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QUALITY REGULATION AND COMPETITION: EVIDENCE FROM PHARMACEUTICAL MARKETS

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ABSTRACT

Quality regulation attempts to ensure quality and foster competition by reducing vertical differentiation, but it may also have adverse 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 introduction of bioequivalence in Chile, we find that stronger regulation decreased the number of drugs in the market by 21% and increased average paid prices by 13%. We estimate a model of drug entry, certification, and demand to study the role of drug quality, aversion against generics, and certification costs in shaping the equilibrium effects of quality regulation. We find that quality regulation increased demand for generic drugs by resolving asymmetric information and reducing aversion against unbranded generics, which induced entry of high-quality drugs in place of low-quality drugs. Consumer welfare increased despite higher prices and a lower number of firms. We compare minimum quality standards to quality disclosure and other designs of quality regulation.

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1 Introduction

Whenever consumers cannot verify the quality of the products offered in the market, the risk of purchasing a low-quality product leads to a lower willingness to pay than under full information. Moreover, the inability of firms to signal quality harms competition, affecting the set of products that are offered and their prices. Quality regulation—often in the form of minimum quality standards—is a widespread policy instrument that attempts to address the market failures produced by asymmetric information about product quality. Despite its widespread adoption in a variety of markets, there is limited empirical evidence on the equilibrium effects of quality regulation and the 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 turn 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 increased quality, reduced vertical differentiation, and changes in market structure due to costly compliance.

In this paper, we study quality regulation in pharmaceutical markets, where issues of quality, asymmetric information, as well as potential misperceptions regarding quality are a central part of the academic and policy debate (see Bate *et al.* 2011, Bronnenberg *et al.* 2015 and WHO 2000, among others). In these markets, quality regulation may ensure drug quality and improve the perception of generic drugs, thus reducing vertical differentiation and increasing competition. However, costly certification may induce exit or deter entry of affordable and yet high-quality drugs, harming competition and potentially overturning the positive effects of the regulation.

We quantify the effects of quality regulation in pharmaceutical markets by exploiting the introduction of bioequivalence requirements in Chile. At the onset of this policy, this market displayed low generic penetration in spite of large price differences with branded alternatives: unbranded generics accounted for less than 30% of sales, even though they were on average 6 and 10 times cheaper than branded generics and innovator drugs, respectively.[1] In this context, the government introduced quality regulation to increase the perceived quality of generics and enhance price competition. Bioequivalence is a central requirement in the approval process of generic drugs in the U.S. and Europe, and has been increasingly adopted elsewhere, including

[1] *Innovator drugs* are the first drugs containing a specific molecule to receive approval for use and are often referred to as originator drugs. *Generics* are drugs with the same molecule 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 trading name, typically advertise, and compete on brand (see, e.g., Danzon and Furukawa, 2008). In the U.S. and Europe, branded generics are often marketed by (subsidiaries of) innovating pharmaceutical firms (Grabowski and Vernon, 1992), whereas in Chile and other Latin American and developing countries, branded generics are produced and marketed by generic manufacturers.

China in 2016 and India in 2017. An innovator drug can be substituted by a bioequivalent generic with the expectation that the generic has the same clinical effect and safety profile.[2]

We start by estimating the effects of quality regulation on market outcomes. Our strategy exploits the staggered implementation of the reform along with features of its enforcement, to compare outcomes across and within markets (molecules) exposed to the regulation. We find that stronger quality regulation affected market structure by decreasing the number of drugs by 21%, and led to a 13% increase in average paid prices, most of which was due to drug-specific price increases. Most of these effects were concentrated among small markets, where the number of drugs decreased by 30%, and average paid prices increased by 26%.

To disentangle the different mechanisms through which quality regulation operates and to study counterfactuals and their welfare implications, we develop and estimate a model for this market. On the demand side, consumers demand drugs subject to two frictions. First, due to asymmetric information, consumers cannot distinguish between high- and low-quality generics before the regulation. Second, consumers may display aversion to generics, even if they have full information about product quality. From the demand side, we recover willingness to pay for drugs. On the supply side, firms first choose whether to participate in the market in an incomplete information entry game, which requires incurring an entry cost, and a certification cost when quality regulation is introduced. In the second stage, entrants compete on prices. From the supply side, we recover entry costs, certification costs, marginal costs, and the prevalence of low-quality drugs before the reform. In the model, quality regulation affects outcomes through both eliminating asymmetric information and changing the extent of generic aversion on the demand side, and through increasing fixed costs on the supply side.

Our estimates imply that the regulation increased the valuation of unbranded generics substantially but did not impact the valuation of branded generics. We also estimate that 67% of unbranded generics and 96% of branded generics were above the standard. Our estimates imply that 87% of the increase in the valuation of unbranded generics stemmed from resolving asymmetric information, and the rest from decreasing generic aversion.

Using the estimated model, we 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 descriptive evidence. However, low-quality drugs are removed from the market, which resolves asymmetric information and increases the demand for generic drugs. As a result, demand shifts towards unbranded generics. Overall welfare increases by between

[2]More precisely, a generic drug is bioequivalent to its reference innovator 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.

$35 and $63 million USD per year (3.4% and 5.1%), depending on the assumption regarding the welfare-relevance of aversion to generics. In sum, the effects of the regulation through increased drug quality dominate its adverse competitive effects from a welfare perspective.

We decompose the equilibrium effects into three mechanisms: the 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. First, we simulate the removal of low-quality drugs, keeping generic aversion at pre-reform levels and setting certification costs to zero. Removing drugs reduces competition, while resolving asymmetric information increases the attractiveness of generics. Both effects lead to the entry of high-quality generics, which partially offsets price increases. Second, we simulate the additional effect of reduced generic aversion. This effect increases demand for unbranded generics mostly at the expense of branded generics, causing moderate price increases for unbranded generics and exit among branded generics. In terms of consumer welfare, the gains from reducing generic aversion are mostly offset by price increases. Finally, we simulate the additional effect of costly certification. This causes additional exit by generics and moderate increases in prices, which reduce welfare. Overall, removing low-quality drugs—hence resolving asymmetric information—is the main channel through which quality regulation increased consumer welfare in this setting.

We then develop a series of counterfactual policy analyses. First, we consider certification subsidies, as a policy that may reduce the adverse competitive effects of quality regulation while preserving the benefits of resolving asymmetric information. 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.

Second, we consider quality disclosure as an alternative policy to deal with asymmetric information about product quality (Dranove and Jin, 2010; Allcott and Knittel, 2019; Barahona *et al.*, 2021; Vatter, 2021). Disclosure limits product exit and hence may curb price increases, but it allows low-quality products to be sold in the market. We find that exit of unbranded generics would be much lower under quality disclosure, leading to lower price increases and similar consumer welfare increases than minimum quality standards. However, the fact that quality standards induce a stronger and better selection of drugs leads to higher overall welfare than disclosure, mostly driven by reducing the amounts of fixed and certification costs incurred.

Finally, we consider the role of generic aversion in shaping the effects of quality regulation. Changing generic aversion affects welfare by modifying choices, prices, and market structure, even if it is not considered welfare-relevant. We find that quality regulation improves consumer welfare even if it does not impact generic aversion. Still, 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 the empirical literature focused on the effects of quality regulation on market outcomes. While there is a well-established theoretical literature on the equilibrium implications of quality regulation (Leland, 1979; Shapiro, 1983; Ronnen, 1991), empirical work on the topic is somewhat limited. The areas that have received most of the attention are input regulation in child-care services (Chipty 1995; Currie and Hotz 2004; Blau 2007; Hotz and Xiao 2011), occupational licensing in labor markets (Kleiner 2000; Kleiner and Krueger 2013; Larsen *et al.* 2020; Farronato *et al.* 2020; Kleiner and Soltas 2021), seller certification in e-commerce (Hui *et al.*, 2018; Jin *et al.*, 2020), and medical devices (Grennan and Town, 2020). This paper contributes to this literature by studying quality regulation in the pharmaceutical market, and by estimating a model of demand and supply that allows to measure welfare effects and to evaluate counterfactual policies.[3] Relatedly, by measuring the relevance of endogenous drug exit and entry in response to quality regulation, we contribute to a growing literature that highlights the importance of accounting for equilibrium firm participation and positioning responses for policy evaluation (Fan, 2013; Wollmann, 2018; Barahona *et al.*, 2021; Vatter, 2021).

Moreover, our paper contributes to different strands of literature that study pharmaceutical markets. First, we build on research on the drivers of entry by generics after patent expiration (Scott Morton, 1999, 2000), and its competitive effects (Caves *et al.*, 1991; Grabowski and Vernon, 1992; Frank and Salkever, 1997; Branstetter *et al.*, 2016). We study a context where incumbent generics face the choice of staying or exiting the market upon stronger regulation. Our results show that quality regulation affects market structure, which in turn affects prices and welfare. In addition, we add to a literature on the regulation of these markets. Much of this work focuses on price regulation (Danzon and Chao, 2000; Brekke *et al.*, 2009; Dubois and Lasio, 2018; Dubois and Sæthre, 2020; Mohapatra and Chatterjee, 2020; Dubois *et al.*, 2021; Maini and Pammolli, 2021), off-label prescription regulation (Tunçel, 2021), physician detailing (Grennan *et al.*, 2021), public competition (Brugués, 2020; Atal *et al.*, 2021), and patent protection (Chaudhuri *et al.*, 2006), whereas quality regulation has yet to be studied. Our paper studies one of the most common forms of pharmaceutical quality regulation. Finally, we contribute to a better understanding of the sources of aversion to generics that sustain brand premiums (Ching, 2010; Bronnenberg *et al.*, 2015; Colgan *et al.*, 2015; Bairoliya *et al.*, 2017; Carrera and Villas-Boas, 2020), by estimating how quality regulation affects information asymmetries and generic aversion, and how those determine equilibrium outcomes.

The remainder of the paper is organized as follows. Section 2 describes the Chilean pharmaceutical market and regulation, and Section 3 describes the data we use. Section 4 provides

[3]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.

descriptive evidence of the effects on market structure, market outcomes, and drug quality. Section 5 provides survey evidence on perceived quality gaps across drug segments and how they relate to bioequivalence. Section 6 describes the model and its estimates, whereas Section 7 discusses our counterfactual and welfare analyses. Finally, 8 concludes.

2 Pharmaceutical Market and Quality Regulation in Chile

2.1 Institutional Framework

Chileans spend 0.9% of GDP on drugs, which is lower than the OECD average of 1.5% (OECD, 2013). However, expenditure on overall health care and pharmaceuticals has grown steadily over recent years, and drug spending accounts for around 40% of all out-of-pocket health spending (Benítez *et al.*, 2018). We focus on the retail market, which provides around 40% of prescription drugs in the country.[4] In this segment of the market, there is very limited insurance coverage, except for individuals enrolled in the public insurance program and for a particular subset of diseases. Osorio (2020) estimates that 80% of purchases in the retail pharmaceutical market are paid out-of-pocket. Moreover, there is no price regulation. Hence, prices play an important role in both consumer choice and drug affordability.

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 that we study.

Three features of our setting influence the workings of the reform. First, direct-to-consumer advertising of prescription drugs is forbidden, which could make consumers more price-sensitive because expensive branded drugs cannot use advertising to boost demand. Second, the retail pharmacy market is highly concentrated, which may affect supply-side reactions to regulation. Three large pharmacy chains account for more than 80% of the market, whereas the remainder of the market is comprised of several small chains without national presence. Third, physicians' prescription behavior and pharmacists' ability to offer alternative versions of prescribed drugs affect consumer choice. In Chile, pharmacists can only offer generic substitution when prescriptions specify the generic name and a bioequivalent substitute is available. Despite recent policy efforts towards constraining discretion in prescribing, physicians still sometimes prescribe by brand name only, which limits substitution towards generics in practice.[5]

[4]This fraction is based on own calculations based on the 2016 National Health Survey. The remainder 60% is accounted for drugs delivered free of charge in primary care clinics to enrollees of the public insurance program.

[5]In February 2014, Law 20,724 was passed to require physicians to prescribe by the generic name to allow for substitution towards bioequivalent generics upon patient request. However, industry actors concede that enforcement has been partial and that some physicians have continued to prescribe branded drugs. This lack of

2.2 Bioequivalence in the Chilean Pharmaceutical Market

Bioequivalence is established to demonstrate therapeutic equivalence between a generic drug and the corresponding reference drug, often the innovator drug. Two drugs are bioequivalent when the rate and extent of absorption of the tested drug and the reference drug do not significantly differ when administered at the same molar dose of the therapeutic ingredient under similar conditions (Davit *et al.*, 2013). These parameters are influenced by, e.g., pharmacokinetic properties of the active ingredient and secondary ingredients in combination with features of the production process (see Pramod *et al.*, 2016, for technical details). Bioequivalent drugs can be substituted with the expectation that the generic drug yields the same clinical effect and safety profile as the reference drug (FDA, 2017). Therefore, bioequivalence allows bridging preclinical and clinical data associated with the reference drug to the generic drug. Bioequivalence is a standard requirement for generic drugs in most high-income countries. Moreover, many OECD countries either allow, encourage, or require generic substitution (OECD, 2000).

Although bioequivalence requirements were originally implemented in the developed world to foster generic entry, they have been recently adopted by developing countries as the primary tool for testing the effectiveness of drugs (Balmaceda *et al.*, 2015). Before 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 not necessarily 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 through increasing the perceived quality of generics.[6] For instance, in the early years of the reform, the Head of the National Drug Agency (*Agencia Nacional de Medicamentos*, ANAMED) stated in La Tercera (2012) that:

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

The first list of molecules subject to bioequivalence was published in 2005 by the Chilean Ministry of Health (*Ministerio de Salud*, MINSAL). This list consisted of molecules included in a

enforcement motivated subsequent policy discussions in Congress (Cámara de Diputados, 2019).

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

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.[7] Each decree specified the deadline for bioequivalence testing among incumbent drugs. In practice, however, enforcement of the requirements occurred mostly by the time of license renewal, when ISP would deny 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.[8]

In most cases, the original deadlines to provide proof of bioequivalence were extended through subsequent decrees due to slow uptake and capacity constraints in laboratories performing the tests. Among molecules with bioequivalence requirements, there are nine unique combinations of policy dates, namely the date of the first decree, date of extensions if any, and corresponding deadlines established in the first decree and the extensions. Table 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 in each group. 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 3-b. We exploit this variation for the estimation of policy effects later in the paper.

Bioequivalence certification is provided after the manufacturer presents successful studies. Generally, bioequivalence is determined through *in vivo* clinical studies for a specific presentation of a drug, although under certain conditions only *in vitro* studies are required for different dosages of the same drug. Bioequivalence certification of imported drugs is often validated in Chile if obtained in countries with high certification standards (e.g., Canada, U.S., the European Union, 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 $48,000 to $240,000 USD per drug, and are covered by the manufacturer (La Tercera, 2012; CIPER, 2015). To put this number in context,

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

[8]In practice, the label could affect 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. We show an example of this label in Figure A.1.

the median drug in our data had annual revenue of $99,100 in 2010. Moreover, 35% and 71% of drugs had annual revenue lower than $48,000 and $240,000, respectively. These amounts only cover the retail market but suggest that the financial burden imposed by bioequivalence testing was non-negligible.[9]

3 Data and Descriptive Statistics

3.1 Data Sources

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

We measure market outcomes using data from IQVIA, which contain information on drug monthly retail prices and sales between January 2010 and December 2017.[10] The data cover 83 local markets, which account for most of the country. To aggregate the data to the national level, we compute monthly sales by aggregating across local markets, and monthly prices as sales-weighted averages of prices across local markets. For branded drugs, the IQVIA data provide price and sales at the product level, 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. We focus on prescription drugs, which account for more than 90% of drugs in the molecules we study.

We define markets at the ATC-5 (molecule) level, following Duggan *et al.* (2016).[11] For our analysis, we focus on 115 markets.[12] The resulting dataset includes 1,780 unique drugs—

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

[10] IQVIA collects data from pharmacy chains and distributors. We adjust prices in two ways. First, we adjust for inflation using the health CPI from the National Institute of Statistics (*Instituto Nacional de Estadística*, INE). Second, we calculate prices per defined daily dose of the drug to normalize prices across presentations by their dosage.

[11] This choice is motivated by the fact that the policy we study was assigned at that level. Other studies define markets at the ATC-4 level (e.g., Dubois and Lasio 2018; Dubois *et al.* 2021), to account for the potential substitution across molecules. Our results for the market effects of the policy in Section 4 are robust to using either definition.

[12] We impose two criteria to construct our sample. We start with the 134 molecules exposed to the policy since 2010. We drop the molecules treated before that because, as noted earlier, it was not until 2009 that the technical norms for bioequivalence testing were developed. In addition, our IQVIA data start in 2010. Second, we drop 19 markets that feature sporadic sales within our period of study. We thus focus on markets that exist both before and after the policy change, so we can study its effects. In particular we drop all drugs within an ATC-4 for which there

defined by unique combinations of drug name, dosage, and presentation—and 101 different laboratories.

3.2 Descriptive Statistics for Quality Certification

The number of bioequivalence certifications increased substantially throughout our period of study, as shown by Figure 1-a. Certification started at a slow pace in early 2010, but increased steadily with a rapid uptake by mid-2012. By December 2017, there were 972 bioequivalent drugs, among which 631 were branded generics. The growth in the number of bioequivalent drugs relates to the staggered policy roll-out. Figure 1-b displays the number of bioequivalence approvals around the first deadline. Note that (i) bioequivalence approval was rare before mandated; and (ii) bioequivalence approval increased substantially after the policy.

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

3.3 Descriptive Statistics for Market Outcomes

Table 2 displays basic descriptive statistics. In terms of prices, the average innovator drug is more than twice as expensive as the average branded generic and more than seven times as expensive as the average unbranded generic. Relative prices across segments reveal large premiums for innovator and branded generics within molecules before the policy change, as displayed by Figure 2.[13] Three facts become apparent. First, price premiums for branded generics and innovators are on average positive across molecules. Second, price premiums are large, with innovators and branded generics having average premiums of 10 and 6 times relative to unbranded generics, respectively. Third, there is substantial heterogeneity in price premiums across molecules, with many molecules displaying price premiums of around 3 to 5 times, but also several other molecules displaying price premiums higher than 10 times.

is a market where the difference between the maximum and the minimum of sales is above the 95*th* percentile.

[13]We estimate premiums by estimating regressions of logged real prices per daily defined dose in 2010 and 2011 on indicators for innovator and branded generics separately for each market. The exponentiated coefficients on the indicators for drug segment measure average price premiums of each segment 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 periods.

Despite these large price differences, innovator drugs and branded generics hold substantial market shares. In 2010, branded generics were the largest segment with an average market share of 41%, followed by innovator drugs and unbranded generics with 34% and 25%, respectively. However, throughout our period of study, innovator drugs lost market share relative to generics, whereas branded and unbranded generics reached market shares of 45% and 38% by 2017. These increases coincide with an increase in the average market share of bioequivalent drugs from 0.03% in 2010 to 30% in 2017. These trends seem to be related: a linear regression of the market share of generic drugs on the share of generics with bioequivalence certification within a market shows a strong correlation between them, even after controlling for market and time fixed effects. In particular, an increase of 10 percentage points in the share of generic drugs that is bioequivalent is associated with a statistically significant increase of 2 percentage points in market share, as shown by Figure 3-a. We further examine this relationship in the remainder of the paper, estimating market effects in the next section and using a model in Section 6.

4 Effects of Quality Regulation on Market Outcomes

4.1 Event Study Evidence

We exploit the staggered roll-out of the regulation across markets to study its effects on market outcomes. We start by implementing an event study analysis with the goals of (i) assessing the assumption of parallel trends across groups of molecules treated by the policy at different moments, and (ii) providing visual evidence of the effects of quality regulation on market outcomes. To accommodate potentially heterogeneous treatment effects, we use the doubly-robust differences-in-differences methods in Callaway and Sant'Anna (2021) and Sant'Anna and Zhao (2020).[14] We use the first bioequivalence deadline as the policy event, and report results for a window of two years before and after that event.

The results from this analysis suggest that the policy had strong effects on market structure, as displayed by Figure 4. Our estimates show that the total number of drugs decreased, which seems to be driven by the exit of unbranded generics. The results also show a large increase (decrease) in the number of bioequivalent (non-bioequivalent) generics after the policy change. Similarly, Figure 5 displays results related to drug prices, sales and market shares.[15] We find

[14] This procedure computes a set of treatment effects t periods after the treatment for each group of markets sharing the same policy date, which is then averaged across groups. To avoid confounding treatment effect dynamics with compositional changes, we balance the sample to only include markets observed within our study window.

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

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

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

that prices increased after the policy change, particularly among unbranded generics. In terms of quantities, we find no clear evidence of effects on total sales, nor on market shares by segment. We provide a more detailed discussion of effects along all these margins in Section 4.2 below.

Overall, the event studies suggest that stronger quality regulation decreased the number of drugs in the market, and increased drug prices. In addition, these results show that trends in outcomes prior to the first bioequivalence deadline are well behaved, with most of the estimated coefficients being close to zero. This fact is reassuring for using the differential timing of bioequivalence requirements across markets as identifying variation in our setting.

4.2 Regression Analysis

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

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

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

For each market m, we define the *share of market under regulation* by month t as the average

period t and w_{it} denotes the share of sales of drug i in market m in period t.

of T_{imt} across the set of generic drugs in market m in the baseline period t_m^d, $\mathcal{G}_m$:

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

where $|\mathcal{G}_m|$ is the number of branded and unbranded generic drugs in market m in month t_m^d. We employ T_{mt} as a treatment variable in our analysis. T_{mt} is a weakly increasing function of time relative to the policy date t_m^d: it is equal to 0 before t_m^d and is equal to 1 after the last renewal date across drugs in $\mathcal{G}_m$. Figure 3-c 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 over time.[16] Finally, Figure 3-d shows that this variable is indeed correlated with the share of bioequivalent drugs in the market.

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

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

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

The key identifying assumption in (2) is that there are no unobserved market-specific trends that drive both the timing of the policy roll-out and the outcomes of interest. This assumption requires that policy deadlines and renewal dates were not set as a function of unobserved shocks not captured by market and time fixed effects. A violation of this assumption would happen if, for example, decrees and deadlines were set earlier for markets expected to have earlier price increases. Although we cannot directly test this assumption, 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 affected by the policy at different points in time. There is substantial heterogeneity across these groups in terms of the number of drugs, market size, and market outcomes, but no clear pattern related to the policy timing. Finally, the evidence of parallel pre-trends in the event study analysis supports our identifying assumption.

We focus on market size as a dimension for heterogeneous effects. This is motivated by the

[16] 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. These plots show how bioequivalence certification increases as bioequivalence requirements become relevant for a market. These examples are highlighted in Figure 3-c.

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

Effects on market structure. We start by estimating equation (2) for the number of drugs in the market.[17] Column 1 in Table 3-A shows that the policy decreased the overall number of drugs by 21%. 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.

The negative effects on the number of drugs are larger in small markets, mostly driven by a significant amount of exit by both branded and unbranded generics. We estimate that the number of drugs decreased by 30% in small markets and 13% in large markets, as shown by Table 3-B. Conversely, bioequivalence certification is higher in large markets.

Effects on drug prices. Price effects of quality regulation are theoretically ambiguous. On the one hand, a lower number of firms may reduce the intensity of price competition and lead to price increases. However, changes in perceived quality may reduce vertical differentiation and increase the intensity of price competition.

We find that average prices across all drugs increased by 13% as a result of the regulation, as shown in Table 4-A. Estimating price effects by drug segment, we find that most of the increase in average paid prices comes from increases among unbranded generics, while we find no statistically significant effects for innovators and branded generics.[18] As shown above, the decrease in the number of drugs is concentrated among small markets, and hence these are the markets where we expect to find the strongest price effects, which is confirmed by our analysis in Table 4-B. The increase in prices across all drugs is driven largely by an increase of 26% in small markets, which is concentrated among unbranded generics.

Decomposition of price effects. The effects on average prices combine drug-specific price changes, changes in shares, and changes in the composition of drugs in each market. To understand the drivers of price effects, we decompose the evolution of average prices into such components. We define $\hat{P}_{mt} \equiv \sum_{i \in \mathcal{I}_{mt}} w_{it} P_{it}$ as the share-weighted average of log prices in

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

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

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

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

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

$$\hat{P}_{mt} = \hat{P}_{m0} + \Delta P_{mt,C} + \Delta P_{mt,RW} + \Delta P_{mt,CS} + \Delta P_{mt,E} + \Delta P_{mt,X} \tag{3}$$

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

Table 4-C displays estimates of effects on each component of our price index, across and within drug segment. Overall, the results reveal that more than half of the price increases come from price changes among incumbents, which supports the interpretation that drug exit reduced the intensity of price competition. In addition, around a third of the increase is due to compositional changes, in particular to the entry of more expensive drugs.

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 the demand for generics. In this section, we estimate the effects of quality regulation on market shares by drug segment and on total sales. Table 5-A shows the results from this analysis. If anything, we find a marginally statistically significant decrease in the market share of branded generics, which translates into slight increases in the market share of the innovator and of unbranded generics. As expected, we find a significant increase in the market share of bioequivalent generics and a decrease for non-bioequivalent generics. In terms of heterogeneity, we find that the extent to which unbranded generics increase their market share as a result of quality regulation is greater in large markets—where adverse effects on the number of firms and on prices were weaker—although these results are not statistically significant.

Theoretically, quality regulation can increase or decrease the market share of the outside option, as a result of the interplay between changes in market structure, price effects, and (perceived) quality. We proceed to estimate the effects of quality regulation on sales volume. As shown by column 6 in Table 5, we do not find statistically significant effects of the regulation on total drug sales.

4.3 Summary of Descriptive Evidence

Stronger quality regulation may have reduced vertical differentiation, increased willingness to pay for generics, and enhanced price competition. However, one interpretation of our estimates is that these positive effects were at least partially overturned by the negative effects of decreased competition due to drug exit. Most of the adverse effects of stronger regulation in terms of drug exit and higher prices are concentrated among small markets. This pattern suggests that drugs exit when the certification cost is large relative to the profitability of the market.[19]

While lower variety and higher prices often suggest welfare decreases, that implication is not immediate in this context. If the distribution of drug quality improved due to the regulation, then consumers may be better off despite lower variety and higher prices. The model we develop and estimate in Section 6 allows us to quantify the welfare effects of quality regulation, to unpack its equilibrium effects, and to study alternative policy designs.

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

5 Evidence on Perceived Quality from Consumer Surveys

Our findings so far show that quality regulation had somewhat unexpected consequences. If anything, the price increases that we estimate suggest that its adverse competitive effects through drug exit more than compensated those from reductions in vertical differentiation. The extent to which quality regulation may affect vertical differentiation depends not only on objective quality metrics but also on how consumers perceive quality. To shed light on potential perceived quality differences and guide our model assumptions, we administer a consumer survey that focuses on aspects of purchase behavior, including attitudes towards generics and knowledge about bioequivalence.

We conducted in-person surveys to frequent consumers recruited outside pharmacies. We focused on Atorvastatin, a common anti-cholesterol drug. We asked consumers for their quality 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, see Appendix B. We surveyed 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.3 provides summary statistics for the main variables in the survey.

Consumers display substantial variation in perceived drug quality. We collect data on perceived quality on a 1-7 scale. We define the perceived quality premium as the difference between the perceived quality of the innovator drug and another drug. Figure 6 displays the distribution of perceived quality premiums. We find that consumers perceive that innovator drugs are of higher quality than branded generics, and that the latter are of higher quality than unbranded generics. Moreover, consumers perceive that bioequivalent drugs are of higher quality than non-bioequivalent drugs. Consumers thus attribute a quality premium to bioequivalence, but not large enough to close the innovator perceived quality premium. This pattern suggests there are gaps in perceived quality that limit the ability of generics to compete. This pattern relates to research on consumer aversion to generics (e.g., Bronnenberg *et al.*, 2015), and motivates allowing for frictions in perceived quality in our model.

6 Empirical Model of Entry, Certification and Demand

In this section, we develop and estimate an equilibrium model of the market. With this model, we aim at understanding the mechanisms driving the effects we documented in Section 4. In particular, we are interested in the relative importance of compliance costs and low baseline quality in inducing exit; and the extent to which price increases can be attributed to less competition and/or to increased willingness to pay for generics. In addition, we are interested

in measuring welfare effects and studying whether the adverse effects from reduced variety and higher prices were compensated by quality assurance and decreased asymmetric information. Finally, we are interested in quantifying the effects of counterfactual policy designs.

6.1 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 $\psi_j \in \{\psi^L, \psi^H\}$. 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.

Timing. The model has two stages. In the first stage, potential entrants decide whether to enter by comparing expected profits to sunk entry costs. At this stage, all relevant characteristics of demand and costs of potential entrants are observed up to quality and idiosyncratic shocks to demand, marginal cost and profits. Quality and profit shocks are private information of each firm at the entry stage. Firm entry choices determine the market structure. Demand and marginal cost shocks are realized after entry choices. In the second stage, prices are determined in a Bertrand-Nash equilibrium, and demand is realized.

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

$$u_{ijmt}^k = \frac{\alpha}{\varphi_{mt}} \ln y_{it} - \alpha \ln p_{jmt} + v_{jmt}^k + x'_{jmt}\beta + \zeta_{imt}^k + (1-\sigma)\epsilon_{ijmt} \tag{4}$$

where y_{it} is the income of the consumer, p_{jmt} is the price of the drug, v_{jmt}^k is perceived drug quality, 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). The functional form in income and price implies that the consumer allocates a constant income share φ_{mt} to the market, which is spent on a single preferred alternative. This is a special case of the discrete-continuous choice framework of Hanemann (1984), and is described as the constant expenditure model by Bjornerstedt and Verboven (2016). We provide more details in Appendix C.1. This specification allows for differences in drug purchases between consumers with different incomes, which is realistic in the Chilean setting, where consumers pay close-to-full price of drugs in the retail market.[20]

[20] In addition, a log price specification fits our data better, due to the large heterogeneity in prices across markets. Related work has also adopted this specification for the same reasons (Dubois *et al.*, 2021).

Note that the additive utility from income does not vary across alternatives, and therefore does not affect choice behavior, but matters for welfare evaluation as we discuss below.

A key object of interest is perceived quality v^k_{jmt}. We consider two frictions that generate a gap between the perceived quality of generics and that of the innovator. First, there is asymmetric information regarding the quality of generics. Consumers cannot discern the quality of any given drug j, but base their assessment on its segment and whether it has certified bioequivalence or not, as denoted by the indicator b_{jmt}. We write the expected quality of generics as $\mathrm{E}[\psi_j \,|\, k, \mathrm{b}_{jmt}]$. Second, consumers may display aversion against generics, even if a generic is bioequivalent. This aversion could come from several microfoundations, including detailing, differences in side effects, lack of information, biased beliefs over quality, among others. We do not attempt to distinguish between these sources, and in our welfare analysis we consider different scenarios regarding whether aversion is welfare relevant. We define $\tau^k_m(\mathrm{b}_{jmt})$ as the magnitude of generic aversion, which depends on the drug segment and certification status. Letting μ^I_m be the valuation for the innovator drug quality, perceived valuation is:

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

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

Consumers have rational expectations about ψ_j, and bioequivalence is a certain signal of high quality. The expected quality of drug j given its segment and certification status is then:

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

such 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. For generics without bioequivalence approval, their expected quality is equal to the baseline share of high-quality drugs, so that $\mathrm{E}[\psi_j \,|\, k \in \{B, U\}, \mathrm{b}_{jmt} = 0] = \pi^k_H$.[21]

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

$$\tau^k_m(\mathrm{b}_{jmt}) = \tau^k_{m0}(1 - \mathrm{b}_{jmt}) + \tau^k_{m1}\mathrm{b}_{jmt}$$

[21] This assumption rules out that consumers update their beliefs about drug quality based on bioequivalence certification by other drugs. This can be viewed as assuming that expectations π^k_H correspond to the share of high-quality drugs in a large set from which drugs in k are drawn. This assumption rules out that the timing of bioequivalence certification is informative for consumers, e.g., an equilibrium where high-quality drugs are more likely to obtain their certification early.

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

Under this structure, perceived quality depends only on the segment and bioequivalence approval of a drug j. Therefore, we can define $v^k_{jmt} = v^k_{m0}(1 - \mathrm{b}_{jmt}) + v^k_{m1}\mathrm{b}_{jmt}$. The we get, for example, that $v^B_{m0} = \mu^I_m(\pi^B - \tau^B_{m0})$ is the perceived quality valuation of branded generics in market m without bioequivalence approval, and $v^U_{m1} = \mu^I_m(1 - \tau^U_{m1})$ is the perceived quality valuation of unbranded generics in market m with bioequivalence approval.

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

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

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

where $q_j(p, x; \mathcal{J})$ is the demand for firm j given prices p and attributes x of all firms in $\mathcal{J}$. If the firm enters, it also gets an idiosyncratic profit shock ε^1_j, whereas if it does not enter, it gets an idiosyncratic profit shock ε^0_j 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 profit shocks $(\varepsilon^1_j, \varepsilon^0_j)$ and quality ψ_j, while their realizations are private information.

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

6.2 Equilibrium

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

and certification costs for new entrants, and net of certification costs for incumbent firms.

Because of private information, firm j does not know the realized market structure $\mathcal{J}$ when considering to enter the market. Let $\mathcal{M}$ be the set of potential market structures and $\mathcal{J}_m$ be an element of $\mathcal{M}$. Then, the expected profits net of fixed costs χ_j that include entry and possibly certification costs are:

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

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. This probability $P_j^M(\mathcal{J}_m;\phi)$ takes the form:

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

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

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

Equilibrium without quality 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 the vector of equilibrium entry probabilities for all potential entrants, which induces probability $P^M(\mathcal{J};\phi^{NQ})$ in equation (5). Then, expected total profits for firm j are:

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

which implies entry probabilities:

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

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 changes in two dimensions when considering the case with quality certification. First, entry costs change because of certification costs. In particular, innovators only incur a fixed cost to enter and thus

$\chi_j = F_j$ for $k_j = I$. In contrast, branded and unbranded generics incur both fixed and certification costs to enter and thus $\chi_j = F_j + \kappa_j$ for $k_j \in \{B, U\}$. Second, entry probabilities change due to the selection of low-quality drugs out of the market. We define entry probabilities under quality regulation as $\phi_{j|L}$ and $\phi_{j|H}$ for low- and high-quality drugs, respectively.

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

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

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:

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

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 first order conditions:

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

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

6.3 Estimation

Demand model. A key object of interest in the demand model is consumer valuation for drugs, v_{jmt}^k. We parametrize perceived quality as:

$$v_{jmt}^k = v_m^I - \Delta_m^k + \eta^k \mathrm{b}_{jmt} \tag{9}$$

where v_m^I, Δ_m^k and η^k are parameters to be estimated. This parametrization allows the value of innovators and generics to be market-specific through the terms v_m^I and $v_m^I - \Delta_m^k$, which are market-segment fixed effects. The parameter Δ_m^k captures the gap in valuation between the innovator and the generic in segment k before bioequivalence approval. Finally, the specification

allows for bioequivalence certification to reduce the gap between the valuation of generics and innovators by a segment-specific factor η^k.

These parameters map to the structural parameters as follows:

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

such that v_m^I is equal to the valuation of innovators, 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 the structural parameters are not identified from demand alone, though estimates of π_H^k from the supply side allow us to recover the remaining structural parameters.

Following Bjornerstedt and Verboven (2016), the discrete-continuous nested logit model in equation (4) implies the estimation equation:

$$\ln s_{jmt} - \ln s_{0mt} = v_m^I - \Delta_m^k + \eta^k \mathrm{b}_{jmt} - \alpha \ln p_{jmt} + x'_{jmt}\beta + \lambda_t + \sigma \ln s_{jmt|k} + \xi_{jmt} \tag{10}$$

where the shares are expenditure shares, rather than quantity shares as in the unit-demand models (Berry, 1994). The expenditure share of a drug j is given by $s_{jmt} \equiv p_{jmt}q_{jmt}/B_{mt}$, where B_{mt} is the total budget allocated by consumers to the market including the outside option.[22] The dependent variable is the difference between the log expenditure shares of drug j and the outside option, λ_t is a vector of time fixed effects, $s_{jmt|k}$ is the expenditure share of drug j among the drugs in segment k, and ξ_{jmt} is an unobserved demand shock.

We use yearly data on market shares, prices and drug attributes to estimate equation (10). For estimation, we define a drug as a combination of ATC-5, segment and producer. While each drug can be offered by a firm in multiple presentations, we treat all of them as a single product and we include the number of presentations as a product attribute, as in Dubois and Lasio (2018). Moreover, we measure prices p_{jmt} as the volume-weighted average price per daily defined dose of each drug, and b_{jmt} as the share of presentations with bioequivalence certification—we allow for heterogeneous effects of this variable on demand for branded and unbranded generics. Besides the number of presentations, drug attributes x_{jmt} include the share of presentations that have been 5 years or more in the market as a measure of product age. Finally, we include a full set of year fixed effects in λ_t to capture overall changes in the relative attractiveness of the outside option over time.[23]

[22] We do not directly observe the total market budget B_{mt}, which motivates a calibration exercise to recover it from the data and be able to calculate expenditure shares. The approach is based on Huang and Rojas (2013, 2014), and we describe it in detail in Appendix C.2. This method has also been adopted by previous work on pharmaceutical markets using similar data (Dubois and Lasio, 2018; Dubois *et al.*, 2021).

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

In terms of identification, the main concern is that pricing and certification choices are potentially driven by unobserved preference shocks ξ_{jt}, which is the error term in equation (10). Moreover, the conditional market share $s_{jt|k}$ is correlated with ξ_{jt} by construction. We employ instrumental variables to obtain consistent estimates of the model parameters and estimate the model using GMM. As an instrument for price, we use the price in Norway each year at the ATC-5 level as an instrument for prices. The Norwegian prices are regulated based on the market prices in a basket of 9 European countries (see Brekke *et al.*, 2015), and therefore capture overall changes in production costs within specific ATC-5s over time. As instruments for bioequivalence certification, we use the share of presentations that have passed the deadline for marketing license renewal after the certification deadline separately for branded and unbranded generics. We use the average age of competing drugs as an instrument for within-segment shares since this drives variation in the relative attractiveness of alternatives within segment.

Supply model. The objects of interest are 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 σ_ε. We parametrize these terms as follows:

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

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

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

To estimate the remaining parameters of the model, we exploit entry choices by firms in

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

We then proceed to simulate variable profits under every potential market structure, using estimates for preferences and marginal costs. We compute 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.[24] We assume that demand and cost shocks are realized after entry and certification choices are made. In particular, we assume that ξ_{jmt} and ω_{jmt} are iid conditional on the information sets held by firms when deciding about entry and certification. This assumption rules out selection into the market based on knowledge of those unobservables by potential entrants.

Finally, we exploit these inputs and the equilibrium conditions on entry probabilities to recover entry costs, certification costs, and the share of high-quality generic drugs among potential entrants.[25] Given the distributional assumption on ε^1_{jmt} and ε^0_{jmt}, the entry probabilities in equations (6) and (7) have the usual logit form. In particular, entry probabilities for environments without and with quality regulation respectively are:

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

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

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

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

in estimation. In particular, we use the latter to take into account 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. For each market, we include all the firms that ever participate in the market during our sample period, along with the 5 firms with the highest participation in each segment across markets at the national level.

In terms of identification, fixed costs are identified by entry choices and variable profits in absence of quality regulation. Given fixed costs, entry choices and variable profits under quality regulation identify certification costs. Knowledge of demand, marginal costs, and market structure is enough to compute variable profits. 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. While low-quality drugs must exit regardless of their profitability once quality regulation is introduced, certification costs only affect low-profitability firms. In other words, the share of high-quality generics 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.

6.4 Results

Demand model. We summarize our demand estimates in Table 6-A. Our estimates imply that price elasticities are substantially higher for generics than for innovators. Own price elasticities are on average 2.4 for innovators, 4.6 for branded generics, and 4.9 for unbranded generics. These elasticities are in line with recent estimates from the literature (e.g., Dubois and Lasio, 2018). Moreover, the estimated nesting parameter $\hat{\sigma} = 0.57$ indicates substantially stronger substitution within segment than across segments.[26]

There are large differences in perceived quality valuation between segments in absence of the regulation. By fitting our demand model at null and full compliance with quality regulation ($b_{jmt} = 0$ and $b_{jmt} = 1$), we obtain estimates of perceived quality valuation for before and after the regulation $\hat{v}^k_{m0}$ and $\hat{v}^k_{m1}$, which we compare across segments. Overall, the perceived valuation of innovator drugs is on average 0.28 and 1.3 times higher than that of branded and unbranded generics, such that branded generics were vertically closer to the innovator. Quality regulation had different effects across segments. Our estimate of η^B is not significantly different from zero and negative, such that, if anything, the valuation of branded generics decreased after the reform. In contrast, our estimate of η^U is large and positive, which implies that the

[26]Table 6-A also shows auxiliary linear regressions of the endogenous variables on the instruments separately. As expected, our instrument for prices based on prices in Norway is associated with higher drug prices in Chile. Moreover, and as expected, license renewals have strong effects on the extent of certification by drugs.

relative valuation of unbranded generics increased after the reform. In particular, the average valuation of innovator drugs under regulation is 0.94 times higher than that of unbranded generics, as shown by Figure 7-a. This result implies that quality regulation decreased vertical differentiation across generic segments, making competition among them more intense.

Supply model. Our estimates of the supply side parameters are displayed in Table 6-C. Our marginal cost estimates imply average markups of 22.1% for unbranded generics, 22% for branded generics, and 44% for innovators. We estimate an average entry cost of $364,676. Note that in our model, this cost does not have the interpretation of the cost of developing a drug, but rather of the cost of marketing it. Entry costs vary across segments, and branded generics incur entry costs 31% higher than unbranded generics, possibly reflecting investments that branded generics incur to establish their brand. In contrast, our estimates imply that innovator drugs face essentially no entry costs. This is somewhat mechanical since only one firm in each market is an innovator and they are almost always active in the market. Finally, we estimate a certification cost of $185,460 for drugs from developing countries—which is within the range of certification costs reported in Section 2.2—and of $6,640 for drugs from developed countries, as expected. To put these numbers in context, our estimates imply that the average generic gets annual variable profits of $50,800, and that 44% of generics had variable profits that were below the annualized certification cost before the policy change.

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 $\hat{\pi}_H^B = 0.96$ and $\hat{\pi}_U^B = 0.67$, 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 operates through changing the pool of drugs in the market and shifting perceived quality of generics upwards since the policy resolves asymmetric information about drug quality.

6.5 Disentangling Generic Aversion and Quality

Combining demand and supply side estimates, we 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. In particular, we map the estimates from the empirical model to the structural parameters using equation (9) and recover generic aversion before and after the regulation as:

$$\hat{\tau}_{m0}^k = \hat{\pi}_H^k - \frac{\hat{v}_{m0}^k}{\hat{v}_m^I}, \qquad \hat{\tau}_{m1}^k = 1 - \frac{\hat{v}_{m1}^k}{\hat{v}_m^I}$$

Our estimates imply substantial aversion against unbranded generics and, to some extent,

against branded generics. We find that before the policy change, generic aversion was on average $\overline{\hat{\tau}_0^U} = 0.99$ and $\overline{\hat{\tau}_0^B} = 0.24$ across markets. These estimates are qualitatively in line with a literature that shows that aversion to generics contributes to brand premiums (e.g., Bronnenberg *et al.*, 2015). The magnitude of generic aversion that we estimate is particularly large for unbranded generics. These large differences in perceived valuation are necessary to rationalize that innovator drugs and branded generics hold large market shares despite charging much higher prices than unbranded generics.

Quality regulation had asymmetric effects on generic aversion across segments. Aversion against unbranded generics decreased to $\overline{\hat{\tau}_1^U} = 0.95$. This lower aversion is explained by the fact that their perceived valuation increased 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. Conversely, aversion against branded generics increased after the policy, with $\overline{\hat{\tau}_1^B} = 0.38$. This result comes from finding no increase in the valuation for branded generics coupled with an increase in their average quality. This finding suggests that the policy revealed to consumers that branded generics are indeed generics and distinguished them more from innovator drugs relative to the baseline environment. This may be driven by the fact that all bioequivalent generics get a distinctive yellow label in their packages. This interpretation is consistent with the large baseline market share of branded generics in spite of their high relative prices.

Figure 7-a displays a decomposition of innovator perceived quality premiums. Around 13% of the increase in the relative perceived valuation of unbranded generics were due to resolving asymmetric information, whereas the remainder was due to decreases in generic aversion.These results are consistent with our survey evidence, which also points towards large baseline gaps in perceived quality, and a partial reduction in them due to the regulation.

6.6 Model Limitations

While our model captures several features that are key to the environment, it also has some limitations. First, we assume that drug quality is exogenous. This assumption limits the extent to which firms could react to quality regulation by investing in quality. In terms of timing, this assumption implies that regulation happens after production technology is set up. Although this is a reasonable assumption in the short run, the long-run effects of quality regulation may include endogenous responses along this margin or more broadly in terms of R&D by pharmaceutical companies. Second, we do not formally model the role of physicians in consumer decision-making. Given that we do not observe prescriptions in our data, we cannot disentangle such influence. Any misalignment between physicians and consumers as well as impediments to generic substitution will load on our estimates of generic aversion.

7 Counterfactual Analysis

In this section, we study the welfare consequences of quality regulation and consider counterfactual policy designs. Throughout these analyses, our outcomes of interest are the number of firms in the market, drug prices, segment market shares, consumer welfare, and firm profits.

When studying welfare in our context, there are two reasons to allow for a distinction between choice utility and experienced utility.[27] First, due to asymmetric information, choice utility v^k_{jmt} depends on expected quality $\mathrm{E}[\psi_j | k, \mathrm{b}_{jmt}]$. In contrast, experienced utility $\tilde{v}^k_{jmt}$ depends on true quality ψ_j. Second, some potential microfoundations for generic aversion imply that aversion should not be part of the welfare metric, e.g., biased beliefs about drug quality. To avoid taking a stance about the welfare-relevance of the different components of choice utility, we consider two different assumptions for $\tilde{v}^k_{jmt}$ when measuring welfare:

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

Under assumption A1, experienced utility is based on actual drug quality and the component of generic aversion that persists after quality regulation is in place, $\tau^k_m(1)$. This assumption is consistent with an environment in which the regulation removes all the welfare-irrelevant components of generic aversion. This view is similar to that in Bronnenberg *et al.* (2015), in that it implies that consumers become "experts" under the regulation. In contrast, assumption A2 is based on the view that there are no such differences between innovators and generics under quality certification, and thus rules out that $\tau^k_m(1)$ is welfare-relevant. We adopt the compensating variation as our measure of consumer welfare. See Appendix C.4 for details.

We calculate the welfare effect of counterfactual policies as:

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

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

To isolate the effects of quality regulation, we start by simulating equilibrium outcomes in absence of quality regulation. Taking the resulting market structure as a baseline, we simulate

[27] Bernheim and Rangel (2009) provides a general treatment of the distinction between choice and experienced utility for welfare analysis, and Grennan *et al.* (2021) applies a similar analysis in their analysis of the effects of physician payments on demand for drugs.

equilibrium outcomes in different policy environments, including the case without quality regulation. All our results compare outcomes under a given policy to outcomes without quality regulation, where all scenarios start from the common, unregulated baseline market structure. See Appendix C.5 for details.

7.1 Equilibrium Effects of Quality Regulation

Quality regulation potentially affects market outcomes through three channels. First, it changes the distribution of drug quality by mechanically removing low-quality drugs. Through this channel, the regulation resolves asymmetric information, increases the expected quality of generics, and thus the willingness to pay for them. 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 channels. Let an equilibrium outcome be summarized by $y = y(\underline{\psi}, \tau, \kappa)$, where $\underline{\psi}$ is the minimum quality standard. We decompose the effects of quality regulation on y as:

$$\Delta y = \underbrace{y(\psi^H, \tau_0, 0) - y(\psi^L, \tau_0, 0)}_{\substack{\Delta \text{ due to} \\ \text{minimum quality standard}}} + \underbrace{y(\psi^H, \tau_1, 0) - y(\psi^H, \tau_0, 0)}_{\substack{\Delta \text{ due to} \\ \text{changes in generic aversion}}} + \underbrace{y(\psi^H, \tau_1, \kappa) - y(\psi^H, \tau_1, 0)}_{\substack{\Delta \text{ due to} \\ \text{certification cost}}}$$

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 $\tau_{mt}^k = \tau_{m0}^k$, and certification costs are $\kappa = 0$. The results for this baseline environment are shown in Column 1 of Table 7. The simulated model matches the basic patterns documented in Section 3.3 in terms of prices, market shares, and market structure across segments.

In the first step, we isolate the effect of the quality standard. On the supply side, drugs with quality $\psi_j = \psi^L$ are forced to exit. On the demand side, we set $E[\psi_j] = \psi^H$ as asymmetric information is resolved, and consumers adjust their perceived quality accordingly. Columns 2 and 3 of Table 7 show the results. Imposing the quality standard removes low-quality branded and unbranded generics from the market and increases the demand for generics. These two forces induce entry of high-quality drugs, such that the net exit rate is lower than the baseline share of low-quality drugs. The increase in willingness to pay for generics induces price increases among generics. In this environment, the market is characterized by high-quality drugs, higher prices, and by a shift in demand towards unbranded generics. Overall, total welfare increases by between \$43 and \$70 million per year, depending on the welfare metric.

In the second step, we quantify the effects that the regulation has in terms of decreasing generic aversion. In particular, we set $\tau_{mt}^k = \tau_{m1}^k$ in the simulation. The results of this exercise are shown in columns 4 and 5 of Table 7. Setting generic aversion to its post-regulation level

makes unbranded generics more competitive and branded generics less competitive, which results in entry of the former and exit of the latter. In the same line, unbranded generics gain substantial market share and increase their prices. Overall, total welfare increases even more than under the quality standard alone.

Finally, in the third step, we introduce the certification cost κ at its estimated level. Columns 6 and 7 of Table 7 show these results. Adding certification costs reduces the number of both branded and unbranded generics in the market, and makes the negative effect of the policy on the total number of drugs in the market 46% larger. This decrease in competition leads to price increases in all segments and reduces the overall welfare gains from the regulation.

Overall, our model predicts reductions in the number of drugs for all segments, coupled with price increases among generic drugs. The magnitudes of these simulated effects are close to those in our descriptive evidence. The model also predicts increases in the market share of unbranded generics, driven by their increased perceived quality. Overall welfare increases by between $35 and $63 million per year as a result of the regulation, driven by benefits for consumers and reduced entry costs by firms. Hence, from a welfare perspective, the increase in drug quality more than compensates for the lower variety and higher prices associated with the adverse competitive effects of certification costs.[28]

7.2 The Role of Certification Costs

Our results from the previous section show that certification costs limit the welfare gains from quality regulation by inducing exit and price increases. In this section, we study whether lower certification costs could limit these unintended consequences. Columns 2 and 3 of Table 8-A show results for an environment in which certification costs are reduced by 50% through a subsidy. Compared to the baseline policy (in columns 6 and 7 of Table 7), equilibrium in this case features more firms in the market and lower prices. Furthermore, fully eliminating certification costs further limit drug exit and price increases, as shown by columns 4 and 5 of Table 8-A. In terms of welfare, consumers are better off in these environments, whereas the overall welfare effects of the policy are slightly lower than in the case with full certification costs, after accounting for a 20% cost of public funds.

The incidence of certification costs varies across markets. We study how the effects of quality regulation with and without certification costs vary between large and small markets, as defined

[28]Note that the exit rate due to the minimum quality standard alone is higher than the share of low-quality drugs for branded generics (15.6% as opposed to 4%), and lower than the share of low-quality drugs for unbranded generics (28.3% as opposed to 33%). Evaluating this policy without accounting for this margin would have led to incorrect conclusions about the distribution of drug quality in the market before the policy. These results underscore the importance of accounting for endogenous firm responses to regulation along the entry and exit margins, something that previous work has also pointed out (Fan, 2013; Wollmann, 2018).

by their position relative to median market size. Our results imply that quality certification when firms incur the full certification cost decreases the number of firms by 32.6% and 18.2% in small and large markets, respectively. When certification costs are fully subsidized, this negative effect on the total number of firms is 14.4 percentage points lower in small markets, as opposed to 4.9 percentage points in large markets. Similarly, the positive effect of quality regulation on average unbranded generic prices is 4.7 percentage points larger with certification costs than without them in small markets, as opposed to only 0.5 percentage point in large markets.[29] These patterns are consistent with our descriptive evidence and suggest that certification costs have more incidence in small markets, which may justify targeted subsidies.

7.3 Quality Disclosure

An alternative to minimum quality standards is quality disclosure. This policy involves delivering information about product quality to consumers while still allowing products below the quality standard to sell. To the extent that these products compete with high-quality products, keeping them in the market may reduce the adverse competitive effects of minimum quality standards, while still resolving asymmetric information. In this section, we study the equilibrium effects of quality disclosure. In particular, we implement the disclosure policy in our model by imposing that firms must pay the same certification cost κ as under a minimum quality standard in order to verify their quality, but can stay in the market even if their drug is not bioequivalent.[30] After a firm tests for bioequivalence, its quality ψ_j becomes observable.

We find that quality disclosure performs better than minimum quality standards in terms of market outcomes, as shown by Table 8-B. Because low-quality firms are allowed to sell under quality disclosure, the number of firms falls less than under minimum quality standards (in columns 6 and 7 of Table 7). Interestingly, the number of unbranded generics decreases by only 3.5%, which comes from more entry of high-quality generics and less exit of low-quality generics than under minimum quality standards—low-quality incumbents are not forced to exit and must pay only the certification cost but not the entry cost to remain in the market, which gives them an advantage relative to potential entrants and limits turnover. The fact that quality disclosure has a weaker effect on market structure leads to weaker price increases among generic drugs than under minimum quality standards. While most consumers turn towards high-quality drugs, some still purchase low-quality drugs under quality disclosure.

[29] To provide more detail on this comparison, Figures A.3-a and A.3-b show the variation in effects of quality regulation with and without certification costs, for all markets. While quality regulation decreases the number of firms and increases unbranded generic prices in most markets, these effects are mostly smaller when firms do not pay certification costs, and that difference is often larger for smaller markets.

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

Quality disclosure has a slightly stronger effect on consumer welfare than minimum quality standards, due to a combination of weaker adverse competitive effects and a substantial increase in the average quality of purchased drugs. However, minimum quality standards dominate in terms of total welfare. By not allowing the low-quality drugs to sell, this policy reduces the total fixed and certification costs incurred, which translates into higher overall welfare despite leading to lower competition. These results illustrate that the choice between quality standards and quality disclosure involves a trade-off between competition and average quality, and their relative desirability will depend on the importance that policymakers place on them.

7.4 The Role of Generic Aversion

Aversion towards generics increases vertical differentiation and limits the extent to which these drugs effectively compete against innovator drugs. In our setting, we find substantial aversion against unbranded generics before quality regulation. We also find that the regulation affects generic aversion. In this section, we study how the equilibrium effects of quality regulation depend on the extent to which it affects aversion. In particular, we simulate the effects of the regulation for a range of post-reform aversion levels defined as $\tilde{\tau}^k_{m1}(s) = (1-s) \cdot \hat{\tau}^k_{m0} + s \cdot 0$, such that s is the share of the aversion towards generics that is corrected by the policy.

We find that the extent to which quality regulation affects aversion against generics is an important determinant of its equilibrium effects. Columns 8 and 9 in Table 8-C show results for a case in which the policy has no effect on generic aversion. In this case, quality regulation has a limited effect on vertical differentiation and has mostly adverse competitive effects. Quality regulation has stronger effects in terms of reducing vertical differentiation when it decreases generic aversion more, as shown to the right of Table 8-C. As aversion to unbranded generics decreases, the intensity of competition towards innovators and branded generics increases. This is reflected in more exit by branded generics, stronger price decreases by innovator drugs, and less exit and stronger price increases by unbranded generics.

The welfare effects of quality regulation depend on how it affects consumer quality perceptions, and whether choice and experienced utility become more aligned as a result. Small decreases in generic aversion improve consumer welfare. However, when the effects on generic aversion are large, competition becomes intense enough that the adverse effects of drug exit more than compensate for the benefits of better consumer choices. This leads to an inverse U-shaped pattern for the effects of the regulation on consumer welfare. In terms of overall welfare, we find that when quality regulation has a stronger effect on generic aversion, its welfare effect is smaller. This pattern is partly driven by a substantial decrease in industry profits. The difference in welfare gains from the policy across scenarios for s ranges between \$10 and \$53 million per year. These results suggest that complementary strategies that close perceived

quality gaps across segments may influence the effectiveness of quality regulation.

7.5 Comparison of Counterfactual Policies

Our framework allows for comparing different designs of quality regulation. Figure 8 compares some of the policies we study in terms of their effects on the number and price of unbranded generics, and consumer and total welfare. Note first that a simple quality standard has the strongest adverse effects on the number of unbranded generics and on unbranded generic prices. That partly explains why the other policies deliver similar or larger consumer welfare increases. Still, as drug exit saves on certification and fixed costs, the simple quality standard dominates the alternative policies in terms of overall welfare.[31] In addition, quality disclosure is the policy for which the number of unbranded generics decreases the least. While this helps limit the price effects of the regulation, the policy is dominated in terms of welfare because some low-quality drugs remain in the market which requires sinking additional fixed and certification costs. These results suggest that quality standards induce stronger and better selection of products into the market. Finally, note that all these designs of quality regulation increase welfare, as their main impact is to improve the quality of the set of drugs offered in the market.

8 Conclusion

Quality regulation in markets with asymmetric information may ensure product quality, change consumer perceptions of product quality, and foster price competition by reducing vertical differentiation. However, costly compliance may also have unintended consequences on the market structure by inducing product exit and thus harming price competition. We study this trade-off in the context of pharmaceutical markets, where issues of quality and asymmetric information are of primary concern. Specifically, we leverage the introduction of bioequivalence requirements in Chile, where pharmaceutical markets are characterized by low generic penetration despite large price differences relative to branded substitutes. Contrary to the motivation of reducing prices through reduced vertical differentiation and increased competition, we find that quality regulation induced drug exit and price increases, particularly in small markets.

We develop and estimate an equilibrium model to quantify the contribution of the different mechanisms at play and evaluate welfare under different policy designs. Using the model, we decompose the overall effect of the regulation into the effects of the three main mechanisms:

[31] This result is partly driven by the strong substitution patterns we estimate within drug segments. When products are more substitutable, it is more likely that the market will feature inefficiently too much entry (Mankiw and Whinston, 1986). In an environment with less within-segment substitutability, minimum quality standards would be less likely to dominate quality disclosure in terms of overall welfare effects.

changes in the composition of quality in the market, changes in aversion against generics, and changes in market structure due to certification costs. We find that the main driver of welfare effects is the quality standard itself, which resolves asymmetric information and improves the composition of quality. Overall, the model predicts that quality regulation induced drug exit and higher prices—similar to our descriptive evidence—but also shows that the increase in average drug quality was high enough to lead to an increase in welfare.

Our analysis provides lessons for the design of quality regulation. On the demand side, this regulation is more likely to be welfare enhancing in environments in which baseline quality is low. Moreover, the extent to which quality regulation affects consumer perceptions about quality plays an important role in terms of shaping the effects of the policy. Hence, knowledge about the distribution of product quality in the market and consumer perceptions about quality should be key inputs in the discussion and design of these policies. On the supply side, compliance costs are a key driver of the unintended consequences of quality regulation. Subsidizing certification costs is a powerful tool to counteract these adverse competitive effects, particularly in small markets. Finally, we also show that quality regulation in the form of minimum quality standards induces a stronger and better selection of products into the market than quality disclosure, which in our context translates into higher welfare. While our quantitative results are specific to the context we study, the same economic forces are likely to be present in other contexts. By capturing these features, our model provides a useful framework to study the design of quality regulation in other settings.

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

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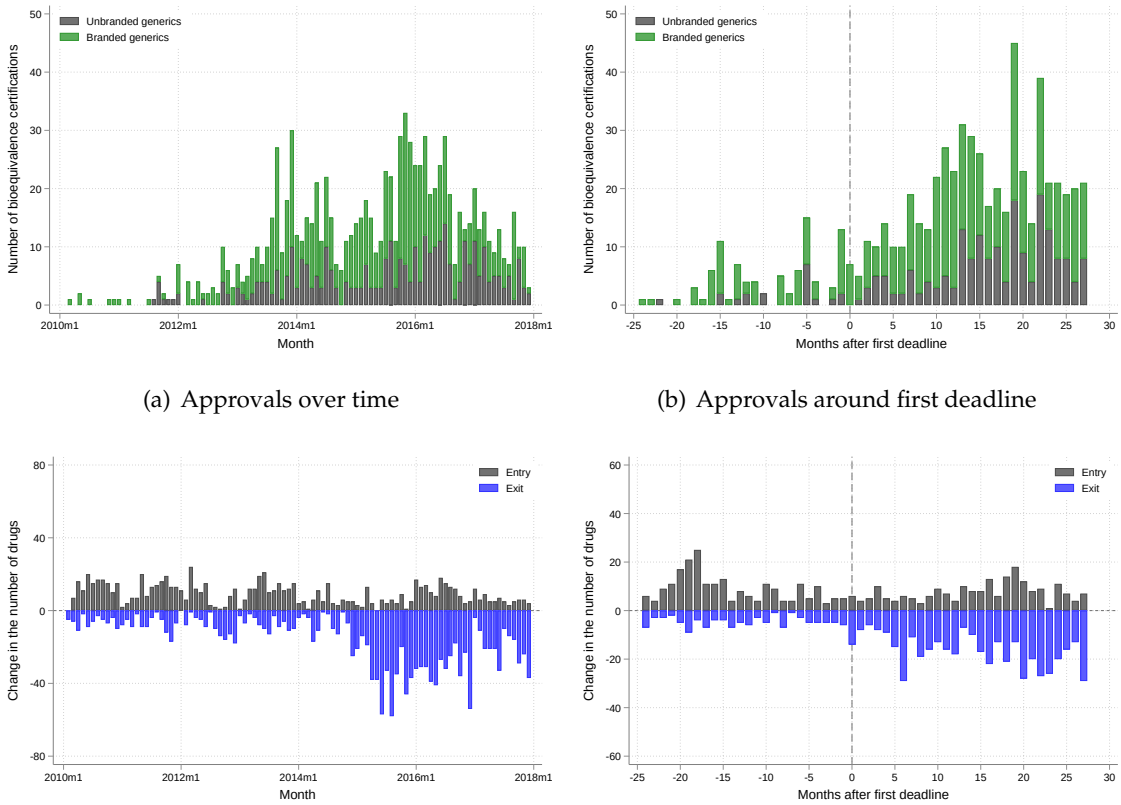
Figure 1: Quality certification, entry, and exit around policy events



(a) Approvals over time

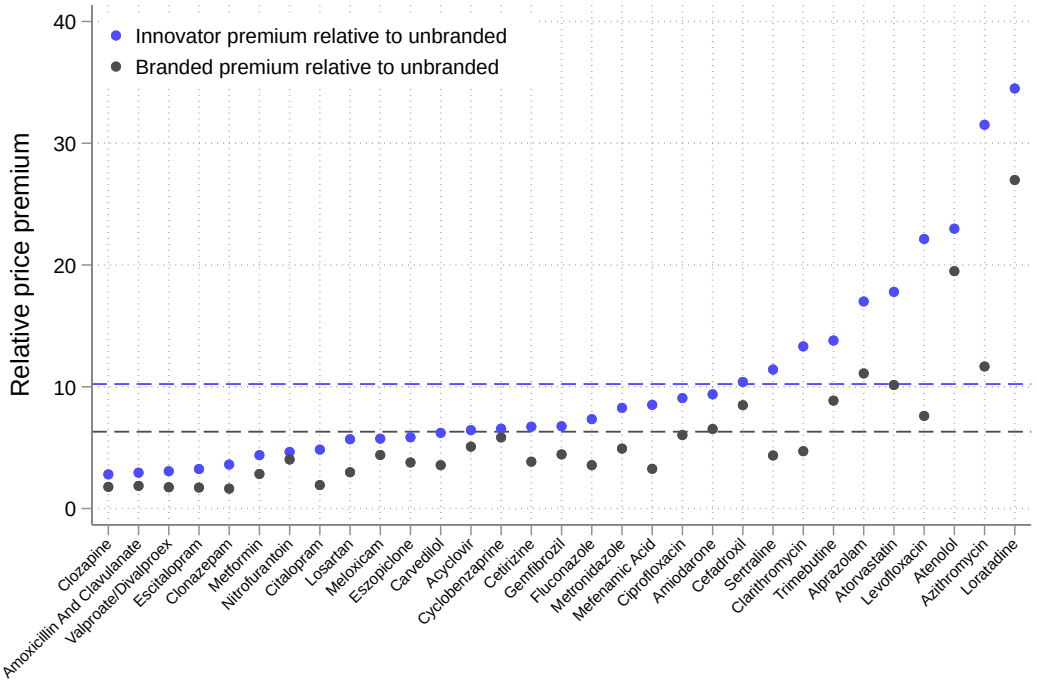
(b) Approvals around first deadline

(c) Entry and exit over time

(d) Entry and exit around first deadline

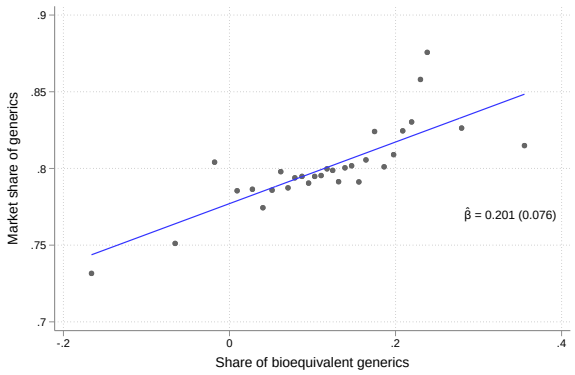
Notes: The top row displays the trends in quality certification. Panel (a) displays the evolution of the number of drugs with bioequivalence approval over time, split by unbranded generics (gray) and branded generics (green). Panel (b) displays the approvals around the first bioequivalence deadline.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

Figure 2: Innovator drugs price premiums relative to unbranded generics

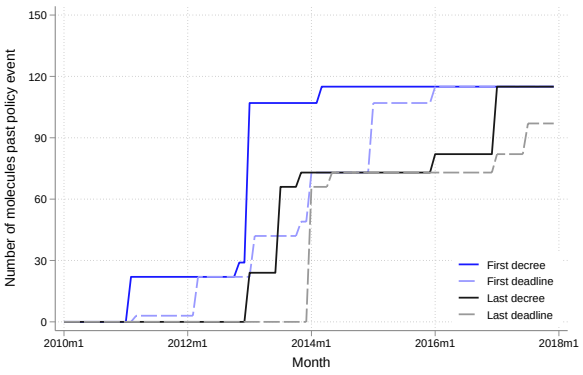


Notes: This figure displays the estimated price premium for innovator and branded generic drugs relative to unbranded generic drugs. Each dot in the figure corresponds to an exponentiated coefficient from a regression of log prices on innovator and branded drug dummies, estimated separately for each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

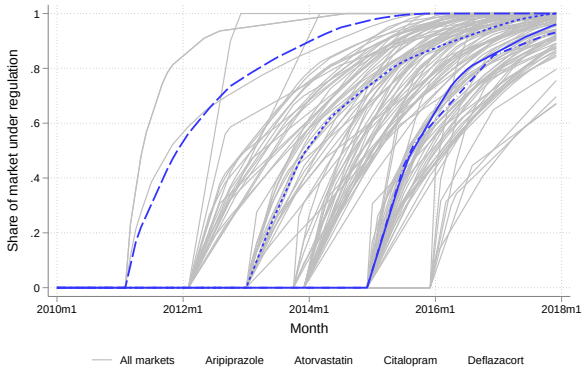
Figure 3: Evolution of quality regulation



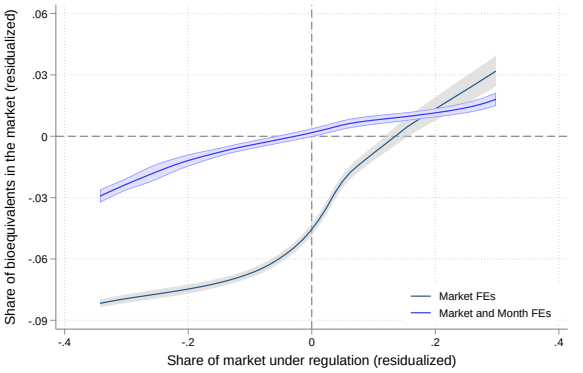
(a) Bioequivalent generics and generic market share



(b) Timing of bioequivalence decrees and deadlines



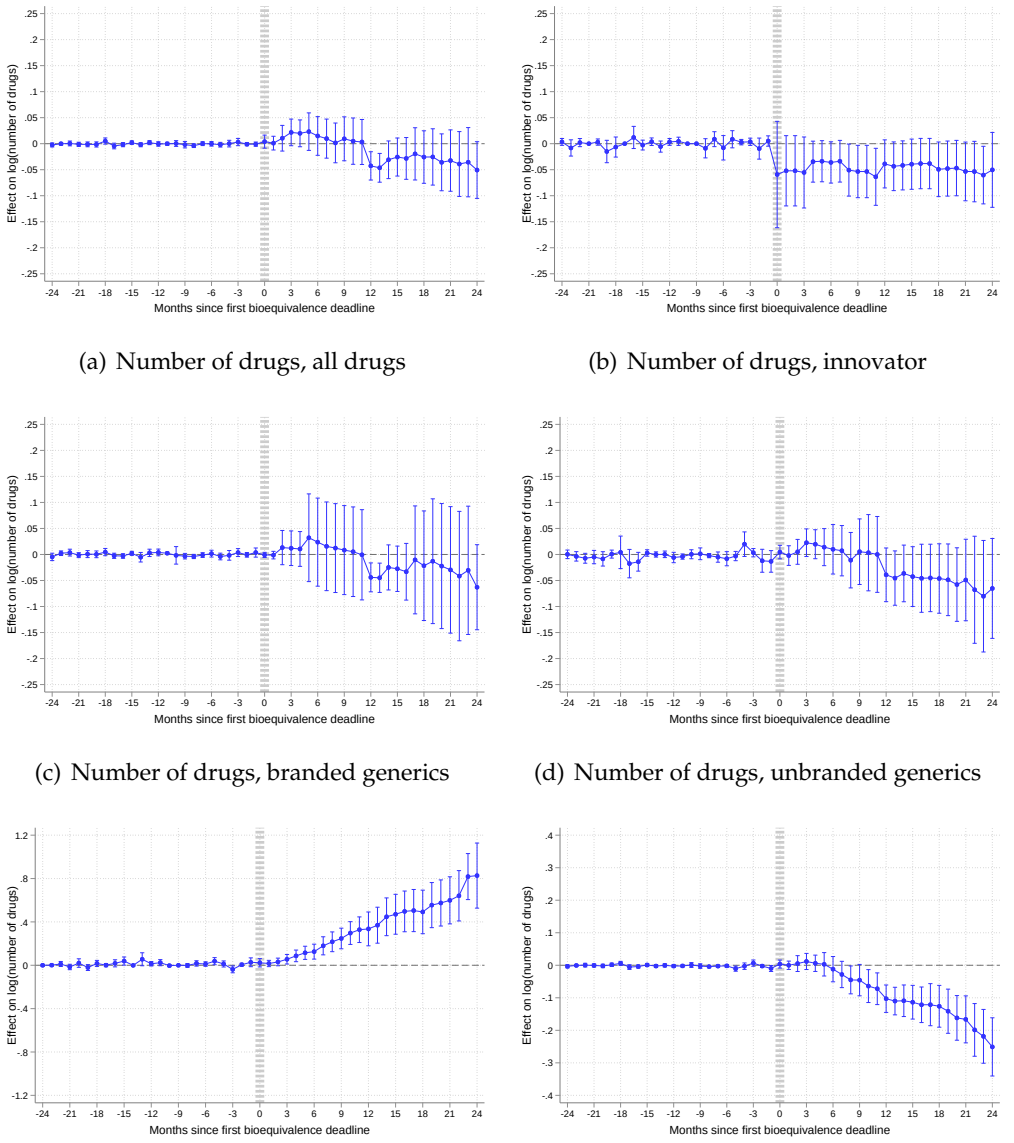
(c) Evolution of quality regulation by market



(d) Quality regulation and share of bioequivalent drugs

Notes: Panel (a) displays a binned scatter plot of the market share of generics on the share of bioequivalent generics in a given market, controlling for market and month fixed effects. Panel (b) 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 (c) displays the evolution over time of the treatment variable defined in equation (1) 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 (d) displays the non-parametric relationship between the residualized policy intensity variable and the share of bioequivalent drugs in the market, controlling for market fixed effects (gray) and market and month fixed effects (blue) over the range of variation of the latter. The bottom and top centiles of the data are not included in the plot.

Figure 4: Event study results for market structure



(a) Number of drugs, all drugs

(b) Number of drugs, innovator

(c) Number of drugs, branded generics

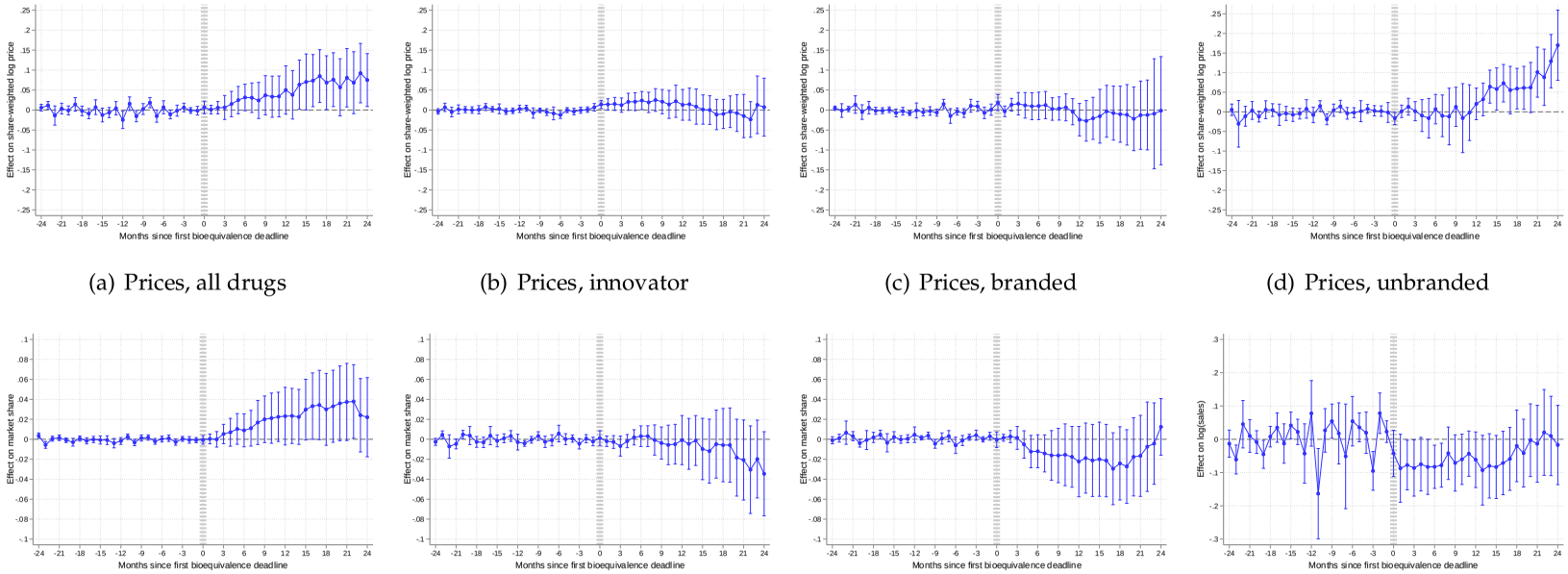
(d) Number of drugs, unbranded generics

(e) Number of drugs, bioequivalent generics

(f) Number of drugs, non-bioequivalent generics

Notes: This figure displays the results from event study specifications described in Section 4.1, 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. Each panel shows results for the number of drugs in a particular set.

Figure 5: Event study results for prices, sales and market shares

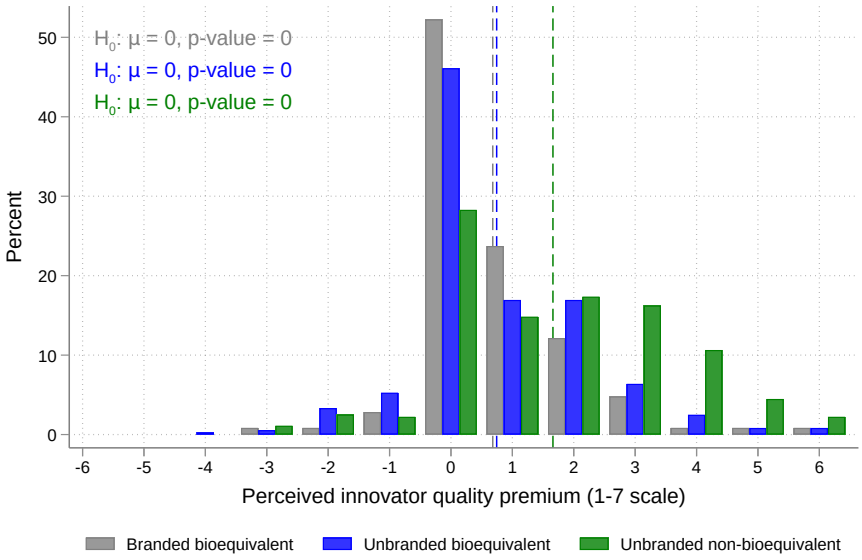


(a) Prices, all drugs (b) Prices, innovator (c) Prices, branded (d) Prices, unbranded

(e) Market share, innovator (f) Market share, branded generics (g) Market share, unbranded generics (h) Total sales

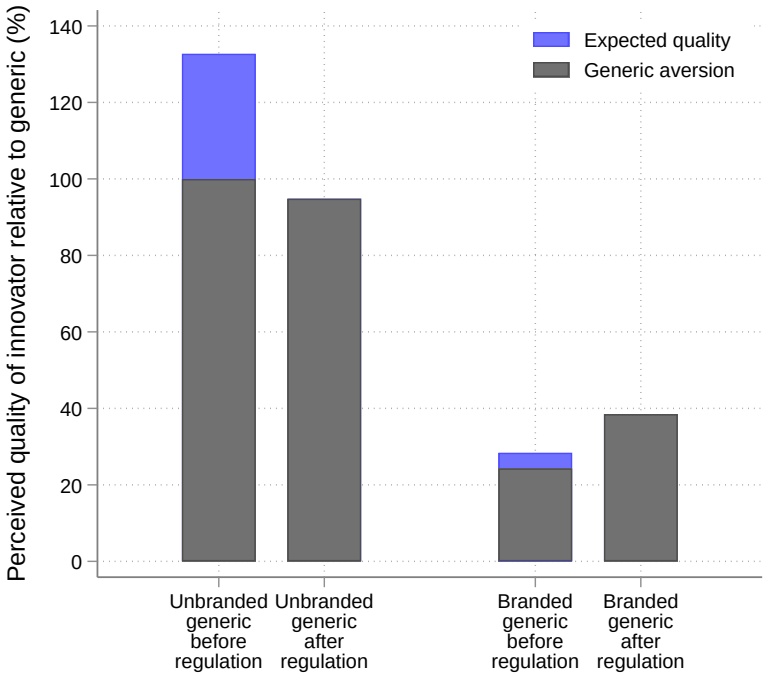
Notes: This figure displays the results from event study specifications described in Section 4.1, using the first bioequivalence deadline as policy event. Dots indicate point estimates and lines indicate 95% confidence intervals based on standard errors clustered at the market level. Coefficients are 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 the results for drug prices, and the second row displays the results for market shares by segment and total sales.

Figure 6: Survey results



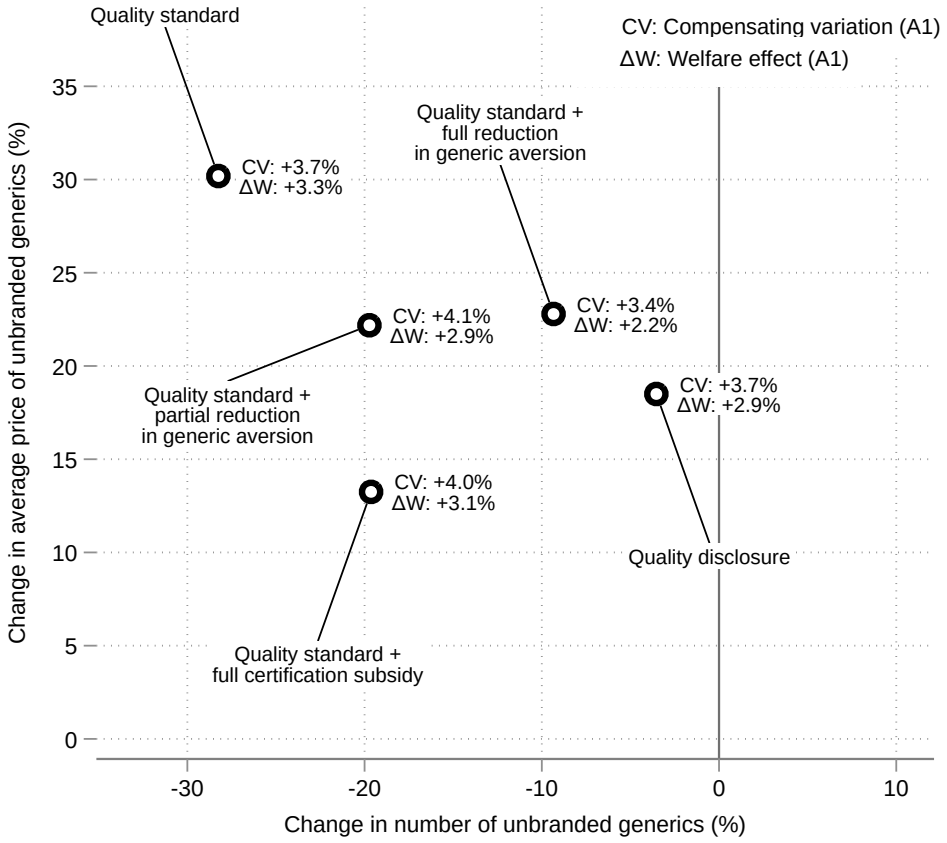
Notes: This figure displays the distribution of perceived quality premiums for different drug segments relative to the innovator drug. The premium is calculated as the difference between the perceived quality of the innovator drug and the perceived quality for each drug segment, where the premium is recorded in a 1-7 scale. Dashed lines indicate the average for each drug segment in the figure.

Figure 7: Perceived quality gaps and quality regulation



Notes: This figure displays the perceived valuation of unbranded and branded generics relative to innovator drugs. Each bar is decomposed into the component of perceived valuation that relates to generic aversion (gray) and to drug quality (blue).

Figure 8: Comparison of counterfactual policies



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

Table 1: Timing of reform to quality regulation

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

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

Table 2: Descriptive statistics for IQVIA data

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

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

Table 3: 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
A - Average effects								
Regulation	-0.23***	-0.04	-0.22***	0.47***	-0.36***	-0.29***	0.58***	-0.43***
	(0.04)	(0.03)	(0.04)	(0.17)	(0.07)	(0.09)	(0.13)	(0.09)
R^2	0.94	0.93	0.96	0.71	0.94	0.89	0.65	0.89
B - Heterogeneity by market size								
Regulation × Low revenue	-0.36***	-0.13**	-0.31***	0.06	-0.33***	-0.47***	0.24*	-0.44***
	(0.06)	(0.06)	(0.07)	(0.18)	(0.09)	(0.11)	(0.13)	(0.11)
Regulation × High revenue	-0.14***	0.02	-0.16***	0.77***	-0.38***	-0.16	0.83***	-0.43***
	(0.05)	(0.04)	(0.05)	(0.19)	(0.07)	(0.10)	(0.15)	(0.09)
R^2	0.94	0.93	0.96	0.73	0.94	0.89	0.68	0.89
Pre-regulation average	22.06	2.40	12.32	0.09	12.23	7.34	0.01	7.33
Observations	11,040	11,040	11,040	11,040	11,040	11,040	11,040	11,040
Market FE	Y	Y	Y	Y	Y	Y	Y	Y
Month FE	Y	Y	Y	Y	Y	Y	Y	Y

Notes: Each column in this table is a 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 total revenue in the market in 2010 relative to the median across markets in that year. Clustered standard errors in parentheses. ***p<0.01, **p<0.05, *p<0.1.

Table 4: Effects of quality regulation on drug prices

	(1)	(2)	(3)	(4)
	Dep. var.: Drug Price Index ($\hat{P}_{mt}$)			
	All drugs	Innovator	Branded generics	Unbranded generics
A - Average effects				
Regulation	0.124**	0.039	-0.008	0.164***
	(0.054)	(0.031)	(0.046)	(0.055)
R^2	0.99	0.99	0.99	0.99
B - Heterogeneity by market size				
Regulation × Low revenue	0.229***	0.052	0.001	0.158**
	(0.082)	(0.042)	(0.053)	(0.072)
Regulation × High revenue	0.048	0.033	-0.013	0.169**
	(0.057)	(0.034)	(0.052)	(0.073)
R^2	0.99	0.99	0.99	0.99
C - Decomposition of price effects				
Dep. var.: Contribution of changes in prices ($\hat{P}_{PC}$)	0.069**	0.015	0.002	0.152***
	(0.028)	(0.025)	(0.024)	(0.056)
R^2	0.63	0.70	0.67	0.65
Dep. var.: Contribution of changes in shares ($\hat{P}_{RW}$)	0.026	0.048*	-0.002	0.010
	(0.035)	(0.025)	(0.018)	(0.011)
R^2	0.53	0.65	0.53	0.49
Dep. var.: Contribution of correlation between shares and prices ($\hat{P}_{CS}$)	-0.000	-0.005	-0.046	0.008
	(0.012)	(0.016)	(0.034)	(0.010)
R^2	0.49	0.63	0.48	0.29
Dep. var.: Contribution of drug entry ($\hat{P}_{E}$)	0.034**	0.001	0.041**	-0.007
	(0.016)	(0.014)	(0.020)	(0.007)
R^2	0.52	0.61	0.61	0.44
Dep. var.: Contribution of drug exit ($\hat{P}_{X}$)	-0.005*	-0.019**	-0.004	0.001
	(0.003)	(0.008)	(0.006)	(0.001)
R^2	0.38	0.28	0.31	0.06
Observations	11,040	8,141	8,707	5,238
Market FE	Y	Y	Y	Y
Month-Segment FE	Y	Y	Y	Y

Notes: 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 (3). Each coefficient in Panel C comes from a separate regression of the component indicated in the left for the drug segment indicated in the top row on the policy roll-out variable constructed using the first decree deadline. Clustered standard errors in parentheses. ***p<0.01, **p<0.05, *p<0.1.

Table 5: Effects of quality regulation on market shares and sales

	(1)	(2)	(3)	(4)	(5)	(6)
	Market shares					log(Sales)
	Innovator	Branded generic			Unbranded	All
		All	BE	Non-BE	generic	
A - Average effects						
Regulation	0.09**	-0.07*	0.05	-0.12***	-0.02	-0.04
	(0.04)	(0.04)	(0.04)	(0.05)	(0.03)	(0.08)
R^2	0.86	0.94	0.53	0.87	0.95	0.98
B - Heterogeneity by market size						
Regulation × Low revenue	0.13***	-0.06	0.01	-0.07	-0.08	-0.08
	(0.05)	(0.03)	(0.05)	(0.05)	(0.05)	(0.13)
Regulation × High revenue	0.05	-0.08*	0.10*	-0.18***	0.03	(0.00)
	(0.05)	(0.05)	(0.05)	(0.06)	(0.03)	(0.09)
R^2	0.86	0.94	0.54	0.88	0.95	0.98
Pre-regulation average	0.21	0.44	0.00	0.44	0.35	12.21
Observations	11,040	11,040	11,040	11,040	11,040	11,040
Market FE	Y	Y	Y	Y	Y	Y
Month FE	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. Column 6 displays a regression of total log sales 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 total revenue in the market in 2010 relative to the median across markets in that year. Clustered standard errors in parentheses. ***p<0.01, **p<0.05, *p<0.1.

Table 6: Model estimates

	(1)	(2)	(3)	(4)	(5)
A - Demand side estimates		Linear first stage regressions			
	GMM	$\ln s_{jmt\|k}$	$\ln p_{jmt}$	b^{B}_{jmt}	b^{U}_{jmt}
log Price (α)	1.85				
	(0.71)				
Bio, branded (η^{B})	-0.33				
	(0.33)				
Bio, unbranded (η^{U})	1.23				
	(0.50)				
Nesting parameter (σ)	0.57				
	(0.10)				
log Price, Norway		0.01	0.19	-0.16	0.02
		(0.18)	(0.03)	(0.02)	(0.00)
Average age of competitors		-1.95	-0.20	0.05	-0.01
		(0.21)	(0.04)	(0.03)	(0.00)
Past renewal, branded		-0.27	-0.07	0.37	-0.01
		(0.14)	(0.03)	(0.02)	(0.00)
Past renewal, unbranded		-0.64	0.20	-0.67	1.08
		(0.76)	(0.14)	(0.10)	(0.02)
R^2		0.44	0.92	0.51	0.76
F-stat IV		23.41	16.88	142.56	922.97

B - Generic aversion	Before regulation (τ^{k}_{0})		After regulation (τ^{k}_{1})	
	Mean	SD	Mean	SD
Branded	0.24	0.43	0.38	0.43
Unbranded (τ^{U}_{0})	0.99	0.93	0.95	0.91

C - Supply side estimates	Marginal cost (γ_c)	Entry cost (\$1,000s)	Certification cost (\$1,000s)	Profit shock (γ_{σ_ϵ})	Drug quality (π_H)
Innovator		0.00			1.00
		(0.01)			–
Branded	-0.26	433.24			0.96
	(0.02)	(39.39)			(0.02)
Unbranded	-1.51	329.68			0.67
	(0.03)	(33.34)			(0.03)
Developing country origin			185.46		
			(45.04)		
Developed country origin			6.64		
			(114.7)		
log(Market size)				0.34	
				(0.03)	
Constant				8.62	
				(0.48)	

Notes: Panel A shows demand estimates. The specification includes market and year fixed effects. Column 1 displays main estimates. Columns 2-5 display auxiliary regressions of each endogenous variable in the model on the instrumental variables. Panel B shows the mean and standard deviation of estimated generic aversion before and after the regulation. Panel C shows the estimates of the supply model. Marginal cost is estimated on a panel of yearly observations for 2010–2017, and the specification includes market and year fixed effects. The remaining parameters are estimated on the cross sections of observations for 2010 and 2017. Entry and certification costs are reported in USD 1,000s, and the distribution of drug quality is reported as the probability that a drug in each segment is of high quality. Standard errors in parentheses.

Table 7: Decomposition of the effects of quality regulation

		(1)	(2)	(3)	(4)	(5)	(6)	(7)
		Baseline	+Δ Due to quality standard		+Δ Due to generic aversion		+Δ Due to certification cost	
	Segment	y	Δy	$\Delta\%y$	Δy	$\Delta\%y$	Δy	$\Delta\%y$
Market outcomes								
Number of firms	Innovator	0.85	-0.02	-1.07	-0.01	-0.46	-0.01	-0.46
	Branded	6.05	-0.43	-5.54	-0.61	-7.89	-1.06	-15.66
	Unbranded	5.14	-1.46	-21.88	-1.35	-19.63	-1.81	-28.25
Average price	Innovator	3.76	-0.05	-2.18	0.02	0.02	0.06	2.98
	Branded	2.08	0.01	0.74	0.00	0.51	0.05	2.29
	Unbranded	0.59	0.04	11.73	0.05	13.25	0.09	30.19
Market share	Innovator	0.26	-0.04	-2.88	-0.00	-0.27	0.01	0.68
	Branded	0.48	-0.04	-2.52	-0.12	-7.64	-0.12	-7.58
	Unbranded	0.26	0.07	6.02	0.12	9.94	0.11	9.17
Share-weighted quality		0.91	0.09		0.09		0.09	
Welfare effects (MM/year)								
Compensating variation (A1)		972.85	41.92	4.31	40.31	4.14	36.07	3.71
Compensating variation (A2)		1,165.19	69.18	5.94	69.55	5.97	64.25	5.51
Variable profits		102.55	-2.57	-2.51	-0.19	-0.19	0.72	0.71
Certification costs		0.00	0.00		0.00		6.74	
Fixed costs		21.36	-3.30	-15.45	-3.52	-16.46	-5.23	-24.49
Total profits		81.19	0.73	0.90	3.32	4.09	-0.79	-0.97
Welfare (A1)		1,054.04	42.65	4.05	43.63	4.14	35.28	3.35
Welfare (A2)		1,246.38	69.91	5.61	72.87	5.85	63.46	5.09

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

Table 8: Counterfactual analysis: certification costs, quality disclosure, and generic aversion

		(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)	(9)	(10)	(11)	(12)	(13)
			A - Role of certification costs				*B - Disclosure*		*C - The role of generic aversion*					
			Amount of subsidy				Quality		Share of generic aversion corrected by regulation					
		Baseline	50%		100%		disclosure		s = 0%		s = 50%		s = 100%	
	Segment	y	Δy	$\Delta\%y$	Δy	$\Delta\%y$	Δy	$\Delta\%y$	Δy	$\Delta\%y$	Δy	$\Delta\%y$	Δy	$\Delta\%y$
Market outcomes														
Number of firms	Innovator	0.85	-0.01	-0.46	-0.01	-0.46	-0.01	-0.46	-0.02	-1.07	-0.07	-3.28	-0.22	-10.98
	Branded	6.05	-0.87	-12.31	-0.61	-7.90	-0.85	-12.99	-0.86	-13.17	-1.17	-16.99	-1.87	-25.05
	Unbranded	5.14	-1.60	-24.45	-1.35	-19.63	-0.19	-3.54	-1.93	-30.45	-1.42	-19.73	-0.97	-9.34
Average price	Innovator	3.76	0.04	1.41	0.02	0.03	0.05	1.49	-0.02	0.73	-0.18	-5.46	-0.28	-7.71
	Branded	2.08	0.03	1.50	0.00	0.51	0.05	1.91	0.06	2.84	0.06	3.44	0.07	4.38
	Unbranded	0.59	0.07	22.72	0.05	13.25	0.07	18.50	0.09	28.17	0.07	22.19	0.08	22.79
Market share	Innovator	0.26	0.00	0.23	-0.00	-0.27	0.01	0.50	-0.02	-1.95	-0.13	-9.93	-0.22	-16.51
	Branded	0.48	-0.12	-7.53	-0.12	-7.64	-0.12	-7.88	-0.04	-2.49	-0.13	-8.00	-0.33	-19.79
	Unbranded	0.26	0.11	9.47	0.12	9.94	0.11	9.44	0.06	5.33	0.27	23.81	0.55	50.94
Share-weighted quality		0.91	0.09		0.09		0.08		0.09		0.09		0.09	
Welfare effects (MM/year)														
Compensating variation (A1)		972.85	37.99	3.80	40.27	4.03	36.71	3.67	37.48	3.75	40.98	4.10	34.21	3.42
Compensating variation (A2)		1,165.19	66.45	5.59	69.49	5.84	64.91	5.46	63.07	5.30	63.15	5.31	17.21	1.45
Variable profits		102.55	0.30	0.29	-0.19	-0.19	0.63	0.61	-1.71	-1.66	-7.73	-7.53	-9.12	-8.89
Certification costs		0.00	8.00		8.47		8.35		6.79		7.01		6.88	
Cost of public funds (20%)		0.00	0.80		1.69		0.00		0.00		0.00		0.00	
Fixed costs		21.36	-4.48	-20.97	-3.52	-16.46	-2.13	-9.95	-4.98	-23.33	-4.83	-22.61	-5.59	-26.18
Total profits		81.19	-3.23	-3.98	-5.15	-6.34	-5.60	-6.90	-3.52	-4.33	-9.91	-12.20	-10.41	-12.82
Welfare (A1)		1,054.04	33.96	3.14	33.43	3.09	31.11	2.88	33.96	3.14	31.07	2.87	23.80	2.20
Welfare (A2)		1,246.38	62.42	4.91	62.65	4.93	59.31	4.67	59.56	4.69	53.24	4.19	6.80	0.54

Notes: Column 1 shows outcomes in the baseline without the reform. Panel A displays results for equilibria under regulation with subsidies to certification costs. Columns 2 and 3 display the changes relative to column 1 under a 50% subsidy. Columns 4 and 5 show changes relative to column 1 under a full subsidy. Panel C displays results for equilibria under quality disclosure relative to column 1. Panel C describes how generic aversion mediates the effects of quality regulation on market outcomes. Columns 8-13 display the effect of the regulation on market outcomes relative to that baseline for different degrees of correction of generic aversion. 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 $\tilde{\tau}^k_{m1}(s) = (1-s)\cdot\hat{\tau}^k_{m0} + s\cdot 0$, where s measures the effect of quality regulation on generic aversion. Compensating variation and total welfare are reported according to assumptions A1 and A2 in Section 7. To compute baseline consumer welfare, we calculate the compensating variation between the baseline equilibrium and and an alternative environment in which only the outside option is available. Fixed and certification costs are reported in annualized terms. Results for market outcomes report average across markets. In particular Δy is the average level change in an outcome relative to baseline across markets, and $\Delta\%y$ is the average percentage change in an outcome relative to baseline across markets. Results for welfare report aggregate outcomes across all markets.