixed, perceived quality of generics increases because consumers know that these producers have quality $\psi_g \geq \underline{\psi}_1$. Decreased vertical differentiation resulting from this increase in perceived quality leads to more intense price competition with the innovator. Thus, keeping the set of generics fixed, the price of the innovator decreases. Prices of generics might increase or decrease, because the increased willingness-to-pay for the higher perceived quality is counteracted by the higher intensity of price competition with the innovator.

However, stronger quality regulation also has effects on market structure. First, there is a direct effect through the exit of all $N_G(F_\psi(\underline{\psi}_1) - F_\psi(\underline{\psi}_0))$ producers with quality $\psi_g < \underline{\psi}_1$ that were previously in the market. The exit of these drugs decreases the intensity of price competition, particularly among generics. In addition, fewer generic competitors leads to higher demand for the remaining generic drugs and for the innovator. Second, an increase in perceived quality—together with higher demand for any single generic drug—may induce $N_G(F_\psi(\hat{\psi}_1) - F_\psi(\hat{\psi}_0))$ higher quality generics to enter the market at the margin, further increasing the perceived quality of generics and the intensity of price competition with the innovator. Overall, stronger quality regulation increases the quality of generics in the market and has an uncertain effect on prices that depends on the changes in vertical differentiation and price competition.[27]

Although it is not possible to determine a priori what the equilibrium effects of stronger quality regulation are in our framework, higher fixed costs of quality certification are generally associated with worse equilibrium outcomes. In particular, large certification costs decrease generic entry; therefore, they harm price competition. We discuss the role of certification costs in detail in the next section.

[26]Note that there is an incentive for generics to keep quality lower than the innovator to soften price competition, such that we have in mind a situation where perceived quality is lower than a quality level that would be optimal from the generic firms' view (i.e., trading off higher willingness to pay of consumers and less differentiation from the innovator).

[27]Note that, to the extent that the stronger quality regulation results in both higher generic quality and higher prices, consumers with a sufficiently low willingness-to-pay for quality are worse off, and some reduce their consumption of the drug. This happens for consumers with $\tau_i \leq \Delta p_G / \Delta \overline{\psi}$, where Δp_G is the change in prices and $\Delta \overline{\psi}$ is the change in perceived generic quality.

Our model provides a framework to analyze the effects of quality regulation and shows that a variety of outcomes are possible. Depending on the primitives of the market, stronger quality regulation may lead to higher perceived quality and lower prices of all drugs, thus increasing access; but it could also lead to substantial exit of generics and higher prices due to reduced price competition. It is even theoretically possible that the equilibrium with higher quality standards entails lower perceived quality and reduced access, say, if certification costs are large enough to induce substantial exit among high-quality generics. The ambiguity of theoretical predictions partly motivates the empirical analysis we develop in the remainder of the paper.

3.3 The Importance of Fixed Compliance Costs and Market Size

In this section, we simulate our model to illustrate the equilibrium effects of stronger quality regulation. In particular, we study the effects of stronger quality regulation and their relationship with the cost of quality certification C_{QC}. The effect of C_{QC} is of particular interest, because it is a reform-specific cost that is fully covered by generics and acts as a sunk cost to participate in the market, with the potential for affecting market structure.

Our simulation consists of solving for market equilibrium across a range of minimum quality standards, separately for the cases with free and costly compliance, $C_{QC} = 0$ and $C_{QC} > 0$ respectively. In particular, we highlight three regulatory environments in which: (a) there is a baseline level of quality regulation in the form of a minimum quality standard; (b) there is stronger quality regulation but it does not impose any certification costs C_{QC} on generic producers; and (c) there is stronger quality regulation and quality certification is costly for generic producers. Details on the model specification and parametrization used for this exercise and formulas for all calculations are provided in Appendix A.1.1.

Figure 1 displays the simulation results, where we highlight the three environments, labelled by **a**, **b** and **c** respectively. Compared with the baseline scenario (**a**), quality regulation with costless certification (**b**) increases consumer surplus and welfare. These effects are driven by increased perceived generic quality without large decreases in generic competition, which limits the extent to which generic prices increase; and decreased innovator price due to decreased vertical differentiation with generics. Moreover, generic prices increase slightly and the market share of generics increases at the expense of the innovator. For the case with costly certification (**c**), consumer surplus and welfare fall, driven by higher prices of all drugs due to reduced competition caused by substantial generic exit. In this case, the market share of generics decreases, and that of the outside good increases. Overall, our illustration suggests that stronger quality regulation may be able to decrease vertical differentiation and increase the intensity of price competition, but that fixed compliance costs may counteract such forces and lead to adverse effects.

Higher market size M reduces the importance of fixed costs, and might thus intuitively be a source of heterogeneity in the effects of the reform. As we illustrate in Appendix A.1.2, it is the case

that detrimental competitive effects of fixed compliance costs are stronger in smaller markets than in large markets. In particular, the model predicts that fixed compliance costs induce more exit and larger price increases in small markets. We exploit this theoretical result in our empirical analysis to test the model predictions related to C_{QC} by contrasting results for small and large markets.

4 Data and Descriptive Statistics

4.1 Data Sources

We employ three sources of data for our empirical analysis. First, we use the drug registry maintained by ISP for the Chilean pharmaceutical market, which provides licensing data for the universe of drugs marketed in the country. The registry provides information on manufacturer (laboratory), the date when the drug was first licensed in Chile, the date of the last license approval, and the due date of the next license renewal. It also includes information on the drug dosage (e.g., number of milligrams of the active ingredient contained in each tablet), presentation (i.e. tablet, capsule, injectable, or other), and marketing status (prescription, over-the-counter, or discontinued). We restrict our analysis to molecules under a bioequivalence requirement within the sample period, which includes all molecules with bioequivalence requirements initiated after 2010. Our data cover all licensed drugs up to December 2017. Second, we combine the drug registry data with data on bioequivalence certification by drugs in the market, which are also available from ISP. These data contain a list of all drugs with bioequivalence certification, including certification date and the corresponding reference drug.

Finally, we use data from IMS Health Chile, which contain detailed information on monthly prices and sales of drugs sold across the market for the period between January 2010 and December 2017. IMS Health collects data from two sources. The four largest pharmacy chains in the country, accounting for more than 90% of drugs sold in Chile, report retail prices and sales directly to IMS Health. Sales from other pharmacies are supplied by wholesalers, which report wholesale prices and sales to IMS Health. Wholesale prices are transformed to retail prices using a standard methodology.[28,29] We employ monthly sales and prices from all 83 local markets included in the IMS Health data, which cover most of the urban areas of the country. We aggregate prices and sales for each drug across local markets. In particular, we compute total monthly sales by aggregating monthly sales across local markets and calculate monthly drug prices as sales-weighted averages of prices across local markets.[30]

[28]This methodology consists of adding a VAT of 19% and a retail margin of 30%.

[29]We adjust retail prices in two ways. First, we transform nominal prices to real prices in 2013 using the health CPI from the National Institute of Statistics (*Instituto Nacional de Estadística*, INE). Second, we normalize drug prices across drug presentations by their drug content by calculating prices per gram of the active ingredient.

[30]There is little variation in drug prices across local markets, and no geographic variation in any of the sources of identifying variation we use in the main analysis of the paper.

The IMS Health dataset provides price and sales at the product level for branded drugs, identifying the laboratory, dosage and presentation of each drug. For unbranded drugs, it provides price and sales at the dosage and presentation level, aggregated across laboratories.[31] We focus prescription drugs, which account for more than 90% of drugs in the molecules we study.

4.2 Descriptive Statistics for Quality Certification

The number of bioequivalent drugs in the Chilean market increased substantially throughout our study period. Figure 2-a shows the number of bioequivalent drugs between January 2010 and December 2017. Bioequivalence certification started at a low pace in early 2010, but increased steadily since then, with a rapid uptake by mid-2012. By December 2017, there were 1,433 drugs with bioequivalence certification in our sample, among which 909 were branded generics.

The growth in the number of bioequivalent drugs relates to the regulation roll-out, which was announced and implemented at different dates through the decrees and deadlines described in Section 2.2. Figures 2-b through 2-e display the number of bioequivalence approvals around four policy events of each market: (1) the first decree, (2) the last decree, (3) the first deadline, and (4) the last deadline. We highlight three facts from these figures. First, bioequivalence approval was uncommon before the first decree, which shows that bioequivalence incidence was rare before it was mandated by law. Second, bioequivalence approval increased markedly after the first decree, which suggests that bioequivalence regulation had an impact on bioequivalence incidence. Third, several bioequivalence approvals occurred after the first and last deadlines, which shows that deadlines were only imperfectly enforced, a point to which we return in our empirical strategy.

4.3 Descriptive Statistics for Market Outcomes

We merged the price and sales data from IMS health with the drug registry from ISP, to construct a monthly panel dataset for the period between January 2010 and December 2017. After some data cleaning, the resulting dataset covers 131 molecules. The data contain 2,292 unique drugs, defined as a unique combination of drug name, dosage, and presentation. These drugs are manufactured by 80 different laboratories.[32] Importantly, not all drugs in the panel are sold in every period. In fact, only 65.5% of the drug-month observations in our panel dataset display positive sales. Drug prices are not observed for months in which a drug registers no sales.

Table 2 displays basic descriptive statistics. On average, innovator drug prices are around twice

[31] This limitation of the IMS Health data imposes some restrictions on our analysis, because all unbranded generics of a given molecule, presentation, and dosage are coded together as if they were manufactured by a single laboratory. In particular, it limits the extent to which we can track the composition of sales of a given unbranded generic across laboratories over time.

[32] As stated above, for this calculation, all unbranded generics within a given molecule, dosage, and presentation, are counted as being produced by the same laboratory due to limitations in the IMS Health data.

as high as those of the average drug in the market, whereas branded (unbranded) generic prices are around two thirds (one fifth) of the average drug in the market. We go beyond these raw averages and estimate price premiums within markets for innovator and branded generics below. The highest market share is captured by branded generics, with an average market share of 43%, followed by innovator and unbranded generics with market shares of 30% and 27%, respectively. On average, bioequivalent drugs hold a market share of only 7%. However, the average market share of bioequivalent drugs increased substantially during our study period, from only 0.06% in 2010, to 22.8% by the end of 2017. This shift in market shares is also displayed by Figure 4. The average market has around 13 drugs and five laboratories in a given month. As expected, the numbers of drugs and laboratories are remarkably larger in the segment of branded generics than in the innovator and the bioequivalent segment.[33]

Figure 5 shows pre-reform price premiums per drug type, using 2010 and 2011 prices.[34] Four facts become apparent: First, price premiums are on average positive across all molecules in the sample. Second, price premiums are large overall: innovators and branded generics are substantially more expensive than unbranded generics, with average relative premiums of 10 and 6 times, respectively. Third, relative price premiums are much larger for innovator drugs than for branded generics. Fourth, there is substantial heterogeneity in price premiums across molecules. Whereas several molecules display relative price premiums on the order of 3 to 5 times, several other molecules display relative price premiums beyond 10 times, particularly for innovator drugs.

5 Effects of Quality Regulation on Quality Certification, Entry and Exit

We start our analysis by studying quality certification and exit by drugs in the market. First, we study whether drugs that became exposed to bioequivalence requirements obtained bioequivalence approval. Second, we study whether drugs were more likely to exit the market once bioequivalence requirements were imposed. For this analysis, and for the remainder of the paper, we follow Duggan et al. (2016) and treat each molecule as a separate market, because there is generally little to no substitution across molecules for the treatment of health conditions.

5.1 Evidence for Bioequivalence Approval

In section 4.2, we provided suggestive evidence that bioequivalence certification increased substantially after the reform. We now turn to survival analysis to study its determinants. Survival analysis

[33] This partly comes from our inability to identify different producers of unbranded drugs in IMS Health, as explained in Section 4.1.

[34] We calculate these premiums by estimating regressions of logged (real) prices per gram in 2010 and 2011 on indicators for innovator and branded generics separately for each market. The exponentiated coefficients on the indicators for drug type provide a measure of average price premiums of each type relative to unbranded generics (the omitted category). We restrict the estimation sample to molecules with price information for at least one innovator drug, one branded drug and one unbranded drug during the period, which limits the sample to 56 molecules.

is a convenient method to describe bioequivalence approval, because it flexibly accommodates the absorbing nature of bioequivalence, right-censoring, and time-varying covariates.

The hazard function $h(s)$ measures the probability of becoming bioequivalent in period s. We parameterize $h(s)$ using a proportional hazard model for drug i in market m and calendar month t that takes the following functional form:

$$h(s|X_{imt}, t) = \lambda_s \times \exp(X'_{imt}\beta + \psi_t). \tag{1}$$

where λ_s is a *baseline* hazard that depends on drug tenure s (measured in months since entry to the market) and is estimated non-parametrically. Coefficients in β measure the proportional increase in the hazard following a one-unit increase in the corresponding covariate. The vector X_{imt} includes indicators for branded and imported drugs, logged average market revenue in the past 12 months, and logged counts of branded and unbranded drugs in the market, as well as indicator variables for time periods after policy decrees and deadlines. We consider the same four market-specific events analyzed in section 4.2: date of first deadline, date of first decree, date of last deadline, and date of last decree. We quantify the changes in the probability of becoming bioequivalent after each event date t_m^d with indicators $\mathbb{1}(t > t_m^d)$. Finally, ψ_t are calendar month fixed effects.

Table 3-A displays estimates from equation (1). Column (1) through (4) include each policy event separately, whereas column (5) includes all of them jointly. The most relevant policy events are the first decree and the first deadline, which increase the probability of becoming bioequivalent by $\exp(2.52) = 12.4$ and $\exp(1.78) = 5.9$ times, respectively, whereas posterior policy events do not significantly increase the hazard of quality certification. These results reinforce the graphical evidence of Figure 2: periods after the first decree and first deadline are stronger predictors of bioequivalence certification than periods after the last decree and last deadline. Also, drugs are more likely to become bioequivalent after the first deadline than after the last deadline, showing that the first deadline triggered a higher rate of bioequivalence certification than subsequent extensions.

We then turn to analyze the relationship between bioequivalence approval rates and drug characteristics as well as market variables. Branded and imported drugs are estimated to be more likely to obtain bioequivalence approval, although the coefficients are not statistically significant. Market variables are strong predictors of bioequivalence approval: A 10% increase in market revenue is associated with a 5.8% increase in the hazard of becoming bioequivalent. Moreover, the number of competing drugs in a market is negatively associated with bioequivalence approval. A 10% increase in the number of branded drugs is associated with a 2.9% lower hazard rate, whereas a 10% increase in the number of unbranded drugs is associated with a 3% lower hazard rate.

Heterogeneity. We study how baseline drug attributes affect quality certification choices. Table A.1-A displays results from a version of equation (1) in which policy events are interacted with

indicators for drug covariates at baseline.[35] We focus on the first deadline of bioequivalence requirements for a market, which showed to be the most relevant in our baseline analysis. The most relevant pattern of heterogeneity we find is that drugs with higher baseline revenue are differentially more likely to engage in quality certification after bioequivalence requirements are imposed, as predicted by the model in Section 3. In particular, a 10% increase in revenue is associated with a differential increase in the hazard rate of 1.3%.

5.2 Evidence for Entry and Exit of Drugs

We turn to analyze the relationship between bioequivalence regulation and the dynamics of entry and exit. We construct measures of entry and exit using the ISP registry data on licensing and renewals. For each registered drug, we record an entry as the event of obtaining a license for the first time, and an exit as the event of not renewing a license upon expiration.[36] Figure 3-a shows the total number of drugs that entered and exited the market during our sample period. We find that drug exit was relatively stable up to late 2014, and that there was a large increase in the number of exiting drugs afterwards. On the other hand, we do not find a large change in entry during the period. Figures 3-b through 3-e display the number of drugs that entered and exited the market at each point in time relative to relevant policy events. These figures show that the marked increase in exit of drugs occurred after the enactment of the bioequivalence policy.

We estimate a hazard model for drug exit to quantify these patterns, analogous to that in equation (1). Our results are shown in Table 3-B. We focus on Column (10), which displays estimates from a specification that includes all policy variables jointly. The results imply that the first deadline is the policy variable that most strongly influences drug exit. In particular, the probability of exiting increases by $\exp(0.42) = 1.52$ times after the first deadline. Branded drugs have a lower propensity to exit compared with unbranded, and innovator drugs display a lower exit hazard rate than generics. Interestingly, imported drugs are more likely to exit. We do not find significant effects of market variables on exit, which display similar effects across specifications.

Heterogeneity. We implement a heterogeneity analysis of exit rates. Table A.1-B displays results for heterogeneity in the effect of the first deadline of bioequivalence requirements on drug exit. We do not find any strong patterns of heterogeneity. However, we find suggestive evidence of the overall determinant of exit: conditional on market size and the number of competing drugs, drugs with higher sales and revenues at baseline are less likely to exit the market, as expected.

[35] Baseline drug characteristics are measured as indicators for whether a drug was, on average, above or below the median drug in their market during 2010. These characteristics are constructed using the IMS Health data. The number of observations decreases relative to that in Table 3-A because several drugs were not in the market in 2010. The comparison between column (2) in Table 3 and column (1) in Table A.1 shows that both samples deliver similar results for the baseline specification in equation (1).

[36] Thus, for the purpose of this exercise, we assume that exit happened exactly at the due date of the failed renewal (i.e. five years after the last renewal) although the decision to exit was likely taken some time before the due date.

6 Effects of Quality Regulation on Market Outcomes

We now turn to the main analysis of the paper, where we estimate the effects of quality regulation on market outcomes. We employ an empirical strategy that exploits variation in the roll-out timing of bioequivalence requirements within and across markets. We explore potentially heterogeneous effects of the policy in line with the model in Section 3, focusing on the differences in the effects of quality regulation across small and large markets.

6.1 Empirical Strategy

Our empirical strategy exploits two sources of policy variation across and within markets to construct a measure of policy roll-out over time at the market level. We then use this variable for the estimation of the effects of quality regulation.

The first source of identifying variation is the staggered roll-out of the reform, as already discussed in Section 2.2. This variation is displayed in Figure 6-a. In practice, the differences in the timing of the regulation generate a series of comparison groups comprised of markets that faced bioequivalence requirements at different dates throughout our period of study.

The second source of identifying variation comes from a particular feature of the institutional setting. In practice, deadlines for incumbent drugs become binding every time a drug must renew its marketing license with ISP, i.e. every five years. As stated by ISP officials, regulation enforcement occurs mostly at the time of license renewal, when ISP is likely to deny renewal to drugs without bioequivalence approval (Vasallo, 2010). Thus, for each drug, the first license renewal after the policy deadline marks the effective deadline to comply. License-renewal dates vary across drugs within each market, reflecting the date at which the drug was first licensed, and are arguably exogenous for drugs that were in the registry before the deadline was known. Differences in renewal dates across drugs generate variation in the share of drugs for which the policy is effectively binding, both across markets sharing the same deadline, as well as within markets over time.

We combine these two sources of variation by constructing a variable that measures the evolution of the policy roll-out within each market. This variable captures three main features of the regulation. First, the policy becomes relevant for a market only after its first corresponding decree. Second, the policy becomes increasingly relevant for each drug in the market as its respective license renewal date approaches. Finally, the policy is fully in place for a market when the license renewal date has been reached for all drugs in it. Formally, denote the policy date for market m by t_m^d and renewal date of drug i in m by t_{im}^r. For a given drug i, the share of time between the decree

and next renewal date that has elapsed by time any time t is given by:

$$T_{imt} = \begin{cases} 0 & \text{if } t \leq t_m^d \\ \frac{t - t_m^d}{t_{im}^r - t_m^d} & \text{if } t_m^d < t \leq t_{im}^r \\ 1 & \text{if } t_{im}^r < t \end{cases}$$

For each market m, we then define the *share of market under regulation* by month t as the average of T_{imt} across the set of generic drugs (branded and unbranded) present in market m in period t_m^d, $\mathcal{G}_m$:

$$T_{mt} = \frac{1}{|\mathcal{G}_m|} \sum_{i \in \mathcal{G}_m} T_{imt} \tag{2}$$

where $|\mathcal{G}_m|$ is the number of generic drugs present in market m in month t_m^d.

We employ T_{mt} as a treatment variable for our analysis of the effect of the regulation on market outcomes. T_{mt} is a weakly increasing function of time relative to the policy date t_m^d: it is equal to 0 before t_m^d and is equal to 1 after the latest renewal date across drugs in $\mathcal{G}_m$ is reached. Figure 6-b displays the evolution of T_{mt} over time for all markets in the sample, showing substantial variation across markets at any given point in time, as well as variation within market across time.[37] Finally, Figure 6-c shows that this variable is correlated with the share of bioequivalent drugs in the market, even after accounting for market and month fixed effects.

Our main specification for measuring policy effects on market-level outcomes y_{mt} is given by:

$$y_{mt} = \beta T_{mt} + \theta_m + \delta_t + \varepsilon_{mt} \tag{3}$$

where the coefficient of interest, β, is interpreted as the effect of the fully implemented bioequivalence policy on outcome y_{mt}. We include two sets of fixed effects: θ_m are market fixed effects that control for permanent differences across markets that may be correlated with T_{mt}, and δ_t are time (year and month) fixed effects that control for shocks common to all markets in a given period of time. To interpret our results, we discuss the effect of an increase in T_{mt} from zero to one, corresponding to the estimated effect of moving from not having bioequivalence regulation to having the regulation fully in place for a given market.

The key identifying assumption in (3) is that there are no unobserved market-specific trends that drive both the timing of the policy roll-out and the outcomes of interest. The main assumption behind this strategy is that decree deadlines and renewal dates for a given molecule were not set as a function of unobserved shocks not captured by market and time fixed effects. A violation to this assumption would happen if, for example, decrees and deadlines were set earlier for markets that

[37] For further illustration, Figure A.2 shows particular examples for the evolution of T_{mt} over time for four markets, along with the evolution in the number of bioequivalent drugs in each of them. These examples are highlighted in Figure 6-b. These plots show how bioequivalence certification increases as bioequivalence requirements become relevant for a market.

were expected to have earlier price increases. Although we cannot directly test this hypothesis, the fact that decrees were set and modified mostly based on capacity constraints of laboratories testing bioequivalence makes it unlikely that they were timed according to unobserved future demand or supply shocks. Moreover, market-level observable characteristics do not show a clear correlation with the timing of the policy. Table 1-B shows descriptive statistics for market outcomes in 2010 for markets affected differently by the policy. Overall, these statistics display substantial heterogeneity across different groups in terms of number of drugs, market size, and market outcomes, but do not display a clear pattern related to the timing of bioequivalence requirements roll-out.

Event-Study Evidence. As a complement to this strategy, we implement an event-study analysis. The event study serves two purposes: (i) assessing the plausibility of the assumption of parallel trends across groups of molecules treated by the policy at different dates; and (ii) providing transparent visual evidence of the effects of bioequivalence on relevant market outcomes. The main advantage of the empirical strategy proposed above relative to this event-study analysis is that we can exploit an additional dimension of identifying variation coming from the pattern of license-renewal dates for drugs in the market. We describe this analysis in Appendix A.2 and provide results in Figure A.6. Overall, trends in outcomes before the first deadline of bioequivalence requirements are well behaved, as most of the estimated coefficients are close to zero. This fact is reassuring in terms of exploiting the differential timing of decrees across markets as exogenous variation to estimate the effects of quality regulation in our setting. Moreover, the results obtained from this event-study analysis are consistent with those from our main analysis in this section.

Heterogeneity. The model in Section 3 suggests that whenever compliance is costly, quality regulation should have stronger effects in smaller markets because it would induce more drug exit. To test this prediction, we estimate differential effects of the policy according to market size, measured as the average sales in the pre-reform period. Specifically, we divide markets according to whether the average monthly market revenue in 2010 was above or below the median and identify them as large and small markets respectively.

6.2 Effects of Quality Regulation on Market Structure

We start by discussing the estimated effects of bioequivalence regulation on market structure. We focus on two key features of market structure, the number of drugs of different types that are in the market and the number of laboratories offering drugs in each segment of the market.

6.2.1 Results for Number of Drugs

Table 4-A displays estimates of equation (3) on the number of drugs.[38] Column (1) shows the results for drugs of all types. We find that the bioequivalence policy decreased the number of drugs in the market by 25%. Columns (2)–(8) split these results across different drug types. The overall reduction is driven by exit of branded and unbranded generics. We estimate a 26% decrease in the number of branded generics and a 25% decrease in the number of unbranded generics. However, we estimate a negative effect for innovator drugs, although it is not statistically significant. Even though there is an increase in the number of bioequivalent generics, it is not enough to compensate for the exit of non-bioequivalents. The fact that the number of drugs in the market decreased as a result of the stronger quality regulation is consistent with the predictions of our model in Section 3, which suggests that the intensity of price competition in the market may have decreased.

Table 4-B shows estimates separately for small and large markets. Consistent with our model predictions, the negative effects on the number of drugs are particularly pronounced in small markets, driven by a significant amount of exit by both innovator drugs and generics. We estimate that the number of drugs decreased by 35% in small markets and 15% in large markets. Conversely, bioequivalence certification is significantly larger in high-revenue markets. This is also consistent with our model, because a larger market makes bioequivalence certification relatively less costly.

6.2.2 Results for Number of Laboratories

In the previous section, we document a large decrease in the number of drugs, particularly in low-revenue markets. Since most manufacturers are multiproduct firms, we turn to study whether drug exit is driven by laboratory exit or changes in their drug portfolios. Evidence of laboratory exit as a result of stronger quality regulation would imply unintended competitive effects.

Table 5-A displays results for the effects of the regulation on the number of laboratories in the market.[39] Our estimates imply that the number of laboratories decreased by 14% on average as a result of the reform. These reductions in the number of competitors is concentrated among laboratories offering generics, whereas we find no significant effect on the number of laboratories offering innovator drugs. However, we find a large increase in the number of laboratories offering bioequivalent generics. Table 5-B displays heterogeneous effects across small and large markets. Our results are consistent with our findings for the number of drugs and with the model predic-

[38] We use $\ln(1 + N_{mt})$ as the dependent variable, where N_{mt} is the number of drugs (in particular, the number of presentations), to accommodate observations where there are no drugs of a certain category, e.g., no bioequivalent unbranded generics. As a robustness check, we show that the results are virtually unchanged when using $\sinh^{-1}(N_{mt})$ as the dependent variable in Table A.2. This transformation also reduces skew, yields coefficients approximating percentage changes, and allows for zeros, all of which are desirable statistical properties with this type of data (see, e.g., Kline et al. 2017).

[39] For this analysis, we treat different laboratories owned by a same conglomerate as the same laboratory. We thank Gastón Palmucci and Thomas Krussig at the National Economic Prosecutor of Chile (*Fiscalía Nacional Económica*, FNE) for help in constructing this dataset.

tions. We find that stronger quality regulation reduced the number of competing firms in small markets: the number of laboratories in small markets decreased by 23%, whereas it did not change significantly in large markets. The decrease in the number of laboratories in small markets is mostly driven by exit of laboratories offering unbranded drugs. Conversely, entry of laboratories to the segments of branded and unbranded bioequivalents was stronger in large markets.[40]

Combining the estimates of policy effects on the number of drugs and the number of laboratories, we can measure the effect on the number of drugs per laboratory. Our estimates imply that, across markets, 40% of the decrease in the number of drugs is driven by a reduction in the number of drugs offered by laboratories rather than by the exit of laboratories. Consistent with our previous findings, this result is heterogeneous across market sizes. As much as 68% of the effect on the number of drugs comes from laboratory exit in small markets, whereas 43% of the effect on the number of drugs comes from laboratory exit in large markets.[41]

The finding that a large share of drug exit is due to a reduction in the size of the portfolio of laboratories gives some support to the notion that laboratories selectively test for bioequivalence. It is reasonable to believe that (the underlying) bioequivalence status of drugs is highly homogeneous within laboratories, such that variation in bioequivalence certification within laboratories reflects heterogeneity in drug profitability. Selective testing based of drug profitability is consistent with regulation compliance costs being a driver for our results.

6.3 Effects of Quality Regulation on Drug Prices

We turn to studying the effects of quality regulation on drug prices. Having documented large changes in market structure, we interpret these price effects as the combination of different forces at play. A reduction in the number of competitors—particularly a large exit of branded generics—may lead to price changes due to reduced competition. As described in Section 3, the sign of the price change of incumbent competitors is ambiguous. Innovators are expected to increase their prices to exploit their increased market power[42]. Moreover, changes in market structure are coupled with potential changes in consumer perceived quality, changing the scope for vertical differentiation and the intensity of price competition.

We estimate the effects of quality regulation on a market price index constructed as the share-

[40] As a robustness check, we estimate the same regressions using $\sinh^{-1}(N_{mt})$ as the dependent variable. See footnote 38 for details. Table A.2 displays results for these specifications. Overall, the results are remarkably similar to those using $\ln(1+N_{mt})$ as the dependent variable.

[41] For completeness, we report results of regressions using the average number of drugs per laboratory as the dependent variable. Table A.4 displays results for those specifications.

[42] Another theoretical possibility is that innovators decrease their prices to cater a more elastic part of the demand (see, e.g., Frank and Salkever (1992), which we illustrate using our model in Appendix A.1.2).

weighted average of log prices (see, e.g., Chevalier et al., 2003; Nevo and Hatzitaskos, 2006):

$$\hat{P}_{mt} = \sum_{i \in \mathcal{I}_{mt}} w_{it} P_{it} \tag{4}$$

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

Table 6-A displays estimates for effects on drug prices. We find that average prices across all drugs increased by 10% as a result of the regulation. We then estimate price effects by drug type and find that most of the increase in average prices comes from increases among unbranded generics, whereas innovators and branded generics display no statistically significant changes.[43]

We now consider heterogeneity in price effects across small and large markets in Table 6-B. As shown in Section 6.2, the decrease in the number of drugs is concentrated in small markets; therefore, these are the markets where we expect to find the strongest competitive effects, which is largely confirmed by our findings. The increase in prices across all drugs is concentrated in small markets, with an estimated increase of 26%. Our estimates show that stronger quality regulation induced price increases of 7% and 18% among innovator drugs and unbranded generics respectively in small markets. On the other hand, our estimates for price effects in large markets are close to zero and not statistically significant.

6.3.1 Decomposition of Price Effects

The effects on average prices at the market level documented in the previous section combine drug-specific price changes (changes in P_{it}), changes in shares (changes in w_{it}), and changes in the composition of drugs offered in each market. To better understand the drivers of price effects, we decompose the evolution of average market prices into such components.

Consider the change in the share-weighted average of log prices between a baseline period $t = 0$ and any period $t > 0$. 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 period 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 decompose the change in the

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

share-weighted average of log prices as:

$$\sum_{i\in\mathcal{I}_{mt}} w_{it}P_{it} - \sum_{i\in\mathcal{I}_{m0}} w_{i0}P_{i0} = \underbrace{\sum_{i\in\mathcal{S}_{mt}} w_{i0}(P_{it}-P_{i0})}_{\Delta P_{mt,C}} + \underbrace{\sum_{i\in\mathcal{S}_{mt}} (P_{it}-P_{m0})(w_{it}-w_{i0})}_{\Delta P_{mt,RW}} + \underbrace{\sum_{i\in\mathcal{S}_{mt}} (w_{it}-w_{i0})(P_{it}-P_{i0})}_{\Delta P_{mt,CS}} + \underbrace{\sum_{i\in\mathcal{E}_{mt}} w_{it}(P_{it}-P_{m0})}_{\Delta P_{mt,E}} - \underbrace{\sum_{i\in\mathcal{X}_{mt}} w_{i0}(P_{i0}-P_{m0})}_{\Delta P_{mt,X}}$$

The first term, $\Delta P_{mt,C}$, measures the change in share-weighted average due to the price changes among incumbent drugs, holding weights fixed at their baseline level. The second term, $\Delta P_{mt,RW}$, measures the change in the share-weighted average due to changes in relative market shares, holding prices fixed. This term is positive (negative) when relatively expensive (cheap) incumbent drugs increase their market share. The third term, $\Delta P_{mt,CS}$, measures the change in sales-weighted prices due to the correlation between price changes and changes in market shares. This term is positive (negative) when drugs that increase their prices are also those that increase (decrease) their market shares. The fourth term $\Delta P_{mt,E}$, captures price changes due to the entry of drugs in the market. This component is positive (negative) whenever drugs that enter the marker are more (less) expensive that the average drug in the baseline period. Finally, the fifth term, $\Delta P_{mt,X}$, measures the change in the share-weighted average due to the exit of drugs. This component is positive (negative) whenever drugs that exit the market are less (more) expensive than the average drug in the baseline period. It follows that the price index can be decomposed as:

$$\hat{P}_{mt} = \hat{P}_{m0} + \Delta P_{mt,C} + \Delta P_{mt,RW} + \Delta P_{mt,CS} + \Delta P_{mt,E} + \Delta P_{mt,X} \tag{5}$$

To evaluate the effect of the policy on these components of price changes, we estimate equation (3) for the following dependent variables: $\hat{P}_{mt,C} \equiv \hat{P}_{m0} + \Delta P_{mt,C}$, $\hat{P}_{mt,RW} \equiv \hat{P}_{m0} + \Delta P_{mt,RW}$, $\hat{P}_{mt,CS} \equiv \hat{P}_{m0} + \Delta P_{mt,CS}$, $\hat{P}_{mt,E} \equiv \hat{P}_{m0} + \Delta P_{mt,E}$ and $\hat{P}_{mt,X} \equiv \Delta\hat{P}_{m0} + P_{mt,X}$. By construction, the sum of the OLS coefficients on T_{mt} from these regressions is equal to the coefficient on T_{mt} in equation (3). Each coefficient measures the policy effect on the corresponding component of the price index.

Table 6-C, shows estimates for policy effects on each of the components, both for the overall market price and for the price of each drug type. We find that most of the increase in overall prices is due to within-drug price changes. Of the 10% increase in average prices, 7 p.p come from price changes within drugs ($\hat{P}_{PC}$) and 2 p.p from the entry of relatively expensive drugs ($\hat{P}_{E}$). Similarly, we also find that most of price increases among unbranded generics are due to within-drug price changes ($\hat{P}_{PC}$). As noted above, unbranded generics are aggregated across laboratories; therefore, the decomposition for this segment should be interpreted with caution. Overall, the finding that the estimated increase in average drug prices is due mostly to price increases of products already in the market before the policy supports our interpretation that the exit of drugs documented in Section 6.2 reduced the intensity of price competition in the market.

6.4 Effects of Quality Regulation on Market Shares and Sales

We now estimate the effect of quality regulation on quantity outcomes. We are mostly interested in exploring whether quality regulation significantly affected generic penetration. Given our model, we expect changes in market shares due to changes in the market structure and changes in demand.

Table 7-I-A displays estimates of equation (3) using market shares as the outcome of interest. Overall, we do not find significant changes in the market shares of innovator drugs and generics. If anything, we find a non statistically significant increase of 4 p.p in the market share of innovator drugs and a decrease of the same magnitude in the market share of generics. The decrease in the market share of generics is concentrated among branded generics, whereas the market share of unbranded generics remains unchanged. As expected, we find a significant increase of 10 p.p. in the market share of bioequivalent generics and a decrease of 14 p.p. in non-bioequivalent generics.[44] Considering the decrease in the number of branded generics found in Table 4, these results are consistent with consumers mostly substituting towards innovator drugs as generics exit the market.

Table 7-I-B shows heterogeneity in effects on market shares across small and large markets. Most of the increase in the market share of innovator drugs comes from small markets, where it increases by 8 p.p. In contrast, we do not find a significant change in the market share of innovators in large markets. Moreover, in large markets—where we find smaller exit among generics—we find a shift from branded generics to unbranded generics: we estimate a decrease of 6 p.p in the market share of branded generics and a 4 p.p increase in the market share of unbranded generics.

Finally, we estimate the effects of the policy on total sales. Estimating the effect on sales allows us to disentangle changes in market shares of different types of drugs from changes in the size of the outside option. We are particularly interested in evaluating whether the substantial drug exit induced substitution towards stayers, or if it increased the share of the outside option. In theory, stronger quality regulation can either increase or decrease the share of the outside option. However, an increase in the perceived quality of generics could induce individuals choosing the outside option to purchase generics. Moreover, there are endogenous price effects caused by changes in the market structure and the extent of vertical differentiation.

Table 7-II-A displays estimates of equation (3) using sales volume as the outcome of interest. Overall, we estimate that drug sales decreased as a result of the regulation. Whereas point estimates are negative and large in magnitude, we find no statistically significant effect on sales of innovator drugs and unbranded generics across all markets. However, we estimate a large decrease in sales of branded generics by 37%. Overall, these results indicate that stronger quality regulation generated substitution towards the outside option.

In Table 7-II-B, we study heterogeneous policy effects across large and small markets. We find that decreases in sales are concentrated in small markets. In particular, we estimate that

[44] As previously explained, we are unable to separate unbranded generics between bioequivalents and non-bioequivalents due to limitations of the IMS Health data.

sales decreased by 29% across all drugs as opposed to a smaller and non-statistically significant decrease in sales in large markets of 9%. The overall decrease in sales in small markets is driven by decreases in sales of both branded and unbranded generics. This result is consistent with our results showing substantial exit and reduced competition in small markets. In contrast, we estimate that in large markets there is a large but not statistically significant decrease in sales of branded generics, whereas there is an increase in sales of unbranded generics of 60%.

6.5 Effects of Quality Regulation on Drug Quality

Imposing bioequivalence requirements as a minimum quality standard was successful in inducing generics willing to stay or enter the market to obtain bioequivalence certification. However, we have documented that stronger quality regulation affected market structure.

Theoretically, we expect the rate of bioequivalence certification to be higher in larger markets even if the underlying drug quality is constant across markets of different size, as shown in our model of Section 3. The compliance cost associated with the regulation acts as a fixed entry cost that only firms expecting to earn profits large enough are willing to incur, as predicted by standard entry models (e.g., Bresnahan and Reiss 1991). Therefore, the regulation compliance cost induces the exit of drugs of high quality but low revenue, with potentially adverse welfare consequences. Alternatively, the underlying drug quality prevailing before the policy change could have varied across markets of different size. When product quality is endogenous and produced with fixed costs, larger markets can sustain higher quality levels (Berry and Waldfogel, 2010). In that context, market revenue and underlying product quality are positively correlated; therefore, a higher exit in low-revenue markets may imply that the average quality in the market increased after the reform.

In this section, we study whether the bioequivalence regulation had any measurable effects on improving the quality of drugs present in the market. Finding no quality effects would be consistent with a situation where the higher exit within low-revenue markets had negative welfare consequences. Whereas direct measures of quality (e.g., results from laboratory drug testing) are not available in our setting, we use the frequency of product recalls as an indirect measure of the overall manufacturing and therapeutic quality of the drugs available in the market. We collected data on the 266 recalls that occurred between January 2010 and December 2017. Recalls are implemented by ISP upon notice of adverse events associated with a licensed drug that justify recall as a preventative sanitary measure.[45]

Figure 7 shows the monthly recall frequency during our sample period, split into drugs subject to bioequivalence requirements (and included in our sample), and drugs without bioequivalence requirement. In the period, there is an average of 1.9 recalls per month, corresponding to 1.4 (0.5) from active ingredients without (with) bioequivalence requirement. As a first test for quality effects,

[45] Reasons for these recalls can be categorized broadly into: quality (26%), manufacturing defects (23%), manufacturing accidents (21%), labeling (19%) and contamination (9%). Due to the small number of recall events, we use all data irrespective of the specific reason.

we cannot reject the null hypothesis of a same trend in recalls over time across these two groups.[46]

We next turn to our main estimation sample and test whether our treatment variable T_{mt} explains recall rates over time. Specifically, we run a conditional fixed-effect negative binomial model including fixed effects for active ingredients. Formally, we model the mean recall rate as:

$$\mu_{mt} = N_{mt} \exp(\theta_m + \gamma T_{mt}) \tag{6}$$

where T_{mt} is the policy intensity variable defined in Section 6.1, θ_m is a set of market fixed effects and N_{mt} is the total number of drugs in the market, which serves as the exposure measure. Our coefficient of interest, γ, measures the change in the recall rate after the bioequivalence requirement for market m is fully implemented. We estimate $\hat{\gamma} = 0.05(0.40)$, which reinforces our result of no statistically significant evidence for changes in recall rates due to the reform. Although these findings are suggestive of the absence of effects on product recalls, we do not claim this is conclusive evidence for an absence of overall effects of the policy we study on drug quality.

6.6 Discussion

We provide evidence for the equilibrium effects of quality regulation and interpret it using our model in Section 3. Our estimates imply that stronger quality regulation had sizable effects. We start by showing that stronger quality regulation induced drugs to exit the market. Drug exit combines reductions in the portfolio of drugs offered by laboratories within a market with exit of laboratories. Whereas one could have expected stronger quality regulation to reduce vertical differentiation and increase the intensity of price competition, our estimates suggest that the negative effect through market structure overturned those positive competitive effects. We find that drug prices increased as a result of the policy. Furthermore, we find no evidence of an increase in the market share of generics, which was one of the main motives behind the policy. Finally, we provide suggestive evidence that drug quality did not improve, at least as measured by drug recalls.

Most of the adverse effects from stronger quality regulation are concentrated among small markets. This pattern of heterogeneity suggests that laboratories decide to exit the market whenever the fixed cost of regulation compliance is large enough relative to the profitability of the market, as predicted by our model. In particular, our estimates for small markets follow the model predictions for changes in equilibrium under costly compliance (a shift from **a** to **c** in Figure 1), whereas our estimates for large markets are consistent with the model predictions under free compliance (a shift from **a** to **b** in Figure 1).

It is important to stress that the overall welfare effects of quality regulations are theoretically ambiguous and, in particular, that lower compliance costs make the policy more likely to yield

[46] We test the null hypothesis of no differential trends by fitting a negative binomial model for the recall rates on an indicator of having a requirement, and its interaction with a time trend. We find that the interaction term is not significantly different than zero.

increases in welfare. On the demand side, a higher willingness-to-pay for quality tends to both increase the likelihood of high-quality generics to enter the market and increase the impact on consumer surplus from higher average quality in the market. We formalize these arguments and provide an illustration of them in Appendix A.1.2.

In the next section, we explore complementary explanations for our results. We use consumer survey data to document the existence of demand-side frictions that are likely to limit the welfare-enhancing mechanisms of quality regulation.

7 Complementary Evidence from Consumer Surveys

Our findings show that quality regulation had unexpected adverse effects. Whereas its goal was to increase price competition by reducing quality differentiation, we find that drug exit due to compliance costs reduced competition and led to price increases. There are several potential explanations for why stronger quality regulation had these adverse effects. For instance, consumers may not update their perceived quality of generics accordingly. Large biases against generics reduce incentives for bioequivalence certification and, in turn, reduce the scope for the intended competitive effects of the policy. Part of those biases could be related to a lack of understanding of what bioequivalence means. Moreover, consumers may understate the (often large) price differences between innovators and generics, reducing search. Finally, physicians may limit the extent to which bioequivalence affects consumer choices through prescribing innovators or branded generics.

We collect survey data on consumers to assess different aspects of their purchase behavior, including attitudes towards generics, their understanding and familiarity with bioequivalence, as well as the role of physicians in influencing their purchase decisions. We conducted in-person surveys to frequent consumers of drugs who were recruited outside pharmacies after a drug purchase. To collect perceptions, we focus on Atorvastatin, a common anti-cholesterol drug with a large market presence in Chile. We asked consumers for their quality and price perceptions for different drugs representing the different drug types, namely the innovator drug (Lipitor, by Pfizer), a bioequivalent branded generic (Lipoten, by Pharmavita) and bioequivalent and non-bioquivalent unbranded generics (Atorvastatina, by Mintlab). For more details about the survey design and methodology, see Appendix A.3. We collected surveys from $N = 401$ consumers, of which 58% reported having a household member with a chronic disease, and 34% reported purchasing Atorvastatin for a household member. Table A.5 provides summary statistics for the main variables in the survey.

7.1 Main Results

Knowledge About Bioequivalence. There is substantial heterogeneity in knowledge about bioequivalence among consumers in our sample, despite the fact that 84% of consumers are familiar

with the label attached to bioequivalent drugs. Figure 8-a shows that almost 30% of consumers are not familiar at all with bioequivalence and 55% is not able to provide a good definition for it.Limited knowledge about bioequivalence might reduce the extent to which bioequivalence effectively signals drug quality and induce consumers to switch from innovator or branded generic drugs to cheaper bioequivalent unbranded generics.

Perceived Quality Differences. Consumers display substantial variation in their perceived quality of drugs in the market. We collect data on the perceived quality for each drug on a 1-7 scale. We define the perceived quality premium as the difference between the perceived quality of the innovator drug and that of another drug type. Figure 8-b displays the distribution of perceived quality premiums relative to the innovator. As expected, consumers perceive that the innovator drug is of higher quality than branded and unbranded generics. Branded generics are perceived to have a slightly better quality than unbranded generics. Additionally, consumers perceive that bioequivalent drugs are of higher quality than non-bioequivalent drugs. Therefore, consumers attribute a quality premium to bioequivalence, although not large enough as to close the quality premium attributed to innovators. This might be partly due to a poor understanding of what bioequivalence means. We explore this possibility in Figure 8-c, which shows that for all drug types, the quality premiums attached to innovators are weakly lower for consumers with high knowledge about bioequivalence than for consumers with low knowledge about it, which is consistent with Bronnenberg et al. (2015).[47] This pattern is particularly strong for bioequivalent unbranded generics.

Perceived Price Premiums. To complement these facts about perceived quality, we collect data on perceived price differences. An additional explanation for our findings is that consumers underestimate the price differences between drug types. This demand-side friction would decrease substitution towards generics and limit incentives for laboratories to stay or enter the market under stronger quality regulation. Figure 8-d displays perceived price premiums of the innovator drug relative to other drug types.[48] Consumers perceive that prices of generics are substantially lower than those of innovator drugs. On average, consumers perceive that branded generics, bioequivalent unbranded generics and non-bioequivalent unbranded generics have discounts of 49%, 68%, and 75% relative to the innovator, respectively. Moreover, a large share of the consumers identify discounts of unbranded generics between 90% and 100%. Whereas perceived price differences are lower than actual price differences, these patterns suggest that consumers are to a large extent aware of differences in market prices across drug types.

[47] We classify consumers with none or low knowledge about bioequivalence as uninformed and those with medium, high or excellent knowledge about bioequivalence as informed consumers.

[48] The actual price of the innovator drug we consider is around \$50,000 CLP, whereas the prices of the branded and unbranded generics are around \$10,000 CLP and \$2,500, respectively (\$77.5, \$15.5 and \$7.8 U.S. dollars, respectively). Actual discounts are therefore in the order of 80% and 95%, respectively.

The Role of Physicians. Prescription behavior by physicians plays a key role in drug purchase behavior and generic penetration (Dickstein, 2015). This has motivated policies of *generic substitution* in different countries, so as to limit the extent to which physicians prescribing expensive named drugs may limit generic penetration. We gather information regarding consumer experiences with prescription behavior of physicians. We find that 65% of consumers answer that physicians often prescribe drugs by the name instead of the active ingredient. However, consumers display some degree of willingness to deviate from physicians' recommendations. Conditional on a physician prescription, only 15% of consumers state they purchase the prescribed named drug *always and regardless of drug prices*, whereas 52% state that they deviate from the brand prescribed by the physician whenever there is a large enough price difference. Finally, 34% of respondents state that they shop only on price, disregarding the brand recommended by their physician.

7.2 Discussion

We employ a consumer survey to explore potential explanations for the unintended consequences of stronger quality regulation that we document in our main analysis. We show that, after almost 10 years since the beginning of the reform to quality regulation, a large share of consumers has none or an imprecise understanding of what bioequivalence means. In terms of the model in Section 3, this evidence implies that $\overline{\psi} < \psi_1$.[49] Additionally, we find that perceived quality premiums are lower for consumers with a higher understanding of bioequivalence. This evidence is related to research on how biases against generics limit generic penetration (Bronnenberg et al., 2015; Colgan et al., 2015; Bairoliya et al., 2017). Moreover, it suggests that information policies might be complementary to quality regulation by inducing consumers to update their perception about perceived generic quality in accordance with the regulation.

Additionally, our survey highlights two additional barriers for generic penetration. On the one hand, whereas consumers are aware about the existence of price differences across different drug types, they underestimate them. On the other hand, consumers argue that physicians most often prescribe brand-named drugs, which limits the extent to which consumers choose generics. The fact that consumers mention they are willing to disregard physicians' recommendations whenever price differences are large enough limits, but do not eliminate, the effect of physician behavior on generic penetration. These are two additional barriers for generic penetration.

Overall, the results of the survey point towards the existence of barriers to generic penetration in our setting. These frictions undermine the ability of the regulation to effectively shift consumers towards generics that have proven to be bioequivalent. These barriers, in turn, reduce the profitabil-

[49] This survey does not allow the direct measurement of the perceived quality of generics before the reform, and thus the estimation of changes in the perceived quality of generics due to it. Making a strong assumption on the evolution of perceived quality, one could argue that the policy influenced the perceived quality by comparing the perceived quality of bioequivalent and non-bioequivalent unbranded generics: the perceived quality premium of bioequivalent unbranded generics is 60% lower than that of non-bioequivalent unbranded generics, which suggests the policy did affect perceived quality.

ity of generic manufacturers to entering or remaining in the market, relative to the fixed regulation compliance cost. This is consistent with the finding in our main analysis, where we documented a reduction in the number of drugs in the market and an increase in drug prices as a result of stronger quality regulation, particularly for small markets.

8 Conclusion

Quality regulation in markets with asymmetric information may ensure product quality, change consumer perceptions of product quality and foster price competition by reducing vertical differentiation. However, costly compliance with these regulations may also have unintended adverse consequences on market structure by inducing product exit and, thereby, harm price competition.

We study a reform to bioequivalence requirements in the Chilean pharmaceutical market. Our findings suggest that quality regulation may have unintended competitive effects. Contrary to the motivation of reducing prices through increased competition, we find that average paid prices increased, and that the market share of generics did not increase. These effects are concentrated among low-revenue markets, where we also find sizable drug exit. We employ an equilibrium model of competition in pharmaceutical markets to interpret these findings. We argue that fixed compliance costs imposed by stronger quality regulation induced exit, which, in turn, decreased the intensity of price competition.

Stronger quality regulation can generate desirable competitive effects, and our analysis provides lessons for the design of a quality regulation to achieve them. Through the lens of our model, we find that the main driver of the unintended consequences we find are regulation compliance costs. Inefficiencies caused by compliance costs point towards the desirability of subsidizing certification costs, which may limit drug exit from the market and, therefore, prevent decreases in the intensity of price competition. Additionally, the competitive effects of quality regulations depend crucially on how they affect demand, and pharmaceutical markets impose particular challenges in this regard. First, demand reactions are limited by prescribing behavior of physicians, whose incentives may differ from those of their patients (Dickstein, 2015). Second, attitudes towards generics may only change slowly over time as consumers learn about their quality (Bairoliya et al., 2017). Unexperienced consumers may have long-lasting biases against generics; therefore, quality regulation may not achieve its desired effects in the short run. Consumer survey data we gathered from the Chilean market confirms the presence of these lasting biases and frictions, and points towards the need of complementary policies to achieve the desired competitive effects of minimum quality standards.

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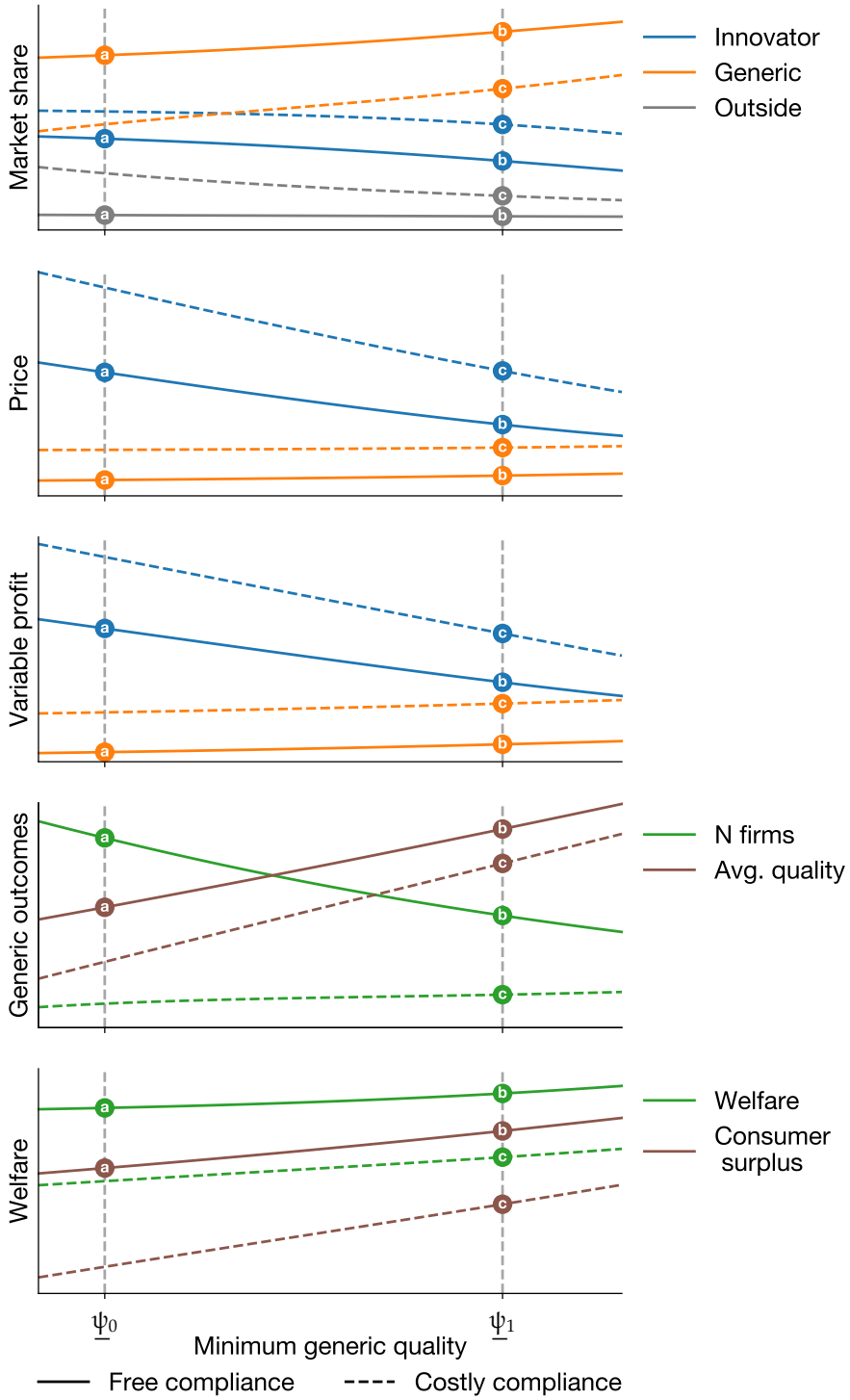
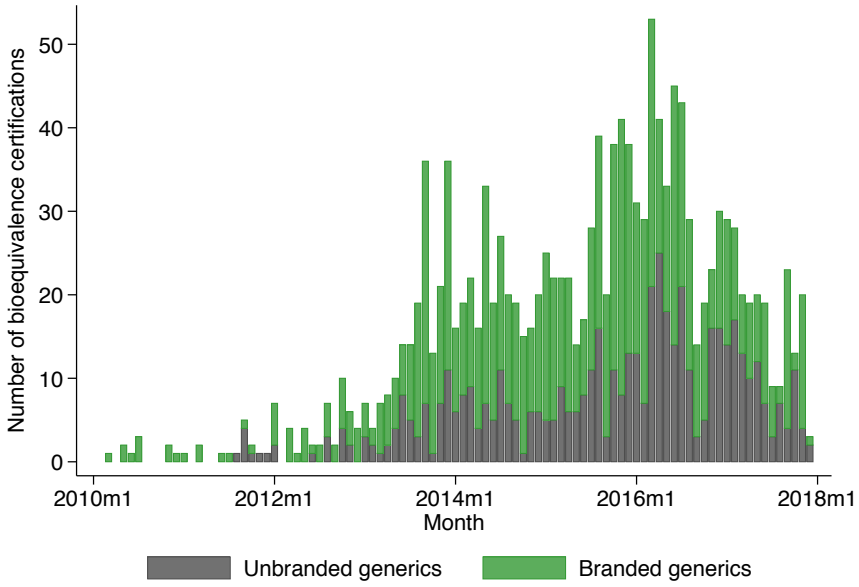
Figure 1: Effects of Quality Regulation: With and without Costly Compliance/Certification

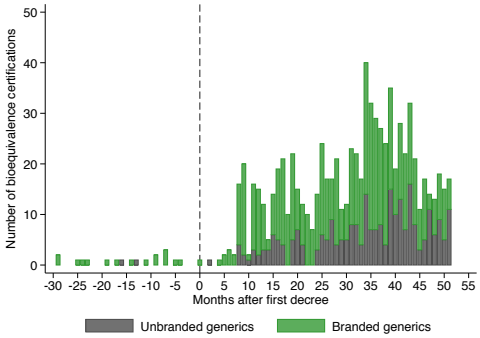


Notes: Market outcomes for different levels of minimum quality in the market. The dashed (solid) lines represent a situation with (no) compliance costs. Example minimum qualities before and after regulation are indicated by $\underline{\psi}_0$ and $\underline{\psi}_1$, where points **a** indicate pre-reform outcomes, **b** indicates post-reform outcomes if compliance was free, while **c** indicates post-reform outcomes with costly compliance. Simulation details are provided in Appendix A.1.

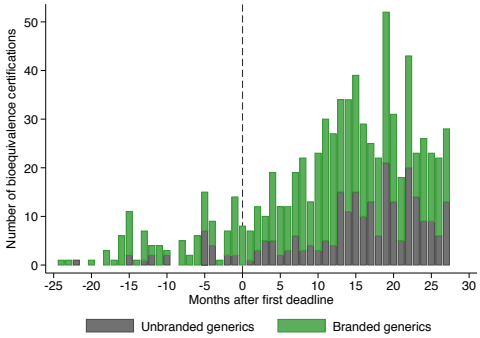
Figure 2: Bioequivalence Approvals around Policy Events



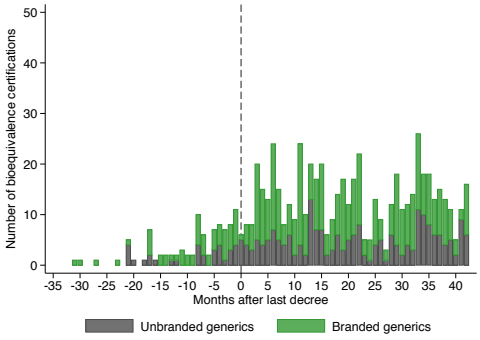
(a) Approvals over time



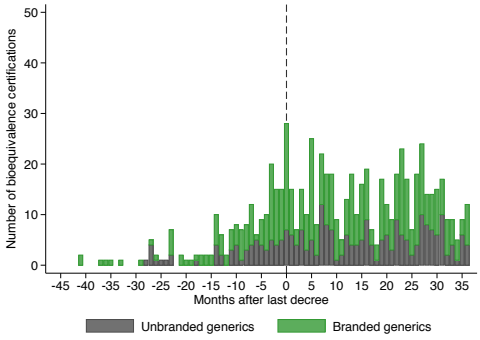
(b) Approvals around first decree



(c) Approvals around first deadline



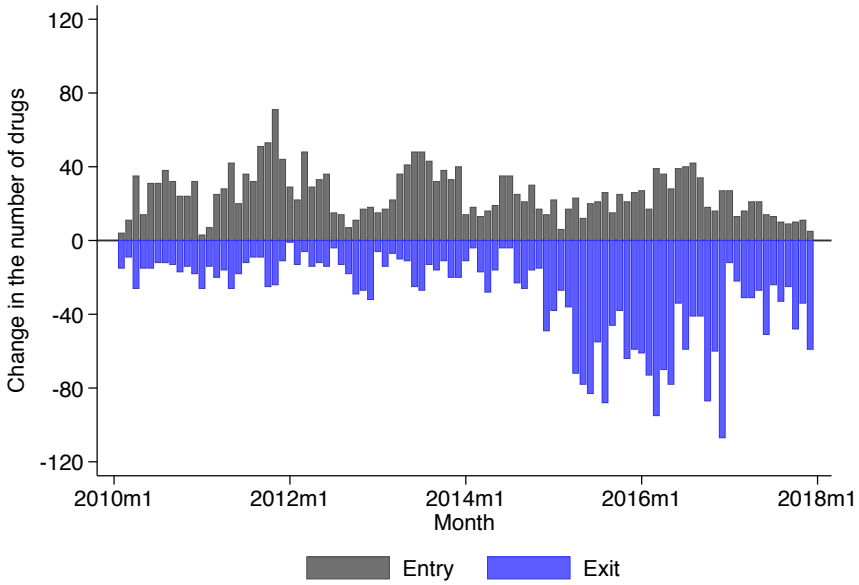
(d) Approvals around to last decree



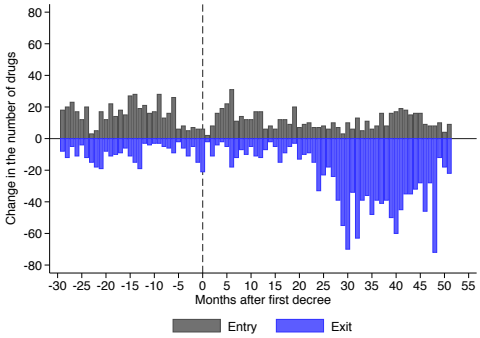
(e) Approvals around to last deadline

Notes: Panel (a) in this figure displays the evolution of the number of drugs with bioequivalence approval over time, split by unbranded generics (gray) and branded generics (green). Panels (b) through (e) display the number of bioequivalence approvals around bioequivalence decrees and deadlines.

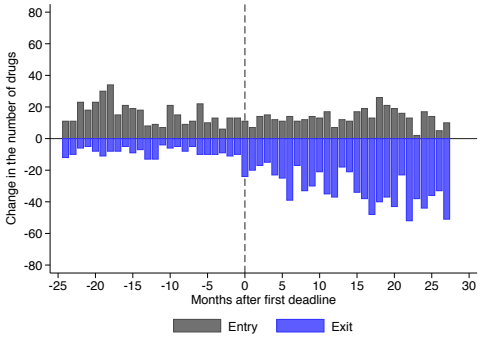
Figure 3: Number of Entry and Exit of Drugs around Policy Events



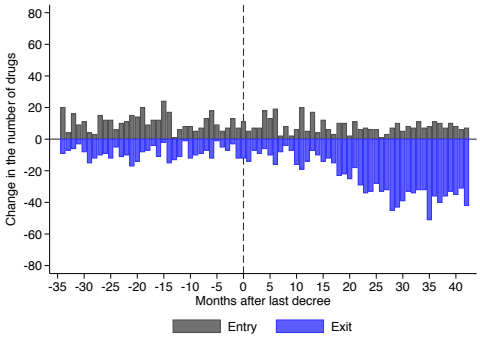
(a) Entry and exit over time



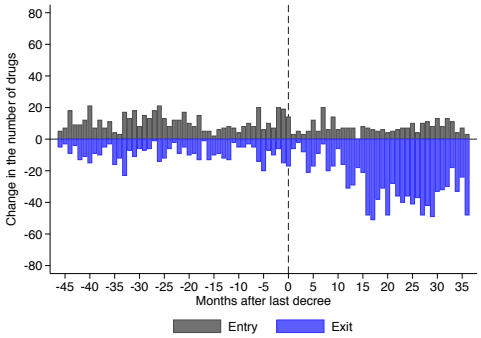
(b) Relative to first decree



(c) Relative to first deadline



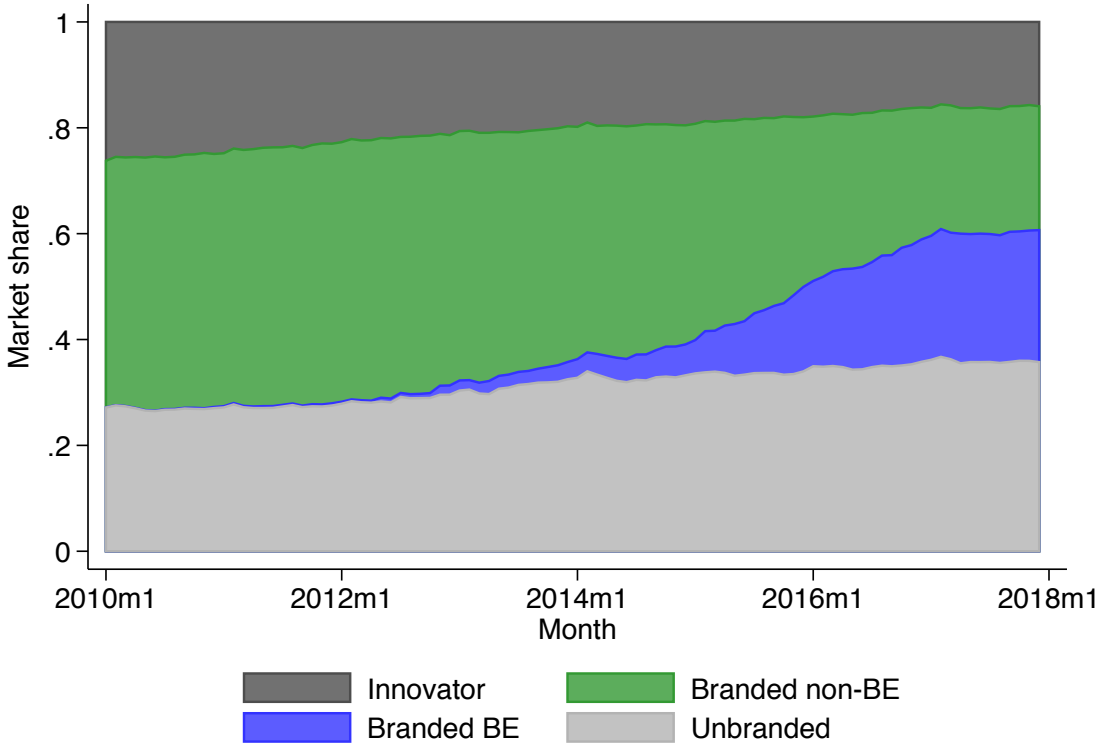
(d) Relative to last decree



(e) Relative to last deadline

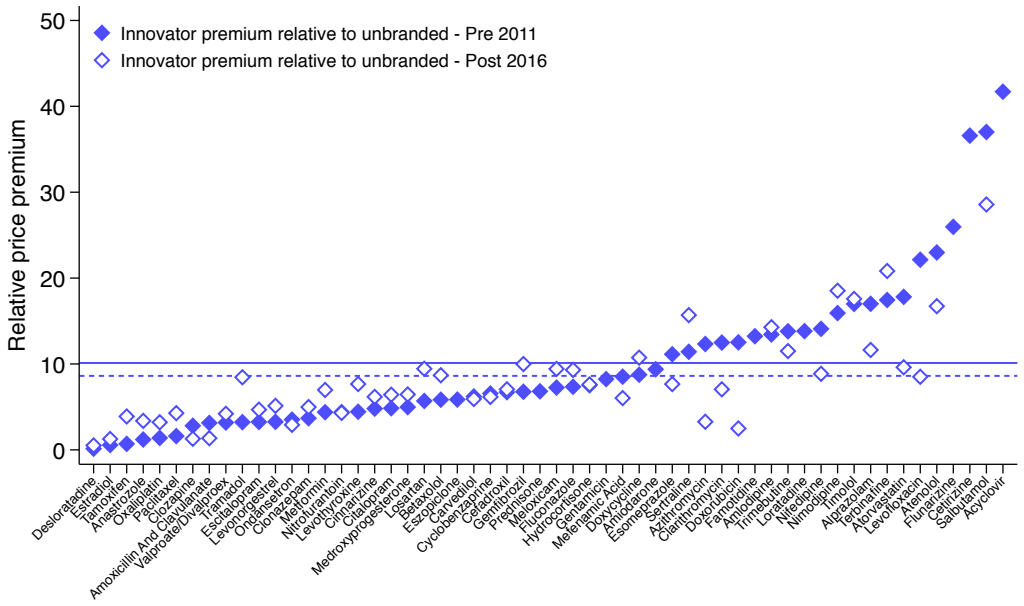
Notes: This figure displays the number of entering (gray) and exiting (blue) drugs around bioequivalence decrees and deadlines. The vertical axis displays the count of such events. Panel (a) display the evolution of entry and exit of drugs over time, while panels (b) through (e) display the evolution of entry and exit relative to bioequivalence decrees and deadline.

Figure 4: Market Shares by Drug Type

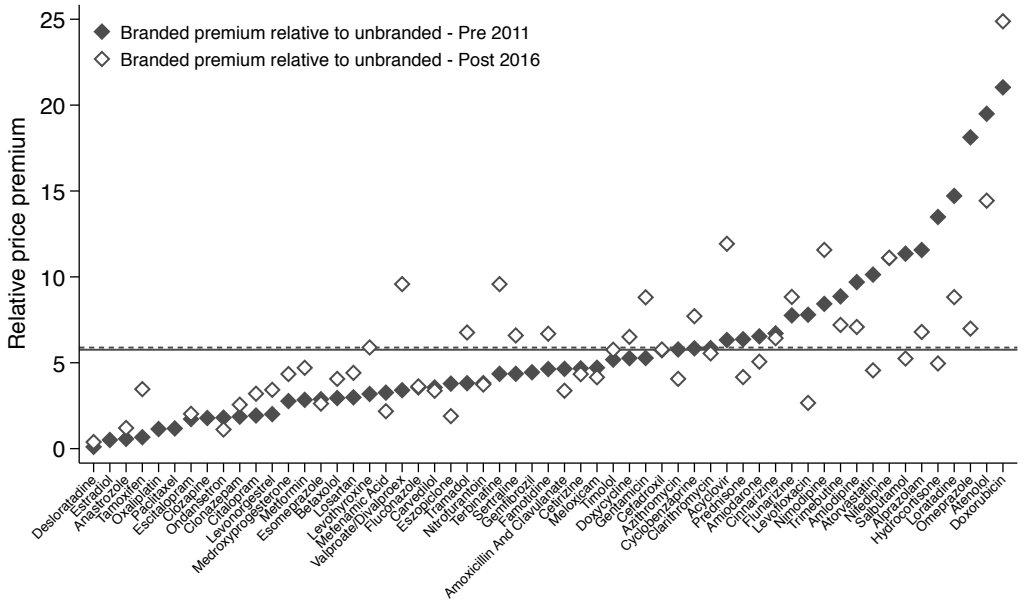


Notes: This figure displays the evolution of market shares of different drug types over time. For each type, we plot the average market share across markets for each month in our sample.

Figure 5: Innovator and Branded Drugs Price Premiums by Market



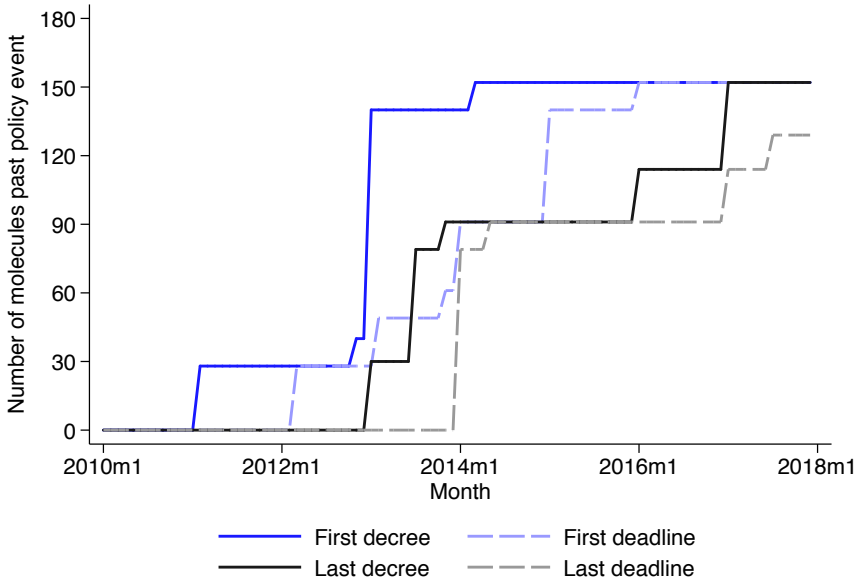
(a) Innovator drugs price premiums relative to unbranded generics



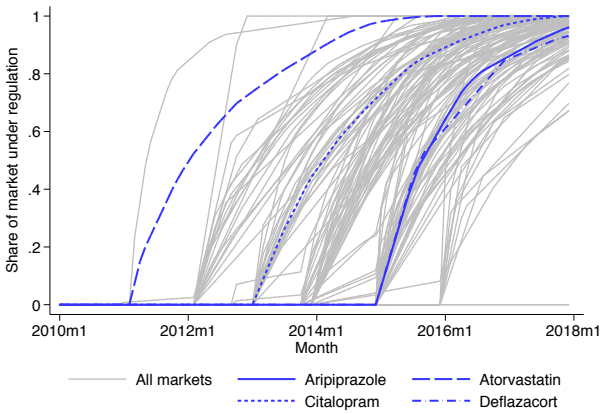
(b) Branded drugs price premiums relative to unbranded generics

Notes: This figure displays 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 and 2016-2017 for the pre and post periods respectively. The sample of markets is that with price information for at least one innovator, one branded and one unbranded drug during that period. Solid and dashed lines indicate the average price premium across this set of molecules for the pre and post period respectively.

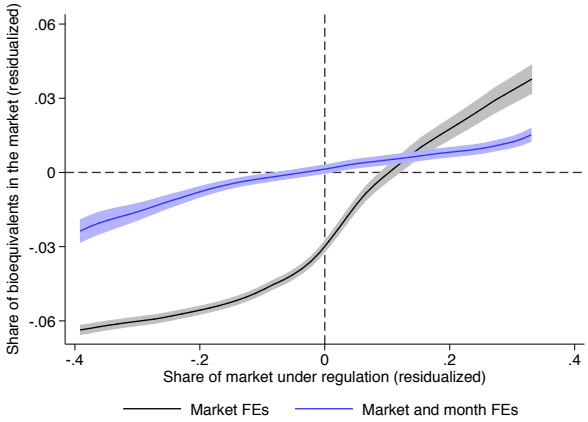
Figure 6: Evolution of Quality Regulation



(a) Timing of bioequivalence decrees and deadlines



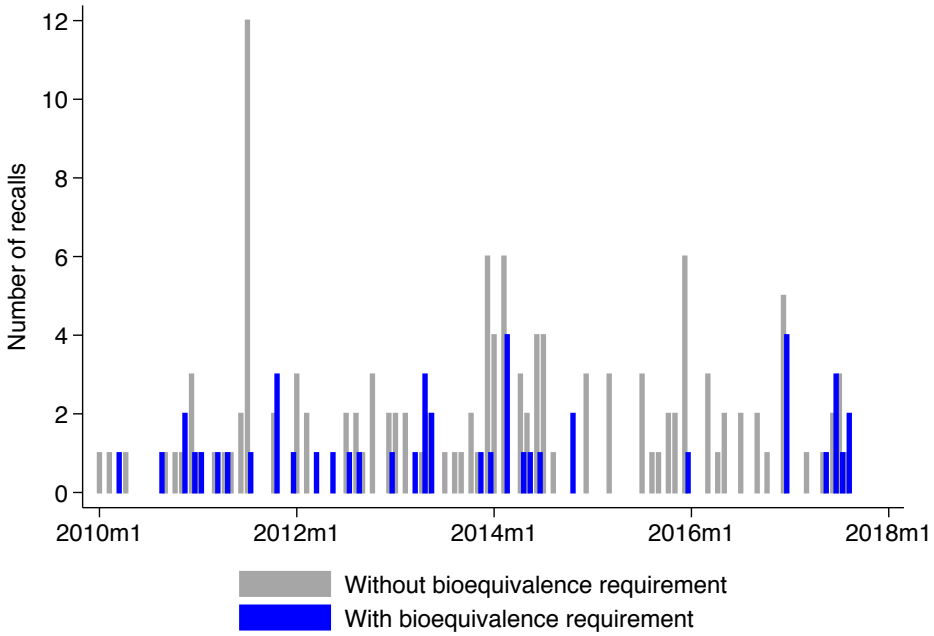
(b) Evolution of quality regulation by market



(c) Quality regulation and share of bioequivalent drugs

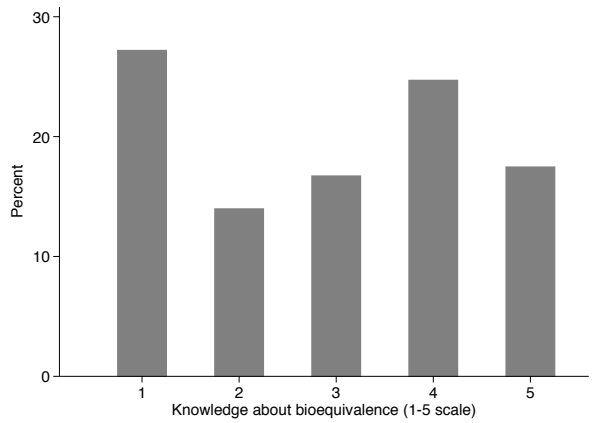
Notes: Panel (a) in this figure displays the number of markets affected by different policy events associated to bioequivalence regulation, from the first decree to the last deadline. Panel (b) displays the evolution over time of the treatment variable defined in equation (2) for each market in the sample. This version of the treatment variable uses the first deadline as the relevant date. We highlight some particular examples in blue, which are displayed in more detail in Figure A.2. Panel (c) displays the non-parametric relationship between the residualized policy intensity variable and share of bioequivalent drugs in the market, controlling for market fixed effects (gray) and market and month fixed effects (blue) over the range of variation of the latter. The bottom and top centiles of the data are not included in the plot.

Figure 7: Number of Recalls per Month

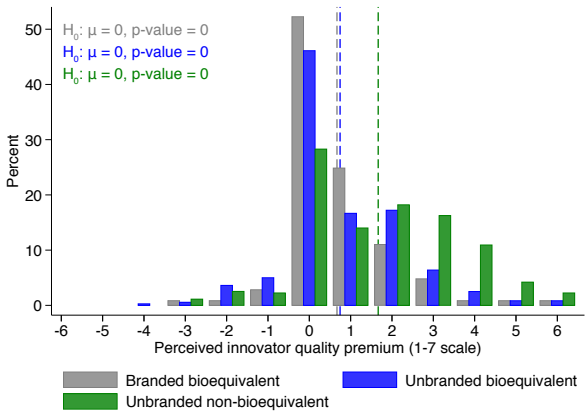


Notes: The figure shows the number of product recalls over time split into markets with bioequivalence requirements and markets without bioequivalence requirements.

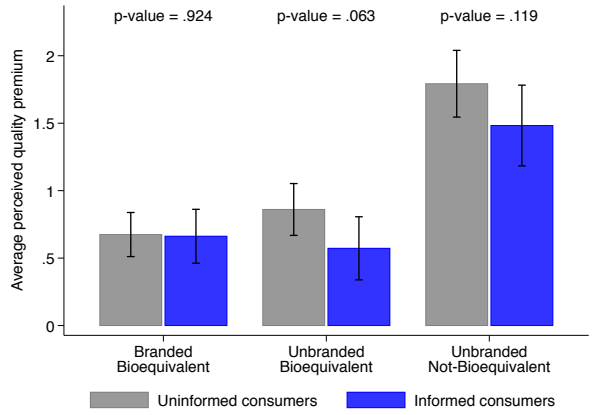
Figure 8: Survey Results



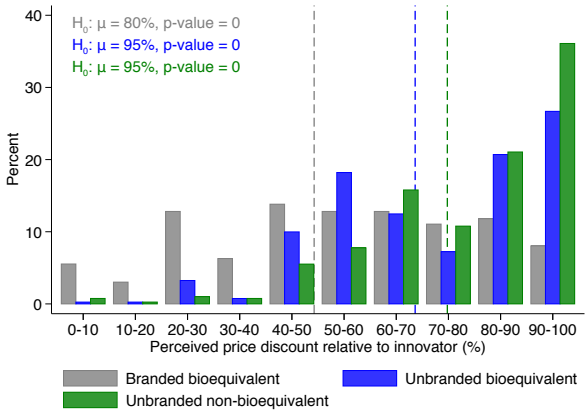
(a) Knowledge about bioequivalence



(b) Perceived quality premium



(c) Knowledge and perceived quality



(d) Perceived price premium

Notes: Panel (a) displays the distribution of consumer knowledge about bioequivalence in a 1-5 scale, where 1 means the consumer is not familiar with bioequivalence at all, and 5 means the consumers is able to provide a good definition of what it is. Panel (b) displays the distribution of perceived quality premiums for different drug types relative to the innovator drug. The premium is calculated as the difference between the perceived quality of the innovator drug and the perceived quality for each drug type, where premium is recorded in a 1-7 scale. Panel (c) displays average quality premium for each drug type across uninformed and informed consumers, where the former are those with knowledge between 1 and 2 in panel (a), and the latter are those with knowledge between 3 and 5 in it. The figure displays 95% confidence intervals for each mean, as well as p-values from a two-sided test of equality between average perceived quality premiums of uninformed and informed consumers. Finally, panel (d) displays the distribution of perceived price discounts of each drug type relative to the innovator drug. Dashed lines in panels (b) and (d) indicate the average for each drug type in the figure.

Table 1: Timing of Reform: Policy Variables and Descriptive Statistics

		Panel A: Relevant policy dates				*Panel 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	4	2011-01	2011-02	2013-06	2013-12	67	101	29,190	0.26	0.63	0.10
2	20	2011-01	2012-02	2013-06	2013-12	193	562	29,900	0.31	0.55	0.14
3	11	2012-10	2013-10	2013-10	2014-04	91	485	19,650	0.17	0.58	0.25
4	25	2012-12	2013-12	2012-12	2013-12	378	302	20,607	0.24	0.66	0.10
5	20	2012-12	2013-01	2013-06	2013-12	354	218	23,754	0.22	0.74	0.04
6	10	2012-12	2014-12	2015-12	2016-12	108	1,280	29,255	0.24	0.76	0.00
7	15	2012-12	2014-12	2016-12	2017-06	227	390	21,407	0.26	0.71	0.03
8	16	2012-12	2014-12	2016-12	2017-12	133	672	18,165	0.25	0.64	0.10
9	10	2014-02	2015-12	2016-12	2017-12	28	10	8,414	0.04	0.33	0.63

Notes: Panel A in this table displays the dates of announcement and deadlines of BE requirements for different groups of molecules. The groups are defined as a unique combination of decrees and deadlines. Panel B in this table displays average product characteristics in 2011, by groups of molecules. The group NA corresponds to molecules without BE approval. Prices per gram and revenues are measured in 2013 U.S. dollars.

Table 2: Descriptive Statistics for IMS Data

Variable	N	Mean	SD	p10	p50	p90
Panel A: Price per gram						
All drugs	144,106	461.1	4,183.2	2.3	36.0	583.3
Innovators	33,251	900.2	3,886.7	4.3	73.7	1,868.0
Branded generics	96,909	365.8	4,552.7	3.1	36.9	391.9
Unbranded generics	13,946	76.1	327.3	0.4	3.0	130.3
Bioequivalents	17,455	164.3	594.4	2.2	22.6	278.6
Panel B: Market shares						
Innovators	12,576	0.30	0.30	0.00	0.22	0.80
Branded generics	12,576	0.43	0.34	0.00	0.44	0.89
Unbranded generics	12,576	0.27	0.36	0.00	0.04	0.99
Bioequivalents	12,576	0.07	0.16	0.00	0.00	0.29
Panel C: Number of drugs						
All drugs	12,576	12.56	11.30	2.00	9.00	29.00
Innovators	12,576	2.92	2.61	0.00	2.00	6.00
Branded generics	12,576	8.44	9.57	0.00	5.00	23.00
Unbranded generics	12,576	1.20	1.38	0.00	1.00	3.00
Bioequivalents	12,576	1.46	3.88	0.00	0.00	5.00
Panel D: Number of laboratories						
All drugs	12,576	4.77	3.25	1.00	4.00	10.00
Innovators	12,576	0.82	0.50	0.00	1.00	1.00
Branded generics	12,576	3.38	3.05	0.00	2.00	8.00
Unbranded generics	12,576	0.57	1.36	0.00	0.00	2.00

Notes: This table displays descriptive statistics from the IMS data. Statistics for prices are displayed in 2013 U.S. dollars and calculated at the drug level, while the remainder are calculated at the market level. Market shares are only observed for markets in which at least one drug is sold in the period. Statistics for the number of drugs and laboratories are computed using only observations for which the drug or laboratory is found to be active in the corresponding market.

Table 3: Hazard Model for Bioequivalence and Exit

	(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)	(9)	(10)
	Panel A: Bioequivalence approval hazard					*Panel B: Exit hazard*				
After first decree	2.52***				1.29**	0.16				-0.05
	(0.48)				(0.58)	(0.16)				(0.16)
After first deadline		1.78***			1.63***		0.42***			0.41***
		(0.31)			(0.31)		(0.14)			(0.16)
After last decree			-0.11		-0.23			0.17**		0.02
			(0.20)		(0.26)			(0.08)		(0.12)
After last deadline				-0.22	-0.25				0.16*	0.09
				(0.21)	(0.27)				(0.08)	(0.12)
Reference						-0.68***	-0.69***	-0.67***	-0.68***	-0.68***
						(0.14)	(0.14)	(0.14)	(0.14)	(0.14)
Branded	0.08	0.08	0.07	0.07	0.07	-0.36***	-0.35***	-0.35***	-0.35***	-0.35***
	(0.10)	(0.10)	(0.10)	(0.10)	(0.10)	(0.07)	(0.06)	(0.06)	(0.06)	(0.06)
Imported	0.15	0.14	0.17	0.17	0.15	0.52***	0.52***	0.52***	0.52***	0.51***
	(0.13)	(0.12)	(0.13)	(0.13)	(0.12)	(0.07)	(0.07)	(0.07)	(0.07)	(0.07)
log(Market revenue)	0.62***	0.57***	0.65***	0.66***	0.58***	-0.02	-0.03	-0.02	-0.02	-0.03
	(0.14)	(0.13)	(0.14)	(0.14)	(0.13)	(0.03)	(0.03)	(0.03)	(0.03)	(0.03)
log(Number of branded)	-0.30*	-0.28	-0.30*	-0.31*	-0.29*	0.01	0.01	0.01	0.01	0.01
	(0.17)	(0.17)	(0.17)	(0.17)	(0.16)	(0.06)	(0.06)	(0.06)	(0.06)	(0.06)
log(Number of unbranded)	-0.30*	-0.36**	-0.26	-0.24	-0.30*	-0.09	-0.10	-0.11	-0.11	-0.11
	(0.17)	(0.17)	(0.17)	(0.17)	(0.17)	(0.08)	(0.08)	(0.08)	(0.07)	(0.08)
Time FE	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y
Observations	230,971	230,971	230,971	230,971	230,971	288,594	288,594	288,594	288,594	288,594
ln L	-3,420	-3,387	-3,447	-3,446	-3,372	-11,081	-11,073	-11,079	-11,079	-11,071

Notes: This table displays results from hazard models in equation (1) for bioequivalence approval and market exit. Estimation is implemented through maximum likelihood. All specifications include time fixed effects. Standard errors in parentheses are clustered at molecule level. *p<0.10, **p<0.05, ***p<0.01.

Table 4: Effects of Quality Regulation on Market Structure: Number of Drugs

	(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)
	Dep. var.: log(1 + Number of drugs)							
	All	Innovator	Branded generics			Unbranded generics		
			All	BE	Non-BE	All	BE	Non-BE
Panel A: Average effects								
Share of market under regulation	-0.29***	-0.10	-0.30***	0.59***	-0.43***	-0.29***	0.61***	-0.41***
	(0.07)	(0.07)	(0.05)	(0.15)	(0.07)	(0.07)	(0.11)	(0.08)
R^2	0.95	0.94	0.96	0.70	0.96	0.92	0.64	0.92
Panel B: Heterogeneity by baseline market size								
Share of market under regulation × Low revenue	-0.44***	-0.21***	-0.41***	0.20	-0.46***	-0.43***	0.32***	-0.43***
	(0.08)	(0.08)	(0.07)	(0.16)	(0.08)	(0.09)	(0.12)	(0.09)
Share of market under regulation × High revenue	-0.16**	-0.00	-0.20***	0.92***	-0.40***	-0.17**	0.85***	-0.39***
	(0.08)	(0.07)	(0.06)	(0.19)	(0.08)	(0.09)	(0.14)	(0.09)
R^2	0.95	0.95	0.96	0.73	0.96	0.92	0.66	0.92
Pre-regulation average	31.25	3.43	17.36	0.10	17.26	10.45	0.01	10.45
Observations	12,576	12,576	12,576	12,576	12,576	12,576	12,576	12,576
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 regression of the log 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 a low or high revenue according to the average level of the variable 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 5: Effects of Quality Regulation on Market Structure: Number of Laboratories

	(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)
	Dep. var.: log(1 + Number of Laboratories)							
	All	Innovator	Branded generic			Unbranded generic		
			All	BE	Non-BE	All	BE	Non-BE
Panel A: Average effects								
Share of market under regulation	-0.15***	-0.01	-0.13***	0.52***	-0.19***	-0.18***	0.55***	-0.25***
	(0.04)	(0.02)	(0.04)	(0.12)	(0.03)	(0.06)	(0.09)	(0.06)
R^2	0.93	0.96	0.96	0.71	0.96	0.92	0.65	0.92
Panel B: Heterogeneity by baseline market size								
Share of market under regulation × Low revenue	-0.26***	-0.05*	-0.23***	0.21	-0.24***	-0.30***	0.31***	-0.26***
	(0.05)	(0.03)	(0.05)	(0.13)	(0.05)	(0.07)	(0.11)	(0.08)
Share of market under regulation × High revenue	-0.06	0.03**	-0.05	0.79***	-0.14***	-0.09	0.75***	-0.24***
	(0.05)	(0.01)	(0.04)	(0.15)	(0.04)	(0.07)	(0.12)	(0.07)
R^2	0.96	0.99	0.98	0.88	0.98	0.95	0.89	0.90
Pre-regulation average	10.63	0.96	6.85	0.08	6.83	5.64	0.01	5.63
Observations	12,576	12,576	12,576	12,576	12,576	12,576	12,576	12,576
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 regression of the log number of firms that are active in a segment on the policy roll-out variable constructed using the first decree deadline. Panels B provides results by pre-reform revenue. Markets are classified as having a low or high revenue according to the average level of the variable 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 6: Effects of Quality Regulation on Drug Prices

	(1)	(2)	(3)	(4)
	Dep. var.: Drug Price Index ($\hat{P}_{mt}$)			
	All drugs	Innovator	Generic	
			Branded	Unbranded
Panel A: Average effects				
Share of market under regulation	0.099**	0.032	-0.007	0.140***
	(0.049)	(0.030)	(0.055)	(0.048)
R^2	0.99	1.00	0.99	0.99
Panel B: Heterogeneity by baseline market size				
Share of market under regulation × Low revenue	0.260***	0.072*	0.053	0.183***
	(0.075)	(0.037)	(0.066)	(0.059)
Share of market under regulation × High revenue	-0.037	0.008	-0.053	0.089
	(0.050)	(0.037)	(0.059)	(0.062)
R^2	0.992	0.996	0.992	0.995
Panel C: Decomposition of price effects				
Dep. var.: Contribution of changes in prices ($\hat{P}_{PC}$)	0.074***	0.012	0.009	0.129***
	(0.023)	(0.021)	(0.023)	(0.047)
R^2	0.64	0.67	0.62	0.67
Dep. var.: Contribution of changes in market shares ($\hat{P}_{RW}$)	0.006	0.017	0.018	0.004
	(0.034)	(0.044)	(0.034)	(0.009)
R^2	0.47	0.50	0.78	0.45
Dep. var.: Contribution of correlation between market shares and prices ($\hat{P}_{CS}$)	-0.002	0.007	-0.042	0.001
	(0.010)	(0.014)	(0.031)	(0.008)
R^2	0.47	0.53	0.44	0.31
Dep. var.: Contribution of drug entry ($\hat{P}_{E}$)	0.023*	0.035	0.011	0.002
	(0.014)	(0.034)	(0.024)	(0.004)
R^2	0.54	0.49	0.66	0.53
Dep. var.: Contribution of drug exit ($\hat{P}_{X}$)	-0.003	-0.039*	-0.003	0.003**
	(0.003)	(0.020)	(0.007)	(0.001)
R^2	0.27	0.35	0.60	0.23
Observations	12,576	9,634	9,903	6,481
Market FE	Y	Y	Y	Y
Month-Type FE	Y	Y	Y	Y

Notes: Panel A displays regressions of share-weighted logged 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 B provides results by baseline market size. Markets are classified as having a low or high revenue according to their average revenue in 2010 relative to the median revenue across markets in 2010. Panel C displays results for each component of the decomposition of price changes in equation (5). Each coefficient in Panel C comes from a separate regression of the component indicated in the left for the drug type indicated in the top row on the policy roll-out variable constructed using the first decree deadline. Clustered standard errors in parentheses. ***p<0.01, **p<0.05, *p<0.1.

Table 7: Effects of Quality Regulation on Drug Market Shares and Sales

	(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)	(9)	(10)	(11)
	Panel I: Dep. var.: Market share					*Panel II:* Dep. var.: log(1 + Sales)					
	Innovator	Generic				All	Innovator	Generic			
		Branded			Unbranded			Branded			Unbranded
		Total	BE	Non-BE				Total	BE	Non-BE	
Panel A: Average effects											
Share of market under regulation	0.04	-0.04	0.10***	-0.14***	-0.00	-0.23*	-0.11	-0.48*	2.92***	-1.22***	-0.08
	(0.03)	(0.03)	(0.03)	(0.03)	(0.02)	(0.12)	(0.18)	(0.25)	(0.67)	(0.36)	(0.23)
R^2	0.91	0.93	0.53	0.86	0.96	0.97	0.97	0.94	0.64	0.90	0.95
Panel B: Heterogeneity by baseline market size											
Share of market under regulation × Low revenue	0.08**	-0.02	0.04	-0.07	-0.05	–0.37**	-0.17	-0.54**	1.55**	-1.04**	-0.76**
	(0.04)	(0.03)	(0.04)	(0.04)	(0.04)	(0.15)	(0.23)	(0.23)	(0.76)	(0.47)	(0.36)
Share of market under regulation × High revenue	0.02	-0.06*	0.15***	-0.21***	0.04**	-0.12	-0.06	-0.44	4.06***	-1.37***	0.49**
	(0.03)	(0.03)	(0.03)	(0.04)	(0.02)	(0.13)	(0.19)	(0.38)	(0.80)	(0.39)	(0.23)
R^2	0.92	0.93	0.55	0.86	0.96	0.97	0.97	0.94	0.66	0.90	0.95
Pre-regulation average	0.19	0.55	0.00	0.55	0.26	-	-	-	-	-	-
Observations	12,576	12,576	12,576	12,576	12,576	12,576	12,576	12,576	12,576	12,576	12,576
Market FE	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y
Month FE	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y

Notes: Columns (1) through (5) in this table is a regression of the market share of a segment on the policy roll-out variable constructed using the first decree deadline. Columns (6) through (11) display regressions of logged sales of 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 a low or high revenue according to the average level of the variable 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.

A Online Appendix - Not for Publication

A.1 Model Simulation

A.1.1 Specification and Details

In order to simulate the model, we need to specify several of its elements. In this section, we introduce our assumptions. Moreover, we derive several outcomes of interest given those assumptions. In all cases, we focus on the symmetric equilibrium we discuss in the main text, which only depends on the innovator drug price, the common generic price and the number of generic firms, namely $\{p_I, p_G, n_G\}$.

Equilibrium Conditions. Formally, the symmetric equilibrium is defined by the conditions:

$$\begin{aligned}
\tfrac{\partial \pi_I}{\partial p_I}(p_I^*, p_G^*, n_G^*, \overline{\psi}(n_G^*; \underline{\psi})) &= 0, \\
\tfrac{\partial \pi_g}{\partial p_G}(p_I^*, p_G^*, n_G^*, \overline{\psi}(n_G^*; \underline{\psi})) &= 0 \quad \forall g, \text{and} \\
Ms_G(p_I^*, p_G^*, n_G^*, \overline{\psi}(n_G^*; \underline{\psi}))p_G^* &= C_G(\hat{\psi}(n_G^*; \underline{\psi})) + C_{QC}
\end{aligned}$$

where we use the fact that there is a one-to-one relationship between n_G on the one hand and $\hat{\psi}$ and $\overline{\psi}$ on the other, conditional on the minimum quality $\underline{\psi}$. The first two equations are the conditions for a Bertrand-Nash equilibrium for the innovator and generic producers respectively, whereas the third equation is the zero-profit entry condition for the marginal generic entrant.[50]

Demand Side. First, we assume that ε_{iI} and ε_{ig} are drawn i.i.d. from an extreme value type I distribution. Second, we assume that τ_i is drawn i.i.d. from F_τ. In particular, we assume that $\tau_i \sim U[\underline{\tau}, \overline{\tau}]$. Furthermore, we normalize the quality of the innovator drug (ψ_I) to 1. These assumptions imply that market shares take the mixed logit form:

$$\begin{aligned}
s_I &= \int s_I(\tau)\, \mathrm{d}F_\tau(\tau) = \frac{e^{\tau - p_I}}{1 + e^{\tau - p_I} + \sum_{k \in \mathcal{G}} e^{\tau \overline{\psi} - p_g}}\, \mathrm{d}F_\tau(\tau) \\
s_g &= \int s_g(\tau)\, \mathrm{d}F_\tau(\tau) = \int \frac{e^{\tau \overline{\psi} - p_g}}{1 + e^{\tau - p_I} + \sum_{k \in \mathcal{G}} e^{\tau \overline{\psi} - p_k}}\, \mathrm{d}F_\tau(\tau) \quad \forall g
\end{aligned}$$

where $s_I(\tau)$ and $s_g(\tau)$ are choice probabilities conditional on τ, and $\mathcal{G}$ is the set of active generic producers. In particular, for a symmetric equilibrium with generic price as p_G and n_G active generic

[50] Note that we omit the condition for innovator participation. Allowing innovator exit is straightforward, though at the expense of added complexity in the equations describing the equilibrium and the model simulations. Since it is trivial to study when exit happens (lower innovator variable profits increases the likelihood of exit), and the qualitative effect of innovator exit is intuitive (positive effect on generic profits and entry), we exclude this aspect from the exposition.

drugs, the market share of generic drugs is given by:

$$s_G = s_g\Big|_{p_g=p_G \forall k \in \mathcal{G}} = \int \frac{e^{\tau\overline{\psi}-p_G}}{1+e^{\tau-p_I}+n_G e^{\tau\overline{\psi}-p_G}}\,\mathrm{d}F_\tau(\tau)$$

Finally, Given the logit structure of the demand system, consumer surplus for a given set of parameters can be computed as:

$$CS = M\int\left(1+e^{\tau-p_I}+n_G e^{\tau\overline{\psi}-p_G}\right)\mathrm{d}F_\tau(\tau)$$

where M measures market size.

Supply Side. We let the distribution of quality among potential generic producers be given by $\psi_g \sim U[0,1]$, which implies that the quality of the n^{th} potential generic producer is $\frac{n}{N_G}$. Under this assumption, the marginal and average quality in the market (conditional on a minimum quality $\underline{\psi}$) are:

$$\begin{aligned}\hat{\psi}(n_G;\underline{\psi}) &= \frac{n_G}{N_G}+\underline{\psi}\\ \overline{\psi}(n_G;\underline{\psi}) &= E[\psi|\underline{\psi}<\psi<\hat{\psi}] = \frac{1}{2}\frac{n_G}{N_G}+\underline{\psi}\end{aligned}$$

Moreover, we assume that fixed manufacturing costs are given by $C_I = \kappa$ and $C_G(\psi) = \kappa\psi$ for the innovator and generic drugs respectively, where $\kappa \geq 0$ is a parameter governing the sensitivity of fixed costs to drug quality.

In the symmetric equilibrium we discuss, the profit the innovator drug is:

$$\pi_I = p_I s_I - C_I$$

while the profit of all active generic drugs is given by:

$$\begin{aligned}\int \pi_G(n)\,\mathrm{d}n &= \int_0^{n_G}\left[p_G s_G - C_G(\hat{\psi}(n)) - C_{QC}\right]\mathrm{d}n\\ &= n_G(p_G s_G - C_{QC}) - \int_0^{n_G} C_G(\hat{\psi}(n))\,\mathrm{d}n\end{aligned}$$

where total manufacturing fixed costs for generics are $\int_0^{n_G} C_G(\hat{\psi}(n))\,\mathrm{d}n = n_G\kappa\left(\frac{1}{2}\frac{n_G}{N_G}+\underline{\psi}\right) = n_G C_G(\overline{\psi})$ under the assumed functional form and distributions.

Total Welfare. Given this structure and assumptions, total welfare in the market is given by:

$$W = CS + \pi_I + n_G(p_G s_G - C_G(\overline{\psi}) - C_{QC})$$

such that it combines consumer surplus, profits for active producers and the cost of quality certification for generic drug producers.

Parametrization for Simulation The common parameters used when solving the model to produce the results in Figure 1 are listed below:

Parameter	Value
$(\underline{\tau}, \overline{\tau})$	$(0, 9)$
M	3
C_{QC}	0.5
κ	0.4
N_G	20

Finally, the minimum quality standard ($\underline{\psi}$) is set to 0.2 in scenario **a** of Figure 1, and to 0.6 for scenarios **b** and **c**. In **c**, the cost of quality certification is set to 0.5, while in **a** and **b** it is set to 0.

A.1.2 Additional Model Analysis

Relationship between Fixed Costs and Market Size. Consider the equation describing profits of the marginal generic entrant when compliance costs apply ($C_{QC} > 0$),

$$Ms_G p_G - C_G(\hat{\psi}) - C_{QC} = 0.$$

Let us consider how a change in C_{QC} will affect the quality of the marginal generic entrant, $\hat{\psi}$, keeping in mind that the number of active generics can be described as a function of $\hat{\psi}$ (conditional on $\underline{\psi}$). For this exercise, we will keep prices fixed, noting that the change in equilibrium prices will be determined by the change in $\hat{\psi}$. From the equation above, we get

$$\frac{\partial \hat{\psi}}{\partial C_{QC}} = \left[Mp_G \left(\frac{\partial s_G}{\partial n_G} \frac{\partial n_G}{\partial \hat{\psi}} + \frac{\partial s_G}{\partial \overline{\psi}} \frac{\partial \overline{\psi}}{\partial \hat{\psi}} \right) - C'_G(\hat{\psi}) \right]^{-1},$$

such that a higher M leads to a lower response to compliance costs on the quality of the marginal entrant (and thus on total entry) for any given minimum quality standard. It should be pointed out that this is conditional on the size of all other terms in the expression above.

Since one would generally expect markets of larger size to have a different equilibrium, a direct comparison is difficult. However, we consider the case of two markets with all parameters equal,

except M and the addition of a fixed cost term FC, such that the equilibrium is equal,

$$0 = M_0 p_G^* s_G^* - C_G(\hat{\psi}^*) - C_{QC}$$
$$0 = M_1 p_G^* s_G^* - C_G(\hat{\psi}^*) - C_{QC} - FC,$$

where $M_1 > M_0$, implying $FC = (M_1 - M_0) p_G^* s_G^*$. In this case, it is easy to see that the response to changes in the compliance costs will be smaller in the larger market. This situation is illustrated in Figure A.3, where the left panels show the effects for a small market ($M_0 = 2$), while the right panels show the effects for a large market ($M_1 = 6$). Welfare and consumer surplus has been normalized by the market size (a per capita measure). Note that, for each outcome, point **a** coincides between the small and large market, except for variable profits which are less sensible to compare between these scenarios. Horizontal lines are added to indicate the level of post-equilibrium outcomes with costly compliance (points **c**) for the small market.

Quality Regulation with Desirable Competitive Effects. There are several factors in our model that can improve the welfare effect from quality regulation. The most obvious and direct one is lower compliance costs, which yields less exit/more entry on the high-quality margin, thereby both increasing the average quality and strengthening price competition compared to a scenario with higher compliance costs. Another is high overall willingness to pay for quality, which tends to both increase the viability of high-quality entry and increase the impact on (consumer) welfare from higher average quality in the market. This latter situation is illustrated in Figure A.4, where we have set $(\underline{\tau}, \overline{\tau}) = (5, 9)$, which makes consumer surplus increase quicker along the minimum quality (primarily driven by higher average quality).

Furthermore, if $C_G(\psi)$ is relatively flat, this will increase the effect of stronger quality regulation on marginal quality (and thus average quality). Particularly, in markets where there is entry on the high-quality margin, this entry will be larger in markets with a lower $C'_G(\psi)$.

The Role of a Loyal Segment. We consider the effect of allowing brand loyalty above quality differences. In our model, we can add brand loyalty as an extra term ν in u_{iI} for a fraction ϕ of consumers, capturing additional utility from purchasing the innovator drug.[51] The existence of a brand-loyal segment can help rationalize certain price strategies by the innovator, such as increasing the price when competition from generics increases (i.e., the "Generic Paradox"). This situation is illustrated in Figure A.5.

The presence of a loyal segment generally dampens price-responses of the innovator firm, and might make the innovator's price response to stronger quality regulation non-monotonic, as the innovator may decide to set prices targeting either mainly the loyal segment or a larger share of the market.

[51] For simplicity, we let ν be a constant among the brand-loyal consumers.

A.2 Event Study Evidence of Policy Effects

The empirical strategy we propose in Section 6.1 exploits the staggered roll-out of the regulation across molecules as a useful source of identifying variation, which we complement with within market variation in drug license renewal dates. As a complement to estimates of policy effects using that strategy, we implement an event study analysis. The event study serves two purposes: (i) assessing the assumption of parallel trends across groups of molecules treated by the policy at different moments; and (ii) providing transparent visual evidence of the effects of bioequivalence on relevant market outcomes.

We implement an event study by replacing the treatment variable T_{mt} in equation (3) by a set of event-time dummies that capture the policy effect for each month around the policy event. Concretely, we estimate the following variant of equation (3):

$$y_{mt} = \sum_{\tau} \beta_{\tau} D_{mt,\tau} + \theta_m + \delta_t + \varepsilon_{mt}$$

where we have replaced T_{mt} in equation (3) for indicators $D_{mt,\tau}$ of the time period where the policy event occurred exactly τ periods before. Formally, if the policy for market m occurred in period t_{0m}, then:

$$D_{mt,\tau} \equiv \mathbb{1}(t - t_{0m} = \tau).$$

In practice, we consider the first policy deadline as the event that defines t_{0m}. Although decrees were extended, we cannot rule out that extensions were unexpected. This choice allows us to remain agnostic about potential reactions to the announcement of the first decree. We also place the following end-point restrictions:[52]

$$\beta_{\tau} = \begin{cases} \bar{\beta} & \text{if } \tau > 24 \\ \underline{\beta} & \text{if } \tau < -24 \end{cases}$$

Finally, we normalize the coefficient $\beta_{\tau=-1} = 0$. Therefore, all effects are interpreted as relative to the month before the first deadline. Finally, we include the same sets of fixed effects as in equation (3).

Figure A.6 plots estimates with their corresponding 95% cluster-robust confidence intervals. The first row displays results for the number of drugs across drug types. Our estimates show a slight decrease in the number of drugs overall, which seems to be driven by non-bioequivalent generics. As expected from the policy, our estimates show a large increase in the number of bioequivalent generics. The second row displays results for drug prices. We find no clear price effects

[52]Note that for some markets, our data covers as much as seven years of data after the policy event, such that this window will not show effects for all the period after the policy that we observe. Results in Section 6 do consider the full period after the policy implementation that we observe in our data.

overall, though the price of innovator drugs and unbranded generics show signs of increase in the second year after the policy event, while there might be a small decrease in the price of branded generics. Finally, the third row displays the estimated effects on market shares. Our results show substitution from non-bioequivalent to bioequivalent branded generics, while unbranded generics possibly decrease and innovator drugs possibly increase their market shares. We provide a detailed discussion of effects on all these and other margins in our main analysis in Section 6.

Overall, trends in outcomes before the first deadline appear to be well behaved: most of the estimated coefficients are close to zero. This fact is reassuring for using the differential timing of bioequivalence requirements across markets as identifying variation in estimating the effects of quality regulation on market outcomes in our setting.

A.3 Description of Consumer Survey

In order to inform potential explanation for the results from our main analysis, we collect additional survey data in which we interview consumers and gather information on perceived quality, perceived price differences, relationship between physician prescription behavior and consumer choices and some additional characterization variables.

A surveying team composed by 6 members conducted surveys in 4 counties in the city of Santiago, namely Ñuñoa, Providencia, Puente Alto and Santiago. Within such counties, surveyors recruited consumers for the study outside pharmacies, 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 for it.

In order to collect data on perceived quality and price differences, we focus on a particular market, Atorvastatin, a molecule commonly prescribed as a treatment to cholesterol. Within that market, we focus on 4 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 U.S. dollars respectively). Perceived quality and price differences are elicited using a paper sheet that showed the 4 drugs, which is displayed in Figure A.7.

The final sample includes $N = 348$ consumers. Table A.5 provides summary statistics for the main variables in the survey. Among consumers in the sample, 62% report having a household member with a chronic disease, and 36% report purchasing Atorvastatin for a household member. In terms of purchase behavior, 41% often purchases innovator drugs, 21% often purchases branded generics, and the remainder 38% often purchases unbranded generics. The main results of the

survey and their relationship to the results in our main analysis are discussed in Section 7. We code observations in which a consumer answered "I don't know" or "I don't recall" as missing. Finally, the questions regarding physicians' prescription behavior have less observations because they were added to the survey with a lag and are therefore not available for a around a fourth of the sample.

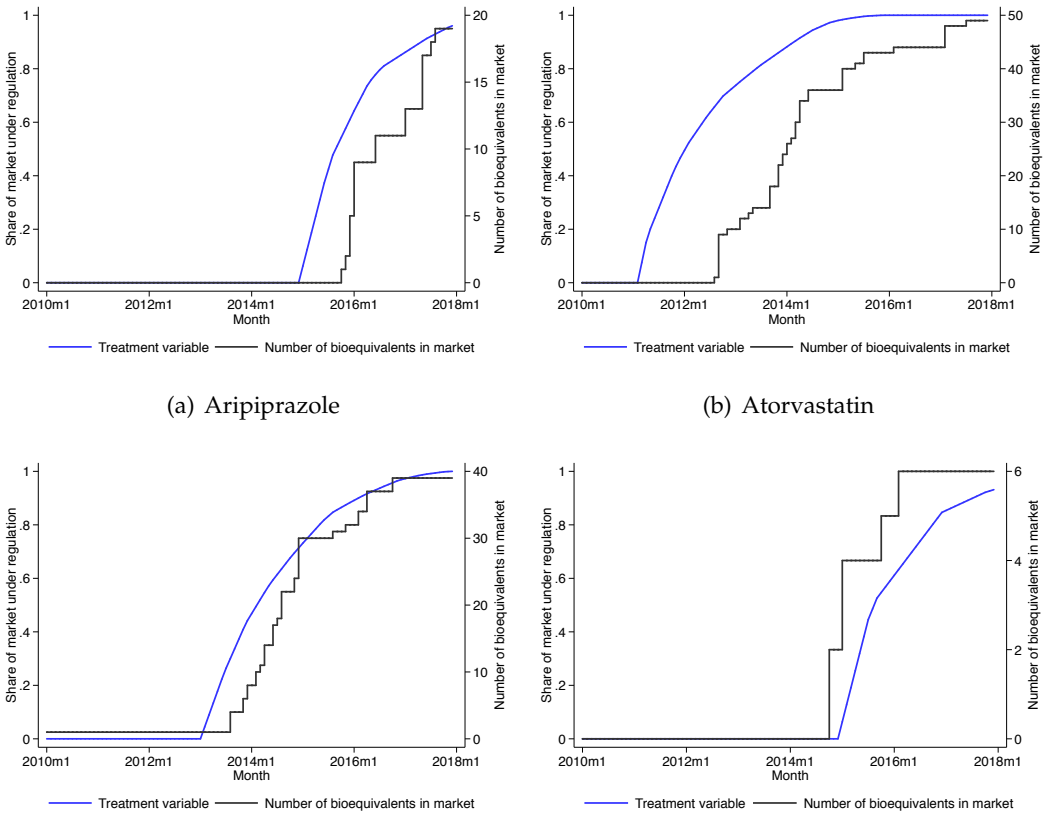
Figure A.1: Labeling of Bioequivalent Drugs

(a) Instructions for bioequivalent drugs labeling

(b) Examples of labeled bioequivalent drugs

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

Figure A.2: Policy Variation induced by Bioequivalence Requirements



(a) Aripiprazole

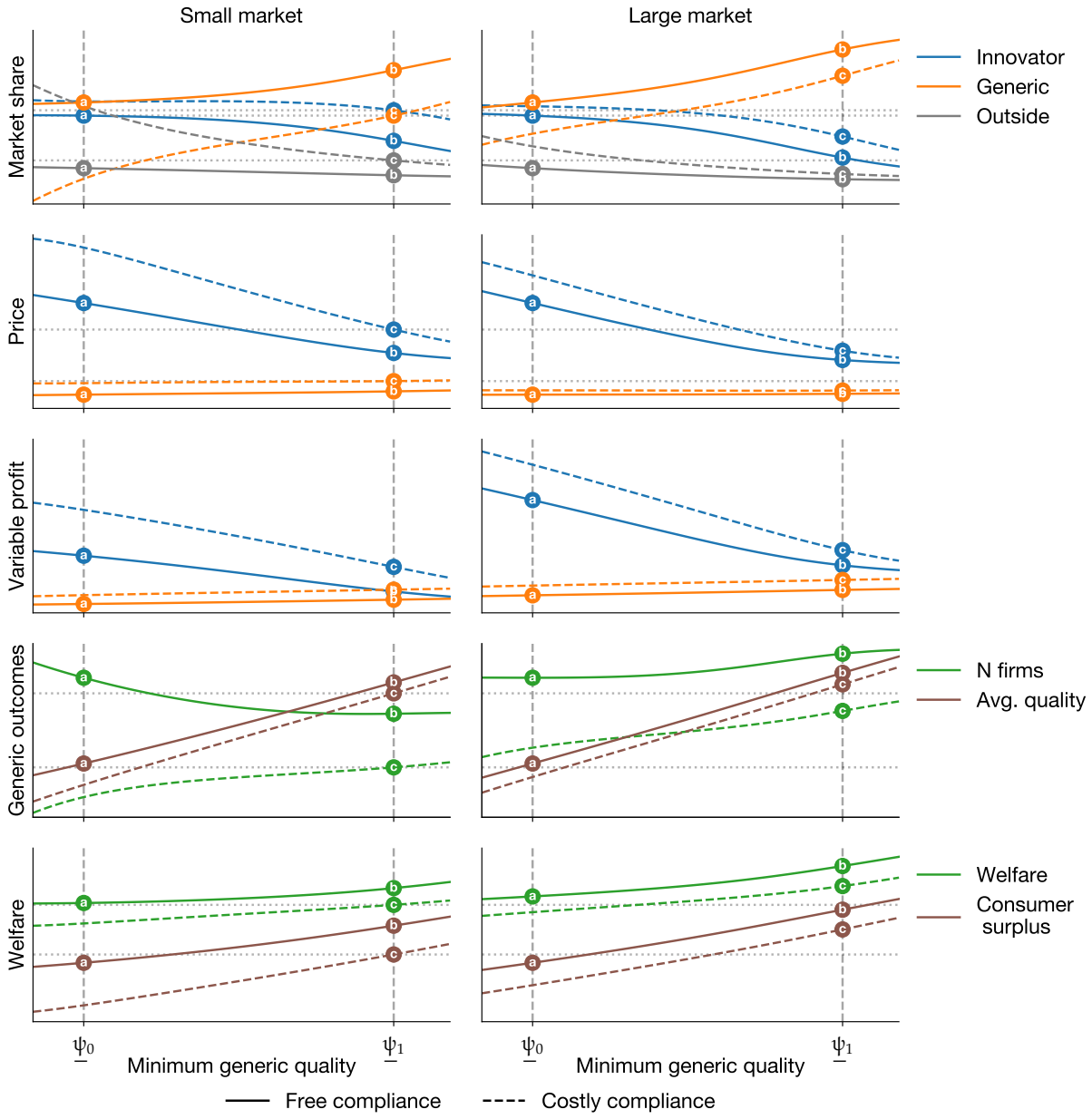
(b) Atorvastatin

(c) Citalopram

(d) Deflazacort

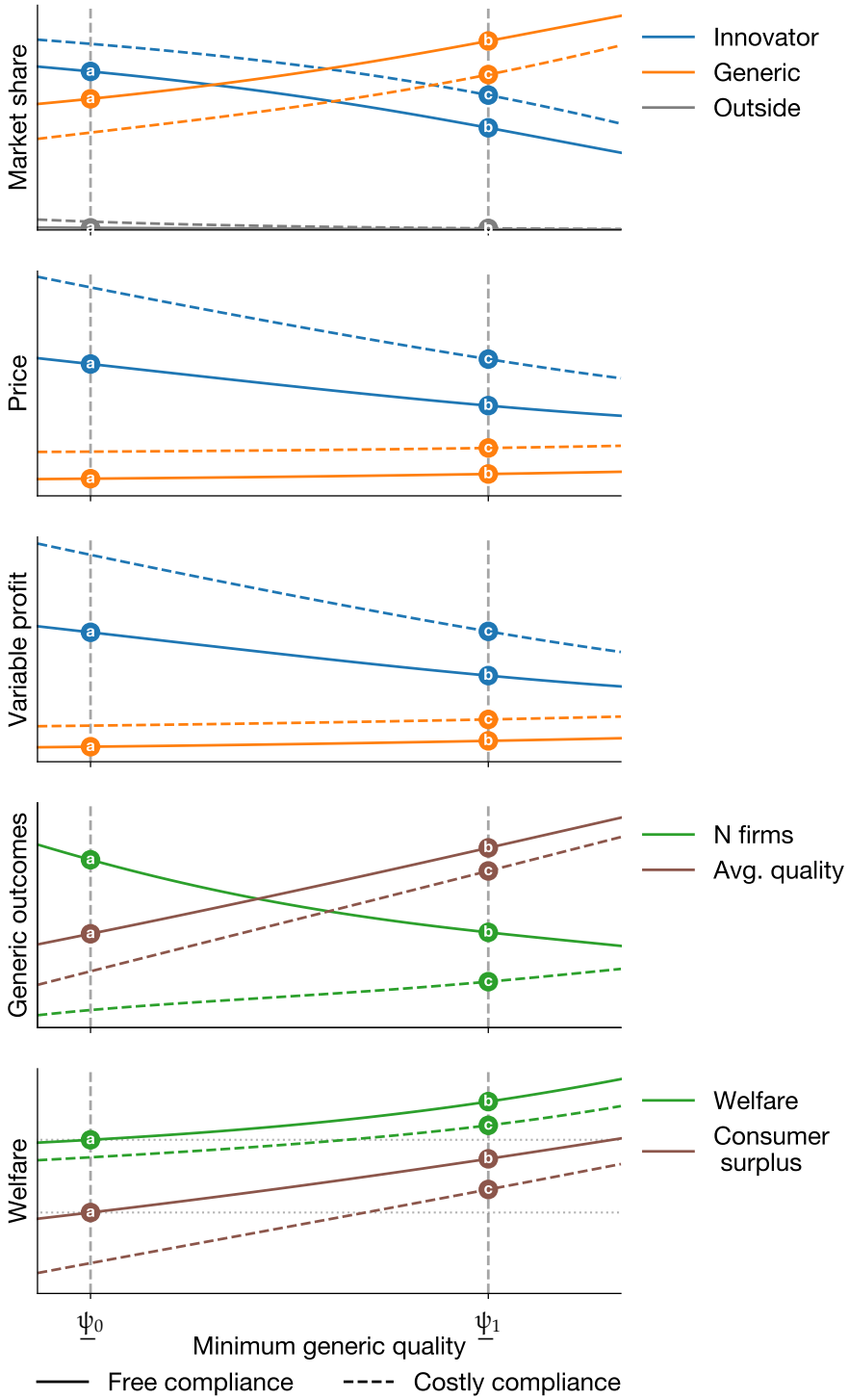
Notes: Each figure displays the values of the treatment variable and the number of BEs in a different market. This version of the treatment variable uses the first deadline as the relevant date. The instrument is displayed in blue, and takes a value of 0 before the first decree, and then increases as renewal dates of drugs in the molecule approach. The number of BE drugs in the molecule is displayed in gray. These four examples are plotted along all other markets in our sample in Figure 6-b.

Figure A.3: Effects of Quality Regulation, Small versus Large markets



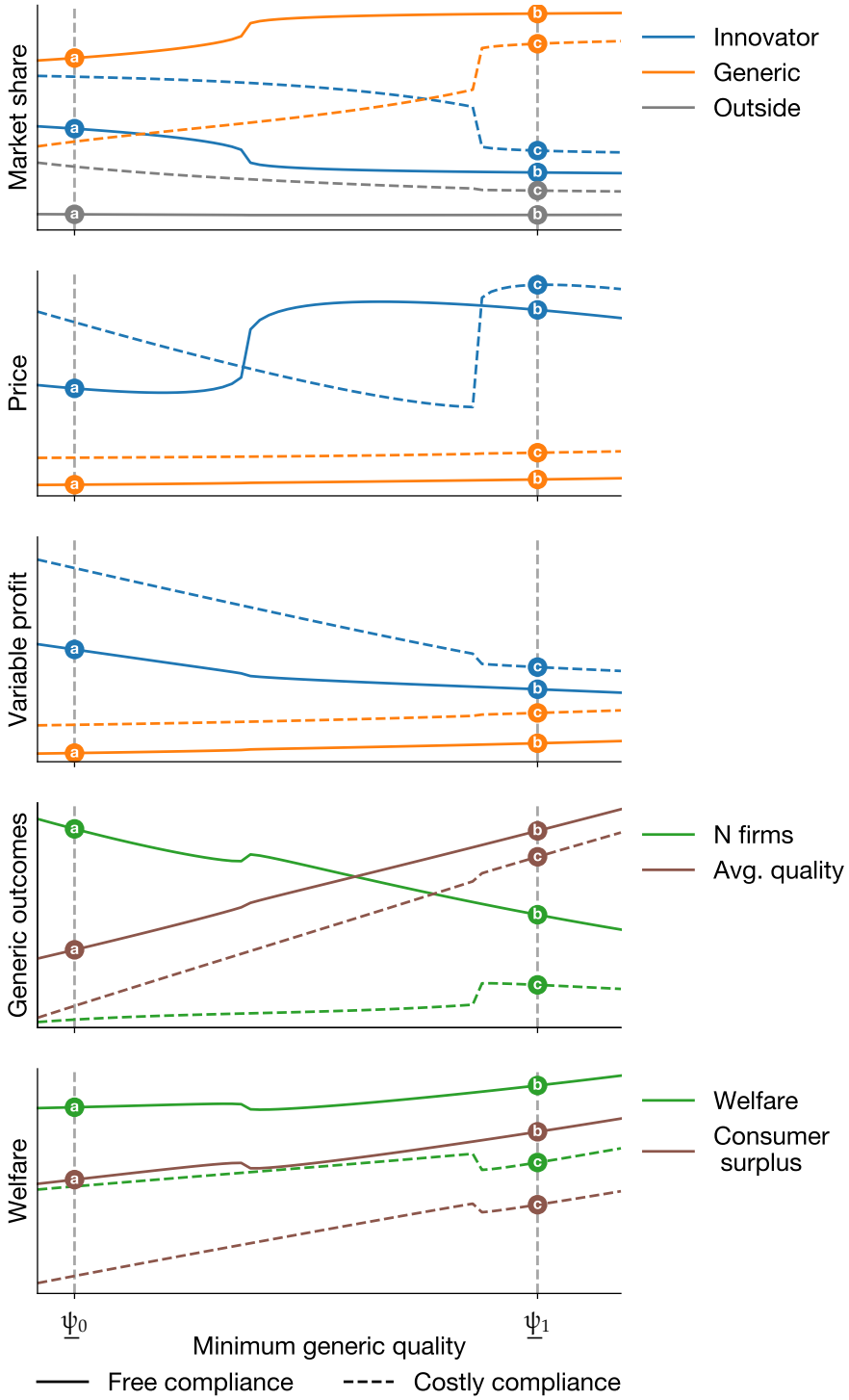
Notes: Market outcomes for different levels of minimum quality in a small market (left column) and large market (right column). The dashed (solid) lines represent a situation with (no) compliance costs. Example minimum qualities before and after regulation are indicated by $\underline{\psi}_0$ and $\underline{\psi}_1$, where point **a** indicates pre-reform outcomes, **b** indicates post-reform outcomes if compliance was free, while **c** indicates post-reform outcomes with costly compliance. Dotted horizontal lines indicating post-reform outcomes with costly compliance in small markets.

Figure A.4: Effects of Quality Regulation, welfare enhancing



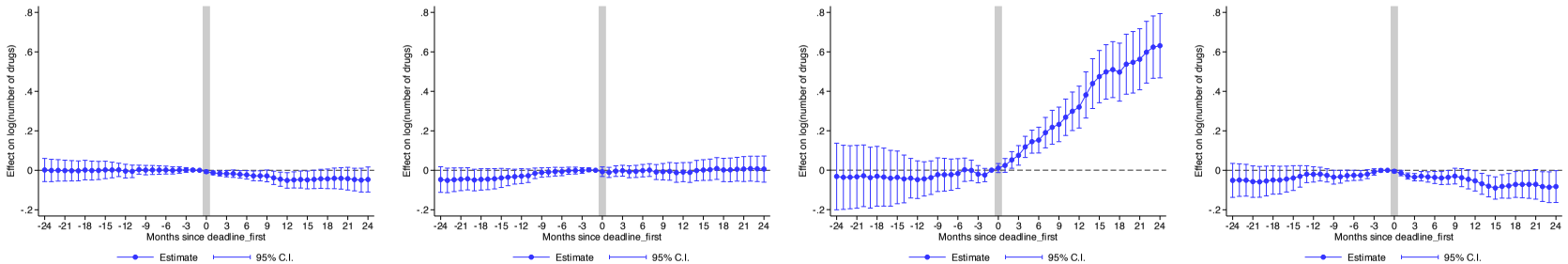
Notes: Market outcomes for different levels of minimum quality in the market. The dashed (solid) lines represent a situation with (no) compliance costs. Example minimum qualities before and after regulation are indicated by $\underline{\psi}_0$ and $\underline{\psi}_1$, where point **a** indicates pre-reform outcomes, **b** indicates post-reform outcomes if compliance was free, while **c** indicates post-reform outcomes with costly compliance.

Figure A.5: Effects of Quality Regulation with a loyal segment

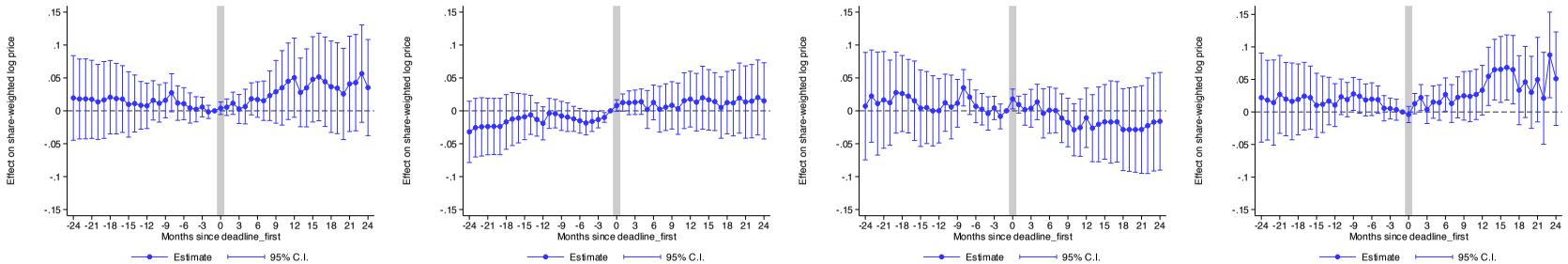


Notes: Market outcomes for different levels of minimum quality in the market. The dashed (solid) lines represent a situation with (no) compliance costs. Example minimum qualities before and after regulation are indicated by $\underline{\psi}_0$ and $\underline{\psi}_1$, where point **a** indicates pre-reform outcomes, **b** indicates post-reform outcomes if compliance was free, while **c** indicates post-reform outcomes with costly compliance.

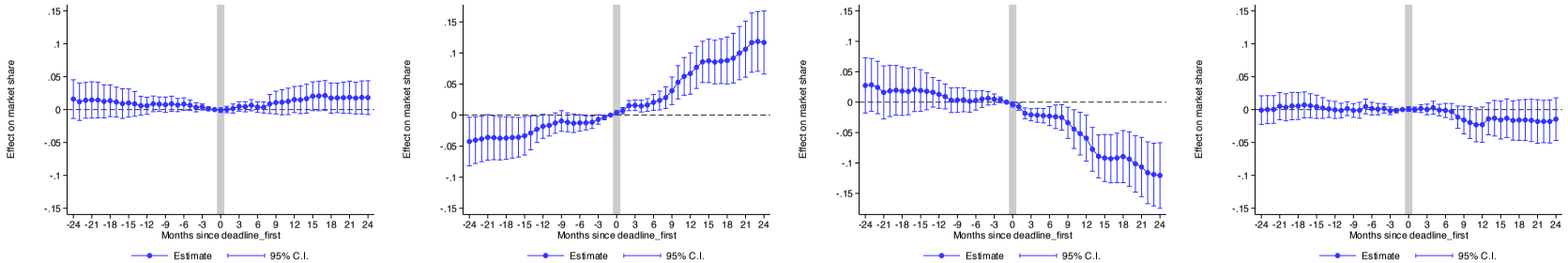
Figure A.6: Policy Effects using an Event Study Approach



(a) Number of drugs, all drugs (b) Number of drugs, innovator (c) Number of drugs, BE generics (d) Number of drugs, non-BE generics



(e) Prices, all drugs (f) Prices, innovator (g) Prices, branded (h) Prices, unbranded



(i) Shares, innovator (j) Shares, branded BE (k) Shares, branded non-BE (l) Shares, unbranded

Notes: This figure displays results from event study specifications described in Section A.2, using the first bioequivalence deadline as policy event. Dots indicate point estimates and lines indicate 95% 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 coefficient on the month previous to the event is normalized to zero. The first row displays results for the number of drugs in the market, the second row displays results for the price index defined in equation (4), and the third row displays results for drug market shares.

Figure A.7: 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 U.S. dollars).

Table A.1: Heterogeneity in Hazard Model for Bioequivalence and Exit

	(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)	(9)	(10)
	Panel A: Bioequivalence approval hazard					*Panel B: Exit hazard*				
After first deadline=1	2.38***	2.77***	1.69**	0.21	0.94	0.40	0.66	-0.05	0.19	-0.18
	(0.47)	(0.57)	(0.85)	(1.27)	(1.28)	(0.38)	(0.45)	(0.36)	(0.46)	(0.52)
× Above median price, 2010		-0.87*			-1.03**		-0.41			0.07
		(0.45)			(0.44)		(0.39)			(0.43)
× log(Sales, 2010)			0.12		0.00			0.20**		0.11
			(0.12)		(0.11)			(0.09)		(0.12)
× log(Revenue, 2010)				0.15*	0.13				0.04	0.04
				(0.09)	(0.08)				(0.03)	(0.05)
Above median price, 2010		0.46			0.67*		0.34			-0.17
		(0.43)			(0.41)		(0.39)			(0.43)
log(Sales, 2010)			0.08		0.14			-0.42***		-0.29**
			(0.11)		(0.09)			(0.09)		(0.12)
log(Revenue, 2010)				-0.01	-0.05				-0.14***	-0.08*
				(0.07)	(0.06)				(0.03)	(0.04)
Reference						-1.20***	-1.20***	-1.18***	-1.03***	-1.10***
						(0.34)	(0.34)	(0.32)	(0.32)	(0.31)
Imported	0.38**	0.37**	0.39**	0.37**	0.38**	0.60***	0.61***	0.54***	0.56***	0.55***
	(0.17)	(0.17)	(0.16)	(0.17)	(0.16)	(0.19)	(0.19)	(0.16)	(0.17)	(0.16)
log(Market revenue)	0.67***	0.67***	0.49***	0.63***	0.53***	-0.32***	-0.32***	-0.07	-0.22**	-0.07
	(0.15)	(0.15)	(0.17)	(0.15)	(0.16)	(0.10)	(0.10)	(0.11)	(0.10)	(0.10)
log(Number of branded)	-0.01	-0.00	0.05	0.01	0.05	0.01	0.01	-0.12	-0.03	-0.11
	(0.27)	(0.27)	(0.22)	(0.26)	(0.22)	(0.15)	(0.15)	(0.14)	(0.14)	(0.14)
log(Number of unbranded)	-0.29	-0.26	-0.37**	-0.28	-0.32*	0.11	0.11	0.09	0.08	0.09
	(0.18)	(0.18)	(0.18)	(0.18)	(0.18)	(0.17)	(0.17)	(0.14)	(0.15)	(0.14)
Time FE	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y
Observations	51,114	51,114	51,114	51,114	51,114	79,657	79,657	79,657	79,657	79,657
ln L	-1,209	-1,203	-1,181	-1,191	-1,173	-891	-890	-853	-864	-848

Notes: This table displays results from hazard models in equation (1) for bioequivalence approval and market exit. Results in this table highlight heterogeneity in the relationship between quality regulation and drug bioequivalence approval or exit along baseline drug characteristics. Estimation is implemented through maximum likelihood. All specifications include time fixed effects. Standard errors in parentheses clustered at molecule level. *p<0.10, **p<0.05, ***p<0.01.

Table A.2: Effects of Quality Regulation on Market Structure: Number of Drugs

	(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)
	Dep. var.: $\sinh^{-1}$(Number of Drugs)							
	All	Innovator	Branded generics			Unbranded generics		
			All	BE	Non-BE	All	BE	Non-BE
Panel A: Average effects								
Share of market under regulation	-0.32***	-0.12	-0.35***	0.74***	-0.49***	-0.36***	0.79***	-0.49***
	(0.09)	(0.09)	(0.06)	(0.20)	(0.08)	(0.09)	(0.14)	(0.10)
R^2	0.95	0.94	0.96	0.71	0.95	0.92	0.64	0.92
Panel B: Heterogeneity by baseline market size								
Share of market under regulation × Low revenue	-0.48***	-0.27***	-0.49***	0.26	-0.55***	-0.52***	0.42***	-0.51***
	(0.10)	(0.10)	(0.09)	(0.21)	(0.11)	(0.11)	(0.15)	(0.12)
Share of market under regulation × High revenue	-0.18**	-0.00	-0.23***	1.15***	-0.44***	-0.22**	1.10***	-0.47***
	(0.09)	(0.09)	(0.08)	(0.23)	(0.10)	(0.11)	(0.18)	(0.11)
R^2	0.95	0.95	0.96	0.73	0.95	0.92	0.66	0.92
Pre-regulation average	31.25	3.43	17.36	0.10	17.26	10.45	0.01	10.45
Observations	12,576	12,576	12,576	12,576	12,576	12,576	12,576	12,576
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 regression of the inverse hyperbolic sine of 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 a low or high revenue according to the average level of the variable 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.3: Effects of Quality Regulation on Market Structure: Number of Laboratories

	(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)
	Dep. var.: $\sinh^{-1}$(Number of Laboratories)							
	All	Innovator	Branded generics			Unbranded generics		
			All	BE	Non-BE	All	BE	Non-BE
Panel A: Average effects								
Share of market under regulation	-0.18***	-0.01	-0.17***	0.67***	-0.23***	-0.23***	0.71***	-0.31***
	(0.05)	(0.02)	(0.04)	(0.16)	(0.04)	(0.08)	(0.12)	(0.08)
R^2	0.93	0.96	0.96	0.71	0.96	0.92	0.65	0.91
Panel B: Heterogeneity by baseline market size								
Share of market under regulation × Low revenue	-0.30***	-0.07*	-0.29***	0.28	-0.30***	-0.37***	0.41***	-0.32***
	(0.06)	(0.04)	(0.06)	(0.17)	(0.06)	(0.09)	(0.14)	(0.10)
Share of market under regulation × High revenue	-0.08	0.04**	-0.07	1.00***	-0.16***	-0.12	0.97***	-0.30***
	(0.05)	(0.02)	(0.05)	(0.19)	(0.04)	(0.09)	(0.15)	(0.09)
R^2	0.93	0.96	0.96	0.73	0.96	0.92	0.67	0.91
Pre-regulation average	24.97	3.37	17.31	0.10	17.21	4.29	0.01	4.29
Observations	12,576	12,576	12,576	12,576	12,576	12,576	12,576	12,576
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 regression of the inverse hyperbolic sine of number of laboratories in a segment on the policy roll-out variable constructed using the first decree deadline. Panels B provides results by baseline revenue. Markets are classified as having a low or high revenue according to the average level of the variable 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.4: Effects of Quality Regulation on Market Structure: Number of Drugs per Laboratory

	(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)
	Dep. var.: log(1 + Number of drugs per laboratory)							
	All	Innovator	Branded generic			Unbranded generic		
			All	BE	Non-BE	All	BE	Non-BE
Panel A: Average effects								
Share of market under regulation	-0.10	-0.10	-0.13***	0.24***	-0.18***	-0.14**	0.37***	-0.17***
	(0.06)	(0.07)	(0.04)	(0.09)	(0.05)	(0.06)	(0.08)	(0.06)
R^2	0.93	0.94	0.91	0.67	0.90	0.80	0.60	0.78
Panel B: Heterogeneity by baseline market size								
Share of market under regulation × Low revenue	-0.12*	-0.20**	-0.15**	0.09	-0.18***	-0.16**	0.26***	-0.18**
	(0.06)	(0.08)	(0.06)	(0.09)	(0.06)	(0.07)	(0.08)	(0.07)
Share of market under regulation × High revenue	-0.08	-0.01	-0.11**	0.35***	-0.18***	-0.12*	0.47***	-0.17***
	(0.07)	(0.07)	(0.05)	(0.10)	(0.05)	(0.06)	(0.09)	(0.06)
R^2	0.93	0.94	0.91	0.68	0.90	0.80	0.61	0.78
Pre-regulation average	2.79	3.14	2.11	0.10	2.10	1.70	0.00	1.70
Observations	12,576	12,576	12,576	12,576	12,576	12,576	12,576	12,576
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 regression of the log number of drugs per laboratory in a segment on the policy roll-out variable constructed using the first decree deadline. Panels B provides results by baseline revenue. Markets are classified as having a low or high revenue according to the average level of the variable 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 physicians' prescription behavior, which were added to the survey with a lag and are therefore not available for a around a fourth of the sample.