Quality Regulation and Competition: Evidence from Pharmaceutical Markets*

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Abstract. Quality regulation attempts to ensure quality and to foster competition by reducing vertical differentiation, but may also have unintended consequences through its effects on market structure. We study this trade-off in the context of pharmaceutical bioequivalence, which is the primary quality standard for generic drugs. Exploiting the staggered phase-in of bioequivalence requirements in Chile, we show that stronger regulation decreased the number of drugs in the market by 25% and increased average paid prices by 10%. These adverse effects were concentrated among small markets, which suggests compliance costs played an important role. We estimate a structural model with endogenous entry and certification to study the role of drug quality, aversion against generics and certification costs in shaping the equilibrium effects and welfare impacts of quality regulation. We find that quality regulation increased consumer valuation of generic drugs through reducing asymmetric information and aversion against unbranded generics, which generated entry of high quality product in place of low quality products. Consumer surplus increased despite higher prices and a lower number of firms.

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

Asymmetric information about product quality is a pervasive market failure. Whenever consumers cannot verify the quality of the products offered in the market, they risk purchasing a low quality product, and also have a lower willingness to pay than under full information. The inability of firms to signal quality harms competition, affecting the set of products offered and their prices. Quality regulation—often in the form of a minimum quality standard—is a policy instrument that attempts to protect consumers from low quality and induce competition. In spite of its widespread adoption in a variety of important markets such as professional labor markets, childcare services, and pharmaceuticals, little is known about the equilibrium effects of quality regulation and the different mechanisms at play.

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

In this paper, we study quality regulation in pharmaceutical markets. In such setting, quality regulation is expected to ensure drug quality, and to improve the perception of generic drugs and thus increase competition.[1] This regulation is indeed considered a key precondition for the success of policies to foster penetration of generic drugs and increase price competition (WHO, 2000). However, certification costs may also induce the exit or deter the entry of affordable and yet high-quality drugs, harming competition and potentially overturning the positive effects of the regulation.

To study the equilibrium effects of quality regulation in pharmaceutical markets, we exploit the roll-out of bioequivalence requirements for generics in Chile. Bioequivalence is a central requirement in the process of approving generics in the U.S. and Europe, and has been increasingly adopted in the rest of the world, including China in 2016 and India in 2017.[2] An innovator drug can be substituted by a bioequivalent generic with the full expectation that the generic has the same clinical effect and safety profile.[3] In spite of their widespread adoption, to the best of our knowledge there are no studies analyzing the welfare consequences of bioequivalence requirements.

[1] Price differences between innovator and generic drugs are often attributed to market segmentation (see, e.g., Frank and Salkever, 1992), consistent with vertical differentiation models where consumers with high willingness-to-pay for perceived quality choose higher priced innovator drugs.

[2] See, e.g., Scroll.in (2019) and GaBI (2019) for the cases of India and China.

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

The primary objectives of introducing quality regulation in our setting were to increase the perceived quality of generics and enhance price competition. At the onset of this policy, unbranded generics accounted for less than 30% of total retail sales on average, even though they were on average 6 and 10 times cheaper than branded generics and innovator drugs, respectively. [4,5] After the reform, generics without bioequivalence certification were no longer allowed to be sold in Chile, which effectively induced firms to obtain bioequivalence certification, particularly in more profitable and less competitive markets.[6]

Conceptually, quality regulation affects market equilibrium through different channels. First, it directly changes the set of products available in the market by forcing the exit of non-bioequivalent drugs. The exit of drugs decreases the intensity of price competition, particularly among generics. In addition, a lower number of generics leads to higher demand for both the generic drugs that remain in the market and for the innovator. On the other hand, forcing the exit of non-bioequivalent drugs increases the perceived quality of generics, as consumers realize that drugs in the market are of quality higher than the standard set by the regulation. Quality regulation may also change quality perceptions by reducing consumer biases against generics. An increase in perceived quality—together with higher demand for each generic drug—potentially induces higher quality generics to enter the market at the margin, and higher intensity of price competition with the innovator. As a consequence, the price of the innovator may decrease. Prices of generics might increase or decrease, because their higher quality is compensated by the higher intensity of price competition with the innovator. Finally, certification costs may force the exit of bioequivalent drugs that are not profitable enough to achieve positive profits in equilibrium, which has detrimental competitive effects. The overall effects of quality regulation are thus ambiguous, which motivates the empirical analysis we develop in the remainder of the paper.

We start by estimating the overall effects of this reform to quality regulation on market outcomes. Our empirical strategy exploits the staggered implementation of the reform along with features of its enforcement, to compare outcomes across and within markets (molecules) differentially exposed to the regulation. We find that stronger quality regulation had large effects on market structure, prices, market shares and sales. First, we estimate that stronger quality regulation affected market structure by decreasing the number of drugs by 25%. Second, we estimate a 10% increase in average

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

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

[6] Using a hazard model, we show that drugs were 18 times more likely to have bioequivalence certification after requirements were implemented. We also show that certification was more frequent in more profitable and less competitive markets.

paid prices, most of which was due to drug-specific price increases rather than changes in market shares or changes in the composition of drugs driven by entry and exit. Third, we show that the policy shifted sales from branded generics to innovator drugs. Fourth, total sales volume decreased by 20%. Most of these effects are concentrated among small markets, where the number of drugs decreased by 36%, and average paid prices increased by 26%. Furthermore, the market share of innovator drugs among small markets increased by 8 percentage points (p.p.) at the expense of generics, whereas total sales volume decreased by 30%. In contrast, for large markets we estimate a 15% decrease in the number of drugs, but no significant effect on average paid prices or the market share of generics.

To disentangle the different mechanisms through which quality regulation operates and to study its welfare implications, we develop and estimate an equilibrium model of drug demand, and firm entry and certification in a pharmaceutical market exposed to quality regulation. On the demand side, the model accounts for two frictions in how consumers value generic drugs. First, due to asymmetric information, consumers cannot distinguish high- and low-quality generics. Second, consumers may display aversion to generics, even if they had full information about their quality. The supply side of the model consists of an incomplete information entry game. In the first stage of this game, firms choose whether to participate in the market, which requires incurring an entry cost, and also a certification cost when quality regulation is introduced. In the second stage, entrants compete on prices. Key for our analysis, the supply model allows us to estimate the prevalence of low-quality drugs before the reform. From the supply side, we are also able to recover entry costs, certification costs, and marginal costs.

Our demand estimates imply that the regulation increased the valuation of unbranded generics by almost 60%, but did not impact the valuation of branded generics. From the supply side, we estimate that 74% of unbranded generics and 88% of branded generics were below the standard. The demand and supply results combined show that two-thirds of the increased valuation of unbranded generics stemmed for resolving asymmetric information, and the rest from decreasing generic aversion.

Using the estimated model, we also study the equilibrium effects of quality regulation on market outcomes and welfare. We find that quality regulation induces drug exit and price increases, consistent with our reduced form evidence. However, low quality drugs are removed from the market, which solves the asymmetric information problem and shifts the demand for generic drugs upwards. As a result, demand shift towards unbranded generics, and share-weighted prices decrease. Overall, consumer surplus increases by 30%. In summary, we find that the effects of increased drug quality dominate the adverse competitive effects from a consumer welfare perspective.

We then use our model to decompose the equilibrium effects into the three mechanisms at play; removal of low quality drugs from the market through a minimum quality standard, changes in generic aversion, and changes in market structure due to certification costs. In a first step, we

simulate the removal of low-quality drugs, keeping generic aversion fixed at pre-reform levels and setting certification costs to zero. Removing products from the market reduces competition, while solving the asymmetric information problem increases the attractiveness of generics. Both of these effects lead to entry of high-quality generics in the market, which partially offsets incentives to increase prices. Solving the asymmetric information problem is indeed the main channel for increased consumer welfare from the reform, since the welfare gain from higher average utility of generics dominates the welfare loss from higher prices. In a second step, we simulate the additional effect of reduced generic aversion. This increases demand for unbranded generics, mostly at the expense of branded generics, causing moderate price increases for unbranded generics and exit among branded generics. We find that the increase in consumer surplus from making less biased choices is mostly offset by the increase in prices. Finally, we simulate the additional effect of costly certification. This causes large exit among generics, with additional moderate increases in prices and reduced consumer surplus as a consequence.

We then develop a counterfactual analysis to study certification subsidies, as a policy which may reduce the adverse competitive effects of quality regulation while preserving its benefits associated with solving the asymmetric information problem. We find that subsidizing certification counteracts the negative competitive effects of quality regulation, particularly in small markets where adverse competitive effects from exit are more severe. Our analysis shows that subsidizing small markets can increase consumer welfare at a lower cost of public funds than unconditional subsidies.

Finally, we consider the role of generic aversion in shaping the effects of quality regulation. Changing generic aversion does not directly affect consumer welfare if it is not considered to be welfare-relevant. However, it does affect choices and therefore also prices and market structure, all of which potentially have important effects on welfare. We find that even without any effect on generic aversion, quality regulation improves consumer welfare. When quality regulation induces a moderate decrease in generic aversion, vertical differentiation decreases and quality regulation is more effective. However, large enough decreases in generic aversion intensify competition to a point where exit harms consumers more than the benefits of better choices.

This paper contributes to an empirical literature focused on the effects of quality regulation on market outcomes. The areas that have received most of the attention are input regulation in child-care services (Chipty 1995; Chipty and Witte 1997; Currie and Hotz 2004; Blau 2007; Hotz and Xiao 2011), occupational licensing in labor markets (Kleiner 2000; Kleiner and Krueger 2013; Kleiner and Soltas 2019; Larsen et al. 2020; Farronato et al. 2020) and e-commerce (Hui et al., 2018). This paper contributes to this literature by studying quality regulation in a market that has not been studied before, and by estimating a model of demand and supply that allows to measure the welfare consequences of quality regulation and to evaluate counterfactual policy designs.

Additionally, this paper is also related to research that studies the effect of regulation on phar-

maceutical markets. Much of this research focuses on equilibrium implications of price regulation (Danzon and Chao, 2000; Brekke et al., 2009; Dubois and Lasio, 2018; Lakdawalla, 2018; Dubois and Sæthre, 2020; Dubois et al., 2019; Mohapatra and Chatterjee, 2020; Maini and Pammolli, 2021), off-label prescription regulation (Tunçel, 2021), public competition (Brugués, 2020; Atal et al., 2021), and patent protection (Chaudhuri et al., 2006), whereas equilibrium effects of quality regulation have yet to be studied. We contribute to this literature by analyzing the equilibrium effects of one of the most common forms of quality regulation in pharmaceutical markets. Directly related to our setting, Balmaceda et al. (2015) provide an early exploration of the reform in Chile, estimating its short-term effects on drug prices. We implement a broader analysis by evaluating effects on market structure, sales and quality outcomes after the full implementation of the policy, as well as counterfactual and welfare analyses.

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

The remainder of the paper is organized as follows. Section 2 describes the Chilean pharmaceutical market and bioequivalence regulation, and Section 3 describes the data we use. Section 4 shows the extent of bioequivalence certification, entry and exit induced by the regulation at the drug level; whereas Section 5 provides our main estimates of the effects on market structure, market outcomes and drug quality. Section 6 provides survey evidence on perceived quality gaps across drug segments and how they relate to bioequivalence. Motivated by this evidence, Section 7 describes the model and its main estimates, and Section 8 discusses our counterfactual and welfare analyses. Finally, Section 9 concludes.

2 Pharmaceutical Market and Quality Regulation in Chile

2.1 Institutional Framework

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

One third of Chileans pay for their prescription drugs fully out-of-pocket (Minsal, 2013). The level of financial coverage for prescription drugs depends both on whether the individual opts to enroll in the public insurance system (*Fondo Nacional de Salud*, FONASA) or in a private insurance plan, and on the specific disease to be treated.[7] FONASA enrollees who opt to receive health care within the network of public providers face copayment rates that depend on socioeconomic variables, although outpatient claims are free of charge, including prescription drugs.[8] FONASA enrollees who instead opt for receiving care in private hospitals pay procedure-specific prices negotiated between FONASA and each provider.[9] Insurance plans in the private system do not generally include coverage for prescription drugs.

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

Two additional features of the retail pharmaceutical market in Chile may influence the workings of the reform. First, as opposed to the U.S., direct-to-consumer advertisement of prescription drugs is forbidden, which could, in principle, make consumers more price sensitive because expensive branded drugs cannot use advertising to signal quality and boost demand. Second, the retail pharmacy sector in Chile is highly concentrated, which might affect the degree of supply-side reactions to bioequivalence requirements. Three large pharmacy chains account for more than 80% of the market, with a fraction of their sales corresponding to private-label drugs. The remainder of the market is comprised of several small chains without national presence.[10]

Prescription behavior of physicians and the ability of pharmacists to offer alternative versions of prescribed drugs to consumers are important mediators of consumer choice in the pharmaceutical

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

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

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

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

market. In Chile, pharmacists may only offer generic substitution for prescriptions that specify the generic name and when a bioequivalent substitute is available. However, and despite recent policy efforts towards constraining discretion in prescriptions, physicians still often prescribe by brand name only, which limits substitution towards generics in practice.[11]

2.2 Bioequivalence in the Chilean Pharmaceutical Market

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

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

"We have no doubts that drug prices will decrease, because the population will have

[11] In February 2014, Law 20,724 was passed with the objective of requiring physicians to include the generic name in the prescription and allow for substitution towards bioequivalent generics upon patient request. However, industry actors concede that the requirement has not been enforced, and that physicians have continued to prescribe branded drugs. This lack of enforcement is well known, and has motivated a new pharmaceutical law that is currently under discussion in Congress (e.g., Cámara de Diputados 2019).

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

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

access to a wider and more competitive drug market"

Elizabeth Armstrong, Head of National Drug Agency, May, 2012

The first list of active ingredients subject to bioequivalence was published in 2005 by the Chilean Ministry of Health (*Ministerio de Salud*, MINSAL). This list consisted of active ingredients included in a major reform to the public health insurance system called AUGE (Bitrán et al., 2010). However, it was not until 2009 that the regulator established technical norms for bioequivalence testing (Balmaceda et al., 2015). Bioequivalence requirements were phased in since then, with 167 molecules covered as of March 2018. All new drugs containing the molecule listed in each decree were mandated to certify bioequivalence before obtaining a marketing license.[14] Each decree specified the deadline for bioequivalence testing among incumbent drugs already registered. In practice, however, enforcement of the requirements occurred mostly by the time of license renewal, when ISP often denied renewal to drugs without bioequivalence approval (Vasallo, 2010). This is a feature of the institutional environment that we exploit in our empirical strategy. Drugs with bioequivalence certification carry a distinctive label that indicates such status to the consumer.[15] We show an example of this label in Figure A.1.

In most cases, the original deadlines to provide proof of bioequivalence were extended—through a series of subsequent decrees—due to slow uptake and capacity constraints in laboratories performing the tests. Among molecules with bioequivalence requirement, there are nine unique combinations of policy dates, namely the date of the first decree, date of extensions (if applicable), and corresponding deadlines established in the first decree and the extensions. Table 1 shows the dates of the first decree (the first date when a bioequivalence requirement was announced), the last decree (the last date when an extension to the original deadline was announced) and the corresponding deadlines for each group, as well as the number of molecules included in each group.[16] For example, Group 1 includes four molecules that had their first decree announced in January 2011, which established a deadline for February 2012. However, the original deadline was extended, and its final decree was announced in June 2013, with a deadline for December 2013. Variation in the timing of bioequivalence regulation is summarized in Figure 5-a. We exploit this variation for estimation of policy effects later in the paper.

Bioequivalence certification is provided after the manufacturer presents successful studies. Generally, bioequivalence is determined through *in vivo* clinical studies for a specific presentation of a drug, although under certain conditions only *in vitro* studies are required for different dosages

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

[15]In practice, the label could have an effect on demand through quality disclosure (see Dranove and Jin (2010) for a review of the literature on quality disclosure). However, drugs without bioequivalence approval must exit the market, so that, if consumers are aware of the policy, the label does not carry any additional informational content in our setting.

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

of the same drug. Bioequivalence certification of imported drugs is often validated in Chile if obtained in countries with high certification standards (e.g., Canada, US, the European Union, New Zealand, among others). Although the certification is awarded *ad eternum* for a given formula and production technology, any change in these dimensions requires a new certification.

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

3 Data and Descriptive Statistics

3.1 Data Sources

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

Finally, we use data from IQVIA, which contain detailed information on monthly drug prices and sales between January 2010 and December 2017. IQVIA collects data from two sources. The four largest pharmacy chains in the country—which account for more than 90% of drug sales—report retail prices and sales directly to IQVIA. Sales from other pharmacies are supplied by wholesalers, which report wholesale prices and sales to IQVIA. Wholesale prices are transformed to retail prices using a standard methodology.[19,20] We employ monthly sales and prices from all 83 local markets

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

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

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

[20] 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.

included in the IQVIA data, which cover most of the urban areas of the country. We aggregate drug prices and sales across local markets. In particular, we compute total monthly sales by aggregating monthly sales across local markets and calculate monthly drug prices as sales-weighted averages of prices across local markets.[21]

The IQVIA data provide price and sales at the product level for branded drugs, identifying the laboratory, dosage and presentation of each drug. For unbranded drugs, the data provide prices and sales at the dosage and presentation level, aggregated across laboratories.[22] We focus on prescription drugs, which account for more than 90% of drugs in the molecules we study.

3.2 Descriptive Statistics for Quality Certification

The number of bioequivalent drugs in the market increased substantially throughout the period we study, as shown by Figure 1-a. Bioequivalence certification started at a low pace in early 2010, but increased steadily since then, with a rapid uptake by mid-2012. By December 2017, there were 1,467 drugs with bioequivalence certification in our sample, among which 918 were branded generics.

The growth in the number of bioequivalent drugs relates to the policy roll-out, which was staggered as described in Section 2.2. Figures 1-b through 1-e display the number of bioequivalence approvals around four policy events of each market: the first and last decree, and the first and last deadline. Note that (i) bioequivalence approval was uncommon before the first decree, and thus its incidence was rare before mandated; (ii) bioequivalence approval increased after the first decree, which suggests that the policy affected its incidence; and (iii) several bioequivalence approvals occurred after the deadlines, which shows that deadlines were imperfectly enforced.

3.3 Descriptive Statistics for Market Outcomes

We merged the price and sales data from IQVIA with the drug registry from ISP, to construct a monthly panel dataset for our period of study. The resulting dataset covers 132 molecules and 2,307 unique drugs, defined as a unique combination of drug name, dosage, and presentation. These drugs are manufactured by 80 different laboratories.[23] Importantly, not all drugs in the data are sold every period. In fact, only 65.5% of the drug-month observations display positive sales. Drug prices are not observed for months in which a drug registers no sales.

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

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

[22] This feature of the IQVIA data somewhat restricts our analysis, because all unbranded generics of a given molecule, presentation and dosage are coded together as if manufactured by a single laboratory. In particular, it limits the extent to which we can track the composition of sales of a given unbranded generic across laboratories over time.

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

as high as those of the average drug, whereas branded (unbranded) generic prices are around two thirds (one fifth) of the average drug. We go beyond these raw averages and estimate price premiums within markets for innovator and branded generics below. The highest market share is captured by branded generics, with an average market share of 44%, followed by innovator and unbranded generics with market shares of 30% and 27%, respectively. On average, bioequivalent drugs hold a market share of only 7%. However, the average market share of bioequivalent drugs increased substantially, from only 0.06% in 2010, to 22.8% by the end of 2017. This shift in market shares is also displayed by Figure 3. The average market has around 13 drugs and five laboratories in a given month. As expected, the numbers of drugs and laboratories are remarkably larger for branded generics than for innovator and bioequivalent drugs.[24]

Relative prices across drug segments reflect large pre-reform premiums for innovator and branded generics, as displayed by Figure 4.[25] Three facts become apparent. First, price premiums are on average positive across molecules in the sample. Second, price premiums are large overall: innovators and branded generics are substantially more expensive than unbranded generics, with average premiums of 10 and 6 times, respectively. Third, there is substantial heterogeneity in price premiums across molecules. Whereas several molecules display price premiums on the order of 3 to 5 times, several other molecules display price premiums higher than 10 times, particularly for innovator drugs.

4 Effects of Quality Regulation on Certification, Entry and Exit

We study whether drugs that were imposed bioequivalence requirement were more likely to engage in quality certification, to enter or to exit the market. For this analysis, we follow Duggan et al. (2016) and treat each molecule as a separate market, because (i) there is generally limited to no substitution across molecules for the treatment of health conditions, and (ii) the policy we exploit induces variation at that level.

4.1 Evidence for Quality Certification

In Section 3.2, we provided suggestive evidence that bioequivalence certification increased substantially after the reform. We now turn to survival analysis to study its determinants. Survival analysis is a convenient method to describe bioequivalence approval because it flexibly accommodates the absorbing nature of bioequivalence, right-censoring, and time-varying covariates.

[24] This comes partly from our inability to identify unbranded drugs producers in IQVIA.

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

The hazard function $h(s)$ measures the probability of becoming bioequivalent in period s. We specify $h(s)$ using a proportional hazard model for drug i in market m and month t:

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

where λ_s is a *baseline* hazard that depends on drug tenure s, and is estimated non-parametrically. Coefficients in β measure the proportional increase in the hazard following a one-unit increase in the corresponding covariate. The vector X_{imt} includes indicators for periods after policy events, indicators for branded and imported drugs, and either baseline market attributes or market fixed effects. We consider the same four market-specific events analyzed in Section 3.2: first decree, first deadline, last decree and last deadline. Finally, ψ_t are month-year fixed effects.

Table 3-A displays estimates from equation (1) for bioequivalence certification. The most relevant policy events are the first decree and deadline which jointly increase the probability of becoming bioequivalent by 17 times, whereas posterior policy events do not further increase the certification hazard. These results reinforce the graphical evidence of Figure 1: the first decree and deadline are stronger predictors of bioequivalence certification than the last decree and deadline. This result is robust to including market fixed effects in column 2.

We then analyze the relationship between bioequivalence certification, drug attributes and market variables. Unbranded and imported drugs are more likely to obtain bioequivalence approval. Market variables strongly predict bioequivalence approval: a 10% higher market revenue is associated with a 4.7% higher hazard rate. Moreover, the number of competing drugs in a market is negatively associated with bioequivalence approval. A 10% increase in the number of branded drugs and unbranded drugs is associated with a 2.7% and 2.9% lower hazard rate, respectively.

In terms of heterogeneity, we study how baseline drug revenue affects quality certification choices. Table A.3-A displays results from a version of equation (1) in which policy events are interacted with an indicator for whether a drug had a revenue above the median in 2010 (prior to the reform).[26] We focus on the first deadline of bioequivalence requirements. The most salient pattern is that drugs with higher baseline revenue are more likely to engage in quality certification after requirements are imposed. In particular, drugs with baseline revenue above the median are 10 times more likely to get bioequivalence certification after the deadline.

4.2 Evidence for Entry and Exit of Drugs

Quality regulation also affected drug entry and exit. We construct measures of entry and exit using the ISP registry data on licensing and renewals. For each registered drug, we record an entry as the

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

event of obtaining a license for the first time, and an exit as the event of not renewing a license upon expiration.[27] Figure 2-a shows the total number of drugs that entered and exited the market during our sample period. We find that drug exit was relatively stable up to late 2014, and that there was a large increase in the number of exiting drugs afterwards. On the other hand, we do not find a large change in entry during the period. Figures 2-b through 2-e display the number of drugs that entered and exited the market at each point in time relative to relevant policy events. These figures show that the marked increase in exit of drugs occurred after the bioequivalence policy roll-out.

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

The policy did affect exit, as shown by Table 3-B. The first deadline increase the exit rate by more than 110 percent, and a similar increase followed the last decree. Innovator drugs are 42 percent less likely to exit than unbranded generics, while branded generics are 46 percent more likely to exit than unbranded generics. Moreover, drugs in high-revenue markets are less likely to exit, and that competition, as measured by the number of branded drugs, has a marginally significant positive effect on exit. Including market fixed effects in column 4 does not affect the results.

In terms of heterogeneity, we implement a heterogeneity analysis of exit rates. Table A.3-B displays results for heterogeneity in the effect of the first deadline of bioequivalence requirements on drug exit. We find that drugs with high revenues are less likely to exit by 81 percent.

5 Effects of Quality Regulation on Market Outcomes

5.1 Empirical Strategy

Our empirical strategy exploits policy variation across and within markets. The first source of variation is the staggered roll-out of the reform, discussed in Section 2.2 and displayed in Figure 5-a. The differences in the timing of the regulation generate a series of comparison groups comprised of markets that faced bioequivalence requirements at different dates throughout our period of study. The second source of variation comes from a particular institutional feature. In practice, deadlines for incumbent drugs become binding every time a drug must renew its marketing license with ISP, i.e., every five years. At that point, ISP denies license renewal to drugs without bioequivalence

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

approval (Vasallo, 2010). Thus, for each drug, the first license renewal after the policy deadline marks the effective deadline to comply. License renewal dates are arguably exogenous for drugs that were in the registry before the deadline was known. Moreover, renewal dates vary across drugs within markets, driven by variation in licensing dates. Differences in renewal dates across drugs generate variation in the share of drugs for which the policy is effectively binding, both across markets sharing the same deadline, and within markets over time.

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

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

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

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

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

We employ T_{mt} as a treatment variable for our analysis of the effect of the regulation on market outcomes. T_{mt} is a weakly increasing function of time relative to the policy date t^d_m: it is equal to 0 before t^d_m and is equal to 1 after the latest renewal date across drugs in $\mathcal{G}_m$ is reached. Figure 5-b displays the evolution of T_{mt} over time for all markets in the sample, showing substantial variation across markets at any point in time, and within market across time.[28] Finally, Figure 5-c shows that this variable is indeed correlated with the share of bioequivalent drugs in the market.

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

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

where the coefficient of interest is β. We include two sets of fixed effects: θ_m are market fixed

[28]For illustration, Figure A.2 shows examples of 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 plots show how bioequivalence certification increases as bioequivalence requirements become relevant for a market. These examples are highlighted in Figure 5-b.

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

The key identifying assumption in (3) is that there are no unobserved market-specific trends that drive both the timing of the policy roll-out and the outcomes of interest. The main assumption behind this strategy is that policy deadlines and renewal dates were not set as a function of unobserved shocks not captured by market and time fixed effects. A violation to this assumption would happen if, for example, decrees and deadlines were set earlier for markets expected to have earlier price increases. Although we cannot directly test this, the fact that decree extensions were mostly set based on capacity constraints of laboratories testing bioequivalence makes it unlikely that they were driven by unobserved future demand or supply shocks.

Moreover, market-level observables do not show a clear correlation with the policy timing, which supports this identifying assumption. Table 1-B shows statistics for market outcomes in 2010 across markets differently affected by the policy. There is substantial heterogeneity across these groups in terms of number of drugs, market size, and market outcomes, but no clear pattern related to the timing of bioequivalence requirements. Furthermore, Table A.2 displays estimates from an ordered logit for the timing of the policy on market attributes in 2010, including variables related to market structure, market size, prices and medical treatment. Most of these attributes are unrelated to the policy timing, and the only significant predictor of it is having a low branded generic market share. Moreover, the pseudo-R^2 is not larger than 3.7% across specifications. These results suggest that the timing of the policy roll-out is mostly unrelated to baseline market characteristics.

As a complement to estimating equation (3), we implement an event study analysis. This analysis serves two purposes: (i) assessing the assumption of parallel trends across molecules treated at different dates; and (ii) providing visual evidence for the effects on market outcomes. A disadvantage of the event study relative to our main specification is that it does not exploit the within-market variation coming from the pattern of drug license renewal dates. We describe this event study analysis in Appendix A and provide results in Figure A.3. Overall, trends in outcomes before the first deadline of bioequivalence requirements are well behaved, as most of the estimated coefficients are not statistically different from zero. This result is reassuring for exploiting the differential policy timing across markets as identifying variation. Moreover, the results of this event study analysis are consistent with those from our main analysis.

Finally, we focus on market size as a relevant dimension for heterogeneous effects. As discussed in Section 1, when compliance is costly, quality regulation should have stronger effects among small markets because it would induce more drug exit. We test this prediction by estimating differential effects by market size, as measured by average sales before the reform. Specifically, we divide markets according to whether the average monthly market revenue in 2010 was above or below

the median and identify them as large and small markets.

5.2 Effects on Market Structure

We start by estimating equation (3) for the number of drugs in the market.[29] Column 1 in Table 4-A shows that the policy decreased the overall number of drugs by 24%.Columns 2–8 split this result across drug segments. The overall reduction is driven by similar decreases by branded and unbranded generics. Even though the number of bioequivalent generics increases, that does not compensate for the exit of non-bioequivalents. We do not find statistically significant changes in the number of innovator drugs.

Consistent with our model, the negative effects on the number of drugs are larger among small markets, driven by a significant amount of exit by both innovator drugs and generics. We estimate that the number of drugs decreased by 34% among small markets and 14% in large markets, as shown by Table 4-B. Conversely, bioequivalence certification is higher in large markets, which is also consistent with our model, as a larger market size makes certification costs relatively lower.

5.3 Effects on Drug Prices

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

We estimate the effects of quality regulation on a price index constructed as the share-weighted average of log prices in a market (see, e.g., Chevalier et al. 2003; Nevo and Hatzitaskos 2006):

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

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

Average prices across all drugs increased by 10% as a result of the regulation, as shown by Table 5-A. We estimate price effects by drug type and find that most of the increase in average

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

paid prices comes from increases among unbranded generics, whereas innovators and branded generics display no statistically significant effects.[30] As shown in Section 5.2, the decrease in the number of drugs is concentrated among small markets; therefore, these are the markets where we expect to find the strongest price effects, which is confirmed by our heterogeneity analysis in Table 5-B. The increase in prices across all drugs is driven by an increase of 29% among small markets. Our estimates show that stronger quality regulation induced price increases of 7% and 21% among innovator drugs and unbranded generics respectively in small markets. On the other hand, our estimates for price effects in large markets are close to zero and not statistically significant.

5.3.1 Decomposition of Price Effects

The effects on average prices combine drug-specific price changes (P_{it}), changes in shares (w_{it}), and changes in the composition of drugs in each market ($\mathcal{I}_{mt}$). To better understand the drivers of price effects, we decompose the evolution of average prices into such components. Consider the change in the share-weighted average of log prices between a baseline period $t = 0$ and any period $t > 0$. Denote the set of drugs in the market in t that were also in the market in the baseline period as $\mathcal{S}_{m,t} \equiv \mathcal{I}_{mt} \cap \mathcal{I}_{m0}$; the set of drugs that entered market m after the baseline period and remain in the market in period t as $\mathcal{E}_{mt} \equiv \mathcal{I}_{mt} \setminus \mathcal{I}_{m0}$; and the set of drugs that exited between the baseline period and t as $\mathcal{X}_{mt} \equiv \mathcal{I}_{m0} \setminus \mathcal{I}_{mt}$. We decompose the change in the share-weighted average of log prices as:

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

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

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

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

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

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

Most of the increase in overall prices is driven by within-drug price changes. Table 5-C displays estimates of effects on each component of our price index, across and within drug type. Of the 10% increase in average prices, 7 p.p come from price changes among incumbents ($\hat{P}_{PC}$), and 2 p.p from the entry of relatively expensive drugs ($\hat{P}_E$). Similarly, most of the price increases among unbranded generics are due to within-drug price changes ($\hat{P}_{PC}$).[31] Overall, the finding that the estimated increase in overall prices is due mostly to price increases among incumbent drugs supports our interpretation that drug exit reduced the intensity of price competition.

5.4 Effects on Market Shares and Sales

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

Overall, we do not find significant effects on the market shares of innovator drugs and generics, as shown by Table 6-I-A. If anything, we find a marginally statistically significant increase of 5 p.p in the market share of innovator drugs and a similar decrease in the market share of generics. The decrease in the market share of generics is concentrated among branded generics, whereas the market share of unbranded generics remains unchanged. As expected, we find a significant increase of 12 p.p. in the market share of bioequivalent generics and a decrease of 16 p.p. for non-bioequivalent generics. Considering the decrease in the number of branded generics found in Table 4, these results are consistent with consumers mostly substituting towards innovator drugs as generics exit the market. Most of the increase in the innovator market share comes from a 8 p.p increase among small markets, as shown by Table 6-I-B. In contrast, we find no significant effect on the market share of innovators in large markets. Moreover, we find a shift away from branded to unbranded generics in large markets: we estimate a decrease of 7 p.p in the market share of

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

branded generics and a 4 p.p increase in the market share of unbranded generics.

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

Drug sales decreased as a result of stronger quality regulation, as shown by Table 6-II-A. We find no statistically significant effect on sales of innovator drugs and unbranded generics across all markets. Rather, the overall effect is driven by a decrease of 39% in sales of branded generics. These results indicate that stronger quality regulation generated substitution towards the outside option. Consistent with previous results, these decreases in sales are concentrated among small markets, as shown by Table 6-II-B. Sales decreased by 29% across all drug segments in small markets, as opposed to a smaller and non-statistically significant decrease in large markets of 9%. The overall decrease in sales among small markets is driven by decreases in sales of both branded and unbranded generics. This result is consistent with our results showing substantial exit and reduced competition in small markets. In contrast, we find that in large markets there is a large but not statistically significant decrease in sales of branded generics, whereas the sales of unbranded generics increased by 68%.

5.5 Summary of Descriptive Evidence

We provide evidence for the equilibrium effects of quality regulation and interpret it using our conceptual framework. We start by showing that stronger quality regulation induced drug exit. Even if stronger quality regulation could reduce vertical differentiation and increase the intensity of price competition, our estimates suggest that the negative effect through market structure overturned those positive competitive effects in our setting. As a result, drug prices increased. Moreover, we find no evidence of increases in the market share of generics, which was one of the motivations for the policy.[32] Most of the adverse effects from stronger quality regulation are concentrated among small markets. This pattern suggests that drugs exit the market when the certification cost is large relative to the market profitability.

6 Evidence on Perceived Quality from Consumer Surveys

Our findings so far show that quality regulation had somewhat unexpected consequences and that, if anything its adverse competitive effects of drug exit more than compensated those from reductions

[32] In Appendix B, we providence evidence that the incidence adverse health events associated with drug consumption and drug recalls did not increase. These measures of quality are not directly associated with bioequivalence so we take them with caution. In the structural model we are able to indirectly infer the improvement of drug quality as measured by bioequivalence.

in vertical differentiation between the different segments of the market. The extent to which quality regularion may affect vertical differentiation depends not only on objective quality metrics, but also on how consumers perceive quality. To shed more light on potential perceived quality differences, we collect survey administered to consumers that assesses different aspects of their purchase behavior, including attitudes towards generics and their knowledge about bioequivalence.

We conducted in-person surveys to frequent consumers recruited outside pharmacies after a drug purchase. We focus on Atorvastatin, a common anti-cholesterol drug in Chile. We ask consumers for their quality and price perceptions for different drug segments, namely the innovator drug (Lipitor, by Pfizer), a bioequivalent branded generic (Lipoten, by Pharmavita) and bioequivalent and non-bioequivalent unbranded generics (Atorvastatina, by Mintlab). For more details about the survey design and methodology, see Appendix C. We surveyed $N = 401$ consumers, of which 58% reported having a household member with a chronic disease, and 34% reported purchasing Atorvastatin for a household member. Table A.6 provides summary statistics for the main variables in the survey.

We document substantial heterogeneity in knowledge about bioequivalence across consumers, despite the fact that 84% of them are familiar with the label attached to bioequivalent drugs. Figure 6-a shows that almost 30% of consumers are not familiar at all with bioequivalence and 55% are not able to provide a good definition for it. Limited knowledge about bioequivalence might reduce its effectiveness to signal drug quality and induce consumers to switch from innovator or branded generic drugs to cheaper bioequivalent unbranded generics.

Consumers 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 the perceived quality premium as the difference between the perceived quality of the innovator drug and that of another drug type. Figure 6-b displays the distribution of perceived quality premiums relative to the innovator. As expected, consumers perceive that the innovator drug is of higher quality than branded and unbranded generics. Branded generics are perceived to have higher quality than unbranded generics. Additionally, consumers perceive that bioequivalent drugs are of higher quality than non-bioequivalent drugs. Therefore, consumers attribute a quality premium to bioequivalence, although not large enough as to close the quality premium attributed to innovators.

Overall, these results suggests that there are gaps in perceived quality that limit the extent to which generic drugs can compete with innovator drugs. This fact relates to research on how how aversion to generics limits generic penetration (Bronnenberg et al., 2015; Colgan et al., 2015; Bairoliya et al., 2017). This evidence motivates allowing for frictions in perceived quality in the structural analysis we develop in the remainder of the paper.

7 Empirical Model of Entry, Certification and Demand

In this section, we develop and estimate an equilibrium model of the pharmaceutical market. The empirical model allows to disentangle whether exit was driven by certification costs and by low drug quality, which is key to assess the welfare impacts of quality regulation. We then use the model study counterfactual policies that could potentially mitigate the detrimental competitive effects of the regulation.

7.1 Environment

Drug segments, quality and market. A drug j is either an innovator (I), a branded generic (B) or unbranded generic (U). These segments are indexed by k. Each drug has exogenous quality $\psi_j \in \{\psi^L, \psi^H\}$.[33] We normalize ψ^L and ψ^H to 0 and 1, respectively. Innovator drugs are of high quality by definition, and so are all bioequivalent drugs. The share of bioequivalent drugs among branded and unbranded generics in absence of quality regulation is π_H^k. Finally, a market m is comprised by a set of drugs $\mathcal{J}_m$ that treat a particular health condition.

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

$$u_{ijmt}^k = v_{jmt}^k - \alpha \ln p_{jmt} + x'_{jmt}\beta + \zeta_{imt}^k + (1-\sigma)\epsilon_{ijmt} \tag{6}$$

where v_{jmt}^k is perceived drug quality, p_{jmt} is the price of the drug, x_{jmt} is a vector of drug attributes and $\zeta_{imt}^k + (1-\sigma)\epsilon_{ijmt}$ is an idiosyncratic preference shock with a nested structure that allows for asymmetric substitution patterns within and between drug segments (Berry, 1994).[34]

A key object of interest is consumer perceived quality of drugs v_{jmt}^k. Our model considers two frictions that generate a gap between the perceived quality of generics and that of the innovator. First, there is asymmetric information regarding the generic drug quality. Consumers cannot discern the quality of any given drug j, but base their assessment on the segment and whether the drug has certified bioequivalence or not, as denoted by the indicator b_{jmt}. We therefore write the expected quality of generics as $\mathrm{E}[\psi_j \,|\, k, \mathrm{b}_{jmt}]$.

Even if a generic is known to be bioequivalent, consumers may have general aversion against

[33] Drug quality is exogenous as we consider that quality regulation happens after production technology is set up. Although this a good assumption in the short-run, the long-run effects of quality regulation may include endogenous responses along the margin of drug quality. Analyzing those issues is outside the scope of this paper.

[34] The log price specification allows us better fit the data by accommodating the very different prices across molecules, as in Bjornerstedt and Verboven (2016) and Dubois et al. (2019).

generics.[35] We define $\tau_m^k(\mathrm{b}_{jmt})$ as the magnitude of generic aversion, which depends on the drug segment and on whether the drug has certified bioequivalence. Letting μ_m^I be the valuation for the innovator drug quality, perceived valuation is given by:

$$v_{jmt}^k \equiv \underbrace{\tau_m^k(\mathrm{b}_{jmt})}_{\substack{\text{Generic} \\ \text{aversion in } k}} \underbrace{\mathrm{E}[\psi_j \,|\, k, \mathrm{b}_{jmt}]}_{\substack{\text{Expected} \\ \text{drug quality}}} \underbrace{\mu_m^I}_{\substack{\text{Valuation of} \\ \text{drug quality}}}$$

Bioequivalence approval is taken as a certain signal that the drug is of high quality. Then, the expected quality of drug j given its segment and bioequivalence status is:

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

In particular, note that $\mathrm{E}[\psi_j \,|\, k \in \{B, U\}, \mathrm{b}_{jmt} = 1] = 1$, which is equal to $\mathrm{E}[\psi_j \,|\, k = I, \mathrm{b}_{jmt} = 1]$ by definition. Consumer have rational expectations, such that $\mathrm{E}[\psi_j \,|\, k \in \{B, U\}, \mathrm{b}_{jmt} = 0] = \pi_H^k$, and consumers expect the share of high-quality generics without bioequivalence approval to be equal to the baseline such share within the segment.[36] We define τ_{m0}^k and τ_{m1}^k to be the level of aversion against generics in segment k and market m before and after bioequivalence approval, respectively. Therefore, we can write aversion as

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

and by construction there is no aversion against innovator drugs, such that $\tau_m^I = 1$.

Under this structure, consumer perceived quality depends only on the segment and bioequivalence approval of a drug j. Therefore, we can define $v_{jmt}^k = v_{m0}^k(1 - \mathrm{b}_{jmt}) + v_{m1}^k \mathrm{b}_{jmt}$. With this definition we have, e.g., that $v_{m0}^B = \tau_{m0}^B \pi^B \mu_m^I$ is the perceived quality valuation of branded generics in market m that do not have bioequivalence approval, and $v_{m1}^U = \tau_{m1}^U \mu_m^I$ is the perceived quality valuation of unbranded generics in market m that have bioequivalence approval.

Supply. The supply side of the model consists of two stages. In the first stage, firms decide simultaneously whether to enter the market. In the second stage, entrants maximize profits by competing on prices. There is a set $\mathcal{P}$ of potential entrants to the market. Each potential entrant j draws drug attributes x_j, marginal cost c_j, an entry cost F_j, a certification cost κ_j, and quality ψ_j.

[35] Aversion against generics could come from several microfoundations, including differential detailing, potential differences in side effects, lack of information, misconceptions about quality or other form of biases. We do not attempt to distinguish between the different potential sources of this distaste for generics.

[36] This assumption rules out that consumers update their belief about the true quality of a drug based on whether other drugs have obtained bioequivalence approval or not. This can be viewed as assuming that the priors π_H^k correspond to the frequency of high-quality drugs in a large population that each drug of segment k is drawn from. This assumption rules out that the timing of bioequivalence approval is informative for consumers, e.g., an equilibrium where high-quality drugs are more likely to obtain their certification early.

We assume that marginal costs and fixed costs are unrelated to quality within a segment. This assumption allows for differences in these costs across segments, but that high and low quality drugs within a segment have the same systematic component of them.

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

$$\tilde{\Pi}_j(\mathcal{J}) = \max_{p_j} \quad (p_j - c_j)s_j(p, x; \mathcal{J})M$$

where $s_j(p, x; \mathcal{J})$ is the market share of firm j given the vector of prices p and attributes x of all firms in $\mathcal{J}$, and M measures market size. If the firm enters, it also gets an idiosyncratic profit shock ε_j^1. In contrast, if the firm does not enter, it gets an idiosyncratic profit shock ε_j^0 from an outside option.

Firms hold incomplete information about their rivals, as in Seim (2006). Firm attributes, marginal costs, entry costs, and certification costs $\{x_j, c_j, F_j, \kappa_j\}$, and the set of potential entrants $\mathcal{P}$ are common knowledge to all potential entrants. In contrast, firms only know the distributions of idiosyncratic profit shocks ε_j^1 and ε_j^0, but their realizations are private information of the firms.

Quality certification. In an environment with quality certification, branded and unbranded generics must decide whether to sink a cost κ_j to test for bioequivalence, or not to test and exit the market.

We can now discuss the effects of quality regulation. First, once certification is required, only high quality firms with $\psi_j = \psi^H$ stay in the market. Therefore, expected quality is $\mathrm{E}[\psi_j \,|\, k, \mathrm{b}_j = 1] = \psi^H$ for all firms that remain in the market after quality regulation is imposed. Second, quality regulation may also affect consumer perceived quality, in that consumers may reduce their aversion against drug segments that had lower average quality in absence of the regulation, such that τ_m^k may adjust. Finally, quality regulation imposes certification costs κ_j that affects the market structure and equilibrium prices.

7.2 Equilibrium

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

Because of private information, firm j does not know the realized market structure $\mathcal{J}$ when considering to enter the market. Let $\mathcal{M}$ be the set of potential market structures and $\mathcal{J}_m$ an be

element of $\mathcal{M}$. Then, the expected profits net of entry and possibly certification costs χ_j are:

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

where the expectation is taken over a vector of entry probabilities of all potential entrants, ϕ; and $P_j^M(\mathcal{J}_m;\phi)$ is the probability that firm j assigns to market structure $\mathcal{J}_m$ given entry probabilities ϕ. These probabilities $P_j^M(\mathcal{J}_m;\phi)$ take the form:

$$P_j^M(\mathcal{J}_m;\phi) = \frac{1}{\phi_j} \prod_{l \in \mathcal{J}_m, l \in \mathcal{P}} \phi_l \prod_{k \notin \mathcal{J}_m, k \in \mathcal{P}} (1 - \phi_k) \tag{7}$$

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

$$\phi_j = \Pr(\mathrm{E}_\phi[\tilde{\Pi}_j(\mathcal{J})] - \chi_j + \varepsilon_j^1 > \varepsilon_j^0) \tag{8}$$

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

Let ϕ^{NQ} be a vector of equilibrium entry probabilities for all potential entrants, which induces probability $P^M(\mathcal{J};\phi^{NQ})$ given by equation (7). Then, expected total profits for firm j are:

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

which implies entry probabilities:

$$\phi_j^{NQ} = \Pr(\mathrm{E}_{\phi^{NQ}}[\tilde{\Pi}_j(\mathcal{J})] - F_j + \varepsilon_j^1 > \varepsilon_j^0) \qquad \forall j \in \mathcal{P} \tag{9}$$

which is a system of P equations on ϕ^{NQ} that describes the equilibrium of the entry model.

Equilibrium with quality certification. The basic structure of equilibrium under quality regulation is the same than in absence of quality regulation. However, adding quality certification introduces two changes. First, entry costs change because of certification costs. In particular, innovators only incur a fixed to enter and thus $\chi_j = F_j$ for $k_j = I$. In contrast, branded and unbranded generics incur both fixed and certification costs to enter the market and thus $\chi_j = F_j + \kappa_j$ for $k_j \in \{B, U\}$.

The second aspect that changes under quality regulation are entry probabilities, which are

affected through selection of low quality drugs out of the market. We define entry probabilities under quality regulation as $\phi_{j|L}$ and $\phi_{j|H}$ for low and high quality drugs, respectively.

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

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

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

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

$$\begin{aligned} \phi_{j|L}^Q &= 0 && \forall j \in \mathcal{P}, \psi_j = \psi^L \\ \phi_{j|H}^Q &= \Pr(\mathrm{E}_{\phi^Q}[\tilde{\Pi}_j(\mathcal{J})] - \chi_j + \varepsilon_j^1 > \varepsilon_j^0) && \forall j \in \mathcal{P}, \psi_j = \psi^H \end{aligned} \tag{10}$$

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

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

$$p_j = \frac{c_j}{1 - \frac{1-\sigma}{\alpha(1-\sigma s_{j|k} - (1-\sigma)s_j)}} \qquad \forall j \in \mathcal{J}$$

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

7.3 Estimation

7.3.1 Demand model

A key object of interest in the demand model is consumer valuation for drugs, v_{jmt}. Expected quality and aversion against generics are not separately identified from demand only. Therefore, we employ an auxiliary specification for demand estimation, and then combine these estimates with those from the supply to recover all the structural parameter.

We parametrize perceived quality as:

$$v_{jmt} = v_m^I - \Delta_m^k(1 - \eta^k \mathrm{b}_{jmt}) \tag{11}$$

where v_m^I, Δ_m^k and η^k are parameters to be estimated. This parametrization allows the value of

innovators to be market specific through the terms v_m^I and that the valuation of generics is market-segment specific and equal to $v_m^I - \Delta_m^k$ before bioequivalence approval, such that Δ_m^k is the gap in valuation between the innovator and the generic in segment k before bioequivalence approval. Moreover, the specification assumes that bioequivalence certification decreases the gap between the valuation of generics and innovators by a factor of η^k. These parameters map to the structural parameters as follows:

$$v_m^I = \mu_m^I, \qquad \Delta_m^k = \mu_m^I(1 - \tau_{m0}^k \pi_H^k), \qquad \eta^k = \frac{\tau_{m1}^k - \tau_{m0}^k \pi_H^k}{1 - \tau_{m0}^k \pi_H^k}$$

such that v_I^m is equal to the valuation of innovators; estimates of and Δ_m^k and η^k are functions of parameters governing aversion against generics τ_m^k and asymmetric information π_H^k. These expressions make clear that structural parameters are not identified from demand only, but also that obtaining estimates of π_H^k from the supply side is enough to recover all the parameters of interest.

Given this specification and following Berry (1994), the nested logit model in equation (6) implies the following estimation equation:

$$\ln s_{jmt} - \ln s_{0mt} = v_m^I - \Delta_m^k(1 - \eta^k \mathrm{b}_{jmt}) - \alpha \ln p_{jmt} + x'_{jmt}\beta + \lambda_t + \sigma \ln s_{jmt|k} + \xi_{jmt}, \tag{12}$$

where the dependent variable is the difference between the log market share of drug j s_{jmt} and the log market share of the outside option s_{0mt}, λ_t is a vector of time fixed effects, $s_{jt|k}$ is the market share of drug j among the drugs in segment k, and ξ_{jmt} in an unobservable demand shock.

We use yearly data on market shares, prices and drug attributes to estimate equation (12). For estimation and for the remainder of the paper, we define a drug as a combination of ATC code, segment and producer. Thus, while each drug can be offered in multiple presentations, the model treats all of them as a single product, and we capture the number of presentations as a product attribute. Moreover, we measure prices p_{jmt} as the volume-weighted price for each drug in each year for the treatment of a typical user.[37] In terms of drug attributes x_{jmt}, we include the number of presentations and the number of years the drug has been available on the market. Finally, we also include a full set of year-fixed effects in λ_t to capture overall changes in the relative attractiveness of the outside option over time.[38,39]

[37]The information on defined daily doses (DDD) over a year for the typical user is gathered from a combination of medical sources and registry data from Norway on number of unique users and total DDD per year for each ATC code. ATCs predominantly used for chronic conditions will typically feature a consumption of around 350 DDD per year for the average user, while an acutely prescribed antibiotic with recommended treatment duration of three weeks will have around 20 DDD per year for the average user.

[38]A limitation of the data is that unbranded generics are observed as a bundle and laboratories are not identified. We describe how we deal with this issue in Appendix D.1.

[39]We do not directly observe market size in the data, which motivates a calibration exercise to recover it from the data and thus be able to calculate market shares. The approach is based on Huang and Rojas (2013, 2014), and we describe

In terms of identification, the main concern is that pricing and certification choices are potentially driven by unobserved preferences for drugs ξ_{jt}, which is the error term in equation (12). Moreover, the conditional market share $s_{jt|k}$ is correlated with ξ_{jt} by construction. We employ an instrumental variables strategy to obtain consistent estimates of the model parameters, and estimate the model using GMM. We use the real exchange rate between manufacturing countries and Chile as an instrument for prices; the share of presentations that have passed the deadline for marketing license renewal after the certification deadline interacted with drug segment as instruments for bioequivalence certification; the policy rollout index T_{mt} described in Section 5.1 interacted with an indicator for high-revenue markets as instruments for the conditional market share, which shifts entry and exit and thus the number of products in the market (Berry, 1994); and the number of competing drugs within the broader ATC3 class, which should be informative about prices and within-group shares by affecting the competitive situation in the market. Finally, note that the structural parameters of quality valuation τ_m^k and π_H^k are not separately identified from demand only. However, combining the auxiliary parameters Δ_m^k and η^k with estimates of π_H^k from the supply side of the model, we can recover all of the structural parameters.

7.3.2 Supply model

The objects of interest are firms marginal costs c_j, entry costs F_j, certification costs κ_j, the share of high quality drugs among generics π_H, and the variance of profit shocks. We parametrize these objects as follows:

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

such that in practice the parameters of interest are γ_c, γ_F, γ_κ, γ_π and γ_{σ_π}. The covariates included in the specification differ across these equations. Marginal costs c_{jmt} are specified as a combination of a vector of observables x_{cjm} that includes indicators for drug segment, indicators for markets, and the real exchange rate between the manufacturing country and Chile, and cost shocks ω_{jmt}. Entry costs and certification costs are specified as being constant across markets. The probability of being high-quality is specified as constant by segment and governed by γ_π, and Λ is the logistic function, which we adopt to assure that $\pi_{Hj} \in [0, 1]$. Finally, the profit shocks ε^1_{jmt} and ε^0_{jmt} are iid T1EV with scale parameter σ_ε, and we specify the latter as a function of a constant and the log of market size.

it in detail in Appendix D.2. This method has also been adopted by previous work on pharmaceutical markets using similar data studying pharmaceutical markets (Dubois and Lasio, 2018).

The first step of the estimation routine consists of recovering marginal costs. Under the assumed specification of demand, optimal pricing implies

$$\hat{c}_{jmt} = p_{jmt}\left(1 - \frac{1-\sigma}{\alpha(1-\sigma s_{jmt|k} - (1-\sigma)s_{jmt})}\right),$$

where we employ our demand estimates and observed prices to recover marginal costs. Assuming that cost shocks ω_{jmt} are independent of the observable determinants of costs, we recover γ_c from a linear regression of $\log \hat{c}_{jmt}$ on x_{cjm}, and compute expected cost and fitted cost shocks $\hat{\omega}_{jmt}$ using those results.

To estimate the remaining parameters of the model, we exploit entry choices by firms in the environments with and without quality regulation. We start by computing entry probabilities. A common concern related to entry models with incomplete information is the potential for multiple equilibria, which complicates both estimation and counterfactuals. To avoid this issue, we follow Sweeting (2009) and estimate these probabilities directly from the data. In particular, we estimate logit regressions of entry and certification choices on all their determinants as predicted by the model, namely own and rival drivers of variable profits, fixed costs and certification costs. Denote the implied probabilities by $\hat{\phi}^{NQ}$ and $\hat{\phi}^{Q}$.

We then proceed to simulate variable profits under every potential market structure, using estimates for preferences and marginal costs. We proceed by computing optimal pricing and implied demand and variable profits for each potential entrant and potential market structure, market by market. Combining those results with fitted entry probabilities from the previous step, we then compute expected variable profits by integrating over potential market structures.[40] We assume that demand and cost shocks are realized after entry and certification choices are made, such that $\mathrm{E}[\xi_{jmt}] = \mathrm{E}[\omega_{jmt}] = 0$. This assumption rules out selection into the market based on knowledge of those unobservables by potential entrants.

Finally, we exploit these inputs and the equilibrium conditions on entry probabilities in equations (9) and (10) to recover entry costs, certification costs and the share of high quality generic drugs among potential entrants.[41] Given the distributional assumption on ε^1_{jmt} and ε^0_{jmt}, entry probabilities are given by equations (9) and (10) and have the usual logit form. In particular, entry probabilities

[40] Given the number of potential market entrants, the set of potential market structure is remarkably large. We proceed by taking 100 Halton draws from this set for this integration step.

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

for environments without and with quality regulation respectively are:

$$\phi^{NQ}_{jmt} = \frac{\exp(\frac{1}{\sigma_\varepsilon}[\mathrm{E}_{\hat{\phi}^{NQ}}[\tilde{\Pi}_{jmt}(\mathcal{J})] - x'_{Fj}\gamma_F])}{1+\exp(\frac{1}{\sigma_\varepsilon}[\mathrm{E}_{\hat{\phi}^{NQ}}[\tilde{\Pi}_{jmt}(\mathcal{J})] - x'_{Fj}\gamma_F])}$$

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

where d^I_j indicates that j is an innovator drug. We then use these probabilities to estimate the remaining parameters of the model by maximum likelihood.

We estimate the model using two cross sections of drug markets, one for 2010 that captures the pre-reform period, and one for 2017 that captures an environment where the reform had been rolled-out extensively in several markets. We use current and past market participation in estimation. In particular, we use the latter to take into account the fact that firms that were in the market in the past do not have to cover the entry cost again in subsequent periods, but rather only the certification cost once quality regulation is introduced. Estimation requires taking a stance on the set of potential entrants to each market. We define such set for a particular market as all firms that ever participate in the market during our sample period, to which we add the 5 firms of each segment with the highest participation across markets at the national level.

In terms of identification, fixed costs are identified by entry choices and market structure in absence of quality regulation. Given fixed costs, entry choices and market structure under quality regulation identify certification costs. Certification costs are separately identified from the share of high quality drugs because of their differential effects across markets and/or firms with different profitability levels. Whereas low-quality drugs have to exit regardless of their profitability, certification costs only affect low-profitability firms. In other words, the share of high quality generic drugs is identified by the exit of firms for which the model predicts high profits, so that their exit is due to low baseline quality and not due to certification costs.

7.4 Results

7.4.1 Demand Model

We summarize our demand estimates in Table 7-A. Regarding price sensitivity, we estimate that price elasticities are substantially higher for generics than for innovators. Own price elasticities are on average 3.06 for innovators, 5.68 for branded generics and 6.05 for unbranded generics. These elasticities are in line with recent estimates from the literature (e.g., Dubois and Lasio, 2018). Moreover, the estimated substitution parameter $\hat{\sigma} = 0.47$ indicates a substantial extent of nesting

in demand, with stronger substitution within segment than across segments.[42]

Figure 7 summarizes the main findings from the demand estimates of of perceived quality. It plots the implied perceived quality for different drug segments over the domain of quality certification, which we calculate as fitted values from the demand model. There is a clear ranking across segments, by which consumers have the highest perceived quality valuation for innovator drugs, followed by branded generics and then unbranded generics. Quality regulation only partially closes the gap in perceived quality across segments, which suggests there is still aversion against generics by the end of the sample period.

We exploit our demand estimates to quantify these gaps in perceived quality. There are large differences in perceived valuation between innovators and unbranded generics before bioequivalence approval. Overall, we find that in the average market $\overline{\hat{v}^I_m/\hat{v}^U_{jm0}} = 0.54$, such that the perceived value of unbranded generics is almost half the value of innovators. On the other hand $\overline{\hat{v}^I_m/\hat{v}^B_{jm0}} = 0.92$, such that the perceived value of branded generics is 92 percent of the value of innovators. Bioequivalence certification had substantially different effects across segments. Our estimate of η^B is not significantly different from zero, such that the valuation of branded generics did not change after getting bioequivalence approval. In contrast, our estimate of η^U is large and positive, which implies that the relative valuation of generics increased after the reform. In this line, the average relative valuation of unbranded generics once the regulation is in place is $\overline{\hat{v}^I_m/\hat{v}^U_{jm1}} = 0.74$.

7.4.2 Supply Model

Our estimates for the supply side of the model are displayed by Table 8. Our estimates for marginal costs imply an average markup of 18% for both unbranded and branded generics, and of 39% for innovators. Figure 8-a shows the distribution of markups across all drugs for each of the segments. We also estimate an average annualized entry cost of $39,325 and an average annualized certification cost of $17,354. To put these numbers in context, Figure 8-b plots the distribution of yearly variable profits and compares that distribution to the estimated average entry and certification costs. The average firm gets annual variable profits of $75,116.

Baseline quality in the market is high, but not all drugs are of high quality. In particular, we find that the share of high-quality branded and unbranded drugs before the reform are $\hat{\pi}^B_H = 0.88$ and $\hat{\pi}^B_U = 0.73$, respectively. These results are consistent with some of the drug exit we documented early in the paper being driven by generics being of lower quality than the innovator. As we discuss below, this finding implies that part of the effects of quality regulation will operate through changing the pool of drugs in the market and shifting perceived quality of generics upwards given asymmetric information about drug quality is removed by the policy.

[42]Table 7-A also shows auxiliary linear regressions of the endogenous variables in the model on the instruments separately. As expected, the exchange rate with the country of origin is associated with higher drug prices. Moreover, and also as expected, variation from license renewals have strong effects on the extent of certification by drugs.

7.4.3 Disentangling Generic Aversion and Quality

Combining demand and supply side estimates, we are able to disentangle the extent to which the lower valuation of generics is due to lower quality of the set of generics in the market and generic aversion. By fitting our empirical model of demand at null and full compliance with quality regulation ($b_{jmt} = 0$ and $b_{jmt} = 1$), we obtain estimates for the perceived quality valuation for before and after the regulation, namely $\hat{v}^k_{m0}$ and $\hat{v}^k_{m1}$. We can then map the estimates from the empirical model to the structural parameters using equation (11), and recover aversion in perceived quality before and after the regulation as:

$$\hat{\tau}^k_{0m} = \frac{\hat{v}^k_{m0}}{\hat{\tau}_H \hat{v}^I_m}, \qquad \hat{\tau}^k_{1m} = \frac{\hat{v}^k_{m1}}{\hat{v}^I_m}$$

Our estimates imply large baseline aversion against unbranded generics but no such aversion against branded generics, as shown by Table 7-B. In particular, we find that before the policy change the, generic aversion was on average $\overline{\hat{\tau}^B_0} = 1.05$ and $\overline{\hat{\tau}^U_0} = 0.72$ across markets. These estimates are in line with a literature that shows that aversion to generics contributes to sustaining branded drug price premiums (Colgan et al., 2015; Bairoliya et al., 2017).

Quality regulation had asymmetric effects on these two segments. On the one hand, we estimate that $\overline{\hat{\tau}^B}_1 = 0.92$, which means that the policy *increased* the aversion against branded generic. This result is a consequence of finding no increase in valuation for branded generics coupled with an increase in the average quality. We interpret this finding as suggesting that the policy revealed to consumers that branded generics are indeed generics and distinguished them from innovator drugs, particularly so as they are marked with the distinctive yellow label that only (bioequivalent) generics get. This interpretation is consistent with the large market share of branded generics in spite of their high relative prices. On the other hand, aversion against unbranded generics decreased after the policy, with $\overline{\hat{\tau}^U}_1 = 0.87$. This lower aversion is explained by the fact that valuation increased relatively more than the increase in quality.This finding implies that, on top of the direct effects on drug quality, the regulation further decreased vertical differentiation by reducing aversion against unbranded generics. Note that aversion against both types of generics almost coincides after the reform, so that the brand value is mostly lost after the regulation.

8 Counterfactuals

In this section, we study the welfare consequences of quality regulation and consider counterfactual policy designs. We note that these are out-of-sample results as we simulate outcomes when the policy is fully rolled in all markets, such that all generics in the market meet the quality standard.

8.1 Equilibrium Effects of Quality Regulation

Quality regulation potentially affects market outcomes through three channels. First, it directly changes the composition of drug quality, as the regulation mechanically removes low quality drugs from the market. This change in the quality composition solves the asymmetric information problem, increases the expected quality of generics and increases willingness to pay for generics. Second, the regulation affects market outcomes by reducing consumer aversion to generics. Finally, it induces drug exit by imposing certification costs. In this section, we decompose the effects of quality regulation through these three channels. Our outcomes of interest are the number of firms in the market, drug prices, segment market shares, consumer surplus and firm profits. To measure consumer surplus, we account for the fact that consumers have asymmetric information and generic aversion, and thus choice utility differs from experienced utility (Bernheim and Rangel, 2009). In particular, choice utility is based on expected quality $\mathrm{E}[\psi_j \mid k, \mathrm{b}_{jmt}]$, and consumer generic aversion τ_m^k. In contrast, experienced utility is based on true quality ψ_j, and excludes generic aversion. We report consumer surplus using experienced utility, following Allcott (2013).

For this decomposition, we start by simulating market outcomes for an environment without quality regulation, where the share of high quality drugs is the estimated π_H^k, generic aversion is given by $\tau_m^k = \tau_{m0}^k$, and certification costs are $\kappa = 0$. The results for this baseline environment are shown in Column 1 of Table 9. Columns 2–9 then show the counterfactual results of adding the different aspects of the regulation.

In the first step, we isolate the effect of certification requirements through removing low quality drugs. On the supply side, we drop drugs with quality $\psi_j = \psi^L$ from the market. On the demand side, we set $E[\psi_j] = 1$ so asymmetric information is resolved, and consumers adjust their perceived quality for drugs that stay in the market. The results of this exercise are in column 2-3 of Table 9. The quality standard removes low quality branded and unbranded generics from the market and increases demand for generics. The combination of these two forces induces entry of high quality drugs that were out of the market, such that the number of firms increase in net terms, despite the regulation being in place. However, the increase in willingness to pay for generics does induce some exit by innovator drugs and price increases among drugs in all three segments. On net, the market is characterized by high-quality drugs, higher prices, but also by a demand shift from innovators to branded generics that leads to lower share-weighted prices. Overall, imposing the quality standard alone increases consumer surplus by almost 32 percent.

In a second step, we add the effect coming from modifying generic aversion. In particular, we exploit our estimates of changes in generic aversion due to the policy and set $\tau_m^k = \tau_{m1}^k$ fo the simulation. The results of this exercise are shown by columns 4 and 5 of Table 9. Reducing these biases makes unbranded generics more competitive and branded generics less competitive, which results in entry of the former and exit of the latter and of innovator drugs. In the same line, unbranded generics gain substantial market share. In equilibrium, there are mixed effects on drug

prices. Overall, share-weighted prices decrease driven by the shift to unbranded generics, and consumer surplus increases slightly.

Finally, in the third step we set the certification cost κ to its estimated level. Columns 6 and 7 of Table 9 show these results. Adding certification costs reduces the number of both branded and unbranded generics in the market substantially. The decrease in competition associated with such drug exit leads to increases in prices in all three segments. Overall, certification costs decrease consumer surplus by almost 3 percent.

The total effects of the policy are shown in columns 8 and 9. Overall, our model predicts reductions in the number of drugs across all segments, coupled with price increases. Finally, the model predicts large increases in the market share of the unbranded generics, as their perceived quality increases substantially. Overall, share-weighted prices decrease mostly driven by the shift to unbranded generics, and share-weighted quality increases due to the quality standard. Still, consumer surplus increases, mostly driven by the imposition of the quality standard. In sum, the adverse competitive effects of drugs are more than fully compensated by increased perceived quality and reduced vertical differentiation from a consumer welfare perspective.

8.2 The Role of Certification Costs

Or results show that exit induced by certification costs is a mechanism through which quality regulation decreased welfare. In this section, we study whether lower certification costs could limit these unintended consequences. As a baseline reference, column 1 of Table 10 displays market outcomes in an environment in which firms must pay the full certification cost.

Subsidizing certification costs may improve outcomes in the market by lowering the cost of effective certification costs for firms, and thus discouraging drug exit and preserving competition. We find that lower certification costs indeed limit drug exit and price increases. First, column 2 and 3 show results for an environment when certification costs are cut by 50% through a subsidy. Compared to the baseline policy, equilibrium in this case features more firms in the market and lower prices. Overall, consumer surplus increases.

Motivated by our descriptive evidence, we study whether targeting subsidies by market size can achieve the goal of limiting the detrimental competitive effects of quality regulation at a lower cost than non-targeted subsidies. Columns 4 and 5 show the outcomes when certification costs are fully subsidized in the 50 percent of markets with the lowest revenues. We find somewhat stronger price effects than in the case of non-targeted subsidies, although consumer surplus increases less than in the case of the non-targeted policy.

Finally, columns 6 and 7 show the effect of removing certification costs entirely. The effects of increased competition, lower prices, and higher consumer surplus are exacerbated.

8.3 The Role of Generic Aversion

Aversion towards generics increases vertical differentiation and limits the extent to which these drugs can effectively compete against innovator drugs. For our setting, we estimate a large aversion against unbranded generics before the quality regulation, while there is essentially no aversion against branded generics. We also find that the regulation has the ability to affect generic aversion. In this section, we study how the equilibrium effects of the regulation depend on the extent to which it affects aversion. In particular, we simulate the effects of quality regulation for a range of post-reform aversion levels $\tilde{\tau}^k_{m1}(s)$ defined as:

$$\tilde{\tau}^k_{m1}(s) = (1 - s) \times \hat{\tau}^k_{m0} + s \times 1$$

such that s is the share of the aversion towards generics that is corrected by the policy. In these simulations, we remove all low-quality drugs from the markets and impose the full costs of certification on generic producers.

We find that the extent to which quality regulation affects aversion against generics is an important determinant of its equilibrium effects. Table 11 shows the results from this analysis. Columns 2 and 3 show the results when $s = 0\%$, i.e., when the policy has no effect on generic aversion. In this case, quality regulation has a limited effect on vertical differentiation through removing low-quality products from the market, and mostly has negative competitive effects. However, quality regulation has a stronger effects in reducing vertical differentiation when it decreases aversion to a larger extent (s gets closer to 1), as shown to the right of Table 11. As aversion decreases, the intensity of competition towards innovators and branded generics increases. This is reflected in more exit and lower price increases by innovators and branded generics, and less exit and higher price increases by unbranded generics, relative to scenarios where the policy has smaller effects on generic aversion. In the absence of any effect on aversion at $s = 0\%$, the market share of unbranded generics decreases with the regulation, whereas it increases when such effects are large.

Overall, a stronger effect of quality regulation on generic aversion increases the market share of unbranded generics so that share-weighted prices decrease. These results suggest that complementary strategies that close gaps in perceived quality of generics relative to innovator drugs may improve the effectiveness of quality regulation in increase drug affordability.

9 Conclusion

Quality regulation in markets with asymmetric information may ensure product quality, change consumer perceptions of product quality and foster price competition by reducing vertical differentiation. However, costly regulation compliance may also have unintended adverse consequences

on market structure by inducing product exit and, thereby, harm price competition.

We study this trade-off leveraging a reform to bioequivalence requirements in the Chilean pharmaceutical market. Contrary to the motivation of reducing prices through reduced vertical differentiation and increased competition, we find that average paid prices increased, and that the market share of generics did not increase. These effects are concentrated among small markets, where we also find substantial drug exit. We estimate an equilibrium model of competition to quantify the contribution of different mechanism at play and evaluate welfare under different policy designs. The model predicts exit and higher prices as in the descriptive evidence, but also shows that average drug quality increased after quality regulation was implemented, which led in a net increase in consumer surplus.

We use our model to decompose the equilibrium effects into the three mechanisms at play: changes in the composition of quality in the market, changes in aversion against generics, and changes in market structure due to certification costs. We show that the main driver of welfare effects is the change in the composition of quality due to solving the quality standard and to solving the asymmetric information problem. This effect of quality regulation will likely be stronger in environment were baseline quality in the market is lower.

Stronger quality regulation can generate desirable competitive effects, and our analysis provides lessons for the design of a quality regulation to achieve them. Our model suggests that a key driver of the unintended consequences we find are regulation compliance costs. We find that subsidizing certification, particularly in small markets, is a powerful tool to counteract the negative competitive effects of quality regulation. Our analysis shows that subsidizing small markets can increase consumer welfare at lower cost of public funds than unconditional subsidies.

Additionally, the competitive effects of quality regulation depend on how they affect demand, and pharmaceutical markets impose particular challenges in this regard. Our estimates and complementary survey data indicate that consumers have lasting biases against generics after the reform, which limits the desired effects of quality regulation in the short run. It is important to stress that such demand responses are limited by physician prescribing behavior, whose incentives may differ from those of their patients (Dickstein, 2015). Second, policies may not be immediately effective in changing attitudes towards generics, as perceptions are likely to change slowly over time as consumers learn about their quality (Bairoliya et al., 2017).

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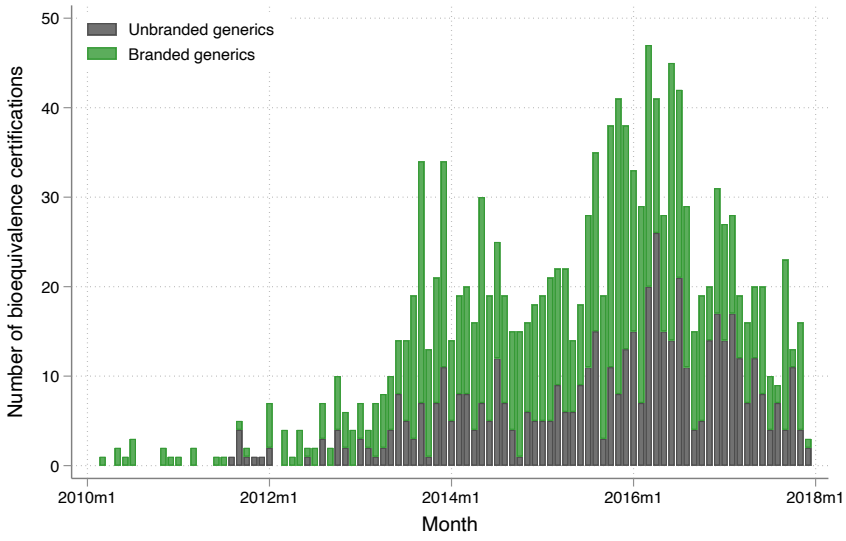
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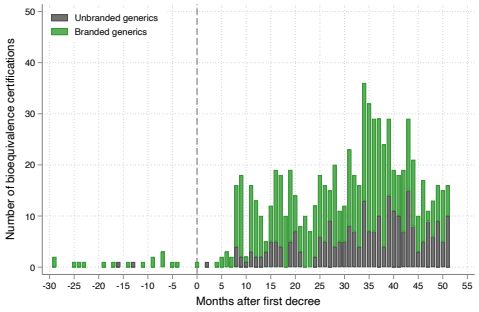
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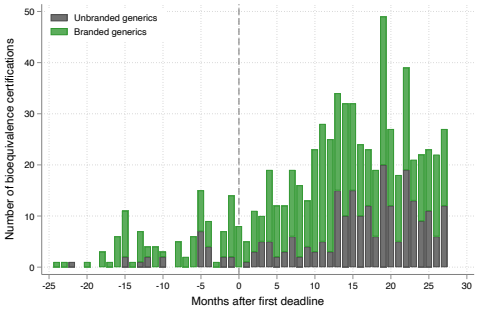
Figure 1: Bioequivalence approvals around policy events



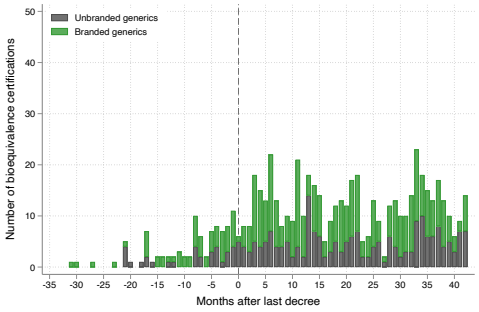
(a) Approvals over time



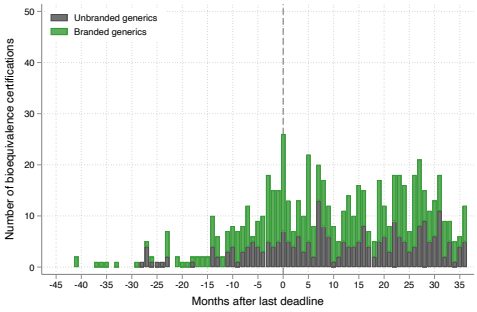
(b) Approvals around first decree



(c) Approvals around first deadline



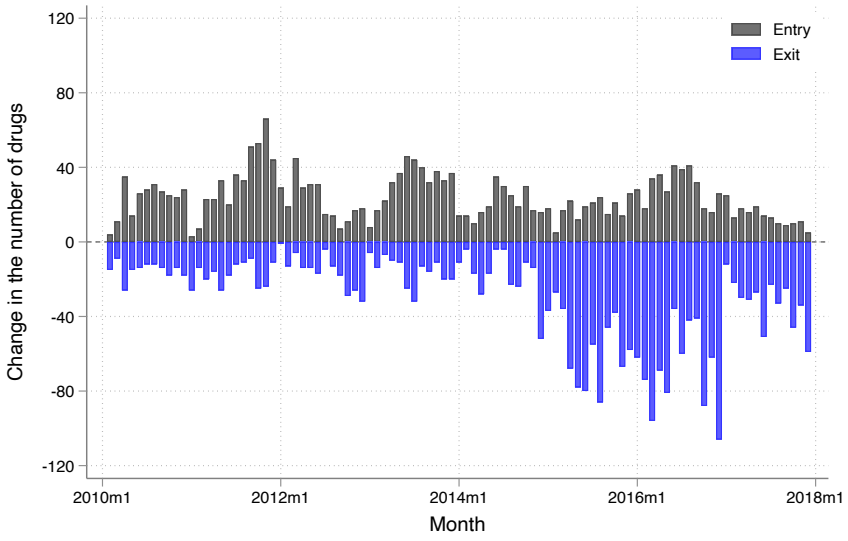
(d) Approvals around to last decree



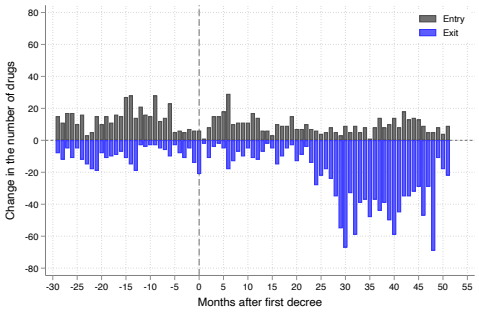
(e) Approvals around to last deadline

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

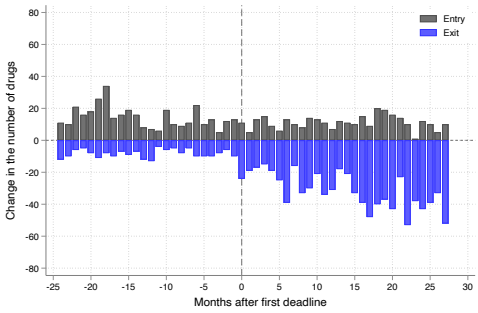
Figure 2: Number of entry and exit of drugs around policy events



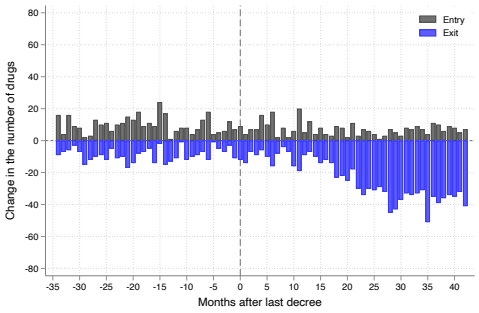
(a) Entry and exit over time



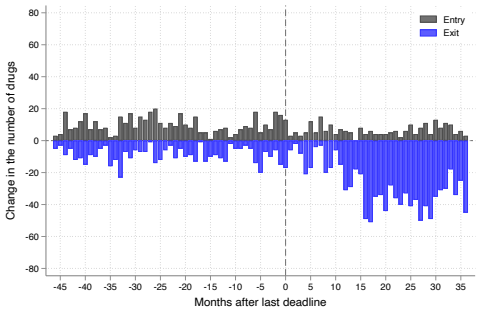
(b) Relative to first decree



(c) Relative to first deadline



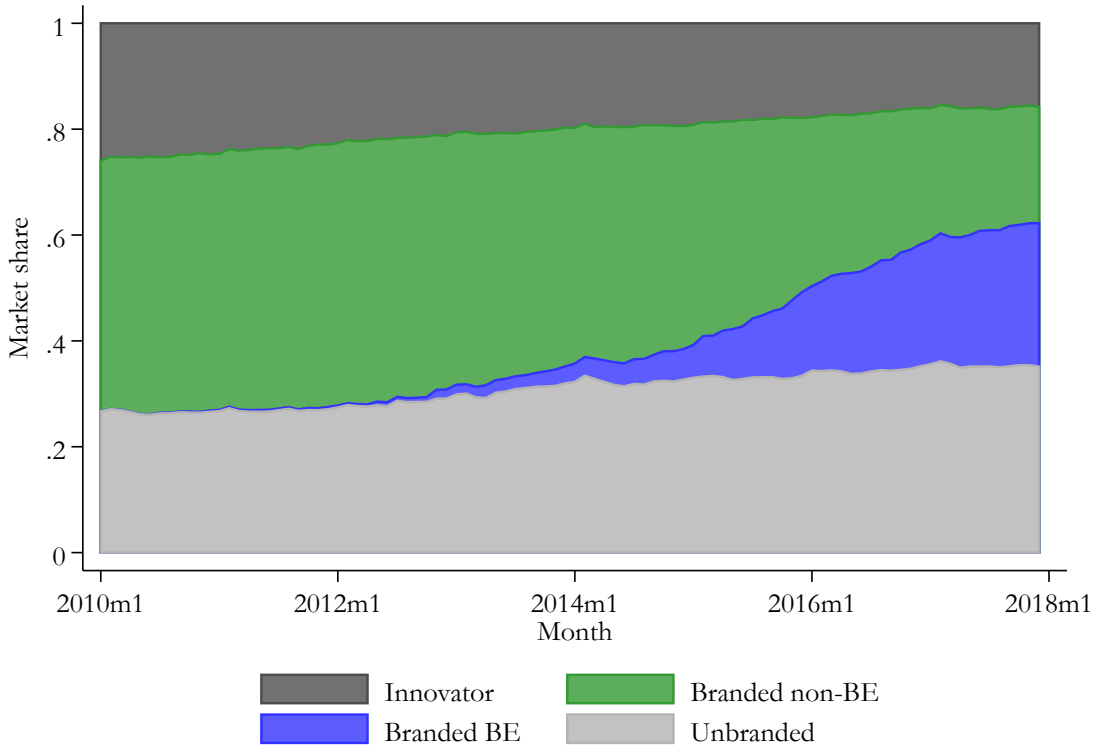
(d) Relative to last decree



(e) Relative to last deadline

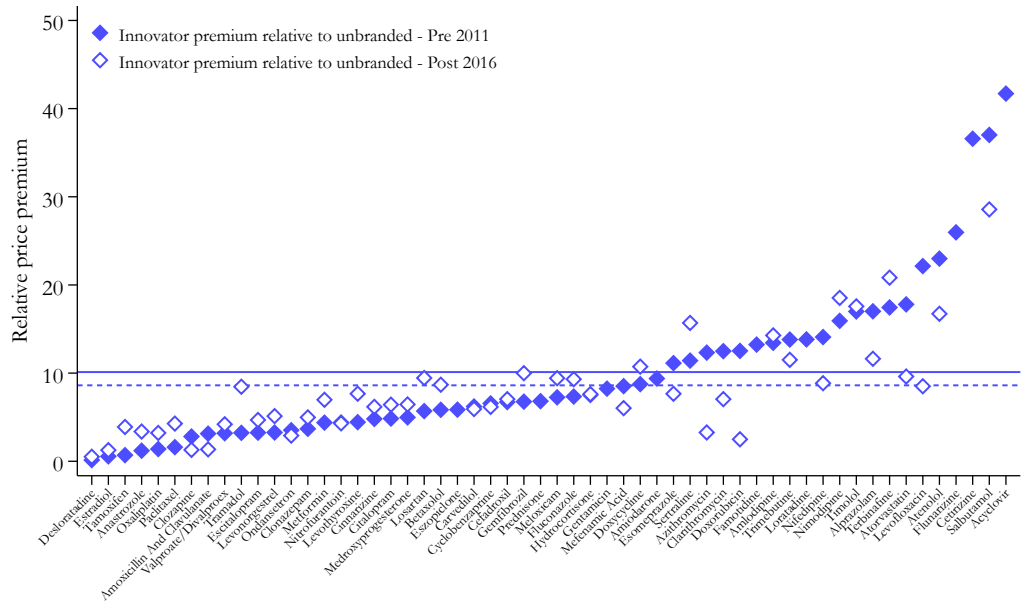
Notes: This figure displays the number of entering (gray) and exiting (blue) drugs around bioequivalence decrees and deadlines. The vertical axis displays the count of such events. Panel (a) display the evolution of entry and exit of drugs over time, while panels (b) through (e) display the evolution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

Figure 3: Market shares by drug type

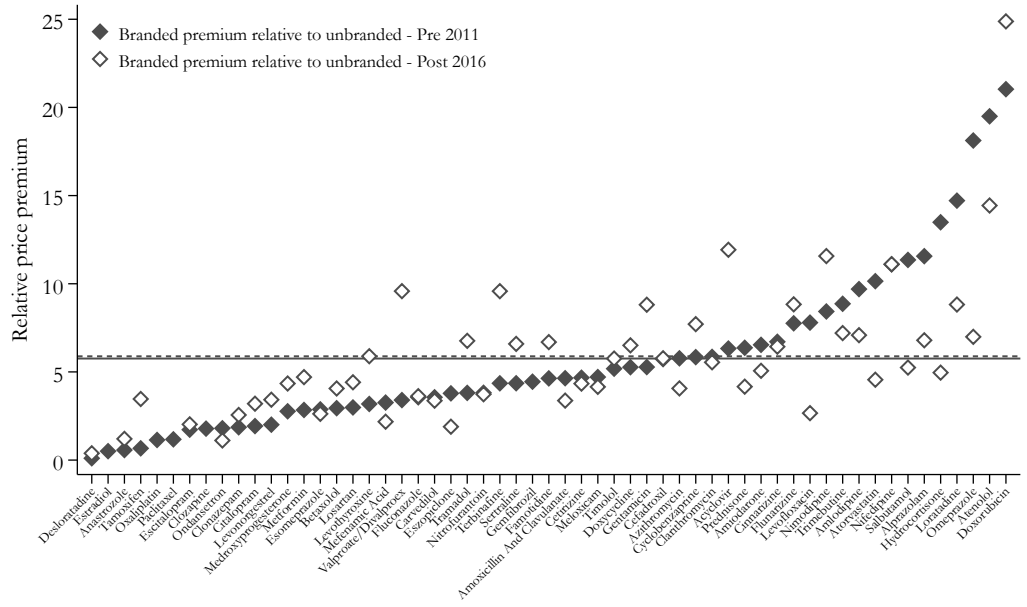


Notes: This figure displays the evolution of market shares of different drug segments over time. For each type, we plot the average market share across markets for each month in our sample.

Figure 4: Innovator and branded drug price premiums



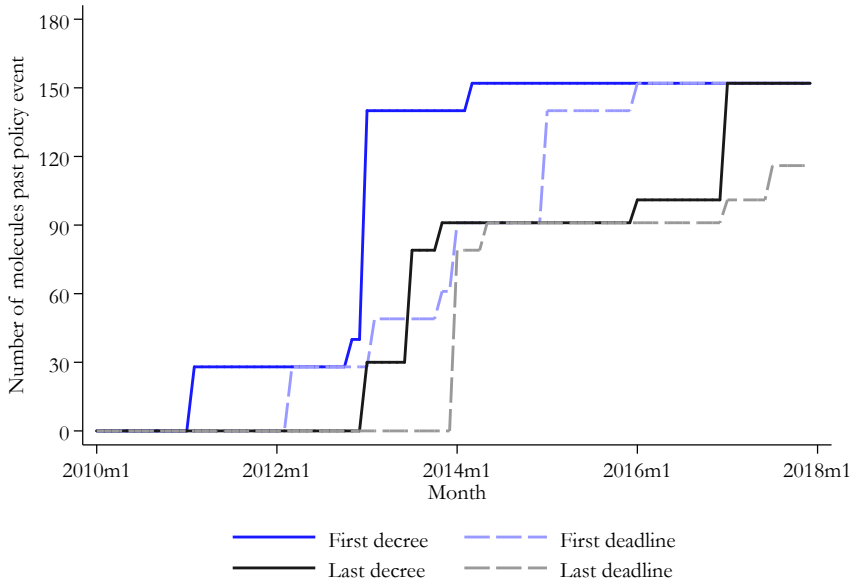
(a) Innovator drugs price premiums relative to unbranded generics



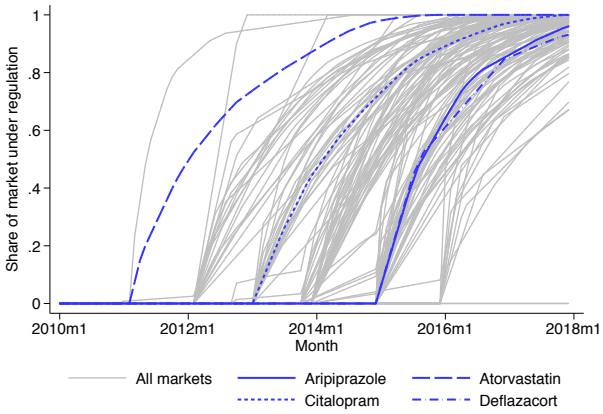
(b) Branded drugs price premiums relative to unbranded generics

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.

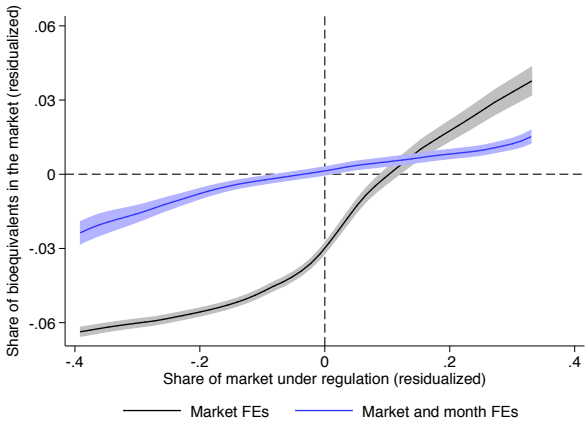
Figure 5: Evolution of quality regulation



(a) Timing of bioequivalence decrees and deadlines



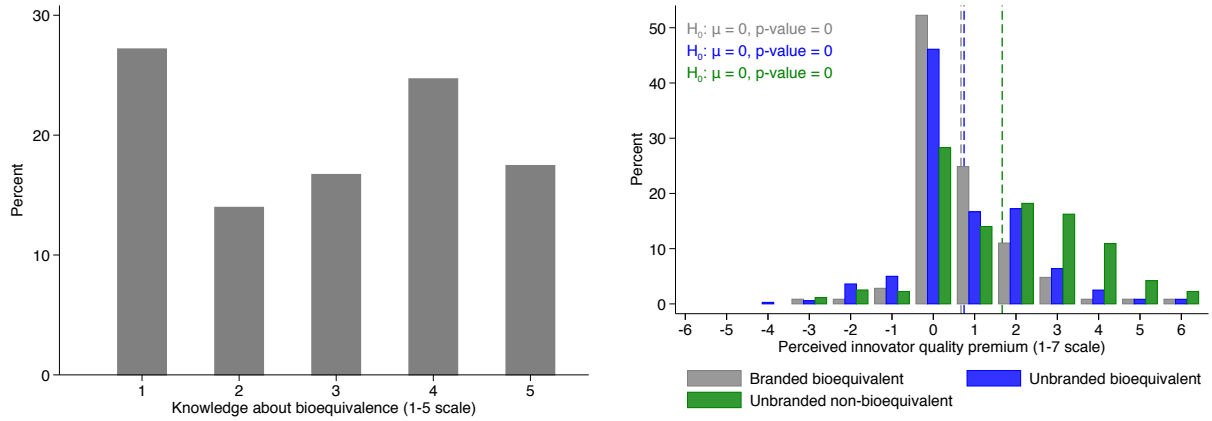
(b) Evolution of quality regulation by market



(c) Quality regulation and share of bioequivalent drugs

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

Figure 6: Survey results

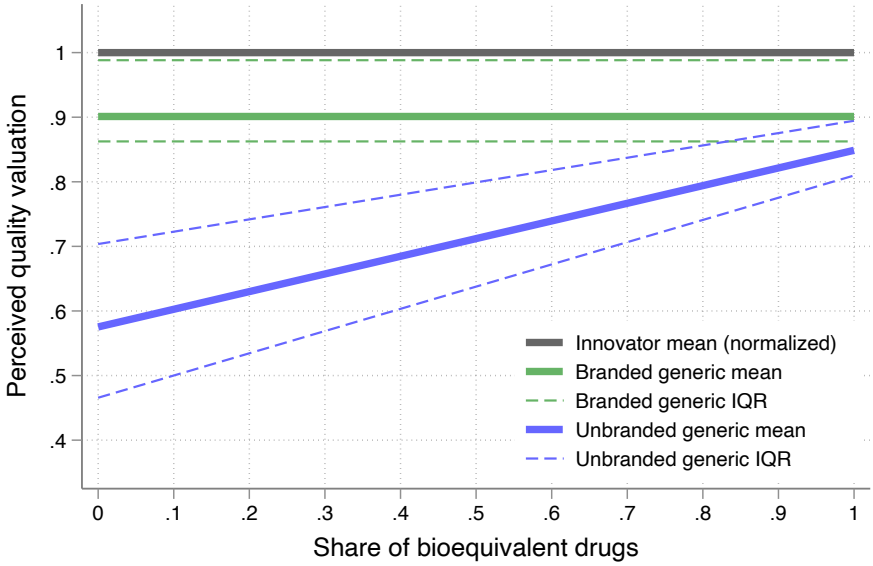


(a) Knowledge about bioequivalence

(b) Perceived quality premium

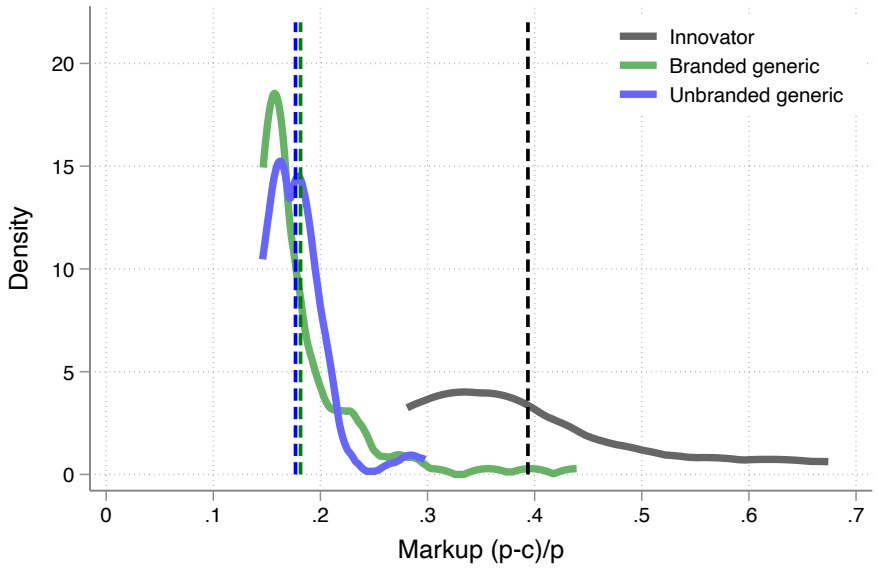
Notes: Panel (a) displays the distribution of consumer knowledge about bioequivalence in a 1-5 scale, where 1 means the consumer is not familiar with bioequivalence at all, and 5 means the consumers is able to provide a good definition of what it is. Panel (b) displays the distribution of perceived quality premiums for different drug segments 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. Dashed lines indicate the average for each drug segment in the figure.

Figure 7: Perceived quality and quality regulation

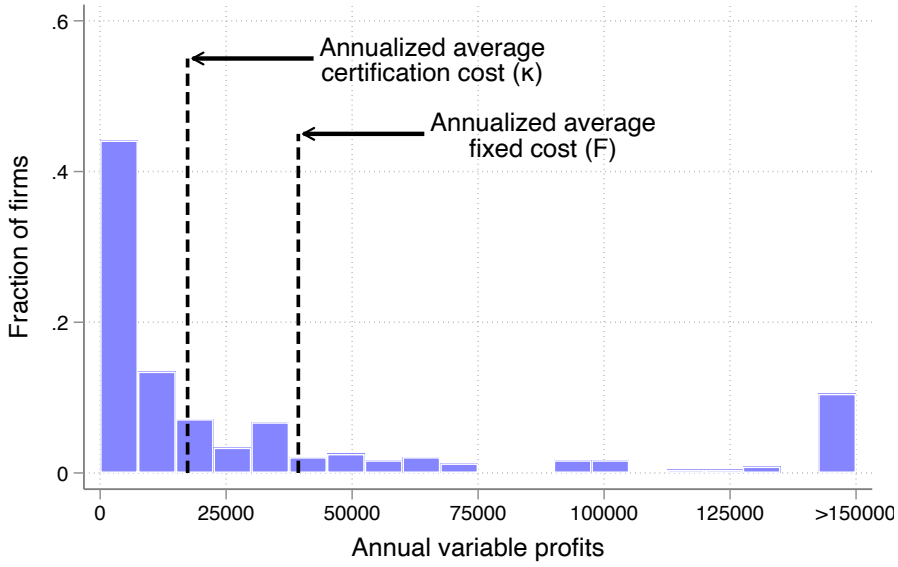


Notes: This figure displays fitted perceived quality valuation for drugs at a range of values for the share of the drugs offered by a firm in a given market that are bioequivalent. All reported values are normalized relative to the perceived quality of the innovator within each market. Solid lines display averages across markets for each segment, whereas dashed lines indicates their interquartile range.

Figure 8: Supply side estimates



(a) Markups by segment



(b) Entry and certification costs

Notes: Panel (a) displays the distribution of markups for innovator, branded generics and unbranded generics in the first year of the estimating sample, before the policy change. Solid lines display the respective densities, whereas vertical dashed lines indicate the average among firms in a given segment across markets. Panel (b) displays a histogram of annual variable profits for all firm in any market in the first year of the estimating sample, before the policy change. Vertical dashed lines indicate the average estimated annualized certification cost and entry cost.

Table 1: Timing of reform to quality regulation

		Panel A: Relevant policy dates				*Panel B: Market characteristics*					
	Number of	First decree		Last decree		Number of	Average	Average	Share of drugs by segment		
Group	Molecules	Decree	Deadline	Decree	Deadline	drugs	price	revenue	Innovator	Branded	Unbranded
1	4	2011-01	2011-02	2013-06	2013-12	67	101	29,190	0.26	0.63	0.10
2	20	2011-01	2012-02	2013-06	2013-12	193	562	29,900	0.31	0.55	0.14
3	11	2012-10	2013-10	2013-10	2014-04	91	485	19,650	0.17	0.58	0.25
4	25	2012-12	2013-12	2012-12	2013-12	378	302	20,607	0.24	0.66	0.10
5	20	2012-12	2013-01	2013-06	2013-12	354	218	23,754	0.22	0.74	0.04
6	10	2012-12	2014-12	2015-12	2016-12	108	1,280	29,255	0.24	0.76	0.00
7	15	2012-12	2014-12	2016-12	2017-06	227	390	21,407	0.26	0.71	0.03
8	16	2012-12	2014-12	2016-12	2017-12	133	672	18,165	0.25	0.64	0.10
9	10	2014-02	2015-12	2016-12	2017-12	28	10	8,414	0.04	0.33	0.63

Notes: Panel A in this table displays the dates of announcement and deadlines of BE requirements for different groups of molecules. The groups are defined as a unique combination of decrees and deadlines. Panel B in this table displays average product characteristics in 2011, by groups of molecules. Prices per gram and revenues are measured in 2013 U.S. dollars.

Table 2: Descriptive statistics for IQVIA data

Variable	N	Mean	SD	p10	p50	p90
Panel A: Price per gram						
All drugs	145,078	458.0	4169.4	2.3	35.3	577.4
Innovators	33,438	895.2	3876.4	4.4	72.6	1850.6
Branded generics	97,694	362.9	4534.5	3.0	36.1	386.3
Unbranded generics	13,946	76.1	327.3	0.4	3.0	130.3
Bioequivalents	17,750	162.0	589.7	2.2	21.9	272.7
Panel B: Market shares						
Innovators	12,672	0.30	0.30	0.00	0.22	0.80
Branded generics	12,672	0.44	0.34	0.00	0.44	0.89
Unbranded generics	12,672	0.27	0.36	0.00	0.03	0.99
Bioequivalents	12,672	0.07	0.17	0.00	0.00	0.30
Panel C: Number of drugs						
All drugs	12,672	12.54	11.26	2.00	9.00	29.00
Innovators	12,672	2.91	2.60	0.00	2.00	6.00
Branded generics.	12,672	8.44	9.53	0.00	5.00	23.00
Unbranded generics	12,672	1.19	1.38	0.00	1.00	3.00
Bioequivalents	12,672	1.50	4.08	0.00	0.00	5.00
Panel D: Number of laboratories						
All drugs	12,672	4.77	3.24	1.00	4.00	10.00
All drugs	12,672	0.81	0.51	0.00	1.00	1.00
Branded generics	12,672	3.40	3.03	0.00	3.00	8.00
Unbranded generics	12,672	0.58	1.41	0.00	0.00	2.00

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

Table 3: Determinants of bioequivalence certification and drug exit

	Panel A: Bioequivalence		*Panel B: Exit*	
	(1)	(2)	3	4
After first decree	1.98***	1.95***	-0.14	-0.26
	(0.33)	(0.34)	(0.28)	(0.34)
After first deadline	0.87***	0.84***	0.50***	0.74***
	(0.12)	(0.14)	(0.18)	(0.22)
After last decree	-0.06	0.06	0.62***	0.61**
	(0.12)	(0.14)	(0.22)	(0.26)
After last deadline	-0.42***	-0.18	-0.42*	-0.35
	(0.12)	(0.16)	(0.22)	(0.27)
Innovator			-0.54***	-0.55***
			(0.16)	(0.18)
Branded generic	-0.21**	-0.27***	0.31**	0.38**
	(0.09)	(0.09)	(0.15)	(0.16)
Imported	0.60***	0.68***	1.26***	1.28***
	(0.07)	(0.08)	(0.11)	(0.13)
log(Market revenue, 2010)	0.47***		-0.11**	
	(0.04)		(0.05)	
log(Number of branded, 2010)	-0.27***		0.13*	
	(0.04)		(0.07)	
log(Number of unbranded, 2010)	-0.29***		-0.11	
	(0.05)		(0.08)	
Observations	219,970	219,970	3,124	2,981
Market FE	N	Y	N	Y
Month FE	Y	Y	Y	Y
$\ln L$	-4,891	-4,655	-1,381	-1,268

Notes: This table displays results from hazard models in equation (1) for bioequivalence approval and logit models for drug exit. Estimation is implemented by maximum likelihood. The omitted drug type in all specifications is unbranded generics. Note that the sample in columns 3 and 4 is the cross section of drugs in the market, as the focus is on their first renewal or exit decision. All specifications include month-year fixed effects, whereas columns 2 and 4 also include molecule fixed effects. Standard errors in parentheses are clustered at molecule level. *p<0.10, **p<0.05, ***p<0.01.

Table 4: Effects of quality regulation on 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	-0.27***	-0.08	-0.27***	0.57***	-0.40***	-0.28***	0.60***	-0.40***
	(0.07)	(0.07)	(0.05)	(0.15)	(0.07)	(0.07)	(0.11)	(0.08)
R^2	0.95	0.94	0.96	0.70	0.96	0.92	0.64	0.92
Panel B: Heterogeneity by market size								
Share of market under regulation × Low revenue	-0.42***	-0.19**	-0.37***	0.20	-0.41***	-0.45***	0.34***	-0.45***
	(0.08)	(0.08)	(0.07)	(0.16)	(0.08)	(0.08)	(0.12)	(0.09)
Share of market under regulation × High revenue	-0.15**	0.01	-0.19***	0.89***	-0.39***	-0.13	0.82***	-0.36***
	(0.07)	(0.07)	(0.06)	(0.18)	(0.07)	(0.08)	(0.14)	(0.09)
R^2	0.95	0.94	0.96	0.73	0.96	0.92	0.66	0.92
Pre-regulation average	29.79	3.19	16.21	0.09	16.12	10.39	0.01	10.38
Observations	12,672	12,672	12,672	12,672	12,672	12,672	12,672	12,672
Market FE	Y	Y	Y	Y	Y	Y	Y	Y
Month FE	Y	Y	Y	Y	Y	Y	Y	Y

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

Table 5: Effects of quality regulation on 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	0.093*	0.030	0.005	0.141***
	(0.048)	(0.028)	(0.062)	(0.049)
R^2	0.99	1.00	0.99	0.99
Panel B: Heterogeneity by market size				
Share of market under regulation × Low revenue	0.257***	0.071*	0.068	0.193***
	(0.073)	(0.036)	(0.075)	(0.059)
Share of market under regulation × High revenue	-0.046	0.006	-0.045	0.074
	(0.050)	(0.035)	(0.063)	(0.064)
R^2	0.992	0.996	0.992	0.995
Panel C: Decomposition of price effects				
Dep. var.: Contribution of changes in prices ($\hat{P}_{PC}$)	0.070***	0.008	0.009	0.129***
	(0.024)	(0.020)	(0.023)	(0.048)
R^2	0.64	0.67	0.62	0.66
Dep. var.: Contribution of changes in shares ($\hat{P}_{RW}$)	0.007	0.021	0.052	0.004
	(0.033)	(0.040)	(0.063)	(0.009)
R^2	0.47	0.50	0.78	0.45
Dep. var.: Contribution of correlation between shares and prices ($\hat{P}_{CS}$)	-0.001	0.008	-0.044	0.002
	(0.010)	(0.013)	(0.031)	(0.008)
R^2	0.48	0.53	0.44	0.31
Dep. var.: Contribution of drug entry ($\hat{P}_{E}$)	0.021	0.031	-0.006	0.002
	(0.013)	(0.030)	(0.029)	(0.004)
R^2	0.54	0.49	0.66	0.53
Dep. var.: Contribution of drug exit ($\hat{P}_{X}$)	-0.004	-0.038*	-0.006	0.003**
	(0.003)	(0.020)	(0.007)	(0.001)
R^2	0.28	0.35	0.60	0.23
Observations	12,672	9,730	9,999	6,481
Market FE	Y	Y	Y	Y
Month-Type FE	Y	Y	Y	Y

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

Table 6: Effects of quality regulation on market shares and sales

	(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)	(9)	(10)	(11)
	Panel I: Dep. var.: Market share					*Panel II:* Dep. var.: log(1 + Sales)					
	Innovator	Generic				All	Innovator	Generic			
		Branded			Unbranded			Branded			Unbranded
		Total	BE	Non-BE				Total	BE	Non-BE	
Panel A: Average effects											
Share of market under regulation	0.05*	-0.05*	0.11***	-0.15***	0.00	-0.21*	-0.09	-0.50**	2.94***	-1.23***	-0.05
	(0.03)	(0.03)	(0.03)	(0.03)	(0.02)	(0.12)	(0.18)	(0.23)	(0.66)	(0.35)	(0.22)
R^2	0.91	0.93	0.54	0.86	0.96	0.97	0.97	0.94	0.64	0.90	0.95
Panel B: Heterogeneity by market size											
Share of market under regulation × Low revenue	0.08**	-0.03	0.05	-0.08*	-0.05	-0.35**	-0.15	-0.63***	1.59**	-1.11**	-0.72**
	(0.03)	(0.03)	(0.04)	(0.04)	(0.04)	(0.14)	(0.23)	(0.23)	(0.75)	(0.47)	(0.35)
Share of market under regulation × High revenue	0.02	-0.07*	0.15***	-0.22***	0.04**	-0.09	-0.04	-0.39	4.10***	-1.33***	0.52**
	(0.03)	(0.03)	(0.03)	(0.04)	(0.02)	(0.13)	(0.19)	(0.36)	(0.78)	(0.39)	(0.24)
R^2	0.92	0.93	0.55	0.86	0.96	0.97	0.97	0.94	0.66	0.90	0.95
Pre-regulation average	0.20	0.55	0.00	0.55	0.26	-	-	-	-	-	-
Observations	12,672	12,672	12,672	12,672	12,672	12,672	12,672	12,672	12,672	12,672	12,672
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 1-5 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 6-11 display regressions of logged sales of a segment on the policy roll-out variable constructed using the first decree deadline. Panel B provides results by baseline revenue. Markets are classified as having a low or high revenue according to the average level of the variable in 2010 relative to the median across markets in that year. Clustered standard errors in parentheses. ***p<0.01, **p<0.05, *p<0.1.

Table 7: Demand estimates and biases against generics

	(1)	(2)	(3)	(4)	(5)
Panel A: Demand estimates		Linear first stage regressions			
	GMM	$\ln p_{jmt}$	$\ln s_{jmt\|k}$	b^B_{jmt}	b^U_{jmt}
log Price (α)	3.61				
	(0.95)				
Bio, branded (η^B)	0.00				
	(0.17)				
Bio, unbranded (η^U)	0.64				
	(0.15)				
Nesting parameter (σ)	0.47				
	(0.19)				
Log exchange rate		0.23	0.91	-0.08	-0.00
		(0.04)	(0.22)	(0.03)	(0.00)
Past renewal, Branded		0.02	-0.60	0.32	-0.00
		(0.03)	(0.18)	(0.02)	(0.00)
Past renewal, Unbranded		0.07	-0.66	-0.10	0.24
		(0.14)	(0.82)	(0.10)	(0.01)
Low revenue market × N rival drugs		-0.01	-0.05	0.02	-0.00
		(0.01)	(0.06)	(0.01)	(0.00)
High revenue market × N rival drugs		-0.01	-0.09	0.02	0.00
		(0.01)	(0.03)	(0.00)	(0.00)
Observations	2,653	2,653	2,653	2,653	2,653
R^2		0.95	0.38	0.55	0.88
F-stat		6.67	5.31	47.96	494.13

Panel B: Biases against generics	Mean	SD
Branded before regulation (τ^B_0)	1.05	0.08
Branded after regulation (τ^B_1)	0.92	0.07
Unbranded before regulation (τ^U_0)	0.72	0.16
Unbranded after regulation (τ^U_1)	0.87	0.05

Notes: Panel A shows the estimates of the demand model. Column 1 displays main estimates. Columns 2-5 display auxiliary regressions of each endogenous variable in the model on the instrumental variables. Standard errors in parentheses. Panel B shows the mean and standard deviation of estimated biases against branded and unbranded generics before and after the quality regulation.

Table 8: Supply estimates

	(1)	(2)	(3)	(4)	(5)
	Marginal cost (c)	Entry cost (F)	Certification cost (κ)	Profit shock (σ_π)	Share high quality (π_H)
Constant	4.02	13.58	12.76	13,147.82	
	(0.07)	(2.756)	(0.887)	(589.295)	
Branded	-0.401				1.965
	(0.04)				(0.284)
Unbranded	-1.899				1.015
	(0.046)				(0.674)
log(Market size)				113,338.53	
				(5455.963)	
Observations	4,496	1,124	1,124	1,124	1,124
Market FE	Y	N	N	N	N

Notes: This table shows the estimates of the supply model. Marginal cost is estimated on a panel of yearly observations for 2010–2017. The remaining parameters are estimated on the cross sections of observations for 2010 and 2017. Standard errors in parentheses.

Table 9: Decomposition of the effects of quality regulation

		(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)	(9)
		Baseline	Δ Due to quality standard		Δ Due to biases against generics		Δ Due to certification cost		Δ Total	
Variable (y)	Segment	y	Δy	$\Delta\%y$	Δy	$\Delta\%y$	Δy	$\Delta\%y$	Δy	$\Delta\%y$
Number of firms	Innovator	0.74	-0.15	-20.60	-0.09	-14.87	0.00	0.00	-0.24	-32.41
	Branded	4.34	0.52	12.03	-1.36	-28.03	-0.57	-16.30	-1.41	-32.51
	Unbranded	2.74	0.00	0.06	0.44	16.22	-0.43	-13.52	0.02	0.57
Average price	Innovator	921.49	75.83	8.23	105.51	10.58	2.76	0.25	184.10	19.98
	Branded	431.21	5.14	1.19	1.12	0.26	8.64	1.98	14.90	3.46
	Unbranded	100.01	5.00	5.00	5.77	5.50	7.34	6.62	18.12	18.11
Market share	Innovator	0.24	-0.17	-73.65	-0.03	-44.78	0.01	26.43	-0.19	-81.60
	Branded	0.51	0.19	36.56	-0.57	-80.89	0.02	17.00	-0.36	-69.47
	Unbranded	0.27	-0.03	-9.47	0.59	244.48	-0.03	-3.74	0.54	200.21
Share-weighted price		551.73	-117.67	-21.33	-273.31	-62.97	10.14	6.31	-380.84	-69.03
Share-weighted quality		0.88	0.12	14.16	0.00	0.00	0.00	0.00	0.12	14.16
Consumer surplus (utils)		-	-	31.82	-	0.76	-	-2.83	-	29.07
Variable profits (MM)		19.31	7.75	40.15	-12.10	-44.71	1.64	10.95	-2.71	-14.03

Notes: This table decomposes the effect of quality regulation on market outcomes into its three main channels. Column 1 shows outcomes in the baseline without the reform. Columns 2 and 3 show changes in outcomes relative to column 1 coming from the quality standard, but assuming no changes in biases and no certification costs. Columns 4 and 5 display additional effects from the regulation through changing biases against generics. Columns 6 and 7 display additional effects from considering certification costs. Columns 8 and 9 show the full effects of the regulation, which aggregate the three channels we describe in this table.

Table 10: The role of certification costs

		(1)	(2)	(3)	(4)	(5)	(6)	(7)
		Full cost	Reduced cost				No cost	
			Non-targeted 50% subsidies		Targeted full subsidies			
Variable (y)	Segment	y	Δy	$\Delta\%y$	Δy	$\Delta\%y$	Δy	$\Delta\%y$
Number of firms	Innovator	0.51	0.00	0.00	0.00	0.00	0.00	0.00
	Branded	2.48	0.24	9.86	0.26	11.11	0.51	20.56
	Unbranded	2.03	0.17	8.50	0.17	9.06	0.34	17.01
Average price	Innovator	1,136.84	-2.24	-0.20	-1.64	-0.15	-3.33	-0.29
	Branded	460.31	-12.83	-2.79	-11.61	-2.66	-20.99	-4.56
	Unbranded	127.33	-2.68	-2.11	-5.55	-4.34	-6.84	-5.37
Market share	Innovator	0.07	-0.01	-11.69	-0.01	-10.61	-0.01	-17.26
	Branded	0.19	-0.01	-5.06	-0.02	-8.45	-0.03	-13.50
	Unbranded	0.74	0.02	2.34	0.02	3.38	0.04	5.03
Share-weighted price		200.22	-6.03	-3.01	-4.55	-2.25	-12.93	-6.46
Share-weighted quality		1.00	-0.00	-0.00	-0.00	-0.00	-0.00	-0.00
Consumer surplus (utils)		-	-	2.57	-	1.37	-	4.40
Variable profits (MM)		19.72	-1.17	-5.94	-0.03	-4.62	-2.22	-11.27

Notes: This table computes counterfactual equilibria with different subsidies to quality certification. Column 1 shows the equilibrium with the estimated certification costs. Columns 2 and 3 show changes relative to baseline under a uniform subsidy that decreases certification costs by 50 percent in all markets. Columns 4 and 5 show changes relative to baseline under a subsidy that fully covers certification costs for the 50 percent of markets with the lowest revenues. Column 6 and 7 show changes relative to baseline under subsidies that fully cover certification costs in all markets.

Table 11: The role of generic aversion

		(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)	(9)	(10)	(11)
			Share s of generic aversion corrected by regulation: $\tilde{\tau}^k_{m1}(s) = (1-s) \times \hat{\tau}^k_{m0} + x \times 1$									
		Baseline	s = 0%		s = 25%		s = 50%		s = 75%		s = 100%	
Variable (y)	Segment	y	Δy	$\Delta\%y$	Δy	$\Delta\%y$	Δy	$\Delta\%y$	Δy	$\Delta\%y$	Δy	$\Delta\%y$
Number of firms	Innovator	0.74	-0.15	-20.60	-0.19	-25.00	-0.24	-32.41	-0.29	-38.43	-0.33	-43.98
	Branded	4.34	-0.56	-12.78	-0.85	-19.61	-1.30	-30.01	-1.66	-38.31	-1.96	-45.14
	Unbranded	2.74	-1.07	-39.12	-0.97	-35.22	-0.82	-30.06	-0.71	-25.72	-0.64	-23.40
Average price	Innovator	921.49	82.64	8.97	134.25	14.57	168.10	18.24	189.61	20.58	52.84	5.73
	Branded	431.21	28.79	6.68	30.98	7.18	39.64	9.19	30.27	7.02	30.37	7.04
	Unbranded	100.01	6.68	6.68	13.02	13.02	24.16	24.16	33.25	33.25	50.65	50.64
Market share	Innovator	0.24	-0.15	-64.95	-0.18	-75.11	-0.19	-82.10	-0.20	-85.15	-0.20	-85.60
	Branded	0.51	0.20	38.86	0.08	14.65	-0.12	-24.09	-0.26	-51.49	-0.33	-64.84
	Unbranded	0.27	-0.06	-21.03	0.09	33.71	0.30	113.68	0.45	168.68	0.52	194.63
Share-weighted price		551.73	-93.69	-16.98	-154.10	-27.93	-266.80	-48.36	-347.14	-62.92	-365.21	-66.19
Share-weighted quality		0.88	0.12	14.16	0.12	14.16	0.12	14.16	0.12	14.16	0.12	14.16
Consumer surplus (utils)		-	-	22.81	-	23.17	-	21.77	-	19.22	-	16.82
Variable profits (MM)		19.31	10.29	53.29	6.22	32.23	4.35	22.51	11.07	57.33	27.94	144.66

Notes: This table describes how generic aversion mediates the effects of quality regulation on market outcomes. Column 1 shows outcomes in the baseline without quality regulation. Columns 2-11 display the effect of the regulation on market outcomes relative to that baseline for different degrees of correction of those biases. We define generic aversion as a linear combination between the baseline generic aversion and and that of a consumer with no aversion towards generics, which is $\tilde{\tau}^k_{m1}(s) = (1-s) \times \hat{\tau}^k_{m0} + s \times 1$, where s measures the effect of quality regulation on generic aversion.

Online Appendix

Quality Regulation and Competition: Evidence from Pharmaceutical Markets

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A Event Study Evidence of Policy Effects

The empirical strategy we propose in Section 5.1 exploits the staggered roll-out of the regulation across molecules as a useful source of identifying variation, which we complement with within market variation in drug license renewal dates. As a complement to estimates of policy effects using that strategy, we implement an event study analysis. The event study serves two purposes: (i) assessing the assumption of parallel trends across groups of molecules treated by the policy at different moments; and (ii) providing transparent visual evidence of the effects of bioequivalence on relevant market outcomes.

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

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

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

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

In practice, we consider the first policy deadline as the event that defines t_{0m}. Although decrees were extended, we cannot rule out that extensions were unexpected. This choice allows us to remain agnostic about potential reactions to the announcement of the first decree. We also place the following endpoint restrictions:[43]

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

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

[43]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 5 do consider the full period after the policy implementation that we observe in our data.

(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 segments. Our estimates show a slight decrease in the number of drugs overall, which seems to be driven by non-bioequivalent generics. As expected from the policy, our estimates show a large increase in the number of bioequivalent generics. The second row displays results for drug prices. We find no clear price effects overall, though the price of innovator drugs and unbranded generics show signs of increase in the second year after the policy event, while there might be a small decrease in the price of branded generics. Finally, the third row displays the estimated effects on market shares. Our results show substitution from non-bioequivalent to bioequivalent branded generics, while unbranded generics possibly decrease and innovator drugs possibly increase their market shares. We provide a detailed discussion of effects on all these and other margins in our main analysis in Section 5.

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.

B Effects on Drug Quality

We study whether the bioequivalence regulation affected observable quality of drugs in the market. The effects of the reform on quality are key to understand its welfare consequences. Unfortunately, direct measures of quality (e.g., results from drug testing) are not available in our setting, so in this section we use adverse health events associated with specific drugs and drug recalls as indirect measures. In Section 7, we estimate changes in unobservable quality due to the regulation using a structural model.

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

$$\frac{y_{mt}}{sales_{mt}} = \mu_{m0} + \gamma_t + \theta T_{mt} + \varepsilon_{mt} \tag{13}$$

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

B.1 Evidence from Adverse Health Events

A first set of outcomes related to quality are the adverse health events associated with drug consumption. We collect data on yearly clinical outcomes between 2010 and 2017 for ICD-10 diagnosis codes associated with active ingredients in our sample. We exploit public records collected by DEIS (2019), which cover admissions, days of hospitalization, and number of surgeries across all hospitals in Chile. We link diagnoses to active ingredients using a crosswalk between American Hospital Formulary Service (AHFS) and ICD codes that tracks adverse health events associated with the consumption of drugs (WHO, 2007).[44,45] We focus on the 71 active ingredients with at least one listed adverse effect.[46] In our setting, these events are rare. In 2010, there were on average 7.3 admissions, 13.2 hospital days and 0.002 surgeries per 100,000 daily doses sold across all markets.

We estimate equation (13) for these outcomes. Columns 1–3 in Table A.5-A display results across all markets. We find no evidence suggesting that stronger quality regulation decreased the number of discharges and the number of days associated with them. Moreover, we find no evidence of heterogeneous effects on these outcomes across small and large markets in Table A.5-B. These results suggest that stronger quality regulation was not able to reduce adverse health effects of drugs.

B.2 Evidence from Drug Recalls

To study effects on drug recalls, we collect data on the 209 recalls for prescription drugs that occurred during our period of study. Recalls are implemented by ISP as preventative sanitary measures upon notice of adverse events linked to licensed drugs.[47] In the period we cover, there is an average of 1.9 recalls per month, of which 1.4 (0.5) relate to active ingredients without (with) bioequivalence requirement.[48]

Our estimates of equation (13) in the sample of active ingredients with bioequivalence requirements provide no evidence suggesting that stronger quality regulation improved drug quality as measured by recalls. Columns 4 and 5 in Table A.5-A display results across all markets, while Table

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

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

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

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

[48]Figure A.4 shows the monthly recall frequency, split into drugs with bioequivalence requirements in our sample, and drugs without bioequivalence requirement. We cannot reject the hypothesis of a same trend in recalls over time across these two groups. We estimate an OLS regression for recall rates on an indicator for requirements and its interaction with a time trend, and find that the coefficient on the latter is not statistically different to zero.

A.5-B does so by market size. Our point estimates are close to zero across specifications.

C Description of Consumer Survey

C.1 Methodology and Results

In order to inform potential explanation for the results from our main analysis, we collect additional survey data in which we interview consumers and gather information on perceived quality, perceived price differences, relationship between physician prescription behavior and consumer choices and some additional characterization variables. The questionnaire is displayed in Section C.2 below.

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

In order to collect data on perceived quality and price differences, we focus on a particular market, Atorvastatin, a molecule commonly prescribed as a treatment to cholesterol. Within that market, we focus on 4 drugs that are relevant products in this market. In particular, we work with (i) a popular innovator drug called Lipitor, which is produced by Pfizer, (ii) a bioequivalent branded generic called Lipoten, produced by Pharmavita, (iii) a bioequivalent unbranded generic called simply Atorvastatina, produced by Mintlab, and (iv) and a non-bioequivalent unbranded generic also called Atorvastatina and produced by Mintlab. For reference, the prices of these drugs in the market are around $50,000 CLP, $10,000 CLP, $2,500 CLP and $2,500 CLP respectively ($77.5, $15.5 and $7.8 U.S. dollars respectively). Perceived quality and price differences are elicited using a paper sheet that showed the 4 drugs, which is displayed in Figure A.5.

The final sample includes $N = 401$ consumers. Table A.6 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 6. We code observations in which a consumer answered "I don't know" or "I don't recall" as missing. Finally, the questions regarding physicians' prescription behavior have less observations because they were added to the survey with a lag and are therefore not available for a around a fourth of the sample.

C.2 Questionnaire

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

1. [Show pictures of four drugs] Consider a scale of 1 to 7, where 1 is a drug of the minimum quality and that does not have the desired therapeutic effects and 7 is a drug of the highest quality that has exactly the expected therapeutic effects. What level of quality do you think the following drug has?
    - Innovator
    - Bioequivalent unbranded generic
    - Unbranded generic
    - Bioequivalent branded generic
2. [Show pictures of 4 drugs] If the price of the innovator drug is $50,000. What price do you think each of these drugs has?
    - Bioequivalent unbranded generic
    - Unbranded generic
    - Bioequivalent branded generic
3. [Show pictures of innovator and bioequivalent unbranded generic] If you were buying a box of Atorvastatin and were offered these two drugs. The innovator is priced at $50,000 in pharmacies. What do you think is the price of this generic?
4. [Show pictures of innovator and unbranded generic] If you were buying a box of Atorvastatin and were offered these two drugs. The innovator is priced at $50,000 in pharmacies. What do you think is the price of this generic?
5. [Show pictures of innovator and bioequivalent branded generic] If you were buying a box of Atorvastatin and were offered these two drugs. The innovator is priced at $50,000 in pharmacies. What do you think is the price of this generic?
6. [Show bioequivalence label] Have you ever seen this label on a drug before this survey?
    - Yes
    - No

7. [Do not read, use the following scale] Do you know what it means for a generic drug to be bioequivalent?
    - Very good response: Bioequivalence implies that two drugs have exactly the same therapeutic effects as the original
    - Good response: The generic is the same as the innovator
    - Regular response: A vague answer in terms of the quality of both drugs
    - Bad response: They are part of the same group of medications (e.g. both are Atorvastatin)
    - He has no idea: He does not know, he has no idea, he has not heard
8. When doctors deliver prescriptions, do they generally prescribe drugs by specifying a particular brand or without specifying a brand?
    - Prescribe drug without a specific brand
    - Prescribe drug with a specific brand
    - Does not know
9. When buying a prescription drug at a pharmacy, how much does your doctor, the pharmacist who serves you, and yourself weight in deciding which version of the medication to buy? In particular, on a scale of 1 to 5, where 1 is no power and 5 is a lot of power, how much power they have:
    - Doctor
    - Pharmacist
    - Customer
10. What type of drug did you buy the last time you needed one?
    - Innovator
    - Bioequivalent unbranded generic
    - Unbranded generic
    - Bioequivalent branded generic
    - Do not remember
    - Never purchased
11. Do you or anyone in your home take any drug for a chronic illness?
    - Yes
    - No
12. Do you or anyone in your household take any drug to control cholesterol?

- Yes
- No

13. What type of drug do you choose when you buy this medication for cholesterol control?

    - Innovator
    - Bioequivalent unbranded generic
    - Unbranded generic
    - Bioequivalent branded generic
    - Do not remember
    - Never purchased

D Empirical Model Details

D.1 Aggregation of Unbranded Drugs for Demand Estimation

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

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

where $I_{gt} \equiv \ln\left(\sum_{j \in \mathscr{J}_g} e^{\delta_{jt}/(1-\sigma)}\right)$ and $I_t \equiv \ln\left(\sum_g e^{(1-\sigma)I_{gt}}\right)$. Define $\delta_{jt} = \delta_{gt} + v_{jt}$, i.e., a decomposition into a group average and deviation from this average, such that

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

where z_{gt} is the average of z across products in the group, and

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

where $\dot{z}^g_{jt} = z_{jt} - z_{gt}$. We can then write

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

where N_{gt} is the number of drugs/producers within group g at t (we are conditioning on market m in these expressions). Note that if $v_{jt} = 0, \forall j \in \mathscr{J}_g$, the last term is zero.[49] We can then write

$$\ln N_{ut} s_{ut} = \ln\left(\sum_{j\in\mathscr{J}_u} s_{jt}\right) = (1-\sigma)I_{ut} - I_t = \delta_{ut} + (1-\sigma)\ln N_{ut} + (1-\sigma)\ln\left(\frac{1}{N_{ut}}\sum_{j\in\mathscr{J}_u} e^{v_{jt}/(1-\sigma)}\right) - I_t,$$

leading to the following estimation equation for the unbranded segment:

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

where $\nu_{ut} = \xi_{ut} + (1-\sigma)\ln\left(\frac{1}{N_{ut}}\sum_{j\in\mathscr{J}_u} e^{v_{jt}/(1-\sigma)}\right)$. The last part of the unobserved demand determinant ν_{ut} is expected to correlate with N_{ut}, leading us to instrument N_{ut} in estimation.

D.2 Market size approximation

In our demand model, we normalize utility of the outside good to be zero, and model the market share of each product as a function of observable characteristics. From observed data on quantities sold, one needs to take a stand on the market size M_{mt} for market m at time t. Since the market size is not observed, and we do not have any measures that would allow us to directly infer it, such as number of individuals with a diagnosis for which a given drug would be relevant, we approximate the market size for each ATC code m and year t using the insights of Huang and Rojas (2013, 2014) for a simplified version of our model. Specifically, we follow Dubois and Lasio (2018) in specifying a simple logit version of our model, where we use the market share equations for two observed, distinct goods j and j' to derive

$$\ln q_{jmt} - \ln q_{j'mt} = v_{jmt} - v_{kmt} + -\alpha\left(\ln p_{jmt} - \ln p_{j'mt}\right) + \left(x_{jmt} - x_{kmt}\right)'\beta + \xi_{jmt} - \xi_{kmt}, \tag{14}$$

which does not depend on the market size. The parameters of this equation can be consistently estimated by 2SLS using similarly constructed instruments. In a second step, we use the equation

$$\ln q_{jmt} - \ln q_{0mt} = \hat{v}_{jmt} - \hat{\alpha}\ln p_{jmt} + x'_{jmt}\hat{\beta} + \xi_{jmt}, \tag{15}$$

where the estimated parameters from equation (14) is taken as given, and $\ln q_{0mt}$ is the quantity sold of the outside good which is common for all products j in ATC code m in year t. We specify sales of the outside good as

$$\ln q_{0mt} = \sum_{r=0}^{4} \varsigma_{rm} t^r + \varsigma_p \overline{\ln p}_{mt} + \overline{x}'_{mt}\varsigma_x, \tag{16}$$

[49] In any other case, it is positive and increasing in N_{gt} by increasing the number of terms in the summation.

where the first sum is a fourth-degree polynomial over time allowed to differ across ATC's, and $\overline{\ln p}_{mt}$ and $\bar{x}_{mt}$ are the average log price and average characteristics in market m in year t. The average terms capture the effect of the attractiveness of the inside goods in competition with the outside good. This equation is estimated using a modified GMM-IV procedure, minimizing

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

where $G(\varsigma) = Z'\boldsymbol{\xi}(\varsigma)$ is the vector of moments, Z is a matrix of the exogenous variables in equation (16) including the average exchange rate as an instrument for average price, and W is the weighting matrix for the moments. The quadratic form in the parameter vector ς is a regularization term, with $\mathbf{\Lambda}$ as a diagonal matrix of regularization parameters. We allow two different regularization parameters, one for parameters controlling the market-time polynomials, and one for the parameters controlling the effect of average characteristics. We add regularization due to the large number of parameters in equation (16), and fit the regularization parameters to minimize RMSE using cross-validation.

Figure A.1: Labeling of bioequivalent drugs



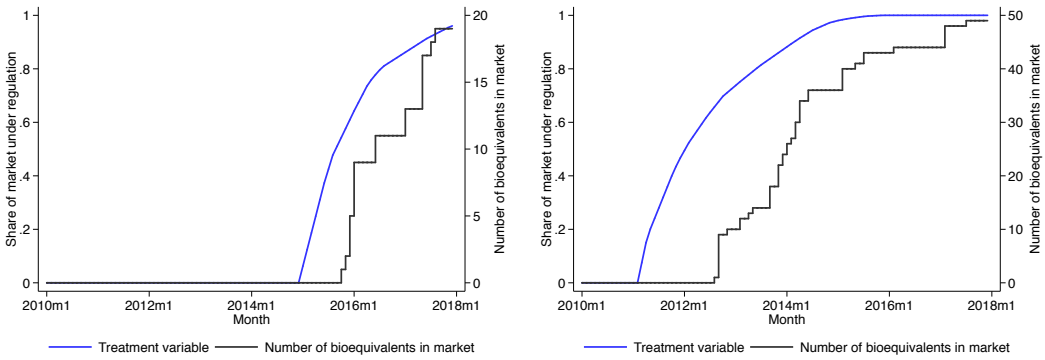
(a) Instructions for bioequivalent drugs labeling



(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 bioequivalence approval.

Figure A.2: Policy variation induced by bioequivalence requirements



(a) Aripiprazole

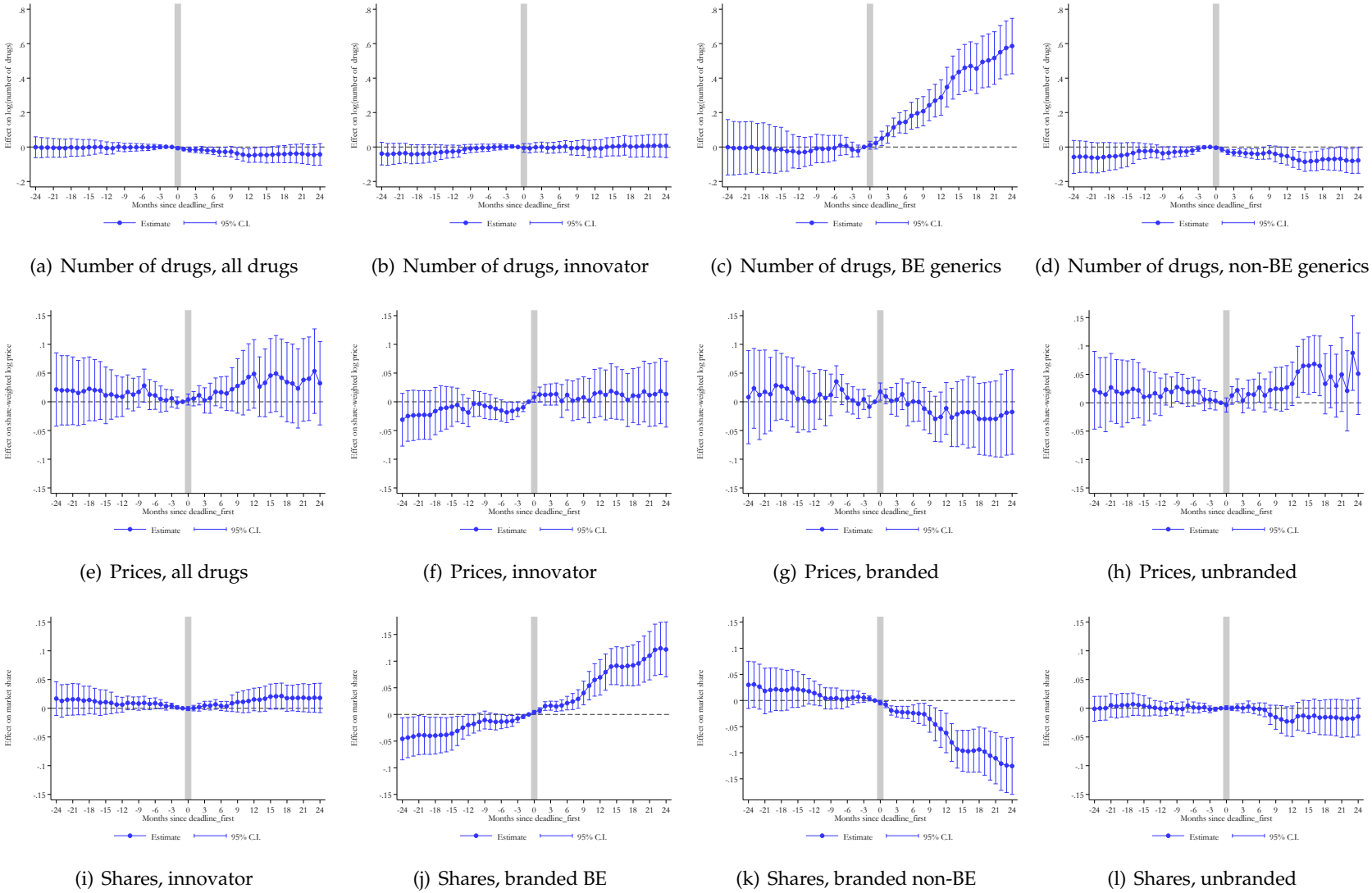
(b) Atorvastatin

(c) Citalopram

(d) Deflazacort

Notes: Each figure displays the values of the treatment variable and the number of bioequivalent drugs in a different market. This version of the treatment variable uses the first deadline as the relevant date. The instrument is displayed in blue, and takes a value of 0 before the first decree, and then increases as renewal dates of drugs in the molecule approach. The number of bioequivalent drugs in the molecule is displayed in gray. These four examples are plotted along all other markets in our sample in Figure 5-b.

Figure A.3: Policy effects using an event study approach



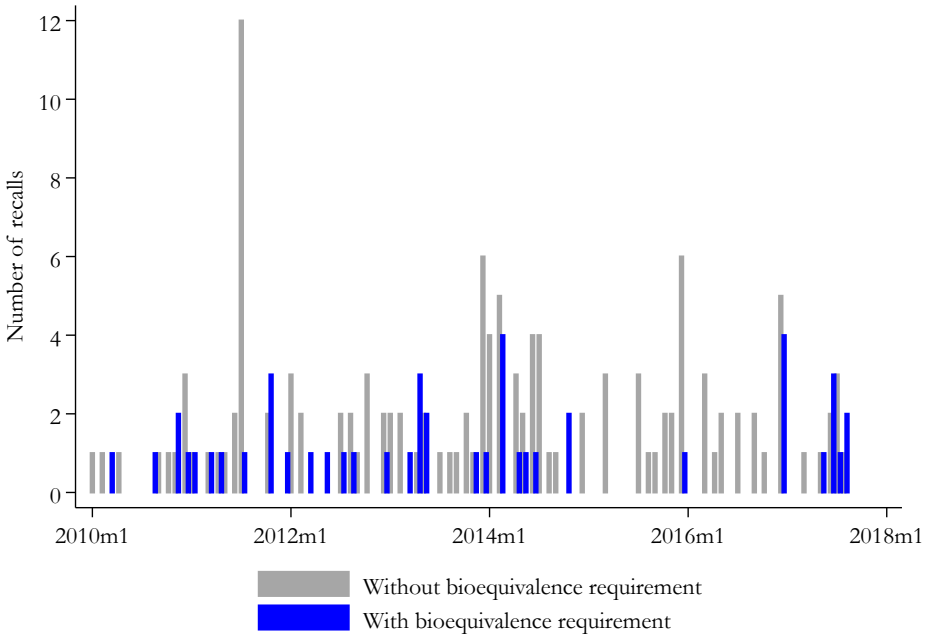
(a) Number of drugs, all drugs (b) Number of drugs, innovator (c) Number of drugs, BE generics (d) Number of drugs, non-BE generics

(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, using the first bioequivalence deadline as policy event. Dots indicate point estimates and lines indicate 95% confidence intervals based on standard errors clustered at the market level. Coefficients are displayed for 24 months before and 24 months after the policy event. The coefficient on the month previous to the event is normalized to zero. The first row displays results for the number of drugs in the market, the second row displays results for the price index defined in equation (4), and the third row displays results for drug market shares.

Figure A.4: Number of recalls per month



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

Figure A.5: Consumer survey elicitation of perceived quality and price



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

Table A.1: Policy roll-out groups, molecules and treatments

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

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

Table A.2: Determinants of assignment of bioequivalence decrees to molecules

	(1)	(2)	(3)	(4)	(5)	(6)	(7)
	Ordered logit for Policy Assignment Groups						
Branded generic market share	-1.561**	-1.563**	-1.956***	-2.475***	-2.168**	-2.226**	-1.997**
	(0.614)	(0.614)	(0.702)	(0.839)	(0.872)	(0.881)	(0.905)
Unbranded generic market share	-0.802	-0.853	-1.795**	-2.078**	-1.484	-1.471	-1.216
	(0.542)	(0.547)	(0.805)	(0.922)	(0.978)	(0.982)	(1.031)
Δ% Branded generic market share		0.052	0.053	0.063	0.079	-0.410	-0.380
		(0.097)	(0.098)	(0.099)	(0.100)	(0.397)	(0.414)
Δ% Unbranded generic market share		-0.175	-0.321	-0.345	-0.359	-0.333	-0.291
		(0.305)	(0.320)	(0.319)	(0.321)	(0.317)	(0.321)
Any branded generic			0.522	0.340	0.367	0.357	0.436
			(0.552)	(0.721)	(0.728)	(0.728)	(0.734)
Any unbranded generic			0.778	0.743	0.765	0.646	0.771
			(0.533)	(0.634)	(0.636)	(0.644)	(0.662)
log(Number of drugs)				0.389	0.520	0.509	0.485
				(0.368)	(0.385)	(0.384)	(0.393)
log(Number of labs)				-0.034	-0.396	-0.382	-0.311
				(0.557)	(0.600)	(0.596)	(0.614)
log(Market revenue)				1.031	0.708	0.607	0.805
				(1.031)	(1.046)	(1.060)	(1.082)
log(Market revenue)					0.300	0.283	0.270
					(0.238)	(0.237)	(0.238)
log(Average price)					0.134*	0.106	0.090
					(0.080)	(0.082)	(0.084)
Δ% Average price						1.000	0.948
						(0.788)	(0.819)
Share imported							0.725
							(0.783)
chronic							0.132
							(0.338)
Observations	131	131	131	131	131	131	131
Pseudo R^2	0.0123	0.0135	0.0198	0.0248	0.0303	0.0337	0.0359

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

Table A.3: Heterogeneity in determinants of bioequivalence certification and drug exit

	Panel A: Bioequivalence		*Panel B: Exit*	
	(1)	(2)	(3)	(4)
After first deadline	1.08***	0.42**	0.46	0.86
	(0.16)	(0.17)	(0.51)	(0.70
After first deadline=1 × Above median revenue, 2010=1		2.25***		-1.63**
		(0.37)		(0.76)
Above median revenue, 2010=1		-1.39***		-1.00**
		(0.36)		(0.46)
Reference			0.11	0.69
			(0.41)	(0.46)
Imported	0.65***	0.67***	1.31***	1.21***
	(0.10)	(0.10)	(0.39)	(0.41)
log(Market revenue, 2010)	0.39***	0.39***	-0.39**	-0.34*
	(0.07)	(0.07)	(0.19)	(0.19)
log(Number of branded, 2010)	-0.10*	-0.13**	0.30	0.34
	(0.06)	(0.06)	(0.24)	(0.24)
log(Number of unbranded, 2010)	-0.21***	-0.16**	0.55*	0.53*
	(0.08)	(0.08)	(0.29)	(0.28)
Month FE	Y	Y	Y	Y
Observations	75,746	75,746	549	549
$\ln L$	-2,270	-2,232	-177	-161

Notes: This table displays results from hazard models in equation (1) for bioequivalence approval and logit models for drug exit. Results in this table highlight heterogeneity in the relationship between quality regulation and drug bioequivalence approval or exit along baseline drug characteristics. Estimation is implemented by maximum likelihood. The omitted drug type in all specifications is unbranded generics. Note that the sample in columns 3 and 4 is the cross section of drugs in the market, as the focus is on their first renewal or exit decision. All specifications include time fixed effects. Standard errors in parentheses clustered at molecule level. *p<0.10, **p<0.05, ***p<0.01.

Table A.4: Effects of quality regulation on 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	-0.30***	-0.10	-0.32***	0.73***	-0.46***	-0.34***	0.78***	-0.48***
	(0.08)	(0.08)	(0.06)	(0.19)	(0.08)	(0.09)	(0.14)	(0.10)
R^2	0.94	0.94	0.96	0.70	0.95	0.92	0.64	0.92
Panel B: Heterogeneity by market size								
Share of market under regulation × Low revenue	-0.46***	-0.24**	-0.45***	0.27	-0.50***	-0.53***	0.45***	-0.54***
	(0.10)	(0.10)	(0.09)	(0.21)	(0.11)	(0.10)	(0.15)	(0.11)
Share of market under regulation × High revenue	-0.16*	0.01	-0.22***	1.12***	-0.43***	-0.17*	1.05***	-0.44***
	(0.09)	(0.09)	(0.08)	(0.23)	(0.09)	(0.10)	(0.18)	(0.11)
R^2	0.95	0.95	0.96	0.73	0.95	0.92	0.66	0.92
Pre-regulation average	29.79	3.19	16.21	0.09	16.12	10.39	0.01	10.38
Observations	12,672	12,672	12,672	12,672	12,672	12,672	12,672	12,672
Market FE	Y	Y	Y	Y	Y	Y	Y	Y
Month FE	Y	Y	Y	Y	Y	Y	Y	Y

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

Table A.5: Effects of quality regulation on drug quality

	(1)	(2)	(3)	(4)
	Drug adverse effects			Drug
	Admissions	Hospital days	Surgeries	recalls
Panel A: Average effects				
Share of market under regulation	-0.023	-0.120	-0.000	0.001
	(0.023)	(0.112)	(0.000)	(0.001)
R^2	0.849	0.869	0.142	0.191
Panel B: Heterogeneity by market size				
Share of market under regulation × Low revenue	-0.072	-0.235	-0.000	0.002
	(0.071)	(0.224)	(0.000)	(0.002)
Share of market under regulation × High revenue	0.022	-0.016	-0.000	-0.001
	(0.024)	(0.014)	(0.000)	(0.002)
R^2	0.850	0.871	0.142	0.191
Pre-regulation average	0.073	0.132	0.000	0.000
Observations	568	568	568	1023
Market FE	Y	Y	Y	Y
Month FE	Y	Y	Y	Y

Notes: Each column in this table is an outcome related to drug quality on the policy roll-out variable constructed using the first decree deadline, as in equation (13). Outcomes are constructed as the ratio of the variable of interest over drug sales measured in thousands of daily doses. Columns 1-3 are related to adverse health effects, whereas column 4 is related to drug recalls, and in particular include all recalls. Panel B provides results by baseline revenue. Markets are classified as having a low or high revenue according to the average level of the variable in 2010 relative to the median across markets in that year. Clustered standard errors in parentheses. ***p<0.01, **p<0.05, *p<0.1.

Table A.6: Summary statistics from consumer survey data

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

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