Price competition in pharmaceuticals – a panel data analysis of the Finnish pharmaceutical market

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Title: Price competition in pharmaceuticals – a panel data analysis of the Finnish pharmaceutical market
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Abstract: Reference pricing is one of the most common regulatory tools used to promote competition between pharmaceutical substances. Finland introduced its reference price system in 2009 in an effort to activate price competition between medicines and to control the rising costs of health care. This thesis studies the effects of increased competition on original and generic medicines within this system. This study uses monthly panel data of medicines included in the Finnish reference price system between the years 2009 and 2021. Using several two-way fixed effects estimators and accounting for the possible endogeneity problem which is often present in price-concentration studies, I provide evidence of significant price effects of increased competition on generic medicines. The prices of generic medicines are found to decrease by 63-75% when the number of interchangeable medicines increases from one to ten. Prices of generic medicines are also found to react to increased competition by medicines with the same active ingredient but with different packaging sizes, strengths, or routes of administration. Original medicines are found to react to increased competition as well, but less so than generics, and the results are more ambiguous. Furthermore, prices of both generic and original medicines appear to be characterized by constant elasticities.
Keywords: Pharmaceutical industry; Reference price system; price competition; original medicine; generic medicine

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1 Introduction

Health care expenditures in Finland are expected to increase to an estimated €28.5 billion by 2030 from €19.5 billion in 2014 (Neittaanmäki *et al*., 2017). Over the last two decades, among other things, the expenses of outpatient prescription medicines have increased over four-fold (Matveinen, 2021). To combat this, several policy measures have been implemented to control the rising costs of prescription medicines, with varying degrees of success. Starting with voluntary generic substitution in 1993, generic prescribing in 1996, generic substitution in 2003, and finally culminating into the introduction of the reference price (RP) system in 2009, policymakers have attempted to activate price competition among pharmaceutical firms to decrease prices and alleviate pressure on the public budget (Heikkilä, 2013).

The RP system supplemented the earlier introduced generic substitution policy by tying the reimbursements of interchangeable medicines to a reference price, based on the least expensive medicine in each exchange group. The significance of the reference price is that it dictates the maximum amount for which patients can receive reimbursement. By now it is well established that the implementation of such policies decreases the average prices of pharmaceuticals considerably in the short term. Koskinen *et al*. (2015) find that the prices of antipsychotic medicines in Finland fell by 24.6-50.6% after the implementation of the RP system. Similar results have been found in other Nordic and European markets (Puig-Junoy, 2010; Galizzi, Ghislandi & Miraldo, 2011). Although past empirical findings are consistent with the fact that pharmaceutical prices fall with the introduction of reference pricing, less is known about the sustained effects and the role of the number of competitors. This thesis aims to fill this gap. Previous research on the price effects of increased competition in pharmaceutical markets has yielded mixed results. Studies by Wiggins and Maness (2004), Aalto-Setälä (2008), and Bergman and Granlund (2018) find that the prices of both original and generic medicines tend to fall following an increase in competition. The results of Frank and Salkever (1997), and

Vandoros and Kanavos (2013) however suggest an increase in the prices of original medicines following generic entry, while Brekke, Holmas and Straume (2011) report no significant price effects of increased generic competition on either original or generic medicines.

The aim of this thesis is therefore not to evaluate the RP system *per se*, but rather the effects of competition within the system, where the primary research objective is to estimate how pharmaceutical prices respond to increased competition. Hence, this thesis contributes to the existing economic literature on RP systems by analyzing the competition within the system and the effects of the number of competitors. Moreover, although reference pricing and generic substitution policies are used in nearly all European countries, the differences in execution vary significantly in practice (Wouters, Kanavos & McKee, 2017). Consequently, this thesis contributes to past research by estimating the effects of the Finnish system. The subject is important from a policy perspective as well. For policymakers, the price effects of increased competition are valuable information in terms of deciding whether incentivizing firms to enter the market is a cost-effective way of controlling health care expenditures.

This thesis uses monthly product-level panel data of pharmaceutical prices in Finland between 2009 and 2021 to study the effects of competition on price. For the estimations, several two-way fixed effects estimators are applied which find significant evidence that the prices of generic medicines react strongly to increased competition. The results suggest that generic medicines decrease their prices by approximately 63-75% when the number of interchangeable products increases from one to ten. Original medicines are found to react to increased competition as well but less so than generics, and the results are more ambiguous.

The thesis is structured as follows: Chapter 2 will provide an overview of how pharmaceutical markets are structured and present the institutional background of the Finnish market. Theoretical frameworks concerning competition in the pharmaceutical market will be discussed in Chapter 3. Chapter 4 reviews past empirical findings, both

from the Finnish market as well as on an international scale. In Chapter 5, the data and descriptive statistics are introduced. Chapter 6 presents the primary econometric models used in the analysis and the results of the various estimations. In Chapter 7, the final findings are discussed more in depth and the implications the results have. Chapter 8 concludes the thesis.

2 Overview of the pharmaceutical market

The pharmaceutical industry is a complex and highly regulated market with various characteristics that distinguishes it from other markets. This chapter presents the most fundamental structures of the pharmaceutical market and the most common regulatory policies within the market, which play a crucial role in understanding competition between pharmaceutical substances.

At the core of the characteristics of the pharmaceutical market is the Anatomical Therapeutic Chemical (ATC) drug classification system developed by the World Health Organization Collaborating Centre for Drug Statistics Methodology (WHOCC). The ATC is a drug classification system used to divide medicines into categories based on the anatomical, therapeutical, and/or pharmacological group the medicine belongs to (WHOCC, 2021). The system consists of 14 main anatomical/pharmacological groups, which are then further divided into four more hierarchical levels. The second hierarchical level is based on either pharmacological or therapeutical properties, while the third and fourth levels can be based on chemical, pharmacological or therapeutic properties. The fifth level is the chemical substance or active ingredient of the medicine. As an example, Table 1 below illustrates the classification of the active ingredient metformin, used in the treatment of type 2 diabetes.

Table 1. ATC classification of metformin

Level	ATC	Description	Definition
1st	A	Alimentary tract and metabolism	Anatomical main group
2nd	A10	Drugs used in diabetes	Therapeutic subgroup
3rd	A10B	Blood glucose lowering drugs, excl. insulins	Pharmacological subgroup
4th	A10BA	Biguanides	Chemical subgroup
5th	A10BA02	Metformin	Active ingredient

Source: (WHOCC, 2021).

The classification of active ingredients is an important aspect of how competition is structured within the pharmaceutical market. As a general rule, products in the ATC system become more similar to each other as the level increases. As such, the fifth level of the classification system is the focus of this thesis, since the products categorized together in this level have the same active ingredient and are therefore in direct competition with each other.

Competing products in the fifth level of the ATC system generally consist of an *original medicine* and one or more *generic medicines*. A generic medicine is one created to be a bioequivalent replica of an already market authorized medicine, called the reference or original medicine (European Medicines Agency, 2022). Firms can freely develop generic medicines once the patent or period of data exclusivity of the original medicine has expired, which is generally 10 years after market authorization. Generic medicines contain the same active ingredient(s), are used with the same dosage(s), treat the same disease(s), and are manufactured to the same standard as the original medicine but can differ in characteristics such as inactive ingredient, name, appearance, and packaging. Since generic medicines are essentially a copy of an already authorized reference medicine, firms that develop them are not required to conduct any animal or clinical

studies that are normally required for medicines to receive market authorization. This reduction in upfront costs of development means that generic medicines can typically be sold for substantially cheaper than their original counterparts. In terms of safety, efficacy and use, generic medicines are identical to the reference medicine and therefore one of the few ways they can differentiate themselves from other products in the market is by competitive pricing.

In addition to generic competition, the ATC system can be used to identify *therapeutic competition.* Therapeutic competition describes the competition between products in the lower hierarchical levels of the ATC classification system. Contrary to generic competition, where nearly identical medicines are competing against each other, therapeutic competition is driven by innovation where pharmaceutical firms differentiate their products by developing new and better medicines to treat the same or similar diseases. The term therapeutic competition is not as clearly defined as generic competition. Therapeutic competition can exist across multiple levels in the ATC system; researchers within the economic literature however often define therapeutic competition as competition between products in the fourth level of the ATC system or in other words products with the same first five-digit ATC code (Grandlund and Bergman, 2018; Brekke, Holmas and Straume, 2011).

As generic medicines have become increasingly more common, many countries have introduced *generic substitution* to lower the prices of pharmaceuticals and to induce savings in the public sector. Generic substitution is the practice of pharmacy personnel replacing a prescribed medicine with a cheaper, generic alternative. As of 2017, almost all EU and EEA countries utilize some form of generic substitution or generic prescribing[1], both hereafter referred to as "generic substitution" (Wouters, Kanavos & McKee, 2017). The fundamental principle for generic substitution is the same in all countries but can significantly differ in execution. Generic substitution can either be

[1] Generic prescribing is the practice of physicians prescribing a medicine using the generic name (active ingredient) thus leaving the brand of choice to the pharmacist.

classified as voluntary or mandatory, with mandatory substitution usually including some sort of increased co-payment for denying substitution.

Generic substitution is only one of the numerous policies governments use to regulate health care expenses. One of the most common price controls is reference pricing, which is the practice of setting price caps on medicines or co-payments in a country (World Health Organization, 2020). In broad terms, reference pricing can be categorized into external reference pricing (ERP) and internal reference pricing (IRP), where ERP refers to deriving a benchmark price by referring to other countries and IRP by referring to the prices of comparable medicines in the domestic market.

Other regulatory practices within the pharmaceutical market include the classification of prescription and over-the-counter (OTC) medicines. OTC medicines are those that consumers can purchase without a prescription from a physician whereas prescription medicines require a prescription from a licensed physician. The prescription medicine market therefore differs from almost all other market types by the fact that the consumer and the decision-maker are not the same individual. Furthermore, medicines can be categorized into outpatient and hospital-only medicines. Outpatient medicines are those that can be bought and administered by the patients themselves while hospital-only medicines can only be administered by a health care professional, for example through injection. Because of the fundamental difference between OTC, hospital-only, and prescription medicines, this thesis focuses solely on the competition within the prescription medicines market.

2.1 Institutional background

Public health care in Finland has generally been considered a success story. The Finnish constitution guarantees adequate social, health, and medical services for all its citizens through the public healthcare system (Ministry of Social Affairs and Health, 2013). As such, the majority of patients use the public sector for their health care services. Consequently, due to factors such as population aging and the emergence of new and expensive medicines, the yearly total expenses for public health care have steadily been increasing. Public health care expenses for 2019 amounted to nearly €22 billion or 9.2% of the GDP of which 76.8% was financed by the public sector (Matveinen, 2021). This is a 3.0% increase compared to 2018 and a 16.5% increase compared to 2010. Furthermore, over the last two decades there have been an increase in expenses especially in outpatient prescription medicines, which have increased over four-fold since the beginning of the century.

The Finnish Medicines Agency (Fimea) acts as the national authority for regulating pharmaceutical products and entry into the market (Finnish Medicines Agency Fimea, 2021a). For a pharmaceutical product to receive marketing authorization, it must satisfy several criteria determined by the European Medicines Agency (EMA) which ensures that its benefits exceed its risks (Finnish Medicines Agency Fimea, 2021b). Fimea recognizes four ways for firms to obtain market authorization in the Finnish market (Finnish Medicines Agency Fimea. 2022a). Products that have no market authorization in any EU country, Norway or Iceland can apply for market authorization through the national procedure, by applying to Fimea. If a product already has market authorization in an EU country, Norway, or Iceland, a firm can apply through the mutual recognition procedure, by which Fimea will grant market authorization based on the authorization of a reference member state. Finally, if a firm wishes to apply for market authorization to multiple or all EU countries, it can apply through the decentralized procedure or the centralized procedure. For the decentralized procedure, a reference member state assesses the application, while for the centralized procedure EMA assesses the application.

Once a medicine has received market authorization, the market authorization holder can apply for reimbursement status from the Pharmaceuticals Pricing Board (Hila). Approximately 60% of all medicines sold in Finnish pharmacies have reimbursement status (Pharma Industry Finland, 2021). The Finnish National Health Insurance scheme includes three levels of reimbursement: basic reimbursement (40%), lower special reimbursement (65%), and higher special reimbursement (100%) (The Social Insurance Institution of Finland, 2022a). Additionally, since 2017, there has been a possibility for conditional reimbursement status, which is a form of risk-sharing agreement between Hila and the market authorization holders. The exact details of these agreements are however not generally available to the public and as of 2021, only a small minority of reimbursable medicines are covered by conditional reimbursement. For patients there is a yearly deductible of €50 and an annual maximum limit on out-of-pocket costs, which for the year 2022 equals to €592.16. After reaching the maximum limit patients are reimbursed the full amount excluding a €2.5 co-payment, for medicines with higher special reimbursement status a co-payment of €4.5 is charged.

Pricing and sales of medicines are strictly regulated by the Finnish government. Medicines can only be sold in licensed pharmacies and must be priced the same in all pharmacies based on a predetermined formula (Association of Finnish pharmacies, 2022). The formula consists of a wholesale price, the pharmacy sales margin, and the value-added tax. The pharmacy sales margin is degressive, meaning that the relative sales margin decreases as wholesale prices increase. In principle, pharmaceutical firms can freely price their medicines in the market; in practice, however, this only applies to OTC medicines. For prescription medicines to be included in the reimbursement scheme, the wholesale prices must follow strict regulations set by Hila. Hila decides a maximum reasonable wholesale price for all medicines with reimbursement status. Additionally, medicines included in the RP system have certain other pricing restrictions they must follow. The Finnish RP system will be presented more thoroughly in the next chapter.

2.1.1 Generic substitution and the reference price system

As spending on health care has increased so have the efforts to find solutions to keep the rising expenses under control. In April 2003, mandatory generic substitution was introduced in the Finnish pharmaceutical market, whereas before it, voluntary generic substitution (1993-1996) and generic prescribing (1997-) was in use (Heikkilä, 2013). The mandatory generic substitution reform made it a requirement for pharmacies to offer the least expensive or close to least expensive available interchangeable medicine to the patient (Finnish Medicines Act, 80/2003). Each quarter, Hila established a price band around the price of the least expensive medicine of each group of interchangeable medicines, which was defined as the price of the least expensive medicine at the start of the quarterly period plus €2 or €3 depending on if the retail price of the medicine was under or over €40. Pharmacies could offer an interchangeable medicine as a substitution if the medicine was within the price band. However, it is important to note that the prescribing physician and more importantly the patient could deny generic substitution without any additional financial repercussions in terms of reimbursement percentage. Although the introduction of generic substitution brought significant savings to the public sector there was still room for improvement as there were no additional repercussions for denying substitution. Ahonen and Martikainen (2005) estimated the cost savings of the first year of generic substitution to be €88 million of which 2/3 stemmed from the resulting price competition between firms and 1/3 from actual substitutions made in pharmacies. However, they found as well that around 2/5 of patients denied substitution in cases where the prescribed medicine was priced above the price band, indicating that the total number of denied substitutions was substantially higher.

In April 2009, in midst of the global economic recession, the Finnish government introduced the RP system as a supplement to generic substitution to further increase cost savings in the healthcare system (Finnish Medicines Act, 802/2008). The Finnish RP system is based on internal reference pricing and operates on the same principle as the price band in the earlier introduced generic substitution reform. With the introduction of

the RP system, the price band was narrowed down to €1.5-2 and later, in 2017, down to €0.5. Perhaps the most notable difference of the RP system compared to generic substitution is that within the RP system, reimbursements only cover patients up to the price band unless the prescribing physician has explicitly forbidden substitution. This substantially increases the financial incentive to substitute for a medicine that is within the price band.

Each quarter Fimea and Hila determines which medicines are included in each RP group, meaning that new medicines can only enter the RP system four times each year (Finnish Medicines Act, 802/2008). For a new generic medicine to be accepted into the RP system, the wholesale price must be below the maximum reasonable wholesale price set by Hila. The maximum reasonable wholesale price is determined based on multiple factors such as prices of similar medicines, the price of the medicine in other EEA countries, and the perceived benefits of the medicine to the healthcare system. In practice, however, the reasonable wholesale price is set to around 60% of its original counterpart which is usually still below the natural market price (Pelkonen, 2011). The reasonable wholesale price is in effect for a maximum of five years, or three years if the decision is for a new active ingredient. During this time, the reasonable wholesale price is not reviewed by authorities. Although generic competition decreases prices by at least 60%, firms operating in RP groups with low competition can optimize their pricing to match the maximum reasonable wholesale price, thus move away from the natural market price (Koskinen *et al*, 2015).

For firms, it is not a requirement to price their medicines within the price band to be included in the RP system, only that the maximum reasonable wholesale price is below the threshold set by Hila. Aalto-Setälä (2008) found for example signs of firms either pricing their products as low as possible in order to be substituted at the pharmacy or price close to the maximum reasonable wholesale price. Firms, generally originals, would then rely on brand awareness and patients paying a higher co-payment to choose the branded and familiar product instead. In a study by Heikkilä, Mäntyselkä and Ahonen (2011), it was found that 24.9% of consumers have refused generic substitution

and that the most important factor for refusing substitution is brand familiarity. A more recent example is by Nokelainen, Lämsä, Ahonen and Timonen (2020) who found that 53.9% of consumers have refused generic substitution at least once. As Heikkilä *et al*. (2011), they concluded that familiarity with the medicine is the most important factor for refusing substitution.

2.1.2 Legislative changes during the study period

During the study period, several changes in legislation have been made that might have influenced the competitive environment of the pharmaceutical market. This chapter will present the most notable legislative changes in the pharmaceutical market during the analysis period. Table 2 below shows the most notable legislation changes in the pharmaceutical market since 2009.

Table 2. Legislative changes in the pharmaceutical market

Date	Description
1 April 2009	Reference price system
1 February 2013	Price cuts to reimbursable medicines not included in the RP system
1 January 2016	Pharmacies must inform patients of the cheapest available alternative
1 January 2016	New generic medicines can only enter the RP system if the maximum reasonable wholesale price is at most 50% of an equivalent medicine
1 July 2016	Price cuts to original medicines included in the RP system
1 January 2017	Reference price system extended to cover parallel imported products
1 January 2017	Adjustments to the price band

Hila has issued mandatory price cuts to the maximum reasonable wholesale price on two separate occasions. In February 2013 Hila reduced the maximum reasonable wholesale price of all reimbursable medicines not included in the RP system by 5% (Health Insurance Act, 622/2012). In July 2016 Hila reduced to the maximum reasonable wholesale prices of original medicines that had been included in the RP system as of January 2016 and had a maximum reasonable wholesale price higher than the maximum reasonable wholesale price of its most expensive generic counterpart. In these cases, the maximum reasonable wholesale price was reduced to match its most expensive generic version (Health Insurance Act, 252/2015).

In January 2016 a new regulation came into effect which made it a requirement that when the first new generic medicine for an active ingredient is accepted into the RP system its maximum reasonable wholesale price must be at most 50% of an equivalent medicine (Health Insurance Act, 252/2015). The regulation applies only to the first generic medicine in each reference price group, the maximum reasonable wholesale price of subsequent medicines can be at most equal to the first generic medicine. In practice, this regulation has already been applied since 2006 when Hila made it a policy to only accept new generic medicines with a maximum reasonable wholesale price of 60% or less of its original counterpart (Kinnunen *et al*., 2021). Turning it from policy to law however, removed the option for pharmaceutical firms to challenge the decision.

In January 2016 the medicines act was changed to require pharmacy personnel to explicitly inform patients of the cheapest available interchangeable medicine (Medicines Act, 253/2015). Before the change pharmacies could offer any interchangeable medicine as long as it was within the price band of the RP group. In theory, pharmacies had an incentive to offer the most expensive substitutable medicine as it would have increased their profits. Similarly, pharmaceutical firms would have had an incentive to price their products in the upper end of the price band following the assumption that pharmacies try to maximize profits. However, there are no empirical studies that have examined whether pharmacies have done this in practice.

In January 2017 there were two major changes to the RP system. The first change made it possible for RP groups to be formed around parallel imports (Health Insurance Act, 1100/2016). Parallel imports are medicines produced under the protection of a trademark or patent, placed in circulation in a market, and then imported into a second market without the authorization of the local market authorization holder. Parallel imports allow for importers to exploit the price arbitrage in other countries with less expensive medicine prices. This new regulation meant that parallel imports could engage in price competition with patent protected original medicines, whereas before the patent of the original medicine needed to be expired for direct competition to be possible through the RP system. The second change was narrowing down the price band from the original €1.5 for medicines under €40 and €2 for medicines over €40 to €0.5 regardless of price (Medicines Act, 1101/2016). The price band was changed to counteract a phenomenon found by the social insurance institution of Finland (Kela) in 2016 in which firms raise their prices during the quarterly RP period to match the price cap of the price band (Koskinen & Kurko, 2016). As a result of this, Kela found that in some RP groups the average prices of medicines had gradually increased between the years 2011-2015. Furthermore, the regulation change might have caused medicine shortages in some sub-markets, which could affect the competitive environment. The Finnish pharmaceutical firm Orion has for example expressed concerns of this to the parliament (Orion Oyj, 2016).

3 Theoretical framework

3.1 Competition within a reference price system

Due to the heavily regulated nature of the pharmaceutical market, traditional economic competition theory might not describe the competition between medicines accurately. Several theoretical frameworks have however been constructed around competition between medicines. Perhaps one of the more notable for this thesis is by Brekke, Canta and Straume (2016), who consider a circular city model (or Salop's Circle) to describe scenarios where generic and original medicines compete in markets characterized by price caps, internal RP, or external RP. As mentioned above in Chapter 2.1.1, in the Finnish RP system, the reference price is internally determined based on the least expensive available interchangeable medicine. This chapter will therefore focus on the model accounting for internal RP.

The circular city model is a spatial model where consumers (or patients) are modelled to exhibit preferences both through geographic location (indicated by where in the circle the consumers are) as well as through product differentiation (indicated in the model as a "cost of transportation"). Consumers' utility depends therefore not only on price but on location and product characteristics as well. In the model by Brekke *et al.*, the circumference of the circle is 1 and both consumers and firms are assumed to be uniformly distributed across the circle. The supply side consists of an original medicine and one or more generic medicines (i= 1,...,n) that can enter the market in exchange for a sunk cost (f). The sunk cost includes all relevant fixed costs associated with entering the pharmaceutical market such as the costs of applying for market authorization or initial investments in production. The demand side consists of two types of consumers: brand-biased consumers and brand-neutral consumers. Brand-biased consumers are those who consider original medicines to be more effective compared to the generic alternatives and will therefore only purchase a generic alternative if the difference in co-payment is high enough to counteract the perceived loss of effectiveness. The degree of bias is

assumed to vary across consumers and is indicated by the costs of transportation within the circle. As briefly discussed in Chapter 2.2, the notion of brand-biased consumers is in line with previous studies in the Finnish pharmaceutical market. Brand-neutral consumers are those who have no preference over different alternatives and will therefore always choose the cheapest available generic alternative. The model assumes that generic medicines can be horizontally differentiated (t_g) but not vertically differentiated, meaning that generic medicines are differentiated in characteristics not associated with price or quality. Original medicines however can be vertically differentiated (t_o) from generic medicines, that is differentiation based on a mix of quality and price. Moreover, it is assumed that the degree of differentiation is higher in the vertical sense compared to the horizontal sense ($t_o \geq t_g$).

Brekke *et al.* consider a two-stage game, where in the first stage, the patent protection of the original medicine expires, and generic medicines have a simultaneous choice to enter the market. The second stage is a Bertrand price competition model. The game occurs only for one period, meaning that the consumers have a choice of either continuing to purchase the original medicine or switching to a generic alternative. The utility function of a brand-biased consumer who continues to consume the original medicine is given by the consumer's gross valuation of the treatment[2] (v) minus the co-payment (C_o) of the original medicine. If the brand-biased consumer instead switches to generic medicine *i*, the consumer incurs a transportation cost, $t_o|x - z_g^i|$, defined as the distance between the consumer (x) and generic medicine *i*:s (z_g^i) location on the circle times the vertical differentiation (*i.e.* the transportation cost) between original and generic medicines.

$$U^{bb}(x) = \begin{cases} v - C_o & when\ consuming\ an\ original \\ v - C_g^i - t_o|x - z_g^i| & when\ consuming\ generic\ i \end{cases} \quad (1.1)$$

Brand-neutral consumers will always switch from the original medicine to the generic alternative as long as it is less expensive than the original medicine. The utility function of the brand-neutral consumer is therefore as follows:

[2] Gross valuation of treatment can be thought of for example as severity of illness.

$$U^{bn}(x) = v - C_g^i - t_g|x - z_g^i| \quad (1.2)$$

where C_g^i is the co-payment for generic medicine *i* and t_g is the horizontal differentiation between different generic medicines.

Co-payments in the Finnish pharmaceutical market are not only dictated by price and the reimbursement percentage but also by the reference price. The co-payments for original medicines (C_o) and generic medicines (C_g^i) are therefore given as a function of the price, co-payment rate, and the reference price where it is assumed that the consumer is reimbursed up until the reference price:

$$C_o = \alpha r + p_o - r \quad (2.1)$$

$$C_g^i = \alpha p_g^i \quad (2.2)$$

Where p_o and p_g^i is the price of the original medicine and generic medicine *i*, respectively, $\alpha \in (0,1)$ is the co-payment rate, and *r* is the reference price. In the model by Brekke *et al.*, the reference price is given as a function of the original medicine and the average price of the generic medicines in the RP group:

$$r = (1 - \beta)p_o + \frac{\beta}{n}\sum_{i=1}^{n} p_g^i \quad (3)$$

where $\beta \in (0,1)$ is a weight that indicates how much of the reference price is determined by generic medicines. In the Finnish market[3], the value of β is 1, when assuming a symmetric equilibrium for generic prices, since the reference price is determined only by the least expensive medicine in the RP group. *n* is the number of generic firms in the market.

[3] The current reference price in Finland is calculated as the price of the cheapest alternative in the RP group plus €0.5. The additional €0.5 is not accounted for in the model.

Brekke *et al* construct their mathematical model based on the aforementioned assumptions. The demand allocations of brand-neutral consumers are given by the average transportation costs for these consumers, which is equal to the locations in the circle where the brand-neutral consumers are indifferent[4] (x_{bn}^{*}) between the two neighboring generic medicines. Similarly, the demand allocations of brand-biased consumers are given by the average transportation costs for brand-biased consumers. Here the average transportation cost is given by the locations where the brand-biased consumers are indifferent (x_{bb}^{*}) between the original medicine and generic medicine *i*.

$$x_{bn}^{*} = \frac{1}{2n} + \frac{C_g^{i+1} - C_g^{i}}{2t_g} \tag{4.1}$$

$$x_{bb}^{*} = \frac{C_o \; - C_g^{i}}{t_o} \tag{4.2}$$

Combining the demand allocations of brand-neutral (4.1) and brand-biased (4.2) consumers as well as considering the fact that, in the circle, there are consumers located on both sides of each medicine gives the total demand for generic medicine *i* (D_g^i). The demand for the original medicine (D_o) is the total generic demand minus the total demand in the market:

$$D_g^i = \frac{2\lambda}{t_o}\left(C_o - C_g^i\right) + (1-\lambda)\left(\frac{1}{n} + \frac{C_g^{i+1} + C_g^{i-1} - 2C_g^i}{2t_g}\right) \tag{5.1}$$

$$D_o \; = \lambda\left(1 - \frac{2n}{t_o}\left(C_o - \frac{1}{n}\sum_{i=1}^{n} C_g^i\right)\right) \tag{5.2}$$

[4] The demand allocation is given by the location of the indifferent consumer since this is the maximum distance where the consumer prefers generic medicine *i* over generic medicine *i*+1.

where λ is the share of brand-biased consumers of which the remaining part (1- λ) are brand-neutral consumers. Simplifying marginal costs to be constant, identical, and equal to zero as well as taking into account the fixed costs (*f*) of entry for generic medicines gives the following profit functions for generic medicine *i* (π_g^i) and the original medicine (π_o):

$$\pi_g^i = p_g^i D_g^i - f \tag{6.1}$$

$$\pi_o \ = p_o \ D_o \tag{6.2}$$

Considering the rules for the reference price given by (3), the consumers' co-payments given by (2.1) and (2.2) as well as the demand functions for each medicine (5.1 and 5.2) gives the profit maximation problems for the original medicine and generic medicine *i*:

$$\max_{p_o} \pi_o \ = p_o \lambda \left(1 - \frac{2n\theta}{t_o} \left(p_o - \frac{1}{n} \sum_{i=1}^{n} p_g^i \right) \right) \tag{7.1}$$

$$\max_{p_g} \pi_g^i = p_g^i \left(\lambda \left(\frac{2}{t_o} \left(\theta p_o - \frac{(1-\alpha)\beta}{n} \sum_{i=1}^{n} p_g^i - \alpha p_g^i \right) \right) + (1-\lambda) \left(\frac{1}{n} + \frac{\alpha(p_g^{i+1} + p_g^{i-1} - 2p_g^i)}{2t_g} \right) \right) \tag{7.2}$$

Where $\theta = \alpha + (1-\alpha)$. The first-order condition for (7.1) and (7.2) is:

$$\frac{\partial \pi_o}{\partial p_o} = \lambda \left(1 - \frac{2n\theta}{t_o} \left(2p_o - \frac{1}{n} \sum_{i=1}^{n} p_g^i \right) \right) = 0 \tag{8.1}$$

$$\frac{\partial \pi_g^i}{\partial p_g^i} = \frac{2\lambda}{t_o} \left(\theta p_o - \frac{(1-\alpha)\beta}{n} \left(2p_g^i + \sum_{j \neq i} p_g^j \right) - 2\alpha p_g^i \right) + (1-\lambda) \left(\frac{1}{n} + \frac{\alpha(p_g^{i+1} + p_g^{i-1} - 4p_g^i)}{2t_g} \right) = 0 \tag{8.2}$$

Finally, applying symmetry for all generic medicine prices ($P_g^i = P_g^{i+1}$) and solving the first-order conditions gives the equilibrium prices for original and generic medicines for a given number of generic competitors:

$$p_o^*(\beta, n) = \frac{\left(n\alpha\left((1-\lambda)t_o + 2(1+\lambda)t_g\right) + 2\beta t_g(1-\alpha)(n+\lambda)\right)t_o}{4n\theta\left(n\alpha\left((1-\lambda)t_o + 3\lambda t_g\right) + \lambda\beta t_g(1-\alpha)(n+2)\right)} \tag{9.1}$$

$$p_g^*(\beta, n) = \frac{(2-\lambda)t_o t_g}{2\left(n\alpha\left((1-\lambda)t_o + 3\lambda t_g\right) + \lambda\beta t_g(1-\alpha)(n+2)\right)} \tag{9.2}$$

The model implies that as the number of generic medicines increases, the prices of both originals and generics decrease. Furthermore, since the reference price is internally determined as a function of the prices of medicines within the RP group, producers of generic medicines have an incentive to strategically lower their prices thus making original medicines more expensive to the consumers. As a result, original medicines have an incentive to lower their prices as well due to the increased co-payment when prices exceed the reference price. In the Finnish market, this effect is at its strongest since the reference price is entirely determined by the cheapest available alternative (β=1). Applying the rules of the Finnish market to equations (9.1) and (9.2) allows for the analysis of the expected effects of increased competition. To demonstrate this more clearly, Table 3 below presents the expected effects in the Finnish market for originals and generics in a situation where the degree of vertical differentiation (t_o) is larger than the degree of horizontal differentiation (t_g) and where 55% of the total consumer base is brand biased. As mentioned in Chapter 2.1.1, Nokelainen *et al.* (2020) found that 53.9% of consumers have denied substitution at least once, indicating that at least 53.9% of Finnish consumers are brand biased. The degree of horizontal and vertical differentiation is more difficult to assess, therefore in Table A1 (Appendix A), I show that similar price effects of increased competition are obtained in a market where the degree of vertical (t_o) and horizontal (t_g) differentiation is equalized but where the share of brand-biased customers is higher.

Table 3. Price effects of increased competition

	Originals			Generics		
Generic firms (*n*)	**α = 60%**	**α = 35%**	**α = 0%**	**α = 60%**	**α = 35%**	**α =0%**
1	1.279	1.327	1.409	1.058	1.153	1.318
2	0.671	0.731	0.869	0.593	0.711	0.989
3	0.456	0.507	0.645	0.412	0.514	0.791
4	0.345	0.389	0.517	0.315	0.403	0.659
5	0.278	0.315	0.432	0.255	0.331	0.565
6	0.232	0.265	0.372	0.215	0.281	0.494

Note: Parameters used in the calculations: λ = 0.55, t_o= 3, t_g= 2, β=1. α indicates the percentual co-payment rate.

The first thing to note in Table 3 above is that the prices of both generic and original medicines decrease as the number of generic medicines increases. Furthermore, the model predicts that original medicines decrease their prices proportionally more than generic medicines as the number of generic competitors increases. This is due to the counteracting effect an increase in the number of generic competitors has on generic medicines incentives to strategically set their prices. The model assumes the reference price to be a function of all generic prices (when β=1), which leads to a reduced ability for each individual generic medicine to influence the reference price as the number of generic medicines increases. In the Finnish market, this might not be the case because the reference price is solely determined by the least expensive alternative in the RP group and not by all generic medicines as the theoretical model would imply. Moreover, the model expects the decrease in prices to be nonlinear in absolute terms, where a decrease in price following one additional competitor is reduced as more competitors enter the market. When comparing the prices between different reimbursement rates (1-α), it is clear that medicines become more expensive as the co-payment percentage decreases, which is intuitive since a decreased co-payment percentage makes medicines less expensive for the consumers.

3.2 The generic competition paradox

An interesting empirical phenomenon found in multiple pharmaceutical markets is the existence of the *generic competition paradox* (see Sherer, 1993; Vandoros & Kanavos, 2013; Frank & Salkever, 1997). The generic competition paradox, first described by Sherer (1993), dictates that as generic medicines penetrate the market, the prices of original medicines increase. The paradox clearly contradicts basic economic theory that would predict a decrease in prices as markets become more competitive.

Sherer (1993) argues that the paradox is explained by two main institutional factors. First, as mentioned in Chapter 2, one of the major differences in the pharmaceutical market compared to other markets is that in the pharmaceutical market, the consumer and the decision-maker are not the same individual. The decision-maker (the physician) is not affected by the financial consequences that emerge from prescribing a more expensive alternative. Because of this, Sherer argues that physicians tend to be "risk-averse, insensitive to cost, and creatures of habit" (Sherer, 1993, p 101), which then leads to prescribing original medicines despite large price differences. Generic substitution and RP systems have however almost certainly mitigated the effects of this. The second factor is consumers having imperfect information. A segment of consumers might not be well informed on the extreme similarities between original medicines and their generic alternatives, leading to consumers opting for the more expensive, familiar medicine.

As a result, consumers become segmented into two groups: price-sensitive (or brand-neutral) consumers who purchase cheap generic alternatives and price-insensitive (or brand-biased) consumers who purchase expensive original medicines (Sherer, 1993). Generic manufacturers would naturally target price-sensitive consumers by having low prices. Manufacturers of original medicines, however, might find it more profitable to completely exit the price-sensitive consumer segment and only focus on the price-

insensitive consumers. This would allow original manufacturers to not only keep their prices high but, in some cases, even increase them from before.

Although the generic competition paradox is mainly an empirical finding which is not supported by most theoretical frameworks, there have been several attempts to explain it from a theoretical modelling perspective. Frank and Salkever (1992) for example proposed a similar model to that of Brekke *et al.* (2016), where the demand side consists of two segments, price-sensitive (brand-neutral) and price-insensitive (brand-biased) consumers. The model relies on two main assumptions to arrive at a result where original producers increase their prices following generic entry. First, the price-insensitive consumers only demand the original medicine. Second, when generic alternatives enter the market, the price-sensitive segment completely shifts their demand towards less expensive generic medicines. This results in a situation where the demand function of original medicines shifts inward but also becomes less elastic, which are both due to the price-sensitive consumers leaving the market for originals, thus allowing original producers to raise their prices. This contrasts with the model by Brekke *et al.* (2016) where, as seen in equation (5.1), the demand of the price-insensitive consumers relies on both generic and original prices, meaning that price-insensitive consumers shift their demand toward generic alternatives if the price difference is sufficiently large.

What can then be expected from the empirical estimations based on the theories presented above? Since the Finnish RP system is based on endogenous reference pricing and generic substitution, theoretically generic prices can be expected to decrease when the number of competitors increases. According to the model by Brekke *et al* (2016), the price-reducing effect is non-linear in absolute terms, meaning that with each additional competitor the prices decrease less. For original medicines, the expectations are mixed. The model by Brekke *et al.* expects the prices of original medicines to decrease with increased competition and even more so than the prices of generics, while the generic competition paradox expects the prices of original medicines to stagnate or even increase. The main identifying assumption in the two theories is how firms and consumers are assumed to behave. The generic competition paradox assumes that

consumers become segmented into price-sensitive and price-insensitive customers, where they are exclusively served by generic and original producers, respectively. Although the model by Brekke *et al.* has consumer segmentation as well, they allow for the demand of the brand-biased (price-insensitive) segment to depend on both the prices of originals and generics. Intuitively this leads to two possible outcomes:

Hypothesis 1: *If the demand of price-insensitive consumers depends on the prices of both originals and generics, then the prices of generic and original medicines decrease following an increase in number of generic medicines.*

Hypothesis 2: *If the demand of price-insensitive consumers only depends on the prices of originals, then an increase in the number of generic medicines is followed by a decrease in the price of generic medicines but no impact (or an increase) in the prices of original medicines.*

4 Literature review

The following chapter presents past empirical results relating to the effects of increased competition on pharmaceutical prices. Economic literature on the effects of competition within the Finnish RP system is lacking. On an international scale, however, several studies have estimated the effects of competition on medicines within different regulatory environments.

Aalto-Setälä (2008) studied the effects of the number of competitors on pharmaceutical prices in Finland using monthly data on prices and sold quantities from March 2003 to April 2004. The dataset included both OTC and prescription medicines. Using 2SLS with sold quantities as an instrument for the number of competitors, Aalto-Setälä found evidence of price reductions following an increase in competition. The results suggest that one additional competitor decreases prices by 1.6% to 4.5% and that the prices of inexpensive medicines decrease more relative to expensive medicines. Aalto-Setälä suggests that this is because of the price band policy, which is more lenient for inexpensive medicines since the width of the price band is relatively larger for these medicines.

A more recent empirical paper by Koskinen *et al*. (2015) studied the medium- to long-term price effects of the RP system on the three most used active ingredients within antipsychotic medicines in Finland: olanzapine, quetiapine, and risperidone. Using panel data from the Social Insurance Institution of Finland between the years 2006 and 2011 they found that the RP system induced price decreases ranging from 24.6% to 50.6%. Additionally, the findings suggest that in the medium to long-term, the RP system does not have a significant impact after the first initial price decreases. Perhaps more interesting for this thesis is that Koskinen *et al*. found that in the case of antipsychotic medicines, the prices tend to stagnate or increase in the medium to long-term. One of the chemical substances in the study, olanzapine, experienced significant changes in the number of firms during the analysis period. Immediately after the introduction of the RP system, there were four firms in the market, with two of them exiting later during the

study period. This allowed Koskinen *et al*. to capture the effect of competition on the prices of olanzapine. Koskinen *et al*. found a significant reduction in price competition after the exit of two of the firms, which led to a defined daily dose[5] price increase of almost 100%, from €1.4 to €2.80.

In the Nordic and European markets, perhaps one of the more notable recent empirical papers for this thesis is "Price competition in pharmaceuticals – evidence from 1303 Swedish markets" by Granlund and Bergman (2018). They study the short- and long-term price effects of increased competition within the Swedish RP system. The Swedish system is based on monthly auctions between products in the exchange groups, where the winner of the auction (*i.e.* the medicine with the lowest price), receives exclusive rights to be substituted to. Using monthly panel data between 2006 and 2012 they find significant price effects of increased competition within RP groups. Granlund and Bergman's results suggest that in the long-term, generic prices fall by 81% when the number of competitors increase from one to ten, while in the same scenario the prices of original medicines fall by 29%. Furthermore, they find evidence for constant elasticities, meaning that the price effects of a percentual increase in competitors are almost equally as large when there are only a few firms compared to many firms.

Using data from six sub-markets in Germany, the United Kingdom, the Netherlands, Sweden, Norway, and Denmark, Vandoros and Kanavos (2013) find evidence for the existence of the generic competition paradox in regulated European markets. They find that in the United Kingdom, the Netherlands, and Sweden, prices of original medicines tend to increase with the entry of generic competition while in Norway and Denmark, generic entry has no effect. In the German market, they find evidence of price decreases following generic entry. Brekke *et al*. (2011) find similar results regarding the Norwegian market, however, their results also suggest that the number of generic firms does not affect the prices of generic or original medicines.

[5] The average maintenance dose per day for a medicine used for its main indication in adults. (WHO, 2022)

Within the US market, Caves *et al*. (1991) and Frank and Salkever (1997) find that prices of generics decrease by almost 50% when the number of competitors increases from one to ten while the prices of originals tend to stagnate or even increase. Wiggins and Manes (2004) find that in the case of anti-infective medicines, the average prices decrease approximately 50% when the number of competitors increases from one to six or more, irrespective if it is a generic or an original medicine. The results of Saha and Xu (2021) suggest that when accounting for inflation-adjusted prices, the prices of originals decrease following the entry of generic competition. Using more recent data from 2007 to 2018, Nguyen, Sheingold, Tarazi and Bosworth (2022) find that generic prices decrease by 80% in the long-term when the number of competitors increase from one to ten or more. In Canada, Lexchin (2004) finds no significant effects following the entry of the first generic medicine however an increase in the prices of originals when the number of competitors increases to four or more.

Virtually all past empirical results, barring a few exceptions, suggest that increased competition results in lower prices for generic medicines. The results differ however in terms of the magnitude of the effects. Differences in regulation, study design, and the fact that several studies only use a small sample of the market are likely causes of this. For original medicines and the existence of the generic competition paradox, past results are mixed. Interestingly the effects of competition seem to be comparatively smaller in the Finnish market. To my knowledge however, only Aalto-Setälä (2008) has included estimates of the effects of number of competitors in the Finnish market.

5 Data and descriptive statistics

5.1 Data

The data used in the analysis is retrieved from two main sources: the Pharmaceuticals Pricing Board, Hila, and the Finnish Medicines Agency, Fimea (Finnish Medicines Agency Fimea, 2022b; Pharmaceuticals Pricing Board, 2022). Starting from the beginning of 2008, Hila has each month released a complete list of outpatient medicines included in the National Health Insurance (NHI) reimbursement scheme; the list includes pricing information on medicines, which RP group the medicine belongs to as well as various other product characteristics. OTC medicines and medicines with conditional reimbursement status are not included in the list. From the data, all medicines that are not included in the RP system are discarded as this thesis focuses specifically on competition within the system. Furthermore, the dataset is unbalanced since medicines can enter and exit the market during the study period.

The data is combined with Fimeas list of interchangeable medicinal products, which includes information on whether the product is an original, generic, or is parallel imported. The data is combined using the product-specific Nordic Product Number (Vnr); a unique six-digit number allocated for each individual medicinal package entering the market. Prices are corrected for inflation using the consumer price index (CPI) provided by Statistics Finland, with the year 2005 set as the base level (Statistics Finland, 2022). Prices of medicines included in the NHI reimbursement scheme are directly regulated by the Finnish government, consisting of the wholesale price, the pharmacy margin, and taxes. Wholesale prices are used in the analysis to be able to consistently compare prices from different periods since the pharmacy margin has changed during the study period (Reinikainen, Kokko, Jauhonen & Happonen, 2021). The dataset includes data between January 2008 and December 2021, but because the RP system was introduced in April 2009, the starting point of the analysis is chosen to

be July 2009. This is to avoid the possible initial price shocks from the introduction of the RP system to introduce bias to the estimations.

As discussed in Chapter 2.2.1, there have been several legislative changes in the Finnish pharmaceutical market during the study period. To account for this, some of the data have been removed from the analysis. First, some medicines such as epilepsy medicines and biologic medicines are included in the RP system but not directly substitutable at pharmacies (The Social Insurance Institution of Finland, 2022b). These observations have therefore been removed from the data. Second, as discussed above, since 2016 for a new generic medicine to be accepted into the RP system its maximum reasonable wholesale price must be at most 50% of its original counterpart. Due to this, only RP groups that have formed before 2016 have been considered. Finally, all RP groups that have included a parallel imported product during the study period are removed from the data to allow this thesis to solely focus on the effects of locally sourced medicines. In addition, this inclusion criteria controls for the new regulation in 2017 which dictated that RP groups can be formed around parallel imported products while original medicines are still covered by patent protection. The final dataset contains approximately 77% of all RP groups within the RP system during the study period.

Finally, for some of the econometric specifications, data retrieved from the Dental and Pharmaceutical Benefits Agency (TLV) in Sweden is used (The Dental and Pharmaceutical Benefits Agency, 2022). The data is based on their list of current medicines included in the Swedish reimbursement scheme, which is combined with TLV's past decisions about the entry and exit of pharmaceutical substances.

5.2 Variables and descriptive statistics

Table 4. Descriptive statistics

	Originals				***Generics***			
Variable	Mean	SD	Min	Max	Mean	SD	Min	Max
Price	66.02	303.09	0.71	7 841.75	26.22	98.93	0.22	4 111.05
lnPrice	3.02	1.22	-0.34	8.97	2.42	1.05	-1.53	8.32
RPgroup	4.22	2.52	1	20	5.10	2.77	1	20
lnRPgroup	1.26	0.61	0	2.99	1.46	0.62	0	2.99
ThAlt	4.23	2.68	1	37	4.31	2.37	1	37
lnThAlt	1.25	0.66	0	3.61	1.29	0.64	0	3.61
ATC7group	6.80	3.92	1	23	7.51	4.16	1	23
lnATC7group	1.74	0.64	0	3.14	1.85	0.60	0	3.14

ATC5 groups	152	*Originals*	988
RP groups	1 177	*Generics*	5 022
Products	6 010		
Observations	386 569		

Note: "ATC5 groups" describes the number of therapeutic groups calculated as the number of distinct five-digit ATC codes in the data.

Table 4 above presents the mean, standard deviation, minimum and maximum values as well as the number of observations for variables used in the estimations. The final dataset contains 386 569 total observations of 6 010 distinct products in 1 177 RP groups. Approximately 80% of all observations included in the dataset are generic medicines. For 1 881 observations the price is 0, these are assumed to be measurement

errors and therefore not included in the analysis. Furthermore, for 14 934 observations the wholesale price is missing and therefore discarded.

The variable *Price* represents the CPI deflated wholesale price for product *i* in month *t*. *lnPrice* is the natural logarithm of the variable *Price* and used in the estimations due to the significant price differences between medicines. The data reveals that approximately 39% of observations are priced equal to the maximum reasonable wholesale price. For generics and originals, it is 26% and 72%, respectively. The variable *RPgroup* and its natural logarithm *lnRPgroup* represents the number of products included in the RP group of product *i* in month *t*. The variable *lnRPgroup* is used in the analysis with the assumption that the price effects of one additional competitor are reduced as the number of competitors increases, which is also supported by the theoretical framework by Brekke *et al.* (2016). The same assumption is made to the variables *lnATC7group* and *lnThAlt*. Specifying the variable *RPgroup* as the number of products in each RP group makes a critical assumption that the effects of competition from original and generic medicines are equal. Another option would be to specify variables for generic and original medicines separately. This would however require adding an arbitrary constant to the log transformation of the variables to avoid missing values, which would almost certainly bias the results (Changyong, 2014). A third option would be to transform the variables using for example a Box-Cox transformation, which would significantly affect the interpretability of the estimations.

Within the sub-market of an active ingredient, multiple RP groups can be formed due to differences in factors such as package size, route of administration, or strength. To control for the possibility of competition between products in different RP groups but within the same active ingredient, I include the natural logarithm of the variable *ATC7group*, which is defined as the number of RP groups within the active ingredient of product *i* in month *t.* The number of products is not used due to the high probability of multicollinearity with the variable *lnRPgroup*. In line with similar empirical papers, the variable *lnThAlt* is included in the estimations to control for the possibility of therapeutic competition influencing prices (Granlund and Bergman, 2018; Brekke *et al*.,2009).

ThAlt and its natural logarithm *lnThAlt* represents the number of therapeutic groups, calculated as the number of active ingredients included in the same five-digit ATC group as product *i* in month *t.* As above, the number of products is not used due to the high likelihood of multicollinearity. Furthermore, the variable *GenericEntry* (not presented in Table 4) is included in the analysis to control for the effects of time since it has been possible to substitute the active ingredient in pharmacies. The variable is defined as the number of months since the first generic product entered the market for each active ingredient and calculated using data from 2005 onwards. Some bias is expected from the variable since it gives the same value for all active ingredients for which generic entry occurred before the year 2005. The preferrable variable would be time since patent expiry but is not used due to lack of data availability.

As discussed throughout the thesis, several policy changes have taken place during the study period that might have had price effects on some products. Some of the policy changes have been accounted for in the data inclusion criteria, but not all. Therefore, to account for the remaining policy changes, policy dummies are included in the econometric estimations. Perhaps the most important policy change in terms of the estimations is the reduction in the maximum reasonable wholesale prices of reimbursable medicines in July 2016, targeted towards original medicines with higher maximum reasonable wholesale prices than their most expensive generic counterpart. To account for this, the variable *PriceCut* is included in the analysis, which takes the value of 1 in July 2016 for medicines affected by the policy and 0 for remaining observations. The data reveals that approximately 1/3 of original medicines were affected by the price cut. Furthermore, the variable *PriceBand2017* is a dummy variable that accounts for the change in the price band in January 2017, taking the value 0 before the policy change and the value 1 after. From 2016 onwards, pharmacy personnel have been required to inform patients of the least expensive available interchangeable medicine instead of any medicine within the price band. This is not accounted for in the estimations and assumed that the price effects are negligible.

Table 5. Descriptive statistics by size of reference price group

			Originals		*Generics*	
No. of products in RP group	**Share of total products (%)**	**Share of RP groups with an original (%)**	**Average price**	**Price = max. wholesale price (%)**	**Average price**	**Price = max. wholesale price (%)**
1	7.06	64,60	26.33	94.06	35.14	82.41
2	13.75	71.50	54.10	72.10	28.31	60.00
3	14.70	69.24	50.79	56.71	32.59	42.91
4	14.56	74.11	73.84	55.83	33.31	30.52
5	12.84	75.34	76.96	60.92	31.65	24.74
6	10.67	80.49	65.50	58.74	25.20	9.99
7	8.40	83.36	48.97	59.91	18.91	5.78
8	7.21	91.16	49.84	60.94	15.07	3.25
9	4.81	91.75	55.22	66.05	11.58	2.66
10+	3.55	95.96	71.31	75.95	9.12	1.51

Note: "*Price = max. wholesale price"* describes the share of products where the wholesale price equals the maximum reasonable wholesale price. Average prices corrected for the consumer price index with the base year set to 2005. "*Share of RP groups with an original (%)"* describes the percentual share of RP groups where an original medicine is included in the RP group.

To further explore the data, Table 5 above presents descriptive statistics of generics and originals by the size the of the RP group. Observing average prices might not be an optimal representation of the effects of increased competition due to the large price differences between medicines. Therefore Table 5 includes the share of products where the wholesale price of the medicine equals the maximum reasonable wholesale price set by Hila. For generics, 82.41% of products are priced equal to the maximum reasonable wholesale price when the RP group contains only one product, while for RP groups with ten products or more, only 1.51% are priced equal to the maximum reasonable wholesale price. In absolute terms, a correlation between RP group size and generic prices is also observed. This would suggest that generic prices respond to competition.

The prices of original medicines however seem to behave differently. In situations where original manufacturers face no generic competition, 94,06% price their products equal to

the maximum reasonable wholesale price. The percentage decreases up until the fourth generic competitor enters the market, after which it appears to slightly increase following each new entry, indicating that the relationship between original medicines and the number of competitors might not be entirely linear. This is somewhat in line with the results of Lexchin (2004), who found in the Canadian market that the prices of originals tend to increase in markets where four or more generic medicines are available but not in markets with less than four competitors. The prices in absolute terms do not seem to exhibit any clear correlation with the size of the RP group. It is however important to note that it is not a causal comparison as all products do not exist across all RP group sizes. Finally, Table 5 presents the percentage of RP groups where an original medicine is included in the RP group. This is to check for the possibility of original medicines exiting the market when the number of competitors increases, either by a complete market exit or by pricing higher than the maximum reasonable wholesale price and consequently not be reflected in the data. The results in Table 5 suggest that this is not a concern for the analysis.

6 Econometric specifications and results

The following chapter presents the empirical strategy used to analyze the effects of increased competition on prices within the Finnish reference price system. In Chapter 6.1 the primary econometric models are presented. Chapter 6.2 presents the results of the main econometric estimations. Chapter 6.2.1 expands the basic econometric models to account for possible endogeneity.

6.1 Econometric specifications

As mentioned above, this thesis does not evaluate the effects of the RP system but rather the effects of competition within the system. To analyze this, a two-way fixed effects regression model is used with time fixed effects on a monthly level and RP group fixed effects to control for variation caused by time and differences in RP groups, respectively. Additionally, the time fixed effects control for the seasonality of medicine prices. Since the reference price for each RP period is determined at the start of the period, the average prices of medicines are likely lower in months when firms compete for setting the reference price. RP group fixed effects are used instead of the more intuitive product fixed effects for two main reasons. First, as discussed in Chapter 2, products within an RP group are essentially identical to each other in all relevant characteristics that affect performance. Second, using RP group fixed effects allows for the use of a dummy variable that differentiates between original and generic medicines, thus allowing to capture the price effects of original versus generic medicines. If product fixed effects were used instead, this dummy variable would most likely be collinear with the product fixed effects and omitted from the estimations (Wooldridge, 2012). The basic econometric model is as follows:

$$lnPrice_{it} = \beta_0 + a_i + a_t + \beta_1 lnRPgroup_{it} + \beta_2 lnATC7group_{it} + \beta_3 lnThAlt_{it} + \beta_4 Original_i + \beta_5 PriceCut_{it} + \beta_6 PriceBand2017_{it} + \beta_7 GenericEntry_{it} + \varepsilon_{it} \quad [1]$$

where the dependent variable *lnPrice* is the natural logarithm of the CPI deflated wholesale price of product *i* in month *t*. The main variable of interest, *lnRPgroup,* is the natural logarithm of the size of the RP group for product *i* in month *t*, *lnATC7group* is the natural logarithm of the number of RP groups within the active ingredient of product *i* in month *t. lnThAlt* is the natural logarithm of the number of active ingredients sharing the same five-digit ATC code as product *i* in month *t. Original* is a dummy variable taking the value 1 for original medicines and 0 for generic medicines. *PriceCut* and *PriceBand2017* are dummy variables that account for policy changes during the study period. *GenericEntry* depicts the number of months since the first generic entry for the active ingredient. a_t are time fixed effects on a monthly level and a_i are fixed effects on an RP group level. ε_{it} is an error term.

An advantage with the data is that the observations are on a product level, therefore, it is possible to distinguish between original and generic products. Because of this, two additional models are specified where the dependent variables are the natural logarithms of original and generic prices, respectively. This allows the effects of competition to be isolated on original and generic medicines. For the estimations, product fixed effects are used since the variable *Original* is excluded from the models. Furthermore, the variable *PriceCut* is excluded from the estimations concerning generic medicines as the regulation did not affect generic medicines. Below are the specifications for the models:

$$lnGenPrice_{it} = \beta_0 + a_i + a_t + \beta_1 lnRPgroup_{it} + \beta_2 lnATC7group_{it} + \beta_3 lnThAlt_{it} + \beta_4 PriceBand2017_{it} + \beta_5 GenericEntry_{it} + \varepsilon_{it} \quad [2]$$

$$lnOrigPrice_{it} = \beta_0 + a_i + a_t + \beta_1 lnRPgroup_{it} + \beta_2 lnATC7group_{it} + \beta_3 lnThAlt_{it} + \beta_4 PriceCut_{it} + \beta_5 PriceBand2017_{it} + \beta_6 GenericEntry_{it} + \varepsilon_{it} \quad [3]$$

As with any classical linear regression model, the two-way fixed effects estimator relies on several assumptions for the estimations to be considered valid (Wooldridge, 2012). To test for these, several different statistical tests are used. To assess for normality of residuals, the data is visually inspected using a histogram of the residuals. The results show that the residuals are normally distributed (see Figure B1 in Appendix B). The modified Wald statistic is used to assess whether groupwise heteroskedasticity is present in the data, for which the null hypothesis is groupwise heteroskedasticity (Baum, 2001). The results confirm that the data is heteroskedastic, therefore, all models are estimated using cluster-robust standard errors clustered by RP group. Possible multicollinearity is tested with the Variance Inflation Factor (VIF), where the general rule of thumb is that the test statistic should not exceed 10 (Belsley, Kuh & Welsch, 2005). The VIF for all specifications is well below 10, implying that multicollinearity is not a problem (see Table B1 in Appendix B). Furthermore, the Hausman specification test proposed by Hausman (1978) is used to choose between random and fixed effects. The null hypothesis is that a_i is uncorrelated with the independent variables in the model. The results of the test (Table 6) reject the null hypothesis, meaning that a fixed effects estimator is more appropriate since fixed effects, as opposed to random effects, allow for correlation between a_i and the independent variables (Wooldridge, 2012).

Finally, one of the major issues with estimating the effect of the number of competitors on price is the underlying assumption of exogeneity. The number of competitors would, in most cases, be considered endogenous as it most certainly is affected by price through the profit margins in the market. Because of the clear and explicit rules in the Finnish pharmaceutical market however, the issue of exogeneity might not be present in the estimations. As mentioned in Chapter 2, all reimbursable medicines are regulated by a maximum reasonable wholesale price set by Hila, and additionally, medicines within the RP system are regulated by the price band. These two regulations might mitigate the effects of a possible endogeneity bias if Hila has been successful at regulating the market. The regulations are however not guaranteed to work, therefore, in Chapter 6.2.1, the econometric model is modified to address the possible endogeneity problem.

6.2 Results

Table 6. Estimated effects of competition on price. Two-way fixed effects

VARIABLES	(1) 2WFE All	(2) 2WFE Generics	(3) 2WFE Originals
lnRPgroup	-0.52***	-0.50***	-0.26***
	(0.033)	(0.022)	(0.021)
Original	0.52***		
	(0.031)		
lnATC7group	-0.28***	-0.36***	-0.026
	(0.075)	(0.042)	(0.036)
lnThAlt	0.058	0.027	-0.022
	(0.063)	(0.041)	(0.036)
PriceCut	-0.082***		-0.19***
	(0.030)		(0.018)
PriceBand2017	0.23**	0.47***	0.47***
	(0.11)	(0.085)	(0.068)
GenericEntry	-0.0040***	-0.0064***	-0.0047***
	(0.00080)	(0.00074)	(0.00055)
Constant	3.87***	4.16***	3.60***
	(0.17)	(0.12)	(0.096)
Observations	386 010	307 850	78 160
R-squared	0.282	0.178	0.210
Number of RP groups	1 177	-	-
Number of products	-	5 022	963
FE RP group	Yes	No	No
FE product	No	Yes	Yes
FE month	Yes	Yes	Yes
Hausman test (p-value)	0.000	0.000	0.000

Note: Cluster-robust standard errors in parentheses. *** p<0.01, ** p<0.05, * p<0.1

The results of the primary econometric specifications are presented in Table 6. All three models yield significant positive effects regarding increased competition on price. Focusing on model [1] first in column (1), the results suggest that when holding all other things constant, an increase in RP group size from one to two (or e.g., three to six) is associated with a price decrease of approximately 30%[6], while an increase from one to ten is associated with a price decrease of approximately 71%. The estimate indicates that original medicines are 68% more expensive relative to generic medicines. The number of RP groups within the active ingredient seems to be associated with price decreases as well, where an increase from one to two RP groups in an active ingredient appears to be associated with an 18% decrease in the average prices of medicines. Furthermore, therapeutic competition, or in other words, competition between different active ingredients within the same therapeutic area does not appear to influence the prices of medicines within the RP system.

As with all estimated models, the point estimate for *PriceBand2017* is significant and positive, which indicates that medicines have increased their prices following the regulation change of the price band. The estimate for model [1] indicates that after narrowing the price band, the average price of medicines has increased by approximately 26%. It is possible that narrowing down the price band has led to non-competitive firms increasing their prices if they have not been able to lower their prices enough to be included in the price band. The variable should however be interpreted with caution as other factors not accounted for in the estimations might influence the point estimate such as the regulation change in 2016 after which pharmacy personnel have been required to inform patients of the cheapest available interchangeable medicine. Finally, the average prices of medicines appear to decrease with the time passed since the first generic medicine entered the market.

For model [2] where the effects of competition on price are isolated only on generic medicines, significant positive effects of increased competition are observed as well. The results suggest that an increase in RP group size from one to two decreases the

[6] The formula used to interpret log-log models:$[\ (1 + \Delta\%)^{\beta_1} - 1] * 100$ (Yang, 2020)

prices of generic medicines by approximately 29%, while an increase from one to ten decreases the prices by 69%. The results obtained here are similar, although slightly smaller than those by Grandlund & Bergman (2018) who estimated a similar model in the Swedish market. Moreover, as in the previous model, prices of generics appear to react to increases in the number of RP groups within the active ingredient, where an increase from one to two RP groups is associated with a price decrease of approximately 22%. As with model [1], therapeutic alternatives do not seem to affect the prices of generic medicines. Surprisingly, the results suggest that that after the regulation change of the price band, when holding all things constant, the prices of generic medicines have increased by almost 60%.

Column (3) presents the estimates for model [3], where the effects are isolated on original medicines. The estimate for *lnRPgroup* indicates that original medicines react to increased competition by lowering their prices, however less than generics. For originals, the estimates suggest that an increase in RP group size from one to two is associated with approximately a 16% decrease in prices and an increase from one to ten products decreases prices by 46%. In absolute terms however, the difference between generics and originals would be smaller and the price decrease could in some cases possibly be higher for originals. When accounting for the fact that original medicines are generally more expensive as shown in the estimates for model [1], a percentual price decrease would be more in absolute terms for originals compared to generics. Furthermore, the number of RP groups in an active ingredient does not appear to affect the prices of original medicines. Intuitively, this can be explained by the fact that it is the manufacturer of the original medicine that determines the number of RP groups in each active ingredient since a RP group cannot be formed without the reference medicine, thus an increase in the number of RP groups should not have a significant effect on the prices of originals. Similarly to the rest of the models, the number of therapeutic groups does not seem to have any significant effect on the prices of original medicines within the RP system. Finally, like in the rest of the models, narrowing the price band appears to have increased the average prices of originals.

Table B2 in Appendix B shows that the results for *lnRPgroup* in the estimations for generics and originals are nearly identical in nested models, where some or all the independent variables are excluded. Furthermore, due to the significant estimated effect of narrowing the price band in January 2017, Table B3 in Appendix B presents separate regressions for before and after the regulation change for models [2] and [3]. For original medicines, the results for the variable *lnRPgroup* differ slightly when comparing before and after the regulations change, but not significantly. The estimates suggest that before the regulation change an increase in RP group size from one to two was associated with a price reduction of approximately 15%, while the same estimate after the regulation change is 13%. An increase from one to ten medicines is estimated to decrease prices by approximately 42% and 38% before and after the regulation change, respectively. Surprisingly, the estimate for therapeutic competition is significant at the 5% level in the estimate after the regulation change. The estimate implies that when a new therapeutic alternative emerges, the prices of originals increase by approximately 7%. Considering the rest of the models, the estimate does not seem to be robust. For generic medicines, the estimations for before and after the regulation change differ more compared to originals. According to the estimates, generic medicines reacted more to increased competition before the regulation change, where an increase in RP group size from one to two was associated with a price decrease of approximately 31%, while after the regulation change the corresponding increase is associated with a price decrease of approximately 25%. When comparing an increase from one to ten medicines, the corresponding price decreases are 72% and 63% before and after the regulation change, respectively. The remaining control variables yield roughly the same results in the two time periods.

Finally, as discussed in Chapter 5.2, the relationship between original medicines and the size of the RP group might not be entirely linear but rather resemble more of a parabolic relationship, where the prices of original medicines decrease when the first few competitors enter the market but start increasing after a certain point. Therefore, in Table B4 in Appendix B, a quadratic model is estimated where the square of *lnRPgroup* is included as an independent variable. Including both the independent variable and its

square allows for estimating how the slope of the regression line changes when the number of competitors increases (Wooldridge, 2012). Comparing the R^2 of the quadratic model (0.211) to the one without (0.210) shows that the R^2 of both models are practically identical, indicating that the quadratic model might not be a better fit for the data. Furthermore, Calculating the vertex[7] of the estimated parabola gives the size of the RP group where the model expects original prices to start increasing in price again. For the estimation, the vertex is far outside of the data range at approximately 840 products, further implying that a linear model is more appropriate.

6.2.1 Accounting for endogeneity

As mentioned in Chapter 6.1, the primary econometric models might be biased due to endogeneity in the size of the RP group. As a result, the regressions might estimate a smaller effect of the number of competitors on price. In this chapter, the issue is addressed by utilizing an instrumental variable (IV) in the context of a Generalized Method of Moments estimator (GMM), which allows for robust estimations in the presence of endogeneity and heteroskedasticity (Baum, Schaffer & Stillman, 2007).

Instrumental variable estimations are commonly used in econometric applications in the economic literature of generic substitution and RP systems (see Aalto-Setälä, 2008; Brekke *et al*., 2011; Granlund & Bergman, 2018). Instrumental variable estimations are used to account for the prospect of omitted variable bias, which occurs when one or more relevant variables are left out of the estimations. As mentioned in Chapter 6.1, the profit margins in the market might lead to such bias. By instrumenting the number of competitors however, the bias can be addressed. The basic premise behind instrumental variables is that changes in the endogenous variable which are caused by changes in the instrument are unconfounded, *i.e.,* changes in the instrument will affect the endogenous

[7] The vertex is calculated using the following formula: $|\beta_1/(2\beta_2)|$ where β_1 is the point estimate for *lnRPgroup* and β_2 is the point estimate for the squared term of *lnRPgroup* (Wooldridge, 2012).

variable but not the error term and therefore not the dependent variable (Woolridge, 2012).

As an instrument, the number of monthly competitors in Sweden for the corresponding active ingredients are used. The number of competitors in Sweden[8] should intuitively be an appropriate instrument as it is reasonable to assume that the number of competitors in Finland and Sweden are correlated. There is however no reason to believe that medicine prices in Finland would be directly affected by the number of competitors in Sweden for several reasons. First, although prescription medicines can be bought in Sweden with a Finnish prescription, to receive reimbursement, the medicine must be bought in person at a Swedish pharmacy. Prescription medicines bought through the internet and delivered by mail are not reimbursable (The Social Insurance Institution of Finland, 2020). Therefore, purchasing medicines from Sweden induces travel costs for the consumer. Furthermore, consumers can only purchase a 1–3-month supply at a time, depending on how expensive the medicine is, leading to increased travel costs. Second, the incentive for firms to lower their prices based on the number of competitors in Sweden is low since the reference price is internally based on the prices within the RP group. Finally, since the Finnish National Health Insurance scheme includes a maximum limit on out-of-pocket costs for prescription medicines, there would only be limited benefits for the consumer to purchase medicines from Sweden. Brekke *et al*. (2011) for example use the same instrument in their analysis of the Norwegian pharmaceutical market.

For an instrumental variable to be valid it must fulfill two main assumptions: *instrument exogeneity* and *instrument relevance*. Instrument exogeneity refers to the assumption that the instrument is not correlated with the error term. For just-identified models, *i.e.,* models where the number of instruments is the same as the number of endogenous variables, exogeneity of the instrument cannot be tested and must be assumed through known economic behavior. This is due to the error term being unobservable, thus the

[8] Here the number of competitors is defined as number of competitors per active ingredient as opposed to the Finnish data which is on an RP group level. This is due to data availability.

correlation between the instrument and the error term is not possible to test. As mentioned above, there is no reason to assume that the number of competitors in Sweden would directly affect Finnish medicine prices. Instrument relevance refers to how well the instrument explains variation in the endogenous variable (Wooldridge, 2012). If the assumptions do not hold, then the estimates and confidence intervals of the 2SLS regression are unreliable. To test for instrument relevance, I first test for underidentification of the instrument with the Kleibergen-Paap *rk* LM statistic. The null hypothesis is that the model is underidentified meaning that the instrument is irrelevant to the endogenous variable (Baum *et al*, 2007). Second, I test for weak identification of the instrument with the Kleibergen-Paap *rk* Wald statistic which tests for how correlated the instrument is with the endogenous variable. For the test, there is no clear consensus on when weak identification can be rejected. Some researchers use a general "rule of thumb" which states that the F statistic should be at least 10 for weak identification not to be considered a problem (Staiger & Stock, 1997). Stock and Yogo (2005) however, have proposed tabulated critical values for the Kleibergen-Paap *rk* Wald statistic, which define thresholds for which the statistic must be above for different levels of bias. The thresholds refer to how much more biased (10%, 15%, 20%, or 25%) the 2SLS estimator is compared to the OLS estimator.

Finally, if the instrument of choice proves to be valid, the endogeneity of the instrumented variable, *lnRPgroup*, is possible to test with the Durbin-Wu-Hausman specification test. The null hypothesis of the test is that the variable is exogenous, meaning that using an instrument is unfounded (Andersson, 2018). Failing to reject the null indicates that both the OLS and IV estimators are unbiased, but that the OLS estimator is more efficient.

Table 7. Estimated effects of competition on price. Two-stage least squares (2SLS)

VARIABLES	(1) 2WFE IV All	(2) 2WFE IV Generics	(3) 2WFE IV Originals
lnRPgroup	-0.51**	-0.58***	-0.048
	(0.24)	(0.16)	(0.20)
Original	0.52***		
	(0.035)		
lnATC7group	-0.28**	-0.33***	-0.16*
	(0.11)	(0.060)	(0.097)
lnThAlt	0.058	0.025	-0.024
	(0.063)	(0.041)	(0.043)
PriceCut	-0.082**		-0.22***
	(0.036)		(0.028)
PriceBand2017	0.20	0.58***	0.45***
	(0.17)	(0.13)	(0.12)
GenericEntry	-0.0039**	-0.0069***	-0.0037***
	(0.0017)	(0.0011)	(0.0010)
Observations	386 005	307 810	78 154
R-squared	0.282	0.175	0.098
Number of RP groups	1 172	-	-
Number of products	-	4 982	957
FE RP group	Yes	No	No
FE product	No	Yes	Yes
FE month	Yes	Yes	Yes
Kleibergen-Paap rk LM statistics (p-value)	0.000	0.000	0.000
Kleibergen-Paap rk Wald F statistic	20.79	46.61	12.34
Stock-Yogo critical value (10%)	16.38	16.38	16.38
Durbin-Wu-Hausman test (p-value)	0.987	0.534	0.0824

Note: Cluster-robust standard errors in parentheses (*** p<0.01, ** p<0.05, * p<0.1). *lnRPgroup* instrumented for the natural logarithm of the number of competitors in Sweden in corresponding active ingredients.

Table 7 above presents the results from the instrumental variable estimations and test statistics. I first note that the instrument of choice seems to be appropriate for the model where all medicines are included and, for the model, where only generic medicines are included. In the model that only includes original medicines, the Kleibergen-Paap rk Wald F statistic is above the rule of thumb of 10, but below the Stock-Yogo critical

value, indicating that the instrument is only weakly identified and therefore the estimates and the Durbin-Wu-Hausman test for original medicines might be unreliable. Were one to trust the results of the 2SLS model for originals, it would indicate that the prices of original medicines do not react to increased competition as the point estimate for *lnRPgroup* is negative but insignificant. The first-stage results are presented in Table B5 in Appendix B.

For the model where both original and generic medicines are included in column (1), the results of the 2SLS estimation are virtually identical to its counterpart without an instrument. Regarding the model that includes only generic medicines, the point estimate for *lnRpgroup* suggests a larger decrease in prices compared to the estimate without an instrument. The estimate suggests that an increase in RP group size from one to two products results in an average price decrease of generic medicines by 33%, compared to 30% in the model not accounting for endogeneity. In a situation where the number of products increases from one to ten, the model estimates a decrease of 75% in generic prices whereas without an instrument the estimate is 69%. The results are in line with the assumption of generic medicines entering markets with higher prices or larger profit margins. The results of the Durbin-Wu-Hausman test however imply that the OLS model is the less biased of the two estimators. The remaining independent variables have nearly the same point estimates as the estimation without an instrument except for the variable *PriceBand2017*, which implies an even larger effect of the regulation change in the price band at a price increase of 78% after the regulation change.

7 Discussion

The results of the econometric estimations suggest that an increase in the number of direct competitors is associated with a significant decrease in the average prices of pharmaceuticals within the Finnish RP system. For generic medicines the results are clear. The estimates suggest that when the size of the RP group increases from one to ten, it is associated with a price decrease of 63-75%, depending on the model and period estimated. Furthermore, the relationship between generic medicine prices and RP group size appears to be characterized by constant elasticities, meaning that prices decrease roughly as much when the size of the RP group increases from for example one to two as when the RP group increases from three to six. These results are in line both with the theoretical predictions by Brekke *et al.* (2016) as well as past empirical results by Wiggins and Maness (2004), Granlund and Bergman (2018), and Nguyen *et al.* (2022). Surprisingly however, the estimated magnitude of the price effects of competition obtained here are substantially larger than the estimated effects in past research concerning the Finnish market by Aalto-Setälä (2008). This is likely due to differences in study design where this thesis focuses on the price effects of increased competition within the RP system whereas the study by Aalto-Setälä (2008) focused on the introduction of the generic substitution reform in 2003. Furthermore, the results are consistent when accounting for the possible endogeneity problem that is often present in price-concentration studies. Although the point estimates differ, a significant price-reducing effect is still present in both models. Moreover, I find that competition between interchangeable products with different package sizes, routes of administration, or strengths influences the prices of generic medicines. Although the effects of one additional competitor within the same active ingredient, but in a different RP group, are not directly obtained from the estimations, I show that the number of RP groups within an active ingredient influences the prices of generic medicines.

Similarly, for original medicines, the results indicate that increased competition has price-reducing effects, although less when compared to generic medicines. The results support the theory by Brekke *et al* (2016) and consequently oppose the generic

competition paradox. Similarly to generic medicines, constant elasticities are observed for original medicines. The results suggest that when the size of the RP group increases from one to ten, original medicines decrease their prices by approximately 38-46%, depending on the model and period used. The estimates are in line with those by Wiggins and Manes (2004) but larger than those by Granlund and Bergman (2018). Furthermore, the prices of original medicines within the RP system do not appear to react to competition by therapeutic alternatives or products within the same active ingredient but with different package sizes, routes of administration, or strengths. The results of the estimations concerning original medicines should however be interpreted with caution as unfortunately, the instrumental variable estimations were only weakly identified and therefore likely biased, meaning that this thesis could not address the possible endogeneity problem.

Based on the results, significant savings in the public sector could be achieved by incentivizing more generic medicines to enter the market, even in RP groups where the number of competitors is already high. As noted by Granlund and Bergman (2018) in their analysis of the Swedish market, a possible incentive could be to decrease or remove administrative fees related to market entry and staying in the market. At present, the reference price for each RP period is determined based on the least expensive medicine in the group at the start of the period, but firms can change their prices every second week. Products within the price band have therefore a competitive advantage only for the first two weeks of the RP period, since after that all products have a chance to enter the price band. Extending the firms pricing periods to match the RP period could attract more firms and further activate price competition due to the increased competitive advantage when pricing below the price band. Although not the focus of the thesis, the results suggest that the regulation change of the price band has had a price increasing effect on both original and generic medicines and additionally negative effects on the price competition regarding generic medicines. In a report by the Social Insurance Institution in 2018, they reported a decrease in the reference price after the regulation change in eight out of the ten RP groups which they examined, meaning that at least one of the products in the RP groups have lowered their prices following the change in

regulation (Koskinen, 2018). They did however not report the effects on average prices within the RP groups, meaning that the average prices might still have increased. This would further support the hypothesis above that narrowing the price band has led to non-competitive firms increasing their prices if they have not been able to lower their prices enough to be included in the price band. Furthermore, the policy change in 2016 which dictated that pharmacies must inform the patient of the least expensive interchangeable medicine might have influenced the estimates of *PriceBand2017* as well, since the policy change reduced the competitive advantage of pricing within the price band and instead increased the competitive advantage of having the lowest price. For a full welfare analysis however, data on sold volumes would be required.

There are some limitations in the study that affect the accuracy of the estimations. As discussed in Chapter 2.1, there are three different levels of reimbursement in the Finnish reimbursement scheme. The level of reimbursement might affect firms' pricing strategies; for example, medicines covered by higher special reimbursement (100%) require no co-payment from patients which might affect the competitive environment. This is also the case for expensive medicines, where the expenses for medicines exceed the maximum out-of-pocket costs for patients faster. Furthermore, the analysis did not consider the relative size differences of the price band. Inexpensive medicines can increase their prices more compared to expensive medicines and still remain within the price band, provided that they do not exceed the maximum reasonable wholesale price. It would therefore be interesting in future research to analyze the price effects of competition in different price ranges. In the analysis, the main variable of interest, *lnRPgroup*, describes the size of the RP group in terms of the number of distinct products rather than the number of distinct firms in the group. Firms might have multiple products in the same RP group which would lead to bias in the estimations since these products would not engage in price competition. To distinguish between products that compete and products that do not would however require data of firms and their subsidiaries. For instance, the multinational pharmaceutical firm Teva pharmaceuticals, operates in Finland under the names Teva, Ratiopharm, and Actavis (Halonen, 2016). Finally, due to the highly heteroscedastic nature of the data, perhaps a more robust

approach than the one applied in this thesis would be to focus on smaller sub-markets within the pharmaceutical industry. Medicines in different therapy areas and price ranges likely react differently to increased competition, therefore more precise results could be obtained by analyzing the differences between therapy areas. For instance, studies have found that patients' adherence to treatment is affected by generic substitution, meaning that in some therapy areas physicians might be inclined to forbid generic substitution, thus affecting firms' pricing strategies (Straka, Keohane & Liu, 2017). Nevertheless, the results of the analysis provide evidence for significant effects on the prices of generic medicines following increased competition within the Finnish RP system.

8 Conclusion

This thesis has studied the effects of increased competition on the prices of generic and original medicines within the Finnish reference price system. Previous research on the effects of competition within pharmaceutical markets has yielded mixed results. Wiggins and Maness (2004), Aalto-Setälä (2008), and Bergman and Granlund (2018) all find that the prices of both generic and original medicines decrease when the number of direct competitors increases. The results of Frank and Salkever (1997) and Vandoros and Kanavos (2013) suggest an increase in the prices of original medicines when generic medicines enter the market. Brekke *et al.* (2011) find no evidence of either generic or original medicines decreasing their prices when the number of direct competitors increases.

Several two-way fixed effects regressions that account for policy changes and the possible endogeneity bias which often is present in price-concentration studies are applied to analyze the price effects of increased competition. The data used in the analysis consists of detailed month and product-level panel data between the years 2009 and 2021. The result of the thesis provides significant evidence of increased competition

having a large effect on the prices of generic medicines. The estimates indicate that generic medicines decrease their prices by 63-75% when the number of products in the RP group increases from one to ten, which implies that significant savings can be achieved by incentivizing generic medicines to enter the market, even in RP groups that already have many competitors. For original medicines, price-reducing effects are found as well, where a corresponding increase in RP group size is associated with a 38-46% decrease in average prices. The results regarding original medicines should however be interpreted with caution as the thesis was not able to properly account for the possible endogeneity problem. This thesis contributes to the existing research on RP systems by estimating the effects of competition within the system, whereas previous research has largely been focused on the effects of the introduction of such systems.

9 Sammanfattning på svenska – Swedish summary

Priskonkurrens inom läkemedel – en analys av den finska läkemedelsmarknaden

Hälsovårdsutgifterna i Finland har uppskattats öka till 28,5 miljarder euro år 2030 från 19,5 miljarder euro år 2014. Under de senaste två decennierna har bland annat utgifterna för receptbelagda läkemedel inom öppenvården mer än fyrdubblats. För att motverka detta har flera statliga åtgärder genomförts för att kontrollera de stigande kostnaderna för receptbelagda läkemedel, med varierande framgång. Den senaste stora reformen inom läkemedelsmarknaden var införandet av referensprissystemet år 2009 som kompletterade det tidigare införda läkemedelsutbytet. Systemet införde ett referenspris för ersättningen av utbytbara läkemedel, det vill säga läkemedel som anses vara identiska i fråga om faktorer som påverkar läkemedlets effekt. Inom det nya systemet ersätts utbytbara läkemedel endast till den del som inte överstiger referenspriset, som är baserat på det förmånligaste läkemedlet inom varje utbytesgrupp. Genom detta uppmuntras patienter att byta ut sina läkemedel mot billigare alternativ vilket därmed uppmuntrar företag att ingå priskonkurrens med varandra.

Tidigare studier är i stort sett eniga om att införandet av ett referensprissystem sänker de genomsnittliga priserna på läkemedel, men däremot vet man mindre om effekterna av ökad konkurrens inom ett sådant här system. I denna avhandling undersöks således effekterna av konkurrens inom det finska referensprissystemet med det huvudsakliga syftet att utreda hur läkemedelspriser reagerar på ökad konkurrens. Avhandlingen särskiljer mellan två olika kategorier av läkemedel, nämligen generiska och originalläkemedel. Ett originalläkemedel är det ursprungliga patentskyddade läkemedlet för en viss aktiv substans medan generiska läkemedel är de kopior som träder in på marknaden efter att patentskyddet på originalläkemedlet upphört. Således undersöker avhandlingen även hur effekten av ökad konkurrens skiljer mellan dessa två typer av läkemedel. Ämnet är även viktigt ur beslutfattarnas perspektiv. För beslutsfattare är det väsentligt att veta vilken effekt ökad konkurrens på läkemedelsmarknaden har, med

tanke på att till exempel avgöra ifall det är kostnadseffektivt att sänka kostnaderna för försäljningstillstånd för företag.

Avhandlingens teoretiska referensram utgår från två motstridiga teoretiska modeller, varav den första, av Brekke et al. (2016), förutspår att priserna på både generiska och originalläkemedel sjunker till följd av ökad konkurrens. Den andra teorin, även kallad ”the generic competition paradox” är ett empiriskt fenomen som har setts på flera länders läkemedelsmarknader och som förutspår en stagnation eller ökning av priserna på originalläkemedel då generiska alternativ träder in på marknaden, vilket strider emot grundläggande ekonomisk teori. Således utgår avhandlingen från två olika hypoteser:

Hypotes 1: Ökad konkurrens på läkemedelsmarknaden leder till att priserna på både generiska och originalläkemedel sjunker.

Hypotes 2: Ökad konkurrens på läkemedelsmarknaden leder till att priserna på generiska läkemedel sjunker och att priserna på originalläkemedel stagnerar eller ökar.

För att undersöka effekterna av ökad konkurrens på läkemedelsmarknaden använder jag paneldata på månads- och produktnivå samlad från läkemedelsprisnämnens databas över receptbelagda läkemedel från åren 2009–2021 som ingått i referensprissystemet. Dessutom används Fimeas (Säkerhets- och utvecklingscentret för läkemedelsområdet) databas över utbytbara läkemedel för att särskilja mellan generiska och originalläkemedel. Datamaterialet innehåller information om läkemedlens månatliga priser, vilken referensprisgrupp läkemedlen ingår i samt urskiljer ifall läkemedlet är ett generiskt eller originalläkemedel. Vidare används data från Tandvårds- och läkemedelsförmånsverket i Sverige i vissa ekonometriska specifikationer.

I den empiriska undersökningen tillämpas flera OLS-modeller som beaktar såväl tids- som utbytesgruppsfixa effekter. Vidare tillämpas 2SLS-modeller för att kontrollera för möjlig endogenitet. Utfallsvariabeln i analyserna är läkemedlens grossistpriser och kontrollvariabeln som avhandlingen fokuserar på är utbytesgruppernas storlek räknat

som antal produkter i gruppen. Utöver effekten av direkt konkurrens, kontrolleras det i analyserna även för konkurrens mellan läkemedel som har samma aktiva substans men olika förpackningsstorlekar, beredningsformer eller styrkor, terapeutisk konkurrens samt policyreformer under analystiden. Estimat görs även skilt för generiska och originalläkemedel i syfte att isolera effekterna för respektive läkemedelstyp.

Avhandlingens resultat tyder på att de genomsnittliga priserna på generiska läkemedel sjunker betydligt då antalet produkter i utbytesgruppen ökar. Resultaten tyder på att när utbytesgruppens storlek ökar från en till två produkter, sjunker de genomsnittliga priserna på generiska läkemedel med ca 30%. En ökning från en till tio produkter förväntas däremot sänka priserna på generiska läkemedel med 63–75%. Resultaten är även robusta när man kontrollerar för endogenitet genom 2SLS, med antalet produkter i Sverige som instrument för utbytesgruppstorleken. Vidare visar resultaten att konkurrens mellan produkter med samma aktiva substans men olika utbytesgrupper har en inverkan på generiska läkemedelspriser. Terapeutisk konkurrens, det vill säga konkurrens mellan olika aktiva substanser verkar inte ha en inverkan på priserna.

Resultaten för modellerna som estimerar effekten för originalläkemedel tyder även på att de genomsnittliga priserna sjunker till följd av ökad konkurrens, dock mindre än i jämförelse med generiska läkemedel och resultaten är mera tvetydiga. Estimaten från grundmodellen tyder på att då utbytersgruppens storlek ökar från en till två, sjunker priserna på originalläkemedel i genomsnitt med ca 16 % och då utbytesgruppens storlek ökar från en till tio, sjunker priserna med ca 46%. Resultaten från 2SLS-modellen tyder däremot på att instrumentet är svagt och således kan avhandlingen inte beakta det möjliga endogenitetsproblemet för originalläkemedlen.

Enligt resultaten i denna avhandling har ökad konkurrens inom det finska referensprissystemet en betydlig effekt på de genomsnittliga läkemedelspriserna. Det går att utläsa ur resultaten att priserna på generiska läkemedel reagerar starkt på ökad direkt konkurrens. För originalläkemedel är resultaten inte lika tydliga även om de också verkar reagera på ökad konkurrens. Avhandlingens resultat tyder på att på att betydliga

besparingar inom hälsovården kan uppnås genom att uppmuntra mera generiska läkemedel att komma in på marknaden, även i utbytesgrupper där antalet konkurrenter redan är stort. På grund av de grova heteroskedastisitetsproblemen i datamaterialet kunde mera robusta resultat fås genom att analysera mindre delmarknader inom läkemedelsmarknaden, till exempel inom olika prisklasser eller terapiområden.

References:

Aalto-Setälä, V. (2008). The impact of generic substitution on price competition in Finland. *The European Journal of Health Economics*, *9*(2), 185-191.

Ahonen, R ja Martikainen, J, toim. (2005): Lääkevaihdon ensimmäinen vuosi.

Anderson, B. (2018). Endogeneity and entrepreneurship research.

Association of Finnish pharmacies (18.2.2022). *Kuka päättää lääkkeen hinnan?*. https://www.apteekki.fi/terveydeksi/laaketietoa/kuka-paattaa-laakkeen-hinnan

Baum, C. F. (2001). Residual diagnostics for cross-section time series regression models. *The Stata Journal*, *1*(1), 101-104.

Baum, C. F., Schaffer, M. E., & Stillman, S. (2007). Enhanced routines for instrumental variables/generalized method of moments estimation and testing. *The Stata Journal*, *7*(4), 465-506.

Belsley, D. A., Kuh, E., & Welsch, R. E. (2005). *Regression diagnostics: Identifying influential data and sources of collinearity*. John Wiley & Sons.

Brekke, K. R., Canta, C., & Straume, O. R. (2016). Reference pricing with endogenous generic entry. *Journal of health economics*, *50*, 312-329.

Brekke, K. R., Grasdal, A. L., & Holmås, T. H. (2009). Regulation and pricing of pharmaceuticals: reference pricing or price cap regulation?. *European Economic Review*, *53*(2), 170-185.

Brekke, K. R., Holmas, T. H., & Straume, O. R. (2011). Reference pricing, competition, and pharmaceutical expenditures: theory and evidence from a natural experiment. *Journal of Public Economics*, *95*(7-8), 624-638.

Caves, R. E., Whinston, M. D., Hurwitz, M. A., Pakes, A., & Temin, P. (1991). Patent expiration, entry, and competition in the US pharmaceutical industry. *Brookings papers on economic activity. Microeconomics*, *1991*, 1-66.

Changyong, F. E. N. G., Hongyue, W. A. N. G., Naiji, L. U., Tian, C. H. E. N., Hua, H. E., & Ying, L. U. (2014). Log-transformation and its implications for data analysis. *Shanghai archives of psychiatry*, *26*(2), 105.

Dylst, P., Vulto, A., & Simoens, S. (2012). Reference pricing systems in Europe: characteristics and consequences. *Generics and Biosimilars Initiative Journal, 1*(3-4), 127-131.

European Medicines Agency. (25 January 2022). *Generic and hybrid medicines.* https://www.ema.europa.eu/en/human-regulatory/marketing-authorisation/generic-hybrid-medicines

Finnish Medicines Agency Fimea. (17 November 2021a). *About Us*. https://www.fimea.fi/web/en/about_us

Finnish Medicines Agency Fimea. (17 November 2021b). *Myyntilupahakemus*. https://www.fimea.fi/myyntiluvat/myyntilupahakemus

Finnish Medicines Agency Fimea. (9 February 2022a). *Marketing Authorisations.* https://www.fimea.fi/web/en/marketing_authorisations

Finnish Medicines Act802/2008. Issued in Helsinki 5.12.2008. https://www.finlex.fi/fi/laki/alkup/2008/20080802

Finnish Medicines Act253/2015. Issued in Helsinki 20.3.2015. https://www.finlex.fi/fi/laki/alkup/2015/20150253

Finnish Medicines Act1101/2016. Issued in Helsinki 9.12.2016. https://www.finlex.fi/fi/laki/alkup/2016/20161101

Frank, R. G., & Salkever, D. S. (1991). *Pricing, patent loss and the market for pharmaceuticals* (No. w3803). National Bureau of Economic Research.

Frank, R. G., & Salkever, D. S. (1997). Generic entry and the pricing of pharmaceuticals. *Journal of Economics & Management Strategy*, *6*(1), 75-90.

Galizzi, M. M., Ghislandi, S., & Miraldo, M. (2011). Effects of reference pricing in pharmaceutical markets. *Pharmacoeconomics*, *29*(1), 17-33.

Granlund, D., & Bergman, M. A. (2018). Price competition in pharmaceuticals–evidence from 1303 Swedish markets. *Journal of health economics*, *61*, 1-12.

Halonen, I, Apteekkiliitto. (3 August 2016). *Teva osti Actavisin rinnakkaislääkkeet*. Apteekkari. https://www.apteekkari.fi/uutiset/teva-osti-actavisin-rinnakkaislaakkeet.html

Hausman, J. A. (1978). Specification tests in econometrics. *Econometrica: Journal of the econometric society*, 1251-1271.

Health Insurance Act 252/2015. Issued in Helsinki 20.3.2015. https://www.finlex.fi/fi/laki/alkup/2015/20150252

Health Insurance Act 1100/2016. Issued in Helsinki 9.12.2016. https://www.finlex.fi/fi/laki/alkup/2016/20161100

Health Insurance Act 622/2012. Issued in Helsinki 16.11.2012. https://finlex.fi/fi/laki/alkup/2012/20120622

Heikkilä, R., Mäntyselkä, P., & Ahonen, R. (2011). Price, familiarity, and availability determine the choice of drug-a population-based survey five years after generic substitution was introduced in Finland. *BMC clinical pharmacology*, *11*(1), 1-6.

Heikkilä, R. (2013). *Lääkevaihto lääkkeiden käyttäjien ja lääkäreiden näkökulmasta Suomessa* (Doctoral dissertation, Itä-Suomen yliopisto).

Hokkanen, J., Linnosmaa, I., & Siikanen, M. (2016). Long-run effects of the generic substitution policy on prices of branded and generic pharmaceuticals.

Kinnunen, M., Laukkonen, M. L., Linnosmaa, I., Mäklin, S., Nokso-Koivisto, O., Saxell, T., ... & Valmari, N. (2021). Mikä lääkkeissä maksaa?: Selvitys lääkkeiden hintaan vaikuttamisesta ja ohjauksesta.

Koskinen, H., Mikkola, H., Saastamoinen, L. K., Ahola, E., & Martikainen, J. E. (2015). Time series analysis on the impact of generic substitution and reference pricing on antipsychotic costs in Finland. *Value in health*, 18(8), 1105-1112.

Koskinen, H., Kurko, T. (2016). Viitehintajärjestelmä ja hintakilpailu – ontuva parivaljakko?. *Kelan tutkimusblogi.* https://tutkimusblogi.kela.fi/arkisto/3198

Koskinen, H. (16 March 2018). Lääkkeiden vaihtamisen vaikutukset kustannuksiin ja hintoihin [PowerPoint-presentation]. *Kela*. https://www.apteekkariliitto.fi/media/3-apteekkariliitto.fi/media/aineistot/koskinen_hanna_2.3.2018.pdf

Lexchin, J. (2004). The effect of generic competition on the price of brand-name drugs. *health Policy*, *68*(1), 47-54.

Martikainen, J. E., Koskinen, H., Maljanen, T., & Saastamoinen, L. K. (2013). Lääkkeiden hintojen ja kustannusten kehitys: mitä lääkevaihdolla ja viitehintajärjestelmällä on saavutettu?.

Matveinen, P. (2021). Terveydenhuollon menot ja rahoitus 2019. *Terveyden ja hyvinvoinninlaitos. Suomen virallinen tilasto. Terveys*.

Ministry of Social Affairs and Health. (2013). *Health care in Finland*. [Brochure]. Ministry of Social Affairs and Health, Finland. https://julkaisut.valtioneuvosto.fi/bitstream/handle/10024/69930/URN_ISBN_978-952-00-3395-8.pdf

Neittaanmäki, P., Ruohonen, T., Malmberg, J., Juutilainen, H., Niinimäki, E., Lempinen, A. (2017). Sosiaali- ja terveystoiminnan kustannusten kasvun hillitsemisen arviointiraportti. *Jyväskylän Yliopisto.*

Nguyen, N. X., Sheingold, S. H., Tarazi, W., & Bosworth, A. (2022). Effect of Competition on Generic Drug Prices. *Applied Health Economics and Health Policy*, *20*(2), 243-253.

Nokelainen, H., Lämsä, E., Ahonen, R., & Timonen, J. (2020). Reasons for allowing and refusing generic substitution and factors determining the choice of an interchangeable prescription medicine: a survey among pharmacy customers in Finland. *BMC health services research*, *20*(1), 1-9.

Orion Oyj. (27 October 2016). *Orion Oyj:n lausunto eduskunnan sosiaali- ja terveysvaliokunnalle 27.10.2016.*

https://www.eduskunta.fi/FI/vaski/JulkaisuMetatieto/Documents/EDK-2016-AK-85875.pdf

Pelkonen, L. (2011). Miten lääke pääsee korvausjärjestelmään?.

Pharma Industry Finland. (16 February 2022). *Lääkkeiden korvattavuus.* https://www.laaketeollisuus.fi/tietoa-laakkeista/laakkeiden-korvattavuus.html

Puig-Junoy, J. (2010). Impact of European pharmaceutical price regulation on generic price competition. *Pharmacoeconomics*, *28*(8), 649-663.

Reiffen, D., & Ward, M. R. (2005). Generic drug industry dynamics. *Review of Economics and statistics*, *87*(1), 37-49.

Reinikainen, L., Hyvärinen, A., Kokko, M., Jauhonen, H. M., & Happonen, P. (2021). Lääketaksan, apteekkimaksun ja apteekkiveron kehittäminen Suomessa: Selvitys muutosehdotuksista, muutosten esteistä ja mahdollisista muutostekijöistä.

Saha, A., & Xu, Y. (2021). The 'Generic Competition Paradox'Revisited. *International Journal of the Economics of Business*, *28*(3), 363-375.

Sarpatwari, A., DiBello, J., Zakarian, M., Najafzadeh, M., & Kesselheim, A. S. (2019). Competition and price among brand-name drugs in the same class: a systematic review of the evidence. *PLoS medicine*, *16*(7), e1002872.

Scherer, F. M. (1993). Pricing, profits, and technological progress in the pharmaceutical industry. Journal of Economic Perspectives, 7 (3), 97–115

Staiger, D., and J. H. Stock. (1997). Instrumental variables regression with weak instruments. Econometrica 65: 557–86.

Stock, J., & Yogo, M. (2005). *Asymptotic distributions of instrumental variables statistics with many instruments* (Vol. 6). Chapter.

Straka, R. J., Keohane, D. J., & Liu, L. Z. (2017). Potential clinical and economic impact of switching branded medications to generics. *American journal of therapeutics*, *24*(3), e278.

The Social Insurance Institution of Finland. (1 April 2022a). *Rates of reimbursement.* https://www.kela.fi/web/en/reimbursements-for-medicine-expences-amount

The Social Insurance Institution of Finland. (1 April 2022b). *Epilepsia.* https://www.kela.fi/yhteistyokumppanit-laakekorvaukset-apteekit-epilepsia

The Social Insurance Institution of Finland. (13 January 2020). *Ulkomailla ostettujen lääkkeiden korvaaminen.* https://www.kela.fi/ulkomailla-ostetut-laakkeet

Vandoros, S., & Kanavos, P. (2013). The generics paradox revisited: empirical evidence from regulated markets. *Applied Economics*, *45*(22), 3230-3239.

Wiggins, S. N., & Maness, R. (2004). Price competition in pharmaceuticals: the case of anti-infectives. *Economic Inquiry*, *42*(2), 247-263.

Wooldridge, J. M. (2012). *Introductory econometrics: A modern approach*. Cengage learning.

World Health Organization collaborating centre. (17 November 2021). *Structures and principles.* https://www.whocc.no/atc/structure_and_principles/

World Health Organization. (19 February 2022). *Defined Daily Dose (DDD).* https://www.who.int/tools/ATC ddd-toolkit/about-ddd

World Health Organization. (2020). *WHO guideline on country pharmaceutical pricing policies: web annex B: evidence to decision (EtD) tables*. World Health Organization.

Wouters, O. J., Kanavos, P. G., & McKee, M. (2017). Comparing generic drug markets in Europe and the United States: prices, volumes, and spending. The Milbank Quarterly, 95(3), 554-601.

Yang, J. (2020). Interpreting Regression Coefficients for Log Transformed Variables. (Statnews #83). Cornell Statistical Consulting Unit. https://cscu.cornell.edu/wp-content/uploads/83_logv.pdf

Data sources:

Finnish Medicines Agency Fimea. (12 February 2022b). *Keskenään vaihtokelpoisten valmisteiden luettelo* [dataset]. https://www.fimea.fi/laakehaut_ja_luettelot/laakevaihto/keskenaan-vaihtokelpoisten-valmisteiden-luettelo

Pharmaceuticals Pricing Board. (12 February 2022). *Korvattavat myyntiluvalliset lääkevalmisteet* [dataset]. https://www.hila.fi/luettelot/korvattavat-myyntiluvalliset-laakevalmisteet/

Statistics Finland. (15 March 2022). *Consumer Price Index (2005=100) yearly data, 2005M01-2022M12* [dataset]. https://pxnet2.stat.fi/PXWeb/pxweb/en/StatFin/StatFin__hin__khi__vv/statfin_khi_pxt_11xc.px/

The Dental and Pharmaceutical Benefits Agency. (15 March 2022). *Sök i databasen* [dataset]. https://www.tlv.se/beslut/sok-i-databasen.html

Appendix A

Table A1. Descriptive statistics by size of reference price group

	Originals			Generics		
Generic firms (*n*)	**α = 60%**	**α = 35%**	**α = 0%**	**α = 60%**	**α = 35%**	**α =0%**
1	0.760	0.767	0.778	0.521	0.535	0.556
2	0.399	0.419	0.458	0.298	0.338	0.417
3	0.271	0.290	0.333	0.208	0.247	0.333
4	0.205	0.222	0.264	0.160	0.195	0.278
5	0.165	0.180	0.219	0.130	0.161	0.238
6	0.138	0.152	0.188	0.110	0.137	0.208

Note: The following parameters are used in the calculation: λ = 0.75, t_o= 2, t_g= 2, β=1. The table presents the expected prices of medicines by number of generic competitors according to the mathematical model by Brekke *et al.* (2016). β=1 indicates that the reference price is entirely based on generic medicines. λ = 0.75 indicates that 75% of consumers prefer original medicines over generic medicines. t_o is the degree of vertical differentiation between original and generic medicines. t_g is the degree of horizontal differentiation between generic medicines. α is the co-payment rate.

Appendix B

Figure B1. Normality of residuals in 2WFE models

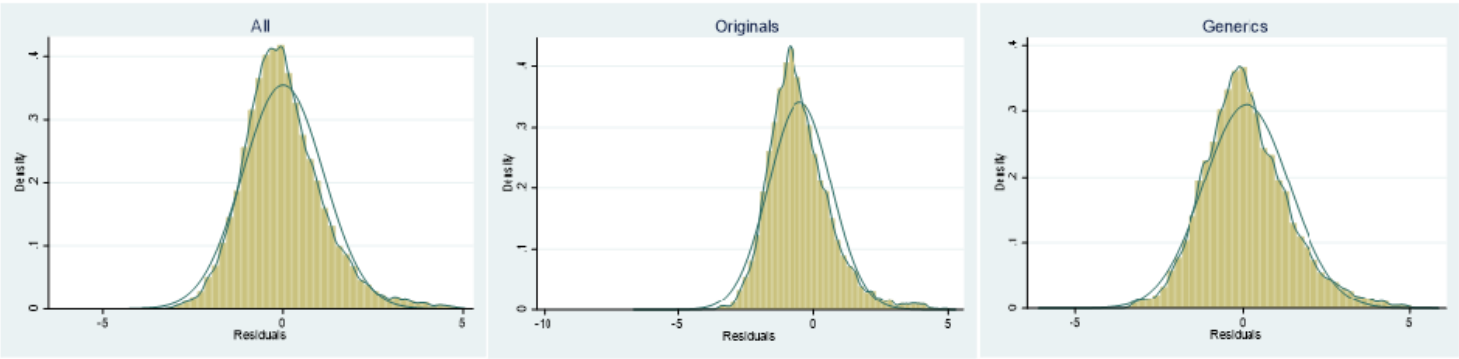

Table B1. Variance Inflation Factor for 2WFE models

VARIABLES	All [1]	Generics [2]	Originals [3]
lnPrice	1.11	1.08	1.10
lnRProup	1.10	1.10	1.15
Original	1.06		
lnATC7group	1.10	1.09	1.13
lnThAlt	1.05	1.05	1.05
PriceCut	1.00	-	1.01
PriceBand2017	1.84	1.89	1.75
GenericEntry	1.92	1.97	1.78
Mean VIF	1.27	1.36	1.28

Note: The table presents the VIF values for the specifications used in the analysis.

Table B2. Estimated effects of competition on price. Nested two-way fixed effects

VARIABLES	(1) 2WFE Originals	(2) 2WFE Originals	(3) 2WFE Originals	(4) 2WFE Generics	(5) 2WFE Generics	(6) 2WFE Generics
lnRPgroup	-0.26***	-0.26***	-0.26***	-0.52***	-0.50***	-0.52***
	(0.020)	(0.021)	(0.020)	(0.022)	(0.022)	(0.022)
lnATC7group		-0.028			-0.36***	
		(0.036)			(0.042)	
lnThAlt		-0.013			0.030	
		(0.035)			(0.041)	
PriceCut			-0.19***			
			(0.018)			
PriceBand2017			0.42***			0.51***
			(0.022)			(0.071)
GenericEntry			-0.0044			-0.0067***
			(0.00016)			(0.00062)
Constant	3.35***	3.41***	3.51***	3.28***	3.88***	3.57***
	(0.036)	(0.081)	(0.041)	(0.040)	(0.11)	(0.052)
Observations	78 719	78 719	78 160	307 850	307 850	307 850
R-squared	0.208	0.208	0.210	0.167	0.178	0.167
Number of products	988	988	963	5.022	5.022	5.022
FE product	Yes	Yes	Yes	Yes	Yes	Yes
FE month	Yes	Yes	Yes	Yes	Yes	Yes

Note: Cluster-robust standard errors in parentheses. *** p<0.01, ** p<0.05, * p<0.1

Table B3. Estimated effects of competition on price. Two-way fixed effects. Before and after narrowing the price band

VARIABLES	(1) 2WFE Originals	(2) 2WFE Originals	(3) 2WFE Generics	(4) 2WFE Generics
lnRPgroup	-0.23***	-0.20***	-0.53***	-0.42***
	(0.026)	(0.027)	(0.024)	(0.029)
lnATC7group	0.051	-0.0071	-0.25***	-0.28***
	(0.043)	(0.039)	(0.052)	(0.042)
lnThAlt	-0.048	0.100**	-0.17***	-0.17**
	(0.043)	(0.046)	(0.031)	(0.069)
PriceCut	-0.27***			
	(0.020)			
GenericEntry	-0.0066***	-0.012***	-0.0094***	0.020***
	(0.00054)	(0.0014)	(0.00038)	(0.00018)
Constant	3.53***	4.67***	4.38***	1.52***
	(0.13)	(0.21)	(0.14)	(0.13)
Observations	46 480	31 680	185 114	122 736
R-squared	0.143	0.100	0.154	0.137
Number of products	792	744	4.219	2.981
FE product	Yes	Yes	Yes	Yes
FE month	Yes	Yes	Yes	Yes
Years	2009-2017	2017-2021	2009-2017	2017-2021

Note: Cluster-robust standard errors in parentheses. *** p<0.01, ** p<0.05, * p<0.1

Table B4. Estimated effects of competition on price. Two-way fixed effects polynomial regression

VARIABLES	(1) 2WFE Originals
lnRPgroup	-0.31***
	(0.037)
$lnRPgroup^2$	0.023
	(0.017)
lnATC7group	-0.023
	(0.036)
lnThAlt	-0.018
	(0.036)
PriceCut	-0.19***
	(0.017)
PriceBand2017	0.45***
	(0.07)
GenericEntry	-0.004***
	(0.0005)
Constant	3.61***
	(0.093)
Observations	78 160
R-squared	0.211
Number of products	963
FE product	Yes
FE month	Yes

Note: Cluster-robust standard errors in parentheses. *** p<0.01, ** p<0.05, * p<0.1

Table B5. Estimated effects of competition on price. Two-stage least squares (2SLS), First stage results

VARIABLES	(1) 2WFE IV All	(2) 2WFE IV Generics	(3) 2WFE IV Originals
lnSweGroup	0.28***	0.27***	0.20***
	(0.06)	(0.04)	(0.05)
Original	-0.08***		
	(0.005)		
lnATC7group	-0.29***	0.26***	0.44***
	(0.05)	(0.033)	(0.06)
lnThAlt	-0.05	-0.05**	-0.007
	(0.047)	(0.026)	(0.07)
PriceCut	0.07***		0.10***
	(0.012)		(0.018)
PriceBand2017	-0.29	-0.56***	-0.27
	(0.45)	(0.16)	(0.29)
GenericEntry	-0.0007	0.0014	-0.0001
	(0.0031)	(0.0011)	(0.002)
Observations	386 005	307 810	78 154
R-squared			
Number of RP groups	1 172	-	-
Number of products	-	4 982	957
FE RP group	Yes	No	No
FE product	No	Yes	Yes
FE month	Yes	Yes	Yes

Note: Cluster-robust standard errors in parentheses. *** p<0.01, ** p<0.05, * p<0.1