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ABSTRACT

We study the equilibrium effects of quality regulation on market outcomes by exploiting the staggered phase-in of bioequivalence requirements for generic drugs in Chile. While the objective of the regulation was to increase the perceived quality of generics to reduce vertical differentiation and enhance price competition, we find mostly adverse effects. Even if a large number of drugs obtained the quality certification mandated by the regulation, we estimate that the number of drugs in the market decreased by 13% as a result of the policy. Moreover, we find that prices increased on average by 13% as well as no significant effects on the market share of generics. These adverse effects were mostly concentrated in molecules with small market size. Put together, our results suggest that the intended effects of the regulation on competition through increased (perceived) quality of generics were overturned by adverse competitive effects arising from the costs of complying with the regulation.

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RESUMEN

En este artículo estudiamos los efectos que introducir regulaciones de la calidad tiene en el equilibrio del mercado, para lo cual hacemos uso de la introducción gradual de requisitos de bioequivalencia para medicamentos genéricos en Chile. Si bien el objetivo de la regulación era aumentar la calidad percibida de los genéricos para reducir la diferenciación y aumentar la competencia en precios, se encontraron mayoritariamente efectos adversos. A pesar de que un gran número de medicamentos obtuvo la certificación de calidad exigida por la regulación, estimamos que el número de medicamentos en el mercado disminuyó en un 13% como resultado de la política. Además, encontramos que los precios aumentaron en promedio en un 12% y que no se obtuvieron efectos significativos en la participación de mercado de los genéricos. Estos efectos adversos se concentraron principalmente en moléculas con mercados pequeños. En suma, nuestros resultados sugieren que los efectos esperados de la regulación en la competencia, resultantes de una mayor calidad (percibida) de los genéricos, fueron revertidos por factores competitivos adversos derivados de los costos de cumplir con la regulación.

Quality Regulation and Competition: Evidence from Pharmaceutical Markets*

Juan Pablo Atal† José Ignacio Cuesta‡ Morten Sæthre§

Abstract

We study the equilibrium effects of quality regulation on market outcomes by exploiting the staggered phase-in of bioequivalence requirements for generic drugs in Chile. While the objective of the regulation was to increase the perceived quality of generics to reduce vertical differentiation and enhance price competition, we find mostly adverse effects. Even though a large number of drugs obtained the quality certification mandated by the regulation, we estimate that the number of drugs in the market decreased by 13% as a result of the policy. Moreover, we find that prices increased on average by 12% as well as no significant effects on the market share of generics. These adverse effects were mostly concentrated in molecules with small market size. Put together, our results suggest that the intended effects of the regulation on 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, L65

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1 Introduction

Increased penetration of generic drugs has been one of the major sources of health care cost savings in the U.S. in recent decades (Grabowski et al., 2006). After a variety policies incentivizing generic adoption and the expiration of several patents, the market share of generics among retail and mail order dispensed drugs in the U.S. rose from 34% in 1994 to 87% in 2015 (Berndt et al., 2017). However, generic penetration has developed at a slower pace in low and middle income countries (UN, 2010).

Quality regulation is considered a key precondition for the success of policies to foster the penetration of generic drugs (WHO, 2000). Weak quality regulation undermines physician and patient trust in generics, and may limit their role in enhancing price competition due to perceived quality differences. Governments introducing quality regulation in pharmaceutical markets expect to ensure drug quality, improve perceived quality of generics and foster 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 that the regulation may have through reducing perceived quality differences between innovators and generics. The equilibrium market outcomes of quality regulation policies are therefore the result of an interplay between reduced vertical differentiation and changes in market structure due to costly compliance.

In this paper, we study the equilibrium effects of quality regulation policies in pharmaceutical markets by exploiting the recent roll-out of bioequivalence requirements for generics in Chile. At the onset of this policy, unbranded generics accounted for less than 30% of total retail sales in the country, despite the fact that they were on average 6 and 10 times cheaper than branded generics and innovator drugs respectively. The primary objectives of the reform were to increase the perceived quality of generics and to enhance price competition. This reform to quality regulation took the form of a set of bioequivalence requirements; the most prevalent quality standard for generics in developed countries and the basis of quality assurance policies prescribed for low and middle income countries. An innovator drug can be substituted by a generic meeting the bioequivalence standard with the full expectation that the substitute will produce the same safety effect and safety profile.[1] After the reform, generics without bioequivalence certification were not allowed to stay in the market.

We measure the effects of the reform to quality regulation on drug prices, market shares, and market structure, with a particular focus on heterogeneity across drug types. For this purpose, we combine administrative data on entry and exit from the national drug registry of Chile with

[1]More precisely, a generic drug is bioequivalent to its reference innovator counterpart when its rate and extent of absorption are not significantly different from 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 Waxman-Hatch Act in 1984, which allowed generics seeking marketing approval to submit proof of bioequivalence to the the reference drugs in lieu of pre-clinical (animal) and clinical (human) testing on safety and efficacy.

price and sales data from IMS Health for 2010–2017. Our empirical strategy exploits the staggered implementation of the reform during this time period, as well as features of its enforcement, to compare outcomes across and within markets (molecules) with different levels of exposure to the regulation. This strategy provides reduced form results regarding the overall effects of the policy on equilibrium market outcomes. We interpret our results using a model where innovator and generic drugs compete in prices in an environment where consumers only imperfectly observe the quality of generic drugs before the regulation.

We start by providing evidence that stronger quality regulation induced drugs to obtain bioequivalence certification. We find that drugs were almost 4 times more likely to obtain bioequivalence certification after bioequivalence requirements are put in place. Moreover, we show that certification was more frequent in more profitable and less competitive markets. These results are in line with previous research studying the entry of generics after patent expiration in the U.S., which highlights the importance of market variables in entry decisions (Scott Morton, 1999, 2000). This paper expands this evidence by studying the Chilean context and a different set of regulations, where generic drugs that are already in the market face the decision of whether or not to continue producing under the new regulatory environment.

We then turn to analyze the effects of the regulation on market structure and other relevant market outcomes. First, we find that bioequivalence requirements changed the market structure by inducing a decrease of the number of drugs in the market. Our estimates indicate that the total number of drugs in the market decreased by around 13% after the regulation was fully phased in. Second, we find that bioequivalence requirements affected drug prices significantly. We find a 12% increase in sales-weighted average drug prices, most of which was due to drug-specific price increases rather than due to changes in market shares or to compositional changes as a result of entry and exit. Third, we provide evidence that stronger quality regulation shifted sales from branded generics to innovator drugs. Most of these effects are concentrated in small markets: In markets with below-median revenues we find higher exit, increases in average drug prices were as high as 27% and the market share of innovator drugs increased by 8 p.p. Conversely, we find no effect on prices nor on markets shares in large markets.

Overall, our results suggest that any direct effect of the increased intensity of price competition due to decreased scope for (perceived) quality differentiation were in equilibrium overturned by indirect adverse competitive effects due to drug exit. Our results on heterogeneity of these effects across markets of different size reinforces this interpretation, and suggests that fixed costs to comply with the regulation played a significant role in determining these outcomes.

We complement our main analysis with survey data from a sample of consumers in the market. Our survey provides suggestive evidence that a variety of demand-side frictions may continue to undermine the ability of the regulation to generate its intended effects. In particular, we find that our interviewees (i) lack an appropriate understanding of what bioequivalence means and continue to place substantial perceived quality premiums on innovator drugs several years after

the policy change, (ii) underestimate price differences between innovators, branded generics and unbranded generics, and (iii) frequently declare that their physicians prescribe by the brand name. While these results come from a small sample of consumers, they are suggestive of barriers that may reduce incentives for laboratories manufacturing generics to enter or remain in the market in the presence of fixed costs to complying with the regulation. The lessons from our survey suggest that policies complementary to quality regulations (like consumer information policies or the regulation of prescription behavior) may be necessarily to increase generic penetration and competition in this context.

This paper complements other empirical evaluations of quality regulations on market outcomes that highlight the potential for unintended consequences of quality regulation under costly compliance. Several studies evaluate input regulations in child-care services (Chipty 1995; Chipty and Witte 1997; Currie and Hotz 2004; Blau 2007; Hotz and Xiao 2011, among others) .[2] In line with our findings, these studies show that quality regulations induce exit with potentially harmful crowd-out effects towards other unregulated forms of child care. We contribute to this literature with an application to pharmaceutical markets, and in a setting of direct quality regulation instead of input regulation. Moreover, we are able to evaluate the price effects of such regulations, a key market outcome. Directly related to our setting, we complement an early exploration of the price effects of the bioequivalence requirements in Chile by Balmaceda et al. (2015), who estimate the short term effects of the reform on drug prices. We complement their evidence in several dimensions, particularly by evaluating effects on market structure, sales and quality outcomes after the full implementation of the policy. [3]

We also contribute to the empirical literature on quality disclosure (Dranove and Jin, 2010; Jin and Leslie, 2003). The policy we study introduces a label with the intention to change consumers' perceived drug quality. However, unlike a purely informational policy (as in the report cards analyzed in Jin and Leslie 2003), the label introduced in our setting is coupled with a minimum quality standard that must be certified and which may induce exit.

Finally, our paper is also related to a large literature analyzing the effect of regulatory policies on pharmaceutical markets. While most of this research focuses on the equilibrium implications of price regulation for pharmaceutical markets (Danzon and Chao, 2000; Dubois and Lasio, 2018), the implications of quality regulation have received less attention. To our knowledge, this is the first paper to measure the overall market effects of introducing bioequivalence requirements –one of the most commonly adopted policy instruments for drug quality assurance. Moreover, we build

[2] A broader empirical literature on quality regulation studies the effects of occupational licensing. See e.g., Larsen (2015) for a recent review of this literature.

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

on a large (and yet inconclusive) empirical literature analyzing competition between innovator and generic drugs, which has primarily focused on analyzing the market responses to the entry of generics when innovator drugs go off-patent (see Caves et al. 1991; Grabowski and Vernon 1992; Frank and Salkever 1997; Grabowski et al. 2006; Knittel and Huckfeldt 2012; Branstetter et al. 2016, among others). This paper relates to this literature by providing evidence coming from a regulatory change that induces generic exit, coupled with potential changes in perceived generic quality. In this line, 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). In this paper, we study the impact of a policy that sets minimum quality standards in order to reduce information asymmetries that may bias consumers against generics.

The remainder of the paper is organized as follows. Section 2 describes the institutional framework of the Chilean pharmaceutical market and bioequivalence regulation. Then, Section 3 proposes a simple conceptual framework that guides the analysis of potential effects of quality regulation, and Section 4 describes the data used in our analysis and provides several statistics that describe our setting. Section 5 provides a first set of results that analyze the extent of quality certification, as well as entry and exit choices at the drug level. Our main empirical analysis is in Section 6, where we estimate the effects on market structure and market outcomes. In Section 7, we provide evidence from survey data that sheds lights on potential mechanisms behind our findings. Finally, in Section 8 we conclude by discussing our findings and policy implications.

2 Pharmaceutical Market and Quality Regulation in Chile

2.1 Institutional Framework

Chileans spend a low share of their GDP on pharmaceuticals relative to OECD standards, at 0.9% (OECD, 2013). However, pharmaceutical spending accounts for more than half of all out-of-pocket health expenditures in the country (Cid and Prieto, 2012).

Overall, survey evidence shows that over 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 to buy a health insurance plan in the private sector, and on the specific disease to be treated.[4] 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.[5] FONASA enrollees who instead opt for receiving care in private hospitals pay procedure-specific prices negotiated between FONASA

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

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

and each provider.[6] Insurance plans in the private system do not generally include coverage for prescription drugs.

Our focus in this paper is on the retail pharmaceutical market in Chile. The institution in charge of oversight of this market is the Public Health Institute (*Instituto de Salud Pública*, ISP). Laboratories present applications to ISP in order to obtain marketing licenses for distribution in the local market. These marketing licenses have to be renewed every 5 years. ISP is also the entity in charge of drug quality assurance and has been in charge of the roll-out of the bioequivalence reform.

Two additional features of the retail pharmaceutical market in Chile may influence the workings of the bioequivalence reform. First, as opposed to the U.S., direct advertisement of prescription drugs is forbidden in the Chilean pharmaceutical market, which could in principle make consumers more price sensitive as expensive branded drugs cannot use advertisement to signal quality and boost demand.Second, the retail pharmacy sector in Chile is highly concentrated, which might affect the degree of supply-side reaction to the bioequivalence requirements. Three large pharmacy chains account for more than 90% of market share, and a fraction of their sales correspond to own-brand drugs. The remainder of the market is comprised by several small chains without national presence.[7]

2.2 Bioequivalence in the Chilean Pharmaceutical Market

Drugs within an off-patent molecule can be classified as either innovator, branded generics or unbranded generics. Innovator drugs are marketed under the name of the company that originally patented the molecule. Branded generics are non-innovators that adopt a fantasy name and are often packaged in ways as visually as attractive as innovator drugs. Branded generics compete on brand and product recognition. Finally, unbranded generics are marketed by molecule name and compete primarily on price.

Bioequivalence is established in order to demonstrate therapeutic equivalence between the generic (test) drug product and the corresponding reference drug (which normally corresponds to the innovator drug). In particular, two drugs are considered bioequivalent when the rate and extent of absorption of the test drug does not show a significant difference from the rate and extent of absorption of the reference drug when administered at the same molar dose of the therapeutic ingredient under similar experimental conditions (Davit et al., 2013).[8] Therapeutically equivalent drugs can be substituted with the full expectation that the substituted (generic or test)

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

[7]For a more detailed description of the retail pharmacy market, see Alé (2017).

[8]Bioequivalence only applies for orally-administered drugs, i.e. it does not apply to topical medications, vaccines, or any other type of drugs that are not orally administered.

product will produce the same safety effect and safety profile as the reference drug (FDA, 2017). Therefore, the establishment of bioequivalence allows bridging of pre-clinical and clinical data associated with the reference drug to the generic drug. Bioequivalence is a standard request for commercialization in most high income countries (Balmaceda et al., 2015). Moreover, many OECD countries either allow, encourage or require substitution of innovators for cheaper bioequivalent drugs (OECD, 2000). Although bioequivalence requirements were originally implemented in the developed world to foster generic entry, they have been recently adopted by low and middle income countries as the primary tool for testing the effectiveness of the drugs allowed in their markets. Prior to bioequivalence, quality standards in Chile only required generic manufacturers to follow guidelines of International Pharmacopeia books, which does not ensure therapeutic efficiency.

Bioequivalence requirements were adopted in Chile because of the low perceived quality of generic drugs. The stated goals of the bioequivalence regulation were to increase generic quality, increase competition, and reduce prices. For instance, in the early years of the reform, the Head of the National Drug Agency (*Agencia Nacional de Medicamentos*, ANAMED) stated:[9]

> "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*

A first list of active ingredients subject to bioequivalence was published in 2005 by the Chilean Ministry of Health (*Ministerio de Salud*, MINSAL). This list was originally constructed with active ingredients that were deemed to be potentially prescribed for chronic conditions included in a major reform to the public health insurance system called AUGE (Bitran et al., 2010). However, it was not until 2009 that the regulator established the technical norms for bioequivalence testing (Balmaceda et al., 2015). Bioequivalence requirements were rolled out step-wise since then, and 167 molecules were covered by this regulation by March 2018. All new drugs containing the molecule listed in each decree have to obtain bioequivalence certification before obtaining a marketing license. Each decree also specifies the deadline for bioequivalence testing among incumbent drugs already registered. Along with the sales permit, drugs with bioequivalence certification carry a distinctive label intended to serve an as indication of bioequivalence status for the consumer. We show an example of such label in Figure A.1. The cost of bioequivalence testing is in the range of $50,000 to $250,000 U.S dollars per drug, and are fully borne by the manufacturer.

In most cases, the original deadlines to show proof of bioequivalence were extended –through a series of subsequent decrees– due to the slow uptake and capacity constraints of testing laboratories. Among the molecules with bioequivalence requirement, there are 9 unique combinations

[9]This quote is taken from an article published in May, 2012 in La Tercera, and can be found in this link: https://bit.ly/2JeMuYR.

of decrees, deadlines and extensions. Table 1-A shows the dates of the first and last decree and deadlines for each of these 9 groups, as well as the number of molecules included in each group.[10] For example, group 1 includes 4 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 7-a. We exploit this variation for estimation of policy effects later in the paper.

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

3 Conceptual Framework

A body of theoretical work analyzes potential effects of quality regulation on market outcomes. Different models provide different insights depending on their assumptions on market structure, informational structure, and the ability of firms to adjust product quality. We review the main lessons from this literature below. To help guide our empirical exercise, we then provide a simple model that includes features that are relevant for the Chilean pharmaceutical market.

The theoretical framework that is closest to our setting studies quality regulation when consumers and producers have asymmetric information regarding product quality. Leland (1979) shows that, when producing quality is expensive but not rewarded due to asymmetric information, the competitive equilibrium generates less than efficient average quality. In this setting, quality regulation that weeds out the lower quality spectrum changes consumer beliefs about the quality distribution of the remaining firms in the market. Thus, quality standards increase willingness to pay for the remaining drugs, inducing high-quality suppliers to offer their drugs in response.

Models with strategic interaction show that market structure plays a critical role in minimum quality regulations. Ronnen (1991) introduces a duopoly model with price and quality competition as well as endogenous quality, but where quality is perfectly observed by consumers. Minimum quality standards may exacerbate the degree of quality and price competition, potentially

[10] We exclude from this classification all molecules that received their first decree before 2010, as we exclude them from the sample we use in our main analysis. Similarly, we exclude molecules that were not affected at all by any bioequivalence requirement.

leading all firms to adjust their quality in response to the lesser degree of allowed quality differentiation, as in Shaked and Sutton (1982). These equilibrium effects imply that quality regulation should increase quality and reduce prices, with positive welfare effects for consumers. However, Scarpa (1998) shows that this result depends crucially on the duopoly setup.

Finally, Garella and Petrakis (2008) introduce imperfect information to strategic games with endogenous quality, as well as the possibility of horizontal and vertical quality differentiation. Their analysis shows that updated beliefs regarding quality and increasing willingness to pay increases overall quality, even if the strategic effect goes in the opposite direction.

The insights from the theoretical literature allow us to classify the effects of bioequivalence requirements on market outcomes and consumer welfare broadly as a combination of *valuation effects* and *composition effects*. The former arise from changes in the quality perceived following bioequivalence certification, while the latter arise from changes in the competitive environment following the induced change in the set of drugs offered in the market.

Valuation Effects. Consider a setting where (i) consumers value drug quality, (ii) bioequivalence is a useful quality signal, and (iii) consumers (and physicians) receive information about drug bioequivalence (e.g., through labeling as in the case of Chile). Then, we would expect that, *ceteris paribus*, an increase in demand for generics receiving bioequivalence certification. Similarly, we expect a decrease in demand for generics that have not yet obtained bioequivalence certification, as well as a decrease in demand for the innovator drug.

Competition between branded and unbranded generic drugs may also intensify if both obtain bioequivalence certification –potentially reducing their price gap– if the certification induces consumers to consider them as closer substitutes. This would for instance be the case if branding is a strategy for signaling higher quality, and if the market structure before the reform reflects incentives to differentiate on (perceived) quality to reduce price competition. Bioequivalence requirements could thus induce a reduction in the scope for quality differentiation, as it limits the extent of perceived quality differences.

Composition Effects. Bioequivalence requirements may induce changes in the pharmaceutical market structure. The main driver of those changes is that laboratories are forced by this policy to choose between certifying bioequivalence or exiting the market. If compliance with bioequivalence requirements is costly, then some drugs may indeed choose to exit.

An induced exit of generics would decrease the extent of competition faced by the innovator, with theoretically ambiguous price effects. On the one hand, fewer drugs in the market should decrease price competition. However, generic exit is not expected to necessarily increase drug prices as it may induce innovators to target a more elastic part of the demand curve (Frank and Salkever, 1992).

3.1 A Simple Model of Bioequivalence Requirements

We present a simple calibrated model to formalize our previous discussion. The model has four main features that aim at reflecting the basic structure of our empirical application. First, we assume for simplicity a duopoly market structure where the innovator competes with a single bioequivalent generic.[11] Second, there is asymmetric information with respect to drug quality so that consumers only imperfectly observe the quality of the generic. Although producers can observe quality, their technology is fixed, so that quality is exogenous. Third, the generic has to pay a fixed cost to show proof of bioequivalence and remain in the market. Finally, some consumers have a positive willingness to pay for the innovator drug on top of any perceived quality differences. Both a higher perceived quality and the presence of this loyal segment are consistent with evidence showing that individuals prefer innovator drugs over generic drugs, even in markets where bioequivalence requirements have been in place for decades, like Europe and the U.S. (see e.g., Colgan et al. 2015; Bairoliya et al. 2017)

The main mechanism in our model is that quality regulation increases consumers' perceived quality of generic drugs. Higher perceived quality in turn increases willingness to pay for the generic but, at the same time, reduces the scope for vertical differentiation with the innovator. This is turn increases the intensity of price competition with the innovator. The generic drug may decide to exit the market if not able to obtain enough profits as to cover the cost of quality certification under this competitive environment, which may induce further equilibrium price changes by the innovator drug.

Baseline Model. Consumers are indexed by c and choose between an innovator i, a generic g and an outside option o. Drugs are vertically differentiated products, where the key dimensions of differentiation are quality ψ and whether the drug is an innovator or a generic itself. We assume that ψ is predetermined and exogenous, but unobserved to consumers. Therefore, consumers choose drugs based on their expected indirect utility, where expectations are taken over the perceived quality distribution. There are two periods in the model: we denote by $t = 0$ the pre-reform period and by $t = 1$ in the post-reform period. We assume all consumers hold the same beliefs regarding each drug's quality, although this belief changes after the reform.

While consumers are homogeneous with respect to beliefs, they are heterogeneous in two dimensions. First, there is an individual-specific willingness to pay for quality, denoted by τ_c. Also, each individual has an additional willingness to pay for the innovator, denoted by ν_c. The distribution of ν_c captures the existence of a set of loyal consumers, who are willing to pay ν_c for reasons unrelated to perceived quality differences.

We denote by $E_t[\psi_i]$ and $E_t[\psi_g]$ the expected quality of the innovator and generic drug, respec-

[11] We focus on the non-trivial case in which the generic is bioequivalent, to illustrate the case of exit due to the cost of complying with the regulation. In the other case, in which the generic exits because it does not meet the requirement, the innovator becomes a monopoly.

tively. The expected indirect utility from innovator and generic drugs is given by:

$$\begin{aligned} E_{ct}[u_i] &= \tau_c E_t[\psi_i] + \nu_c - p_{it} \\ E_{ct}[u_g] &= \tau_c E_t[\psi_g] - p_{gt} \end{aligned}$$

where the expected utility of the outside option is normalized to zero. We also normalize innovators' expected quality in both periods to be equal to 1, $E_t[\psi_i] = 1 \quad \forall t$, so that $E_t[\psi_g] \equiv \delta_t \in [0,1]$ is the expected relative quality of the generic. Low expected quality of generics can arise both from uncertainty over its bioequivalence status and from the belief that the innovator drug has higher quality even if the generic was known to be bioequivalent. This latter feature of the model allows for perceived differences between bioequivalent generics and innovators even after bioequivalence certification.

We study the equilibrium consequences of a quality regulation in a simple example where the distribution of willingness to pay for quality is uniform, $\tau_c \sim U[\underline{\tau}, \overline{\tau}]$. We analyze the consequences of the presence of loyal consumers by analyzing two possible scenarios: (i) there are no loyal consumers ($\nu_c = 0 \quad \forall c$), and (ii) a certain fraction of consumers have brand loyalty ($\nu_c > 0$).[12]

Equilibrium in Absence of Quality Regulation. Figure 1-a shows the equilibrium before regulation for scenario (i) without loyal consumers. The x-axis corresponds to pre-reform perceived quality of generics, δ_0, and each sub-panel (from top to bottom) displays equilibrium prices, market shares and profits. In this situation, higher pre-reform (expected) generic quality is associated with lower innovator prices but has ambiguous effects on the equilibrium price of the generic. As generic quality increases, more individuals prefer to buy the generic instead of the outside option, and thus the generic can respond by increasing its price. However, when the quality of the generic and the innovator become close enough, the reduction in vertical differentiation becomes strong enough for price competition to drive the price of the generic down. Relatedly, profits of the innovator decrease with δ_0 while profits of the generic have an inverted U-shape. Finally, market shares of both drug types increase with δ_0, due to a dominating price effect for the innovator and a combination of quality and price effects for the generic.

Figure 2-a displays the pre-reform equilibrium in the presence of a loyal segment of consumers. In this case, the innovator might cater exclusively to the loyal segment, which happens in our illustration for all but the lowest values of expected generic quality δ_0.[13]

[12] The specific distribution of brand loyalty used to generate our results in this Section is that 20% of customers have $\nu_c = 5$, while the remaining 80% have $\nu_c = 0$. The maximum and minimum willingness to pay for the innovator based on quality alone are set at $\overline{\tau} = 3$ and $\underline{\tau} = 0$. This implies that brand loyalty is relatively more important than quality for the brand-loyal consumers in scenario (ii).

[13] From the model, we can see that it is more likely that the innovator will maximize profits by setting price based on the preferences of the brand-loyal segment when (i) the quality of generics is sufficient to make them a close substitute for less loyal (non-loyal) consumers, (ii) the loyal segment has a large excess willingness to pay for the innovator, and

Introducing Quality Regulation. The reform imposes a bioequivalence standard to generics: all generic drugs must obtain bioequivalence certification to remain in the market. The cost of such certification is fixed and equal to K. Therefore, non-bioequivalent generics do not attempt to get bioequivalence proof and exit the market. Post-reform, consumers internalize that all generics in the market are bioequivalent, leading to an update in the expected (relative) quality of generics δ_1, where $0 \leq \delta_0 \leq \delta_1 \leq 1$. The quality level δ_1 corresponds to the expected quality of a bioequivalent drug, which is equal to one if consumers do not attribute additional quality traits to the innovator drug beyond bioequivalence.

Generics obtain bioequivalence certification if profitable, i.e., $\pi_{g1} \geq K$, where π_{g1} are the equilibrium profits of the generic after bioequivalence. On the other hand, the reform could also induce generic exit if post-reform profits do not compensate for the cost of the bioequivalence test, generating *composition effects*. In our duopoly model, it is clear that exit will be *less* likely in larger markets, everything else equal, since the volume sold by each player will be larger without any decrease in margins. The post-reform equilibrium crucially depend on the presence of a loyal segment. We analyze each scenario below.

Quality Regulation without a Loyal Segment. In the absence of loyal consumers, the effects of the regulation are intuitive. Imposing higher quality standards increases consumers' expected quality of the generic. For intermediate levels of the updated expected quality, the generic makes enough profits to stay in the market and compete with the innovator and, as a result, the price of the innovator decreases. This situation falls among *valuation effects* and is illustrated by Figure 1-b.

However, the effect on the price of the generic is ambiguous. The increase in perceived quality means less competition with the outside option but more competition with the innovator. In fact, if updated expected quality is too high, price competition with the innovator drives profits down to the extent that it is not worthwhile to invest in the certification and the generic drug exits. On the other hand, the generic drug also exits when updated expected quality is low enough so that increases in demand are not enough to compensate the certification cost K. When the generic drug exits, the innovator drug becomes a monopoly and increases its price. This situation falls among *composition effects* is illustrated in Figure 1-c.

Quality Regulation with a Loyal Segment. The presence of a loyal segment changes the pricing behavior of the innovator, changing the nature of price competition with the generic. In this case, the innovator targets prices to the preferences of loyal consumers, thereby reducing the intensity of price competition with the generic relative to a case without loyal segment. In fact, profits of the generic drug are strictly increasing on expected quality in this case, and the generic is not more

(iii) the loyal segment is large. When this happens, the innovator sets a high price (reflecting the higher willingness to pay of loyal consumers), and sells almost exclusively to loyal consumers (obtaining a share reflecting the distribution of brand loyalty in the market).

likely to exit as vertical differentiation decreases due to high δ_1. This situation is illustrated in Figure 2-b.

However, when expected quality of the generic drug remains low enough, such that profits would not be enough as to cover the certification cost K, then the generic drug exits. In this case, the innovator may decrease its price in order to serve both both segments and increase sales significantly. This behavior mirrors the generic paradox (Frank and Salkever, 1992), where innovators increase their price after generic entry as they target a more inelastic part of the demand curve. This situation is illustrated in Figure 2-c.

3.2 Discussion

From this example, we see that the effect of stronger quality regulation is not immediately clear. On the one hand, the effect of the regulatory change will depend on market fundamentals, in particular on (i) the extent to which quality regulation changes perceived quality of generic drugs, and (ii) the extent to which individuals are loyal to the innovator drug even in the absence of perceived quality differences. On the other hand, the model emphasizes the role that regulation compliance costs may have in terms of inducing exit of generic drugs. In light of the ambiguity of these theoretical predictions, we turn to analyze the effects of quality regulations empirically.

4 Data and Descriptive Statistics

4.1 Data Sources

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

Second, we combine the registry data with data on bioequivalence certification. This data contains 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 contains detailed information on monthly prices and sales for drugs sold across the market for the period between January 2010 and Decem-

ber 2017. IMS collects data from two sources. The four largest pharmacy chains in the country, accounting for more than 90% of market share, report retail prices and sales directly to IMS. The rest of the pharmacies are supplied by wholesalers, which report wholesale prices and sales to IMS. Wholesale prices are transformed to retail prices using a standard methodology.[14] We employ monthly sales and prices from all 83 local markets included in the IMS data, which cover most of the urban areas of the country. We aggregate prices and sales for each drug across local markets. In particular, we compute total monthly sales by aggregating monthly sales across local markets and calculate monthly drug prices as sales-weighted averages of prices across local markets.[15]

The IMS dataset provides price and sales information at the product level for branded drugs, identifying the laboratory, dosage an presentation of each drug. For unbranded drugs, however, it only includes dosage and presentation, but aggregates sales across laboratories.[16] We restrict our attention to prescription drugs, which account for more than 90% of the drugs in the molecules in our sample.

4.2 Descriptive Statistics on Quality Certification

The number of bioequivalent drugs in the Chilean market increased substantially throughout our study period. Figure 3-a shows the number of bioequivalent drugs between January 2010 and December 2017. Bioequivalence certification started at a low pace in early 2010, but has risen steadily since then, with a rapid uptake by mid 2012. By December 2017, there were 1,276 drugs with bioequivalence certification.[17]

The growth in the number of bioequivalent drugs relates to the roll-out of bioequivalence regulation, which was announced and implemented at different dates through the decrees and deadlines described in Section 2.2. Figures 3-b through 3-e display the number of new bioequivalence approvals around the following four policy events of each market: (1) the first decree, (2) the last decree, (3) the first deadline, and (4) the last deadline. We highlight three facts from these figures. First, bioequivalence approval was uncommon before the first decree, which shows that bioequivalence incidence was rare before it was mandated by law. Second, bioequivalence ap-

[14] This methodology consists of adding a VAT of 19% and a retail margin of 30%. We adjust retail prices in two ways. First, we transform nominal prices to real prices in 2013 using the health CPI from the National Institute of Statistics (*Instituto Nacional de Estadística*, INE). Second, we normalize drug prices across drug presentations by their drug content by calculating prices per gram of the active ingredient.

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

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

[17] Although the original list contains more drugs, we treat all unbranded generics produced by different laboratories as the same drug. This is consistent with limitations in IMS Health described previously.

proval increased markedly after the first decree, which suggests that bioequivalence regulation had an impact on bioequivalence incidence. Third, several bioequivalence approvals occur after the first and last deadlines, which shows that deadlines were only weakly enforced, a point to which we return in our empirical strategy.

4.3 Descriptive Statistics on Market Outcomes

We merged the price and sales data from IMS with the drug registry from ISP, to construct a monthly panel dataset for the period between January 2010 and December 2017. After some data cleaning, the resulting dataset covers 131 molecules. The data contain 2,292 unique drugs, defined as a unique combination of drug name, dosage, and presentation. These drugs are manufactured by 80 different laboratories.[18] Importantly, not all drugs in the panel are sold every period. In fact, only 65.5% of the drug-month observations in our panel dataset register positive sales. Monthly prices are not observed in months when a drug registers no sales.

Table 2 displays basic descriptive statistics. On average, innovator drugs are priced around twice as high as the average drug in the market, while branded generics are priced around two thirds of the average drug and unbranded drugs are remarkably below, at around a fifth. We go beyond these raw averages and estimate price premiums within markets for innovator and branded generics below. The highest market share is captured by branded generics, with an average market share of 43%, followed by innovator and unbranded generics with market shares of 30% and 27% respectively. On average, bioequivalent drugs hold a market share of only 7%. However, the average market share of bioequivalent drugs increased substantially during our study period, from only 0.06% in 2010, to 22.8% by the end of 2017. This shift in market shares is also displayed by Figure 5. The average market has around 13 drugs and 5 laboratories in a given month. As expected, the number of drugs and laboratories is remarkably larger in the segment of branded generics than in the innovator and the bioequivalent segment.[19]

Figure 6 shows pre-reform price premiums per drug type, using 2011 prices.[20] Four facts become apparent: First, price premiums are positive on average across all molecules in the sample. Second, price premiums are large overall: innovators and branded generics are substantially more expensive than unbranded generics in this setting, with average relative premiums being close to 10 and 6 respectively. Third, relative price premiums are much larger for innovator drugs than for

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

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

[20] We calculate these premiums by estimating regressions of logged drug prices in 2011 on indicators for innovator and branded generics separately for each market. The exponentiated coefficients from such regressions provide a measure of average price premiums of each such drug types relative to unbranded generics. We restrict the estimating sample to molecules with price information for at least one innovator, one branded and one unbranded drug during 2011, which limits the sample to 56 molecules.

branded generics. Fourth, there is substantial heterogeneity in price premiums across molecules. While several molecules display relative price premiums on the order of 3 to 5, a number of other molecules display relative price premiums beyond 10, particularly for innovator drugs, but also for branded generics.

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

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

5.1 Evidence for Bioequivalence Approval

In section 4.2 we provided suggestive evidence that bioequivalence approval increased substantially after the roll-out of the reform. We turn to survival analysis to study the determinants of bioequivalence approval. Survival analysis is a convenient method to describe bioequivalence approval, as it can flexibly accommodate the absorbing nature of the bioequivalence event, right-censoring, and time-varying covariates.

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

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

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

Table 3-A displays estimates from equation (1). Column (1) through (4) include each policy

event separately, while column (5) includes all of them jointly. The most relevant policy events seem to be the first decree and the first deadline: both increase the probability of becoming bioequivalent by $\exp(1.41) \approx 4.1$ and $\exp(1.36) \approx 3.9$ times, while posterior policy events do not significantly increase the hazard of quality certification further. Overall, these results reinforce the graphical evidence of Figure 3: periods after the first decree and first deadline are stronger predictors of bioequivalence certification than periods after the last decree and last deadline. Also, drugs are more likely to become bioequivalent after the first deadline than after the last deadline. We interpret this evidence as showing than the first deadline triggered a stronger rate of bioequivalence certification than subsequent extensions.

Estimates of the relationship between drug characteristics, market variables and bioequivalence approval rates are statistically significant and robust across specifications. Branded drugs are estimated to be less likely to obtain bioequivalence approval compared to unbranded drugs, while imported drugs are fifty percent more likely to obtain approval ($\exp(0.43) \approx 1.5$). A ten percent increase in market revenue is associated with a 5.7% increase in the hazard of becoming bioequivalent. Moreover, the number of competing drugs in a market is negatively associated with bioequivalence approval. A ten percent increase in the number of branded drugs is associated with a 1.3% lower hazard rate, while a 10 percent increase in the number of unbranded drugs is associated with a 5.2% lower hazard rate. While we do not interpret these as causal effects as bioequivalent requirements, these results are useful to understand the drivers of drug quality certification.

Heterogeneity. We study how baseline drug attributes affect quality certification choices. Table A.1-A displays results from a version of equation (1) in which policy events are interacted with indicators for drug covariates at baseline.[21] We focus on the first deadline of bioequivalence requirements for a market, which showed to be the most relevant in our baseline analysis. The most relevant pattern of heterogeneity we find is that drugs with higher baseline revenue are differentially more likely to engage in quality certification after bioequivalence requirements are imposed, as predicted by the model in Section 3.1. A 10 percent increase in revenue is associated with a differential increase in the hazard rate of 1.5%.

5.2 Evidence for Entry and Exit of Drugs

We turn to analyze the relationship between bioequivalence regulation and the dynamics of entry and exit. We construct measures of entry and exit using the ISP registry data on license inscriptions and renewals. For each registered drug, we record an entry as the event of obtaining a license for

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

the first time, and an exit as the event of not renewing a license upon expiration.[22] Figures 4-b through 4-e display trends in the number of drugs that enter and exit the market at each point in time relative to relevant policy events. These figures show a marked increase in exit of drugs over time, particularly after the enactment of the bioequivalence policy.

We estimate a hazard model for exit to quantify these patterns, analogous to the model in equation (1). Results are shown in Table 3-B. We focus on Column (10), which displays estimates from a specifications that includes all policy variables jointly. The results imply that the first deadline is the policy variable that most strongly influences drug exit. In particular, the probability of exiting increases by $\exp(0.39) = 1.47$ times after the first deadline. Branded drugs have a slightly higher propensity to exit compared to unbranded, while reference drugs display a lower exit hazard rate. Interestingly, imported drugs are more likely to exit. Market variables display similar effects on exit hazard across specifications. We find that markets with higher revenue have lower exit probabilities: a 10% increase in market revenue is associated with a the probability of exit being 0.90% lower. Relatedly, markets with a higher number of competing branded and unbranded drugs also display lower exit rates: a 10% increase in the number of branded (unbranded) drugs is associated with a 2% (11%) decrease in the probability of exit. Overall, these results suggests that drugs are less likely to exit in larger markets.

Heterogeneity. We implement a heterogeneity analysis of exit rates similar to that in Section 5.1. Table A.1-B displays results for heterogeneity in the effect of the first deadline of bioequivalence requirements on drug exit. We do not find any strong patterns of heterogeneity. However, we find suggestive evidence of the overall determinant of exit: conditional on market size and the number of competing drugs, drugs with higher sales and revenue at baseline are less likely to exit the market, as expected.

6 Effects of Quality Regulation on Market Outcomes

We now turn to the main analysis of the paper, where we estimate the effects of quality regulation on market outcomes. We employ an empirical strategy that exploits variation in the roll-out timing of the bioequivalence policy within and across markets. We explore potentially heterogeneous effects of the policy in line with the model proposed in Section 3.1, focusing in particular on the differences in the effects of the regulation across small and large markets.

[22] Thus, for the purpose of this exercise, we assume that exit happened exactly at the due date of the failed renewal (i.e. 5 years after the last renewal) although the decision to exit was likely taken some time before the due date.

6.1 Empirical Strategy

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

1. The first source of identifying variation is the staggered roll-out of the reform, as already discussed in Section 2.2. This variation is displayed in Figure 7-a. In practice, the differences in the timing of the regulation generate a series of comparison groups comprised of markets that faced bioequivalence requirements at different moments throughout our period of study.

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

We combine these two sources of variation by constructing a variable that measures the evolution of the policy roll-out within each market. This variable captures three main features of the regulation. First, the policy becomes relevant for a market only after its first corresponding decree. Second, the policy becomes increasingly relevant for each drug in the market as its respective registry renewal dates approaches. Finally, the policy is fully in place for a market when the registry renewal date has been reached for all drugs in it. 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 given drug i, the share of time between the decree and next renewal date that has elapsed by time any time t is given by:

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

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

We employ T_{mt} as a treatment variable for our analysis of the effect of the regulation on market outcomes. T_{mt} is a weakly increasing function of time relative to the policy date t_m^d: it is equal to 0 before t_m^d and is equal to 1 after the latest renewal date across drugs in $\mathcal{G}_m$ is reached. Figure 7-b displays the evolution of T_{mt} over time for all markets in the sample, showing substantial variation across markets at any given point in time, as well as variation within market across time.[23] Finally, Figure 7-c shows that this policy intensity variable is indeed correlated with the share of bioequivalent drugs in the market, even after controlling for market and month fixed effects.

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

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

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

The key identifying assumption in (3) is that there are no unobserved market-specific trends that drive both the timing of policy roll-out and the outcomes of interest. The main exclusion restriction behind this strategy is that decree deadlines and renewal dates for a given molecule were not set as a function of unobserved shocks not captured by market and time fixed effects. A violation to this assumption would happen if, for instance, decrees and deadlines were set earlier for markets that were expected to have earlier price increases. Although we cannot directly test this hypothesis, the fact that decrees were set and modified mostly based on capacity constraints of laboratories testing bioequivalence makes it unlikely that they were timed in line with unobserved future demand or supply shocks. Moreover, market-level observable characteristics do not show a clear correlation with the timing of the policy. Table 1-B shows descriptive statistics for baseline market outcomes in 2010 for markets affected differently by the policy, as well as for drugs in markets without bioequivalence requirement. Overall, these statistics display substantial

[23] For further illustration, Figure A.2 shows particular examples for the evolution of T_{mt} over time for four markets, along with the evolution in the number of bioequivalent drugs in each of them. These examples are highlighted in Figure 7-b. These plots show how bioequivalence certification increases as bioequivalence requirements become relevant for a market.

heterogeneity across different policy groups of markets in terms of number of drugs, market size and market outcomes, but do not display a clear pattern related to the timing of bioequivalence requirements roll-out.

Event Study Evidence. As a complement to this strategy, we implement an event-study analysis. The event study serves two purposes: (i) assessing the 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. The main advantage of the empirical strategy proposed above relative to this event study analysis is that we are able to exploit an additional dimension of identifying variation coming from the pattern of license renewal dates for drugs in the market. We describe this event study analysis in detail in Appendix A.1 and provide results in Figure A.3. Overall, trends in outcomes before the first deadline of bioequivalence requirements look relatively well behaved: most of the estimated coefficients are close to zero. This fact is reassuring in terms of exploiting the differential timing of decrees across markets as exogenous variation to estimate the effects of quality regulation in our setting. Moreover, the results obtained from this event study analysis are mostly in line with the results from our main analysis in the remainder of this section.

Heterogeneity. The model in Section 3.1 suggests that whenever compliance is costly, quality regulation should have stronger effects in smaller markets, as it would induce more drug exit. To test this prediction, we estimate differential effects of the policy according to market size, measured as the average sales in the pre-reform period. Specifically, we divide markets according to whether the average monthly market revenue in 2010 was above or below median and identify them as large and small markets respectively.

6.2 Effects of Quality Regulation on Market Structure

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

6.2.1 *Results for Number of Drugs*

Table 4-A displays estimates of equation (3) on the logged number of drugs.[24] Column 1 shows the results for drugs of all types. We find that the bioequivalence policy decreased the number of drugs in the market by 13%. Columns (2) through (8) split these results across different drug types. The overall reduction is driven by exit of branded generics. We estimate a 24% decrease in the number of branded generics on average. On the other, hand the estimated effect large and positive for innovator drugs, although not statistically significant, while it is small and insignificant for unbranded generics overall. Even though there is an increase in the number of bioequivalent generics, it is not enough to compensate for the exit of non-bioequivalents. The fact that the number of drugs in the market decreased as a result of the policy suggests that the degree of competition in the market may have decreased and generate the composition effects described in Section 3.

Table 4-B shows estimates separately for small and large markets. We see that the negative effects on the number of drugs are particularly pronounced in small markets, driven by a significant exit of both innovators and branded generics. The entry of bioequivalent generics is also significantly larger in high-revenue markets. This is consistent with our model, as a larger market makes bioequivalence certification relatively less costly. In high-revenue markets, there is an increase in the number of innovator drugs, which is somewhat surprising. Potentially, this can be due to the innovator expanding into different segments after the reform, such as different concentrations of the active ingredient or package sizes, since the reform reduces the number of branded generics. Overall, there is no statistically significant impact on the number of unbranded generics either in markets with low or high revenue, which might also be somewhat surprising.

6.2.2 *Results for Number of Laboratories*

In the previous section, we find that the number of drugs in different segments of the market changed as a results of stronger quality regulation. We turn to study the extent to which those changes were driven by entry and exit of laboratories or by changes in their portfolios of drugs. Finding a decrease in the number of competitors as a result of the reform could imply unintended consequences for competition.

Table 5-A displays results for the effects of the regulation on the number of laboratories in the market.[25] Our estimates imply that the number of laboratories did not change overall although, as

[24] We use $\ln(1+N)$ as the dependent variable, where N is the number of drugs (or, more precisely, the number of presentations), to accommodate observations where there are no drugs of a certain category, e.g., no bioequivalent unbranded generics. As a robustness check, we show that the results are virtually unchanged when using $\sinh^{-1}(N)$ as the dependent variable in Table A.3. This transformation also reduces skew, yields coefficients approximating percentage changes, allows for zeros, all of which are desirable statistical properties with this type of data (see e.g., Kline et al. 2017).

[25] In this analysis we treat different laboratories owned by a same conglomerate as the same laboratory. We thank

expected, we do find a large increase in the number of laboratories selling bioequivalent generics. Table 5-B displays heterogeneous effects across small and large markets. The results show that small markets were more affected by quality regulation: the overall number of laboratories in small market decreased by 17% on average. This decrease is mostly driven by a decrease in the number of laboratories selling unbranded drugs. Conversely, entry of laboratories to the segments of branded and unbranded bioequivalents was stronger in large markets.[26]

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. If all the decrease in the number of drugs was driven by exit of laboratories, that could be interpreted as laboratories choosing not to certify bioequivalence due to low quality. Conversely, if all the decrease was driven by a decrease in the size of the portfolio offered by laboratories, that could be interpreted as selective testing of drugs by laboratories and would be more related to costly compliance as a driver for drug exit. Our estimates imply that, across markets, 75% 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. However, this result is heterogeneous across market sizes: in small markets, as much as 63% of the effect on the number of drugs comes from laboratory exit, whereas in large markets, all of the effect on the number of drugs comes from a reduction in the portfolio of drugs offered by laboratories.[27]

6.3 Effects of Quality Regulation on Drug Prices

We turn to studying the effects of the quality regulation on drug prices. Having documented large changes in the market structure, we interpret these price effects as the combination of different forces at play. On the one hand, a reduction in the number of competitors —particularly a large exit of branded generics— may lead to large price changes due to reduced competition. Still, the sign of the price change of incumbent competitors in ambiguous. Innovators may decide to increase their prices to exploit their increased market power, or conversely, decrease their prices to cater a more elastic part of the demand (see discussion in section 3.1). Moreover, these changes in market structure are coupled with potential changes in consumer perceived quality, changing the scope for vertical differentiation and, in turn, the extent of price competition.

Table 6-A shows the results of estimating equation (3) on average drug prices across all drugs and by drug type. Our measure of average price is the sales-weighted average of prices within

Gastón Palmucci and Thomas Krussig at the National Economic Prosecutor of Chile (*Fiscalía Nacional Económica*, FNE) for help in constructing this dataset.

[26] As a robustness check, we estimate the same regressions using $\sinh^{-1}(N)$ as the dependent variable. See footnote 24 for details. Table A.3 displays the result for these specifications. Overall, results are remarkably similar to those using $\ln(1+N)$ as the dependent variable.

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

each market, normalized by its value in January 2010.[28] Specifically, let $P_{mt} = \sum_{i \in \mathcal{I}_{mt}} w_{it} P_{it}$ the sales-weighted price in market m in period t, where $\mathcal{I}_{mt}$, is the set of drugs in the market in period t, w_{it} denotes the share of sales of drug i in market m in period t. Our price index is defined $\hat{P}_{mt}$ for market m in period t is defined as

$$\hat{P}_{mt} \equiv \frac{\sum_{i \in \mathcal{I}_{mt}} w_{it} P_{it}}{\sum_{i \in \mathcal{I}_{m0}} w_{i0} P_{i0}} = \frac{P_{mt}}{P_{m0}}$$

In column (1), we estimate that average prices across all drug types increased by 12% as a result of the regulation. Measuring price effects by drug type reveals that most of the increase in average prices comes from increases in the price of unbranded generics, while innovators and branded generics display no statistically significant changes.[29]

The high price premiums paid by consumers to purchase innovator drugs and branded generics documented in section 4.3 suggest that, before the regulation, unbranded generics had a relatively low perceived quality. In the presence of a strong loyal segment for innovators, and if stronger quality regulation has a large enough effect on perceived quality of generics, generics would stay in the market and increase their prices, as predicted by the model and illustrated in Figure 2. These changes in the price of the generics can occur without affecting the optimal price of the innovator, as also shown by Figure 2.

We now consider heterogeneity in price effects across small and large markets in Table 6-B. As shown in section 6.2, the decrease in the number of drugs is concentrated in small markets, and thus these are the markets where we expect to find the strongest competitive effects of the policy. This prediction is largely confirmed by our findings. In column (1), we see that the increase in prices across all drugs is concentrated in low-revenue markets, with an estimated increase of 27%, while prices in high-revenue markets were unaffected by the policy. Our estimates show that the regulation induced a price increase unbranded generics of 17% in these markets. On the other hand, the price effects in large markets are close to zero and not statistically significant.

6.3.1 Decomposition of Price Effects

Changes in average prices at the market level combine price changes within each drug with price effects due to changes on drug sales, as well as changes in the composition of drugs sold in the market. In order to better understand the drivers of the price changes at the market level, we decompose the evolution of average market price into components that reflect individual drug price changes, changes in market shares, and changes in the composition of drugs in the market.

[28] As an alternative measure, we used the logged sales-weighted prices. The results are robust to that alternative specification. We favor our normalized index because it allows us to perform the decomposition analysis of section 6.3.1.

[29] These price changes at the market level combine price changes at the drug level with compositional changes in the pool of drugs in the market. We decompose those different sources below.

Consider the change in the sales-weighted price between a baseline period $t = 0$ and any period $t > 0$. Let $\mathcal{S}_{m,t} \equiv \mathcal{I}_{mt} \cap \mathcal{I}_{m0}$ be the set of drugs in the market in t that were also in the market in the baseline period; $\mathcal{E}_{mt} \equiv \mathcal{I}_{mt} \setminus \mathcal{I}_{m0}$ the set of drugs that entered market m after the baseline period and remain in the market in period t; and $\mathcal{X}_{mt} \equiv \mathcal{I}_{m0} \setminus \mathcal{I}_{mt}$ be the set of drugs that exited between the baseline period and t. We can decompose changes in sales-weighted prices as:

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

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

$$\hat{P}_{mt} = 1 + \frac{\Delta P_{mt,C} + \Delta P_{mt,RW} + \Delta P_{mt,CS} + \Delta P_{mt,E} + \Delta P_{mt,X}}{P_{m0}}$$

To evaluate the effect of the policy on each component of the time series, we estimate equation (3) using the following dependent variables: $\hat{P}_{mt,C} \equiv \Delta P_{mt,C}/P_{m0}$, $\hat{P}_{mt,RW} \equiv \Delta P_{mt,RW}/P_{m0}$, $\hat{P}_{mt,CS} \equiv \Delta P_{mt,CS}/P_{m0}$, $\hat{P}_{mt,E} \equiv \Delta P_{mt,E}/P_{m0}$ and $\hat{P}_{mt,X} \equiv \Delta P_{mt,X}/P_{m0}$. By construction, the sum of the OLS coefficients on T_{mt} from these five regressions is equal to the coefficient for T_{mt} in equation (3). Each coefficient reflects the effect of the policy on the corresponding component of the evolution of average prices.

Table 6-C, shows estimates for policy effects on each of the components, both for the overall market price and for the price of each drug type. We find that most of the increase in overall prices is due to within-drug price changes in the period. Of the 12% increase in average prices, 8% comes from price changes within drugs ($\hat{P}_{PC}$) and 3% from the entry of relatively expensive drugs

($\hat{P}_E$). We also find that most of the price increase among unbranded generics is due to within-drug price changes ($\hat{P}_{PC}$). As noted above, unbranded generics are aggregated across laboratories, and therefore the decomposition for this segment should be interpreted with caution. Overall, the finding that the estimated increase in average drug prices is due mostly to price increases of products already in the market before the policy confirms our interpretation that the exit of drugs documented in Section 6.2 reduced the intensity of price competition in the market.

6.4 Effects of Quality Regulation on Market Shares and Sales

We turn to evaluate the effect of the policy on market shares. We are mostly interested in exploring whether the policy significantly changed the extent of generic penetration. Our empirical strategy allows to evaluate the overall effect of the policy on market shares due to changes in the market structure as well as changes in demand.

Table 7-I-A displays estimates of equation (3) using market shares as the outcome of interest. Overall, we do not find significant changes in the market share of generics after the implementation of the reform. On the contrary, the results show that the market share of innovator drugs increases by 5 p.p. due to the policy, while the market share of branded generics decreases by a similar amount, and the market share of unbranded generics remains unchanged. As expected there is a significant increase of 12 p.p. in the market share of bioequivalent drugs and a decrease of 8 p.p. in non-bioequivalent drugs. However, the larger presence of generics holding bioequivalence certification does not translate into a larger market share of the generic segment as a whole. [30] Considering the decrease in the number of branded generics found in Table 4, these results are consistent with consumers mostly substituting towards innovator drugs as generics exit the market.

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

Finally, we estimate the effects of the policy on total sales. Estimating the effect on sales allow us to disentangle changes in the market shares of different types of drugs from changes in the size of the outside option. We are particularly interested in evaluating whether the large drug exit induced substitution towards stayers, or if it increased the share of the outside option. In theory, the quality regulation can either increase or decrease the share of the outside option. On the one hand, an increase in the perceived quality of generics could induce individuals choosing

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

the outside option to purchasing generics. Moreover, there are endogenous price effects caused by changes in the market structure and the extent of vertical differentiation. Finally, former buyers of drugs that exit could decide for the outside option instead of switching towards to another drug.

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

In Table 7-II-B, we study heterogeneous policy effects across large and small markets. We find that decreases in sales are larger in smaller markets. In particular, we estimate that sales decreased by 29% across all drug types as opposed to a smaller and non-statistically significant decrease in sales in large markets of 9%. The overall decrease in sales in small markets is driven by decreases in sales of both branded and unbranded generics. This result is consistent with our results showing substantial exit and reduced competition in small markets. In contrast, we estimate that in large markets there is no statistically significant decrease in sales of branded generics, while there is an increase in sales of unbranded generics of 60%. These findings for large markets are consistent with increased perceived quality of unbranded generics in a context where the number of drugs and the intensity of competition did not decrease with the regulation.

6.5 Effects of Quality Regulation on Drug Quality

Imposing bioequivalence requirements as a minimum quality standard was successful in inducing generics willing to stay or enter the market to obtain bioequivalence certification. On the other hand, we have documented that stronger quality regulation generated changes in market structure, particularly in small markets.

Theoretically, we expect the rate of bioequivalence certification to be higher in larger markets even if the underlying drug quality is constant across markets of different size, as shown in our simple model of section 3.1. The regulation compliance cost acts as a fixed entry cost, and only firms expecting to earn profits large enough as to cover it will be willing to incur it, as predicted by classical entry models (e.g., Bresnahan and Reiss 1991). In this case, entry costs imposed by the regulation induces the exit of drugs of high-quality but low-revenue, with negative welfare consequences. Alternatively, the underlying drug quality prevailing before the policy change could have varied across markets of different size. When product quality is endogenously determined and produced with fixed costs, larger markets can sustain higher quality levels (Berry and Waldfogel, 2010). In such a context, market revenue and underlying product quality are positively correlated, so that higher exit in low-revenue markets may imply that the average quality in the market increased after the reform.

We examine evidence on whether the bioequivalence regulation had any measurable effects on improving the quality of drugs present in the market. Finding no quality effects would favor an interpretation of the higher exit within low-revenue markets as having negative welfare consequences.

While direct measures of quality (e.g., results from laboratory drug testing) are not available in our setting, we use the frequency of product recalls as a indirect measure of the overall manufacturing and therapeutical quality of the drugs available in the market. We collect data on the 266 recalls that occurred between January 2010 and December 2017. Recalls are implemented by ISP whenever it receives notice about an adverse event associated with a licensed drug that justifies recall as a preventative sanitary measure.[31]

Figure 8 the monthly recall frequency during our sample period, split into drugs subject bioequivalence requirements (and included in our sample), and drugs without bioequivalence requirement. In the period, there is on average 1.9 recalls per month, corresponding to 1.4 from active ingredients without requirement and 0.5 from active ingredients with a requirement. We cannot reject the null hypothesis of a same trend in recalls over time across these groups.[32]

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

$$\mu_{mt} = N_{mt} \exp(\beta_0 + \theta_m + \gamma T_{mt}) \tag{4}$$

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

6.6 Discussion

In this Section, we have provided evidence for the equilibrium effects of stronger quality regulation. We exploited identifying variation arising from a combination of the staggered phase-in of bioequivalence requirements across markets and heterogeneity in enforcement of the policy due

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

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

to variation in drug license renewal dates. We use these sources of variation to construct a variable that measures the evolution of this policy for each market in our data. This empirical strategy allows for estimation of policy effects, which we interpret using our model in Section 3.1.

Our analysis provides evidence of large equilibrium effects of quality regulation. We start by showing that stronger quality regulation induced drugs to exit the market. Most of the exit was due to reductions in the portfolio of drugs offered by laboratories within a market rather than due to the exit of laboratories. While one could have expected stronger quality regulation to reduced vertical differentiation and increase the intensity of price competition, our estimates show that this effect on market structure overturned those effects. In fact, we find that drug prices increased as a result of the policy. Furthermore, we find no evidence of an increase in the market share of generic, which was the main motivation behind the policy. Finally, we provide evidence that suggests that drug quality did not improve, at least as measured by drug recalls.

We show that most of the adverse effects from stronger quality regulation are concentrated in small markets. This pattern of heterogeneity suggests that laboratories decide to exit the market whenever the fixed cost of regulation compliance is too large relative to the profitability of the market, as predicted by our model. In the next section, we explore complementary explanations for our results using data from a consumer survey.

7 Additional Evidence from Consumer Surveys

Our findings suggest that quality regulation had unexpected adverse effects. While its goal was to increase price competition by reducing quality differentiation, we find that the drug exit due to compliance costs reduced competition and lead to price increases. There are several potential explanations for why stronger quality regulation may have had these adverse effects. For instance, consumers may not update their perceptions about the quality of generics sufficiently. Large biases against generics reduce the 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 price differences between innovator drugs and generics, which are often large, reducing search. Finally, physicians may limit the extent to which bioequivalence can affect consumer choices through prescribing innovator drugs or branded generics.

We collect survey data on consumers in order to assess different aspects of their purchase behavior, including attitudes towards generics, their understanding and familiarity with bioequivalence, as well as the role of physicians in influencing their purchase decisions. We conducted in-person surveys to frequent consumers of drugs who are recruited outside pharmacies after a drug purchase. In order to collects perceptions, we focus on a particular large market, Atorvastatin. Within that market, we ask consumers for their quality and price perception for for drug types, namely an innovator drug (Lipitor, by Pfizer), a bioequivalent branded generic (Lipoten,

by Pharmavita) and bioequivalent and non-bioquivalent unbranded generics (Atorvastatina, by Mintlab). For more details about the survey design and methodology, see Appendix A.2. We collect surveys from $N = 348$ consumers, of which 60% report having a household member with a chronic disease, and 36% report purchasing Atorvastatin for a household member. Table A.5 provides summary statistics for the main variables in the survey.

7.1 Main Results

Knowledge About Bioequivalence. There is substantial heterogeneity in knowledge about bioequivalence among consumers in our sample, despite the fact that 84% of consumers are familiar with the label attached to bioequivalent drugs. Figure 9-a shows that almost 30% is not familiar at all with bioequivalence while, on the other hand, almost 50% is able to provide a good or excellent definition for it.[33] Limited knowledge about bioequivalence might reduce the extent to which bioequivalence may effectively signal drug quality and induce consumer to switch from innovator drugs or branded generics to cheaper bioequivalent unbranded generics.

Perceived Quality Differences. Consumer display substantial variation in their perceived quality of drugs in the market. We collect data on perceived quality for each drug on a 1-7 scale. We define perceived quality premium as the difference between the perceived quality of the innovator drug and that of other drug type. Figure 9-b displays the distribution of perceived quality premiums relative to the innovator. As expected, consumers perceive that the innovator is of higher quality than branded generics, and that branded generics are of higher quality than unbranded generics. Additionally, they perceive that bioequivalent drugs are of higher quality than non-bioequivalent drugs. Therefore, consumers do attribute a quality premium to bioequivalence, although not large enough as to close the innovator and branded drug perceived quality premium. This might be partly due to a poor understanding of what bioequivalence means. We explore this possibility in Figure 9-c, which shows that for all drug types, the quality premium 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).[34] 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 are unaware of, or underestimate, the price differences between innovator drugs, branded generics

[33]Market experience seems to be correlated with knowledge about bioequivalence. For instance, consumers who report having a household member with a chronic illness –and are thus more likely to be constantly interacting with the pharmaceutical market– show on average to have 9.8% (p-value=0.069) higher knowledge than consumers without a households member with a chronic illness.

[34]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.

and unbranded generics. 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 9-d displays perceived price premiums relative of the innovator drug relative to other drug types.[35]. Consumers do 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 48%, 68% and 74% relative to the innovator respectively. Moreover, a large share of the consumers identify discounts of unbranded generics between 90% and 100%. While perceived price differences are lower than actual price differences, these patterns suggest that consumers are to a large extent aware of differences in market prices across drug types.

The Role of Physicians. Prescription behavior by physicians plays a key role in drug purchase behavior and generic penetration (Dickstein, 2015). This has motivated policies of *generic substitution* in different countries, so as to limit the extent to which physicians prescribing expensive named drugs may limit generic penetration. We gather information regarding consumer experience with physician prescription behavior. We find that 67% of consumers answer that physicians often prescribe drugs by the name instead of the active ingredient. However, consumers display some degree of willingness to deviate from physicians' recommendations. Conditional on a physician prescription, only 13% of consumers state that purchase the prescribed named drug *always and regardless of drug prices*, while 53% state that they deviate from the brand prescribed by the physician whenever there is a large enough price difference. Finally, 34% of respondents state that they shop only on price, disregarding the brand recommended by their physician.

7.2 Discussion

We employ a consumer survey to explore potential explanations for the unintended consequences of stronger quality regulation we document in our main analysis. We show that, after almost 10 years since the beginning of the reform to quality regulation we study, a large share of consumers have none or an imprecise understanding of what bioequivalence means. In terms of the model in Section 3, this evidence implies that $\delta_1 < 1$.[36] Additionally, we find that perceived quality premiums are lower for consumers with a higher understanding of bioequivalence. This evidence is related to research on how biases against generics limit generic penetration (Bronnenberg et al.,

[35]The actual price of the innovator drug we consider is around $50,000 CLP, while the prices of the branded and unbranded generics are around $10,000 CLP and $2,500 respectively. Actual discounts are therefore in the order of 80% and 95% respectively.

[36]This survey does not allow to directly measure perceived quality of generics before the bioequivalence reform, and therefore estimate changes in perceived quality of generics due to it. Making a strong assumption on the evolution of perceived quality, one could argue that the policy did have an effect on perceived quality by comparing perceived quality of bioequivalent and non-bioequivalent unbranded generics: the perceived quality premium of bioequivalent unbranded generics is 61% lower than that of non-bioequivalent unbranded generics, suggesting the policy did have an effect on perceived quality.

2015; Colgan et al., 2015; Bairoliya et al., 2017). Moreover, it suggests that information policies might be complementary to quality regulation by inducing consumers to update their perception about perceived generic quality in accordance with the regulation.

Additionally, our survey highlights two additional barriers for generic penetration. On the one hand, while 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 will choose generics. The fact that consumers mention they are willing to disregard physicians' recommendations whenever price differences are large enough limits, but do not eliminate, the effect of physician behavior on generic penetration. These are two additional barriers for generic penetration.

Overall, the results of the survey point towards the existence of barriers to generic penetration in our setting. These frictions undermine the ability of the regulation to effectively shift consumers towards generics that have proven to be bioequivalent. These barriers, in turn, reduce the profitability of generic manufacturers to entering or remaining in the market, relative to the fixed regulation compliance cost. This is consistent with the finding in our main analysis, where we documented a reduction in the number of drugs in the market and an increase in drug prices as a results of stronger quality regulation, particularly for small markets.

8 Conclusion

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

Our findings, drawn from the Chilean pharmaceutical market, show the importance of quantifying the market effects of quality regulations in order to assess their welfare consequences. Contrary to the intended outcomes of the policy, we find that average prices paid by consumers increased as a result. These price increases are particularly large in low-revenue markets, where we also find significant exit. Moreover, we do not find significant increases in the market share of generics. Overall, these results suggest an increase in market power that was particularly pronounced in small markets, showing that quality regulation may have unintended adverse effects due to costly compliance, in particular in markets on the margin of profitability.

The market effects of quality regulations depend crucially on the extent to which demand reacts accordingly, and pharmaceutical markets impose particular challenges in this regard. First, the extent to which demand can react is limited by physicians' prescribing behavior, whom may have different incentives than their patients' (Dickstein, 2015). Moreover, attitudes towards generic drugs are expected to change slowly over time as consumers learn about their quality. Unexperi-

enced consumers may have long-lasting biases against generics (Bairoliya et al., 2017) and as such, quality regulations may not have it desired effects in the short run. Consumer survey data from the Chilean market confirm the presence of these lasting biases and frictions, and points towards the need of complementary policies to avoid the unintended consequences of policies that impose minimum quality standards.

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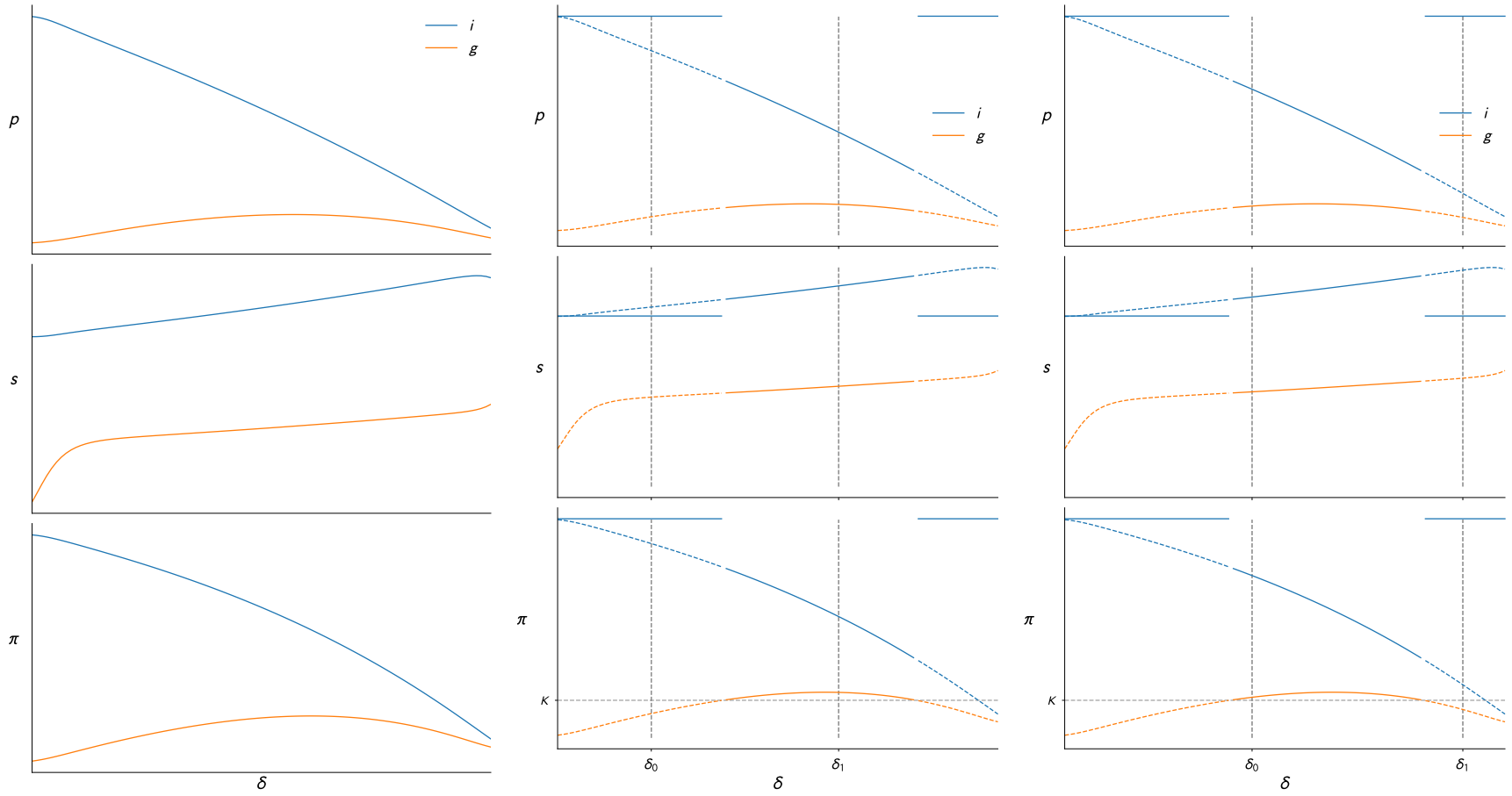
Figure 1: Market Equilibrium before and after Quality Regulation without Loyal Segment



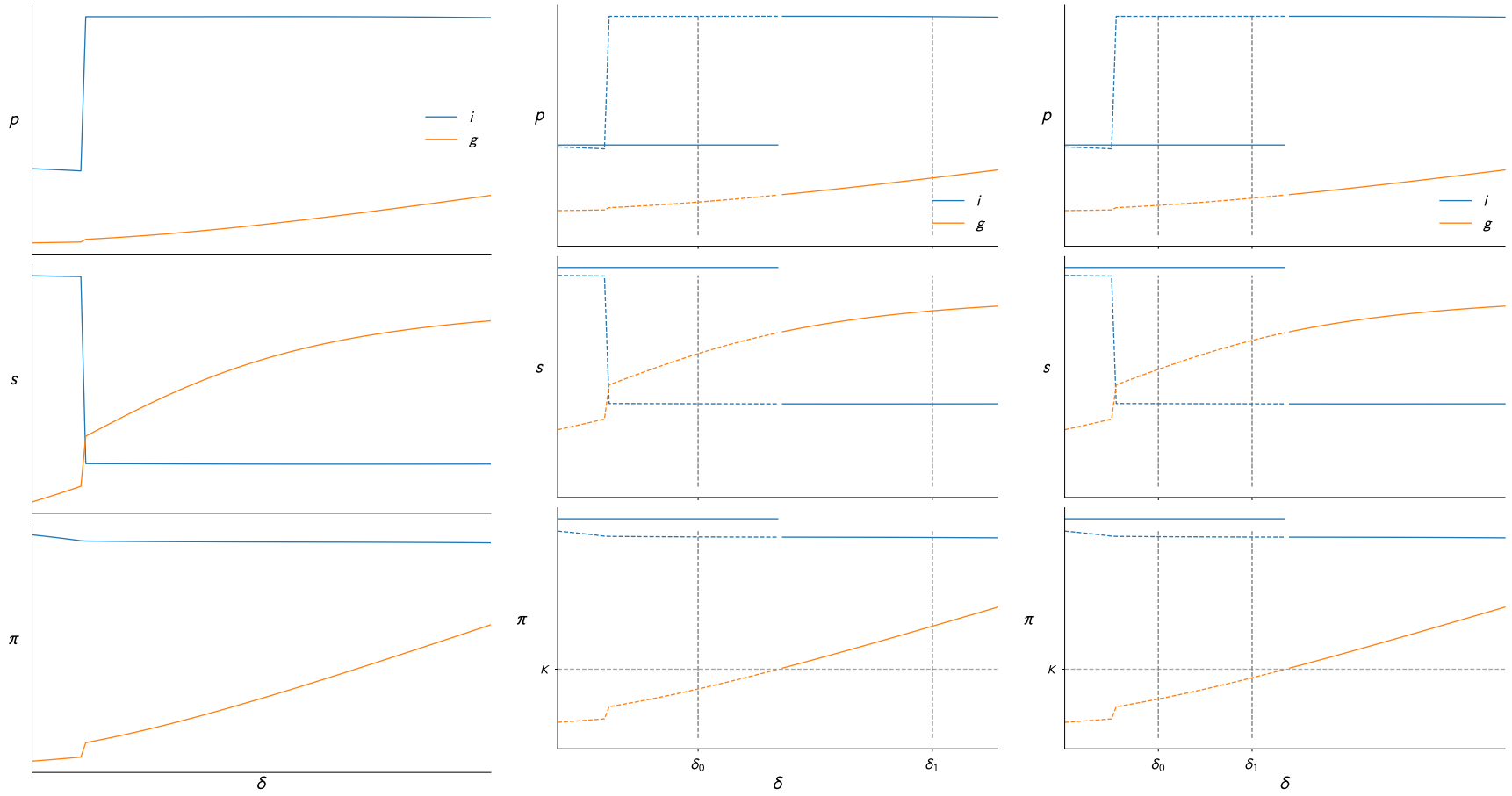
(a) Pre-reform equlibrium

(b) Post-reform equlibrium without exit

(c) Post-reform equlibrium with exit

Notes: This figure displays results for simulated equilibrium outcomes from our model in Section 3.1. Each panel displays outcomes for the innovator (blue) and the generic (red) in the market for price, market share and profits. Panel (a) focuses on the pre-reform equilibrium. Panels (b) and (c) focuses on post-reform equilibria for different brand premiums, where K indicates the fixed cost associated with proof of bioequivalence. In Panels (b) and (c) solid lines indicate actual outcomes, while dotted lines indicate outcomes in absence of quality regulation.

Figure 2: Market Equilibrium before and after Quality Regulation with Loyal Segment



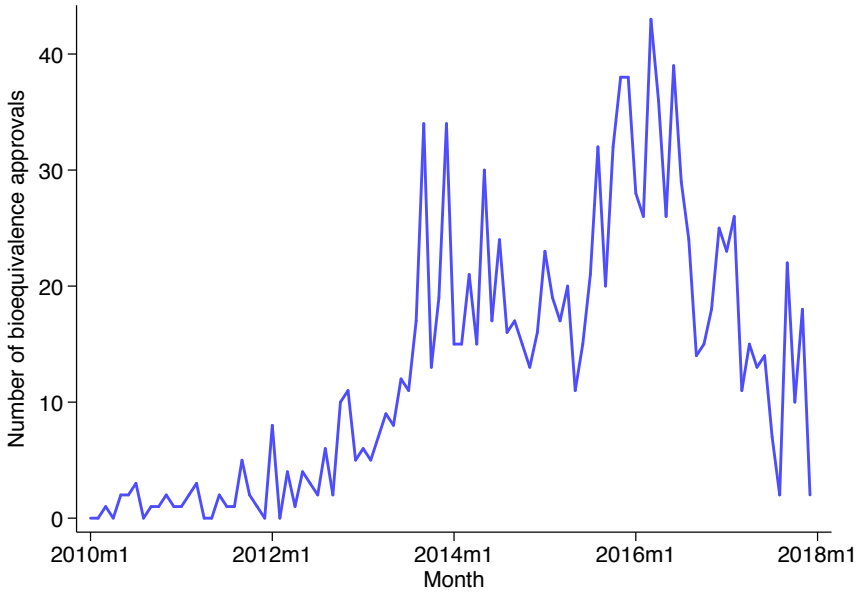
(a) Pre-reform equlibrium

(b) Post-reform equlibrium without exit

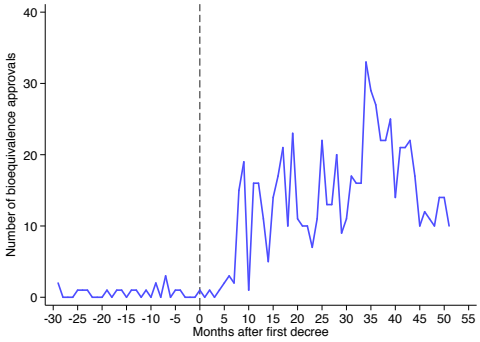
(c) Post-reform equlibrium with exit

Notes: This figure displays results for simulated equilibrium outcomes from our model in Section 3.1. Each panel displays outcomes for the innovator (blue) and the generic (red) in the market for price, market share and profits. Panel (a) focuses on the pre-reform equilibrium. Panels (b) and (c) focuses on post-reform equilibria for different brand premiums, where K indicates the fixed cost associated with proof of bioequivalence. In Panels (b) and (c) solid lines indicate actual outcomes, while dotted lines indicate outcomes in absence of quality regulation.

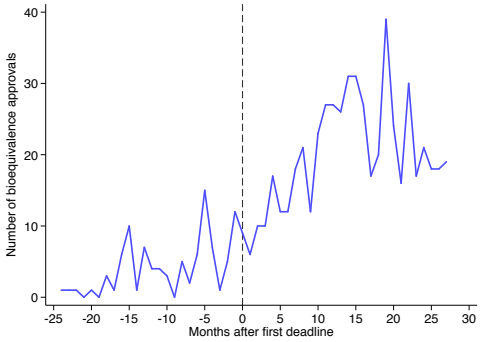
Figure 3: Bioequivalence Approvals around Policy Events



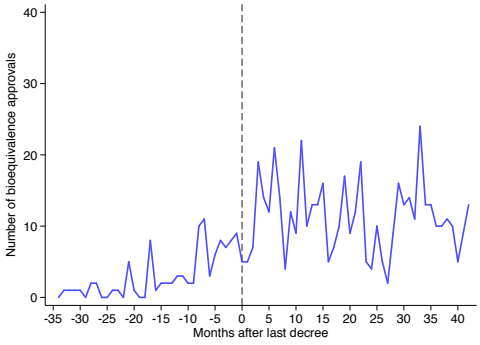
(a) Approvals through time



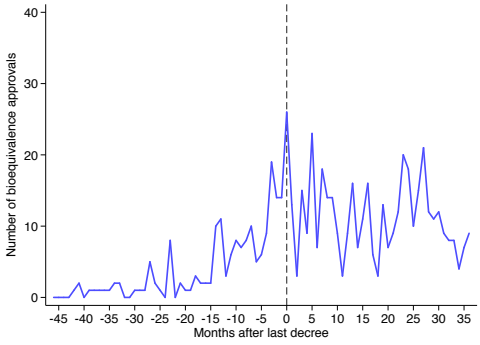
(b) Approvals around first decree



(c) Approvals around first deadline



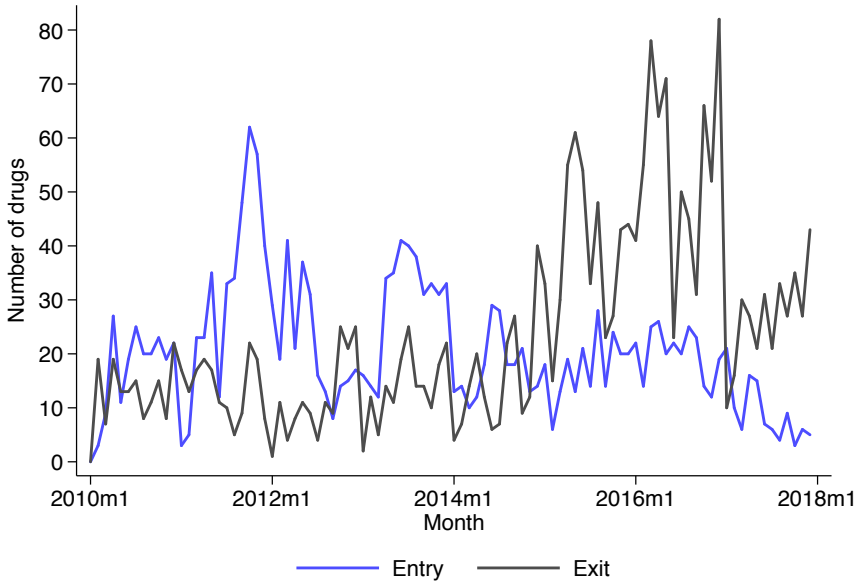
(d) Approvals around to last decree



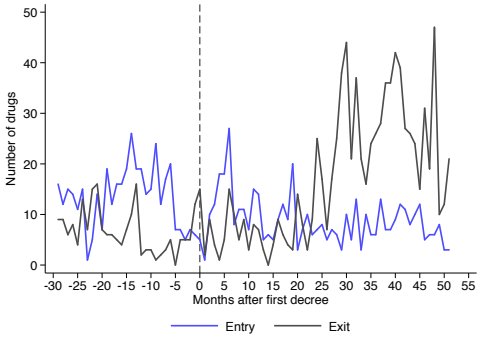
(e) Approvals around to last deadline

Notes: Panel (a) in this figure displays the evolution of the number of drugs with bioequivalence approval over time. Panels (b) through (e) display the number of bioequivalence approvals around bioequivalence decrees and deadlines.

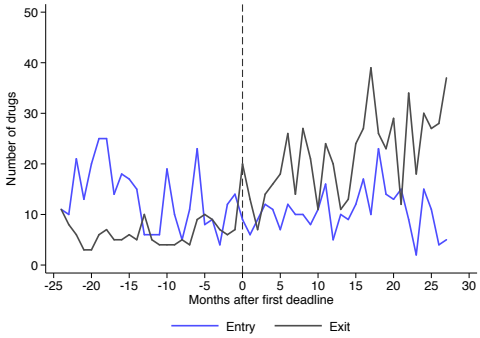
Figure 4: Number of Entry and Exit of Drugs around Policy Events



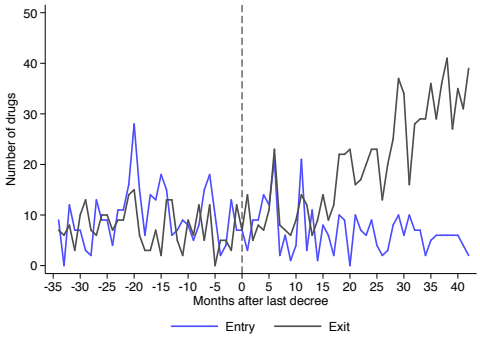
(a) Entry and exit through time



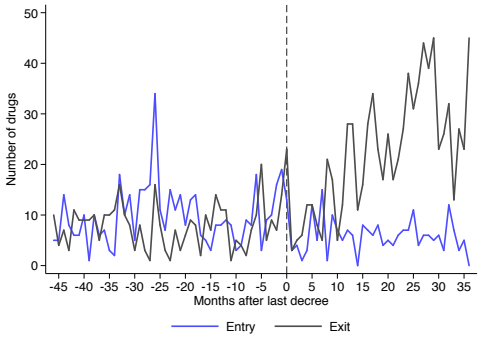
(b) Relative to first decree



(c) Relative to first deadline



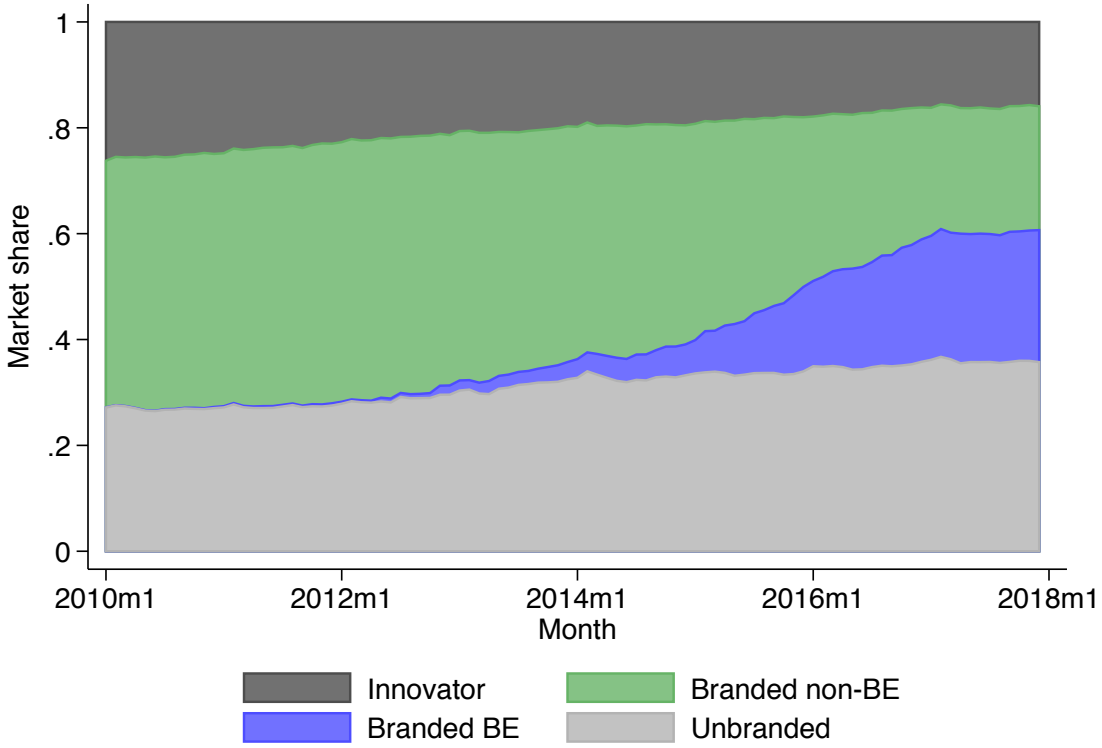
(d) Relative to last decree



(e) Relative to last deadline

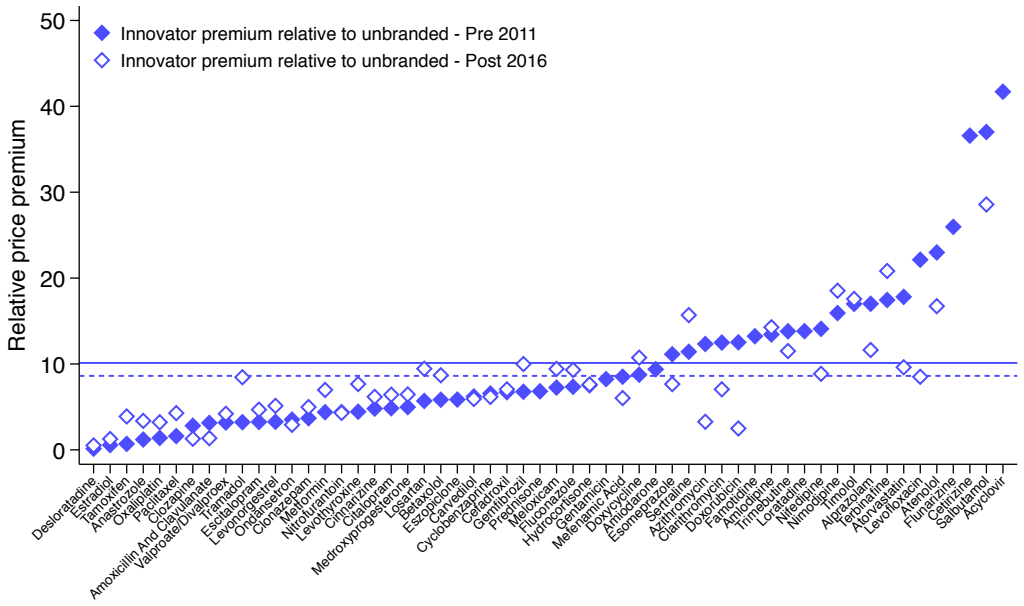
Notes: This figure displays the number of entering (blue) and exiting (black) drugs around bioequivalence decrees and deadlines. The vertical axis displays the count of such events. Panel (a) display the evolution of entry and exit of drugs over time, while panels (b) through (e) display the evolution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

Figure 5: Market Shares by Drug Type

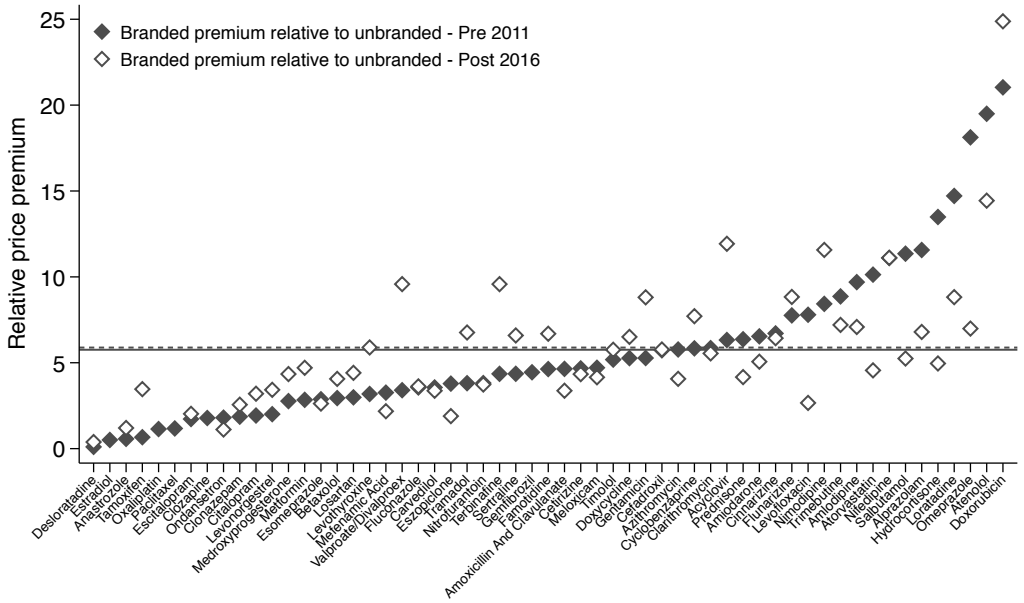


Notes: This figure displays the evolution of market shares of different drug types over time. For each type, we plot the average market share across markets for each month in our sample.

Figure 6: Innovator and Branded Drugs Price Premiums by Market



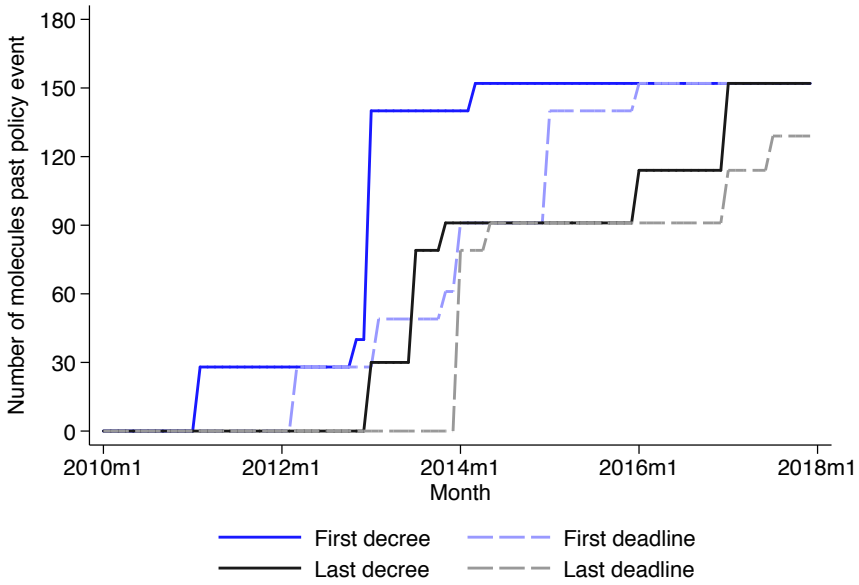
(a) Innovator drugs price premiums relative to unbranded generics



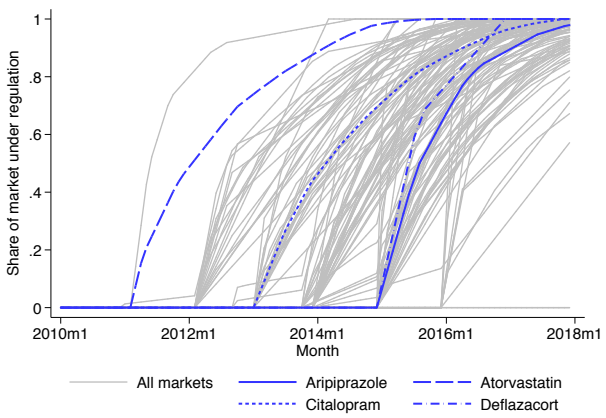
(b) Branded drugs price premiums relative to unbranded generics

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.

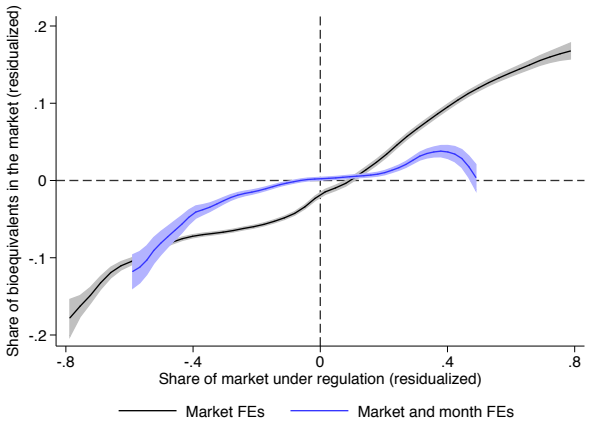
Figure 7: Evolution of Quality Regulation



(a) Timing of bioequivalence decrees and deadlines



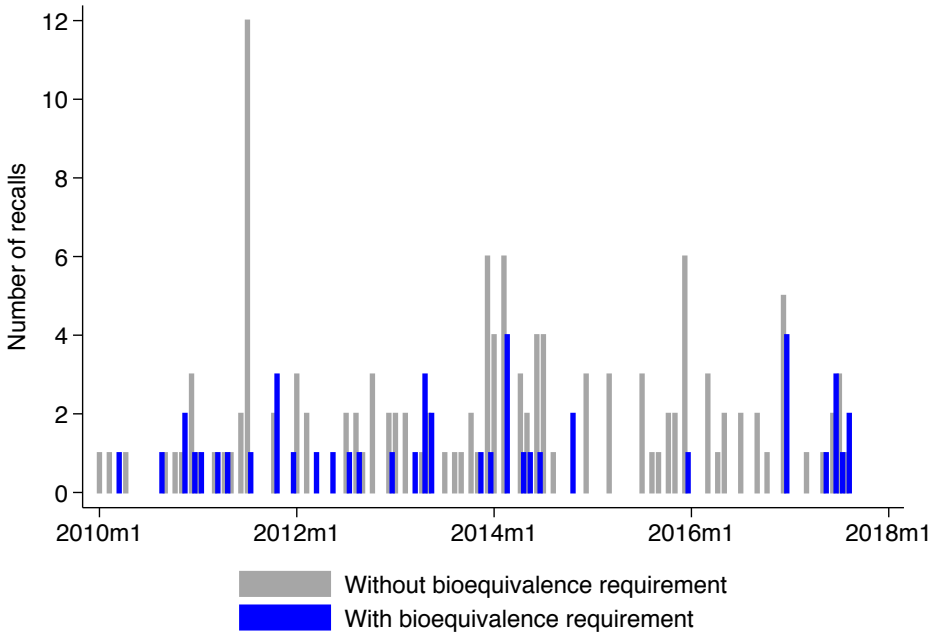
(b) Evolution of quality regulation by market



(c) Quality regulation and share of bioequivalent drugs

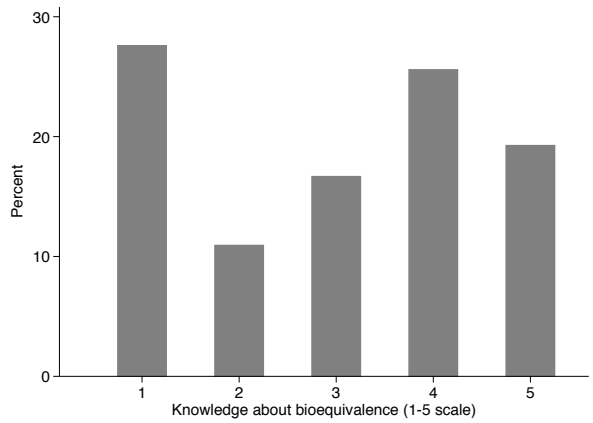
Notes: Panel (a) in this figure displays the number of markets affected by different policy events associated to bioequivalence regulation, from the first decree to the last deadline. Panel (b) displays the evolution over time of the treatment variable defined in equation (2) for each market in the sample. 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).

Figure 8: Number of Recalls per Month

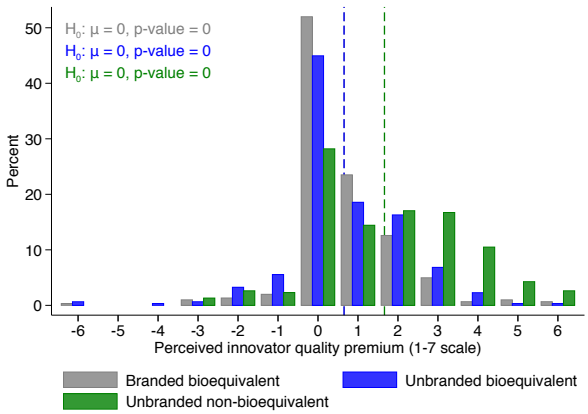


Notes: The figure shows the number of product recalls over time split into markets with bioequivalence requirements and markets without bioequivalence requirements.

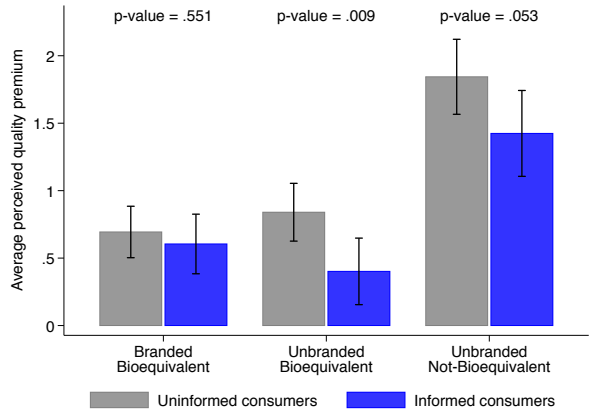
Figure 9: Survey Results



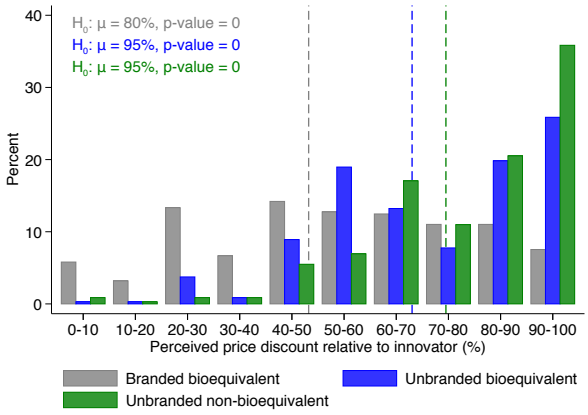
(a) Knowledge about bioequivalence



(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	53	12,111	0.22	0.69	0.08
2	20	2011-01	2012-02	2013-06	2013-12	193	297	10,517	0.28	0.60	0.12
3	11	2012-10	2013-10	2013-10	2014-04	91	257	7,890	0.18	0.62	0.20
4	25	2012-12	2013-12	2012-12	2013-12	378	160	7,495	0.23	0.68	0.09
5	20	2012-12	2013-01	2013-06	2013-12	354	115	9,046	0.18	0.76	0.05
6	10	2012-12	2014-12	2015-12	2016-12	108	677	8,126	0.17	0.78	0.04
7	15	2012-12	2014-12	2016-12	2017-06	227	206	7,947	0.21	0.74	0.05
8	16	2012-12	2014-12	2016-12	2017-12	133	356	6,677	0.26	0.66	0.08
9	10	2014-02	2015-12	2016-12	2017-12	28	5	3,622	0.06	0.35	0.59

Notes: Panel A in this table displays the dates of announcement and deadlines of BE requirements for different groups of molecules. The groups are defined as a unique combination of decrees and deadlines. Panel B in this table displays average product characteristics in 2011, by groups of molecules. The group NA corresponds to molecules without BE approval. Prices per gram and revenues are measured in 2013 1,000s CLP.

Table 2: Descriptive Statistics for IMS Data

Variable	N	Mean	SD	p10	p50	p90
Panel A: Price per gram						
All drugs	144,106	243.9	2212.9	1.2	19.1	308.6
Innovators	33,251	476.2	2056.1	2.3	39.0	988.2
Branded generics	96,909	193.5	2408.4	1.7	19.5	207.3
Unbranded generics	13,946	40.3	173.1	0.2	1.6	68.9
Bioequivalents	17,270	87.0	315.9	1.2	11.8	146.8
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 thousands of 2013 CLP and calculated at the drug level, while the remainder are calculated at the market level. Market shares are only observed for markets in which at least one drug is sold in the period. Statistics for the number of drugs and laboratories are computed using only observations for which the drug or laboratory is found to be active in the corresponding market.

Table 3: Hazard Model for Bioequivalence and Exit

	(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)	(9)	(10)
	Panel A: Bioequivalence approval hazard					*Panel B: Exit hazard*				
After first decree	2.48***				1.41***	0.02				-0.18
	(0.36)				(0.40)	(0.16)				(0.18)
After first deadline		1.51***			1.36***		0.38***			0.39***
		(0.18)			(0.18)		(0.10)			(0.13)
After last decree			-0.16		-0.24			0.17**		0.03
			(0.11)		(0.21)			(0.07)		(0.11)
After last deadline				-0.27**	-0.27				0.16**	0.09
				(0.11)	(0.20)				(0.07)	(0.11)
Reference						-0.62***	-0.63***	-0.61***	-0.62***	-0.62***
						(0.10)	(0.10)	(0.10)	(0.10)	(0.10)
Branded	-0.46***	-0.47***	-0.46***	-0.46***	-0.47***	0.41***	0.41***	0.41***	0.41***	0.41***
	(0.11)	(0.11)	(0.11)	(0.11)	(0.11)	(0.08)	(0.08)	(0.08)	(0.08)	(0.08)
Imported	0.49***	0.49***	0.50***	0.50***	0.49***	0.44***	0.43***	0.43***	0.43***	0.43***
	(0.08)	(0.08)	(0.08)	(0.08)	(0.08)	(0.06)	(0.06)	(0.06)	(0.06)	(0.06)
log(Market revenue)	0.59***	0.55***	0.62***	0.63***	0.57***	-0.08***	-0.09***	-0.09***	-0.08***	-0.09***
	(0.06)	(0.06)	(0.06)	(0.06)	(0.06)	(0.03)	(0.03)	(0.03)	(0.03)	(0.03)
log(Number of branded)	-0.14*	-0.13*	-0.14*	-0.14*	-0.13*	-0.02	-0.02	-0.02	-0.02	-0.02
	(0.07)	(0.07)	(0.07)	(0.07)	(0.07)	(0.04)	(0.04)	(0.04)	(0.04)	(0.04)
log(Number of unbranded)	-0.55***	-0.57***	-0.50***	-0.49***	-0.52***	-0.09*	-0.10*	-0.10**	-0.10**	-0.11**
	(0.08)	(0.08)	(0.08)	(0.08)	(0.08)	(0.05)	(0.05)	(0.05)	(0.05)	(0.05)
Time FE	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y
Observations	180,110	180,110	180,110	180,110	180,110	233,056	233,056	233,056	233,056	233,056
ln L	-3,056	-3,041	-3,082	-3,080	-3,023	-7,054	-7,049	-7,052	-7,052	-7,048

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

Table 4: Policy Effects 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	-0.14**	0.15	-0.27**	2.14***	-0.41***	0.04	0.96***	-0.05
	(0.04)	(0.08)	(0.10)	(0.45)	(0.09)	(0.04)	(0.12)	(0.09)
R^2	0.99	0.97	0.98	0.85	0.98	0.96	0.84	0.93
Panel B: Heterogeneity by baseline market size								
Low revenue	-0.36***	-0.28*	-0.39**	1.06***	-0.45**	-0.13	0.22	-0.00
	(0.08)	(0.14)	(0.12)	(0.29)	(0.13)	(0.09)	(0.19)	(0.15)
High revenue	-0.09*	0.26***	-0.25*	2.41***	-0.40***	0.07	1.14***	-0.06
	(0.04)	(0.06)	(0.10)	(0.46)	(0.09)	(0.04)	(0.12)	(0.09)
R^2	0.99	0.98	0.98	0.87	0.98	0.96	0.88	0.93
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 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: Policy Effects 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	-0.03	0.06	-0.05	1.99***	-0.05	-0.12**	1.91***	-0.10
	(0.05)	(0.06)	(0.06)	(0.38)	(0.05)	(0.05)	(0.29)	(0.09)
R^2	0.96	0.99	0.98	0.86	0.98	0.95	0.87	0.90
Panel B: Heterogeneity by baseline market size								
Low revenue	-0.19***	0.03	-0.12	1.23***	-0.06	-0.22***	1.14***	0.09
	(0.05)	(0.07)	(0.09)	(0.28)	(0.08)	(0.05)	(0.38)	(0.18)
High revenue	0.01	0.07	-0.04	2.18***	-0.05	-0.09*	2.10***	-0.14*
	(0.05)	(0.06)	(0.06)	(0.39)	(0.05)	(0.05)	(0.29)	(0.08)
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: Policy Effects 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	0.123**	0.040	0.002	0.141***
	(0.054)	(0.028)	(0.098)	(0.045)
R^2	0.50	0.66	0.85	0.64
Panel B: Heterogeneity by baseline market size				
Low revenue	0.268***	0.055	0.002	0.167***
	(0.099)	(0.040)	(0.143)	(0.058)
High revenue	-0.010	0.031	0.002	0.105
	(0.046)	(0.030)	(0.072)	(0.069)
R^2	0.52	0.66	0.85	0.64
Panel C: Decomposition of price effects				
Changes in prices ($\hat{P}_{PC}$)	0.076***	0.013	0.003	0.135***
	(0.020)	(0.019)	(0.025)	(0.043)
R^2	0.62	0.68	0.61	0.65
Changes in market shares ($\hat{P}_{RW}$)	0.019	0.017	0.054	-0.019
	(0.041)	(0.019)	(0.074)	(0.019)
R^2	0.37	0.52	0.83	0.36
Correlation between market shares and prices ($\hat{P}_{CS}$)	0.002	0.006	-0.032	0.000
	(0.011)	(0.012)	(0.025)	(0.007)
R^2	0.41	0.51	0.61	0.34
Drug entry ($\hat{P}_E$)	0.034**	0.019	-0.022	0.013
	(0.016)	(0.013)	(0.061)	(0.014)
R^2	0.35	0.50	0.77	0.44
Drug exit ($\hat{P}_X$)	-0.007**	-0.016**	-0.001	0.011**
	(0.003)	(0.006)	(0.007)	(0.005)
R^2	0.35	0.26	0.64	0.12
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 log volume-weighted drug prices for each molecule on the policy roll-out variable constructed using the first decree deadline. The average is taken over all drugs for each market. Panel B provides results by baseline. 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. Panel C displays results for each component of the decomposition of price changes in section 6.3.1. 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: Policy Effects on Drug Market Shares

	(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	0.05*	-0.04	0.08***	-0.12***	-0.01	-0.21	-0.15	-0.47**	2.46***	-1.10***	-0.12
	(0.03)	(0.03)	(0.03)	(0.04)	(0.02)	(0.13)	(0.18)	(0.24)	(0.68)	(0.35)	(0.23)
R^2	0.91	0.93	0.53	0.86	0.96	0.97	0.97	0.94	0.64	0.90	0.95
Panel B: Heterogeneity by baseline market size											
Low revenue	0.08**	-0.02	0.03	-0.05	-0.06	-0.34**	-0.21	-0.53**	1.14	-0.93*	-0.75**
	(0.03)	(0.03)	(0.04)	(0.04)	(0.04)	(0.14)	(0.23)	(0.22)	(0.74)	(0.48)	(0.35)
High revenue	0.02	-0.06*	0.13***	-0.19***	0.04*	-0.09	-0.09	-0.42	3.67***	-1.25***	0.47*
	(0.03)	(0.04)	(0.03)	(0.04)	(0.02)	(0.14)	(0.19)	(0.37)	(0.81)	(0.38)	(0.24)
R^2	0.92	0.93	0.55	0.87	0.96	0.97	0.97	0.94	0.65	0.90	0.95
Pre-regulation average	0.19	0.55	0.00	0.55	0.26	-	-	-	-	-	-
Observations	12,576	12,576	12,576	12,576	12,576	12,576	12,576	12,576	12,576	12,576	12,576
Market FE	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y
Month FE	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y

Notes: Columns (1) through (5) in this table is a regression of the market share of a segment on the policy roll-out variable constructed using the first decree deadline. Columns (6) through (11) display regressions of logged sales of a segment on the policy roll-out variable constructed using the first decree deadline. Panel B provides results by baseline revenue. Markets are classified as having a low or high revenue according to the average level of the variable in 2010 relative to the median across markets in that year. Clustered standard errors in parentheses. ***p<0.01, **p<0.05, *p<0.1.

A Appendix

A.1 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):

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

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

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

In practice, we consider the first policy deadline as the event that defines t_{0m}. Although decrees were extended, we cannot rule out that extensions were unexpected. This choice allows us to remain agnostic about potential reactions to the announcement of the first decree. We also place the following end-point restrictions:[37]

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

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.3 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

[37] 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.

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.

A.2 Description of Consumer Survey

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

A surveying team composed by 6 members conducted surveys in 4 counties in the city of Santiago, namely Ñuñoa, Providencia, Puente Alto and Santiago. Within such counties, surveyors recruited consumers for the study outside pharmacies, where consumers were purchasing drugs. This recruiting strategy aimed at constructing a sample of consumers familiar with the pharmaceutical market. Recruited participants were asked to participate in a survey with a duration of between 5 and 10 minutes, and were offered no compensation for it.

In order to collect data on perceived quality and price differences, we focus on a particular market, Atorvastatin, a molecule commonly prescribed as a treatment to cholesterol. Within that market, we focus on 4 drugs that are relevant products in this market. In particular, we work with (i) a popular innovator drug called Lipitor, which is produced by Pfizer, (ii) a bioequivalent branded generic called Lipoten, produced by Pharmavita, (iii) a bioequivalent unbranded generic called simply Atorvastatina, produced by Mintlab, and (iv) and a non-bioequivalent unbranded generic also called Atorvastatina and produced by Mintlab. For reference, the prices of these drugs in the market are around $50,000 CLP, $10,000 CLP, $2,500 CLP and $2,500 CLP respectively. Perceived quality and price differences are elicited using a paper sheet that showed the 4 drugs, which is displayed in Figure A.4.

The final sample includes $N = 348$ consumers. Table A.5 provides summary statistics for the main variables in the survey. Among consumers in the sample, 62% report having a household member with a chronic disease, and 36% report purchasing Atorvastatin for a household member.

In terms of purchase behavior, 41% often purchases innovator drugs, 21% often purchases branded generics, and the remainder 38% often purchases unbranded generics. The main results of the survey and their relationship to the results in our main analysis are discussed in Section 7. We code observations in which a consumer answered "I don't know" or 'I don't recall" as missing. Finally, the questions regarding physicians' prescription behavior have less observations because they were added to the survey with a lag and are therefore not available for a around a fourth of the sample.

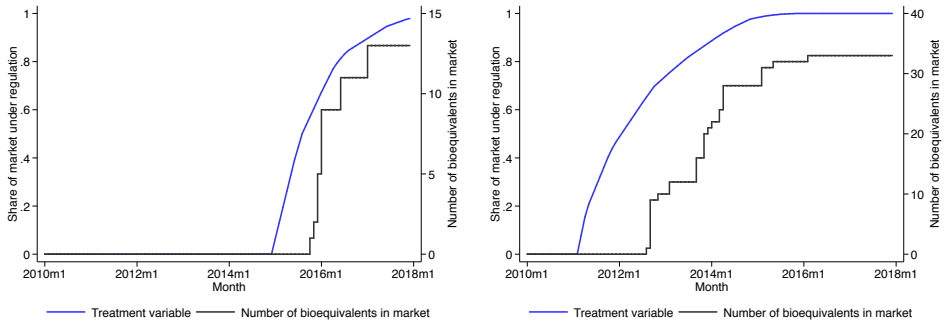
Figure A.1: Labeling of Bioequivalent Drugs

(a) Instructions for bioequivalent drugs labeling

(b) Examples of labeled bioequivalent drugs

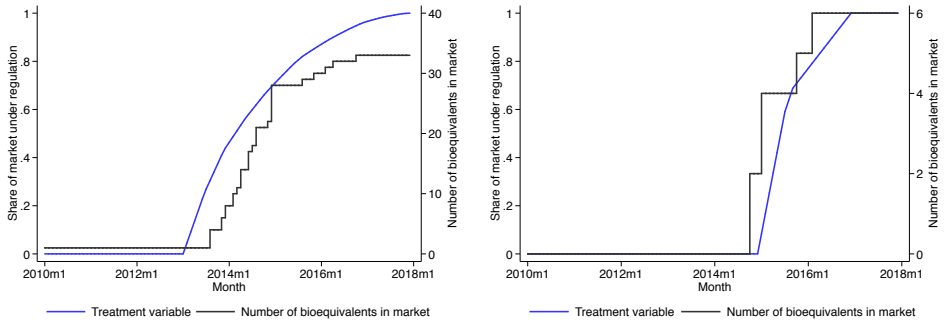
Notes: This figures display both instructions and examples of required labeling of bioequivalent drugs. The objective of this labeling was to highlight drugs with BE approval.

Figure A.2: Policy Variation induced by Bioequivalence Requirements



(a) Aripiprazole

(b) Atorvastatin

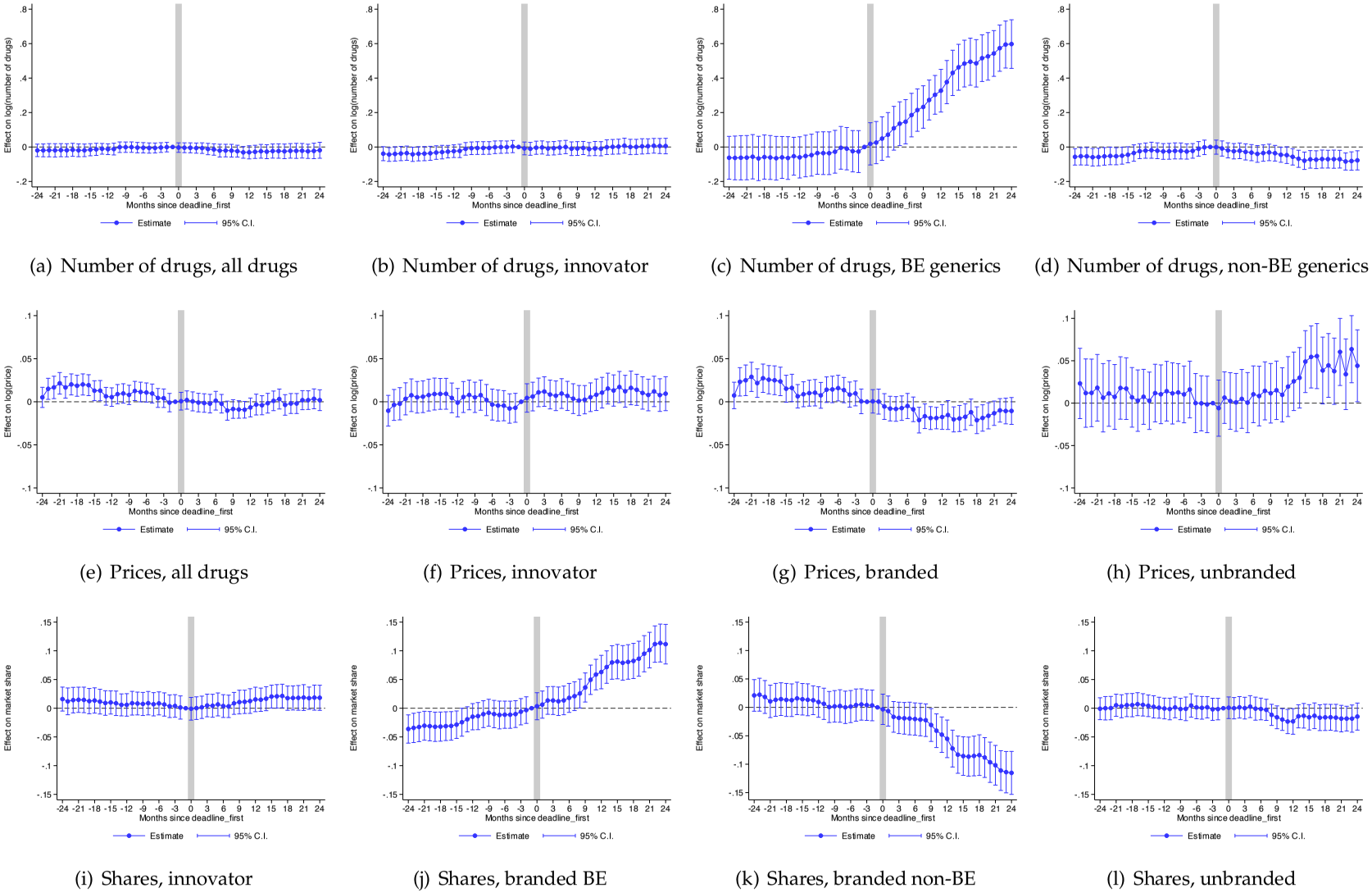


(c) Citalopram

(d) Deflazacort

Notes: Each figure displays the values of the treatment variable and the number of BEs in a different market. This version of the treatment variable uses the first deadline as the relevant date. The instrument is displayed in blue, and takes a value of 0 before the first decree, and then increases as renewal dates of drugs in the molecule approach. The number of BE drugs in the molecule is displayed in gray. These four examples are plotted along all other markets in our sample in Figure 7-b.

Figure A.3: Policy Effects using an Event Study Approach



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

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

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

Notes: This figure displays results from event study specifications described in Section A.1, using the first bioequivalence deadline as policy event. Dots indicate point estimates and lines indicate 95% confidence intervals based on robust standard errors. 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.

Figure A.4: 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 scor 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.

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

	(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)	(9)	(10)
	Panel A: Bioequivalence approval hazard					*Panel B: Exit hazard*				
After first deadline	2.41***	2.79***	1.68**	0.13	0.89	0.39	0.66	-0.09	0.15	-0.22
	(0.39)	(0.54)	(0.73)	(1.25)	(1.24)	(0.33)	(0.42)	(0.37)	(0.41)	(0.53)
× Above median price, 2010		-0.85			-1.01		-0.43			0.05
		(0.65)			(0.65)		(0.40)			(0.43)
× log(Sales, 2010)			0.12		0.00			0.21**		0.12
			(0.10)		(0.09)			(0.09)		(0.12)
× log(Revenue, 2010)				0.15*	0.13*				0.04	0.04
				(0.08)	(0.07)				(0.03)	(0.04)
Above median price, 2010		0.45			0.67		0.33			-0.17
		(0.64)			(0.64)		(0.39)			(0.42)
log(Sales, 2010)			0.08		0.15*			-0.43***		-0.30***
			(0.10)		(0.08)			(0.08)		(0.11)
log(Revenue, 2010)				-0.01	-0.05				-0.14***	-0.08**
				(0.07)	(0.06)				(0.02)	(0.04)
Reference						-1.14***	-1.13***	-1.11***	-0.99***	-1.03***
						(0.26)	(0.26)	(0.24)	(0.24)	(0.24)
Imported	0.40***	0.39***	0.43***	0.40***	0.41***	0.57***	0.58***	0.51***	0.54***	0.52***
	(0.13)	(0.13)	(0.13)	(0.13)	(0.13)	(0.15)	(0.15)	(0.15)	(0.15)	(0.15)
log(Market revenue)	0.55***	0.56***	0.37***	0.51***	0.41***	-0.25***	-0.25***	-0.02	-0.17*	-0.02
	(0.10)	(0.10)	(0.10)	(0.10)	(0.11)	(0.09)	(0.09)	(0.10)	(0.09)	(0.10)
log(Number of branded)	0.08	0.09	0.14	0.09	0.13	0.04	0.04	-0.06	0.01	-0.05
	(0.13)	(0.13)	(0.13)	(0.13)	(0.13)	(0.11)	(0.11)	(0.11)	(0.11)	(0.11)
log(Number of unbranded)	-0.31**	-0.29**	-0.41***	-0.28**	-0.37***	-0.11	-0.11	-0.14	-0.11	-0.12
	(0.12)	(0.13)	(0.13)	(0.13)	(0.13)	(0.16)	(0.15)	(0.14)	(0.15)	(0.14)
Time FE	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y
Observations	50,966	50,966	50,966	50,966	50,966	79,508	79,508	79,508	79,508	79,508
ln L	-1,210	-1,205	-1,181	-1,192	-1,174	-888	-887	-848	-860	-843

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

Table A.2: Policy Effects 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	-0.15***	0.17*	-0.32***	2.71***	-0.47***	0.03	1.25***	-0.07
	(0.05)	(0.09)	(0.12)	(0.55)	(0.12)	(0.05)	(0.16)	(0.11)
R^2	0.99	0.97	0.98	0.85	0.98	0.96	0.84	0.93
Panel B: Heterogeneity by baseline market size								
Low revenue	-0.39***	-0.38**	-0.45***	1.44***	-0.52***	-0.17*	0.29	-0.04
	(0.09)	(0.16)	(0.14)	(0.38)	(0.16)	(0.10)	(0.25)	(0.17)
High revenue	-0.10**	0.30***	-0.29**	3.02***	-0.46***	0.08*	1.49***	-0.07
	(0.04)	(0.08)	(0.12)	(0.57)	(0.12)	(0.05)	(0.15)	(0.11)
R^2	0.99	0.98	0.98	0.87	0.98	0.96	0.88	0.93
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 drugs in a segment on the policy roll-out variable constructed using the first decree deadline. Panel B provides results by baseline revenue. Markets are classified as having a low or high revenue according to the average level of the variable in 2010 relative to the median across markets in that year. Clustered standard errors in parentheses. ***p<0.01, **p<0.05, *p<0.1.

Table A.3: Policy Effects 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	-0.04	0.08	-0.08	2.54***	-0.08	-0.14**	2.48***	-0.11
	(0.05)	(0.08)	(0.08)	(0.48)	(0.07)	(0.05)	(0.37)	(0.10)
R^2	0.95	0.99	0.97	0.86	0.98	0.94	0.87	0.90
Panel B: Heterogeneity by baseline market size								
Low revenue	-0.21***	0.04	-0.16	1.61***	-0.10	-0.26***	1.50***	0.10
	(0.06)	(0.09)	(0.10)	(0.36)	(0.09)	(0.06)	(0.47)	(0.20)
High revenue	0.01	0.09	-0.06	2.77***	-0.08	-0.11*	2.71***	-0.16
	(0.05)	(0.08)	(0.08)	(0.49)	(0.07)	(0.06)	(0.37)	(0.10)
R^2	0.96	0.99	0.97	0.88	0.98	0.95	0.89	0.91
Pre-regulation average	24.97	3.37	17.31	0.10	17.21	4.29	0.01	4.29
Observations	12,576	12,576	12,576	12,576	12,576	12,576	12,576	12,576
Market FE	Y	Y	Y	Y	Y	Y	Y	Y
Month FE	Y	Y	Y	Y	Y	Y	Y	Y

Notes: Each column in this Table is a regression of the inverse hyperbolic sine of number of laboratories in a segment on the policy roll-out variable constructed using the first decree deadline. Panels B provides results by baseline revenue. Markets are classified as having a low or high revenue according to the average level of the variable in 2010 relative to the median across markets in that year. Clustered standard errors in parentheses. ***p<0.01, **p<0.05, *p<0.1.

Table A.4: Policy Effects 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	-0.09***	0.12	-0.16***	0.78***	-0.27***	0.07*	0.40***	0.01
	(0.03)	(0.08)	(0.04)	(0.16)	(0.05)	(0.04)	(0.09)	(0.05)
R^2	0.98	0.92	0.97	0.83	0.96	0.88	0.58	0.79
Panel B: Heterogeneity by baseline market size								
Low revenue	-0.11**	-0.31**	-0.19**	0.51***	-0.29***	0.04	0.27*	-0.07
	(0.05)	(0.14)	(0.08)	(0.14)	(0.11)	(0.04)	(0.14)	(0.08)
High revenue	-0.08**	0.23***	-0.15***	0.85***	-0.26***	0.08*	0.43***	0.03
	(0.03)	(0.06)	(0.04)	(0.16)	(0.05)	(0.04)	(0.09)	(0.06)
R^2	0.99	0.94	0.97	0.84	0.96	0.88	0.59	0.80
Pre-regulation average	2.28	3.13	2.10	0.10	2.10	0.90	0.00	0.90
Observations	12,576	12,576	12,576	12,576	12,576	12,576	12,576	12,576
Market FE	Y	Y	Y	Y	Y	Y	Y	Y
Month FE	Y	Y	Y	Y	Y	Y	Y	Y

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

Table A.5: Summary Statistics from Consumer Survey Data

Variable	N	Mean	SD	p10	p50	p90
Perceived quality of innovator drug (1-7)	308	6.31	1.01	5.00	7.00	7.00
Perceived quality of bioequivalent branded drug (1-7)	326	5.67	1.33	4.00	6.00	7.00
Perceived quality of bioequivalent unbranded drug (1-7)	333	5.64	1.27	4.00	6.00	7.00
Perceived quality non-bioequivalent unbranded drug (1-7)	329	4.68	1.69	2.00	5.00	7.00
Perceived price of bioequivalent branded drug (CLP 1,000s)	345	25.90	14.12	7.00	25.00	45.00
Perceived price of bioequivalent unbranded drug (CLP 1,000s)	348	15.98	11.05	3.00	15.00	30.00
Perceived price of non-bioequivalent unbranded drug (CLP 1,000s)	346	12.74	10.00	2.00	10.00	25.00
Recognizes bioequivalent drug label	348	0.84	0.37	0.00	1.00	1.00
Understanding about bioequivalence (1-5)	348	2.98	1.50	1.00	3.00	5.00
=1 if physicians specify brand in prescriptions	247	0.67	0.47	0.00	1.00	1.00
=1 if always purchases doctor recommendation	257	0.13	0.34	0.00	0.00	1.00
=1 if sometimes deviate from doctor recommendation	257	0.53	0.50	0.00	1.00	1.00
=1 if always chooses cheapest available drug	257	0.34	0.47	0.00	0.00	1.00
Purchases innovator drugs	298	0.41	0.49	0.00	0.00	1.00
Purchases bioequivalent branded drugs	298	0.21	0.41	0.00	0.00	1.00
Purchases bioequivalent unbranded drugs	298	0.28	0.45	0.00	0.00	1.00
Purchases non-bioequivalent unbranded drugs	298	0.11	0.31	0.00	0.00	1.00
Chronic illness by household member	348	0.60	0.49	0.00	1.00	1.00
Atorvastatin consumption by household member	348	0.36	0.48	0.00	0.00	1.00

Notes: This table displays summary statistics from our consumer survey. The total number of surveys is $N = 348$. 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.