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Quality Regulation and Competition: Evidence from Pharmaceutical Markets*

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Abstract. Quality regulation attempts to ensure quality and to foster price competition by reducing vertical differentiation, but may also have unintended consequences through its effects on market structure. We study these effects in the context of pharmaceutical bioequivalence, which is the primary quality standard for generic drugs. Exploiting the staggered phase-in of bioequivalence requirements in Chile, we show that stronger quality regulation decreased the number of drugs in the market by 25%, increased average paid prices by 10%, decreased total sales by 20%, and did not have a significant effect on observed outcomes related to drug quality. 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 were overturned by adverse competitive effects arising from the costs of complying with the regulation.

Keywords: quality regulation, competition, bioequivalence, generic pharmaceuticals
JEL Codes: I11, L11, L15

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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).

Quality regulation is considered a key precondition for the success of policies to foster penetration of generic drugs and increase price competition (WHO, 2000). Weak quality regulation undermines physician and patient trust in generics, and may limit price competition due to differences in perceived quality. Governments introducing quality regulation in pharmaceutical markets expect to ensure drug quality and improve the perception of generic alternatives, which increases the propensity to prescribe and choose generics, leading to increased competition. However, these regulations may also induce the exit of affordable and yet high-quality drugs due to costly compliance. Drug exit might in turn reduce price competition, overturning the positive effects of reduced (perceived) quality differences between innovators and generics brought on by the regulation. Therefore, the equilibrium effects 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 in pharmaceutical markets by exploiting the roll-out of bioequivalence requirements for generics in Chile. To the best of our knowledge, this is the first paper to measure the market effects of bioequivalence requirements. 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 branded generics and innovator drugs, respectively.[2,3] The primary objectives of the reform were to increase the perceived

[1] In models of vertical differentiation, quality differences are a source of market power (see, e.g., Gabszewicz and Thisse, 1979), such that smaller differences are expected to increase price competition (conditional on market structure). Price differences between innovator and generic drugs are often 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 higher priced innovator drugs.

[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.

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 (see, e.g., Scroll.in, 2019; GaBI, 2019, for the cases of India and China). 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 along with features of its enforcement, to compare outcomes across and within markets (molecules) differentially exposed to the regulation. This strategy delivers reduced form estimates of the 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 showing that stronger quality regulation induced laboratories to obtain bioequivalence certification for their drugs. Drugs were 18 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.

Stronger quality regulation had large effects on market structure, prices, market shares and sales. First, we estimate that stronger quality regulation affected market structure by decreasing the number of drugs by 25%. Second, we estimate a 10% increase in average paid 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 show that the policy shifted sales from branded generics to innovator drugs. Fourth, total sales volume decreased by 20%. Most of these effects are concentrated among small markets.In small markets, the number of drugs decreased by 36%, and average paid prices increased by 26%. Furthermore, the market share of innovator drugs among small markets increased by 8 percentage points (p.p.) at the expense of generics, whereas total sales volume decreased by 30%. In contrast, for large markets we estimate a 15% decrease in the number of drugs, but no significant effect on average paid prices or the market share of generics.

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

[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 based on poor quality of generic drugs.

[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.

drug exit. The heterogeneity of these effects across market size reinforces this interpretation, and suggests that fixed compliance costs played a significant role in driving these outcomes.

In principle, these adverse effects on market outcomes could have been compensated by improvements in drug quality. However, we find no evidence suggestive of such improvements. We leverage administrative data on hospital admissions associated with adverse drug effects and drug recalls as measures of quality. We do not find evidence of a significance decrease in these outcomes following the reform, neither overall nor among small markets. The lack of effects on drug quality suggests that the negative welfare effects from changes in market structure and higher prices were not compensated by higher underlying drug quality.

We complement our main analysis with a survey of pharmacy customers in Chile. Our survey suggests that a variety of demand-side frictions may undermine the ability of the regulation to achieve its intended effects. In particular, we find that consumers: (i) lack a full understanding of what bioequivalence entails and continue to assign perceived quality premiums to 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 branded drugs. Although these results come from a small sample, they are suggestive of barriers that reduce incentives for generic drug manufacturers to enter or remain in the market in the presence of regulation compliance costs. These lessons 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 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 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]

Moreover, we contribute to a literature that studies participation of generics in pharmaceutical markets. First, our study relates to research on 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 incumbent

[6]This paper differs from Balmaceda et al. (2015) along several dimensions. First, their sample ends in March 2014, when 75% of bioequivalence approvals to date and several policy events had not occurred. Second, our empirical strategy exploits policy variation across and within markets, instead of assuming parallel-trends across markets affected and unaffected by the policy in a simpler differences-in-differences analysis. Third, we develop a a model of price competition with vertical differentiation to interpret our results. Fourth, we study effects on drug quality.

generic drugs face the choice of staying or exiting the market under stronger quality regulation, and by focusing on a middle-income market. Our results highlight that quality regulation indeed affects drug exit decisions. Second, we build on an empirical literature analyzing competition between innovator and generic drugs, which has primarily focused on market responses to generic entry when innovator drugs go off-patent (see e.g., Caves et al. 1991; Grabowski and Vernon 1992; Frank and Salkever 1997; Grabowski et al. 2006; Knittel and Huckfeldt 2012; Branstetter et al. 2016). 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 which could 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 we use; Section 5 shows the extent of bioequivalence certification, entry and exit induced by the regulation at the drug level; Section 6 provides our main estimates of the effects on market structure, market outcomes and drug quality; 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 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

[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).

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

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 apply to ISP for marketing licenses. These 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 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 reactions to 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]

2.2 Bioequivalence in the Chilean Pharmaceutical Market

Bioequivalence is established to demonstrate therapeutic equivalence between a generic drug and the corresponding reference drug (mainly 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

[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 case in early 2008, almost two years before our study period. See Alé (2017) for a discussion of the 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 upon patient request. However, industry actors concede that the requirement has not been enforced, and that physicians have continued to prescribe branded drugs. Our survey evidence in Section 7 is consistent with this view. This lack of enforcement is well known, and has motivated a new pharmaceutical law that is currently under discussion in Congress (e.g., Cámara de Diputados 2019).

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 pre-clinical 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, recently they have been adopted by developing countries as the primary tool for testing effectiveness of 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 previous quality standards.

The stated goals of the regulation 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 La Tercera (2012) that:

> "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 Ministry of Health (*Ministerio de Salud*, MINSAL). This list consisted of active ingredients included in a major reform to the public health insurance system called AUGE (Bitrán et al., 2010). However, it was not until 2009 that the regulator established technical norms for bioequivalence testing (Balmaceda et al., 2015). Bioequivalence requirements were phased in since then, with 167 molecules covered as of March 2018. All new drugs containing the molecule listed in each 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, requirements' enforcement occurred mostly by the time of license renewal,

[12]To the best of our knowledge, there was no public discussion justifying this regulation based on poor quality of generic drugs. 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 referenced in footnote 11.

[13]In a context where quality is heterogeneous and unobservable to consumers, voluntary quality disclosure may take place and lead to unravelling. In that case, consumers become aware of quality differences and low quality drugs might exit (Dranove and Jin, 2010). However, this prediction does not hold if disclosure is costly enough (Jovanovic, 1982). In our setting, generic drugs were not aware of whether they were bioequivalent prior to costly certification. Moreover, consumers were likely not familiar with the concept of bioequivalence before the policy, which would limit the returns to disclosure. These two factors may jointly explain the lack of voluntary quality disclosure.

[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.

when ISP often denied renewal to drugs without bioequivalence approval (Vasallo, 2010). This is a feature of the institutional environment that we exploit in our empirical strategy. Drugs with bioequivalence certification carry a distinctive label that indicates such status to the consumer.[15] We show an example of this label in Figure A.1.

In most cases, the original deadlines to provide proof of bioequivalence were extended—through a series of subsequent decrees—due to slow uptake and capacity constraints in laboratories performing the tests. Among molecules with bioequivalence requirement, there are nine unique combinations of 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 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 group, as well as the number of molecules included in each group.[16] For example, Group 1 includes four molecules that had their first decree 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.

Bioequivalence certification is provided after the manufacturer presents successful studies. Generally, bioequivalence is determined through *in-vivo* clinical studies for a specific presentation of a drug, although under certain conditions only *in vitro* studies are required for different dosages of the same drug. Bioequivalence certification of imported drugs is often validated in Chile if obtained in countries with high certification standards (e.g., Canada, US, the European Union, New Zealand, among others). Although the certification is awarded *ad eternum* for a given formula and production technology, any change in these dimensions requires a new certification.

The costs of bioequivalence testing range between of $50,000 to $240,000 U.S dollars per drug, and are covered by the manufacturer.[17] To put this number in context, the median drug in our data had a yearly revenue of $103,600 in 2010. Moreover, 35% and 71% of drugs had yearly revenues lower than $50,000 and $250,000 respectively. Although these figures only cover the retail market, they suggest that the financial burden imposed by bioequivalence testing was not negligible.[18]

[15] In practice, the label could have an effect on demand through quality disclosure (see Dranove and Jin (2010) for a review of the 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] We exclude from this classification all molecules that received their first decree before 2010, as they are excluded from 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.

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

[18] All monetary values are inflation-adjusted to December 2013, when the exchange was of $529 CLP per U.S. dollar.

3 Conceptual Framework

We develop a novel model to study the mechanisms through which quality regulation affects market outcomes. The goal is to formalize the main economic intuitions behind our analysis, and to motivate the dimensions of heterogeneity we explore empirically below. Our model incorporates important features of the pharmaceutical 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 brand value; (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 and of quality certification, which lead to entry and exit considerations.

The importance of vertical differentiation follows from the 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 these models. Asymmetric information on generic quality is introduced to allow for the possibility that 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 particular, when quality regulation imposes substantial compliance costs, 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 is similar to Leland (1979), from which we differ by including vertical differentiation. Vertical differentiation has been considered by theoretical work on minimum quality standards,[19] though mostly under 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 $n_G = N_G\Big(F_\psi(\psi_b) - F_\psi(\psi_a)\Big)$. Drugs decide to participate in the market or

[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 on its treatment of asymmetric information on quality, on which we are closer to Leland (1979), and by allowing for endogenous market structure.

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:

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

where τ_i is the willingness to pay 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. Heterogeneity in preference for quality, τ_i, provides a role for vertical differentiation: whenever $\overline{\psi} < \psi_I$, a consumer with high τ_i is more likely to purchase the innovator drug at a higher price, whereas a consumer with low τ_i is more likely to buy a 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:

$$\pi_I = M s_I p_I - C_I$$
$$\pi_g = M s_g p_g - C_G(\psi_g) - \kappa_{QC} \quad \forall g$$

where M is market size, C_I is the fixed cost of the innovator drug, $C_G(\cdot)$ is a quality-dependent fixed cost of generic drugs; and κ_{QC} is a sunk fixed cost of quality certification. For simplicity, we set marginal cost to zero for all producers.[23] 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, as incentives to enter the market are higher for lower quality drugs.

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 a price

[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 longer horizons, such that experience with any given generic can be assumed to reveal no information, neither to 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] 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.

p_G and obtain market share s_G. In this equilibrium, generic producers participate in the market if:

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

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.

Quality certification takes the form of a minimum quality standard $\underline{\psi}$. Given $\underline{\psi}$, there is a one-to-one relationship between the number of generics in the market and the quality of the marginal entrant $\hat{\psi}$, given by $n_G = N_G(F_\psi(\hat{\psi}) - F_\psi(\underline{\psi}))$. Then, the average generic quality $\overline{\psi}$ equals the expected quality among the n_G active generic producers, which are those with quality between $\underline{\psi}$ and $\hat{\psi}$.[24]

The market equilibrium is 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 variable profits that cover 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.[25] When perceived quality of generics is very low, additional entry can lead to higher generic prices and/or market shares.

3.2 Comparative Statics: The Equilibrium Effects of Quality Regulation

Consider an increase in the minimum quality standard from $\underline{\psi}_0$ to $\underline{\psi}_1$, requiring a certification cost κ_{QC}. Stronger quality regulation directly affects the willingness-to-pay for generics. Keeping the set of active producers fixed, the 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, such that the price of the innovator decreases. Prices of generics might increase or decrease, because the increased willingness-to-pay for higher perceived quality is compensated by the higher intensity of price competition with the innovator.

However, stronger quality regulation also affects 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

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

[25] 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 what would be optimal from the generic firms' view (i.e., trading off higher willingness to pay of consumers and less differentiation from the innovator).

generic drugs and for the innovator. Second, an increase in perceived quality—together with higher demand for each generic drug—induces $N_G(F_\psi(\hat{\psi}_1) - F_\psi(\hat{\psi}_0))$ 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.[26]

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, 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.

Although the equilibrium effects of stronger quality regulation are ambiguous in our framework, higher fixed costs of quality certification are generally associated with worse equilibrium outcomes. In particular, large certification costs decrease generic entry and therefore harm price competition.

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 and their relationship with the certification cost κ_{QC}. The effect of κ_{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.

In our simulation, we solve for equilibrium across a range of minimum quality standards, for the cases with either free or costly compliance, $\kappa_{QC} = 0$ or $\kappa_{QC} > 0$ respectively. We highlight three regulatory environments: (a) a baseline level of quality regulation in the form of a minimum quality standard; (b) a high level of quality regulation that does not impose any costs on firms; and (c) a high level of quality regulation that is costly. For details about the model specification and parametrization, and formulas for all calculations, see Appendix A.1.

Figure 1 displays the simulation results, where we label the three environments by **a**, **b** and **c**. 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. Moreover, generic

[26] Whenever stronger quality regulation results in both higher generic quality and higher prices, consumers with sufficiently low willingness-to-pay for quality are worse off, and some reduce their consumption. 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.

prices increase slightly, and the market share of generics increases at the expense of the innovator. When certification is costly (**c**), consumer surplus and welfare fall, driven by higher prices of all drugs due to reduced competition induced by the exit of generics. In this case, the market share of generics decreases, and that of the outside good increases. These results suggest that stronger quality regulation may 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 is a source of heterogeneity in the effects of the reform. As we illustrate in Appendix A.2, the detrimental competitive effects of fixed compliance costs are stronger in smaller markets than in large markets, everything else constant. In particular, 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 κ_{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, which provides matketing license data for the universe of drugs 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 renewal, and the due date of the next license renewal. It also includes information on the drug dosage, presentation (tablet, capsule, injectable, or other), and marketing status (prescription or over-the-counter). We restrict our analysis to molecules under a bioequivalence requirement within the sample period, which includes all molecules with bioequivalence requirements imposed after 2010. Our data cover all licensed drugs up to December 2017. Second, we combine the drug registry data with data on drug bioequivalence certification, 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 drug prices and sales between January 2010 and December 2017. IMS Health collects data from two sources. The four largest pharmacy chains in the country—which account for more than 90% of drug sales—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.[27,28] We employ monthly sales

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

[28]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

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 drug prices and sales 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.[29]

The IMS Health data provide price and sales at the product level for branded drugs, identifying the laboratory, dosage and presentation of each drug. For unbranded drugs, the data provide prices and sales at the dosage and presentation level, aggregated across laboratories.[30] We focus on 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 market increased substantially throughout the period we study, as shown by Figure 2-a. 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 policy roll-out, which was staggered as described in Section 2.2. Figures 2-b through 2-e display the number of bioequivalence approvals around four policy events of each market: the first and last decree, and the first and last deadline. Note that (i) bioequivalence approval was uncommon before the first decree, and thus its incidence was rare before mandated; (ii) bioequivalence approval increased after the first decree, which suggests that the policy affected its incidence; and (iii) several bioequivalence approvals occurred after the deadlines, which shows that deadlines were imperfectly enforced.

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 our period of study. The resulting dataset covers 131 molecules and 2,292 unique drugs, defined as a unique combination of drug name, dosage, and presentation. These drugs are manufactured by 80 different laboratories.[31] Importantly, not all drugs in the data are sold every period. In fact, only 65.5% of the drug-month observations display positive sales. Drug

drug presentations by their drug content, by calculating prices per gram of the active ingredient.

[29] There is limited 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.

[30] This feature of the IMS Health data somewhat restricts our analysis, because all unbranded generics of a given molecule, presentation and dosage are coded together as if 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.

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

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 as high as those of the average drug, whereas branded (unbranded) generic prices are around two thirds (one fifth) of the average drug. 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, 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 for branded generics than for innovator and bioequivalent drugs.[32]

Relative prices across drug types reflect large pre-reform premiums for innovator and branded generics, as displayed by Figure 5.[33] Four facts become apparent. First, price premiums are on average positive across molecules in the sample. Second, price premiums are large overall: innovators and branded generics are substantially more expensive than unbranded generics, with average premiums of 10 and 6 times, respectively. Third, 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 price premiums on the order of 3 to 5 times, several other molecules display price premiums higher than 10 times, particularly for innovator drugs.

5 Effects of Quality Regulation on Certification, Entry and Exit

We study whether drugs that were imposed bioequivalence requirement were more likely to engage in quality certification, to enter or to exit the market. 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 limited to no substitution across molecules for the treatment of health conditions.

5.1 Evidence for Quality Certification

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

[32] This comes partly from our inability to identify unbranded drugs producers in IMS Health.

[33] We estimate 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 measure 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 specify $h(s)$ using a proportional hazard model for drug i in market m and month t:

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

where λ_s is a *baseline* hazard that depends on drug tenure in the market s, 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 periods after policy events, indicators for branded and imported drugs, and either baseline market attributes or market fixed effects. We consider the same four market-specific events analyzed in Section 4.2: first decree, first deadline, last decree and last deadline. Finally, ψ_t are month-year fixed effects.

Table 3-A displays estimates from equation (1) for bioequivalence certification. The most relevant policy events are the first decree and deadline which jointly increase the probability of becoming bioequivalent by 18 times, whereas posterior policy events do not further increase the certification hazard. These results reinforce the graphical evidence of Figure 2: the first decree and deadline are stronger predictors of bioequivalence certification than the last decree and deadline. This result is robust to including market fixed effects in column (2).

We then analyze the relationship between bioequivalence certification, drug attributes and market variables. Unbranded and imported drugs are more likely to obtain bioequivalence approval. Market variables strongly predict bioequivalence approval: a 10% higher market revenue is associated with a 6.1% higher hazard rate. Moreover, the number of competing drugs in a market is negatively associated with bioequivalence approval. A 10% increase in the number of branded drugs and unbranded drugs is associated with a 2.4% and 2.6% lower hazard rate, respectively.

Heterogeneity. We study how baseline drug revenue affects quality certification choices. Table A.3-A displays results from a version of equation (1) in which policy events are interacted with an indicator for whether a drug had a revenue above the median in 2010 (prior to the reform).[34] We focus on the first deadline of bioequivalence requirements. The most salient pattern is that drugs with higher baseline revenue are more likely to engage in quality certification after requirements are imposed, as predicted by our model. In particular, drugs with baseline revenue above the median are 10% more likely to get bioequivalence certification after the deadline.

[34]Calculations performed using the IMS Health data. The number of observations is lower than in Table 3-A because several drugs were not in the market in 2010. Comparing column (2) in Table 3 to column (1) in Table A.3 shows that both samples deliver similar results for the specification in equation (1).

5.2 Evidence for Entry and Exit of Drugs

Quality regulation also affected drug 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.[35] 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 bioequivalence policy roll-out.

To analyze the determinants of drug exit, we estimate a logit model of failure to renew the license. Since license renewal happens every fifth year, we observe at most two renewal events for a drug in our sample. As previously pointed out, the timing of a renewal depends on the drug entry date, and should thus be unrelated to the timing of the reform. However, we only use the first renewal event for each drug for this exercise. This avoids selection concerns driven by the number of renewal events in the sample being a combination of the endogenous choice to renew or not, and the exogenous timing of renewal events.

Table 3-B shows the policy did affect exit. The marginal effect of the first deadline on the exit rate was 7 p.p. and a similar increase followed the last decree, relative to a baseline exit rate of 16.5% before the reform. Innovator drugs are 8 p.p. less likely to exit than unbranded generics, while branded generics are slightly more likely to exit than the latter. We do not find significant effects of market variables, and including market fixed effects in column (4) does not affect the results.

Heterogeneity. We implement a heterogeneity analysis of exit rates. Table A.3-B displays results for heterogeneity in the effect of the first deadline of bioequivalence requirements on drug exit. We find that drugs with high revenues are less likely to exit by 9 p.p., increasing to an 18 p.p. lower exit probability after the first deadline.

6 Effects of Quality Regulation on Market Outcomes

6.1 Empirical Strategy

Our empirical strategy exploits policy variation across and within markets. The first source of variation is the staggered roll-out of the reform, discussed in Section 2.2 and displayed in Figure 6-a.

[35] Thus, for 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.

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 variation comes from a particular institutional feature. In practice, deadlines for incumbent drugs become binding every time a drug must renew its marketing license with ISP, i.e., every five years.[36] At that point, ISP denies license 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 are arguably exogenous for drugs that were in the registry before the deadline was known. Moreover, renewal dates vary across drugs within markets, driven by variation in licensing dates. Differences in renewal dates across drugs generate variation in the share of drugs for which the policy is effectively binding, both across markets sharing the same deadline, and within markets over time.

We combine these two sources of variation in a variable that measures the evolution of the policy roll-out for each market. This variable captures three features of the regulation. First, the policy becomes relevant for a market only after its first 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 of all drugs in it has been reached. Formally, denote the policy date for market m by t^d_m and renewal date of drug i in m by t^r_{im}. For a drug i, the share of time between the decree and next renewal date that has elapsed by time t is:

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

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

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

where $|\mathcal{G}_m|$ is the number of generic drugs (branded and unbranded) in market m in month t^d_m.

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^d_m: it is equal to 0 before t^d_m 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 point in time, and within market across time.[37] Finally, Figure 6-c shows that

[36] In the data, we observe no deviations from a five-year renewal schedule since entry date among incumbent drugs.

[37] For illustration, Figure A.2 shows examples of the evolution of T_{mt} over time for four markets, along with the

this variable is indeed correlated with the share of bioequivalent drugs in the market.

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

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

where the coefficient of interest is β. We include two sets of fixed effects: θ_m are market fixed effects that control for permanent differences across markets, and δ_t are year-month fixed effects that control for shocks common to all markets in a given period of time. When discussing our results, we focus on the effect of moving from not having bioequivalence regulation to having the regulation fully in place, which is captured by increasing T_{mt} from zero to one.

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 policy deadlines and renewal dates 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 expected to have earlier price increases. Although we cannot directly test this, the fact that decree extensions were mostly set based on capacity constraints of laboratories testing bioequivalence makes it unlikely that they were driven by unobserved future demand or supply shocks.

Market-level observables do not show a clear correlation with the policy timing, which supports this identifying assumption. Table 1-B shows statistics for market outcomes in 2010 across markets differently affected by the policy. There is substantial heterogeneity across these groups in terms of number of drugs, market size, and market outcomes, but no clear pattern related to the timing of bioequivalence requirements. Furthermore, Table A.2 displays estimates from an ordered logit for the timing of the policy on market attributes in 2010, including variables related to market structure, market size, prices and medical treatment. Most of these attributes are unrelated to the policy timing, and the only significant predictor of it is having a low branded generic market share. Moreover, the pseudo-R^2 is not larger than 3.6% across specifications. These results suggest that the timing of the policy roll-out is mostly unrelated to baseline market characteristics.

Event Study Evidence. As a complement to estimating equation (3), we implement an event study analysis. This analysis serves two purposes: (i) assessing the assumption of parallel trends across molecules treated at different dates; and (ii) providing visual evidence for the effects on market outcomes. A disadvantage of the event study relative to our main specification is that it does not exploit the within-market variation coming from the pattern of drug license renewal dates. We describe this event study analysis in Appendix B and provide results in Figure A.6. Overall,

evolution in the number of bioequivalent drugs in each of them. These plots show how bioequivalence certification increases as bioequivalence requirements become relevant for a market. These examples are highlighted in Figure 6-b.

trends in outcomes before the first deadline of bioequivalence requirements are well behaved, as most of the estimated coefficients are not statistically different from zero. This result is reassuring for exploiting the differential policy timing across markets as identifying variation. Moreover, the results of this event study analysis are consistent with those from our main analysis.

Heterogeneity. Our model suggests that when compliance is costly, quality regulation should have stronger effects among small markets because it would induce more drug exit. We test this prediction by estimating differential effects by market size, as measured by average sales before the reform. 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.

6.2 Effects on Market Structure

6.2.1 Results for Number of Drugs

We start by estimating equation (3) for the number of drugs in the market.[38] Column (1) in Table 4-A shows that the policy decreased the overall number of drugs by 25%. Columns (2)–(8) split this result across drug types. The overall reduction is driven by decreases of 26% and 25% by branded and unbranded generics, respectively. Even though the number of bioequivalent generics increases, that does not compensate for the exit of non-bioequivalents. We do not find statistically significant changes in the number of innovator drugs.

Consistent with our model, the negative effects on the number of drugs are larger among 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% among small markets and 15% in large markets, as shown by Table 4-B. Conversely, bioequivalence certification is higher in large markets, which is also consistent with our model, as a larger market size makes certification costs relatively lower.

6.2.2 Results for Number of Laboratories

Since most laboratories are multiproduct firms, we turn to study whether drug exit is driven by exit of laboratories or changes in their drug portfolios. The number of laboratories decreased by 14% on average across markets as a result of the reform, as shown by Table 5-A.[39] This reduction comes mostly from a decrease in the number of laboratories offering generics, whereas we find no

[38] We use $\ln(1 + N_{mt})$ as dependent variable, where N_{mt} is the number of drugs (i.e., presentations), to accommodate observations where there are no drugs of a certain type. Our results are virtually unchanged when using $\sinh^{-1}(N_{mt})$ as the dependent variable in Table A.4. This transformation also reduces skew and yields coefficients approximating percentage changes, all of which are desirable statistical properties with this type of data (see, e.g., Kline et al. 2017).

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

significant effect on the number of laboratories offering innovator drugs. On the other hand, we find a large increase in the number of laboratories offering bioequivalent generics. Table 5-B shows that effects are heterogeneous across small and large markets. Stronger quality regulation reduced the number of laboratories in small markets by 23%, but it did not affect it 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] These results are consistent with our findings for the number of drugs and with the model predictions.

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 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 from a given market. 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 among small markets, whereas 43% of the effect on the number of drugs comes from it among large markets.[41]

The finding that a large share of drug exit is due to reduction in laboratories' drug portfolios suggests that laboratories selectively test for bioequivalence. The (underlying) bioequivalence status of drugs within laboratories is likely somewhat homogeneous, such that variation in bioequivalence certification within laboratories reflects heterogeneity in drug profitability. Selective testing based on drug profitability is consistent with compliance costs being a main driver of our results.

6.3 Effects on Drug Prices

Having documented large changes in market structure, we turn to study the price effects of quality regulation. Price effects are driven by a combination of mechanisms. On the one hand, a reduction in the number of competitors may reduce the intensity of price competition and lead to price increases. Innovators are expected to increase their prices to exploit their increased market power.[42] However, changes in market structure are coupled with potential changes in perceived quality, which reduce the scope for vertical differentiation and increase the intensity of price competition. Therefore, the direction of price effects is ambiguous, as predicted by our model.

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

[40] As a robustness check, we estimate the same regressions using $\sinh^{-1}(N_{mt})$ as dependent variable. See footnote 38 for details. Table A.4 displays results for these specifications. The results are mostly similar to those in our main analysis.

[41] We also report results using the average number of drugs per laboratory as dependent variable in Table A.6.

[42] Another theoretical possibility is that innovators decrease their prices to cater a more elastic part of the demand, which we illustrate using our model in Appendix A.2 (see, e.g., Frank and Salkever 1992).

average of log prices in a market (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 market m in period t, P_{it} is the logarithm of price per gram of drug i in period t and w_{it} denotes the share of sales of drug i in market m in period t.

Average prices across all drugs increased by 10% as a result of the regulation, as shown by Table 6-A. We estimate price effects by drug type and find that most of the increase in average paid prices comes from increases among unbranded generics, whereas innovators and branded generics display no statistically significant effects.[43] As shown in Section 6.2, the decrease in the number of drugs is concentrated among small markets; therefore, these are the markets where we expect to find the strongest price effects, which is confirmed by our heterogeneity analysis in Table 6-B. The increase in prices across all drugs is driven by an increase of 26% among small markets. 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 combine drug-specific price changes (P_{it}), changes in shares (w_{it}), and changes in the composition of drugs in each market. To better understand the drivers of price effects, we decompose the evolution of average 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 share-weighted average of log prices as:

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

[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.

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

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

To estimate the effect of quality regulation on each component of price changes, we estimate equation (3) using $\hat{P}_{mt,C} \equiv \hat{P}_{m0} + \Delta P_{mt,C}$, $\hat{P}_{mt,RW} \equiv \hat{P}_{m0} + \Delta P_{mt,RW}$, $\hat{P}_{mt,CS} \equiv \hat{P}_{m0} + \Delta P_{mt,CS}$, $\hat{P}_{mt,E} \equiv \hat{P}_{m0} + \Delta P_{mt,E}$ and $\hat{P}_{mt,X} \equiv \Delta \hat{P}_{m0} + P_{mt,X}$ as dependent variables. The sum of the OLS coefficients on T_{mt} from these regressions equals the coefficient on T_{mt} when estimating equation (3) for $\hat{P}_{mt}$.

Most of the increase in overall prices is driven by within-drug price changes. Table 6-C displays estimates of effects on each component of our price index, across and within drug type. Of the 10% increase in average prices, 7 p.p come from price changes among incumbents ($\hat{P}_{PC}$), and 2 p.p from the entry of relatively expensive drugs ($\hat{P}_E$). Similarly, most of the price increases among unbranded generics are due to within-drug price changes ($\hat{P}_{PC}$).[44] Overall, the finding that the estimated increase in overall prices is due mostly to price increases among incumbent drugs supports our interpretation that drug exit reduced the intensity of price competition.

6.4 Effects on Market Shares and Sales

Changes in market structure driven by generic drug exit may shift drug consumption away from generics and potentially reduce overall consumption. Price increases may in turn exacerbate these effects. However, changes in perceived quality may increase demand for generics. In this section, we estimate the effects of quality regulation on market shares and sales by drug type.

Overall, we do not find significant effects on the market shares of innovator drugs and generics, as shown by Table 7-I-A. If anything, we find a non statistically significant increase of 4 p.p in the

[44] As noted above, unbranded generics are aggregated across laboratories, and therefore the decomposition for this segment should be interpreted with caution.

market share of innovator drugs and a similar decrease 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. for non-bioequivalent generics. 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. Most of the increase in the innovator market share comes from a 8 p.p increase among small markets, as shown by Table 7-I-B. In contrast, we find no significant effect on the market share of innovators in large markets. Moreover, we find a shift away from branded to unbranded generics in large markets: 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.

Theoretically, stronger quality regulation can either increase or decrease the market share of the outside option, as a result of the interplay between changes in market structure, price effects and effects on perceived drug quality. We now focus on the effects of quality regulation on sales volume across and within drug types.

Drug sales decreased as a result of stronger quality regulation, as shown by Table 7-II-A. We find no statistically significant effect on sales of innovator drugs and unbranded generics across all markets. Rather, the overall effect is driven by a decrease of 37% in sales of branded generics. These results indicate that stronger quality regulation generated substitution towards the outside option. Consistent with previous results, these decreases in sales are concentrated among small markets, as shown by Table 7-II-B. Sales decreased by 29% across all drug types in small markets, as opposed to a smaller and non-statistically significant decrease in large markets of 9%. The overall decrease in sales among 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 find that in large markets there is a large but not statistically significant decrease in sales of branded generics, whereas the sales of unbranded generics increased by 60%.

6.5 Effects on Drug Quality

Imposing bioequivalence requirements as a minimum quality standard induced generics willing to enter or stay in the market to certify bioequivalence. However, stronger quality regulation also affected market structure by inducing drug exit, particularly from small markets. Theoretically, we expect a higher rate of bioequivalence certification in larger markets even if the underlying drug quality is constant across markets of different size, as shown by our model. The regulation compliance cost acts as a fixed cost that only firms expecting to earn large enough profits are willing to incur, as in standard entry models (e.g., Bresnahan and Reiss 1991). Therefore, the 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 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 product quality are positively correlated; therefore, a higher exit in small markets may imply that the average quality in the market increased after the reform.

To inform this margin, we study whether the bioequivalence regulation affected the quality of drugs in the market. Finding no quality effects would be consistent with higher exit from small markets being associated with negative welfare consequences. Direct measures of quality (e.g., results from laboratory drug testing) are not available in our setting, which motivates using adverse health events associated with specific drugs and drug recalls as indirect measures of quality.

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

$$\frac{y_{mt}}{sales_{mt}} = \mu_{m0} + \gamma_t + \theta T_{mt} + \varepsilon_{mt} \tag{6}$$

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

6.5.1 Evidence from Adverse Health Events

A first set of outcomes related to quality are the adverse health events associated with drug consumption. We collect data on yearly clinical outcomes between 2010 and 2017 for ICD-10 diagnosis codes associated with active ingredients in our sample. We exploit public records collected by DEIS (2019), which cover admissions, days of hospitalization, and number of surgeries across all hospitals in Chile. We link diagnoses to active ingredients using a crosswalk between American Hospital Formulary Service (AHFS) and ICD codes that tracks adverse health events associated with the consumption of drugs (WHO, 2007).[45,46] We focus on the 71 active ingredients with at least one listed adverse effect.[47] In our setting, these events are rare. In 2010, there were on average 7.3

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

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

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

admissions, 13.2 hospital days and 0.002 surgeries per 100,000 daily doses sold across all markets.

We estimate equation (6) for these outcomes. Columns (1)–(3) in Table 8-A display results across all markets. We find no evidence suggesting that stronger quality regulation decreased the number of discharges and the number of days associated with them. Moreover, we find no evidence of heterogeneous effects on these outcomes across small and large markets in Table 8-B. These results suggest that stronger quality regulation was not able to reduce adverse health effects of drugs.

6.5.2 Evidence from Drug Recalls

To study effects on drug recalls, we collect data on the 209 recalls for prescription drugs that occurred during our period of study. Recalls are implemented by ISP as preventative sanitary measures upon notice of adverse events linked to licensed drugs.[48] In the period we cover, there is an average of 1.9 recalls per month, of which 1.4 (0.5) relate to active ingredients without (with) bioequivalence requirement.[49]

Our estimates of equation (6) in the sample of active ingredients with bioequivalence requirements provide no evidence suggesting that stronger quality regulation improved drug quality as measured by recalls. Columns (4) and (5) in Table 8-A display results across all markets, while Table 8-B does so by market size. Our point estimates are close to zero across specifications.

6.6 Summary of Results

We provide evidence for the equilibrium effects of quality regulation and interpret it using our model. We start by showing that stronger quality regulation induced drug exit, which combined reductions in the portfolio of drugs offered by laboratories with decreases in the number of laboratories in a given market. Whereas stronger quality regulation could 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 in our setting. As a result, drug prices increased. Moreover, we find no evidence of increases in the market share of generics, which was one of the motivations for the policy. Finally, we provide evidence that drug quality did not improve, as measured by adverse health events associated with drug consumption and drug recalls.

Most of the adverse effects from stronger quality regulation are concentrated among small

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

[49]Figure A.7 shows the monthly recall frequency, split into drugs with bioequivalence requirements in our sample, and drugs without bioequivalence requirement. We cannot reject the hypothesis of a same trend in recalls over time across these two groups. We estimate an OLS regression for recall rates on an indicator for requirements and its interaction with a time trend, and find that the coefficient on the latter is not statistically different to zero.

markets. This pattern suggests that laboratories remove drugs from the market when the regulation compliance cost is large enough relative to the market profitability, as predicted by our model. In particular, our results for small markets follow the model predictions for equilibrium effects under costly compliance—a shift from **a** to **c** in Figure 1—, whereas our results for large markets are consistent with the model predictions for free compliance—a shift from **a** to **b** in Figure 1.

Overall, we stress that the welfare effects of quality regulations are theoretically ambiguous in general and, in particular, that lower compliance costs make the policy more likely to increase 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 illustrate these arguments in Appendix A.2.

7 Complementary Evidence from Consumer Surveys

Our findings show that stronger quality regulation had unexpected adverse effects. There are several potential explanations 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 knowledge about bioequivalence, and the role of physicians in their purchase decisions. We conducted in-person surveys to frequent consumers recruited outside pharmacies after a drug purchase. To collect perceptions, we focus on Atorvastatin, a common anti-cholesterol drug in Chile. We ask consumers for their quality and price perceptions for 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 C. We surveyed $N = 401$ consumers, of which 58% reported having a household member with a chronic disease, and 34% reported purchasing Atorvastatin for a household member. Table A.7 provides summary statistics for the main variables in the survey.

7.1 Main Results

Knowledge About Bioequivalence. Consumers display substantial heterogeneity in knowledge about bioequivalence, despite the fact that 84% of them are familiar with the label attached to

bioequivalent drugs. Figure 7-a shows that almost 30% of consumers are not familiar at all with bioequivalence and 55% are not able to provide a good definition for it.Limited knowledge about bioequivalence might reduce its effectiveness to signal 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 7-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 7-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).[50] 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 7-d displays perceived price premiums of the innovator drug relative to other drug types.[51] 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 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 prices across drug types.

[50]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.

[51]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, to limit the extent to which physicians prescribing named drugs may deter generic penetration. We gather information on consumer experiences with physician prescription behavior. 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 prescription, only 15% of consumers purchase the prescribed named drug *always and regardless of drug prices*, whereas 52% deviate from the brand prescribed by the physician when there is a large enough price difference. Finally, 34% of consumers 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. Almost 10 years after 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 our model, this evidence implies that $\overline{\psi} < \psi_I$.[52] Additionally, we find that perceived quality premiums are lower for consumers with a higher understanding of bioequivalence. This evidence relates 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 perceived generic quality.

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, these results suggest there are barriers to generic penetration in our setting. These frictions undermine the ability of the regulation to effectively shift consumers towards bioequivalent generics. These barriers reduce the profitability for generic manufacturers from entering or remaining in the market relative to the regulation compliance cost. This is consistent with our main

[52] This survey does not provide a direct measure of perceived quality of generics before the reform, and thus does not allow to estimate changes in it due to the reform. Making a strong assumption on the evolution of perceived quality, one could asses whether 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.

findings, 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 among 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 regulation compliance 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 reduced vertical differentiation and increased competition, we find that average paid prices increased, and that the market share of generics did not increase. These effects are concentrated among small markets, where we also find substantial drug exit. We employ an equilibrium model of competition in pharmaceutical markets to interpret these findings. The model suggests that fixed compliance costs imposed by stronger quality regulation may induce exit, which in turn may decrease 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. Our model suggests that a key driver of the unintended consequences we find are regulation compliance costs. Subsidizing certification costs may limit drug exit and, therefore, prevent decreases in the intensity of price competition. Additionally, the competitive effects of quality regulation depend on how they affect demand, and pharmaceutical markets impose particular challenges in this regard. First, demand responses are limited by physician prescribing behavior, 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, which could limit the desired effects of quality regulation in the short run. Consumer survey data we collected from the Chilean market confirms the presence of these lasting biases and frictions, and suggests the need of complementary policies to achieve the desired competitive effects of minimum quality standards.

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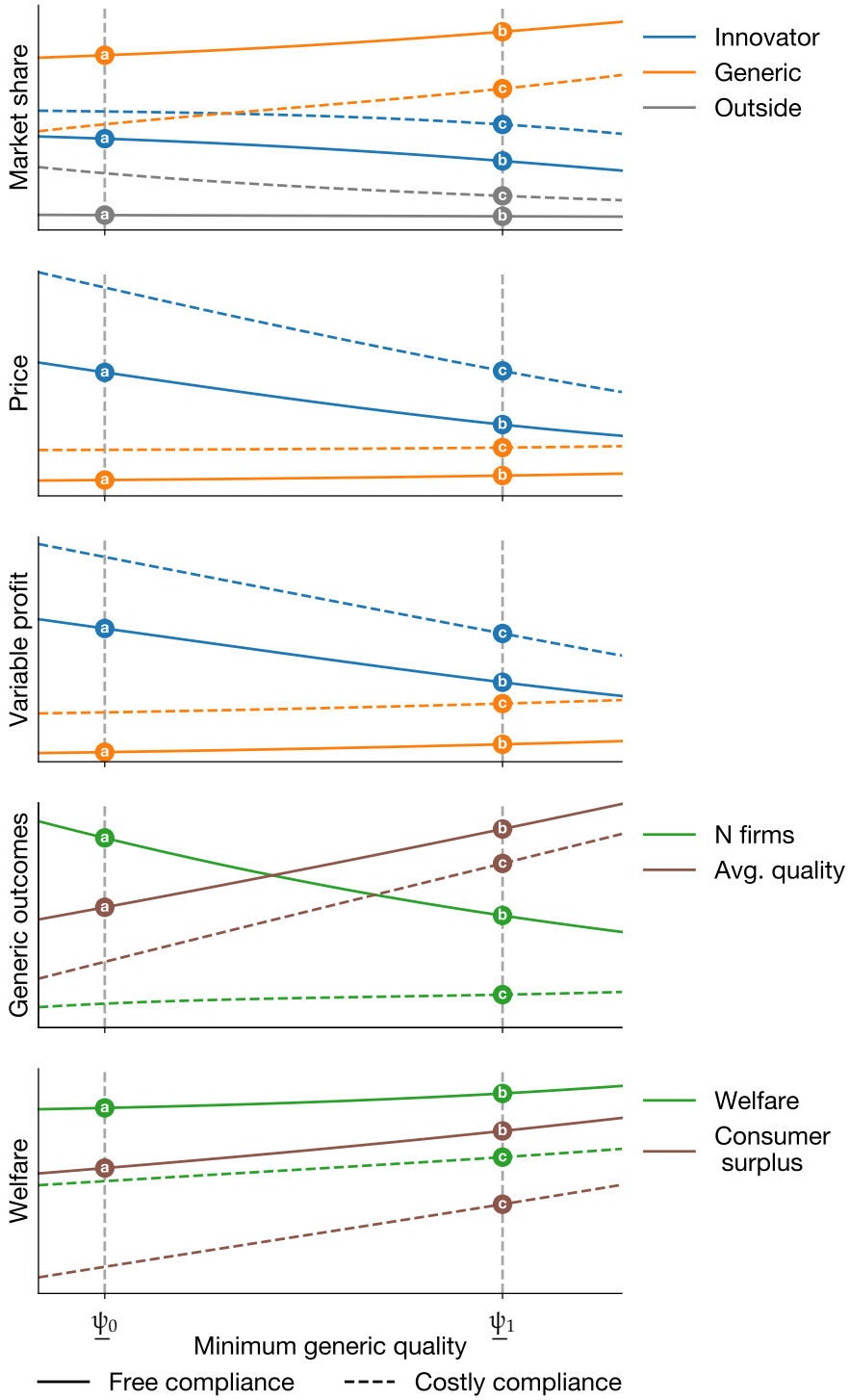
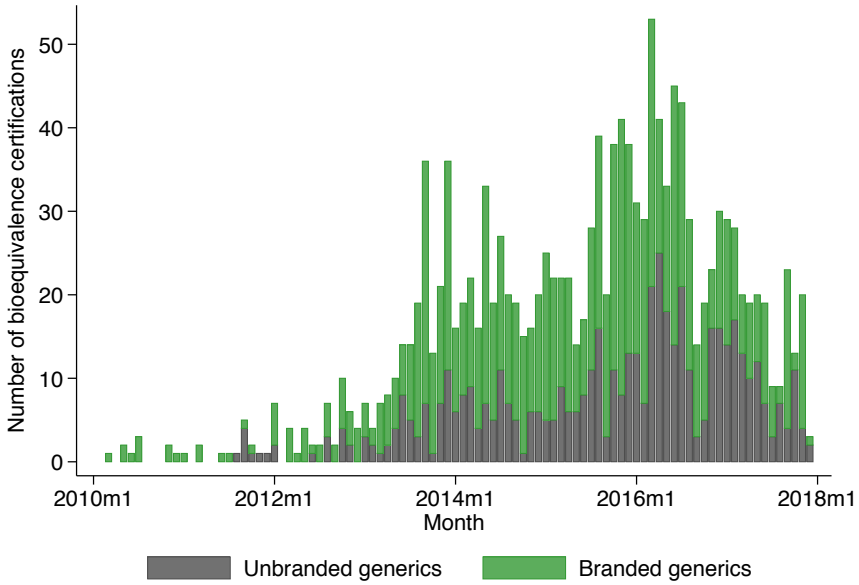
Figure 1: Effects of Quality Regulation: With and without Costly Compliance/Certification

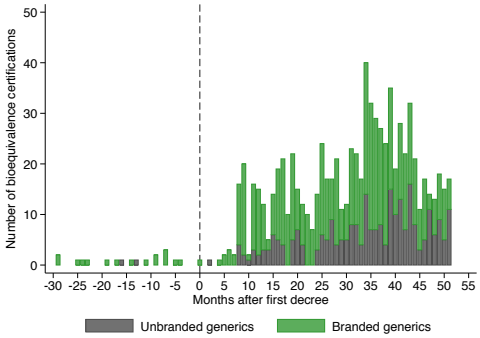


Notes: Market outcomes for different levels of minimum quality in the market. The dashed (solid) lines represent a situation with (no) compliance costs. Example minimum qualities before and after regulation are indicated by $\underline{\psi}_0$ and $\underline{\psi}_1$, where points **a** indicate pre-reform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

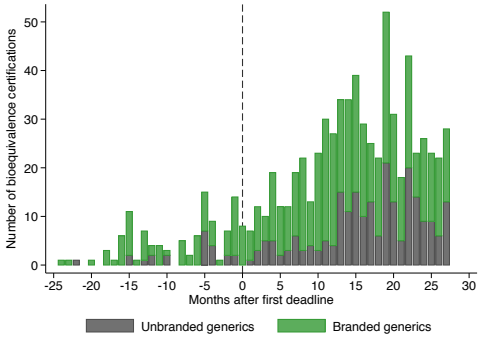
Figure 2: Bioequivalence Approvals around Policy Events



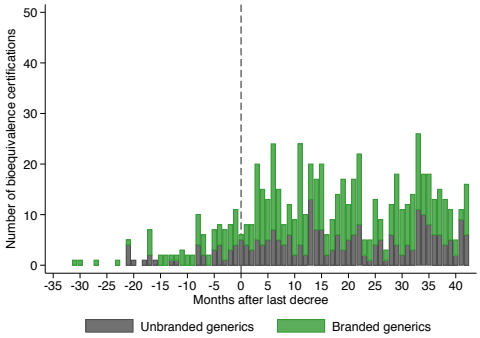
(a) Approvals over time



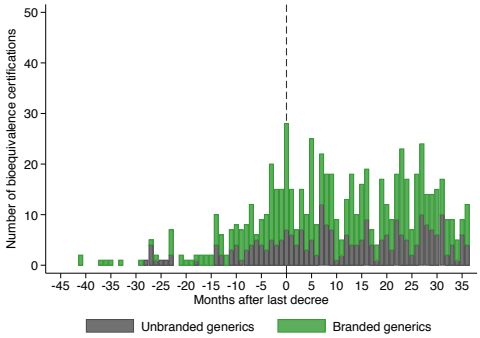
(b) Approvals around first decree



(c) Approvals around first deadline



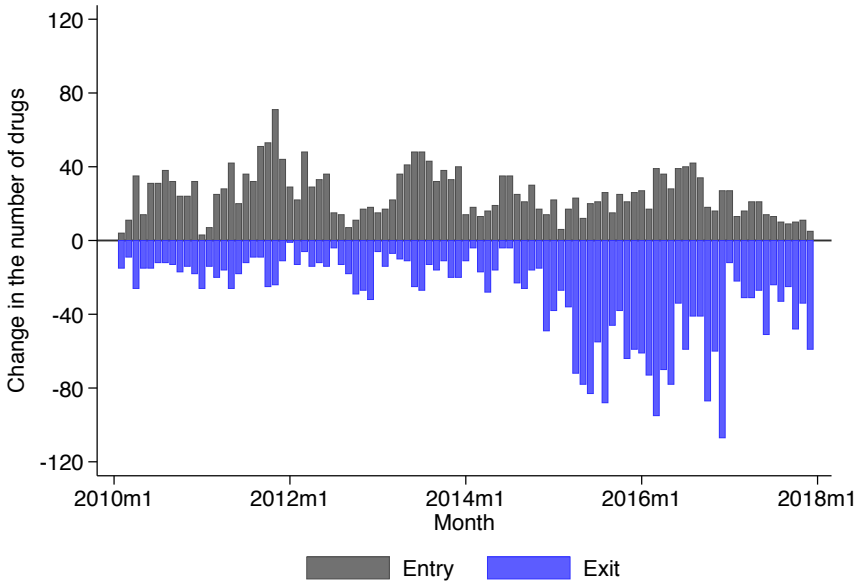
(d) Approvals around to last decree



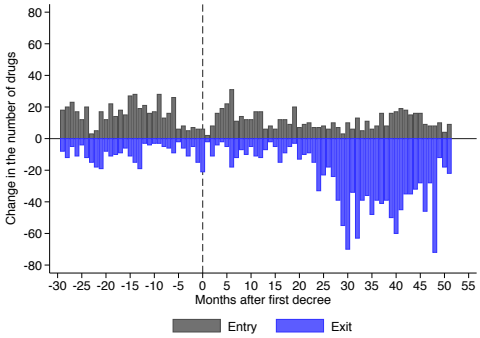
(e) Approvals around to last deadline

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.

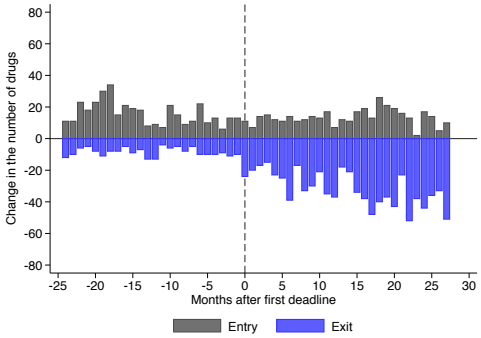
Figure 3: Number of Entry and Exit of Drugs around Policy Events



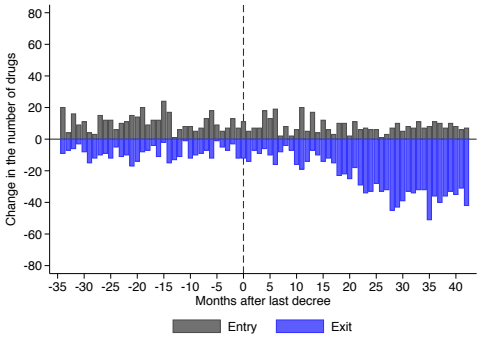
(a) Entry and exit over time



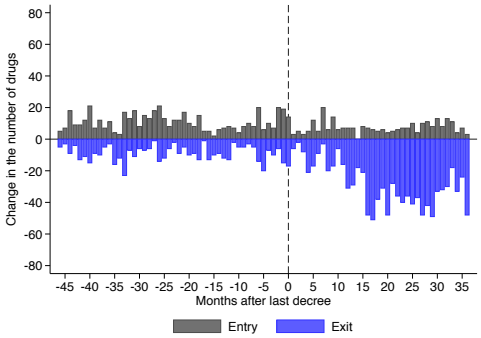
(b) Relative to first decree



(c) Relative to first deadline



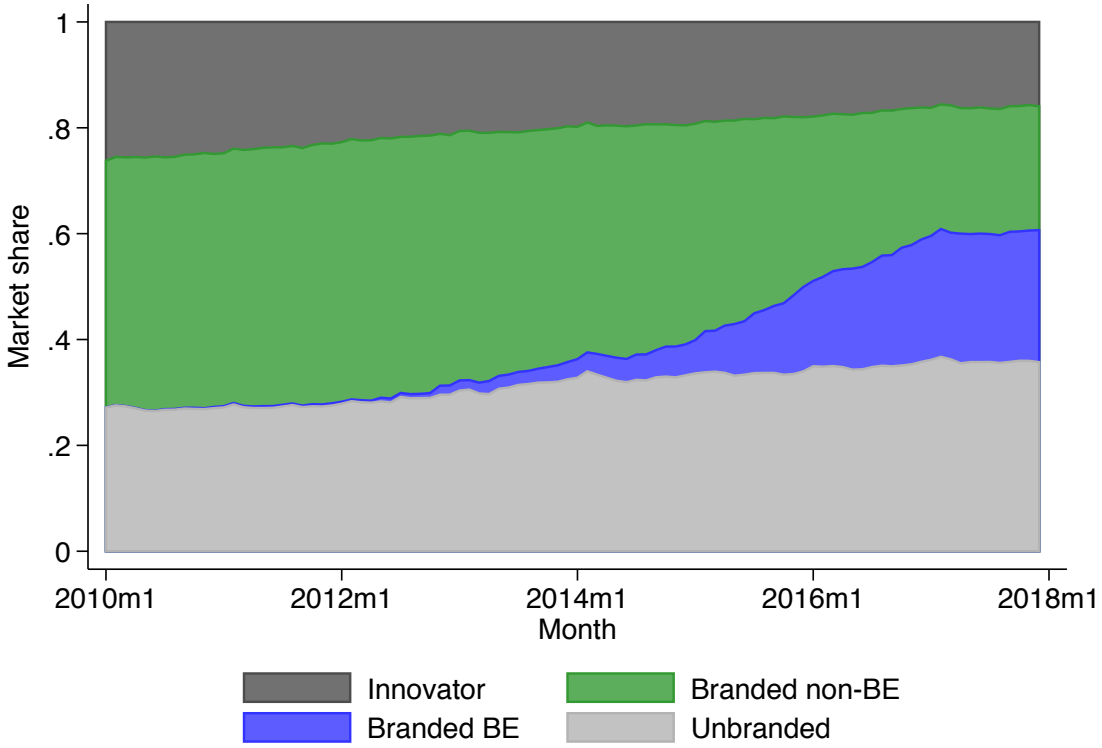
(d) Relative to last decree



(e) Relative to last deadline

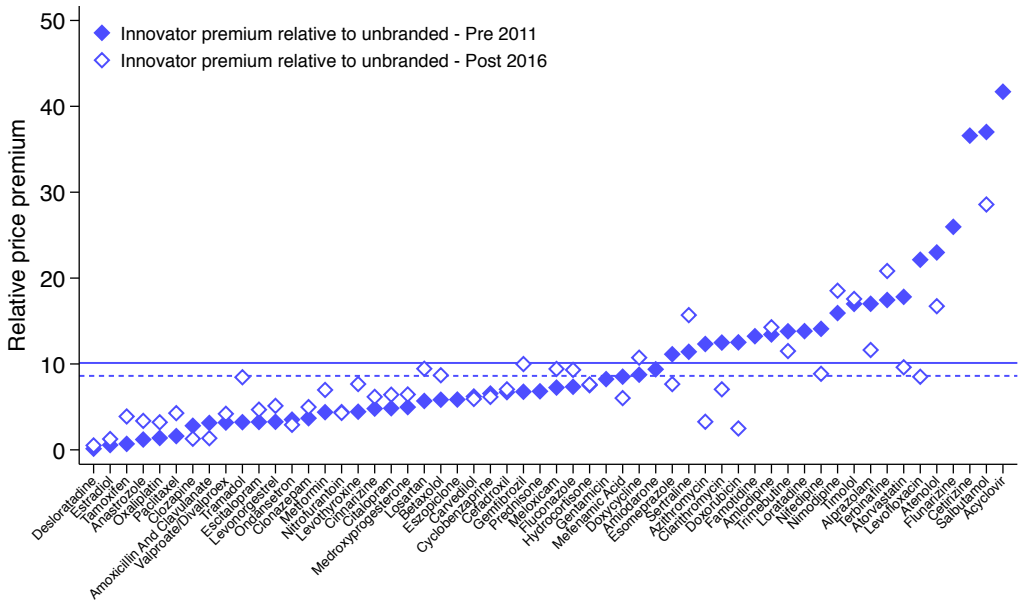
Notes: This figure displays the number of entering (gray) and exiting (blue) drugs around bioequivalence decrees and deadlines. The vertical axis displays the count of such events. Panel (a) display the evolution of entry and exit of drugs over time, while panels (b) through (e) display the evolution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

Figure 4: Market Shares by Drug Type

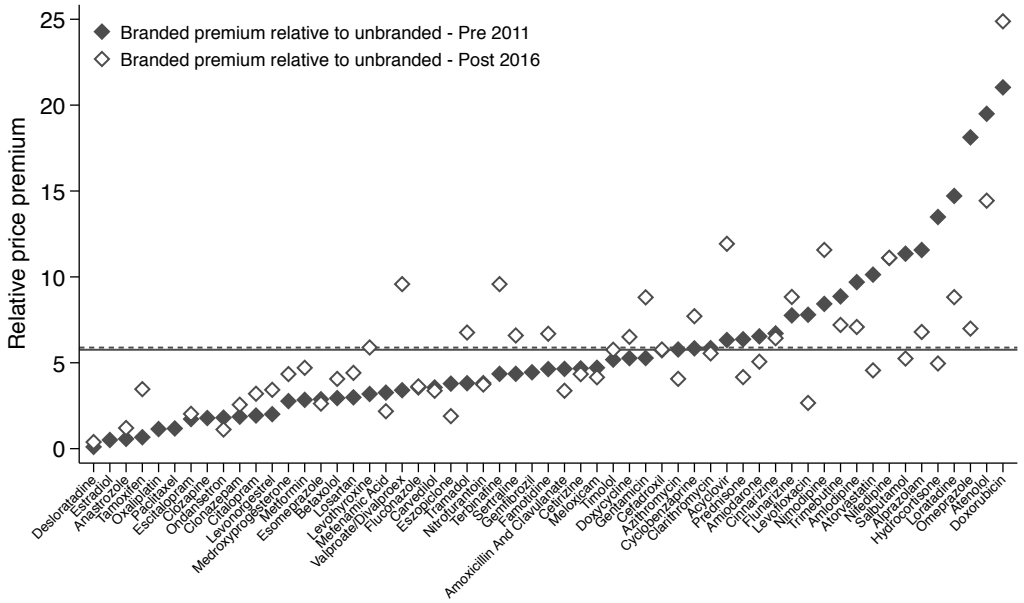


Notes: This figure displays the evolution of market shares of different drug types over time. For each type, we plot the average market share across markets for each month in our sample.

Figure 5: Innovator and Branded Drugs Price Premiums by Market



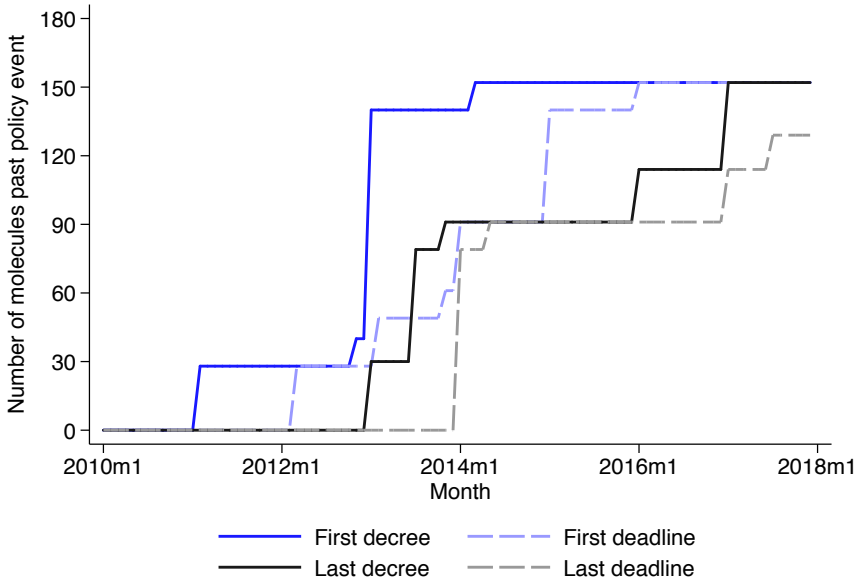
(a) Innovator drugs price premiums relative to unbranded generics



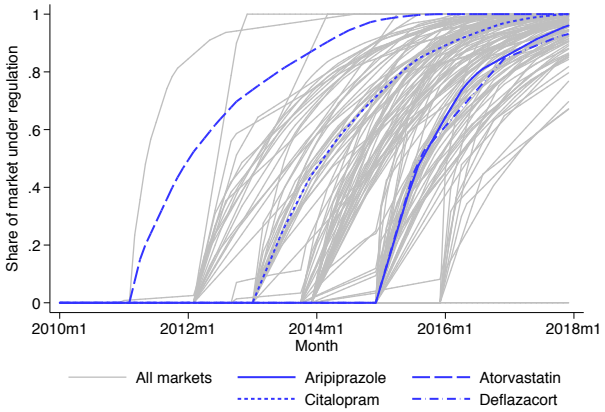
(b) Branded drugs price premiums relative to unbranded generics

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.

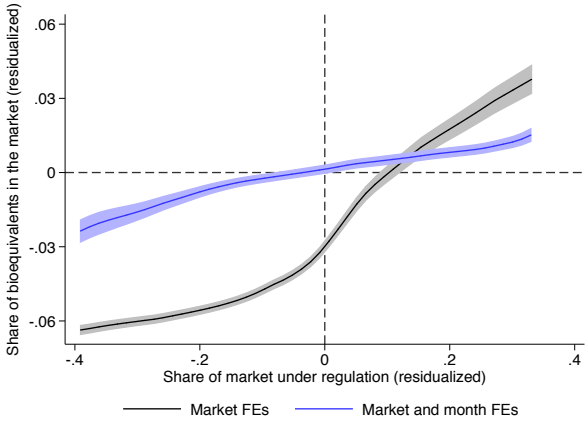
Figure 6: Evolution of Quality Regulation



(a) Timing of bioequivalence decrees and deadlines



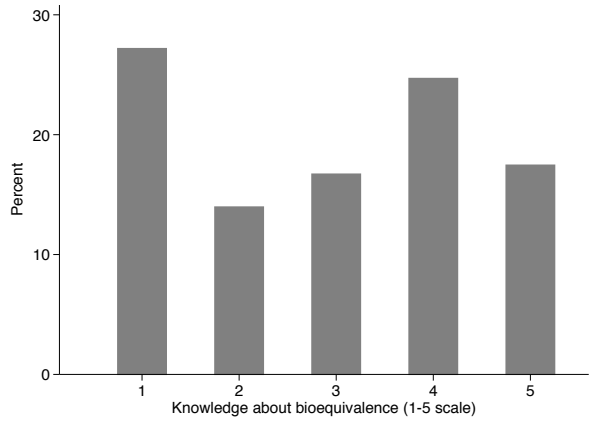
(b) Evolution of quality regulation by market



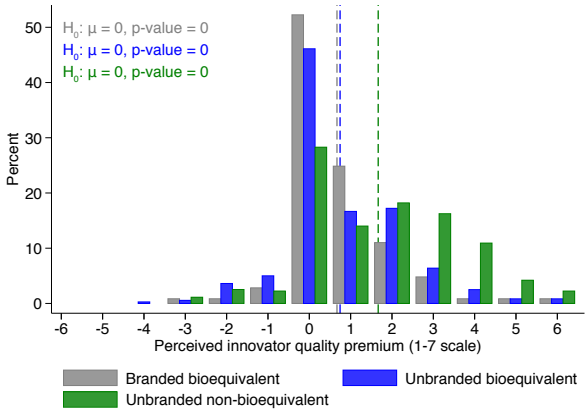
(c) Quality regulation and share of bioequivalent drugs

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.

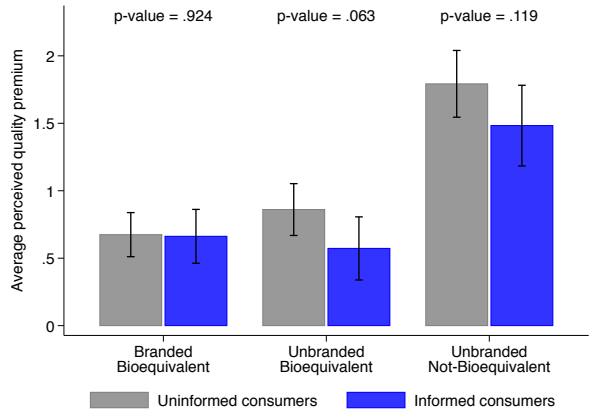
Figure 7: Survey Results



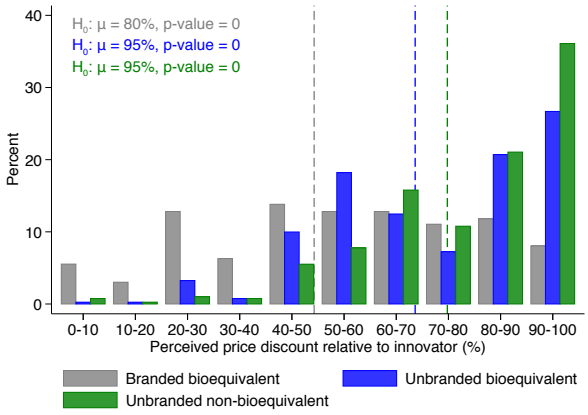
(a) Knowledge about bioequivalence



(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. 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: Determinants of Bioequivalence Certification and and Drug Exit

	Panel A: Bioequivalence		*Panel B: Exit*	
	(1)	(2)	(3)	(4)
After first decree	2.01***	2.03***	-0.14	-0.25
	(0.32)	(0.34)	(0.28)	(0.33)
After first deadline	0.85***	0.86***	0.50***	0.75***
	(0.12)	(0.14)	(0.18)	(0.22)
After last decree	-0.03	0.06	0.56***	0.55**
	(0.12)	(0.14)	(0.22)	(0.25)
After last deadline	-0.33***	-0.06	-0.33	-0.24
	(0.11)	(0.16)	(0.22)	(0.26)
Innovator			-0.58***	-0.65***
			(0.16)	(0.18)
Branded generic	-0.28***	-0.34***	0.26*	0.35**
	(0.08)	(0.09)	(0.14)	(0.16)
Imported	0.61***	0.71***	1.29***	1.32***
	(0.07)	(0.08)	(0.11)	(0.13)
log(Market revenue, 2010)	0.39***		-0.07	
	(0.04)		(0.05)	
log(Number of branded, 2010)	-0.24***		0.08	
	(0.04)		(0.07)	
log(Number of unbranded, 2010)	-0.26***		-0.07	
	(0.05)		(0.08)	
Observations	228,652	228,652	3,241	3,101
Market FE	N	Y	N	Y
Month FE	Y	Y	Y	Y
$\ln L$	-5,097	-4,867	-1,415	-1,303

Notes: This table displays results from hazard models in equation (1) for bioequivalence approval and logit models for drug exit. Estimation is implemented by maximum likelihood. The omitted drug type in all specifications is unbranded generics. Note that the sample in columns (3) and (4) is the cross section of drugs in the market, as the focus is on their first renewal or exit decision. All specifications include month-year fixed effects, whereas columns (2) and (4) also include molecule 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 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 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 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 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 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 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.

Table 8: Effects of Quality Regulation on Market Structure: Drug Quality

	(1)	(2)	(3)	(4)
	Drug adverse effects			Drug
	Admissions	Hospital days	Surgeries	recalls
Panel A: Average effects				
Share of market under regulation	-0.023	-0.120	-0.000	0.001
	(0.023)	(0.112)	(0.000)	(0.001)
R^2	0.849	0.869	0.142	0.223
Panel B: Heterogeneity by market size				
Share of market under regulation × Low revenue	-0.072	-0.235	-0.000	0.003
	(0.071)	(0.224)	(0.000)	(0.003)
Share of market under regulation × High revenue	0.022	-0.016	-0.000	-0.001
	(0.024)	(0.014)	(0.000)	(0.002)
R^2	0.850	0.871	0.142	0.224
Pre-regulation average	0.073	0.132	0.000	0.000
Observations	568	568	568	1021
Market FE	Y	Y	Y	Y
Month FE	Y	Y	Y	Y

Notes: Each column in this table is an outcome related to drug quality on the policy roll-out variable constructed using the first decree deadline, as in equation (6). Outcomes are constructed as the ratio of the variable of interest over drug sales measured in thousands of daily doses. Columns (1) through (3) are related to adverse health effects, whereas Column (4) is related to drug recalls, and in particular include all recalls. 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.

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Quality Regulation and Competition: Evidence from Pharmaceutical Markets

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A Model Simulation

A.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:

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

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.[53]

Demand Side. First, we assume that ε_{il} 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

[53] 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.

imply that market shares take the mixed logit form:

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

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

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

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

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

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:

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

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:

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

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:

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

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
κ_{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.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 ($\kappa_{QC} > 0$),

$$M s_G p_G - C_G(\hat{\psi}) - \kappa_{QC} = 0.$$

Let us consider how a change in κ_{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

$$\frac{\partial \hat{\psi}}{\partial \kappa_{QC}} = \left[M p_G \left(\frac{\partial s_G}{\partial n_G} \frac{\partial n_G}{\partial \hat{\psi}} + \frac{\partial s_G}{\partial \bar{\psi}} \frac{\partial \bar{\psi}}{\partial \hat{\psi}} \right) - C'_G(\hat{\psi}) \right]^{-1},$$

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,

$$\begin{aligned} 0 &= M_0 p_G^* s_G^* - C_G(\hat{\psi}^*) - \kappa_{QC} \\ 0 &= M_1 p_G^* s_G^* - C_G(\hat{\psi}^*) - \kappa_{QC} - FC, \end{aligned}$$

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.[54] 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.

B 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

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

the following endpoint restrictions:[55]

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

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 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.

C Description of Consumer Survey

C.1 Methodology and Results

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. The questionnaire is displayed in Section C.2 below.

[55] 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.

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.8.

The final sample includes $N = 401$ consumers. Table A.7 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.

C.2 Questionnaire

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

1. [Show pictures of four drugs] Consider a scale of 1 to 7, where 1 is a drug of the minimum quality and that does not have the desired therapeutic effects and 7 is a drug of the highest quality that has exactly the expected therapeutic effects. What level of quality do you think

the following drug has?

- Innovator
- Bioequivalent unbranded generic
- Unbranded generic
- Bioequivalent branded generic

2. [Show pictures of 4 drugs] If the price of the innovator drug is $50,000. What price do you think each of these drugs has?

   - Bioequivalent unbranded generic
   - Unbranded generic
   - Bioequivalent branded generic

3. [Show pictures of innovator and bioequivalent unbranded generic] If you were buying a box of Atorvastatin and were offered these two drugs. The innovator is priced at $50,000 in pharmacies. What do you think is the price of this generic?

4. [Show pictures of innovator and unbranded generic] If you were buying a box of Atorvastatin and were offered these two drugs. The innovator is priced at $50,000 in pharmacies. What do you think is the price of this generic?

5. [Show pictures of innovator and bioequivalent branded generic] If you were buying a box of Atorvastatin and were offered these two drugs. The innovator is priced at $50,000 in pharmacies. What do you think is the price of this generic?

6. [Show bioequivalence label] Have you ever seen this label on a drug before this survey?

   - Yes
   - No

7. [Do not read, use the following scale] Do you know what it means for a generic drug to be bioequivalent?

   - Very good response: Bioequivalence implies that two drugs have exactly the same therapeutic effects as the original
   - Good response: The generic is the same as the innovator
   - Regular response: A vague answer in terms of the quality of both drugs
   - Bad response: They are part of the same group of medications (e.g. both are Atorvastatin)
   - He has no idea: He does not know, he has no idea, he has not heard

8. When doctors deliver prescriptions, do they generally prescribe drugs by specifying a particular brand or without specifying a brand?
    - Prescribe drug without a specific brand
    - Prescribe drug with a specific brand
    - Does not know
9. When buying a prescription drug at a pharmacy, how much does your doctor, the pharmacist who serves you, and yourself weight in deciding which version of the medication to buy? In particular, on a scale of 1 to 5, where 1 is no power and 5 is a lot of power, how much power they have:
    - Doctor
    - Pharmacist
    - Customer
10. What type of drug did you buy the last time you needed one?
    - Innovator
    - Bioequivalent unbranded generic
    - Unbranded generic
    - Bioequivalent branded generic
    - Do not remember
    - Never purchased
11. Do you or anyone in your home take any drug for a chronic illness?
    - Yes
    - No
12. Do you or anyone in your household take any drug to control cholesterol?
    - Yes
    - No
13. What type of drug do you choose when you buy this medication for cholesterol control?
    - Innovator
    - Bioequivalent unbranded generic
    - Unbranded generic
    - Bioequivalent branded generic

- Do not remember
- Never purchased

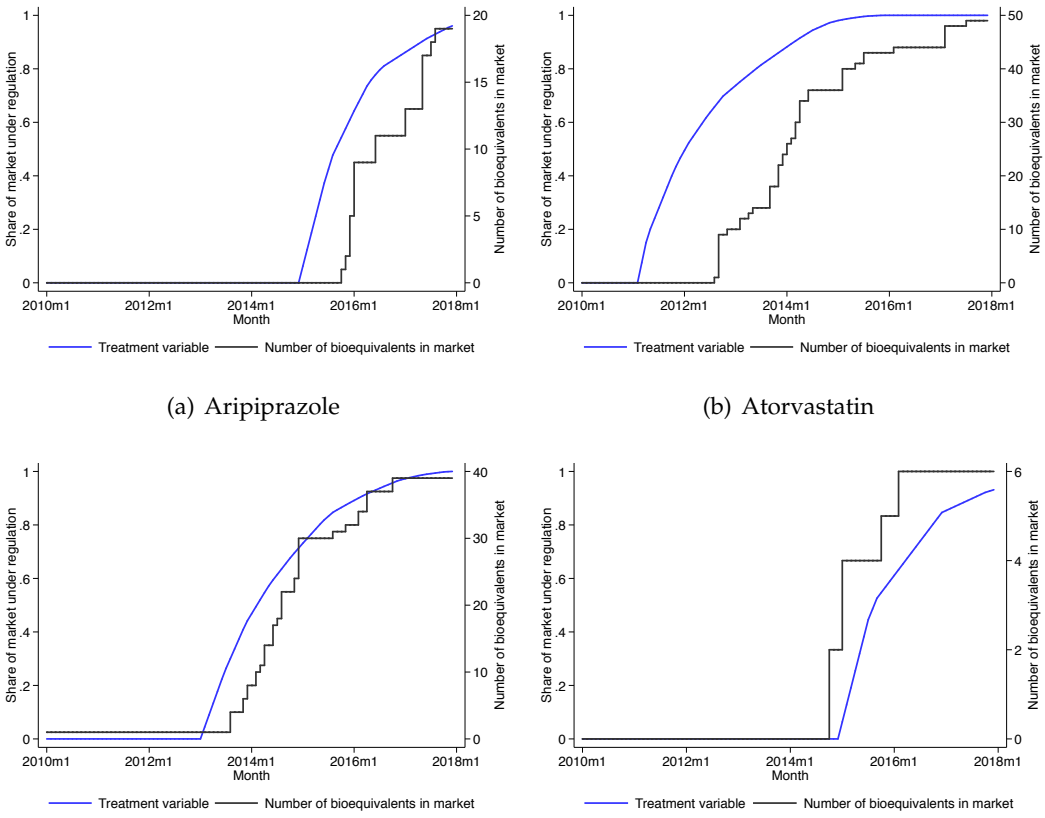
Figure A.1: Labeling of Bioequivalent Drugs

(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

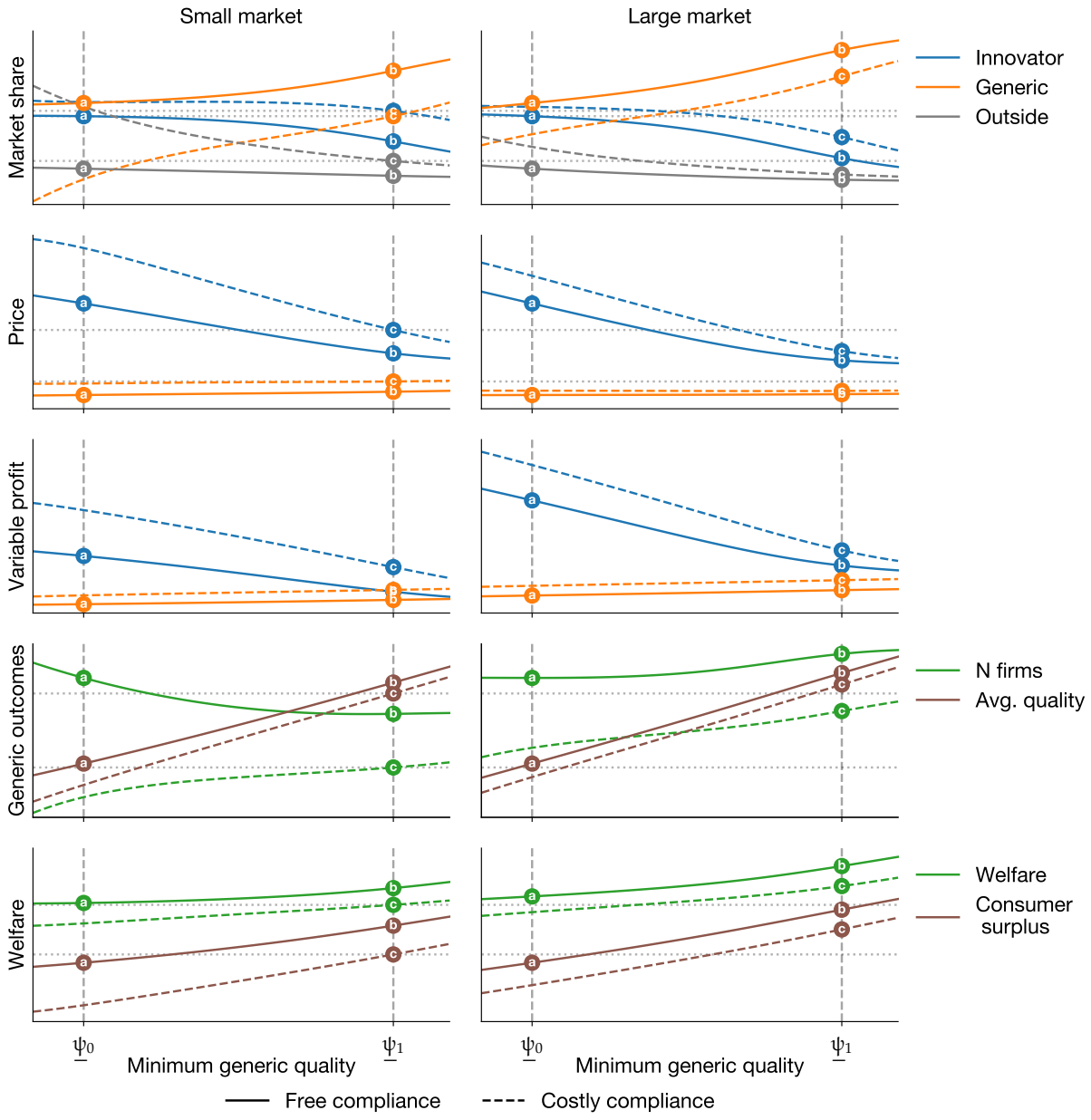
(b) Atorvastatin

(c) Citalopram

(d) Deflazacort

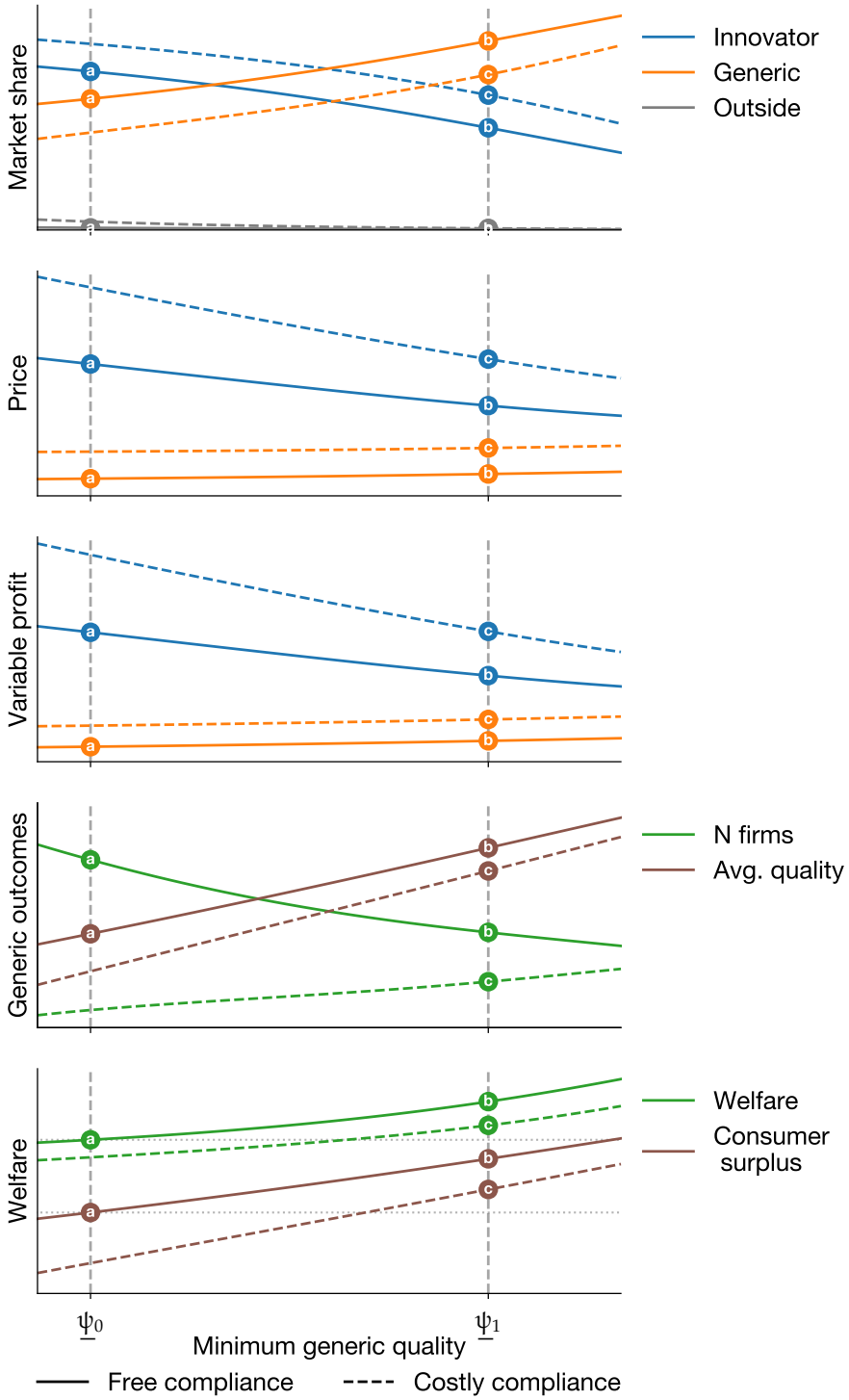
Notes: Each figure displays the values of the treatment variable and the number of BEs in a different market. This version of the treatment variable uses the first deadline as the relevant date. The instrument is displayed in blue, and takes a value of 0 before the first decree, and then increases as 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



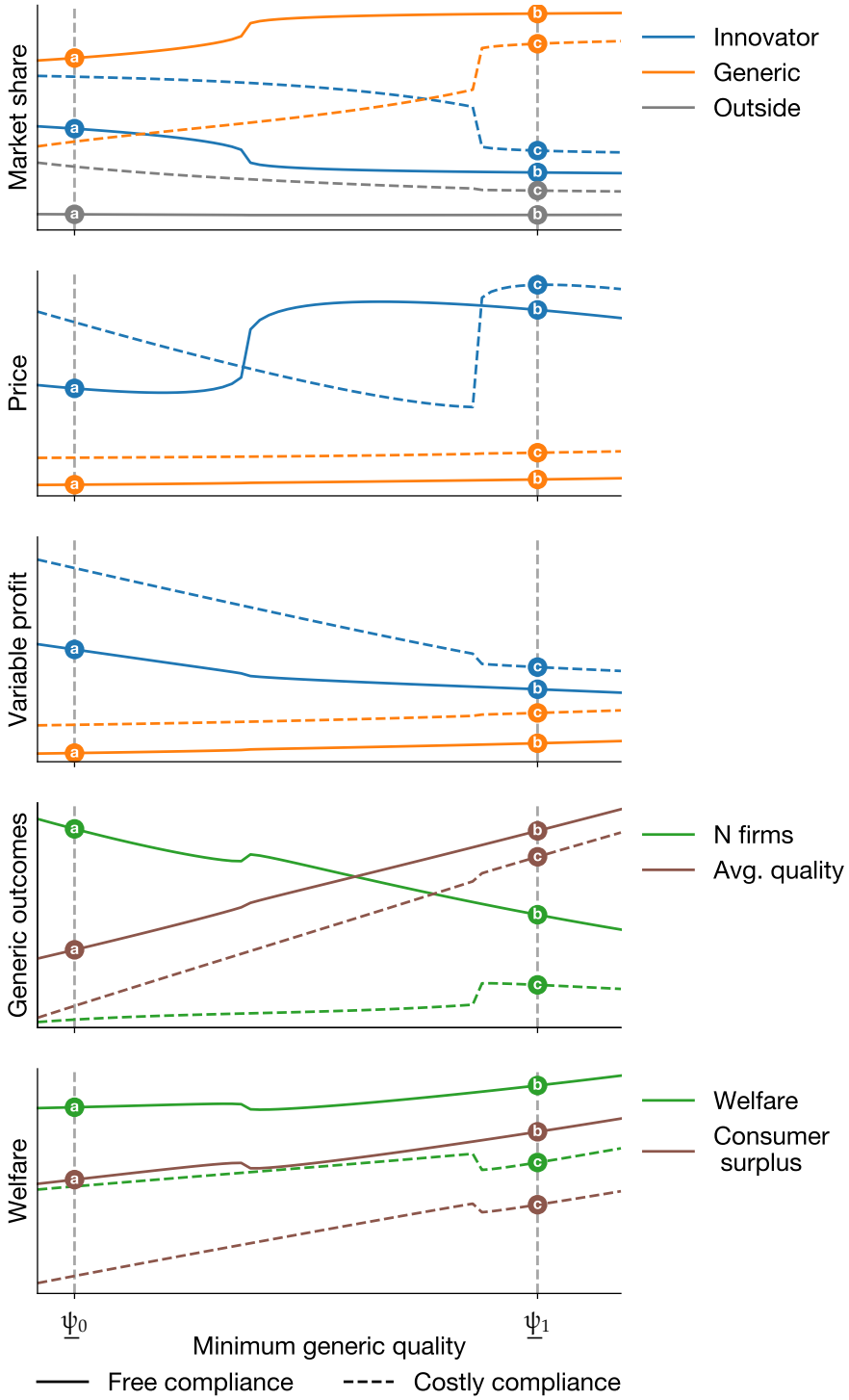
Notes: Market outcomes for different levels of minimum quality in a small market (left column) and large market (right column). The dashed (solid) lines represent a situation with (no) compliance costs. Example minimum qualities before and after regulation are indicated by $\underline{\psi}_0$ and $\underline{\psi}_1$, 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



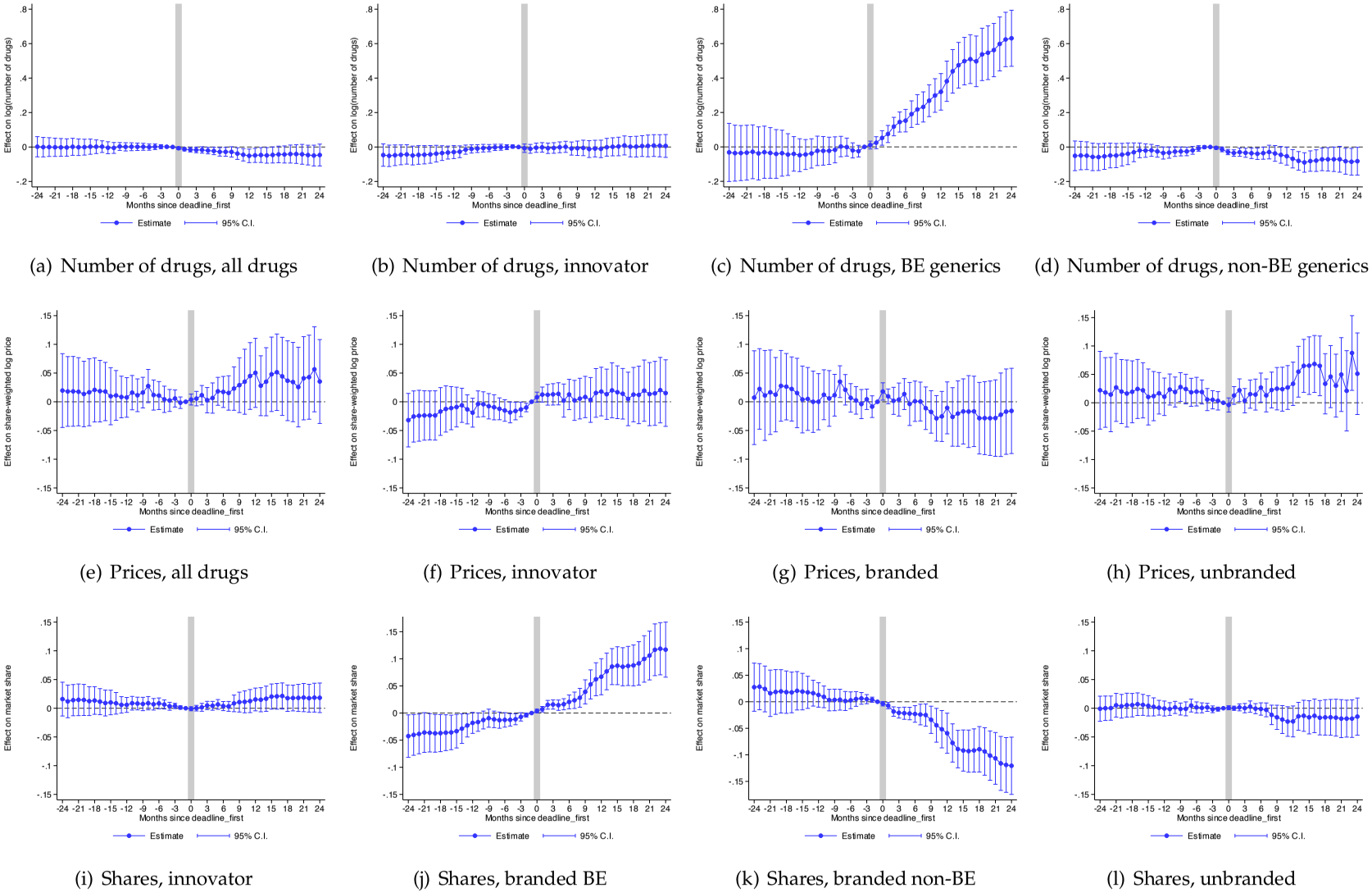
Notes: Market outcomes for different levels of minimum quality in the market. The dashed (solid) lines represent a situation with (no) compliance costs. Example minimum qualities before and after regulation are indicated by $\underline{\psi}_0$ and $\underline{\psi}_1$, where point **a** indicates pre-reform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



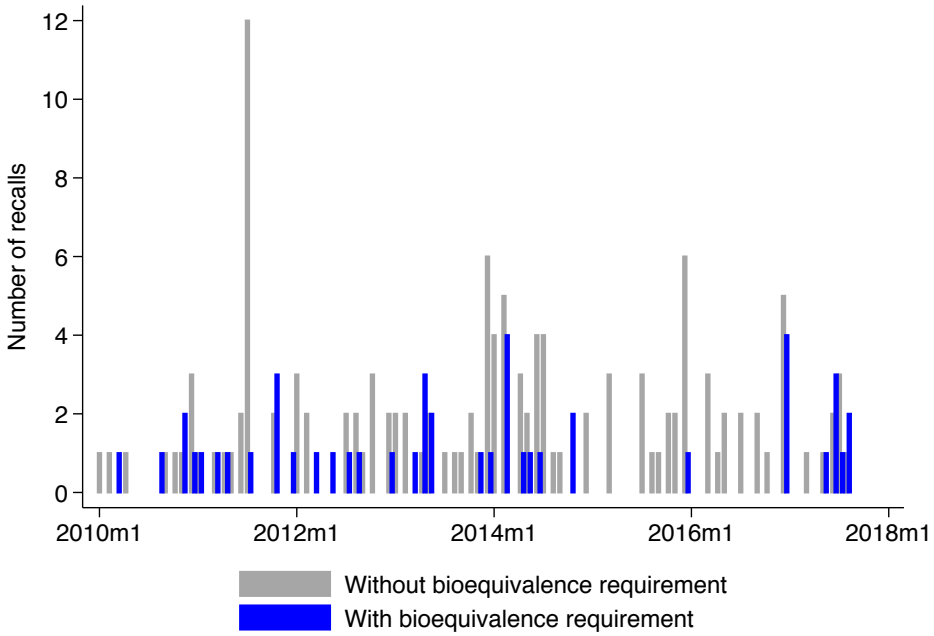
(a) Number of drugs, all drugs (b) Number of drugs, innovator (c) Number of drugs, BE generics (d) Number of drugs, non-BE generics

(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 B, 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: Number of Recalls per Month



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

Figure A.8: 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: Policy roll-out groups, molecules and treatments

Group	Molecule	Treatment
1	Acenocumarol	Anticoagulant
1	Acido Valproico	Anticonvulsant
1	Atazanavir	HIV antiviral
1	Atorvastatina	Statin
2	Cefadroxilo	Antibiotic
2	Ciprofloxacino	Antibiotic
2	Clomifeno	Infertility
2	Clomipramina	Antidepressant
2	Clonazepam	Anxiety
2	Digoxina	Antiarrhythmic
2	Furosemida	Diuretic
2	Glibenclamida	Diabetes Mellitus
2	Isosorbida Dinitrato	Chest pain
2	Lamivudina	HIV antiviral
2	Losartan	High blood pressure
2	Metformina	Diabetes Mellitus
2	Metoclopramida	Gut motility stimulator
2	Metotrexato	Cancer
2	Micofenolato Mofetilo	Immunosuppressive
2	Nevirapina	Antiviral
2	Ritonavir	Antiviral
2	Tacrolimus	Immunosuppressive
2	Tenofovir	Antiviral
2	Verapamilo	High blood pressure
3	Alprazolam	Anxiety
3	Atenolol	High blood pressure
3	Darunavir	HIV antiviral
3	Diazepam	Anxiety
3	Enalapril	High Blood Pressure / Heart Failure
3	Espironolactona	Diuretic
3	Fluoxetina	Antidepressant
3	Hidroclorotiazida	Diuretic
3	Propranolol	High blood pressure
3	Salbutamol	Bronchodilator
3	Tamoxifeno	Cancer
4	Aciclovir	Antiviral
4	Acido Mefenamico	Analgesic / Antiinflamatory
4	Amiodarona	Antiarrhythmic
4	Amoxicilina+Clavulanico	Antibacterial
4	Azitromicina	Antibacterial
4	Cefuroxima	Antibiotic
4	Celecoxib	Analgesic / Antiinflamatory
4	Ciclobenzaprina	Muscle Relaxant
4	Claritromicina	Antibiotic
4	Clorpromazina	Antipsychotic
4	Clozapina	Mental disorders
4	Estradiol	Contraceptive
4	Famotidina	Gastric Ulcer and Reflux
4	Fluconazol	Anfifungal
4	Gemfibrozilo	High cholesterol
4	Lorazepam	Anxiety
4	Metilfenidato	Central nervous system stimulant
4	Metronidazol	Antibiotic / Antiparasitic
4	Midazolam	Sedative
4	Montelukast	Antiallergic / Anti-Asthmatic
4	Nitrofurantoina	Antibiotic
4	Olanzapina	Antipsychotic
4	Ondansetron	Antiemetic
4	Zidovudina+Lamivudina	HIV antiviral
4	Zopiclona	Insomnia
5	Amitriptilina	Nerve pain and antidepressant
5	Cetirizina	Antiallergic
5	Citalopram	Antidepressant
5	Desloratadina	Antiallergic
5	Diltiazem	High blood pressure / Angine
5	Donepecilo	Alzheimer
5	Doxazosina	Benign prostatic hyperplasia / High blood pressure
5	Escitalopram	Antidepressant
5	Fexofenadina	Antiallergic
5	Finasterida	Benign prostatic hyperplasia
5	Loratadina	Antiallergic
5	Mirtazapina	Antidepressant
5	Paroxetina	Antidepressant
5	Rivastigmina	Dementia
5	Sertralina	Antidepressant
5	Sildenafil	Erectile dysfunction
5	Terbinafina	Antifungal
5	Trimebutina	Antispasmodic
5	Valaciclovir	Antiviral
5	Zolpidem	Insomnia
6	Acido Ibandronico	Osteoporosis
6	Betahistina	Vertigo
6	Deflazacort	Corticotherapy
6	Hidroxicloroquina	Antimalarial
6	Levofloxacino	Antibiotic
6	Naratriptan	Migraine
6	Pramipexol	Parkinson's disease
6	Pregabalina	Anticonvulsant / Neuralgia
6	Quetiapina	Mental disorders
6	Telmisartan	High blood pressure
7	Aripiprazol	Antipsychotic
7	Atomoxetina	Antidepressant
7	Carvedilol	High Blood Pressure / Heart Failure
7	Cilostazol	Vasodilator
7	Clopidogrel	Blood thinner
7	Haloperidol	Mental disorders
7	Isotretinoina	Acne
7	Lamotrigina	Anticonvulsant / Mood stabilizer
7	Meloxicam	Analgesic / Antiinflamatory
7	Moxifloxacino	Antibiotic
7	Nebivolol	High blood pressure
7	Olmesartan	High blood pressure
7	Risperidona	Mental disorders
7	Topiramato	Anticonvulsant
7	Valsartan	High blood pressure
8	Alendronato	Osteoporosis
8	Bromazepam	Anxiety
8	Candesartan	Antihypertensive
8	Cinarizina	Antihistamine
8	Flunarizina	Migraine
8	Leflunomida	Arthritis
8	Levetiracetam	Anticonvulsant / Mood stabilizer
8	Levocetirizina	Antiallergic
8	Levonorgestrel	Contraceptive
8	Lovastatina	Statin
8	Medroxiprogesterona	Hormone Imbalance
8	Nifedipino	Antihypertensive
8	Nimodipino	Antihypertensive
8	Nitrendipino	High blood pressure / Angine
8	Sulpirida	Antipsychotic
8	Tibolona	Hormone replacement therapy
9	Acetazolamida	Diuretic
9	Captopril	High Blood Pressure / Heart Failure
9	Colchicina	Antiinfalamtory
9	Griseofulvina	Antifungal
9	Imipramina	Nerve pain and antidepressant
9	Metildopa	High blood pressure
9	Nistatina	Antifungal
9	Tetraciclina	Antibiotic
9	Tinidazol	Anti-parasite and antibiotics
9	Tioridazina	Antipsychotic

Notes: This Table displays the list of molecules included in the sample used for the analysis in the paper, including its group withing the policy roll-out and the treatment of each of them. The 9 policy roll-out groups are the same as in Table 1.

Table A.2: Determinants of Assignment of Bioequivalence Decrees to Molecules

	(1)	(2)	(3)	(4)	(5)	(6)	(7)
	Ordered logit for Policy Assignment Groups						
Branded generic market share	-1.585***	-1.587***	-1.996***	-2.515***	-2.236**	-2.310***	-2.076**
	(0.615)	(0.615)	(0.705)	(0.841)	(0.874)	(0.884)	(0.907)
Unbranded generic market share	-0.844	-0.896	-1.808**	-2.037**	-1.518	-1.509	-1.265
	(0.544)	(0.549)	(0.806)	(0.921)	(0.975)	(0.978)	(1.023)
Δ% Branded generic market share		0.052	0.052	0.065	0.078	-0.451	-0.424
		(0.097)	(0.098)	(0.099)	(0.100)	(0.394)	(0.412)
Δ% Unbranded generic market share		-0.181	-0.322	-0.349	-0.360	-0.332	-0.288
		(0.305)	(0.321)	(0.319)	(0.322)	(0.317)	(0.320)
Any branded generic			0.548	0.304	0.332	0.319	0.406
			(0.553)	(0.723)	(0.728)	(0.728)	(0.735)
Any unbranded generic			0.745	0.662	0.699	0.563	0.706
			(0.534)	(0.637)	(0.640)	(0.648)	(0.667)
log(Number of drugs)				0.382	0.497	0.483	0.461
				(0.369)	(0.385)	(0.384)	(0.393)
log(Number of labs)				0.005	-0.323	-0.301	-0.234
				(0.559)	(0.604)	(0.599)	(0.615)
HHI of drug types				0.925	0.661	0.541	0.753
				(1.034)	(1.046)	(1.062)	(1.085)
log(Market revenue)					0.260	0.237	0.225
					(0.240)	(0.239)	(0.240)
log(Average price)					0.121	0.090	0.073
					(0.081)	(0.083)	(0.085)
Δ% Average price						1.081	1.033
						(0.785)	(0.817)
Share imported							0.743
							(0.783)
Chronic							0.149
							(0.338)
Observations	131	131	131	131	131	131	131
Pseudo R^2	0.0123	0.0135	0.0198	0.0248	0.0303	0.0337	0.0359

Notes: This table displays results from ordered logit models for the policy groups defined in Table 1. The analysis is implemented using the cross section of molecules in the sample for 2010, before the first decree for the first group. Percentage changes in variable measure the change between 2011 and 2010 relative to the baseline level of the variable in 2010. A caveat with this definition is that the first decrees occur in 2011. However, lack of data for 2009 limit the extent to which we can compute growth rates for these variables using data from before the first policy events. Positive coefficients indicate that molecules with a higher value in that variable had a higher likelihood of being assigned to an earlier policy group. Standard errors in parentheses. *p<0.10, **p<0.05, ***p<0.01.

Table A.3: Heterogeneity in Determinants of Bioequivalence Certification and and Drug Exit

	Panel A: Bioequivalence		*Panel B: Exit*	
	(1)	(2)	(3)	(4)
After first deadline	2.46***	1.67***	0.57	0.97
	(0.38)	(0.55)	(0.54)	(0.70)
× Above median revenue, 2010		1.10**		-1.68**
		(0.54)		(0.76)
Above median revenue, 2010		-0.13		-0.97**
		(0.52)		(0.46)
Reference			0.16	0.71
			(0.41)	(0.47)
Imported	0.46***	0.42***	1.24***	1.16***
	(0.12)	(0.12)	(0.38)	(0.41)
log(Market revenue, 2010)	0.62***	0.52***	-0.32*	-0.22
	(0.11)	(0.11)	(0.19)	(0.19)
log(Number of branded, 2010)	-0.22*	-0.16	0.26	0.25
	(0.13)	(0.13)	(0.24)	(0.23)
log(Number of unbranded, 2010)	-0.23**	-0.21**	0.53*	0.46*
	(0.10)	(0.10)	(0.29)	(0.28)
Month FE	Y	Y	Y	Y
Observations	63,047	63,047	535	535
$\ln L$	-1,336	-1,316	-175	-159

Notes: This table displays results from hazard models in equation (1) for bioequivalence approval and logit models for drug 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 by maximum likelihood. The omitted drug type in all specifications is unbranded generics. Note that the sample in columns (3) and (4) is the cross section of drugs in the market, as the focus is on their first renewal or exit decision. 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.4: 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 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.5: 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 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.6: 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 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.7: 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.