DISCUSSION PAPER SERIES

DP18497

THE EFFECTS OF PRICE REGULATION ON PHARMACEUTICAL EXPENDITURE AND AVAILABILITY

Mika Kortelainen, Jaakko Markkanen, Markku Siilkanen and Otto Toivanen

INDUSTRIAL ORGANIZATION



THE EFFECTS OF PRICE REGULATION ON PHARMACEUTICAL EXPENDITURE AND AVAILABILITY

Mika Kortelainen, Jaakko Markkanen, Markku Siilkanen and Otto Toivanen

Discussion Paper DP18497 Published 02 October 2023 Submitted 31 August 2023

Centre for Economic Policy Research 33 Great Sutton Street, London EC1V 0DX, UK Tel: +44 (0)20 7183 8801 www.cepr.org

This Discussion Paper is issued under the auspices of the Centre's research programmes:

• Industrial Organization

Any opinions expressed here are those of the author(s) and not those of the Centre for Economic Policy Research. Research disseminated by CEPR may include views on policy, but the Centre itself takes no institutional policy positions.

The Centre for Economic Policy Research was established in 1983 as an educational charity, to promote independent analysis and public discussion of open economies and the relations among them. It is pluralist and non-partisan, bringing economic research to bear on the analysis of medium- and long-run policy questions.

These Discussion Papers often represent preliminary or incomplete work, circulated to encourage discussion and comment. Citation and use of such a paper should take account of its provisional character.

Copyright: Mika Kortelainen, Jaakko Markkanen, Markku Siilkanen and Otto Toivanen

THE EFFECTS OF PRICE REGULATION ON PHARMACEUTICAL EXPENDITURE AND AVAILABILITY

Abstract

Quasi-experimental evidence on the effectiveness of price regulation policies in curbing pharmaceutical expenditure is scarce. We analyze widely utilized generic substitution and reference price policies using data from the Nordic countries. Constructing treatment and control groups by matching data across countries by active ingredients and employing difference-in-difference methods on market-level observations, we find that expenditure per dose decreases by 40% moving from the laxest to the strictest regime. Prices decrease less: Reallocation of demand to cheaper products likely explains the difference. We find no adverse effects on pharmaceutical availability and non-existent or positive quantity effects.

JEL Classification: I11, I18, H51, L51, L65, C23

Keywords: pharmaceutical expenditure, pharmaceutical pricing, generic competition, reference pricing, Regulation

Mika Kortelainen - mika.kortelainen@utu.fi
University of Turku, THL, VATT and Helsinki GSE

Jaakko Markkanen - jaakko.m.markkanen@aalto.fi Aalto University and Helsinki GSE

Markku Siilkanen - markku.siikanen@vatt.fi VATT and Helsinki GSE

Otto Toivanen - otto.toivanen@aalto.fi

Aalto University and Helsinki GSE and CEPR

The Effects of Price Regulation on Pharmaceutical Expenditure and Availability*

Mika Kortelainen Jaakko Markkanen Markku Siikanen Otto Toivanen

August 28, 2023

Abstract

Quasi-experimental evidence on the effectiveness of price regulation policies in curbing pharmaceutical expenditure is scarce. We analyze widely utilized generic substitution and reference price policies using data from the Nordic countries. Constructing treatment and control groups by matching data across countries by active ingredients and employing difference-in-difference methods on market-level observations, we find that expenditure per dose decreases by 40% moving from the laxest to the strictest regime. Prices decrease less: Reallocation of demand to cheaper products likely explains the difference. We find no adverse effects on pharmaceutical availability and non-existent or positive quantity effects.

Keywords: pharmaceutical expenditure, pharmaceutical pricing, generic competition, reference pricing, regulation

JEL-Classification: *I11*, *I18*, *H51*, *L51*, *L65*, *C23*

^{*}Mika Kortelainen: U. of Turku, THL, VATT and Helsinki GSE. Email: mika.kortelainen@utu.fi. Jaakko Markkanen: Aalto U. and Helsinki GSE. Email: jaakko.m.markkanen@aalto.fi. Markku Siikanen VATT and Helsinki GSE. Email: markku.siikanen@vatt.fi. Otto Toivanen: Aalto U., Helsinki GSE and CEPR. Email: otto.toivanen@aalto.fi. We thank Nano Barahona, Pierre Dubois, David Granlund, Ben Handel, Aljoscha Janssen, Luca Maini, Thomas Rønde, Tobias Salz, Johan Stennek, Jo van Biesebroeck, Shoshana Vasserman and seminar audiences at NBER Health Care Program Meeting, CEPR Health Economics Conference, EARIE, IIOC, NHESG, NORIO, Helsinki GSE, CBS, U. of Turku and VATT for comments and suggestions. We also thank Hertta Hankimaa and Hung Le for excellent research assistance and the Finnish Social Insurance Institution and the Yrjö Jahnsson Foundation for financial support. The statements, findings, conclusions, views and opinions contained and expressed in this report are based in part on data obtained under license from the following IQVIA AG information services: IQVIA Pricing Insights and IQVIA MIDAS Quarterly Sales, 2007–2013. All Rights Reserved. The statements, findings, conclusions, views, and opinions contained and expressed herein are not necessarily those of IQVIA Inc. or any of its affiliated or subsidiary entities. All errors are ours.

1 Introduction

Spending on medicine has increased everywhere (Figure 1) and global spending has doubled in the last 10 years, reaching 1.3 trillion dollars in 2019.¹ It is therefore not surprising that most OECD countries have adopted various cost-containment policies. An important part of such policies are those targeting markets with generic competition.² Such policies are often needed to counter the low price-sensitivity of consumers which is caused by public or private insurance and low consumer co-payments. Consequently, various price regulation policies for prescription drugs are common especially in Europe, but have recently been promoted also in the US.³ Despite the wide-spread utilization of price regulation policies, credible causal evidence on whether such policies have decreased pharmaceutical expenditure is scant. The objective of this paper is to provide such evidence.

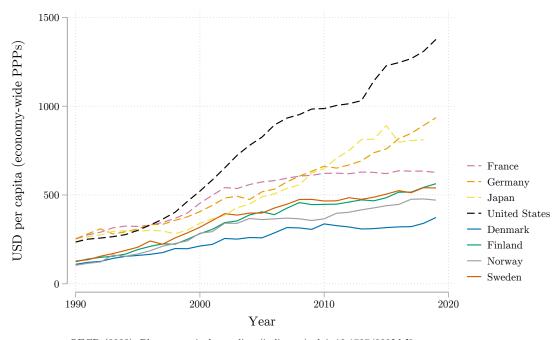
We investigate the effects of different Reference Pricing (RP) and Generic Substitution (GS) policies on pharmaceutical expenditure per dose, availability, prices, and quantities using data on generic markets from four Nordic countries—Denmark, Finland, Norway and Sweden. GS refers to changing the product from the prescribed one keeping the active substance, strength, pack size and even the dosage form the same, whereas RP is a policy that dictates product-level eligibility for, or the level of, reimbursement. Generic markets are an important part of the overall pharmaceutical market: Almost one third of sales in our data are in such markets, and in the US, more than 90% of prescriptions are for generic drugs.

We study the Nordic countries for two primary reasons: First, they are examples of societies that provide generous public insurance against pharmaceutical expenditure. They have adopted several variants of Internal Reference Pricing (IRP) and External Reference Pricing (ERP) policies during the 2000s, moving toward stricter regimes with greater financial incentives for patients. The main objective of these policies is to reduce pharmaceutical expenditure through (generic) competition and to increase consumer price sensitivity within generous reimbursement systems. Second, these countries are as homogeneous as

^{1.} See Exhibit 17 in Iqvia (2021).

^{2.} These are markets where the patent protection of the original (branded) drug has already lapsed, thus enabling competitor entry with products based on the same chemical molecule. The rest are monopoly markets with patent protection, some of which may face competition through parallel imports.

^{3.} See e.g., the Trump administration's Executive Order 13948 of September 13, 2020 on external reference pricing and the Biden administration's Executive Order 14036 of July 9, 2021 on promoting generic and biosimilar competition.



OECD (2022), Pharmaceutical spending (indicator). doi: 10.1787/998febf6-en (Accessed on 28 February 2022). Solid lines represent countires whose reforms are investigated.

Figure 1: Pharmaceutical expenditure in OECD countries

groups of countries come, making the use of them as controls for each other appealing.⁴

We contribute to the literature in the following ways: First, in contrast to the existing literature, we utilize the market-level average expenditure per purchased dose (henceforth (average) expenditure) as our key dependent variable. When studying the prices of individual products based on within-country data—the approach of the vast majority of the existing quasi-experimental literature⁵—the Stable Unit Treatment Value Assumption (SUTVA) assumption translates into the untenable assertion that the price of a product is not affected by the prices of its substitutes within the country. This assumption of no equilibrium effects runs against both theoretical models of competition and empirical evidence. Furthermore, because of substitution between products, using prices as the outcome variable may lead to different conclusions than using expenditure and our results

^{4.} We provide evidence on their similarity vis-á-vis pharmaceutical markets and demand in Appendix Section A.1.

^{5.} The only exception we know of is one of the analyses in Brekke, Holmas, and Straume (2011).

demonstrate that this is not just a theoretical possibility. Our key dependent variable encapsulates equilibrium effects and allows us to directly analyze whether a reform has the effect intended by the regulator. Our market definition is an active ingredient since the reforms studied in this paper influence consumer choices within active ingredients; we test and find support for this modeling choice.

Second, a central worry related to price regulation is its impact on product availability: Unlike any of the existing papers on the effects of regulation on pharmaceutical prices, we also study the market-wide impact of regulation on product availability using the number of product names as outcome variable.

Third, we design our control group by employing the same markets (active ingredients) in a neighboring country of similar appearance.⁶ This is important in terms of both the quantity of data and the quality of the match between the treatment and control groups. The existing quasi-experimental literature has almost exclusively had to rely on different active ingredients within the same country in constructing the control group, or on products in the same group that entered the new regulatory regime at a different time. Different active ingredients often have different price trends due to differences in regulation and competition or can be indirectly affected by the regulatory change ("spillover effects" or therapeutic competition), violating standard identification assumptions. In addition, our data allows us to study several regulatory reforms within a common framework, whereas the existing literature has concentrated on studying one policy reform at a time.

We find that price regulations decrease expenditure per dose without adversely affecting quantity or availability of products, with some policies being more effective than others: The move in Finland in 2003 from Voluntary Generic Substitution (VGS), the most producer-friendly regime in our data that required the prescribing physician to explicitly allow substitution, to GS with automatic possibility of substitution, but little customer incentives, had no significant impact on the expenditure per dose sold. The Finnish move in 2009 from GS to IRP, thereby introducing customer incentives, reduced expenditure by 13%. Denmark reduced expenditure by some 5% moving from IRP very similar to that adopted in Finland in 2009 to ERP in 2000, and lost this gain when moving back to IRP

^{6.} The recent paper by Tazhitdinova and Vazquez-Bare (2023) raises issues related to the use of data when the control group has a different baseline policy than the treatment group. While this is the case in some of our analyses, in others it is not. We find, in line with what they suggest, evidence of the data satisfying the necessary assumptions, that the estimated treatment effect is stable over time.

^{7.} The reported magnitudes are based on our ATT-estimates displayed in Table 4. Naturally, one must keep in mind their confidence intervals.

five years later. Sweden, on the other hand, moved in 2009 from an IRP system that was stricter than that adopted by Finland the same year to a Product of the Month Auction (Auction-IRP) regime where reimbursement is only granted for the prescribed product and the winner of the monthly auction. This reform reduced expenditure by 29%. Similarly, Norway was able to reduce expenditure by 21% in 2005 when moving from GS to a system with government-dictated price cuts after the introduction of generic competition. Going from the laxest regime (Finnish VGS) to the strictest (Swedish Auction-IRP) we find a decrease in expenditure of $(1 - 0.97 \times 0.87 \times 0.71) \times 100\% \approx 40\%$ without an adverse (negative) change in availability or quantity.

We also study average posted prices per dose, which has been the key dependent variable in most of the existing literature. We observe that in half of our studied reforms the treatment effect estimates are smaller in absolute value for prices than for expenditure, and in the other half of the reforms, this pattern is reversed. This shows that focusing on posted prices does not yield a good picture of the performance of the reforms in reducing expenditure. As an example, the Swedish 2009 IRP \rightarrow Auction-IRP reform lowered average posted prices by 14%, i.e., less than half the effect it had on average expenditure per dose. When we compare our market-level average price analyses to package-level analyses found in most previous studies, we find that possible violations of SUTVA lead to minor differences in the results.

The Swedish 2009 IRP \rightarrow Auction-IRP reform demonstrates the likely mechanism behind the difference between the effects on average posted prices and on average expenditure. In Auction-IRP, the vast majority of consumers need to buy the cheapest available product to be reimbursed, but some consumers may be prescribed a more expensive product. By definition, all other products are priced higher than the product of the month, and some firms, the producer of the branded original drug in particular, may have an incentive to price their product very high to cream-skim locked-in customers. The average posted price in a market may thus remain relatively high, while at the same time the lowest price—the price of the product that most patients are dispensed and which therefore dominates expenditure—can be very low, thereby resulting in a large expenditure decrease. In fact, our results suggest that a substantial part of the savings came from customers reallocating their purchases.

Our paper contributes to three strands of literature. We contribute foremost to the literature on the effects of pharmaceutical price regulation on expenditure and prices. The existing literature has mostly shied away from studying the effect of price regulation

directly on expenditure, the likely explanation being restrictions in data and research designs. Researchers have either used package or product level data on posted prices as a proxy for pharmaceutical expenditure (e.g. Danzon and Chao 2000; Brekke, Holmas, and Straume 2011) or used a structural approach to evaluate the impact of price regulation on competition, welfare, and savings in public expenditure (Dubois and Lasio 2018; Maini and Pammolli 2022; Dubois, Gandhi, and Vasserman 2022). Our results cast doubt on the credibility of the first approach, and our methods provide a complementary approach to the second, which requires carefully modeling the sometimes intricate details of price regulation. The only quasi-experimental analysis of the effect of a regulatory reform on pharmaceutical expenditure that we know of is Brekke, Holmas, and Straume (2011).

Several articles have used single-country data and quasi-experimental variation in price regulation to evaluate the effect of an individual reform (e.g. Pavcnik 2002; Brekke, Grasdal, and Holmås 2009; Brekke, Holmas, and Straume 2011; Herr and Suppliet 2017) on package prices. In related work, Feng, Hwang, and Maini (2023) study the effects of most favored customer clauses in Medicaid and find that removing them would decrease expenditure by 3.5%. In contrast to these papers, we use market-level average prices of active ingredients instead of package-level prices to encapsulate the equilibrium effects of price regulation reforms in four countries and examine their relative effectiveness using, when appropriate, modern difference-in-difference and event-study methods.

Dubois and Lasio (2018) is an important precursor of our study in that they also use multi-country data. Although the structural approach of Dubois and Lasio (2018) has the potential to allow for an evaluation of the welfare effects of regulation, they are careful to point out that the complicated process of choosing a particular drug, involving the physician, the patient, and the pharmacist, makes the interpretation of traditional welfare measures difficult. We shy away from structural modeling because of the scale of the challenge: Depending on the level of detail one would adopt in the modeling, our data contain 7–11 different regulatory regimes that we would have to model.

The second literature to which we contribute is concerned with demand reallocation, i.e., steering patients to choose generic and less expensive drugs affecting pharmaceutical expenditure also in markets where private insurance providers play an important role. Several studies have investigated the effects of Medicare Part D and its incentive structures

^{8.} Using within-country data on 24 Anatomical Therapeutic Chemical classification system (ATC) level 5 groups, 8 of which were treated, they find that the introduction of RP reduced expenditure in Norway by 30%.

on drug prices and pharmaceutical expenditure. For example, Duggan and Scott Morton (2010) demonstrate that private insurers have been able to decrease prices for previously uninsured with incentive-based formularies, which encourage patients to choose generic and cheaper drugs. Einav, Finkelstein, and Polyakova (2018) show complementary evidence that private insurance plans in Medicare Part D systematically set higher out-of-pocket (OOP) prices (coinsurance rates) for drugs or classes associated with more elastic demand. Starc and Swanson (2021) find that Medicare Part D plans can save money by utilizing preferred pharmacy networks, but that the savings are reduced by enrollees' low price sensitivity. Our results are in line with these observations.

Third, to complement the analysis of expenditure and prices, we also evaluate the effects of price regulation policies on the availability of pharmaceuticals. A common concern and source of criticism for pharmaceutical price regulation is its possible adverse effect on pharmaceutical availability and innovation (see, e.g., Lakdawalla 2018). The literature has focused on pharmaceutical shortages and has documented that consolidation and fierce price competition can increase pharmaceutical shortages (Yurukoglu, Liebman, and Ridley 2017; Stomberg 2016; Lee, Lee, Shin, and Krishnan 2021). However, we are not aware of any papers that study the direct effect of price regulation policies on pharmaceutical availability. Although the effect of pharmaceutical price regulation on innovation is an obvious concern in general (Acemoglu and Linn 2004; Yin 2008; Ornaghi 2009; Dubois, Mouzon, Scott-Morton, and Seabright 2015; Frech, Pauly, Comanor, and Martinez 2023), the regulations we study are unlikely to have a first-order impact on pharmaceutical innovation, as they mainly concern off-patent drugs in markets that even combined are small. ¹⁰

The rest of the paper is structured as follows. In Section 2 we present the relevant institutions and regulatory regimes. We also discuss the minor reforms and other insti-

^{9.} Several papers have studied the same issue regarding other health treatments, see e.g. Einav, Finkelstein, and Williams (2016) who study RP or margin pricing effects for breast cancer treatment.

^{10.} The share of Nordic countries is around 1% of the global pharmaceutical market. To illustrate the impact that patent life has, consider the following back-of-the-envelope calculation: Let us assume a discount rate of 0.95 and that the inventor firm can enjoy patent protection for 10 or alternatively 15 years. These period lengths are motivated by how the patent system works and how long it takes to launch a pharmaceutical product after filing for a patent. Patent protection is usually 20 years from the filing of the patent application, but pharmaceutical patents are often granted a 5-year extension. It is well known that the time to market from patent filing can be long for pharmaceuticals, e.g., Lexchin (2021) reports an average time to market in Canada of 11.8 years. Keeping the annual profits constant, the Net Present Value (NPV) of the profits in year 11 is 5.95% and in year 15 0.21% of the NPV of the profits in the first year. Even the NPV of the sum of profits from year 11 to year 50 (by which time one might expect a superior substitute to have arrived, rendering profits zero) are modest at 12.93% of the NPV of the first-year profits under patent protection, and those from year 15 to year 50 even more so at 0.37%.

tutional changes that take place during our observation periods. We introduce the data, motivate our choice of control countries and explain our procedure of matching markets in the treatment countries in Section 3. We present our difference-in-difference approach in Section 4. We also discuss the timing of reforms and the choice of estimation periods in that Section. Section 5 is devoted to the presentation and discussion of the results. We present our main results using event study graphs, and a summary of the main and auxiliary results based on average treatment effects. We discuss most of our robustness analyses along the way, but conclude Section 5 with an analysis of whether the reforms had an impact on markets that were not directly affected. This analysis tests whether our market definition is too narrow. We offer conclusions in Section 6.

2 Institutions and Regulatory Regimes

All Nordic countries have a universal single-payer insurance system, also called the Beveridge model, in which all citizens receive insurance coverage through the state (Bhattacharya, Hyde, and Tu 2013). The system is financed by taxes, and enrollment into the system is automatic and free. The government operates most hospitals and clinics and decides their locations. Publicly provided care is offered at very low or non-existent prices, and patients do not face deductibles or premiums when using public services. There are some exceptions to this rule, prescription drugs being a notable one. Pharmaceuticals are reimbursed by the public sector in all Nordic countries (see Appendix A.1 for details). Although there are differences both across countries and across time, the reimbursements are generous and individuals' annual drug expenditures are capped in all countries (the highest cap being Finland's 610 euros, see Table A.2 in Appendix A.1).

We next define the different regulatory regimes found in our data and then describe the regimes in place in different countries at different points in time, as well as the reforms that we analyze.

2.1 Regulatory Regimes

In official use, different regulatory regimes can share the same name in different countries. We use the following definitions and acronyms:

Definition 2.1. Voluntary Generic Substitution (VGS). Substitution with a cheaper interchangeable product is possible, but requires the active decision of the prescribing

physician.

Definition 2.2. Generic Substitution (GS). Substitution with a cheaper interchangeable product must be offered to the consumer in the pharmacy. The medicines authority determines which products are substitutable.

Definition 2.3. Reference Pricing (RP). The consumer has to pay out of pocket the price difference between the price of the prescribed product and the price of the reference product if she declines generic substitution. RP is determined within a basket of same-molecule drugs. RP is sometimes called "margin pricing" (Einav, Finkelstein, and Williams 2016). RP can be implemented in a number of ways which fall under the following two main approaches:

Definition 2.4. External Reference Pricing (ERP). The reference price is determined as a function of prices in both foreign and domestic markets.

Definition 2.5. Internal Reference Pricing (IRP). The reference price is determined as a function of domestic prices only.¹¹

Definition 2.6. Step-Price (SP). A reference price system in which after generic entry the government enforces gradual and predetermined price decreases to the maximum reimbursed price.

Definition 2.7. Product of the Month Auction (Auction-IRP). An internal reference price system where reimbursement is only granted for the prescribed product and the winner of the monthly auction. The lowest bid in the auction determines the reference price. Customers pay 100% out of pocket in case they choose any other product than the product of the month or the prescribed product.

Regulatory policies often consist of a combination of GS and some form of RP, but sometimes only one or the other is used. For example, in the early 2000s, Finland and Norway adopted GS systems without RP, meaning there were no financial incentives for customers to choose a cheaper product. On the other hand, the Swedish GS system has always been coupled with RP. Even when not explicitly stated—as in Step-Price (SP)—these regulations are complemented by a maximum price regulation of varying degrees of severity in all other Nordic countries but Denmark.

^{11.} Our definitions of reference pricing contain generic substitution, i.e., in what follows IRP and ERP should be understood as GS+IRP and GS+ERP.

Some regulations come from European Union (EU) law, which sets the principles for market entry and the freedom of movement of goods in the single market. Parallel trade, that is, imports of pharmaceuticals (irrespective of patent status) from a low-priced Member State to high-priced Member States, is protected. Other types of pharmaceutical regulation, such as public reimbursement, price regulation, and regulation of the distribution of pharmaceuticals are left to individual Member States. However, EU can place some restrictions on national regulators.¹²

2.2 Summary of Reforms

We now summarize the relevant regulatory regimes in place in the four countries during our observation period and explain which regime changes we study. We provide detailed information on each of the regimes in Appendix Sections A.3.2–A.3.5.

Figure 2 shows the regimes that are in place and the reforms (= changes in regime) that take place during our observation period, organized by country and chronologically. We exclude two reforms from our analysis: The Norwegian 2001 reform that combines pharmacy market liberalization and GS reform is excluded because we cannot separately identify their effects on the outcomes. The Norwegian 2003 reform introducing the so-called Index Pricing is excluded because 1) it directly influenced only eight markets (active ingredients), and thus a market-level analysis becomes difficult, and 2) given the timing of reforms in the other countries, we cannot form a good control group. We analyze the 2005 Norwegian reform using data on pharmaceuticals not included in the Index Price regulation.¹³

A more illuminating way to group the reforms is through the increasing strictness of the price regulation regimes, shown in Figure 3. The laxest regime in our data is the VGS regime of Finland, followed by the GS regime in the same country. Neither put much pressure on firms to lower their prices nor gave consumers incentives to substitute toward cheaper products. GS coupled with internal or external reference pricing, as adopted by

^{12.} The Treaty on European Union, Articles 34 and 36, provides the legal basis for parallel imports. For reference, see the precedent of the Court of Justice of the European Union in Pfizer Inc. v Eurim-Pharm GmbH. (1981). An example on EU restrictions on national regulation is the maximum processing time for reimbursement decisions: 180 days for new pricing and reimbursement decisions, 90 days for review of an application to increase prices. See Directive 89/105/EEC.

^{13.} The Index Price system was an IRP system where the reference price was calculated as a sales-weighted average of producer prices by each reference price group; for a review of the Index Price system, see Brekke, Grasdal, and Holmås (2009) and Brekke, Holmas, and Straume (2011). We do not analyze the Index Price reform because the small number of treated markets (8) does not leave room to study market level outcomes.

Denmark 1997 IRP ERP Denmark 2000 Denmark 2005 IRP Finland 1998 VGS Finland 2003 GS Finland 2009 IRP Norway 2000 No GS Norway 2001 Norway 2003 Index Norway 2005 SPSweden 2002 IRP Sweden 2009 Auction-IRP Month

Figure 2: Timeline of reforms

Timeline of reforms by country and data availability.

Notes: Abbreviations used: Internal Reference Pricing (IRP), External Reference Pricing (ERP), Voluntary Generic Substitution (VGS), Generic Substitution (GS), Step-Price (SP), Voluntary Generic Substitution (VGS), Product of the Month Auction (Auction-IRP)

all four countries at some point, constitutes a clear tightening of the regulatory regime by giving consumers incentives to substitute toward cheaper products. Finally, while it is not clear whether the Norwegian SP is stricter than the Swedish Auction-IRP, they were both further steps toward ever tighter price regulation and, in the case of Auction-IRP, greater induced price sensitivity of consumers. Notice though that this feature of Auction-IRP was achieved by the auction rules, not by the rule that the customer would have to pay 100% OOP the price of any but the cheapest or the prescribed product, as the Swedish IRP regulation in place before Auction-IRP already incorporated the 100% rule.

We find it useful to organize the reforms into three categories. The first category consists of the Finnish 2003 VGS \rightarrow GS and 2009 GS \rightarrow IRP reforms, i.e., moves from VGS toward

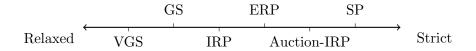


Figure 3: Reform Strictness Scale

Table 1: Treatment and Control Countries

Year	Treatment Country	Reform	Control Country	Control Regime
2003	Finland	$\mathrm{VGS} \to \mathrm{GS}$	Denmark	ERP
2009	Finland	$GS \to IRP$	Norway	SP
2000	Denmark	$\mathrm{IRP} \to \mathrm{ERP}$	Finland	VGS
2005	Denmark	$\mathrm{ERP} \to \mathrm{IRP}$	Finland	GS
2005	Norway	$GS \to SP$	Finland	GS
2009	Sweden	$\operatorname{IRP} \to \operatorname{Auction-IRP}$	Denmark	IRP

Notes: IRP = Internal reference pricing, ERP = External reference pricing, VGS = Voluntary Generic substitution, GS = Generic substitution, SP = Step-price, Auction-IRP = Product of the Month Auction.

IRP. These reforms demonstrate how well a simple substitution reform without financial incentives can reduce average expenditure and what happens when financial incentives in the form of RP are introduced to consumers. The second category of reforms consists of different ways of implementing RP: the Danish 2000 IRP \rightarrow ERP and 2005 ERP \rightarrow IRP reforms, which allow us to analyze the benefits of using ERP as opposed to IRP. The third category of reforms consists of moves from the "regular" IRP to stricter versions of it. The Norwegian 2005 IRP \rightarrow SP and Swedish 2009 IRP \rightarrow Auction-IRP reforms either introduce price caps that are based on a predetermined pricing rule set by the regulator (Norway 2005) or channel demand to the cheapest product (Sweden 2009).

We have collected the analyzed reforms into Table 1, ordered in increasing strictness of the regimes. The table shows the treatment country in question; the reform, i.e., the regulatory regimes before and after the reform; the country the markets of which act as the control group; and the regulatory regime in the control country during the estimation period. We discuss the choice of the control countries in Section 3.2.

2.3 Minor Reforms and Institutional Changes

Most of our analyses are affected by minor reforms or institutional changes that occur before or after the studied reform. These minor reforms can happen either in the treated country or in the control country. We detail in Appendix A.3.6 all minor reforms. Next, we list the minor reforms that mechanically influence our results and explain how we take these into account.

Finland implemented a 5% price cut to the maximum wholesale prices (price caps) of all reimbursed pharmaceuticals in January 2006.¹⁴ Since the caps were cut instead of wholesale prices, the price cut likely only influences products (i.e. brand-name products) that were priced to the price cap at the time of the cut. The effect of the mechanical wholesale price cut is visible in our event studies for the Danish ERP \rightarrow IRP and Norwegian IRP \rightarrow SP reforms in 2005, especially when price outcomes are studied. In both reforms, Finland is used as a control group. We limit the post-periods in the main result event studies to time periods before the price cut and report results using a longer post-treatment period in Appendix Section A.9.

The second set of minor reforms are the maximum price cuts that occur before and after the Swedish 2009 IRP \rightarrow Auction-IRP reform. The Auction-IRP reform was a combination of four regulatory changes that were implemented before and after the start of the monthly auctions. With respect to our analysis, price cap changes implemented in July 2009 are the most relevant. The price of off-patent products was capped at 35\% of the price that prevailed during the patent period if certain conditions were met. The Swedish 2009 price cut influences products (i.e., brand-name products) that were priced to the price cap at the time of the cut. We deal with the price cap changes by timing the reform anticipation period start to April 2009 when the Swedish Parliament passed the law changes related to Auction-IRP reform package. This allows us to treat the 2009 price cap cut as an anticipation to the Auction-IRP reform. Since markets with generic competition were subject to the price cut, our estimates identify the joint effect of the price cut and the regulatory change. In 2011, Sweden changed the rules for the maximum wholesale price regulation, which led to a 35% reduction in the price cap if all required conditions were met. The latter Swedish price cap change is less problematic than the first cut because the 2009 IRP \rightarrow Auction-IRP reform directs market demand toward the cheapest product, which rarely is priced to the price cap. We explain in Appendix Section A.3.6 in more

^{14.} Declared in the commencement order of 885/2005.

detail how price caps were imposed and what are the other minor changes that occurred during the Auction-IRP analysis sample.

The third minor reform that mechanically influences our results is the change in the Danish reimbursement system in 2000. This policy change gave consumers an incentive to stockpile products before the rules on the calculation of annual reimbursement expenses were changed (Simonsen, Skipper, Skipper, and Christensen 2021). This change in the reimbursement system happened 9 months before the Danish 2001 IRP \rightarrow ERP regulation regime change. The results of an auxiliary event study presented in Appendix Section A.11 show that the demand shock arising from the anticipation of the reform is transitory and pricing is not influenced by the change.

3 Data and Matching

3.1 Sales and Reform Data

We use data from four different data providers on monthly revenues and quantities of drugs purchased by community pharmacies. Our data set covers the Nordic countries, excluding Iceland. The data sets contain information on the sales value and volume of each pharmaceutical package sold in the respective country. The sales values are defined in pharmacy purchase prices and volumes in Defined Daily Dosages (DDD) for each respective active ingredient according to the ATC. ¹⁵ To capture potential equilibrium (SUTVA) effects we deviate from the literature and aggregate our sales and quantity data to the active ingredient (-month) level. We construct our aggregate sales and quantity variables from products that have a defined daily dosage. The country-specific data sets also provide rich information on product characteristics. We supplement our sales data with rich regulatory information obtained from market regulators and directly from the relevant legislation. We list the data source for each country and reform in Appendix Section A.4 Table A.6.

We use wholesale prices, i.e., the price a pharmacy pays for the product when the product is purchased from the wholesaler, for two reasons: First, the regulations target wholesale prices. Second, with one exception, the retail price in each country is determined using a mechanical formula based on the wholesale price. The only exception is the Nor-

^{15.} The ATC system classifies active ingredients according to their therapeutic, pharmacological, and chemical properties. The classification groups active substances into five different categories. Active substances in the fifth category have the same active ingredients and are considered equivalent for the treatment of the same disease.

wegian 2005 SP regime, where only an upper bound on the retail price is based on the wholesale price. We show how price formulas work in the Nordic pharmaceutical market in Appendix Table A.3.

Our main outcomes are (logarithms of) average expenditure per dose at the market level $(\frac{\sum P_j \times Q_j}{M})^{16}$ and availability, the latter of which we measure by the number of product names. Our secondary outcome variables are the main outcome of the previous literature: The average price per dose $\left(E\left[\frac{P_j}{Doses_j}\right]\right)$ and the total quantity (M) though in contrast to the literature, we measure them at the market rather than the product level. The former measures the average price of a dose on the pharmacy shelf, but does not take into account which products are actually bought. The latter allows us to analyze whether the reforms affect the amount of pharmaceuticals consumed.

Prices and sales are measured in nominal national currencies.¹⁷ Nominal values are used because in all Nordic countries price regulations work with nominal prices. As the sample periods are relatively short (2–4 years) and from an era of low inflation, differential inflation trajectories should not cause bias.

3.2 Choice of Control Countries

An important decision is the choice of a control country. We sought to identify a country where no major regulatory changes occur in the years right before and right after a given reform. Figure 2, presented already in previous Section, reveals that one or two countries are available as control countries for the reforms we study. Optimally, one would want to have a control country that had the same regulatory regime as the treatment country prior to adoption. For most of the reforms this is not possible, the exception being the Swedish 2009 IRP \rightarrow Auction-IRP reform: Denmark has the same regime as Sweden until the reform. We discuss in Subsection 4.1 the implications of the control country regulatory regime on identification using concepts from Tazhitdinova and Vazquez-Bare (2023).

We use Denmark as the control country for the Finnish 2003 VGS \rightarrow GS reform. The

^{16.} P_j is the price of a package j (in a given time period; we suppress time subscripts), Q_j is the number of packages j sold and $M := \sum Q_j \times Doses_j$ is the aggregate, i.e., market-level quantity of daily doses, summed over all packages j in the given market. Each package is by definition only available in a particular ATC5 market within each country.

^{17.} Sales data from Finland is in euros, because the switch from FIM to EUR occurs during our sample (2002). The reason for not converting prices to the same currency is the possibility of exchange rate shocks. Exchange rate shocks are problematic when data from Norway or Sweden are used, because these currencies are not linked to the euro like the Danish krone. A visual inspection of the data showed that this is a real concern. We show in Appendix A.5 how exchange rates evolve within our sample periods.

Danish regime at that time was ERP. When studying the Finnish 2009 GS \rightarrow IRP reform, we use Norway as a control country. Norway was using SP at the time. Denmark is available as an alternative control country: Those results, reported in Appendix Section A.8, are in line with the main results reported below.

We then move on to analyze the Danish 2000 IRP \rightarrow ERP switch using Finland as the control country. The Finnish regime at that time was VGS. We continue to use Finland as the control country when we study the Danish 2005 ERP \rightarrow IRP reform that reverses the previous Danish reform. We use Denmark and Finland as control countries for each other. This choice is supported by the following facts: First, the overlap between the different analyses in the time dimension is minor. Second, as we demonstrate below, the effects of the reforms stabilize rather quickly. Third, in our analysis of pre-trends, we do not find worrying signs. Furthermore, our different estimation samples consist neither of exactly the same markets (because the number of markets with generic competition increases over time due to patent expirations) nor of exactly the same products (due to generic entry): The overlap in products is usually less than 20% and always less than 30% (see Table A.8 in Appendix Section A.4.1).

The fifth reform is the Norwegian 2005 IRP \rightarrow SP reform. Figure 2 reveals that the country with a stable regulatory regime is Finland, where GS was in place at that time. We discard 8 treated Norwegian markets due to the Index Price regulation implemented in 2003 in Norway because otherwise the pre-period market institutions would not be the same for all Norwegian markets.

The only Swedish reform that we study is the implementation of the product of the month system in 2009. Sweden 2009 IRP \rightarrow Auction-IRP reform converted IRP system to a first-price sealed bid procurement auction. We use Denmark as the control country in the main analysis and perform a robustness test substituting Denmark for Norway, and using both Denmark and Norway (see Appendix Section A.8). The results using different control countries are in line with each other.

3.3 Sample Matching

Our empirical strategy is based on comparing the pharmaceutical retail markets of a country subject to a reform (treatment country) with identical retail markets in another Nordic

country (control country) before and after each reform.¹⁸ We match the markets by active ingredient (i.e., ATC5 level).¹⁹ The matching process proceeds in four steps: i) We discard non-prescription pharmaceutical products (over-the-counter (OTC) products) and the hospital market for pharmaceuticals; ii) we identify the markets that are affected by the reform in question in the treated country; iii) we find the same markets in the control country; and iv) we drop non-treated markets, treated markets without a match, and matched markets where generic competition starts during the pre-period. Our estimation samples thus include different products and package sizes in the treatment and control markets.

Our matching process leads to the exclusion of some treated markets. A treated market is excluded from the sample if the control country does not have the corresponding market, or if generic competition begins during the reform pre-period.²⁰ The matching process also discards treated markets where generic competition has started during the reform pre-period, as otherwise we could confound changes caused by the reform with changes caused by increased competition through patent expiration and generic entry.

Table 2 illuminates how the estimation samples cover the pharmaceutical market, excluding the hospital sector. In Panel A, we describe how our matching process progresses from the number of existing markets to the number of markets included in each estimation sample. Panel B shows the same information in terms of share of sales.

The first Column in Panel A gives the number of markets in the treated country in the pre-period while the second Column shows the number of markets with generic competition. For example (see Row 1), there were 881 (ATC5) markets in Finland in 2003 during the pre-period of the VGS \rightarrow GS reform, 113 of which had generic competition. Out of these, 100 (Column 3) are affected by the change from VGS to GS. Column 4 reveals that 90 of these 100 markets have experienced generic entry before the pre-period and are therefore included in the estimation sample. Thus, we end up with 80 matched markets (Column 5) after having discarded markets due to pre-period entry and due to markets not existing in Denmark.

^{18.} Pharmaceuticals used in inpatient care (hospital market) are excluded from the analysis, because competitive bidding is used in these markets and our data-set does not contain hospital prices.

^{19.} We illustrate package level match rates between treatment and control countries before each studied reform in Appendix Section A.4.1 Table A.8. At the package level our match rates are less than 30%. This suggests that matching based on active ingredients is better modeling choice.

^{20.} A control country may not have the same markets as the treated country due to differences between countries in the markets served through the pharmacy sector, how OTC drugs are classified, or because some small markets may have experienced entry in one country but not yet in the other.

Table 2: Matching Descriptive Statistics

	All Markets (1)	Generic Competition (2)	Treatment Markets (3)	Pre-Study Generic Competition (4)	Matched Markets (5)				
Panel A: Number of ATC 5 markets									
Finland 2003	881	113	100	90	80				
Finland 2009	896	133	133	124	106				
Denmark 2000	815	110	68	64	59				
Denmark 2005	822	150	114	100	91				
Norway 2005	1,016	171	26	22	15				
Sweden 2009	1,007	137	137	132	112				
Panel B: Share of total pharmacy sales, %									
Finland 2003	100.00	24.24	23.28	19.40	18.35				
Finland 2009	100.00	29.26	29.26	25.57	23.83				
Denmark 2000	100.00	26.32	23.51	21.30	21.05				
Denmark 2005	100.00	33.52	32.22	26.24	25.56				
Norway 2005	100.00	28.91	12.24	8.03	3.64				
Sweden 2009	100.00	20.78	20.78	19.50	18.33				

All Markets = number of/market share of ATC 5 markets in pre-period; Generic Competition = number of markets/market share of markets with generic competition during the observation period; Treatment Markets = number of markets/market share of markets where the new regulation is implemented; Pre-Study Competition = number of markets/market share of markets in which generic competition started before our observation period; Matched Markets = number of/market share of successfully matched markets. Outcome data source: DLI-MI (1999–2013), Farmastat (2004–2013), Fimea (1999–2012), IQVIA MIDAS Quarterly Sales and IQVIA MIDAS (2007–2013).

The difference between Columns 3 and 4 in Table 2 is informative about the exogeneity of reform timing with respect to markets becoming competitive. If regulators design new regulation policies while taking into account how patents expire, we might see that many markets become competitive during the reform pre-period (the difference between Columns 3 and 4 in Panel A) or that the market size of markets with generic entry during pre-period was substantial (the difference between Columns 3 and 4 in Panel B). All reforms have markets that become competitive during the pre-period, but the number and the economic significance of these markets is relatively low.

In Panel B, Column 2 reveals that 20%–35% of pharmaceutical sales in the treated

countries come from markets with competition, the rest coming from monopoly markets. Columns 3 and 4 show the sales share of the treated markets and markets with generic entry before the pre-period. The sales share of the treated markets varies from a low of 12% for the Norwegian GS \rightarrow SP reform in 2005 to a high of 33% for the Danish ERP \rightarrow IRP reform in 2005. The sales share of unmatched markets (the difference between Columns 4 and 5) is small, as expected. The only exception is the Norwegian 2005 GS \rightarrow SP reform, where the large decrease can be explained by the fact that we need to discard 8 markets that had been exposed to Index Price regulation in 2003.

A feature of the markets that affects the coverage of our analysis is the share of pharmaceuticals distributed through hospitals rather than through pharmacies. The share of pharmacy sales is close to or above 80% in all other countries in our sample but Denmark where pharmacy sales are around 70% in the early 2000s, but decrease to somewhat less than 50% by 2012 (see Appendix Figure A.5).

4 Empirical Strategy

4.1 Research Design

The primary obstacle in identifying the effects of price regulation policies on product market outcomes based on single-country data is that regulations are either rather broad, covering almost all markets, or targeted, covering markets of special interest. As a consequence, non-regulated products are typically quite different from regulated products, making it difficult to form a plausible control group. The most prominent example is that price regulation policies related to GS can only be applied to markets with generic competition. Products that remain outside of regulation presumably come from markets without competition. This leads to comparisons in which the treatment and control group products are at different stages of their product life cycle and the products under comparison come from different drug markets. Furthermore, price regulation reforms can also indirectly affect prices and sales of products not affected by the reform, thereby potentially contaminating the control group in within-country comparisons.

The second major challenge in evaluating the effects of (price) regulation in pharmaceutical markets using the difference-in-difference approach is SUTVA, which rules out equilibrium effects. The existing quasi-experimental literature on pharmaceutical market

^{21.} We display the number of observations for all estimation samples in Table A.7.

price regulation reforms has measured outcomes at the package or product-level, thereby imposing the assumption that competing products' pricing decisions are independent.

To address these shortcomings, we base our empirical strategy on cross-country comparisons between two Nordic countries using market-level (ATC5) outcomes rather than within-country comparisons using product-level data. This approach allows comparisons between identical markets in different countries and takes SUTVA into account by using outcome measures that encompass rival reactions.

Our approach necessitates somewhat different assumptions than those invoked in the existing literature: First, we assume that there are no major pricing spillovers between countries that would change due to a reform, and that the trends in prices and sales of pharmaceuticals in a given ATC5 market are comparable between countries.²² Second, we assume that there are no spillovers between ATC5 markets within a country. This is motivated by the fact that the price regulations are built on comparing products within an ATC5 group and hence substitution happens mostly within ATC5 markets. We test this assumption in Section 5.4 and find no economically significant spillover effects.

As we estimate difference-in-difference models, we need to maintain an assumption on common trends: While the specific assumption is estimator-specific, the assumptions concern the (counterfactual) outcome-variable trends in the control and treatment markets. There are two main dangers to the common trends assumptions in our setting, where the control markets are from a different country: First, there could be country-market-specific demand or supply trends. We address these by matching the treated and control markets at the ATC5 level on the one hand, and using the relatively similar Nordic countries as each others' comparators on the other hand. The second challenge could arise if the control country has a different price regulation regime than the treatment country, which is the case for most of our settings. Tazhitdinova and Vazquez-Bare (2023) have documented that this setup can lead to biased estimates if the estimated treatment effect is not constant or non-immediate. We believe that this issue does not influence our results for two reasons. First, we find treatment effects that are stable over time.²³ Second, the Swedish 2009 IRP

^{22.} Pricing spillovers are possible in the European pharmaceutical market, because many countries have incorporated the ERP system to their institutional setup. Furthermore, Nordic countries use the system and other Nordic countries as a benchmark. We argue that pricing spillovers are not a problem in our setting because we study markets where generic competition has started before our sample period. We also find that the overlap between products in the treatment and control countries is surprisingly small (See Appendix Section A.4.1 Table A.8). The danger of spillovers through the ERP therefore seems modest.

^{23.} More specifically, the time-varying treatment estimates are within each others' confidence intervals.

→ Auction-IRP reform can be studied using a control group that has the same baseline treatment status (Denmark) and using a control group that has a different baseline status (Norway). We find very similar effects (See Section 5 and Appendix A.8), suggesting that at least in this case the control country having a different regulatory regime is not of material consequence. Finally, as will become clear in Section 5, in none of our estimations do we find problematic pre-trends.

4.2 Difference-in-Difference Estimators

Our empirical approach allows us to include in our difference-in-difference estimator market-country-specific fixed effects to account for level differences between markets and time-fixed effects to account for unobserved aggregate time trends and shocks.

We use either the standard Two-Way Fixed Effects (TWFE) estimator or the estimator proposed by Callaway and Sant'Anna (2021) which is robust for negative weighting issues arising from staggered treatment adoption and imposes a less strict parallel trends assumption. We use the former when there is no variation in treatment timing and the latter when the reform in question is implemented in a staggered fashion. Our TWFE estimation equation has the following form:

$$y_{itc} = \alpha_{ic} + \lambda_t + \sum_{\tau \neq -1} \beta_\tau \text{Reform}_\tau + \epsilon_{itc}$$
 (1)

where y_{itc} represents the (log of) monthly market level average expenditure per dose, the number of product names, the (log of) average price per dose or the (log of) quantity i in country c at time t. The subscript i denotes a market except when we analyze the price effects using package-level data (to provide a comparison to the literature). α_{ic} denotes the country observation unit-specific fixed effect which controls the country-specific time-invariant factors that influence the outcome. The variables Reform_{τ} are relative time-to-treatment indicators which are set to 1 for treated markets if period t is τ periods from the start of treatment. The coefficients of interest (β_{τ}) denote the average change between time τ and the last period before treatment in markets exposed to treatment, relative to control markets. When we estimate the average effect of the reform, we augment Equation (1) by replacing $\sum_{\tau \neq -1} \beta_{\tau} \text{Reform}_{\tau}$ with $\beta_{att} \text{Reform}_{\tau}$. This allows us to interpret β_{att} as the average impact of the reform on the treated units.

The estimation equation for the Callaway and Sant'Anna (2021) estimator has the

following form when the comparisons are based on never treated units (control country) and treated units (treatment country) without conditioning on control variables:

$$ATT_{nev}^{unc}(g, t; \delta) = \mathbb{E}\left[Y_t - Y_{q-\delta-1} | G_q = 1\right] - \mathbb{E}\left[Y_t - Y_{q-\delta-1} | D_{t+\delta} = 0\right]$$
 (2)

 G_g denotes the time period when unit i becomes treated; $D_{t+\delta}$ is an indicator of whether i has been treated at time $t + \delta$; Y_t is the outcome in period t; and $Y_{g-\delta-1}$ is the outcome in period $g - \delta - 1$, where g denotes the period when i becomes treated and δ denotes the number of anticipation periods. The expression for $ATT_{nev}^{unc}(g,t)$ clearly resembles the Average Treatment Effect on the Treated (ATT) in the canonical case of two periods and two groups. We use aggregation formulas derived in Callaway and Sant'Anna (2021) in calculating the reform specific average treatment effects and event studies.

The average effect of participating in the treatment for units in group g is identified by taking the path of outcomes (that is, the change in outcomes between the most recent period before they were affected by the treatment and the current period) actually experienced by that group and adjusting it by the path of outcomes experienced by the control group. Under the maintained parallel trends assumption, discussed in detail in De Chaisemartin and d'Haultfœuille (2023), this latter path is the path of outcomes that units in group g would have experienced if they had not participated in the treatment.

We cluster standard errors at the ATC5 level using a wild bootstrap procedure.²⁴ This clustering scheme allows dependencies within each market (ATC5) and is preferred over a block bootstrap because the number of clusters varies between 15–126 depending on the examined reform. Table A.7 in Appendix Section A.4.1 displays the number of clusters and observations for each reform.

4.3 Timing of Reforms and Choice of Estimation Periods

An important part of estimating causal effects of reforms is the timing of pre- and posttreatment periods. Each reform has an actual start date, which is public information, but it is possible that due to anticipation, companies or consumers react to the reform before

^{24.} In our TWFE estimations, we use the estimator proposed by Correia (2016) to absorb the fixed effects at the market or product level. For our TWFE estimates, we use the method developed in Roodman, Nielsen, MacKinnon, and Webb (2019) in the estimation of the confidence intervals. Our Callaway and Sant'Anna (2021) estimations use the Mammen (1993) method.

Table 3: Sample Periods and Reform Timings

Reform Name	Sample Period	Sample Period Lenght	Reform Start	Reform Timing	Anticipation Length
	(1)	(2)	(3)	(4)	(5)
Finland 2003	2001 m 7 - 2004 m 7	36m	2003 m4	2003 m1	$4\mathrm{m}$
Finland 2009	2008 m2 - 2011 m1	$36 \mathrm{m}$	2009 m4	2009 m 1	$4\mathrm{m}$
Denmark 2000	$1999\mathrm{m}11{-}2001\mathrm{m}11$	$24 \mathrm{m}$	2000 m11	2000 m 11	$0\mathrm{m}$
Denmark 2005	$2003\mathrm{m}12{-}2005\mathrm{m}12$	$24\mathrm{m}$	2005 m4	2004 m 12	$5\mathrm{m}$
Norway 2005	2004m1 - 2005m12	$24 \mathrm{m}$	2005 m1	2004m9	$4\mathrm{m}$
Sweden 2009	$2008\mathrm{m}42012\mathrm{m}10$	$54\mathrm{m}$	2009 m5	2009 m 12	$7\mathrm{m}$

Notes: Sample Period = Sample period used in empirical analyses; Sample Period Length = Length of sample period used in empirical analyses; Reform Start = Public information on when reforms started; Reform Timing = months used for treatment analyses; Anticipation Length = difference between Reform Start and Timing.

the reform is implemented (Alpert 2016). Failing to take anticipation into account could bias the estimates. Our difference-in-difference estimators allow for anticipation,, but the start of the anticipation period must be known (Callaway and Sant'Anna 2021).

Our reform timing is in most cases based on the date when the national parliament in question confirmed the law imposing the new price regulation. The benefits of using the confirmation date compared to the actual introduction of the law are that it ameliorates anticipation concerns and comes from the legislative process. Some reforms were implemented without changes to the legislation (e.g., the Swedish 2009 IRP \rightarrow Auction-IRP reform); in these cases we rely on other sources to pin down the timing of the reform.

Table 3 shows the duration of each sample period and our timing choices. Column 1 shows the sample period and Column 2 its length (end-start) in months. In selecting sample periods, we need to limit overlap between consecutive reforms and also at the same time guarantee that the post-reform period is long enough. The shortest sample period is 24 months and the longest is 54 months.

Column 3 in Table 3 shows the actual start dates of the reforms, and Column 4 the reform timing used in our analysis. The duration of the anticipation period is reported in Column 5. Half of the studied reforms have a staggered implementation, i.e., different ATC5 markets are affected by the reform at a different point in time and the same anticipation length is applied to all cohorts within a given reform. Only the Danish 2000 IRP \rightarrow ERP and 2005 ERP \rightarrow IRP reforms have immediate reform take-up in all ATC5 markets and

the Norwegian 2005 SP reform expands to new markets after our follow-up period ends.

5 Results

We present our results in four parts. First, we show event study graphs of our main analyses of expenditure and availability, reform by reform. We start from the less strict reforms and progress to the stricter ones. We then summarize these results by reporting and discussing the average treatment effects. Third, we turn to our secondary outcomes, i.e., average prices and quantity, by presenting ATT estimates for these outcomes.²⁵ We conclude with an analysis of whether the reforms affected close-by markets not directly affected by the reform in question. This analysis serves as a robustness check on our decision to define markets at the ATC5 level.

When presenting the event study results, we separate the anticipation period point estimates in orange from the blue pre-treatment period and the green post-treatment period point estimates. We do not include anticipation periods in the calculation of ATTs.

5.1 Event Study Analysis of Main Outcomes

5.1.1 Event Study Part I: GS and IRP

As Finland moved from VGS to GS in April 2003, we set the base period to January 2003. Neither regime provided customers financial incentives to switch to a cheaper alternative.²⁶ The results are shown in Figure 4a: They suggest that immediately after implementation there was a 7% decrease in average expenditure (Figure 4a, top panel), but the effect decreases in magnitude and becomes statistically insignificant as time passes (also, the confidence intervals of any pair of treatment period point estimates overlap). The point estimates on availability (Figure 4a, bottom panel) are positive until post-period 14 but very imprecise.

Our analysis of the Finnish 2009 GS \rightarrow IRP reform, which introduced customer incentives, provides different results. The GS system without financial incentives to patients was changed to IRP in April 2009; we set the base period to January 2009. We find in Figure 4b (top panel) that the adoption of IRP decreased average expenditure. Expenditure

^{25.} We present the event study results for these outcome variables in Appendix Section A.11.

^{26.} The Finnish 2003 and 2009 reforms are staggered. We therefore use the Callaway and Sant'Anna (2021) estimator.

decreased by 16% a year after the implementation of the reform; again all point estimates' confidence intervals overlap. The point estimates on availability (Figure 4b, bottom panel) vary. All point estimates are positive and noisily estimated and thus do not support the idea that this reform would have decreased availability.

There is a strong case to be made for why GS alone had only a limited effect. First, GS simply expanded the choice set of consumers when they shop in pharmacies. Although a generic alternative might have had a lower price than the original branded product, deciding against substitution did not affect the level of reimbursement or the co-payment faced by the consumer, thus mitigating the reform's effect on consumers. There were only limited incentives to accept substitution for fully reimbursed products and for consumers who had exceeded their annual maximum limit on out of pocket costs. To test this assertion we performed a subgroup analysis based on the different reimbursement categories of the products, the results of which are provided in Appendix Section A.6, Figure A.7.²⁷ As suspected, we find that package-level price decreases are the largest and statistically significant for products that enjoy only basic levels of reimbursement. The point estimates for products with the full level of reimbursement of 100% are close to zero. Therefore, the Finnish 2003 VGS \rightarrow GS reform did not succeed in decreasing the prices of products that enjoyed the most generous public subsidies. On the other hand, the adoption of IRP in 2009 led to price decreases and savings also for products with full public reimbursement—the same products that were less affected by the earlier 2003 VGS \rightarrow GS reform.

The results of the two Finnish reforms should be interpreted jointly. Unlike the regulatory regimes in the other Nordic countries, the Finnish GS regime was unique in the sense that at first it did not include any kind of reference pricing, i.e., financial incentives to the customers. Our results imply two important conclusions. First, the 2003 GS reform expanded the choice set of consumers because they were no longer tied to the decision made by the prescribing physician. However, the increase in choice had no significant effect on the expenditure per dose. Second, we find the introduction of IRP decreased average expenditure quite substantially. The result indicates that the inclusion of consumer incentives is important in this type of a context. Our package-level subgroup analysis further suggests that for reimbursed products, price decreases are achievable when GS is tied to

^{27.} This subgroup inquiry is based on product (package) level analysis instead of market level analysis, because the reimbursement statuses are defined at the package level. The results demonstrate the weakness of the GS policy when applied without reference price regulation, but the analysis is subject to SUTVA violations.

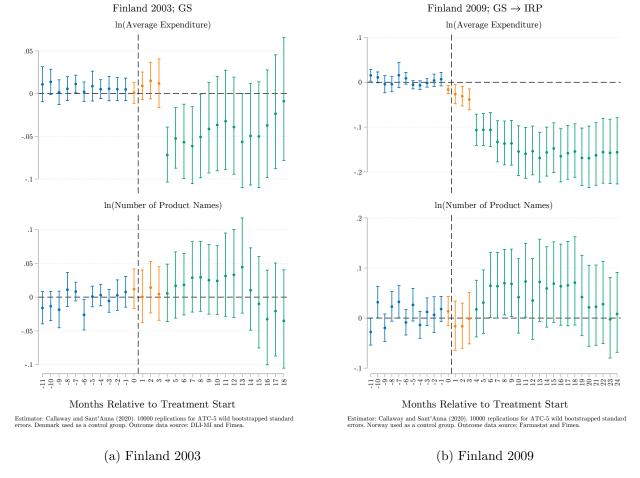


Figure 4: Part I: Main Results

RP for reimbursed products.

We can test the robustness of the Finnish 2009 GS \rightarrow IRP results to a change of the control group. As a robustness checks we use both Denmark only or Denmark and Norway as the control group. We find that our results are robust with respect to the control group choice (see Appendix Section A.8).

5.1.2 Event Study Part II: ERP

This subsection examines the Danish experiment with ERP, going from IRP to ERP in 2000 and back in $2005.^{28}$ As far as we know, we provide the first difference-in-difference analysis of ERP. The Danish 2000 IRP \rightarrow ERP reform leads to an average 5% decrease in average expenditure per dose (Figure 5a, top panel). The point estimates for availability are quite stable at roughly -2%, but statistically insignificant (Figure 5a, bottom panel). The results are highly symmetric when studying the 2005 ERP \rightarrow IRP reform: We find that average expenditure increased by roughly 4%, while the estimated change in availability is not statistically significant.

Our results suggest that the Danish 2000 IRP \rightarrow ERP reform in generic markets lead to savings in expenditure per dose. The underlying mechanism behind the performance is that ERP allows Danish regulators to use domestic and foreign price information from Europe to form the reference prices in comparison to pre-reform (IRP) policy environment where regulator only could use domestic prices. Our results imply that the price levels of off-patent pharmaceuticals were higher in Denmark before the reform than in its reference countries. A decrease in reference prices can lead to demand reallocation from more expensive to cheaper products and at the same time price competition between producers can intensify. The Danish 2005 ERP \rightarrow IRP reform excluded foreign prices from reference price calculations and as a result average expenditure increased.

The results of the removal of the ERP system in Figure 5b are visible only a few months after the implementation of the reform. This is probably due to the fact that firms slowly re-optimized their prices and since the difference-in-difference estimator measures the changes in price relative to the control group, the positive treatment effect is most

^{28.} The baseline in the first reform (the adoption of the ERP) is set to November 2000 while the baseline in the latter reform is coded to the month when the legislation repealing ERP was passed in the Danish Folketing (Parliament), i.e., December 2004. These reforms we implemented simultaneously to all markets in Denmark: We hence use the TWFE estimator. We provide an analysis with an extended post-period in Appendix Section A.9. We also study the effects of ERP transitions for non-competitive markets in Appendix Section A.7 and find similar but weaker results.

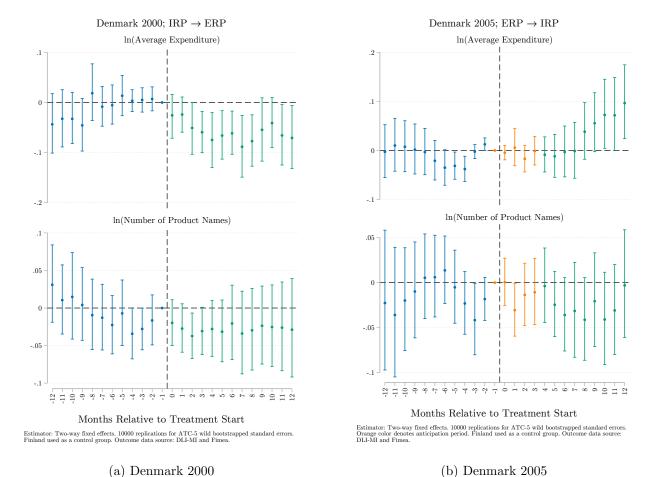


Figure 5: Part II: Main Results

likely due to the fact that prices stopped decreasing or decreased less in Denmark than in the control country (Finland). 29

Our conclusions on the effects of the Danish 2005 ERP \rightarrow IRP reform differ from those of Kaiser, Mendez, Rønde, and Ullrich (2014) who find that the reform substantially decreased pharmaceutical prices. The differences can be explained by differences in the analysed markets and methods. Our difference-in-difference setup covers all generic markets that satisfy our sample selection criteria while Kaiser, Mendez, Rønde, and Ullrich (2014) focus on the statin market using a before-after setup.

5.1.3 Event Study Part III: Stricter IRP Variants

We now turn to the Norwegian 2005 GS \rightarrow SP and the Swedish 2009 IRP \rightarrow Auction-IRP reforms. These reforms are labeled "stricter" because they use polar ways to determine the reference price in regulated markets and imposed either very strict maximum price rules or combined an extreme form of IRP with steep incentives for customers to choose the cheapest product.

In the Norwegian 2005 GS \rightarrow SP reform pre-specified government rules determine the evolution of the reference price after patent expiry. The SP regulatory environment in Norway assigns the same price cap for both the original patented product and its generic alternatives, and the original price cap is based on an average of the prices of the original products in other European Economic Area (EEA) countries. Usually, the price cap is binding or close to binding for the branded manufacturer. Because the SP system forced a gradual decrease in this price cap, the price decrease can be expected to be the largest for products for which the price cap was binding. The reform also required pharmacies to have at least one product at or below the step-price (reference price) in stock. In the vertically integrated Norwegian retail market, wholesale prices for pharmaceuticals are in part just internal prices of the pharmacy chains. After the adoption of the SP model, the pharmacy chains had little incentive to sell generics below the maximum wholesale price (the price cap) or the maximum retail price (the price cap with the retail margin).

In the Swedish 2009 IRP \rightarrow Auction-IRP auction reform, the winner of the first price auction receives close to the entire market demand for each month. The exceptions to the rule are i) patients to whom the physician explicitly prescribes a different product than

^{29.} We have also estimated the effects beyond the 12 months' period shown in Figure 5b. These results are reported in Appendix Section A.9 Figure A.13a

^{30.} We display the SP rule for our observation period in Appendix Table A.4.

the cheapest and forbids substitution, and ii) buyers of the winner of the previous month's auction get reimbursed in the first half of the month. Patients who choose another product than the cheapest or prescribed product must pay the full price, not just the difference in price, out of pocket unless i) holds. The auctions were and are conducted at the package level, which means that there are several winners within an ATC5 market. An analysis of these policies offers new insight on how to design pharmaceutical price regulation policies because these reforms can be used to complement existing IRP regulations.

We start with the Norwegian 2005 GS \rightarrow SP reform: The pre-reform regime is the same which Finland adopted in 2003, i.e., GS without reference pricing. The baseline in our estimations is set to September 2004 when the reform was introduced in the Norwegian Parliament. Our results, shown in Figure 6a (top panel), reveal that average expenditure per dose decreased by approximately 21%. The number of product names is not affected (Figure 6a, bottom panel): The point estimates are positive but imprecisely measured. The post-reform period is only 15 months long since Finland (the control country) imposes a price cut in January 2006. We present the results for the Norwegian 2005 GS \rightarrow SP reform using a post-period of 20 months in Appendix Section A.9 Figure A.14a.

The results of the Swedish 2009 GS \rightarrow Auction-IRP reform are reported in Figure 6b. The pre-reform regime in Sweden was similar to the one that Finland adopted in 2009, i.e., IRP. In contrast to Finland, in Sweden, the customer was reimbursed only when she purchased the cheapest product or the prescribed product already prior to this reform. The baseline in the estimations is set to April 2009 when the Swedish Parliament accepted the law package related to Auction-IRP reform. Our estimates suggest that the reform led to statistically significant decreases between 22%–35% in average expenditure per dose (Figure 6b, top panel; note that again the point estimates are within each others' confidence intervals). Consistent with our previous results, we find (Figure 6b, bottom panel) that even a reform with a large effect on expenditure seems to have no discernible effect on the availability of products.

The importance of the results for the Swedish auction system should not be underestimated. By combining an auction with strong restrictions on the set of products for which consumers are reimbursed, competition increased substantially. In practice, the winner of the monthly auction can expect to gain a very large share of the market. Our results suggest that the Swedish reform works very well from the point of view of curtailing expenditure—

^{31. 22%–35%} refer to ATT estimate confidence intervals presented in Table 4.

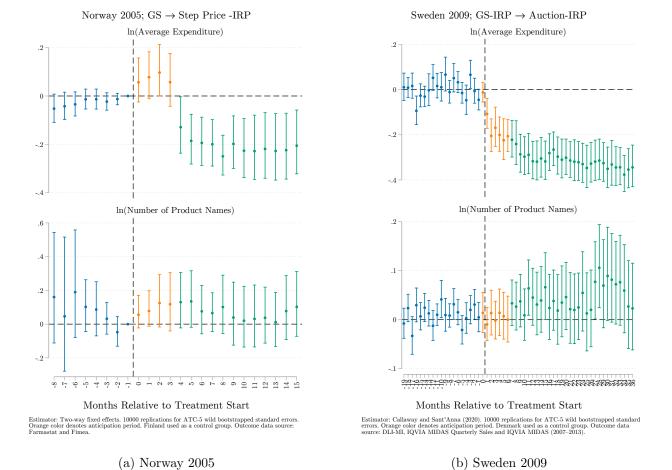


Figure 6: Part III: Main Results

the main objective of pharmaceutical price regulation. However, one should keep in mind that the auction format was introduced almost simultaneously with a tightening of the maximum wholesale price regulation. Our reduced form approach does not allow us to disentangle the effects of the auction format and the tightening of the maximum wholesale price regulation. Finally, as we demonstrate below, the established estimation strategy of studying average prices instead of expenditure would have provided a severe underestimate of the effectiveness of this regulation.

The Swedish 2009 IRP \rightarrow Auction-IRP reform is the second reform where research design robustness with respect to different control groups can be tested. In our preferred specification we use Denmark as the control group and as a robustness check we use Norway or Denmark and Norway as the control group. This robustness check also allows us to experiment what happens when change from a control country (Denmark) that shares the baseline regulation status with the treated country to a control country (Denmark, Norway) that does not (Tazhitdinova and Vazquez-Bare 2023). We find that our results are robust with respect to the choice of the control group even though the baseline regulation also changes.³²

5.2 ATT Results of Main Outcomes

We use ATT estimates to summarize our results and have collected them into Table 4, where each Column is a different reform (in the same order as discussed above) and each Row is dedicated to a specific outcome variable. The results are comparable to the event study results discussed above. The first two Rows contain the results on our main outcome variables; we discuss those results next. The three lower Rows display the results on auxiliary outcome variables; these are discussed in the next Subsection.

We summarize first the results on average expenditure (Row "Average Expenditure per Dose"). The ATT results show significant expenditure decreases going from GS to IRP in Finland in 2009 and from IRP to either SP in Norway in 2005 or to Auction-IRP in Sweden in 2009. Also the results on the Danish reforms mirror nicely the event-study results, albeit with lower point estimates.

All in all, our results suggest four main conclusions: First, that giving consumers incentives to choose cheaper drugs is essential in the settings we study. Second, the results on the Danish reforms suggest that at least in a Nordic context, ERP delivers larger savings

^{32.} We display the robustness results in ATT- and event study format in Appendix A.8.

than regular IRP, albeit smaller than the stricter Norwegian SP and Swedish Auction-IRP regulations. Third, using strict maximum wholesale price rules (SP) and combining them with an auction-setting and steep consumer incentives (Auction-IRP) produces further significant savings. We find that going from the laxest regime—Finland's VGS—to the strictest—Sweden's Auction-IRP—produces savings of 40%.

Our fourth main result is delivered in Row "Number of Product Names" where we present the results regarding product availability. We find that none of the reforms, even those that considerably decreased expenditure per dose, seem to have had any effect on product availability. Our results thus suggest that one of the feared costs of stricter regulation, decreased availability, is not warranted. Our results should however not be taken as definitive evidence in this regard: Our analysis is limited to at most 36 months post reform. Also, our analysis does not cover all aspects of availability. We focus only on markets that are included in the main analysis, and issues related to product entry delays are beyond the scope of our analysis (see Maini and Pammolli 2022).

5.3 ATT Results on Price and Quantity

We have collected our ATT estimates of the effect of the reforms on price and quantity also into Table 4. Turning first to the price results (Row "Average Price per Dose") where the dependent variable is the period-specific arithmetic average of prices per DDD (i.e., measured at the market level), we find coefficients that are clearly smaller in absolute value than the estimated expenditure effects for the Finnish 2009 IRP \rightarrow GS (Column 2), the Norwegian 2005 SP \rightarrow IRP (Column 5) and the Swedish 2009 IRP \rightarrow Auction-IRP (Column 6) reforms. The estimated price effect for the Norwegian reform is at best marginally statistically significant, but the price effect for the Swedish reform is statistically significant. We find price effects that are larger than the expenditure effects for the two Danish reforms and the Finnish 2003 VGS \rightarrow GS reform, although the differences in coefficient size are small.

The most likely explanation for the large differences between estimated expenditure and price effects for the Finnish 2009 GS \rightarrow IRP, the Norwegian 2005 IRP \rightarrow SP and the Swedish 2009 IRP \rightarrow Auction-IRP reforms is that these affected not only prices, but probably even more importantly also increased consumers' financial incentives to choose a cheaper product. When economically meaningful price differences between identical (substitutable) products exist, demand reallocation can lead to a decrease in average ex-

Table 4: Average Treatment Effects

	Part I		Par	t II	Part III		
	Finland 2003 $VGS \rightarrow GS$	Finland 2009 $GS \rightarrow IRP$	Denmark 2000 IRP \rightarrow ERP	Denmark 2005 ERP \rightarrow IRP	Norway 2005 GS \rightarrow SP	Sweden 2009 IRP \rightarrow Auction-IRP	
Average Expenditure per Dose	-0.03	-0.13*	-0.05*	0.04	-0.21*	-0.29*	
	[-0.07, 0.01]	[-0.18, -0.08]	[-0.09, -0.01]	[-0.01, 0.09]	[-0.29, -0.12]	[-0.35, -0.22]	
Number of Product Names	0.01	0.04	-0.02	-0.01	-0.01	0.04	
	[-0.03, 0.05]	[-0.02, 0.10]	[-0.06, 0.02]	[-0.05, 0.03]	[-0.15, 0.15]	[-0.02, 0.09]	
Average Price per Dose	-0.04	-0.05	-0.07*	0.07*	-0.10	-0.14*	
	[-0.12, 0.04]	[-0.09, -0.00]	[-0.12, -0.01]	[0.02, 0.12]	[-0.18, -0.00]	[-0.20, -0.07]	
Number of Doses	0.01	0.04*	0.00	0.07* [0.03, 0.12]	0.04	-0.01 [-0.08, 0.06]	
Package-level Price per Dose	-0.05	-0.10*	-0.09*	0.05	-0.11*	-0.16*	
	[-0.11, 0.02]	[-0.14, -0.07]	[-0.13, -0.05]	[-0.01, 0.12]	[-0.20, -0.01]	[-0.22, -0.09]	

Estimator: Two-way fixed effects (Denmark 2000 and 2005, Norway 2005) and Callaway and Sant'Anna (2020) (Finland 2003 and 2009, Sweden 2009). Outcome data source: DLI-MI (2007–2013), Farmastat (2004–2013), Fimea (2007–2012), IQVIA MIDAS Quarterly Sales and IQVIA MIDAS (2007–2013). Confidence intervals calculated at the 95% confidence level; * = statistically significant at the 95% level. 10000 replications for ATC-5 wild bootstrapped standard errors.

penditure per dose that is larger than the change in average price per dose.

Sweden's Auction-IRP system is a good example of this effect. The Auction-IRP is in practice a monthly auction where the policymaker procures the pharmaceuticals included in the tax-funded funded social insurance. Consumers can only be reimbursed for the product for which they receive the prescription or for the substitutable product that was offered for the lowest price, and they have to pay the price of a more expensive alternative completely out of pocket. This leads to a stark form of the general point we have made earlier: In the Swedish case, where almost all sales are channeled to the cheapest product in the market, the prices of the other products become almost irrelevant. The estimation strategy employed in the existing studies and by us in the analyses of price does not take this substitution effect into account. The conclusion we draw is that when studying price regulation it is not advisable to use prices as a proxy for expenditures when consumer incentives are also affected.

To enable a comparison to the existing literature, we have also estimated price effects using package-level data; these results are reported in Row 'Package-level Price per Dose'. The difference to the Average Price results are mostly modest, suggesting only small bias due to the possible violation of SUTVA: The one exception is the 2009 GS \rightarrow IRP reform in Finland. The small differences in the two price effect estimates are comforting given the prevalence of package-level analyses in the literature, if the objective is to understand what happens to prices. However, these estimates are as different from the expenditure results as are the Average Price per Dose results.

Finally, we find some quantity effects (Row 'Number of Doses' in Table 4). The Finnish 2009 GS \rightarrow IRP reform seems to have increased consumption by 4% while simultaneously reducing expenditure per dose by 13%. The estimated effect on quantity for the Danish 2005 ERP \rightarrow IRP reform seems an anomaly given that we also estimate a positive price effect.

A potential issue with our results is that we do not take into account that different ATC5 markets are of different importance and the results could be driven by small markets. While one could weigh the markets by their size, Solon, Haider, and Wooldridge (2015) show that weighing produces produce the right ATT only under stringent assumptions. This notwithstanding, we have repeated our analysis weighing markets by their pretreatment (monetary) size and found that our results are strengthened. The overall savings going from the laxest to the strictest regime would be over 47% instead of 40% (See Appendix Section A.10).

5.4 Spillovers Between Pharmaceutical Markets

The existing literature has examined the spillovers of regulation to markets not directly affected by the reform in question. We have defined markets at the active ingredient, i.e., ATC5 level, but there are diseases that are treated with pharmaceuticals from more than one ATC5 class. It is possible that a reform indirectly affects those markets that are not directly affected. Spillovers of this type are called *therapeutic competition*, and in some studies, the effect of therapeutic competition on prices has been found to be economically significant (Brekke, Grasdal, and Holmås 2009; Brekke, Holmas, and Straume 2011).

In our test for spillovers, the treatment group consists of ATC5 markets in the treatment country that share the same ATC4 class as an affected ATC5 market but are not directly affected by the reform. The control group consists of the same ATC5 markets in the control country. We use the same estimation methods as in the main analysis and report the ATTs in Table 5. The Danish reforms (2000 and 2005, from IRP to ERP and back) are excluded from the spillover analysis because these reforms influenced all products.³³

The estimated spillover effects on expenditure (Row 'Average Expenditure per Dose') are small in absolute magnitude, negative in sign and statistically insignificant. The effects on availability (Row 'Number of Product Names') are consistently estimated to be very small in magnitude.

^{33.} The results for the monopoly Danish markets are discussed and reported in Appendix Section A.7.

Table 5: Average Treatment Effects (Spillover Samples)

	Pa	rt I	Part III		
	Finland 2003 $VGS \rightarrow GS$	Finland 2009 $GS \rightarrow IRP$	Norway 2005 $GS \to SP$	$\begin{array}{c} \text{Sweden 2009} \\ \text{IRP} \rightarrow \text{Auction-IRP} \end{array}$	
Average Expenditure per Dose	-0.01 [-0.04, 0.03]	-0.03 [-0.06, 0.01]	-0.03 [-0.10, 0.05]	-0.00 [-0.07, 0.06]	
Number of Product Names	-0.01 [-0.03, 0.02]	0.00	-0.02 [-0.08, 0.04]	0.02	
Average Price per Dose	-0.01 [-0.05, 0.02]	-0.03 [-0.17, 0.13]	0.00	-0.02 [-0.07, 0.04]	
Number of Doses	0.07	0.02	0.13*	0.06	
Package-level Price per Dose	0.00 [-0.01, 0.01]	-0.02 [-0.04, 0.00]	-0.04 [-0.12, 0.04]	-0.02 [-0.04, 0.01]	

Estimator: Two-way fixed effects (Norway 2005) and Callaway and Sant'Anna (2020) (Finland 2003 and 2009, Sweden 2009). Outcome data source: DLI-MI (2007–2013), Farmastat (2004–2013), Fimea (2007–2012), IQVIA MIDAS Quarterly Sales and IQVIA MIDAS (2007–2013). Confidence intervals calculated at the 95% confidence level; * = statistically significant at the 95% level. 10000 replications for ATC-5 wild bootstrapped standard errors.

Turning to the secondary outcomes, our market- (Row "Average Price per Dose") and package-level (Row "Package-level Price per Dose") price estimations deliver small and insignificant estimates. The one statistically significant (positive) quantity effect—for the Norwegian IRP \rightarrow SP reform—is possibly a statistical fluke given that the reform was estimated to have no meaningful quantity effect on the directly affected ATC5 markets.

All in all, these results support our decision to define the relevant market at the ATC5 active ingredient level.

6 Conclusions

We investigate the causal effects of different price regulation policies on pharmaceutical expenditure and product availability in the Nordic pharmaceutical markets facing generic competition. Such policies are globally important because pharmaceutical spending has been increasing and because public and private health insurance schemes in many countries have reduced or even removed the price sensitivity of patients which, given the product, may not be that high to start with. We combine product-level price, quantity and sales information with extensive information on different regulatory policies and market institutions that were in place 1999–2010 and analyze the effects of several reforms.

The regimes in our data can for the most part be ordered by the strictness of the price regulations and steepness of the financial incentives of patients to choose a cheaper drugs at the pharmacy. We find that several reforms decrease public expenditure considerably: Moving from the least strict regulatory regime in our data to the strictest reduced expenditure by 40%. The effects on expenditure were, with one exception, greater than those on prices for the four successful reforms that reduced expenditure. This is likely explained by the fact that the successful reforms introduced stronger financial incentives for patients to choose cheaper drugs within the same ATC5 group which led to a reallocation of demand towards cheaper products. This implies that the existing literature that heavily relies on estimating the effect of regulations on prices may have underestimated the effectiveness of price regulations in curbing expenditure. Despite the large effects on expenditure, the reforms did not have an adverse effect on product availability and their effect on quantity was either nonexistent or moderate and positive. Our results suggest that regulations that combine maximum price regulation in markets with intensive forms of generic competition and steep patient incentives to facilitate competition are a powerful tool to decrease pharmaceutical expenditure without having to compromise availability.

References

Acemoglu, Daron, and Joshua Linn. 2004. "Market Size in Innovation: Theory and Evidence from the Pharmaceutical Industry." *The Quarterly Journal of Economics* 119 (3): 1049–1090.

Alpert, Abby. 2016. "The anticipatory effects of Medicare Part D on drug utilization." *Journal of Health Economics* 49 (September): 28–45.

Bergman, Mats, David Granlund, and Niklas Rudholm. 2016. "Reforming the Swedish pharmaceuticals market: consequences for costs per defined daily dose." *International journal of health economics and management* 16:201–214.

Bhattacharya, Jay, Timothy Hyde, and Peter Tu. 2013. *Health Economics*. Macmillan International Higher Education.

Brekke, Kurt R., Astrid L. Grasdal, and Tor Helge Holmås. 2009. "Regulation and pricing of pharmaceuticals: Reference pricing or price cap regulation?" *European Economic Review* 53, no. 2 (February): 170–185.

Brekke, Kurt R., Tor Helge Holmas, and Odd Rune Straume. 2011. "Reference pricing, competition, and pharmaceutical expenditures: Theory and evidence from a natural experiment." *Journal of Public Economics* 95, no. 7 (August): 624–638.

Callaway, Brantly, and Pedro H. C. Sant'Anna. 2021. "Difference-in-Differences with multiple time periods." *Journal of Econometrics* 225, no. 2 (December): 200–230.

Correia, Sergio. 2016. Linear Models with High-Dimensional Fixed Effects: An Efficient and Feasible Estimator. Technical report.

Danzon, Patricia M., and Li-Wei Chao. 2000. "Does Regulation Drive out Competition in Pharmaceutical Markets?" *The Journal of Law and Economics* 43, no. 2 (October): 311–358.

De Chaisemartin, Clément, and Xavier d'Haultfœuille. 2023. "Two-Way Fixed Effects and Differences-in-Differences with Heterogeneous Treatment Effects: A Survey." *Econometrics Journal*.

Dubois, Pierre, Ashvin Gandhi, and Shoshana Vasserman. 2022. *Bargaining and International Reference Pricing in the Pharmaceutical Industry*. Working Paper 30053. National Bureau of Economic Research, May.

Dubois, Pierre, and Laura Lasio. 2018. "Identifying Industry Margins with Price Constraints: Structural Estimation on Pharmaceuticals." *American Economic Review* 108, no. 12 (December): 3685–3724.

Dubois, Pierre, Olivier de Mouzon, Fiona Scott-Morton, and Paul Seabright. 2015. "Market size and pharmaceutical innovation." *The RAND Journal of Economics* 46 (4): 844–871.

Duggan, Mark G, and Fiona Scott Morton. 2010. "The Effect of Medicare Part D on Pharmaceutical Prices and Utilization." *American Economic Review* 100 (1): 590–607.

Einav, Liran, Amy Finkelstein, and Heidi Williams. 2016. "Paying on the Margin for Medical Care: Evidence from Breast Cancer Treatments." *American Economic Journal: Economic Policy* 8, no. 1 (February): 52–79.

Einav, Lirav, Amy Finkelstein, and Maria Polyakova. 2018. "Private Provision of Social Insurance: Drug-Specific Price Elasticities and Cost Sharing in Medicare Part D." American Economic Journal: Economic Policy 10(3):122–153.

Feng, Josh, Thomas Hwang, and Luca Maini. 2023. "Profiting from Most-Favored-Customer Procurement Rules: Evidence from Medicaid." *American Economic Journal: Economic Policy* 15 (2): 166–197.

Frech, HE, Mark V Pauly, William S Comanor, and Joseph R Martinez. 2023. *Pharmaceutical Pricing and R&D as a Global Public Good*. Technical report. National Bureau of Economic Research.

Herr, Annika, and Moritz Suppliet. 2017. "Tiered co-payments, pricing, and demand in reference price markets for pharmaceuticals." *Journal of Health Economics* 56 (December): 19–29.

Iqvia. 2021. "Global Medicine Spending and Usage Trends: Outlook to 2025."

Kaiser, Ulrich, Susan J. Mendez, Thomas Rønde, and Hannes Ullrich. 2014. "Regulation of pharmaceutical prices: Evidence from a reference price reform in Denmark." *Journal of Health Economics* 36 (July): 174–187.

Lakdawalla, Darius N. 2018. "Economics of the Pharmaceutical Industry." *Journal of Economic Literature* 56, no. 2 (June): 397–449.

Lee, Junghee, Hyun Seok (Huck) Lee, Hyoduk Shin, and Vish Krishnan. 2021. "Alleviating Drug Shortages: The Role of Mandated Reporting Induced Operational Transparency." *Management Science* 67, no. 4 (April): 2326–2339.

Leopold, Christine, Sabine Vogler, Aukje K Mantel-Teeuwisse, Kees de Joncheere, Hurbert GM Leufkens, and Richard Laing. 2012. "Differences in external price referencing in Europe — A descriptive overview." *Health policy* 104 (1): 50–60.

Lexchin, Joel. 2021. "Time to market for drugs approved in Canada between 2014 and 2018: an observational study." BMJ Open 11 (7).

Maini, Luca, and Fabio Pammolli. 2022. "Reference Pricing as a Deterrent to Entry: Evidence from the European Pharmaceutical Market." *American Economic Journal: Microeconomics Forthcoming*.

Mammen, Enno. 1993. "Bootstrap and Wild Bootstrap for High Dimensional Linear Models." The Annals of Statistics 21 (1): 255–285.

Ornaghi, Carmine. 2009. "Mergers and innovation in big pharma." *International Journal of Industrial Organization* 27 (1): 70–79.

Pavcnik, Nina. 2002. "Do Pharmaceutical Prices Respond to Potential Patient Out-of-Pocket Expenses?" The RAND Journal of Economics 33 (3): 469–487.

Roodman, David, Morten Ørregaard Nielsen, James G. MacKinnon, and Matthew D. Webb. 2019. "Fast and wild: Bootstrap inference in Stata using boottest." *The Stata Journal* 19, no. 1 (March): 4–60.

Simonsen, Marianne, Lars Skipper, Niels Skipper, and Anne Illemann Christensen. 2021. "Spot price biases in non-linear health insurance contracts." *Journal of Public Economics* 203 (November): 104508.

Solon, Gary, Steven J. Haider, and Jeffrey M. Wooldridge. 2015. "What Are We Weighting For?" The Journal of Human Resources 50 (2): 301–316.

Starc, Amanda, and Ashley Swanson. 2021. "Preferred pharmacy networks and drug costs." *American Economic Journal: Economic Policy* 13 (3): 406–46.

Stomberg, Christopher. 2016. "Drug Shortages, Pricing, and Regulatory Activity." In *Measuring and Modeling Health Care Costs*, 323–348. University of Chicago Press, October.

Tazhitdinova, Alisa, and Gonzalo Vazquez-Bare. 2023. Difference-in-Differences with Unequal Baseline Treatment Status. Working Paper, Working Paper Series 31063. National Bureau of Economic Research, March.

Yin, Wesley. 2008. "Market incentives and pharmaceutical innovation." *Journal of Health Economics* 27 (4): 1060–1077.

Yurukoglu, Ali, Eli Liebman, and David B. Ridley. 2017. "The Role of Government Reimbursement in Drug Shortages." *American Economic Journal: Economic Policy* 9, no. 2 (May): 348–382.

A Appendix

The Subsections of the Appendix are ordered as they are referred to in the main text.

A.1 Nordic Countries, Reimbursement systems and Pharmacy Markuprules

This Subsection provides an overview of the four Nordic countries included in this study and gives details on the reimbursement systems in use, as well as the pharmacy markup-rules in place.

Country overview. Figure A.1 shows the Nordic countries on a map and Table A.1 displays some relevant descriptive statistics of the four countries. All countries except Norway are EU member states. All four countries belong to the EEA, meaning that Norway also follows many EU regulations. Finland is the only Nordic country without her own national currency, having adopted the Euro in 2002. In 2007 Sweden had the largest population, which was more than 9 million, while Norway's population of 4.7 million was the smallest. The percentage of population aged 65 years and older was also the highest in Sweden and the lowest in Norway. In 2007, GDP per capita was the highest in Norway and the lowest in Finland. Sweden had the largest pharmaceutical market with total sales of more than 2.7 billion euros in 2007, while Norway had the smallest market with sales of 1.46 billion euros. At 8.5%, the Swedish pharmaceutical market was also the largest relative to GDP. In Finland and Denmark, the pharmaceutical market represented approximately 6.3% of GDP, and in Norway 3.3%.

Figure A.2 displays the core demographics of the Nordic countries we study. Panel A.2a displays the (log) Years of life lost from mortality (YLL) which represents how many years are lost due to premature mortality. The differences between countries are quite small and the trend is decreasing in all countries. Panel A.2b in Figure A.2 displays the median equalized net income (PPS) and panel Panel A.2c displays (log) population. Sweden is the largest Nordic country (Panel A.2c). During our observation period there are no sudden population increases in any of the examined countries. Norway is the wealthiest country (Panel A.2b). Excluding Norway, our PPS-measure evolves quite similarly in the studied countries.

Demographic trends presented in Figure A.2 show that demographics that are closely related to pharmaceutical expenditures evolve similarly in in the studied countries. For

Table A.1: Nordics Descriptive Statistics

	Population	Population aged 65 and above, %	EU Member	EEA Country	Currency	GDP per capita	Market Size, €Mio	GDP share, %
Denmark	5.4	15.5	Yes	Yes	Danish krone	30800	1951	1.16
Finland	5.3	16.5	Yes	Yes	Euro	29900	1879	1.19
Norway	4.7	14.6	No	Yes	Norwegian krone	44200	1444	0.70
Sweden	9.1	17.4	Yes	Yes	Swedish krona	32300	2862	0.97

Notes: The values are from 2007 and population is expressed in millions. The second column displays the percentage of total population that were aged 65 and above. The EU member column indicates whether a country is an European Union member state and the EEA country column indicates whether the countries belong to the European Economic Area. The currency column shows which currency is used in each country. GDP per capita is expressed in euros (PPS). Market size is expressed in millions of euros and is calculated as the sum of sales using pharmacy purchase prices (wholesale prices) in 2007. Market share denotes the share that the pharmaceutical market forms of the country's total GDP. Outcomes data source: DLI-MI, Farmastat, Fimea, IQVIA MIDAS Quarterly Sales and IQVIA MIDAS (2007).

some demographics there are clear level differences, but all countries share the same approximate trend during our study period.

Reimbursement systems. Table A.2 summarizes the structure of reimbursement systems in Nordic countries. Although their reimbursement systems are quite similar, individual countries have different reimbursement rates and annual out-of-pocket ceilings. The Finnish reimbursement system is the least generous, because the smallest reimbursement rate is 42% and the annual out-of-pocket cost ceiling is 610 euros, almost three times higher than in Norway or Sweden.

There are two distinct approaches to public reimbursement of pharmaceutical in the Nordic countries: A needs-based and a product-specific calculation. In the needs-based system, used in Sweden and Denmark, the level of reimbursement and the consumer's copayment are tied and capped to the consumer's annual pharmaceutical spending. The share of reimbursement (co-payment) increases (decreases) as the consumer spends more on reimbursed pharmaceuticals. After crossing a legal threshold, the consumer is fully reimbursed. In addition, the state typically grants full reimbursement for certain drugs and vulnerable groups. In the product-based reimbursement system, used in Finland and Norway, public reimbursement varies product by product. The level of reimbursement (usually 40% to 100%) is based on the severity of the disease; however, annual consumer spending is capped as in the needs-based system. The crucial difference is that in the needs-based system, conditional on the price negotiations with the manufacturer, the government only decides whether a product receives reimbursement or not. In the product-specific reimbursement system, the government also decides on the level of reimbursement product by product.

Pharmacy mark-ups. All countries except Norway have a mathematical formula for

Table A.2: Reimbursement Systems in the Nordics

	Reimbursement % **	Annual out- of-pocket ceiling	Out-of-pocket threshold	Time period for annual ceiling	Reference countries (2012)	Type of referencing	Annual reimburse- ment expenditure
Panel A: Product specific							
Finland	Basic: 42% Lower special: 72% Higher special: 100%	610 EUR **	N/A	calendar year	EEA (excl. Croatia) + UK	directional	1142 EUR***
Norway	Standard: 64% Serious contagious diseases: 100%	205 EUR**	N/A	calendar year	avg. of 3 low- est countries	direct	11480 NOK**
Panel B: Consumption based							
Sweden	901-1700 SEK: 50% 1701-3300 SEK: 75% 3301-4300 SEK: 90% 4301 SEK: 100%	194 EUR **	900 SEK**	calendar year	N/A	N/A	21500 SEK**
Denmark	0-480 DKK: 0% 480-1165 DKK: 50% 1165-2730 DKK: 75% > 2730 DKK: 85%	Only for chronically ill after 472 EUR **	480 DKK**	continuous 12 month period	N/A	N/A	11447 DKK***

Notes: Reimbursement (%) = Different reimbursement categories and reimbursement classes; Annual out-of-pocket ceiling = Annual limit for out-of-pocket expenditures; Out-of-pocket threshold = Threshold for out-of-pocket expenditure; Time period for annual ceiling = Time window where the out-of-pocket annual ceiling contributes; Reference countries (2012) = Countries that are used in external reference price calculations; *: 2005, **: 2006, **: 2007, Annual reimbursement expenditures are expressed in millions. Sources: PPRI, KELA (The Finnish Social Insurance Institution) and Leopold, Vogler, Mantel-Teeuwisse, Joncheere, Leufkens, and Laing (2012).

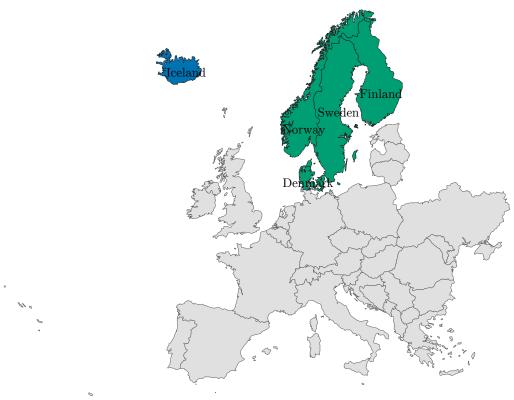
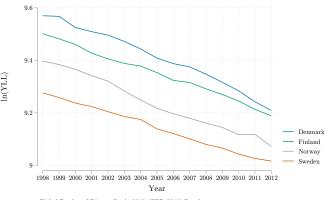


Figure A.1: Nordic Countries in Europe

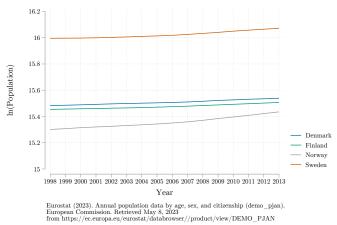
Colored countries denote the Nordic siblings. Green denotes the Nordic countries included in this study.





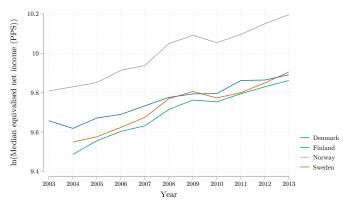
Global Burden of Disease Study 2019 (GBD 2019) Results. Seattle, United States: Institute for Health Metrics and Evaluation (IHME), 2020. Available from https://vizhub.healthdata.org/gbd-results/.





(c) ln Population

Figure A.2: Demographic Trends in the Nordics



Eurostat (2023). Mean and median income by age and sex - EU-SILC and ECHP surveys (ILC_DI03). European Commission. Last updated April 27, 2023. Retrieved May 8, 2023 from https://ce.europa.eu/eurostat/databrowsey/iew/lic_di03/default/table?lang=en

(b) ln Income

the pharmacy mark-up, i.e., pharmacies do not decide retail prices. Table A.3 shows how these formulas (we display formulas for the year 2009) convert the pharmacy purchase price (PPP) into the pharmacy retail price (PRP), which is the price from which reimbursements are calculated. The main takeaway from the table is that the retail price formulas transmit changes in pharmacy purchase prices to pharmacy retail prices.

Norway is a slight exception because the institutional setting allows pharmacies to charge a lower markup than what the formula presented in Table A.3 would yield.

Table A.3: Pharmacy Retail Price Formulas

Effective Period	Type	Register Price
26/03/2004 - 21/03/2007	Denmark Prescription drugs (DDK) <= 30 30-60 > 60 Finland	$PPP + 0.61 \times (0.6 \times PPP + 1.8 \text{ DKK})$ $PPP + 0.61 \times (0.4 \times PPP + 7.8 \text{ DKK})$ $PPP + 0.61 \times (0.2 \times PPP + 19.8 \text{ DKK})$
1/1/2003 - 1/1/2014	Prescription drugs (€) 0-9.25 9.26-46.25 46.26-100.91 100.92-420.47 > 420.47	$1.5 \times \text{PPP} + 0.50 \in$ $1.4 \times \text{PPP} + 1.43 \in$ $1.3 \times \text{PPP} + 6.05 \in$ $1.2 \times \text{PPP} + 16.15 \in$ $1.125 \times \text{PPP} + 47.68 \in$
1/1/2001 - 1/1/2009	Norway Prescription drugs (NOK) 0-200 > 200 Sweden	$1.08 \times PPP$ $1.05 \times PPP$
15/7/2009 - 1/11/2009	Prescription drugs (SEK) 0-75 > 75-300 > 300-6000 > 6000	$PPP \times 1.20 + 31.25$ $PPP \times 1.03 + 44.00$ $PPP \times 1.02 + 47$ PPP + 167.00

Notes: Effective Period = Period when the retail price formula was in use; Type = Price range where the retail price formula applies; Register Price = How list price is determined from the wholesale price.

A.2 Branded, generic and parallel imported pharmaceuticals

By origin, there can be three types of products in a given ATC5 category: the unique branded (original patented) product that was (is) protected by a patent;³⁴ generic products that feature the same molecule as the original drug, but are most of the time produced by different firms than the branded drug (brand manufacturers sometimes have their own generic products, too); and third, so-called parallel imported products, which are manufactured by the producer of the branded drug, but originally sold to a different geographic market (= EU Member State), bought there and shipped to the country in question by an intermediary company (parallel importer).

Figure A.3 illustrates how three different substitutable products (the original patented product, the parallel import, and the generic copy) look. The packages are from Finland and all three products contain the same active ingredient venlafaxine (ATC5: N06AX16), which is an antidepressant. If the patient received a prescription for the branded product displayed on top of the figure, substitution could be made for the products at the bottom of the figure.

The branded product has a unique product name "Efexor". The generic product is at the bottom left, and the parallel imported product is at the bottom right. All packages provide information on package size (98 tablets), strength (150 mg) type of product, product id (Nordic Article Number (VNR)) and the company that sells the product. All packages contain detailed instructions related to pharmaceutical use and information on possible adverse effects on the use of the product. The parallel imported product and the standard generic are produced by the same firm.

^{34.} Parallel imports may take place while patent protection is in place.

Figure A.3: Example of a branded (top), generic (bottom left) and parallel (bottom right) imported pharmaceutical



A.3 EU Regulations, Price Regulation Regimes and Minor Price Regulation Reforms

Here we provide more details on the regulatory institutions regarding market entry at the European level (A.3.1), and then details for the price regulation that we study in each of the four countries in our data: Finland (A.3.2), Denmark (A.3.3), Norway (A.3.4) and Sweden (A.3.5). We close the Subsection with a discussion of minor price regulation reforms (A.3.6).

A.3.1 Relevant EU Regulations

We briefly describe the regulatory process for a given pharmaceutical product to be allowed to enter the market in a EU Member State. There are two routes: obtaining market authorization and (after that has been granted), so-called parallel imports.

Obtaining market authorization. There are four distinct processes through which a product can receive market authorization for sale in the European common market and in its Member States. Three of these processes, namely, the centralized, decentralized, and mutual recognition processes, are based on legislation passed by the EU. The fourth option, national market authorization, is regulated by the Member States themselves. In the centralized procedure, authorization is granted by the European Medicines Agency (EMA) through which the authorization is valid in the European Economic Area (EEA).³⁵ In the decentralized process, a company simultaneously applies for market authorization in more than one Member State through the respective national authorities, on the condition that the product has no market authorization in any of the Member States. The decentralized process is led by one of the Member States, and other national authorities provide assistance in the process. In the mutual recognition process, a company applies for market authorization for a product that has already been approved in at least one Member State.

Parallel imports. Parallel imports are a feature of European pharmaceutical markets. The market share of parallel imported products varies from country to country, but the possibility of parallel imports from within the EU exists in all EU Member States and banning them is illegal.

A.3.2 Finland

Up to March 2003: VGS. Throughout the 1990s, the Finnish VGS required prescribing physicians to actively opt-in to allow GS to occur. In practice, GS and prescription of generics was almost non-existent.³⁶

April 2003–March 2009: GS. The Finnish government adopted mandatory GS in April 2003.³⁷ In the new regime, pharmacies were required to stock one of the products at or close to the cheapest price.³⁸ The reimbursement of a consumer was not affected if she decided against substitution; the monetary incentives to substitute were small in drug categories with high reimbursement rates. Unlike Finland, other countries combined substitution policies with financial incentives for the patient. After 2009 GS continued to be applied for non-reimbursed and parallel imported products.

^{35.} The EEA covers the EU Member States and Iceland, Liechtenstein, and Norway.

^{36.} See the government proposal HE 165/2002 vp, page 6.

^{37.} See 80/2003 §57b.

^{38.} Pharmacies were required to offer substitution if the prescribed product was either $2 \in (\text{retail price less})$ than $40 \in)$ or $3 \in (\text{retail price more than } 40 \in)$ more expensive than the cheapest product in the substitution group.

April 2009—: **IRP.** To address the incentive problems related to GS and high reimbursement rates, Finland adopted IRP in April 2009.³⁹ Reference pricing was applied to products that were publicly reimbursed and to which at least one generic substitute was available. The reference price in a substitution group is the highest reimbursed retail price. During our sample period, the reference price was defined as the cheapest retail price within the reference price group 1.5€ (retail price less than 40€) or 2.5€ (retail price greater than 40€). Reference prices were updated quarterly. If the price of the purchased product exceeds the reference price, the consumer is reimbursed on the basis of the reference price and pays the price difference out of pocket. Parallel imports were not included in the system until 2017.⁴⁰

In addition to the above major reforms, Finland has implemented minor reforms in the 2000s. The first minor reform in 2006 imposed that the price cap for new entrants should be 40% lower than the cap of the original product. The second reform was a 5% price cap cut on all reimbursement drugs. These minor reforms are explained in more detail in Appendix Section A.3.6.

A.3.3 Denmark

May 1997–Oct. 2000: IRP. In 1997, Denmark adopted mandatory substitution of generics on top of an existing RP system for generics.⁴¹ This regime corresponds to our definition of an IRP system. The Danish system required pharmacies to substitute to the cheapest interchangeable available product unless the price differential was (roughly) less than 5%.⁴² The prescribing physician could still opt out of substitution for medical reasons. If a consumer did not buy the reference-priced product, she was required to pay the price difference between the products out of pocket.

Nov. 2000– Dec. 2004: ERP. Denmark switched from generic IRP to ERP in November 2000. Reference prices were calculated using prices in other European countries.⁴³ If a product was sold only in Denmark or the domestic price was lower than the

^{39.} See Chapter 6 §18-§23

^{40.} See 1100/2016 Chapter 6 §18. Before this, parallel imports could be included in reference price groups if other generics were on the market. After the 2017 change, this requirement was lifted. In practice, this allowed RP to start even during the patent period.

^{41.} See BEK nr 308 af 06/05/1997 §36–§37.

^{42.} This "price corridor" in Denmark has remained mostly the same since 1996. See BEK nr 724 af 01/08/1996 §37.

^{43.} EU-15 excluding Greece, Luxembourg, Spain, and Portugal.

price calculated using the other European prices, the price in Denmark was used as the reference price.

The implementation process of ERP on the Danish market had already started in 1998 when manufacturers of new pharmaceutical substances (defined by market entry after April 1, 1997) were required to inform the Danish government of their prices in other European countries.⁴⁴ The process was finalized in November 2000 when the Danish government stopped the reimbursement of all products that exceeded their European average prices.⁴⁵ While the use of ERP was included in the legislation in summer 2001, the regulator started applying ERP already in November 2000.⁴⁶ We use November 2000 as the date of the reform.

Jan. 2005—: IRP. ERP lasted until April 1, 2005, when it was replaced by IRP. ⁴⁷ In the new regime, the reference price was again the lowest domestic price within a substitution group. The government also abolished the ERP of patented pharmaceuticals.

There are two other institutional changes that occur in Denmark during our study period that are not directly related to the reforms studied. The first is the overhaul of the reimbursement system. In March 2000, the Danish government adopted a new reimbursement model in which the fixed product-specific reimbursement level was replaced by a system in which the patient's reimbursement level was non-linearly calculated based on spending (see Simonsen, Skipper, Skipper, and Christensen 2021). The other change is a price freeze agreement between the Danish government and an association of pharmaceutical manufacturers. We explain these changes in more detail in Appendix A.3.6.

A.3.4 Norway

March 2001–2005: GS. Norway adopted a GS policy and liberalized the pharmacy sector simultaneously in 2001.⁴⁸ Prior to the 2001 reform Norway had an ERP system.⁴⁹ Thus, the GS system with ERP elements is the baseline regulatory regime for subsequent

^{44.} The government would then use this price information to cap the public reimbursement to the average of the two lowest prices.

^{45.} As stated in LOV nr 1031 af 23/11/2000 §7j.

^{46.} See LOV nr 495 af 07/06/2001 §7d.

^{47.} See LOV nr 1431 af 22/12/2004 §7d.

^{48.} We do not study the effects of this substitution reform because the effects of the reform cannot be separated from the effects of pharmacy market liberalization. For further information, see LOV-2000-06-02-39.

^{49.} The maximum reimbursement price was the average of the three lowest prices of the original patented product in the other EEA countries.

reforms in Norway.

If the consumer substituted to the cheapest alternative in that regime, she had to pay the difference in price between the cheapest alternative and the chosen product out of pocket.⁵⁰ The Norwegian GS did not explicitly require pharmacies to substitute for a cheaper alternative available; instead, pharmacies are incentivized to offer GS.⁵¹

Jan. 2005—: The Step-Price regime. Norway implemented a major change to the GS system in 2005 by introducing the current SP system. After generic entry has taken place, the maximum reimbursement price (now called the Step-Price) gradually decreases.⁵² The base level for the price is established as the maximum allowed retail price at the time of generic entry. If a consumer decides not to buy the product priced at the Step-Price, she is required to pay the difference in price out of pocket. The first price cut occurs at the beginning of generic competition, followed by further cuts after 6 months and 12 months.⁵³ The magnitude of the price cuts is related to the total sales prior to generic entry: During our sample period, the first price cut was 30%, the second between 40–50%, and the third between 50–70%.⁵⁴ The Step-Price acts as a reference price whose future development is known and fixed by the government. The reform also required pharmacies to keep at least one product at or below the reference price in stock.

Step Price-IRP Schedule. Table A.4 shows how the SP regulation worked during our observation period. SP regulation uses predetermined rules to set the price where reimbursement is paid, instead of competition determining the reimbursement price. The price formulas for SP regulation start from the onset of generic competition, and the formula depends on the size of the market before the generic competition started. Table A.4 also shows that the steps of price decreases change over time. In the price formulas

^{50.} In comparison to the Finnish GS, the Norwegian regime provided financial incentives while the Finnish policy did not. See LOV-2000-06-02-39 for further information.

^{51.} Originally, if pharmacies sold a product whose wholesale price was below the maximum wholesale price, they could keep 50% of the difference between the retail price and the maximum retail price. See FOR-2001-12-17-1537 §12-3. Generic alternatives received the same maximum pharmacy purchase price as the original manufacturer. The difference was calculated from the product's maximum wholesale price with the maximum retail markup and the actual retail price, which was also subject to the maximum markup rule. Between 2003 and 2005 eight active ingredients were subject to IRP (called the index price). These active ingredients are excluded from our estimation sample for the Norwegian 2005 IRP \rightarrow SP reform; for a review of the index price system, see Brekke, Grasdal, and Holmås (2009) and Brekke, Holmas, and Straume (2011).

^{52.} The Norwegian Medicines Agency determined when generic entry has taken place. In practice, it requires that the generic product be available in pharmacies.

 $^{53.\ {\}rm Appendix\ Section\ A.3.4\ shows\ the\ price\ cut\ timing\ in\ the\ Step-Price\ system}.$

^{54.} See FOR-2004-12-17-1712.

Table A.4: The Step Price Schedule

Starting from	Step-Price Calculation					
01/01/2005	<100 Mill. NOK 12 months before		>= 100 Mill. NOK 12 months b	efore		
	1. Generic competition	-30%	1. Generic competition	-30%		
	2. 6 months after	-40%	2. 6 months after	-50%		
	3. 12 months after	-50%	3. 12 months after	-70%		
01/01/2007	<100 Mill. NOK 12 months before		>= 100 Mill. NOK 12 months b	efore	Cut rate	
	1. Generic competition	-30%	1. Generic competition	-30%	Simvastatin	-85%
	2. 12 months after	-55%	2. 12 months after	-75%		
	3. Final cut if sales >100 Mill. NOK	-85%	3. Final cut if sales >100 Mill. NOK	-85%		

Notes: This table provides the two first Stepped Price rules from Norway. The starting price for calculating the Stepped-Price is the price cap of the original at the start of generic competition. See FOR-2004-12-17-1712 and FOR-2006-12-01-1327 for further details.

valid from January 1, 2005, the largest price decrease was 70% but this was changed to 85% in formulas starting January 1, 2007.

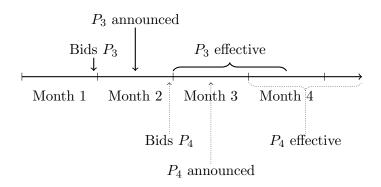
A.3.5 Sweden

Nov. 2002–2009: IRP. Sweden adopted IRP in November 2002.⁵⁵ The system required pharmacies to substitute with the cheapest substitutable product available. Unlike other Nordic countries, patients were reimbursed only for the prescribed product or the product to which the pharmacy offered substitution: This means that if a patient wanted to buy another product (without the decision of the prescribing physician), she would pay the full price (not the price difference between the chosen and the cheapest product) out of pocket. A notable factor in the Swedish GS system was the fact that all pharmacies in the country were operated at the time by the government-owned monopoly Apotek Ab until 2009, when the pharmacy sector was liberalized.

Dec. 2009—: Auction-IRP. Following the liberalization of the pharmacy sector in 2009, a new interpretation of the law was adopted: The cheapest product would be determined at the national level. This led to the establishment of the current "Product of the Month Auction" system, where pharmaceutical manufacturers issue monthly prices (bids) within a given package size and a substitution group. Winners are called products of the month. Consumers can in practice only choose between the prescribed product and the product of the month, although for the first two weeks of each month, the legislation allows pharmacies to also substitute with the winning product of the previous month. The

^{55.} See Lag (2002:160) om läkemedelsförmåner m.m. §21. Before 2002, Sweden used IRP without GS. In practice, this meant that the government issued mandatory price decreases as a function of the lowest price of substitutable products.

Figure A.4: Auction-IRP Timing



winner and the previous winner thus have high market shares. The government also declares secondary and third alternatives to the winner in case the initial winner has problems in supplying the market.

During our sample period, Sweden also implemented minor price regulation reforms that are related to price caps and the mechanics of the Auction-IRP system. Price caps were subject to one-time cuts in 2009, and later price cap rules within substitution groups were changed.⁵⁶ The Auction-IRP system was reformed in 2011 by redefining substitutable products, and in 2012 the backup winners were included in the regulation. These minor reforms are explained in more detail in Appendix Section A.3.6.

Auction-IRP timing. Figure A.4 shows how auction timing works in the Swedish $2009 \text{ IRP} \rightarrow \text{Auction-IRP}$ reform. In the Auction-IRP system, bids for prices are submitted before they become effective. If a bid is submitted during Month 1, the bid is revealed to all participants during Month 2, and the price is effective during Month 3. Another important feature of the timing of the Auction-IRP is that winning the auction provides benefits only for one month at a time. Regulation allows the previous month's winning product to be dispensed two weeks into the month. This is represented by the curly brackets denoting the effective prices in Figure A.4.

⁵⁶. It important to note, that the Swedish Pharmaceutical industry proposed the 2009 price cut to regulator.

Table A.5: Minor Price Regulation Reforms in the Nordics 2001-2012

Country	Year	Reform Type	Studied Reform(s)
Denmark	2000-	Reimbursement system overhaul	Denmark 2000
Denmark	2001-	Price freeze agreements suggested by industry	Denmark 2000, 2005
Norway	2003 – 2004	IRP for 8 active ingredients	Norway 2005
Finland	2006	5% Price cap cut for reimbursed products	Denmark 2005, Norway 2005
Finland	2006-	Price cap rule for generic entrants	Norway 2005, Finland 2009
Sweden	2009	Mandatory price cap cut & pharmacy margins	Sweden 2009
Sweden	2010-	Substitution group redefinition & back-up products	Sweden 2009
Sweden	2011-	Mandatory price caps in substitution groups	Sweden 2009
Sweden	2012	Back-up winners in Auction-IRP system	Sweden 2009

Notes: Country = Country where the minor reform happened; Year = When the minor reform happened; Reform Type = Minor reform type; Studied Reform(s) = Reforms that are studied in the paper, where the minor reform happens during the sample period.

A.3.6 Minor Price Regulation Reforms

During the periods of our estimation samples, Nordic countries implemented reforms that we categorize as minor. These reforms create changes, e.g., in the way pharmaceuticals are priced and reimbursed.⁵⁷ We have collected the minor reforms into Table A.5: There are two minor reforms in Denmark, two in Finland, one in Norway, and four in Sweden during our observation periods.

Denmark. During our sample periods, the Danish regulator made price cap or price "freeze" agreements with pharmaceutical firms represented by the Danish Association of the Pharmaceutical Industry (LIF-DEN). Not all firms present in the Danish market are represented by LIF-DEN, and this leads to a situation where price caps were not imposed on all products. In these agreements, the Danish regulator and the firms agree that a market price from a certain date acts as the price cap for a period of time. These price agreements were in place during our observation periods. ⁵⁸

In March 2000, the Danish government adopted a new reimbursement model where the fixed product-specific reimbursement level was replaced by a system where the patients' reimbursement level was non-linearly calculated based on spending (see Simonsen, Skipper,

^{57.} Changes in the reimbursement rates, reimbursement ceilings and OTC deregulation policies (pricing and distribution) are excluded from the table. OTC-deregulation policies are excluded because we study prescription drugs.

^{58.} Price cap agreement signed on 19.3.2019 states that the first price cap agreement was signed in 2006, but working paper version of Kaiser, Mendez, Rønde, and Ullrich 2014 mentions that the price agreements between LIF-DEN and the Danish government were already implemented in 2001.

Skipper, and Christensen 2021). This reimbursement system change happens in the preperiod of the Danish 2000 reform. The reimbursement reform gave incentives to persons who already exceeded their annual pharmaceutical cost limit to stock pharmaceuticals, because after the reform they faced 100% coinsurance. We see this effect as a pre-period increase in quantity in Figure A.16a where the outcome is the market size in DDD. The change in the reimbursement system does not affect average expenditure because pricing did not respond to the change.

Finland. In 2006 Finland implemented two minor reforms related to pharmaceutical pricing. The first reform was a 5% price cap cut for reimbursed pharmaceuticals, and the second was the price cap rule for generic products. The price cap cut reduced the maximum price of the reimbursed product and led to a decrease in wholesale and retail prices for the products for which the price cap was binding.⁵⁹ These price cuts can indirectly influence the evaluation of the Danish 2005 IRP \rightarrow ERP and the Norwegian IRP \rightarrow SP reforms, because we use Finland as the control group. We deal with this issue by constraining the sample period to the time before the price cut. We present results where the sample period is not constrained by the price cut in Appendix Section A.9.

The second Finnish reform in summer 2006 was the formalization of how price caps of the generic entrants are calculated when the first generic product enters the Finnish market. This reform formalized that generic products are accepted into the reimbursement system only if they are priced at least 40% lower than the cap of the originator product. If a company does not accept this proposed cap, the product can enter the market, but it is not eligible for public reimbursement. This regulation change does not complicate our empirical analyses like the implemented price cut, because the markets we study had generic entry before our observation period.

Norway. The only minor change in price regulation in Norway during our sample period was the IRP-experiment (Index-Price) for eight active ingredients (=ATC5 categories). This policy was in place 2003–2004. The Index-Price policy was an IRP variant similar to the Finnish 2009 policy.⁶⁰ This means that the Index-Price policy change occurs

^{59.} See 885/2005 for additional details.

^{60.} Index price at producer price (so-called GIP) level was calculated as the total turnover value for all products in the index price group for the period, divided by the total quantity sold during the period. The index price was determined at the producer level (GIP), to which a 10% maximum profit was added for the benefit of the wholesalers. The final index price was obtained by adding the maximum pharmacy mark-up to the index price at the PPP (pharmacy purchase price) level. The final index prices were in PRP (pharmacy retail price). See Brekke, Holmas, and Straume (2011) and Brekke, Grasdal, and Holmås (2009) for more details.

during the pre-period of the SP reform. To ensure that all treated markets have the same pre-period regulation regime, we discard the markets where index-price regulation was implemented. Brekke, Grasdal, and Holmås (2009) report that the Index-Price policy was shut down because the policy did not achieve the desired amount of cost savings and price reductions.

Sweden. The minor reforms in Sweden are related to Auction-IRP reform implementation, (re)definition of back-up winners in Auction-IRP regulation and price cap changes. Auction-IRP reform was a package of four regulatory changes that were implemented before and after the start of the monthly auctions. The reform cut mandatory price caps, changed pharmacy margins, redefined substitution groups and specified the use of back-up products in the case of supply problem. In addition to these changes, Sweden changed how price caps are formulated and tweaked the Auction-IRP reform back-up product selection criteria during our sample period.

Sweden introduced a mandatory one-time price cap cut for off-patent products in markets with substitutable products and generic competition in July 2009 as a part of the Auction-IRP reform package (Bergman, Granlund, and Rudholm 2016).⁶¹ The unique feature of this price cut is that it was proposed by Swedish Association of the Pharmaceutical Industry (LIF-SWE), the trade association for the research-based pharmaceutical industry in Sweden.⁶² Prices of off-patent products were capped at 35% of the price of the originator product that prevailed 12 months before the expiration of the patent.⁶³ The price cap decrease was planned so that after the price cut the originator price cannot be lower than the cheapest comparable generic product. Price caps were implemented if three conditions were met: i) An identical generic product must have been sold at a price below 30% of the price during patent protection by a firm that achieved at least 10% of sales within the substitution group; ii) there must have been positive generic sales for at least 4 months; and iii) at least 6 months must have passed since generic competition was first established in the exchange group. Only when all three conditions are met the new price cap becomes effective (Bergman, Granlund, and Rudholm 2016).

In addition to the 2009 mandatory one-time price cap cut for off-patent products, the

^{61.} See The price cut announcement for additional details.

^{62.} The Swedish price cut resembles the Danish price freeze agreements that are based on the negotiations between pharmaceutical industry and the government.

^{63.} For products that experienced patent expiration before October 2002, the price cut is either calculated from the price that was applied on September 2001 or from the price that was applied 12 months before the patent expiration.

Auction-IRP reform package contained three other minor regulatory changes (Bergman, Granlund, and Rudholm 2016). In October 2009 pharmacy retail margins for products that have a substitution group were increased by 10 SEK (approximately one euro). The substitution group definition was changed in February 2010, because before the 2009 IRP \rightarrow Auction-IRP reform substitution groups were defined with respect to the prescribed article. A substitution group contained all products with the same active ingredient, strength, form and package sizes that deviated no more than 12% of the prescribed article. After 2010 the substitution group redefinition regulator pre-defines substitution groups with fixed package size limits (Bergman, Granlund, and Rudholm 2016). The last minor regulation change attributed to the 2009 IRP \rightarrow Auction-IRP reform was the possibility to dispense the second or third cheapest product if national stock-out occurs. This change was implemented in May 2010.

Outside the changes related to the Auction-IRP reform implementation, price cap regulation was changed in 2011 and the new price cap regulation contains two distinct phases.⁶⁴ In the first phase, generic competition has not started within a substitution group and the price cap is defined as the maximum price in the substitution group. This price cap is defined as the initial price cap. In the second phase, the price cap decreases are triggered by (generic) competition. Mandatory price caps were imposed if four months had passed since generic competition has started in the substitution group and at least one product within the substitution group is priced 30% lower than the initial price cap. When these conditions are met, the price cap for all products in the substitution group is reduced by 35% of the initial price cap. This regulation change meant that a decrease in the price of one product triggers a decrease in the price cap for all products in the substitution group.

In 2012 Sweden changed the Auction-IRP regulation to allow multiple winners in the auction.⁶⁵ The reason for the change was to allow pharmacies to substitute with backup products (the second or third cheapest product in the auction) if the auction winner has problems supplying the market. Before this change, the regulator could announce a national stock-out of the cheapest product (procurement winner) after which the pharmacies were allowed to sell the second or third cheapest generic drug (Bergman, Granlund, and Rudholm 2016).

^{64.} TLVFS 2009:4

 $^{65.~\}mathrm{TLVFS}~2009{:}5$

Table A.6: Sales Data Coverage and Data Sources

	Years	Source
Panel A: Sales Data		
Finland	1998-2017	FIMEA
Sweden	$2006 \mathrm{Q2}2017$	IQVIA
Denmark	1991 – 2017	DLI- MI
Norway	2000 – 2018	Farmastat
Panel B: Reform Data		
2000 Denmark	1999 – 2005	Legislation
2003 Finland	2003 – 2009	FIMEA+Legislation
2005 Denmark	2003 – 2007	Legislation
2005 Norway	2003 – 2007	NOMA+Legislation
2009 Finland	2009 – 2015	PPB+Legislation
2009 Sweden	2005–2013	TLV+Legislation

Notes: FIMEA = Finnish Medicines Agency; PPB = (Finnish) Pharmaceutical Pricing Board; NOMA = Norwegian Medicines Agency; TLV = (Swedish) Dental and Pharmaceutical Benefits Agency.

A.4 Data Sources and Sample Statistics

Data sources. Our data sources are detailed in Table A.6.

Number of observations. Our sample sizes are detailed in Table A.7. Panel A displays market-level statistics by reform, and Panel B displays the same for product-level outcomes. The Norwegian 2005 IRP \rightarrow SP reform has the smallest market and product level sample size and the Swedish 2009 IRP \rightarrow Auction-IRP reform has the largest sample market and product level sample size. Table A.7 Panel C and D denote the sample sizes for spillover and monopoly analyses for market and product level analyses by reform. Part I and III denote the spillover sample statistics and Part II denotes the monopoly sample statistics. The monopoly sample sizes are much larger than other samples because these samples contain all monopoly markets that full fill our sample selection criteria.

A.4.1 Additional Descriptive Statistics

Share of identical products in reform comparisons. Nordic countries that use ERP-policies include other Nordic countries in their ERP-baskets, and this can facilitate regulation spillovers or externalities between treatment and control countries. In Table A.8 we

Table A.7: Number of Observations and Clusters

	Pa	rt I	Par	rt II	Par	t III
	Finland 2003	Finland 2009	Denmark 2000	Denmark 2005	Norway 2005	Sweden 2009
Panel A: Market Level						
Number of Observations Number of Clusters	4884 80	7590 106	2842 59	6716 118	1110 15	12211 112
Panel B: Product Level						
Number of Observations Number of Clusters	79756 80	109201 106	58377 59	116703 118	$24780 \\ 15$	224105 112
Panel C: Market Level (Spillover and Monopoly)						
Number of Observations Number of Clusters	3537 71	4555 74	$24153 \\ 727$	$29654 \\ 688$	3014 44	7925 117
Panel D: Product Level (Spillover and Monopoly)						
Number of Observations Number of Clusters	16947 71	16536 74	$108411 \\ 727$	119062 688	37684 44	71481 117

Notes: This table presents the number of observations and number of bootstrap cluster by each estimation (reform). Panel A gives market level statistics from Average Expenditure estimations. Panel B gives product level statistics from Wholesale Price estimations. Other outcomes might have slightly different values due to missing values. Outcome data source: DLI-MI (1999–2013), Farmastat (2004–2013), Fimea (1999–2012), IQVIA MIDAS Quarterly Sales and IQVIA MIDAS (2007–2013).

Table A.8: Package-level Matching Rates

	Treatment (1)	Control (2)	Union (3)	Union-% w.r.t treatment (4)
Finland 2003	1654	1936	369	22.31
Finland 2009	2393	1393	392	16.38
Denmark 2000	1551	1098	250	16.12
Denmark 2005	2183	2146	454	20.80
Norway 2005	331	484	93	28.10
Sweden 2009	2870	2914	610	21.25

This table lists the package level match rates between the treatment and control countries in all estimations. Outcome data source: DLI-MI (1999–2013), Farmastat (2004–2013), Fimea (1999–2012), IQVIA MIDAS Quarterly Sales and IQVIA MIDAS (2007–2013).

calculate how large a share of products (packages) sold in a treatment country is also sold in the control country.

Table A.8 shows the number of unique packages and the number of identical packages in estimation samples by each reform during the reform pre-period. Column 1 shows the unique number of products in the treatment country, and Column 2 shows the same for the control country. Column 3 displays the number of identical unique packages that are found both from treatment and control countries and Column 4 shows how large a share of the treatment country packages are present in both countries during the pre-period. The overlap between products being sold in both countries during the pre-period varies between 16% and 28%. ERP-policies used in the Nordics compare prices at the package-level and hence the relatively small product overlap means that ERP is not likely to invalidate our cross-country research design.

Role of the hospital market. Pharmaceuticals are distributed through pharmacies and hospitals in the Nordic countries. We concentrate on the pharmacy market: Figure A.5 shows the share of pharmaceuticals sold through pharmacies (shares are calculated using wholesale prices).⁶⁶ We find that the share of pharmaceuticals distributed through

^{66.} The Nordic hospital pharmaceutical market works through competitive bidding. Unfortunately, we do not have access to bids and therefore we need to rely on wholesale prices while calculating market shares. This leads to a situation where the market shares presented in Figure A.5 are the upper bound of the actual market share.

Market Share of Retail Sector in the Nordics Pharmaceutical Market 100 Retail Market Share of Total Sales (%) Finland Sweden Norway Denmark 40 2000 2001 2002 2004 2006 2007 2008 2010 2011 2012 2003 2005 2009 Year

Figure A.5: Aggregate Pharmacy Market Share

The development of the retail market share in the Nordics pharmaceutical market from 2000 to 2012. Data source: DLI-MI, Farmastat, Fimea, IQVIA MIDAS Quarterly Sales and IQVIA MIDAS (2000–2012).

pharmacies has been quite stable in Finland, Sweden, and Norway during our observation period. However, in Denmark the share of pharmaceuticals distributed through pharmacies decreased during our observation period from around 70% to less than 50%.

A large hospital share of pharmaceutical sales can be problematic in our cross-country matching procedure because it is possible that a given ATC5 market in Denmark has only hospital market sales, leading to unmatched markets. The difference between Columns 4 and 5 of Table 2 in the main text illustrates the number (Panel A) and economic significance (Panel B) of unmatched markets. All comparisons in which Denmark is used as a control group have unmatched markets, but the economic significance of these markets in the treated country is small (1%–2% of the sales of the pharmacy market).⁶⁷

^{67.} Overall the economic significance of unmatched markets is small with respect to all reforms we study.

Exchange Rates .14 .12 .1 Denmark 2000 Denmark 2005 NOK/EUR SEK/EUR Norway 2005 Sweden 2009 Finland 2003 Finland 2009 DKK/EUR .08 01jan1998 01jan2000 01jan2002 01jan2004 01jan2006 01jan2008 01jan2010 01jan2012 Time period

Figure A.6: Exchange Rate Shocks

Data source: European Central Bank.

A.5 Exchange Rate Shocks

We use domestic currencies in our analyses. The rationale for this is that sudden changes in exchange rates can bias our results. This is illustrated in Figure A.6 which plots the NOK–EUR, SEK–EUR and DKK–EUR exchange rates and the start dates of the reforms we study.

Figure A.6 shows that the DKK–EUR exchange rate evolves differently. This follows from the fact that during the study period, the Danish Krone (DKK–EUR) is linked to the Euro. It is evident from the figure that some reforms start close to sudden and extreme changes in the exchange rate, such as the Swedish 2009 IRP \rightarrow Auction-IRP reform. The 2009 fluctuations in exchange rates were induced by the global financial crisis. If the analyses were done using outcomes converted to the same currency, the exchange rate movements would influence the results because our differences-in-difference specifications cannot be augmented to separate exchange rate movements from the reform effects.

Figure A.7: Finland 2003 and 2009 by Reimbursement Status

A.6 Reimbursement Rates and Finnish 2003 (VGS \rightarrow GS) and 2009 (GS \rightarrow IRP) Reforms

The main text presented results for the Finnish 2003 VGS \rightarrow GS and 2009 GS \rightarrow IRP reforms. The results showed quite clearly that the 2009 GS \rightarrow IRP reform was much more effective than the VGS \rightarrow GS reform of 2003 in reducing pharmaceutical expenditure. The main explanation for this difference is that in the 2003 VGS \rightarrow GS reform consumer choices did not influence the reimbursement consumer received. This meant that a consumer with full reimbursement (100%) has no incentive to substitute to cheaper products. The 2009 GS \rightarrow IRP reform tied consumer reimbursement to the cheapest products in the substitution group, giving consumers an additional incentive to substitute to cheaper products. In this Subsection, we examine how the effects of regulation depend on the reimbursement rate.

The upper part of Figure A.7 shows the results for the 2003 VGS \rightarrow GS reform and the lower part for the 2009 GS \rightarrow IRP reform. Both panels present results for three reimbursement rate sub-samples (40%, 60% and 100%).⁶⁸

^{68.} These sub sample regressions are estimated using product specific data instead of market level data as in the main analysis. This change helps to show whether incentives related to reimbursements explain the differences between the two reforms or not.

The top panel of Figure A.7 clearly shows that the negative price effect is driven by products with the 40% reimbursement rate, because the treatment effect for higher rates is zero. These results help to rationalize why the 2003 VGS \rightarrow GS reform delivered only modest savings. Average expenditure did not decrease much because product prices did not respond to the reform in all reimbursement categories. The bottom panel of Figure A.7 shows that in the 2009 GS \rightarrow IRP reform, all reimbursement categories show decreasing prices due to the reform. These price results are also in line with the expenditure results shown along the main results. Average expenditure substantially with the GS \rightarrow IRP reform, and part of the explanation for the decrease is that the average price in all categories decreased due to the reform.

A.7 The Danish 2000 IRP \rightarrow ERP and 2005 ERP \rightarrow IRP Reforms: Monopoly Markets

The main analysis showed results on Danish 2000 IRP \rightarrow ERP and 2005 ERP \rightarrow IRP reforms for competitive markets. These reforms affected also non-competitive (= monopoly) markets, and this Subsection presents the effects of ERP switches on monopoly markets. The analysis of monopoly markets is an important addition to the discussion of how ERP-like regulatory measures work. The structure of the analysis and sample matching is the same as before; the only change is that now the focus is on markets where (generic) competition has not started yet. The results are displayed in an event study format and are also summarized as ATT measures.

Event studies presented in Figures A.8a and A.8b show that the 2000 IRP \rightarrow ERP and 2005 ERP \rightarrow IRP policy changes had some short-term effects on average expenditure and no effect on pharmaceutical availability in monopoly markets. The results follow the same patterns as the results for the competitive markets in the main text. The only difference between competitive and monopoly market results is that the monopoly results are more imprecise, and the effect size seems to decrease in absolute terms over time. Table A.9 shows that both average expenditure and average price decreased by -4% on average during the IRP \rightarrow ERP reform of 2000 and average expenditure and prices increased statistically insignificantly by 1% and 2% during the ERP \rightarrow IRP reform of 2005.

The main takeaway from the results presented in this Subsection is that ERP policies have the ability to influence the pricing and sales of pharmaceuticals also when the market is not subject to generic competition. This means that ERP can be used to augment simple

Table A.9: Average Treatment Effects (Monopoly Samples)

	Part II		
	Denmark 2000	Denmark 2005	
	$\mathrm{IRP} \to \mathrm{ERP}$	$\mathrm{ERP} \to \mathrm{IRP}$	
Average Expenditure per Dose	-0.04*	0.01	
	[-0.06, -0.02]	[-0.00, 0.03]	
Number of Product Names	0.02	-0.00	
	[0.00, 0.04]	[-0.02, 0.02]	
Average Price per Dose	-0.04*	0.02	
	[-0.06, -0.02]	[0.00, 0.04]	
Number of Doses	-0.04	0.00	
	[-0.08, 0.01]	[-0.04, 0.05]	
Package-level Price per Dose	-0.06*	0.02*	
	[-0.07, -0.05]	$[\ 0.01,\ 0.03]$	

Estimator: Two-way fixed effects. Outcome data source: DLI-MI (1999–2006) and Fimea (1999–2006). Confidence intervals calculated at the 95% confidence level; * = statistically significant. 10000 replications for ATC-5 wild bootstrapped standard errors.

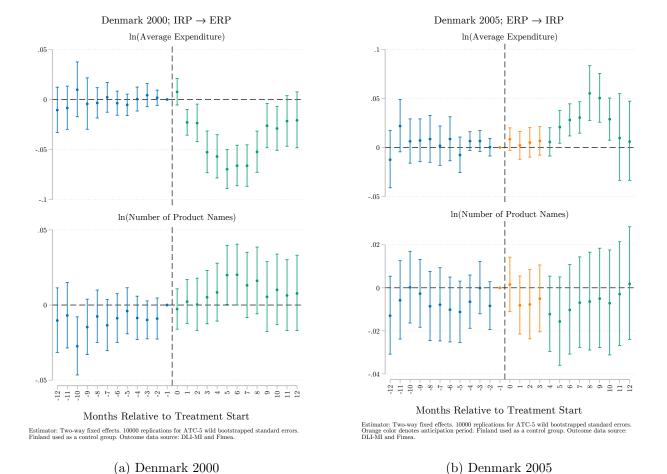


Figure A.8: Part II: Monopoly Markets

price cap regulation when price competition-based regulation cannot be used. However, it is important to note that implementation of ERP policy could also have adverse effects on reference countries, because firms could have an incentive to increase prices or delay entry in order to dilute the benefits of using ERP (Dubois, Gandhi, and Vasserman 2022; Maini and Pammolli 2022). The results from a (small) Nordic country might not be directly applicable to a larger country because it is possible that implementation of ERP in a small geographical market might not cause large adverse effects compared to a situation where ERP is implemented in a larger country.

A.8 The Finnish 2009 GS→IRP and the Swedish 2009 IRP→Auction-IRP Reforms: Alternative Control Groups

As mentioned in the main text, for the Finnish GS \rightarrow IRP and Swedish 2009 IRP \rightarrow Auction-IRP reforms we have the possibility to use either Norway or Denmark as control groups. Here we report the results of this exercise. We summarize our results by estimating ATTs (see Table A.10) and illustrate how reform effects evolve over time by estimating event study regressions.

We find that main results presented in Table A.10 are qualitatively the same regardless of the used control group. There are some differences in estimate sizes, but almost in all cases the point estimates from the model with the alternative control group fall within confidence intervals of the original estimates. The most notable exception is the Finnish $2009 \text{ GS} \rightarrow \text{IRP}$ reform (presented in Figure A.9) where the results using Denmark as a control group yield larger effects when Average Expenditure per Dose is used as the outcome variable.

A.9 The Danish 2005 ERP \rightarrow IRP and the Norwegian 2005 IRP \rightarrow SP Reforms: Extended Sample Period

In the main text, we showed results for the Danish ERP \rightarrow IRP 2005 reform with a short post-reform period. The reason for this choice was the price cut implemented in the control country (Finland) in January 2006. This shock in the control country cannot be "controlled away" in our framework, and the shock directly influences our results. We show event study results using a longer post-reform time window in Figures A.13a and A.14a. We show results for our main outcome variables, expenditure and availability. On the left, we show results for our main markets of interest, i.e., those with generic competition; on

Table A.10: Average Treatment Effects (Control Group Comparison)

	Finland 2009 $GS \to IRP$			Sweden 2009 IRP \rightarrow Auction-IRP		
	NOR	DEN	NOR&DEN	DEN	NOR	NOR&DEN
Average Expenditure per Dose	-0.13*	-0.19*	-0.15*	-0.29*	-0.23*	-0.26*
	[-0.18, -0.08]	[-0.26, -0.12]	[-0.20, -0.10]	[-0.35, -0.22]	[-0.29, -0.16]	[-0.32, -0.20]
Number of Product Names	0.04	-0.00	0.02	0.04	0.06*	0.06*
	[-0.02, 0.10]	[-0.05, 0.05]	[-0.03, 0.08]	[-0.02, 0.09]	[0.02, 0.10]	[0.02, 0.10]
Average Price per Dose	-0.05	-0.11*	-0.07*	-0.14*	-0.04	-0.09*
	[-0.09, -0.00]	[-0.16, -0.04]	[-0.12, -0.02]	[-0.20, -0.07]	[-0.12, 0.04]	[-0.15, -0.02]
Number of Doses	0.04*	0.02	0.03*	-0.01	0.08*	0.03
	[0.01, 0.07]	[-0.02, 0.05]	[0.01, 0.06]	[-0.08, 0.06]	[0.01, 0.16]	[-0.04, 0.10]
Package-level Price per Dose	-0.10*	-0.15*	-0.13*	-0.16*	-0.06	-0.11*
	[-0.14, -0.07]	[-0.21, -0.08]	[-0.17, -0.08]	[-0.22, -0.09]	[-0.11, -0.00]	[-0.16, -0.06]

Estimator: Two-way fixed effects (Denmark 2000 and 2005, Norway 2005) and Callaway and Sant'Anna (2020) (Finland 2003 and 2009, Sweden 2009). Outcome data source: DLI-MI (2007–2013), Farmastat (2004–2013), Fimea (2007–2012), IQVIA MIDAS Quarterly Sales and IQVIA MIDAS (2007–2013). Confidence intervals calculated at the 95% confidence level; * = statistically significant. 10000 replications for ATC-5 wild bootstrapped standard errors.



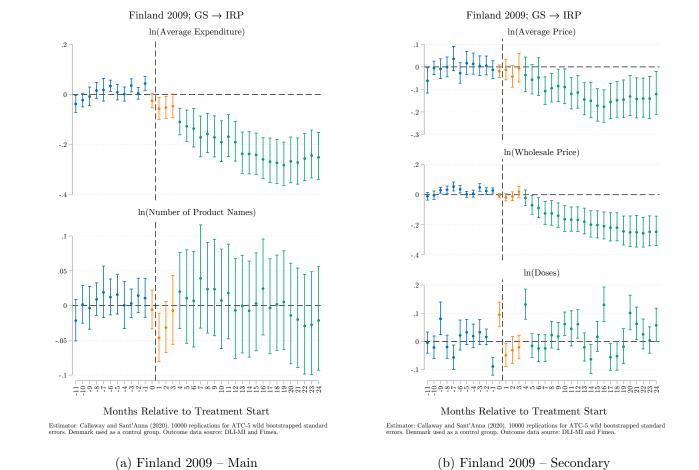


Figure A.9: The Finnish 2009 GS \rightarrow IRP Results with Denmark as the Control Group



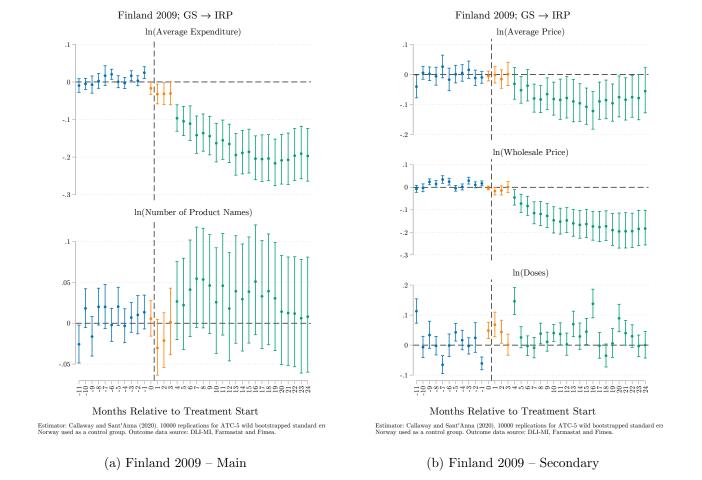


Figure A.10: The Finnish 2009 GS \rightarrow IRP Results with Norway and Denmark as the Control Group

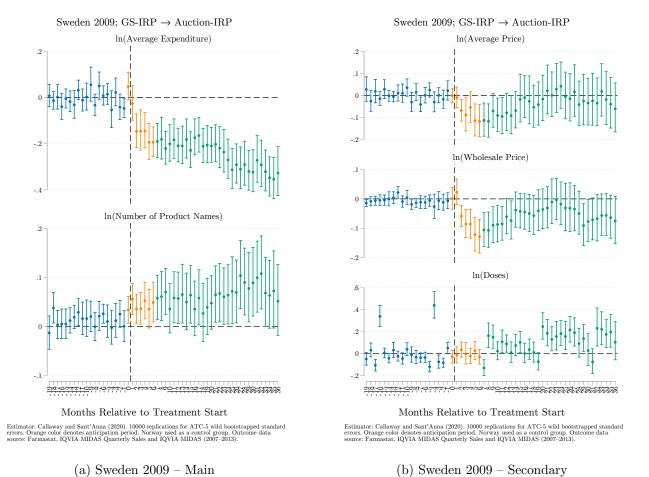


Figure A.11: The Swedish 2009 IRP \rightarrow Auction-IRP Results with Norway as the Control Group

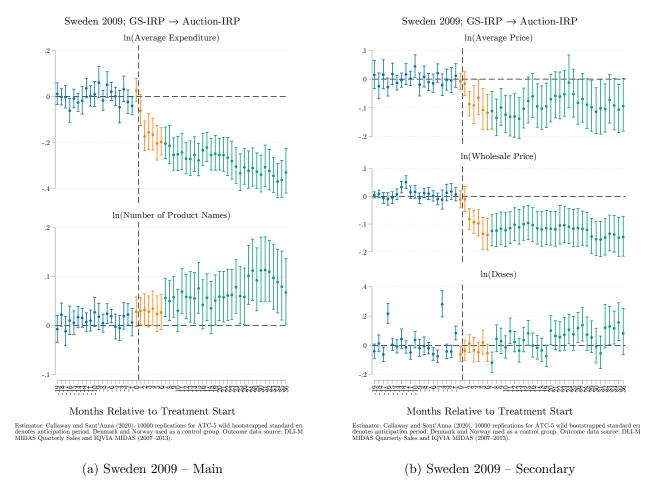


Figure A.12: The Swedish 2009 IRP \rightarrow Auction-IRP Results with Norway and Denmark as the Control Group

the right, we show results for monopoly markets. The solid-green event study estimates represent the results already shown in the main text, and the light-green estimates are the time periods added to the study period. The most notable changes in the event study coefficient sizes occur when monopoly markets or spillovers are studied. The reason for this is that these markets are the markets where the price cut had the largest effect on the wholesale price, and therefore the impact of the price cut is seen in the figures.⁶⁹

A.10 Weighted ATT Results

We estimate weighted versions to analyze whether our results are driven by small markets. Markets are weighted by their share of the treatment country pharmacy sales of prescription pharmaceuticals. We calculate constant weights from the pre-period, because otherwise the studied reform would also influence the weights we use. We use sales from periods -12 to -6 to construct the weights.

We have compiled the weighted results into Table A.11 where panel A repeats for comparison the main results presented in Table 4 and panel B provides the weighted ATT results. Starting from our main outcome variables, we find that the results on expenditure are starker once we weigh markets with their size. The three reforms with the largest impacts—the Finnish 2009 GS \rightarrow IRP, the Norwegian 2005 GS \rightarrow SP and the Swedish 2009 IRP \rightarrow Auction-IRP reforms—are estimated to have the same (the Norwegian and the and Swedish reforms) or clearly larger (the Finnish reform) decreasing impact on expenditure. The results on availability do not change much.

Turning to the secondary outcomes, we find that the Finnish 2009 GS \rightarrow IRP reform would also have had a significant decreasing impact on the average price per dose. The results on quantity and package-level price are quite similar to those reported in the main text.

A.11 Event Study Results for Secondary Outcomes

In this Subsection we present event study results for our secondary outcomes (Average Price, Wholesale Price and Doses) for each reform.

^{69.} The price cut was imposed on the price caps and in competitive markets large share of products are priced under the price cap and a 5~% reduction in the cap does not have a large impact on firm pricing. In monopoly markets or markets included in our spillover analyses, the price cap cut can have a full 5% decrease in wholesale prices because products in these markets do not face competition and are priced to the cap.

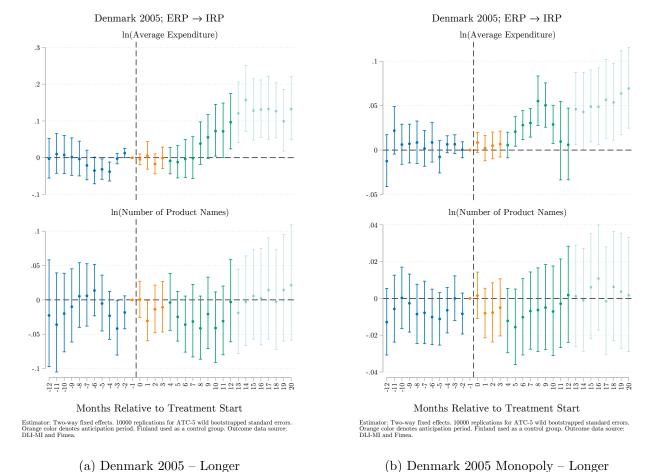


Figure A.13: The Danish 2005 IRP \rightarrow ERP Results with Extended Follow-up Period.



Figure A.14: The Norwegian 2005 IRP \rightarrow SP Results with Extended Follow-up Period.

Table A.11: Average Treatment Effects

	Part I		Part II		Part III	
	Finland 2003 $VGS \rightarrow GS$	Finland 2009 $GS \rightarrow IRP$	Denmark 2000 IRP \rightarrow ERP	Denmark 2005 ERP \rightarrow IRP	Norway 2005 $GS \to SP$	Sweden 2009 IRP \rightarrow Auction-IRP
Panel A: Main Estimations						
Average Expenditure per Dose	-0.03 [-0.07, 0.01]	-0.13* [-0.18, -0.08]	-0.05* [-0.09, -0.01]	0.04 [-0.01, 0.09]	-0.21* [-0.29, -0.12]	-0.29* [-0.35, -0.22]
Number of Product Names	0.01	0.04	-0.02 [-0.06, 0.02]	-0.01 [-0.05, 0.03]	-0.01 [-0.15, 0.15]	0.04
Average Price per Dose	-0.04 [-0.12, 0.04]	-0.05 [-0.09, -0.00]	-0.07* [-0.12, -0.01]	0.07* [0.02, 0.12]	-0.10 [-0.18, -0.00]	-0.14* [-0.20, -0.07]
Number of Doses	0.01 [-0.04, 0.07]	0.04* [0.01, 0.07]	0.00 [-0.04, 0.04]	0.07* [0.03, 0.12]	0.04 [-0.00, 0.09]	-0.01 [-0.08, 0.06]
Package-level Price per Dose	-0.05 [-0.11, 0.02]	-0.10* [-0.14, -0.07]	-0.09* [-0.13, -0.05]	$0.05 \\ [-0.01, 0.12]$	-0.11* [-0.20, -0.01]	-0.16* [-0.22, -0.09]
Panel B: Weighted Estimations						
Average Expenditure per Dose	0.03 [-0.13, 0.23]	-0.25* [-0.34, -0.15]	-0.04 [-0.08, 0.01]	0.00 [-0.08, 0.10]	-0.22* [-0.30, -0.12]	-0.31* [-0.43, -0.17]
Number of Product Names	-0.00 [-0.06, 0.05]	0.12	-0.02 [-0.07, 0.03]	-0.05 [-0.13, 0.04]	-0.03 [-0.21, 0.16]	0.07
Average Price per Dose	0.04	-0.16* [-0.23, -0.08]	-0.06* [-0.11, -0.01]	0.17	-0.05 [-0.18, 0.13]	-0.06 [-0.34, 0.33]
Number of Doses	-0.06 [-0.14, 0.03]	0.07* [0.04, 0.10]	-0.04 [-0.12, 0.04]	0.03 [-0.05, 0.10]	0.02 [-0.04, 0.09]	-0.07 [-0.21, 0.08]
Package-level Price per Dose	0.04 [-0.19, 0.32]	-0.17* [-0.23, -0.10]	-0.08* [-0.13, -0.03]	-0.03 [-0.24, 0.13]	-0.07 [-0.21, 0.16]	-0.17* [-0.27, -0.07]

Estimator: Two-way fixed effects (Denmark 2000 and 2005, Norway 2005) and Callaway and Sant'Anna (2020) (Finland 2003 and 2009, Sweden 2009). Outcome data source: DLI-MI (2007–2013), Farmastat (2004–2013), Fimea (2007–2012), IQVIA MIDAS Quarterly Sales and IQVIA MIDAS (2007–2013). Confidence intervals calculated at the 95% confidence level; * = statistically significant at the 95% level. 10000 replications for ATC-5 wild bootstrapped standard errors.

Part I Event Study Results: Figure A.15 collects event study results for the Finnish $2003 \text{ VGS} \rightarrow \text{GS}$ and $2009 \text{ GS} \rightarrow \text{IRP}$ reforms. The estimated treatment effects are smaller in absolute value when the outcome variable is defined at the market level than when using package level prices. It is interesting to note that when studying the Finnish 2009 reform the treatment effect converges to zero using market-level prices, but to 11% using package level prices.

Part II Event Study Results: Figure A.16 collects event study results for Danish 2000 IRP \rightarrow ERP and 2005 ERP \rightarrow IRP reforms. Event study results for both Danish reforms follow the same patterns as in the case of the Finnish reforms: The treatment effect is larger in absolute value when using package-level wholesale price than when using the market-level average price. The increase in quantity (Doses) for the 2000 reform is a result of the change in the Danish reimbursement system. This change had no effect on pricing, because neither price measure reacts to the change in the reimbursement system.

Part III Event Study Results: Figure A.17 collects event study results for the Norwegian IRP \rightarrow SP and the Swedish 2009 IRP \rightarrow Auction-IRP reforms. The Norwegian 2005 IRP \rightarrow SP reform repeats the earlier finding that package-level prices (Package-level Price per Dose) can yield a different results than the market level price (Average Price per Dose) when consumer choice reforms are studied, but we find almost identical price effect results for the Swedish 2009 IRP \rightarrow Auction-IRP reform.

^{70.} Appendix Section A.3.6 describes the Danish reimbursement system change in detail.



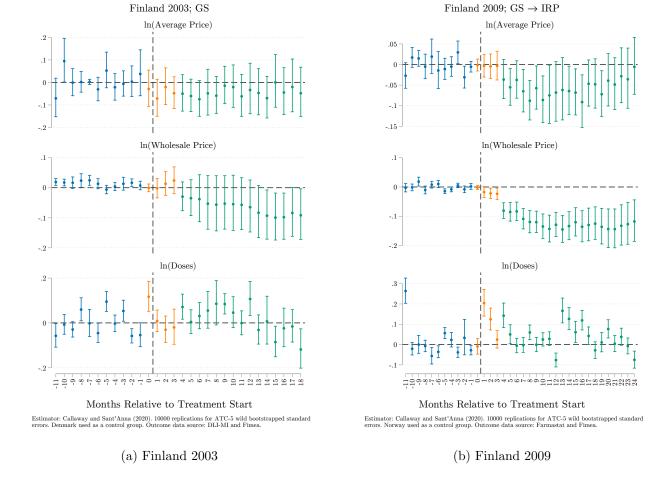


Figure A.15: Part I: Secondary Outcome Variables



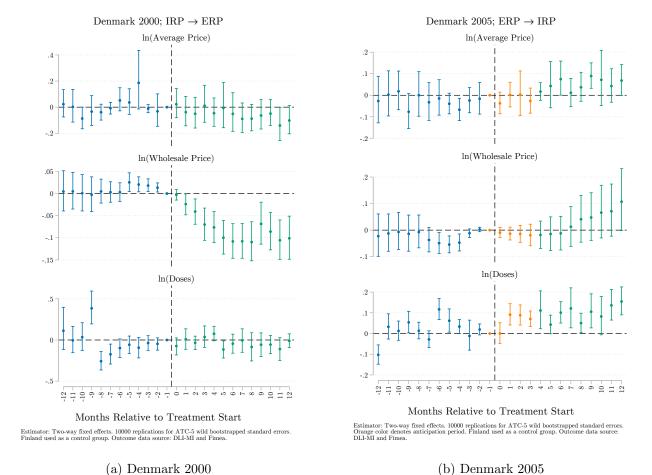


Figure A.16: Part II: Secondary Outcome Variables

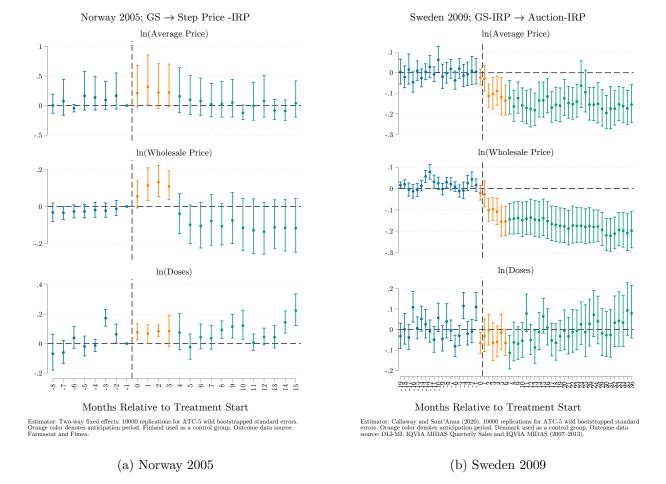


Figure A.17: Part III: Secondary Outcome Variables