Generic medicines and regulatory policies

The effects of differentiated price caps and co-payments on drug prices

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Abstract

When entering the market, pharmaceutical firms face various regulatory factors that will influence the producer prices for their products. Price competition occurs when generic medicines enter the market. Previous studies of the pharmaceutical market have shown different regulatory means and their influence on producer prices and patient demand in the off-patent segment. More regulations are known to have a negative influence on price competition as well as they may attract less generics into the market. A lack of price competition is a problem among most countries. This thesis reviews key studies and introduces a theoretical model into the discussion. It applies price competition à la Bertrand to the Norwegian market for off-patent medicines. The research issue of this thesis is to analyze the effects on producer prices on drugs from introducing differentiated price caps and differentiated patient co-payment rates.

Key words: Generic competition paradox**,** Generic medicines, Price caps, Price competition, Price regulations.

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Abbreviations and Acronyms

ATC	Anatomical Therapeutic Chemical Classification System
AIP	Apotekenes innkjøpspris
AUP	Apotekenes utsalgspris
CP	Competitive Pressure
e.g.	for example
FHI	Folkehelseinstituttet
GRP	Generic Reference Pricing
HOD	Helse- og omsorgsdepartementet
LMI	Legemiddelindustriforeningen
NIS	National Insurance Scheme
NOK	Norwegian Krone
NoMA	Norwegian Medicines Agency
OECD	Organization for Economic Co-operation and Development
PC	Price Cap
PPP	Pharmacy Purchasing Price
PRP	Pharmacy Retail Price
p.	page
pp.	pages
RP	Reference Price
PPI	Reference Price Index
R+D	Research and Development
TRP	Therapeutic Reference Pricing

Operational Definitions

Avoidable Co-payment	An additional co-payment that is due to a drug price that is higher than the applying price cap.
Brand Medicines	Innovative medicine that was first on the market.
Brand-Named Medicines	See Brand Medicines.
Competitive Pressure	More competition makes it optimal for firms to reduce prices.
Co-payment	A patient's financial share of the drug expenses which can vary from a fixed amount to a percentage amount.
Generic (Competition) Paradox	Suggests that brand-name prices increase simultaneously with the entry of generics after patent has been expired.
Generic Medicines	Chemically identical products with similar therapeutic benefits as the branded originator. Objectively perfectly substitutable goods.
Generic Substitution	Pharmacists are allowed to dispense a less expensive drug alternative than prescribed by physicians; this is often a generic.
Monopoly	Situation where one firm is the sole producer / supplier of a good; can be legally permitted by patent protection.
Off-Patent Segment	Pharmaceutical products that lost are not or no longer under patent protection.
On-Patent Segment	Pharmaceutical products that are under patent protection; regularly brand medicines.
Originator	See brand medicines.
Patent	Legal protection of an innovative product or ingredient that prohibits others to copy the innovation; restricted in time.
Pharmaceutical Market	On-patent segment and off-patent segment.
Perfect Competition	Situation where it is optimal to set producer prices equal to marginal costs of production.
Preferred Product Scheme	Requires any physician to prescribe a pre-defined first-choice product by law. The prescribing physician can only exculpate himself from this liability by stating medical reasons for not doing so
Price Cap	Pre-defined maximum reimbursable amount.
Reference Pricing	Similar beneficial drugs are compared systematically. Alternative drug treatments should be priced relatively equal to their therapeutic equivalences.
Substitute	See generic medicines.
Vertical (Product) Differentiation	Although almost perfect substitutes, brand medicines and generics are often seen as vertically differentiated goods with different product qualities.
Vertical Integration	Wholesalers own their own pharmacy chains which could determine the scope of distribution of pharmaceutical products.

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1   Introduction

The determinants of pharmaceutical pricing strategies have received huge attention among policy makers. While the use of relatively less expensive generic medicines is believed to stir more competition within the pharmaceutical industry, innovative pharmaceutical firms need to differ in their pricing strategies to recover the industries typical high costs of research and development and prices are unlikely to converge towards the marginal costs of production. Most countries therefore guarantee new products a certain period under patent protection where competition is restricted because innovative manufacturers have a monopoly on their chemical entities and can charge high product prices to recover their research and development costs. This situation changes once patent protection has expired. Now the pressure through governments and other third-party payers increases to increase the use of generic medicines by generic substitution, preferred product schemes and tight reimbursement regulations. Reference-based pricing secures that similar beneficial drugs are compared systematically and alternative drug treatments should be priced relatively equal to their therapeutic equivalence. By definition and due to certain legal requirements branded originators and their generic copies are supposed to be almost perfectly substitutable goods and chemically identical products with similar therapeutic benefits [MERINO-CASTELLO 2003]. Objectively rather homogeneous, brand-named medicines and generics are often perceived as vertically differentiated treatment options, typically on the demand side. Different policy reforms as well as different regulatory framework among countries suggest that competition is not yet completely utilized in this segment [KANAVOS et al. 2007]. Policy makers are still challenged by significant market shares for more expensive brand-named products after less expensive generics have been launched in the market. It shows that a success of generic medicines strongly depends on setting the right incentives for patients, pharmacists and prescribing physicians [JACOBZONE 2000, p. 42].

This thesis aims to address the cost reduction potential in off-patent drug markets for three reasons: First, in most countries drug expenditure is a significant percentage of overall health care spending. Second, there have been multiple reform proposals during the past. Third, those efforts have often failed in their wish to sustain cost containment and were therefore often displaced with the next reform.

In detail, the paper analyzes the potential results of more differentiated policy instruments in the Norwegian off-patent segment. To the time this thesis is admitted, the current system is a

price cap system with common price caps as well as common patient co-payments for both brand and generic medicines. As a more theoretical example, this thesis approaches to control pharmaceutical expenditure and increase generic use by creating more cost-awareness on the demand side. Chapter 2 gives an overview of the Norwegian pharmaceutical market. In chapter 3, international experiences with off-patent regulations are summarized. The effects of regulatory policies in this field are discussed in chapter 4, while as the most determining variables of Norwegian regulatory means aiming to cost control off-patent medications, patient's co-payments and price cap regulation are discussed in detail. Chapter 5 introduces a theoretical model into the discussion and applies price competition à la Bertrand to the Norwegian market for off-patent medicines. The model grows by implementing differentiated price caps and patient's co-payments. Finally chapter 6 concludes by bringing together the theoretical approach and the performance and weakness of the current regulatory system in Norway.

This work mainly focuses on the producer price level. It aims to illustrate different aspects of pharmaceutical pricing in general and more specific for Norway. It strongly emphasis on the question: *"Can we do any better?"* and tries to answer this for the Norwegian market for off-patent medicines. The research issue of this thesis is to analyze the effects on producer prices on drugs from introducing differentiated price caps and differentiated patient co-payment rates.

2 The Norwegian pharmaceutical market

In this chapter I will give a brief overview of the Norwegian pharmaceutical market by describing the main actors and structures. The chapter will progress as follows: Section 2.1 gives the legal framework, section 2.2 summarizes the key authorities, section 2.3 looks at the public funding and section 2.4 gives an overview of recent reforms in this segment. The last two subsections (section 2.5 and 2.6) discuss supply and demand side characteristics respectively.

2.1 Legislation and legal framework

Although there are various specifications and adjustments, the two key legal Acts are the Norwegian Act on Pharmacies (Lov om apotek[1]) and the Norwegian Act on Medicinal Products (Lov om legemidler[2]).[3] The Pharmacy Act was introduced on the 2nd of June in 2000 and came to work nine months later on the 3rd of march in 2001 replacing the former Pharmacy Act of the year 1963. In this thesis, the Pharmacy Act of 2001 will be given most attention. § 6 regulates sales and marketing issues for pharmacies where § 6-4 and § 6-6 legally permit generic substitution in Norway. Pharmacists are now allowed to dispense a less expensive drug alternative than prescribed by physicians. Furthermore, pharmacists have to inform patients about the cheapest alternative drug available in the market.

§ 6-4 Definition:

> *In cases where more than one prescription drug exist that are equivalent in their health benefits, is the pharmacist in duty to inform the customer about the cheapest alternative. Equivalent prescription drugs are pharmaceuticals that that are substitutable after § 6-6.*

§ 6-6 Definition:

> *Pharmaceuticals have to be dispensed precisely to the referring prescription and legal requirements.*

> *The pharmacy is allowed to substitute a prescribed drug with an equivalent generic or parallel imported pharmaceutical product that has been approved as substitutable for the prescribed drug. A substitution will be dismissed only and only if this substitution is not conform with the legal requirements or if the consumer explicitly wishes not to do so.*

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[1] See the Norwegian definition <http://www.lovdata.no/all/hl-20000602-039.html> (last accessed 26.12.2008).
[2] See the Norwegian definition <http://www.lovdata.no/all/hl-19921204-132.html> (last accessed 26.12.2008).
[3] For more information see e.g. FJÆRTOFT (2003) who provides an extensive overview of the Norwegian Pharmacy Act in 2001, while KJOENNIKSEN's et al. (2006) assesses the patient's attitude towards the new policy.

The legislative institution can give further details in its regulations and may in particular cases make it necessary to state the reason for a rejection of the recommendation the pharmacy offered generic substitute if substitution is denied.

With the dispense of a pharmaceutical in exchange for with the description, the pharmacy is obliged secure that customers are sufficiently well informed about the right use of the pharmaceuticals.

2.2 Public authorities

This section gives an overview of the four key public authorities (agencies) that are concerned with the provision of pharmaceutical drugs in Norway. These agencies are concerned with regulating the Norwegian pharmaceutical market. Their work concentrates on the three following core issues; (i) to regulate product prices and to keep patient - and public expenses at low levels, (ii) to secure equal access to pharmaceutical drugs, and (iii) provide drugs of a sufficient high quality by ensuring that certain legal requirements are fulfilled before they are launched into the market [DALEN 2003].

Norwegian Parliament

The Norwegian Parliament (Stortinget) is the highest legislative institution. Although the overall responsibility for health is given to the Norwegian Medicines Agency (NoMA), in a few cases the Parliament can decide on the resource allocation despite a recommendation of the NoMA.

Norwegian Ministry of Health and Social Affairs

The Norwegian Ministry of Health and Social Affairs (Helse- og omsorgsdepartementet, HOD) consists of seven departments and has the overall responsibility for the government policy on health and care services in Norway.

Norwegian Medicines Agency

The Norwegian Medicines Agency (NoMA, Statens Leggemiddelverk) is responsible to the Norwegian Ministry of Health and Social Affairs. It was formally founded in 2001 by the merging of prior administrative departments. Today the NoMA is concerned with the following tasks:

- new products' market authorization,
- ATC[4] classification,
- general pricing and reimbursement issues
- as well as monitoring the market segment as a whole.

Although the NoMA is in charge of the wholesale prices and retail margins, and controls the pharmacy purchasing price (PPP), like in many other countries, manufacturer prices are not subject to regulations in Norway. Wholesalers are free to price negotiate with manufacturers.

Norwegian Institute of Public Health

The Norwegian Institute of Public Health (Folkehelseinstituttet, FHI) mainly monitors the pharmaceutical consumption in Norway.

2.3   Funding

Norway's public statutory health insurance system (National Insurance Scheme, NIS) is a tax based funding system that finances almost 70% of the total pharmaceutical consumption (see figure 2.1).The share of patients expenses in terms of co-payments amounts to only 6.8 % which is much lower than in other countries (Figure 2.1).
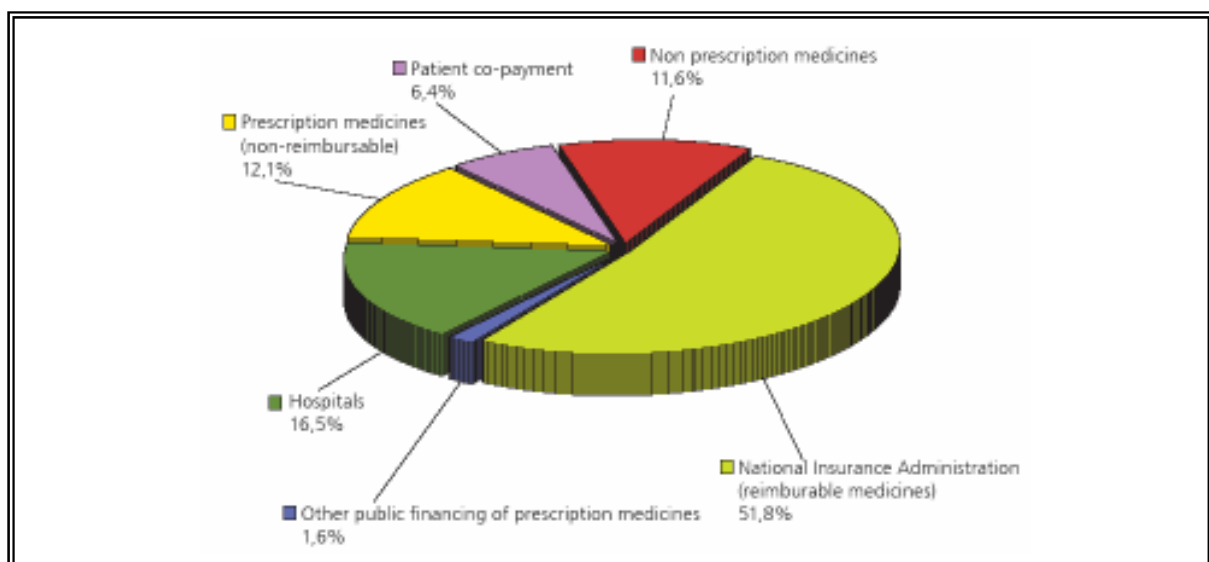
Figure 2.1 Payment for Pharmaceutical Consumption in Norway. Source: LMI 2008.

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[4] The Anatomical Therapeutic Chemical Classification System (ATC) divides drugs into different groups according to the organ or system on which they act and/or their therapeutic and chemical characteristics.

Prescription medicines represent 88.4% of the total sales of medicines for 2006. There is a slight trend towards further expansion of the market growth of this sector during the last years. Prescription medicines grew at a rate of 1.3% in 2006. The public expenditure on medicines was 9.2% of the total public expenditure on health care in 2006 which is significantly lower than the OECD average being equal to 13.9% [LMI 2007] .

Figure 2.2 shows that Norway's public spending on reimbursable prescription medicines has steadily increased from 1997 but has declined from 2005 to 2007. The decline is believed to be a result of the new price regulation system combined with the patent expiry of several branded drugs in 2003 [LMI 2003 and 2008].
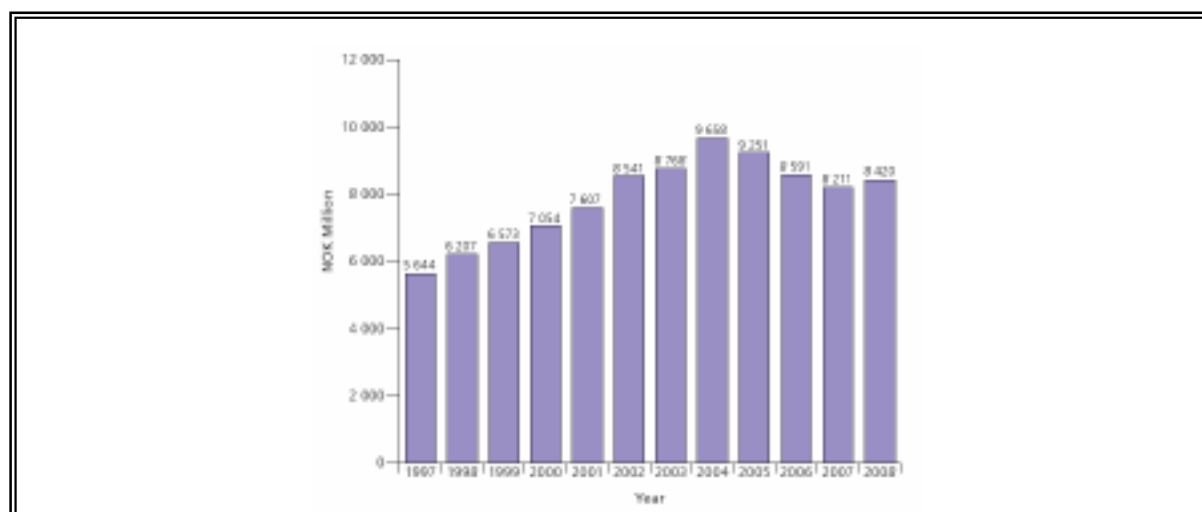
Figure 2.2 Public Spending on reimbursable prescription medicines. Numbers for 2007 and 2008 are estimated. Source: LMI 2008.

2.4 Norwegian policy reforms

There have been several price regulatory approaches (reforms) in Norway the last two decades all trying to curb public costs in the market for prescription medicines. In the period 1993 – 2005, the following reforms were implemented:

- National Reference pricing, 1993-2001
- Standard Profit Margin Controls – AIP and AUP[5], from 1995
- International Reference Pricing and Generic Substitution of Drugs, 2001-2003
- Index Price System, 2003-2005
- Step-Price System and Preferred-Product-Scheme, from 2005

The reforms of generic substitution and preferred product scheme are both concerned with increasing cost awareness among physicians and pharmacies. Reference-, index- and stepped pricing reforms on the other hand can be said to be mainly price reforms (see chapter 4). The step-price system, the index price system and the standard profit margins controls for pharmacies are described briefly in the following, as they are the three most recent reforms in Norway.

Step-Price System

Today's regulatory system is a modified price cap (PC) system that applies international price levels (Reference Pricing, RP[6]). As a step-price system (Trinnprismodellen), the new regulatory approach was implemented in 2005 and reduces step wise the maximum reimbursable amount of pharmaceutical products that lost patent protection according to sales' features as well as the establishment of generic competition. Starting out with 21 active chemical ingredients, the current system covers 45 substances.[7] The actual percentage of the cut depends on the annual sales volume reached before. Modifications have been made, but the current system includes 2 steps. After a first cut of 30% the final step applies after six months and makes the cut from 30% to 55% or 75% depending on the sales volume. A list of in the system included pharmaceutical products as well as their current prices is published by the Norwegian Medicines Agency. The stepped price is the maximum reimbursable price of the pharmaceuticals retail price (PRP) and it applies for reimbursable as well as non-reimbursable drugs [NoMA 2008].

Time when generic competition is established	Pharmaceuticals with annual sales below 100 mill. NOK (AUP)	Pharmaceuticals with annual sales above 100 mill. NOK (AUP)
Immediately After 6 months After 12 months or later (optional)	Prices are cut 30% Prices are cut 55% Prices are cut 65% when the annual turnover exceeds 15 mill. NOK (AUP).	Prices are cut 30% Prices are cut 75% Prices are cut 80% when the annual turnover exceeds 30 mill. NOK (AUP). Prices are cut 85% when the annual turnover exceeds 100 mill. NOK (AUP).

Table 2.3   Step-Price System as from 01.01.2008. Source: NoMA (last accessed 26.12.2008).

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[5]Apotekenes innkjøpspris (AIP) is the pharmacy's purchase price, Apotekenes utsalgspris (AUP) is the pharmacy's selling price respectively.

[6] International Reference Price includes Sweden, Finland, Denmark, UK, Germany, Netherlands, Austria, Belgium, Ireland.

[7] An overview of the included substances and their stepped price can be found under <http://www.legemiddelverket.no/upload/75178/Oversikt%20over%20virkestoff%20i%20trinnprismodellen-på%20nett-2008-02-01%20revidert.xls> (last accessed 26.12.2008).

By law, the pharmacies are obliged to offer at least one product out of each group, priced according to the applying stepped price, whereas the wholesalers are obliged to offer the pharmacies the appropriate products that enable them to fulfill these obligations.

A preferred-product scheme was implemented in 2005. This system requires any physician to prescribe a pre-defined first-choice product by law. The prescribing physician can only exculpate himself from this liability by stating medical reasons for not doing so. The system aims to ensure the use of the most cost-effective medical treatment.

Index Price System

In March 2003 the "index-price" system was introduced in Norway. Replacing former price caps with generic index pricing, this unique policy experiment [BREKKE et al. 2007; DALEN et al. 2006] covered six active chemical ingredients when implemented in 2003 and was restocked with the high cholesterol substance Simavastatin 15 months later. In this price regulatory system, suddenly the pharmacies became the main target for policy makers to give strong financial incentives to promote generic use among consumers. Although generic substitution has been allowed in pharmacies since 2001, its impact was rather small than big. Since the second quarter of 2003, pharmacies were compensated with a pre-defined index-price for the given active ingredients; no matter what the actual product supply to the patient has been. Incentive was given to supply cheaper substitutes than the received physicians' prescription would name. Expected to trigger lower prices and to stir competition among firms operating in the market, the system was knocked-off by the Norwegian government by the end of 2004 when observed savings were argued not to be as significant as expected beforehand. Both BREKKE et al. (2007) and DALEN et al. (2006) strongly emphasize the lack of time under which this system unfolded. This meant that its impact on prices and cost savings was limited. Already evaluated after being just 11 months in practice and just covering a small sub sample of the whole Norwegian market for generics, BREKKE et al. (2007) claims that the governmental report was completed too early and that the system's positive effects on pharmaceutical pricing would have naturally been prolonged in time. BREKKE et al. (2007) analyzes a larger dataset than the policy experiment would provide and includes off-patent drugs still under the normal price cap system. He argues that there have been indications that prices decreased after a while, although the effect was stronger on the branded originators than on the generic substitutes. A similar study of this time by DALEN et al. (2006) derive the same conclusion. They argue that index pricing succeeded in promoting

generic pharmaceuticals as well as in triggering price competition. Their results are based on periodical data before and after the systems' introduction, monitoring the six origin substances covered by the index price regime and estimating the potential effects.

Standard Profit Margin Controls – AIP and AUP

Standard profit margin controls for pharmacies (Gevinnstdelingsmodellen) were implemented in Norway in 1995. This price control system aims to control the prices pharmacies purchase their product panel from wholesalers (Apotekenes innkjøpspris, AIP) as well as to control the consumer price paid by the patient when purchasing a product from the pharmacy (Apotekenes utsalgspris, AUP). Standard profit margin controls were meant to give financial incentive to pharmacies by allowing them to keep half of the profit margin that would occur when purchasing substances priced below the maximum AIP and selling them to the products' AUP. But due to some dominating structural features within the Norwegian pharmaceutical market, this price regime did not show the desired effects. Vertical integration of wholesalers and pharmacies turned out to be a major problem. Vertical integration means that wholesalers own their own pharmacy chains (see section 2.5.2 for the wholesalers operating in Norway). In the absence of further regulations this could determine the distribution of pharmaceutical products. The wholesalers could provide only those drugs that seem most profitable to them.

2.5 Supply side

On the supply side we mainly find the pharmaceutical industry. International and national manufacturers, wholesalers, parallel importers and pharmacies that help supplying Norway with medicines. In the following I will exclude parallel importers from my below presentation since being less important for the research issue.

2.5.1 International and national manufacturers

Most international manufacturers are represented in Norway. National pharmaceutical firms mainly focus on the production of generic medicines [LMI 2008]. Figure 2.3 shows the 25 leading pharmaceutical manufacturers in Norway by their market shares.

Rank 2007 (2006)	Company	Total sales 2007 PPP, NOK mill.	Sales growth	Market share
1 (1)	Pfizer AS	932,6	-13,9 %	8,6 %
2 (2)	AstraZeneca AS	873,0	10,2 %	8,0 %
3 (3)	GlaxoSmithKline AS	731,9	-3,8 %	6,7 %
4 (10)	Schering-Plough AS	584,5	46,5 %	5,4 %
5 (5)	Novartis Norge AS	566,4	12,9 %	5,2 %
6 (6)	Wyeth Norge	446,4	-6,0 %	4,1 %
7 (8)	MSD (Norge) AS	435,1	1,7 %	4,0 %
8 (4)	sanofi-aventis	430,5	-17,1 %	4,0 %
9 (9)	Nycomed Pharma AS	417,6	0,0 %	3,8 %
10 (11)	Roche Norge A/S	347,1	3,2 %	3,2 %
11 (7)	*Farmagon AS	315,2	-32,4 %	2,9 %
12 (12)	Eli Lilly Norge AS	314,8	9,5 %	2,9 %
13 (13)	Novo Nordisk Scandinavia AS	264,3	2,4 %	2,4 %
14 (16)	Abbott Norge as	254,8	7,8 %	2,3 %
15 (17)	Weifa AS	252,6	7,9 %	2,3 %
16 (-)	Bayer Schering Pharma	249,8	-	2,3 %
17 (15)	Janssen-Cilag AS	240,0	-0,8 %	2,2 %
18 (14)	Alpharma AS	228,2	-6,6 %	2,1 %
19 (-)	Bristol-Myers Squibb Norway Ltd	174,8	-	1,6 %
20 (20)	Boehringer Ingelheim Norway KS	168,0	11,2 %	1,5 %
21 (22)	H. Lundbeck A/S	154,9	13,8 %	1,4 %
22 (-)	Merck Serono	144,1	-	1,3 %
23 (19)	ratiopharm AS	134,3	-15,8 %	1,2 %
24 (-)	Amgen	129,1	-	1,2 %
25 (-)	LEO Pharma AS	111,4	-	1,0 %
Aggregate sales top 25 companies		8 901,4	-	81,9 %
Aggregate sales all companies		10 866,1	2,9 %	100,0 %

Figure 2.3 The top 25 pharmaceutical companies on the Norwegian market. Source: LMI 2008.

2.5.2 Wholesalers

Norway has three main wholesalers each owning their own pharmaceutical chains (vertical integration see section 2.4). With the Pharmacy Act in 2001, the independent pharmacies were in Norway replaced by pharmacy chains, controlled by the three wholesalers. As a result, Apokjeden Distribusjion AS (owned by Tamro OY/Phoenix group and with a market share of 33,5% in 2007), the Holtung AS (market share of 20%, owned by Alliance Unichem PLC) and NMD Grossisthandel AS (owned by Celesio, 46,4%) controlled the Norwegian pharmaceutical market.

Since there are no direct price regulations on manufacturers and due to the vertical integration of Norwegian pharmacies, much power is given to the wholesalers. They are permitted to bargain significant discounts and rebates with the producing manufacturers and consequently act as dispensation channel for the pharmacies. Pharmacists are restricted to have at least one generic substitute in their product portfolio. They decide on which portfolio they end up meaning that the wholesalers have much power. In general, wholesalers will prefer to buy

from the manufacturers with the highest discounts (lowest prices), however these discounts need not be passed onto the affiliated pharmacies. In Norway, wholesalers have a major influence on the products being available in the market as well on their prices (pharmacy purchasing price, PPP).

2.5.3 Pharmacies

Figure 2.4 gives an overview of the main Norwegian pharmacy chains and their market shares. Pharmacies provide and dispense pharmaceuticals to the patient as consumer. Apotek 1 AS is integrated into the Apokjeden Distribusjion AS. Vitusapotek AS and Ditt Apotek belong to the NMD Grossisthandel AS, while Alliance apoteken is owned by the Alliance Unichem AS.
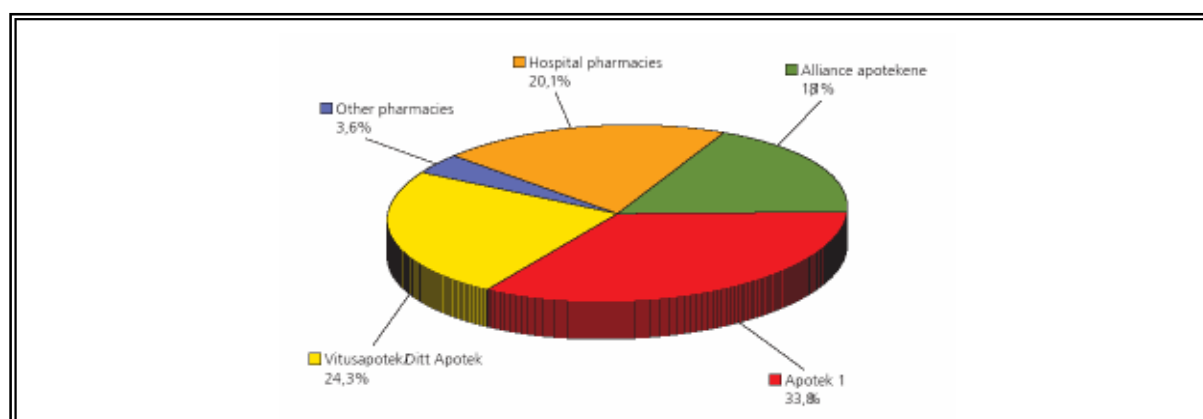
Figure 2.4 Pharmacy chain market shares in Norway. Source: LMI 2008

Manufacturer prices are not directly regulated in Norway, instead pharmacies' margins are a matter of governmental price regulation. Table 2.4 shows these margins. They are 8% for pharmaceuticals with a pharmacy purchasing price below 200 NOK and 5% for pharmaceuticals that exceed 200 NOK [NoMA 2008].

	Pharmacy Purchasing Price (PPP) below 200 NOK	Pharmacy Purchasing Price (PPP) above 200 NOK
Maximum Pharmaceutical Retail Price (PRP) as maximum mark up percentage of the PPP	8 %	5%

Table 2.4 Pharmacy margins in Norway[8]. Source: NoMA (last accessed 26.12.2008).

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[8] An additional fixed fee of 21.50 NOK per pack applies. Narcotic and psychotropic substances will be charged to an additional fee of 10 NOK per pack .

2.6 Demand side

This section provides an overview of the main market actors on the demand side – patients and prescribing physicians.

2.6.1 Physicians

In cases of prescription medicines the physician generally decides if and which pharmaceutical products will be prescribed to patients. Non-prescription medicines are generally chosen by the patient alone. Although a physician will significantly influence the drug demand by his prescribing practice (see informational asymmetries), he or she does not in general bear the financial consequences of his or her prescribing practice [see e.g. SCHERER 2000].

A preferred-product scheme was implemented in 2005. This system legally requires the physician to prescribe a pre-defined first-choice product. The prescribing physician can only exculpate him- or herself from this liability by stating medical reasons for not doing so. The system aims to ensure the use of the most cost-effective medical treatment.

From early march 2008, physicians, pharmacists as well as patients have access to a more transparent information system in terms of comparing pharmaceutical products, prices and their substitutes.

Informational asymmetries

An important demand side limitation is informational asymmetries between patients and physicians. The physicians can, due to his informational advantages, influence the patient's drug demand. He or she can for example influence the frequency of patient visits for example by the prescribed package-size [DANZON 1997a]. Physicians might have an incentive to abuse their position as patients' best agents and trigger consumer demand that is not necessarily in the best interest of the patient. Patient might also think that high prices are a signal about high quality and for this reason prefer physicians that are prescribing the most costly medicines.

2.6.2 Patients

Patients are often not able to evaluate the need for a pharmaceutical treatment and / or to asses which medication is most appropriate given her or his health needs. These decisions are typically delegated to prescribing physicians and dispensing pharmacies. As a result physicians as well as pharmacists can be said to act as the patient's agents.

In the current system patients' pay themselves 36% of their medical expenses in terms of co-payment, however this amount is limited by an annual ceiling of 1.615 NOK (January 2006). The annual ceiling on medication expenses was first introduced in the first half of the 1980s. The ceiling has been raised over time. According to an OECD survey, the ceiling of 2005 was reached by almost a quarter of Norwegians purchasing drugs. After reaching the annual ceiling, further medical expenses are fully born by the government (free drugs for patients) – the reimbursement 100%. In Norway, patient's co-payment rates are not related to individual income. The relatively low annual ceiling is believed to be a result of significant distributive concerns. The official policy is that it is the need rather than income that should determine access to health care services and drugs [OECD 2005].

Figure 2.5 illustrates the co-payment for prescription drugs in Norway. In the current system, there is a minimum flat fee per package of 21.50 NOK (lower ceiling) and the co-payment is limited to 1 650 NOK (upper ceiling). Thus, no patient will pay less than NOK 21.50 and no one has to bear more than NOK 1615 of drug expenses per year or package respectively. The two horizontal lines within the figure represent this threshold. Children under the age of twelve and low-income pensioners are free from any co-payments.
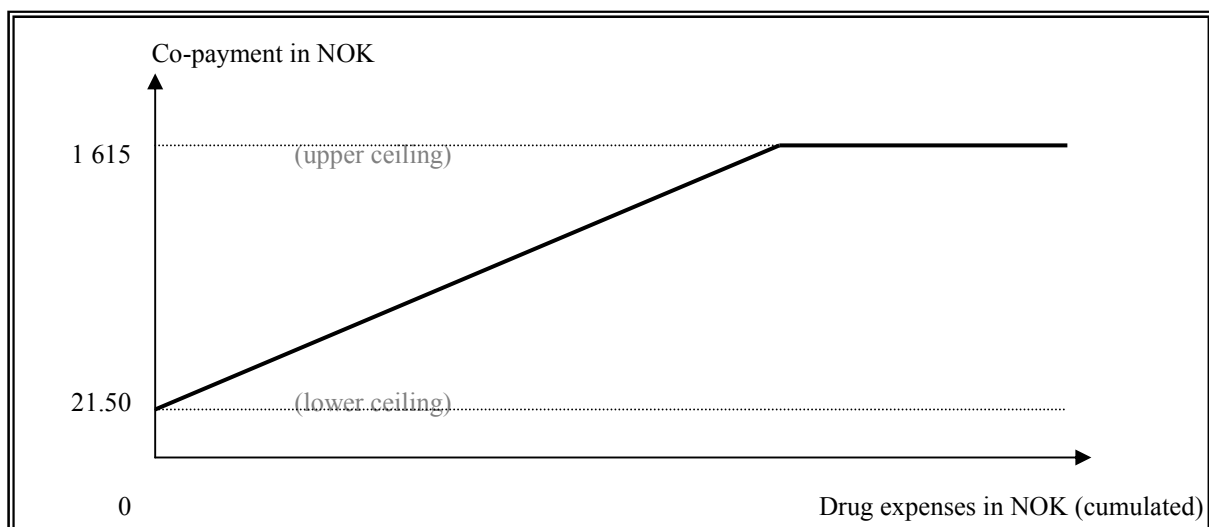
Figure 2.5 Patient co-payment for prescription drugs in Norway (own figure).

Low price elasticity

A second important demand side insufficiency is the lack of cost-awareness and low price elasticity of demand among patients. Subsidized and free drugs prevent patients from being confronted with the full costs of their consumption. The patient is not or only to a minor part involved; in form of co-payments. Under theory of full coverage insurance, the actual price of consuming a drug does not play a role for the patient at all. The patient's marginal willingness to pay for his consumption is equal to zero and the resulting demand is absolutely price inelastic in this case. Any price increase would have no influence on the patient's drug demand under full coverage insurance. Reducing the full coverage insurance to a scenario where the patient has to bear a certain part of his consumption, the resulting demand will be smaller than under full coverage. The patient's demand becomes more price elastic and his marginal willingness to pay for a drug will be higher than the marginal willingness to pay under full coverage. However, any insurance coverage will result in a lower price awareness and a skewed demand. This insufficiency can lead to moral hazard with the incentive for the patient too many and / or unnecessary pharmaceuticals [DANZON and PAULY 2002].

3 International experiences from generic medicine policies

In this chapter I present a selective review of some empirical literature that studies the effects of regulatory policies on off-patent markets in other countries, analyzing the effects on prices mainly. There is not that much literature available for the Norwegian off-patent market. Two exceptions are BREKKE et al. (2006 and 2007) and DALEN and STRØM (2006) – both works focus mainly on the effects of reference pricing. However, since most countries regulate drug prices in one way or another, international regulatory experiences may help shed light onto the Norwegian off-patent market.

3.1 DANZON and CHAO (2000) – Effects on price competition

Price regulation is believed to have a major impact on pharmaceutical price setting.[9] DANZON and CHAO (2000) observe price differences among seven countries and try to identify causal factors to these differences. They apply data from 1992 to analyze behavior in less regulated countries and more regulated countries. Their findings show that pharmaceutical products have lower prices in heavily regulated countries, while the market for generics is comparable small in these more regulated countries. Less regulated countries in contrast, are characterized by a strong competition for pharmaceutical products without patent protection whereas products still under patent protection are relatively high show comparable high prices. Here, competition pressure has led to comparable low prices for generics. Although it is assumed that pharmaceutical price differences between countries might be reduced, when considering the weighted mean (overall effect of countries with more and countries with less regulated markets and their drug prices), the link between regulatory system and pricing is argued to be significant. Regulations are seen to have an effect on prices.

3.2 PAVCNIK (2002) – Effects of co-payment on prices

The work by PAVCNIK investigates the relationship between the degree of patient-out-of pocket expenses and pharmaceutical prices in Germany. She finds that producers significantly change their prices when patient out-of-pocket expenses changes. Brand products in off-patent markets that face more competition reduce their prices more compared to those with

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[9] See also BREKKE et al. (2007) and DANZON (1997b).

less competition. PAVCNIK studies the effects from a change in reimbursement on producer price levels. She used data from the period 1989 – 1996.

3.3   DE WOLF (1988) – Effects of brand loyalty on competition

Under patent protection, physicians are known to gain exclusive experience with the originator (brand) thus creating brand loyalty. For this reason physicians become more insensitive to generics which are launched into the market after patent expiry. Brand loyalty tends to "blind" physicians with respect to less costly substitutes to brand (originator). DE WOLF (1988) interviewed 200 prescribing physicians and observed that generic drugs were very badly represented in the preferred set of product names of physicians. He found that after generics have been launched into the Dutch market, physicians were more likely to stick with the branded products in their prescribing practice. The reason was that these drugs could build up a significant goodwill under patent protection and could gain from this brand loyalty even after the introduction of generics.

3.4   The 'generic competition paradox'

After patent expiry and the entry of generic competitors in the market, the producer of brands might increase the price for its product instead of decreasing. SCHERER (1993) calls this phenomenon "generic competition paradox". Actually there are two things that happen in response to the entrance of generics. First, the branded product increases or stay constant. Second, the branded product looses market share to the cheaper generics. In the following I will present empirical works that are related to the 'generic competition paradox'.

VERNON and GRABOWSKI (1992 and 1996)

VERNON and GRABOWSKI (1992 and 1996) examined 18 (22) branded drugs which faced generic competition in the period between 1983 – 1987 (1989 – 1993). They observed that none of the branded firms responded to the potential generic competitors for example by setting prices lower in order to scare them from entering the segment or at least to slow down their entry. In contrast, the prices of the brands steadily increased, both before and after the market entry of the generic competitors. While brand-named products increased prices, competition among generic copies led to falling prices of the generics relatively to the brands. This price effect was even stronger the higher the number of offered generics was.

FRANK and SALKEVER (1992 and 1997)

FRANK and SALKEVER (1997) came to a similar conclusion when they examined 32 pharmaceutical products that ran out of patent protection in the mid 80s. The prices of brands were observed to increase in response to the market entry of generic competitors. In an earlier paper they developed a theoretical model in order to explain the relationship between the price-setting behavior of producers of brands and the degree of market competition [FRANK and SALKEVER 1992]. They assumes a split of the market into two different segments. The first segment was a brand loyal consumer group, yielding a price inelastic demand for brands (brand loyal consumers). This consumer group could well be patients being covered by a health insurance scheme. The second group had a price elastic demand and could and this group could be hospitalized patients. For this group their pharmaceutical consumption is by hospitals having an incentive to reduce drug costs (hospitals budgets and profit maximization behavior). As long as there are no budget regulations for the prescribing physician, he or she might lack incentives to prescribe the cheapest drug available in the market. The physician may also have low incentive for gathering information on generics since in the collection of information is resource-demanding.

BHATTACHARYA and VOGT (2003)

Another study that tries to explain the mechanisms behind the generic competition paradox is BHATTACHARYA and VOGT (2003). Their empirical work does not split the market into two different segments, rather they focus on the importance of product publicity, recognition and information management. The demand for a pharmaceutical product will besides prices depend on its recognition among consumers. According to BHATTACHARYA and VOGT a firm will set a relatively low price when launching a new brand on the market. Such a policy may increase the product's publicity when being new on the market, but in return will confront the firm with high expenditures for marketing and informing physicians etc. In total, the product's price is low while marketing expenditures are high at the beginning. As soon as the product has reached a certain level of recognition (brand loyalty) in the market, prices are raised and the marketing effort slowed down. A significant brand loyalty might lead to brand loyalty and thus reduce the competitive pressure from generic competitors later on. The model analysis of BHATTACHARYA and VOGT's showed no significant change in the prices of brands in response to the market entry of generics.

4 The determinants of drug pricing

This chapter looks on the determinants of pharmaceutical pricing and their effects. Although this work mainly focuses on the off-patent market, section 4.1 roughly gives an overview on manufacturers' pricing strategies by differentiating patent and post-patent period. Section 4.2 discusses regulatory means that will be important for the theoretical model in chapter 5.

4.1 Pricing strategies

The price of a good is often the most important strategic decision variable[10] of the pharmaceutical manufacturer. Different to other markets, prices are often less flexible due to regulatory policies. Figure 4.1 pictures the different periods during the life-cycle of a innovative pharmaceutical product.
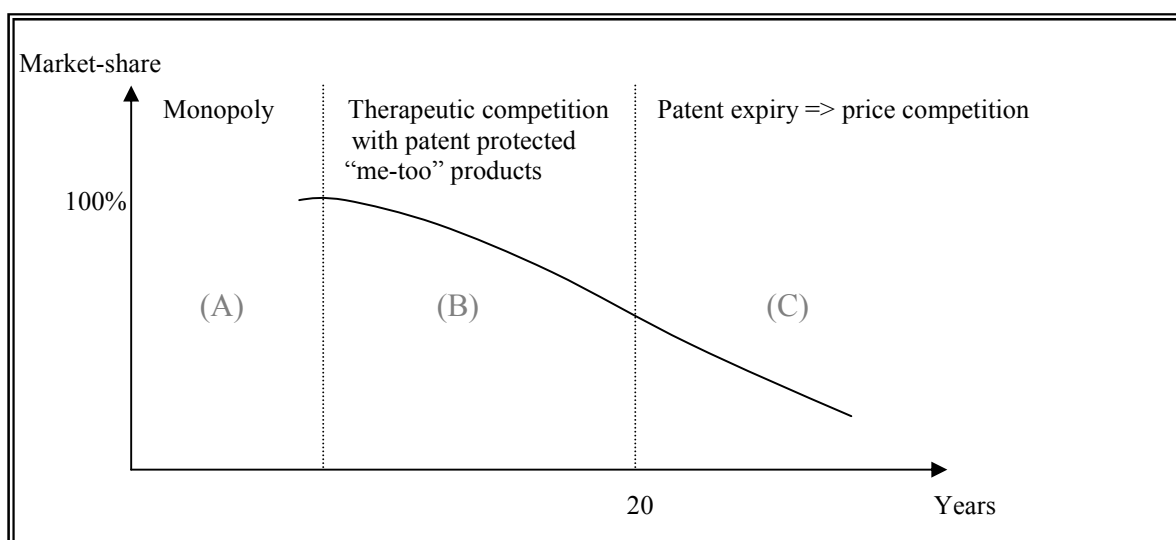
Figure 4.1 Different periods during the life-cycle of a innovative pharmaceutical product. Source: BALLANCE et al. (1992), p. 207.

Figure 4.1 distinguishes three different periods with different pricing strategies according to the life-cycle of a pharmaceutical product: monopoly (A), patent protection with "me-too" product competition (B), no patent protection (C). The vertical axis shows the resulting market shares for each of the periods while the horizontal axis shows the time frame. A monopolist will gain a absolute market share of 100% (A) until therapeutic equivalents with own patent protection are launched (B). The period under patent protection is commonly limited to 20 years. During patent protection (A and B), the manufacturer firm gains from a

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[10] See e.g. SØRGARD (1997), p. 64. In the model he uses, a product's price is the key variable. Both competitors prices are defined as strategic complements.

temporary monopoly market position. The stage after patent protection (C) is characterized by a high potential for price competition since generic firms do not have to include resource intense research and development (R+D) expenditures into their cost calculations.

The following sections will differentiate the problems related to competition before (A and B) and competition after patent expiry (C).

4.1.1 Pricing and competition under patent protection

On the supply side, patent protection guarantees the innovative firm that with market introduction of a new innovative product, there will be no product substitutes available due. Thus, patent protection guarantees the firm's monopolistic position in the market for a certain time. The protected periods is currently 20 years in most countries. But patent protection only prevents from copying the same chemical formula. It is the exactly mix of chemical ingredients the patent is meant to protect, the particular therapeutic effect of the drug is not been covered. Thus, a certain degree of price competition will occur even under patent protection as soon as so-called "me-too" products are launched in the market. "Me-too" products are pharmaceutical products that are very similar in their structural composition, but differ to some extend in their chemical formulation from the innovation. LICHTENBERG and PHILIPSON (2002) for example argue that patents do prevent from competitors offering the very same product in the market, but do not succeed in preventing others launching products in the market that are slightly different in their composition and intend to treat the same symptoms and / or have the same health effects[11]. These products are mostly under patent protection themselves.

However, unless there are imitators launched in the market, new innovative pharmaceutical firms are able to set high introductory prices which they can reduce over time if necessary. DEAN (1969) explains this initial monopoly position as skimming-strategy. The demand for the innovator product becomes more price sensitive after new imitators enter the market. Thus, prices under patent protection slightly decrease over time according to DEAN (1969). Less innovative products and imitator goods in contrast are known to find a penetration

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[11] New pharmaceuticals are often not innovative. For example, LU and COMANOR (1998) find that from 148 newly launched drugs under patent protection only 13 products were new innovations and missed a therapeutic substitute.

strategy with low launching prices more suitable to gain consumers. These drugs start with comparable low prices and increase their prices once they are settled in the market.

4.1.2 Competition after patent expiry

With the removal of the main entry barrier, new generic competitors enter the market after patent expiry. Competition for price and market share can occur from now on. Due to strict approval and security procedures, objectively the new generic competitors are perfect substitutes for the originator drug. Thus, not surprisingly, 'the characteristics of the off-patent pharmaceutical market create a potential for price competition' which 'can be encouraged or stifled by regulations or other market interventions' [MRAZEK and FRANK 2004, p. 245].

After patent expiry, generic copies are launched in the market. Thus, simultaneous competition between the originator product and its generic counterfeits arise as well as the different generic substitutes within one segment compete for market shares.

Brand versus generic competition

As drugs whose active chemical ingredients have lost their patent protection, the main characteristic of generics is that they are sold to relatively lower prices than the established brand-named goods. Although generics are almost perfect substitutes to the branded goods, they do vary in shape, color, packaging and their product names. The consumer therefore might not perceive the generic copy as perfectly substitutable for the branded drug. Hence, the price effects on brands from the entry of generics into the market is not for certain. However, it is widely agreed consensus that brand prices maintain or increase after generic entry while losing market shares. CAVES et al. (1991) analyzes the effects on prices of the established brand-name product in the USA when generic pharmaceuticals are introduced. They studied 30 drugs that lost their patents between the years 1976 and 1987 and estimated a reduction of 2% in brand prices after patent expiry. The entry of 20 generics competitors caused a decrease in prices of 17% for the originator products. CAVES et al. (1991) argue that these price decreases show a rather small price response to the entry of generic competitors in the market.[12]

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[12] Similar effects are observed by GRABOWSKI and VERNON (1992). It is argued throughout scholars that brand prices rather increase after entry of generics than they compete in prices. The so-called 'generic-paradox' suggests that brand-name prices increase simultaneously with the entry of generics after patent has been expired.

Generic versus generic competition

There has not been yet been that much focus on the competition among generic pharmaceuticals themselves. Several empirical studies examined the relationship between the number of generic firms and their product prices and found a negative correlation [CAVES et al. (1991); FRANK and SALKEVER (1997); WIGGINS and MANESS (2004); REIFFEN and WARD (2005)]. REIFFEN and WARD (2005) find that the prices of generic products decrease with a growing number of producers of the same good, although prices maintained above the marginal cost of production and left enough space further generic firms to enter the segment.

A recent study by SEELEY (2007) analyzes the determinants of generic versus generic competition in the market for Omeprazole and Paroxetine. Her findings suggest that also for generic-generic competition, low prices, as predicted under perfect competition, are crowded out by product differentiation and reimbursement schemes. Although almost perfect substitutes, brand-name pharmaceuticals and generics are often seen as vertically differentiated goods with different product qualities. In addition, SEELEY (2007) claims that patients do not always succeed in purchasing the cheapest generic drug available on the market. Vertically integrated structures between e.g. wholesaler and pharmacies as well as financial incentives of relatively big discounts may limit the product portfolio of pharmacies as mentioned in chapter 2.

Branded generics

Another argument for a comparable slow progress in generic price competition is argued to be a well developed branded-generic market. Originator firms find it often more profitable to maintain or even increase prices of their branded goods after patent expiry and fish for those consumers that are willing to pay a higher price still, while losing market shares to new generic competitors. Although cheaper than the originator drug, branded-generics are often significantly more expensive than the unbranded counterpart [MRAZEK and FRANK 2004, p. 247].

4.2   Regulatory policies

Most countries justify the use of regulatory policies with the lack of competition. Monopoly power, informational asymmetries, morals hazard and the existence of insurance schemes make governments highly interested in controlling and containing their expenses. Although

countries vary in their mix of policy instruments, this section gives an overview of the main regulatory policy instruments that are currently determining the Norwegian off-patent pharmaceutical market. The chapter will divide supply side policies as reference pricing of pharmaceuticals (RP) is currently one of the most popular pricing instrument while fixed price cap (PC) systems present a comparable stricter policy instrument. On the demand side the influences of patient's co-payment will be discussed.

4.2.1 Optimal pricing

This section introduces economic theory and determines optimal pricing.
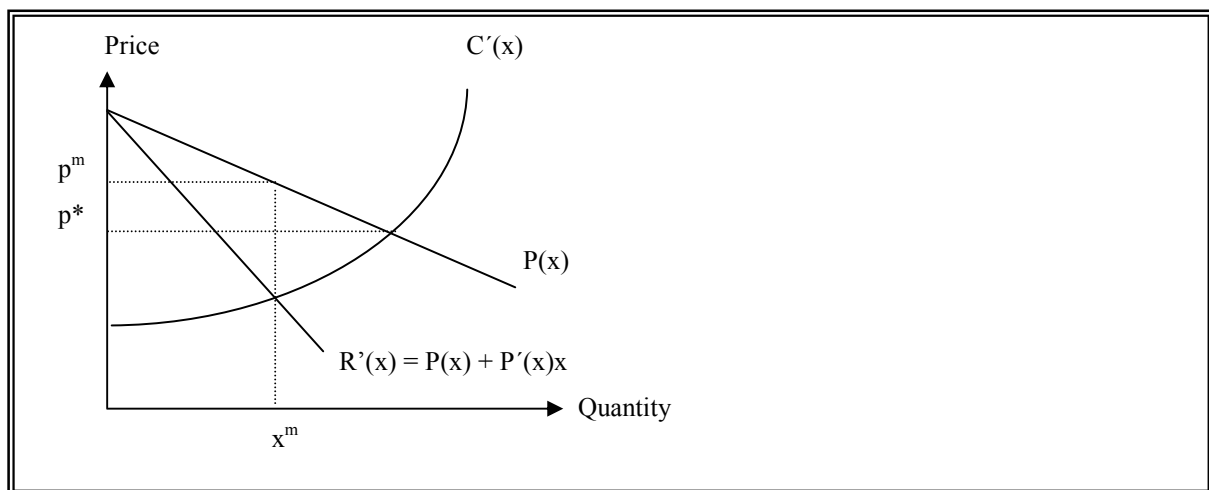
Figure 4.2 Monopoly pricing (m) in comparison to price setting under perfect competition (*). Source: Bester (2004).

Figure 4.2 shows the different price settings under a monopoly and under perfect competition. A producer that enters the market in the absence of any competitor faces a monopoly (m) for his product. In this situation he can set the price for his product (p^m) higher than the marginal costs of production represented by $C'(x)$. $P(x)$ is the function of the price while x denotes the quantity. The supplied quantity in a monopoly is x^m. The monopolist's profit results from the total revenue, which is price multiplied by quantity minus the costs; $P(x)x - C(x)$. A profit maximizing monopolist will set the price p^m to the point where the marginal revenue $R'(x)$ equals the marginal costs $C'(x)$. In figure 4.2 this is the point (p^m ; x^m). In a situation under perfect competition the optimal price p* would equal the marginal costs of production $C'(x)$ instead. In figure 4.2 this would be the point where $P(x)$ and $C'(x)$ cross. Thus, the achieved price under a monopoly (p^m) is higher than under perfect competition (p*) [see e.g BESTER 2004].

Due to the specific characteristics of the pharmaceutical industry, a policy that would per se allow only prices equal to marginal costs of production would strictly lead to negative returns for manufacturing firms. Short term marginal costs account only to 30% of total expenses, while costs for R+D are sunk global fix costs to the time a innovation is launched in the market [BREYER et al. (2005); SCHERER (2000)]. To cover the expenses for recourse intense research and development of pharmaceutical firms, prices have to be higher than marginal costs at least for a certain period. Figure 4.2 shows that therefore, under patent protection innovative firms can charge relatively higher monopoly prices (p^m).

However, even after patent expiry prices are observed less likely to converge towards the marginal costs of production and governments try to overcome these market insufficiencies by multiple regulatory instruments, on the supply as well as on the demand side.

4.2.2 Supply side policy instruments

This section discusses price cap regulation systems and reference pricing as two supply side policy instruments. Both policy instruments are chosen because they determine the current Norwegian regulatory framework for pharmaceutical pricing.

4.2.2.1 Reference pricing

Reference pricing means that similar beneficial drugs are compared systematically and Alternative drug treatments are priced relatively equal to their therapeutic equivalences. Reference pricing was first introduced in Germany in 1989, while different approaches were implemented in the Netherlands 1991, Sweden, Denmark and New Zealand 1993, Australia 1996, Italy and Spain in 2000. Norway introduced international reference pricing in 2001 and the 2003 "index price system" was a pure reference price system.

Reference pricing clusters pharmaceutical products with similar therapeutic effects into groups. These groups might not be equal among countries since they often differ in their definition of therapeutic equivalents. The decision to include or exclude on-patent drugs in the groups will determine the reference price.

Clustering

The tightest way of drug grouping restricts the cluster to drugs with the same active chemical ingredients. Consequently, this approach does not include on-patent pharmaceuticals and will be defined as generic reference pricing (GRP) in the following. DANZON (2001) defines the extension of including other chemical ingredients but with similar therapeutic effects into the group as therapeutic reference pricing (TRP). According to DANZON (2001) the broader the group is defined the bigger is the cost saving potential, but the bigger are the therapeutic differences within the cluster. This trade-off imposes the risk to patients who swap to a cheaper drug which might not be the optimal treatment for them since therapeutic reference pricing imposes a variance in therapeutic effects as well as a variance of potential side effects. The bigger those therapeutic differences are, the more willing are patients to accept a higher price to trade-off potential risks that can arise when swapping from the as "reliable" experienced branded originator to a new and more risky generic substitute, although the later one is cheaper in price.

The decision to include on-patent drugs into the therapeutic reference cluster, adds another trade-off to the controversy when following DANZON's argumentation (DANZON 2001). Including on-patent pharmaceuticals will trade off the aim for cost control and the incentive for innovation and investment in research and development. A high reference price is a positive incentive for new innovations since it guarantees research and development intense firms to invest in the development of new drugs since they can offer their on-patent drugs to a comparable high price without exceeding the reference price or just slightly. On the other hand, there is no incentive for generic firms to offer their goods to a price below the reference price. Thus a relatively high therapeutic reference price significantly limits the generic competition.[13]

4.2.2.2 Price cap regulations

Price caps set a maximum reimbursement price to a specific pharmaceutical segment. The firm is free to charge a higher price, but this difference will result in patient's additional co-payment equal to the difference between price cap and manufacturer price. Compared to

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[13] BREKKE, STRAUME and KÖNIGBAUER (2005) address the same problem in their theoretical model. Their findings differ from the argumentation of DANZON (2001) and suggest that the price of each drug (on-patent brand, off-patent brand, generic) is highest under a system without reference pricing and lowest under therapeutic reference pricing (TRP).

reference pricing, price cap regulations occur to be more regulative. Price caps reduce prices according to a pre-defined cap, while reference pricing aims to create competition.

Depending on the tightness of the regulatory framework, the price cap can be defined as the minimum price found within the cluster, the mean or median value. Stricter policies tend to favor the lowest price within one group to be defined as maximum reimbursable amount. Compared to other direct price regulatory means, under price cap regulations pharmaceutical manufacturer are free to set their prices higher than the price cap. Higher product prices will result in an additional patient co-payment since the patient has to bear the difference between the price cap and the higher manufacturer price.

Originally, price cap regulation policies were introduced on the telecommunication sector in Britain. British Telecom introduced this policy scheme in 1983. The regulation with a upper price limitation was supposed to replace the missing competition and to give incentives to the firms to obtain similar gains in efficiency as under perfect competition. [14] As a retail price index (RPI) regulation system, price capping is argued to be a relatively strict policy instrument.

Figure 4.3 shows that prices might converge towards a common price cap.
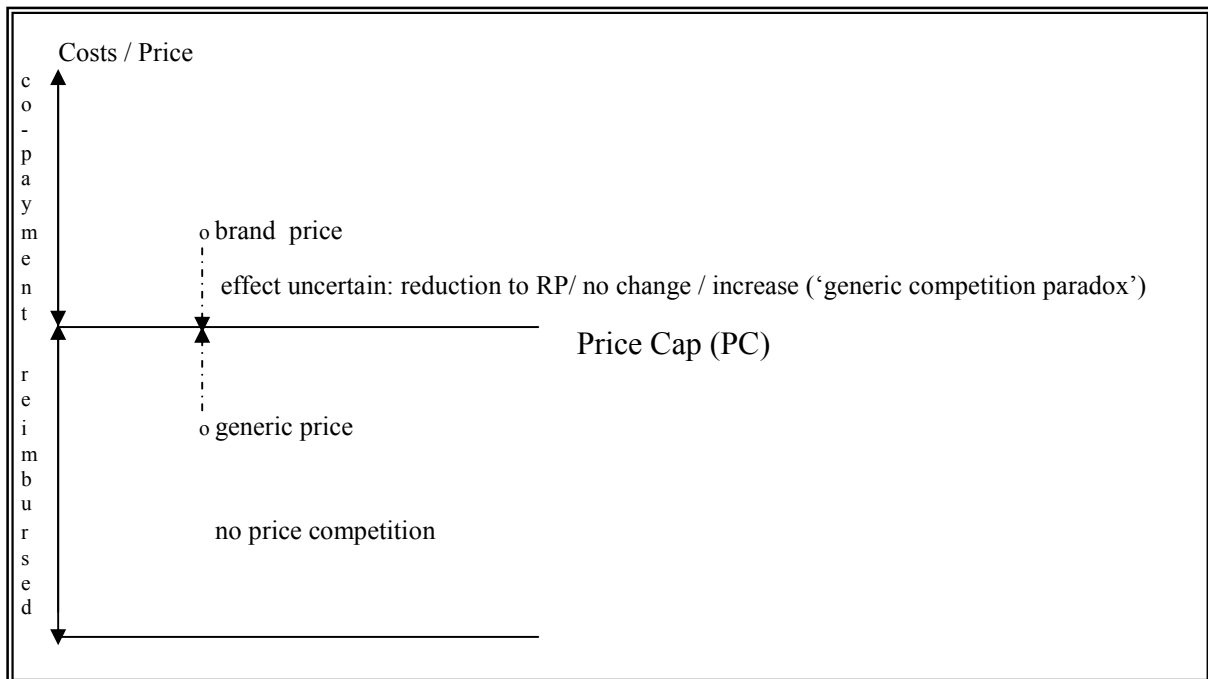
Figure 4.3 Generic and brand pricing under a common price cap (own figure).

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[14] See BERNSTEIN (2000).

Figure 4.3 distinguishes competition above and below the price cap when there is one common price cap for generics and brands. The drug price up to the amount of the price cap will be reimbursed by the insurance coverage. Prices above the price cap will result in additional co-payments equal to the exceeding amount for the patient. An opportunistic firm will rather increase the price to the price cap as this amount is the maximum reimbursable price in any case.

Competition above the price cap

Above the price cap, the brand will move prices towards the price cap or slightly above to avoid an additional co-payment for the patient. Thus, price competition might occur, but is limited in the potential amount of decrease since an opportunistic firm will not decrease prices lower than the cap.

Pharmaceutical products that had a higher price before the introduction of a price cap system and the involved maximum reimbursable amount, are left with two possibilities according to STARGARDT et al. (2005): To leave the product price above the price cap and to accept a decrease in their sales quantity or to reduce their prices to the price cap level and accept a decrease in their sales volume due to lower prices. Firms that choose the first alternative have to hold certain advantages over those firms that set their prices equal or below the price cap and thus avoid additional patient's co-payments. The main determinant here is the perceived utility of the pharmaceutical products by the prescribing physician and the patient as consumer.[15]

Competition below the price cap

Below the price cap, the generic competitors might not compete in prices at all. It seems more reasonable for them to simply converge towards the price cap. The space for price competition below the price cap might be at least limited or even not-existent. In addition, generic medicines might in fact be too expensive under this regulation. This might especially be the case when the same price caps are applied for branded as well as generic goods.

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[15] ZWEIFEL and CRIVELLI (1996) see the physician's role as the patient's agent as influential. They might describe a relatively more expensive drug which if priced above the reference price diminish the patient's overall drug consumption when they believe in the superiority of the brand-named product through prescribing praxis and experience for example.

Some countries are observed to apply additional cuts to the prices to not only maintain public costs but also reduce them. Figure 4.4 shows the Norwegian step-price system where the first price cap is due to reference pricing and the step wise following cuts are reducing the price cap further according to annual sales volume and generic competition (see section 2.4). Figure 4.4 is similar to figure 4.3 and differs only in the circumstance that the maximum reimbursable amount (price cap) is reduced over time. The aimed for effect are reduced prices by making patients more cost aware if prices do not naturally decrease over time.
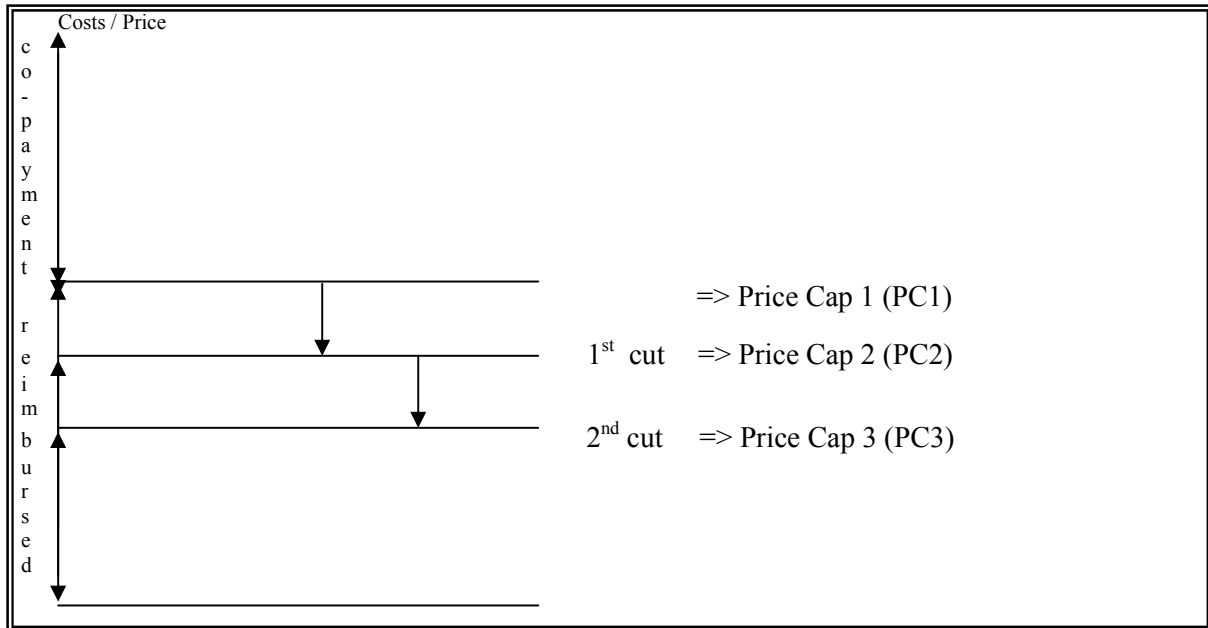
Figure 4.4 The Norwegian step-price as strict price cap system (own figure).

Different price caps

A tight policy instrument such as fixed price cuts is seen as a rather short-lived decrease of pharmaceutical expenditure [see MOSSIALOS et al 2004, p. 10]. On the other hand, setting maximum reimbursement price levels that will be paid by the government, create more cost awareness on the demand side since every cost above this pre-defined price cap has to be borne by the patient.

While Figure 4.3 suggests that patient's cost-awareness as pro-competitive determinant might be crowded out by a common price cap, differentiated price caps for brand-name pharmaceuticals and their generic copies could be able to exploit this potential more sufficient. Figure 4.5 shows a scenario with different price caps for generics and brands.
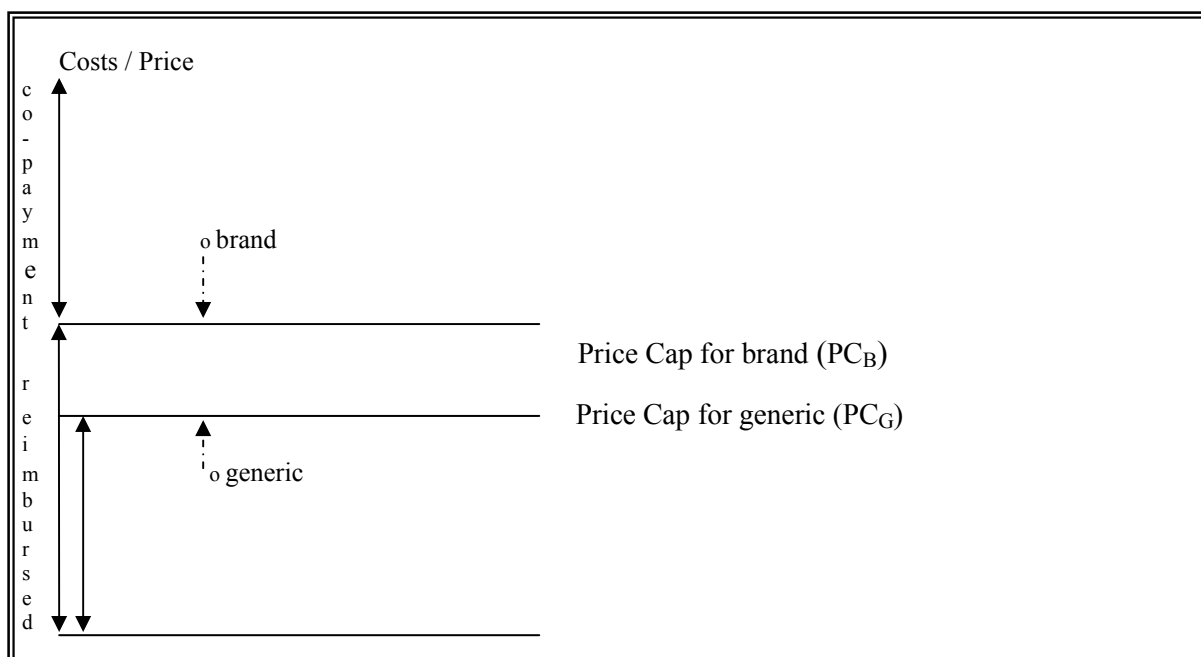
Figure 4.5 Generic and brand pricing under different price caps (own figure).

In figure 4.5 generic and brand medicines have different price caps. PC_B is the price cap for brands and PC_G is the price cap for generics. Again, prices above the price cap for the product will result in additional co-payments equal to the exceeding amount for the patient. For a generic medicine the patient will face an extra co-payment when the price is above PC_G and for a brand when the price exceeds PC_B respectively. If there are sufficient enough generic substitutes on the market[16], there will be at least some generics that converge towards the lower generic price cap (PC_G) of figure 4.5. If so, this lower price cap on the one hand guarantees that generic products are relatively fair priced and are less likely to be over-priced as under a common price cap. In addition, consumers might be more price sensitive towards the whole segment if and only if generic prices converge towards the pre-defined price cap for generics. Opportunistic behavior drives the prices still towards the price cap, but the gap between both price caps creates more cost-awareness.

4.2.3 Demand side policy instruments

Cost awareness on the demand side builds a solid base for regulatory approaches to the patients' and the physicians' financial incentives to increase generic product usage. This section looks on the effects of patient's co-payments since there are no budget limitations for physicians in Norway.

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[16] To the entry of generic see e.g., SCOTT-MORTON (1999) who observes that this is not a random decision. Firms are likely to launch an own generic into the market when this drug fits into their existing portfolio and / or the consumer groups intersect.

Co-payments

Co-payments are the patient's financial share of the drug expenses. An insured patient effectively pays the price that is equal to his or her co-payment for a pharmaceutical product. Co-payments can vary from a fixed amount to a percentage amount of the expenses. According to ZWEIFEL et al. (2005), a positive patient's share is crucial for cost awareness, although the actual high depends on individual risks and preferences.[17]

Whether co-payments come as fixed deductibles per package or as percentage share of the retail price depends on the regulatory framework. A study by NEWHOUSE (1993) found that a co-payment of 25% reduces the demand of 25% while the demand would decrease with 43% nearly half when patients would have to pay 95% of the drug expenses. A fixed deductible per package will result in a more efficient demand for the amount of drugs and prevents from overconsumption. However, in cases where the price is higher than the deductible, the patient lacks a financial incentive to search for the cheapest alternative. Percentage shares on the other hand lead to more cost-awareness on the demand side. The higher the patient's share is the more price sensitive is his or her demand. A share of 100% is equal to the case of no insurance coverage, while the absence of any co-payment means total coverage by the insurer. DANZON (1997) argues that a percentage share is more effective than a fixed deductible.
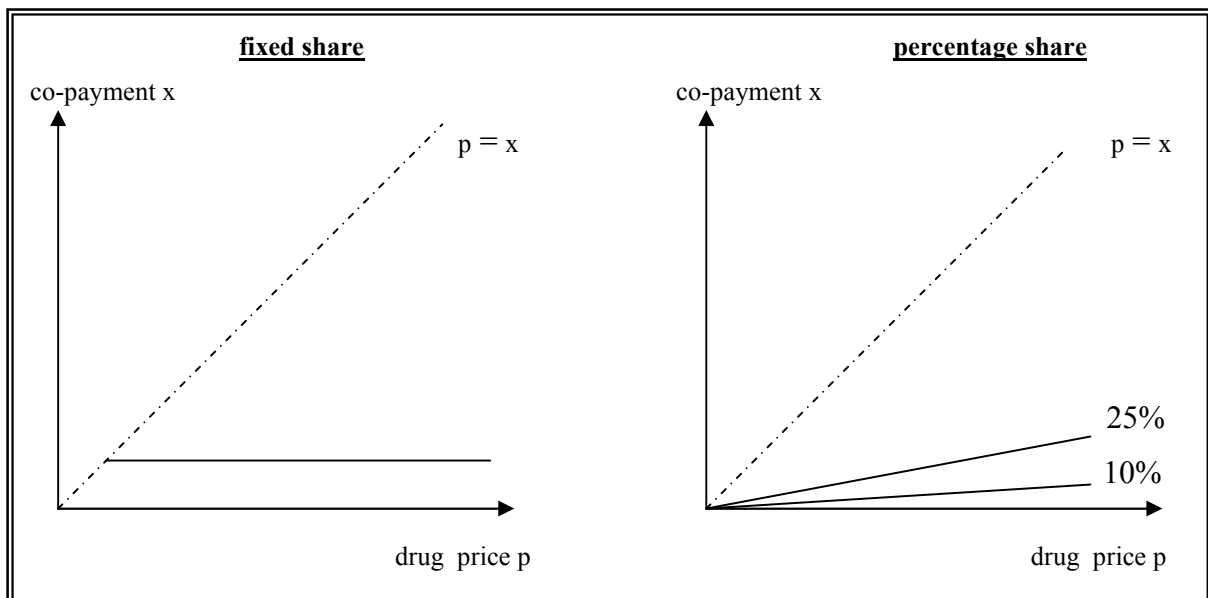
Figure 4.6 The patient's co-payment as a function of prices in dependence from the price (According to NEWHOUSE (1993)).

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[17] To the features of the optimal insurance contract and moral hazard, see ZWEIFEL and MANNING (2000), CUTLER and ZECKHAUSER (2000) and PAULY (2000).

Figure 4.6 shows the patient's co-payment as a function of prices in dependence from the price for the two alternatives: fixed share and percentage share. The vertical axis illustrates the amount of co-payment (x) paid by the patient and the horizontal axis illustrates the actual price of the drug (p). In the absence of insurance the patient would be reliable for the total price of the drug, the co-payment would be 100%. This is illustrated by the 45° axis where the co-payment euqals the drug price, p = x for any given price. From figure 4.6 it can be observed that under a fixed deductible the co-payment is equal for all products. When the price is higher than the deductible, patients have no incentive to search for the cheapest alternative. A percentage share instead links the co-payment directly to the price of the drug. The higher this percentage is, the more price sensitive the patient's choice will be. A percentage co-payment of 25% will make the patient more cost aware than a co-payment of 10%.

Drug Formularies

Drug formularies are positive or negative lists for reimbursement which either include (positive list) or exclude (negative list) pharmaceuticals from reimbursement. To influence the physician's prescribing practice, many countries have implemented so called drug formularies. In order to lower costs, these lists contain drugs which have been approved for to be or be not reimbursed. Positive lists limit the choice of pharmaceutical products to the ones that are listed. Negative lists excludes certain drugs from the reimbursement scheme. Norway has a positive list for drug reimbursement.

5　The model

In this chapter I will analyze the effects on producer prices from introducing differentiating price caps and differentiated patient co-payment rates. Price caps as well as co-payment rates are two of several policy instruments a regulator may apply to affect the price-setting behavior of pharmaceutical companies. Price caps together with patients' co-payments have effects on the degree of reimbursement that occur for drugs.

In this section I will present and analyze a theoretical model. The model will be presented under three different contexts. First, the model is analyzed when assuming that the price caps for brands and generics and the co-payment rates brands and generics are the same (identical price caps and co-payment rates). Second, the same model is presented but now for different price caps for the branded good and the generic (differentiated price caps). Third, the model is analyzed for different co-payment rates for the brand and the generics (differentiated co-payment rates). Finally, the results from the three analysis are compared.

The comparison is done from the manufacturer's point of view in the sense that I will try and identify under which scenario the competitive pressure is highest. The intention is to find out whether differentiated price caps and co-payment rates may lead to more competitive pressure relatively to a situation with identical price caps and co-payment rates.

I will apply a model of Bertrand price competition model for differentiated goods to analyze the above research questions. This model assumes two firms (oligopolistic) and simultaneous price setting behaviour [see SØRGARD 1997].[18] After patent expiry the branded drug producer faces a new market situation for which the producer not any more can charge its monopoly prices any more. The brand producer will now face competition from the producers of generics. According to SØRGARD (1997), horizontal product differentiation will be found when products are not fully substitutable. Consequently, a product perceived as being of higher quality for example will be priced higher than its lower quality rival, even if it is only a perceived quality differentiation.

Using the Bertrand Price competition model for differentiated goods for pharmaceutical products can be justified if not all consumers purchase the good with the lowest price [see

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[18] The model is based on SØRGARD (1997), pp. 61 – 64.

MERINO-CASTELLO (2000); PAVCNIK (2002); GRABOWSKI and VERNON (1992)]. Thus, the branded good and and the generics are are perceived by patients as being being different for identical prices meaning that they are not perfect substitutes.

5.1 Benchmark: common price caps and rates of co-payment

We consider a situation where there exist two alternative drugs to cure a specific illness. Firm B (brand) is the innovating firm that originally launched the drug but has recently lost its patent for this product. A second firm, firm G (generic), has launched its own product, a generic copy of firm B's product. The products are chemically the same but consumers do not perceive them as perfect substitutes. If both products have the same consumer price, the patient is assumed to stringently prefer the branded good to the generic one. θ is the patient's preference, $\theta_B > \theta_G$.

In the benchmark scenario, both products (B and G) are subject to a common price cap regulation $\bar{p}$ as well as a common co-payment α.

The total demand for each drug, Qi (I = B,G) are:

$$Q_B = \theta_B - bp_B^{cons} + kp_B^{cons} \tag{5.1}$$

$$Q_G = \theta_G - bp_G^{cons} + kp_B^{cons} \tag{5.2}$$

Qi denotes the total demand for each drug. This demand results from the consumer's preference θ_i for each drug minus the consumer price p_i^{cons}, plus the consumer price of the competitor p_j^{cons}. b and k are constants. It is assumed that $0 < k < b$. The change of the own producer price has a stronger effect on the firm's sale than a change of the competitors price.[19] If both products have the same consumer price, the patient is assumed to stringently prefer the branded (B) good to the generic one (G) while θ is the patient's preference. It is observed from (5.1) and (5.2) that if both consumer-prices are equal to zero then $Q_G = \theta_G$ and $Q_B = \theta_B$. In the following it will be assumed that $\theta_B > \theta_G$, meaning that the demand for B is strictly higher than for G given zero prices. This follows because we study vertically differentiated goods where the branded product in average is assumed to be valued more by

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[19] See SØRGARD p. 61.

the patients than the generic one. Thus, the patient perceives the two goods as being of different quality for example because of imperfect information and brand loyalty.

The actual consumer prices, p_i^{cons} for the two drugs can be expressed as follows:

$$
p_i^{cons} =
\begin{cases}
\alpha \bar{p} & \text{for} \quad p_i^{prod} \leq \bar{p} \\[2ex]
\alpha \bar{p} + [\, p_i^{prod} - \bar{p}\,] & \text{for} \quad p_i^{prod} > \bar{p}
\end{cases}
\tag{5.3}
$$

where i = B, G.

$\alpha \; \varepsilon \; (0,1)$ is the co-payment rate, p_i^{prod} is the producer drug price and $\bar{p}$ is the price cap. To simplify my forthcoming analysis we assume that $p_i^{prod} > \bar{p}$. This is done in order to avoid taking the discontinuity present in (5.3) into account when deriving equilibria. It follows from (5.3) that the co-payment rate represents a fixed share (in percent) of the price cap. It is also observed that the amount paid by consumers depends on two factors. First, they pay a share of the price cap. Second, they pay the full difference between the producer price and the price cap – meaning that the patients in need of drugs fully have to bear the amount exceeding the price cap.. A producer price, p_i^{prod} , equal to the price cap, $\bar{p}$, gives low patient expenses, now, all patients payments follow because of the share paid of the price cap.

The demand functions can be expressed the following way by inserting (5.3) into (5.1) and (5.2):

$$
Q_B = \theta_B - b(\alpha \bar{p} + [p_B^{prod} - \bar{p}]) + k(\alpha \bar{p} + [p_G^{prod} - \bar{p}])
\tag{5.4}
$$

$$
Q_G = \theta_G - b(\alpha \bar{p} + [p_G^{prod} - \bar{p}]) + k(\alpha \bar{p} + [p_B^{prod} - \bar{p}])
\tag{5.5}
$$

The objective of the two firms are to maximize profits. The profit functions are as follows:

$$
\pi_B = (p_B^{prod} - c)\, Q_B
\tag{5.6}
$$

$$
\pi_G = (p_G^{prod} - c)\, Q_G
\tag{5.7}
$$

where c is the marginal production costs. It follows from (5.6) – (5.7) that c is constant and the same for both firms.

The governments' total expenses, PE, are:

$$PE_i = \sum \overline{p} \, (1 - \alpha) \, Q_i \qquad (5.8)$$

It follows from (5.8) that all expenses not paid by the patient are covered by the third-party payer (government). Public expenses are equal to the fraction of the price cap not covered by the patient multiplied to the number of drug units sold.

Bertrand equilibrium of the game

First, I will derive the equilibrium for the benchmark case where both price caps and patients' co-payments rates are the same for the brand and the generic (homogeneous).

The first-order-conditions are derived by maximizing the profit functions of the two producers with respect to their respective producer prices:

$$\text{Max } \pi_B = (p_B^{prod} - c) \, [\theta_B - b(\alpha \overline{p} + [p_B^{prod} - \overline{p}]) + k(\alpha p + [p_G^{prod} - \overline{p}])] \qquad (5.9)$$
$$p_B$$

$$\text{Max } \pi_G = (p_G^{prod} - c) \, [\theta_G - b(\alpha \overline{p} + [p_G^{prod} - \overline{p}]) + k(\alpha \overline{p} + [p_B^{prod} - \overline{p}])] \qquad (5.10)$$
$$p_G$$

The first-order-condition (FOC) are as follows, where each condition also is rearranged in order to present the reaction functions (the second-order-conditions (SOC) are assumed to be fulfilled):

$$\frac{\partial \pi_B}{\partial p_B} = \theta_B - \overline{p}(\alpha-1)(b-k) - 2bp_B^{prod} + kp_G^{prod} + bc = 0 \implies p_B^{prod} = \frac{\theta_B - \overline{p}(\alpha-1)(b-k) + kp_G^{prod} + bc}{2b} \equiv R_B(P_G)$$

$$(5.11)$$

$$\frac{\partial \pi_G}{\partial p_G} = \theta_G - \overline{p}(\alpha-1)(b-k) - 2bp_G^{prod} + kp_B^{prod} + bc = 0 \implies p_G^{prod} = \frac{\theta_G - \overline{p}(\alpha-1)(b-k) + kp_B^{prod} + bc}{2b} \equiv R_B(P_G)$$

$$(5.12)$$

Expressions (5.11) and (5.12) balance marginal benefits with marginal costs, and it presents the optimal price level of firm *i* as function of the competitor's price level (reaction

___

functions). The reaction functions describe how the optimal choice of price level depends on the price level chosen by the rival.

The Bertrand equilibrium is derived by solving the firms reaction functions simultaneously. An equilibrium is characterized by that no firm wants to change its price level when observing the choice of its competitor as concerning price level. Substituting (5.11) into (5.12) and vice-versa yields the following equilibrium price levels:

$$p^{*prod}_B = \frac{2b(\theta_B - \bar{p}(\alpha-1)(b\text{-}k) + bc) + k(\theta_G - \bar{p}(\alpha-1)(b\text{-}k) + bc)}{(2b+k)(2b\text{-}k)} \qquad (5.13)$$

and

$$p^{*prod}_G = \frac{2b(\theta_G - \bar{p}(\alpha-1)(b\text{-}k) + bc) + k(\theta_B - \bar{p}(\alpha-1)(b\text{-}k) + bc)}{(2b+k)(2b\text{-}k)} \qquad (5.14)$$

From (5.13) and (5.14) I can see that in equilibrium the two price levels differ only because of the demand side valuation of the drugs (θ_i) differ. We have already assumed that $0 < \theta_G < \theta_B$, hence in the benchmark case, firm B will always sets a higher equilibrium producer price than firm G:

$$p^{*prod}_B > p^{*prod}_G \qquad (5.15)$$

By rearranging (5.13) and (5.14) I get the following expressions:

$$p^{*prod\_c}_B = c + \frac{2b(\theta_B - \bar{p}(\alpha-1)(b\text{-}k)) + k(\theta_G - \bar{p}(\alpha-1)(b\text{-}k))}{b(2b + k)} \qquad (5.16)$$

and

$$p^{*prod\_c}_G = c + \frac{2b(\theta_G - \bar{p}(\alpha-1)(b\text{-}k)) + k(\theta_B - \bar{p}(\alpha-1)(b\text{-}k))}{b(2b + k)} < p^{*prod\_c}_B \qquad (5.17)$$

From (5.16) and (5.17) I can see that both equilibrium prices are strictly higher than the marginal costs of production, c. This conclusion derives from the second term on the right hand side being strictly positive. This conclusion is standard in Bertrand models with two differentiated goods. Economic theory predicts that in the case of differentiated products equilibrium prices will exceed marginal costs and that the deviation will increase as products

become increasingly differentiated. Although the brand and the generics are homogeneous in their chemical formulation, patients are assumed to perceive them as being vertically differentiated, e.g. due to certain quality believes.

Substituting (5.13) into (5.4) and (5.14) into (5.5), the equilibrium quantities are as follows:

$$Q^*_B = \theta_B - (k-b) [\bar{p}(\alpha-1) + \frac{2b(\theta_B - \bar{p}(\alpha-1)(b-k)+bc)+k(\theta_G - \bar{p}(\alpha-1)(b-k) + bc)}{(2b+k)(2b-k)}] \qquad (5.18)$$

$$Q^*_G = \theta_G - (k-b) [\bar{p}(\alpha-1) + \frac{2b(\theta_G - \bar{p}(\alpha-1)(b-k)+bc)+k(\theta_B - \bar{p}(\alpha-1)(b-k) + bc)}{(2b+k)(2b-k)}] \qquad (5.19)$$

By subtracting the (5.19) from (5.18), I obtain:

$$Q^*_B - Q^*_G = \frac{\theta_B - \theta_G - (k-b)[2b(\theta_B - \theta_G)+k(\theta_G - \theta_B)]}{(2b+k)(2b-k)} > 0 \quad \Longrightarrow \quad Q^*_B > Q^*_G \qquad (5.20)$$

From (5.20) I can observe that in the equilibrium the demand for B is higher than the demand for G, although (5.15) suggests that in the equilibrium, firm B can set a higher producer price. Subtracting the equilibrium demands, I find that the outcome is strictly positive. In the benchmark equilibrium the demand is higher for the branded drug.

Substituting (5.18) and (5.19) into (5.8), yields the following expression for public expenses evaluated in the equilibrium:

$$PE^*_B = \bar{p}(1-\alpha)(\theta_B - (b-k)[\bar{p}(\alpha-1) + \frac{2b(\theta_B - \bar{p}(\alpha-1)(b-k)+bc)+k(\theta_G - \bar{p}(\alpha-1)(b-k) + bc)}{(2b+k)(2b-k)}])$$
$$\qquad (5.21)$$

$$PE^*_G = \bar{p}(1-\alpha)(\theta_G - (b-k)[\bar{p}(\alpha-1) + \frac{2b(\theta_G - \bar{p}(\alpha-1)(b-k)+bc)+k(\theta_B - \bar{p}(\alpha-1)(b-k) + bc)}{(2b+k)(2b-k)}])$$
$$\qquad (5.22)$$

To sum up, I have shown that given common price caps and co-payment rates, firm B charges a higher producer price than firm G. This again means that the consumer price is highest for the branded product. Furthermore, the demand, and thus the market share, is highest for firm B. This conclusion follows due to the difference in patient valuation of the two goods – despite a higher consumer price for B patients demand B relatively more than G.

In the following I will investigate what the effects on equilibrium producer prices are from changes in two policy instruments (co-payment rates and price caps). In addition, the effect from a change in the valuation parameter will be investigated.

The effect from a change in co-payment follows by differentiating p_i with respect to α, which yields:

$$\frac{\partial p_i^{prod}}{\partial \alpha} = \frac{2b\bar{p}(k\text{-}b) - k\bar{p}(b\text{-}k)}{(2b+k)(2b\text{-}k)} \quad < \quad 0 \tag{5.23}$$

From (5.23) I find a negative relationship between the producer price and the co-payment rate. This finding can be interpreted as being the result of increased demand side cost awareness. The higher the co-payment, the higher the consumer price for a given producer price. Shifting a higher cost burden onto the patient causes a more price-sensitive demand function. The extreme case where the co-payment rate is equal to 1 equals a situation without any insurance, while an co-payment rate equal to 0 means full insurance coverage. It becomes optimal for the firm to lower their producer prices when the co-payment rate is higher. An increased co-payment makes the patient's demand more price sensitive and he or she might react with a lower consumption.

The effect from a change in the price cap follows by differentiating p_i^{prod} with respect to $\bar{p}$, which yields:

$$\frac{\partial p_i^{prod}}{\partial \bar{p}} = \frac{2b(\alpha-1)(k\text{-}b) - k(\alpha-1)(b\text{-}k)}{(2b+k)(2b\text{-}k)} \quad > 0 \tag{5.24}$$

From (5.24) I find a positive relationship between the price cap and the producer price. It follows from (5.24) that the higher the price cap, the more profitable the firm finds it to set a high producer price. The patient has to bear a compulsory share of the price cap in form of $\alpha \bar{p}$ in any case. Thus, opportunistic pharmaceutical firms are likely to converge towards the price cap. A higher price allows the firms to set higher prices without or only slightly exceeding the cap. This in return prevents the patient from facing an additional but avoidable co-payment. On the other hand a higher price cap will increase the co-payments since the co-payment is a fraction of the price cap. Higher co-payments could make it for the producer more optimal to lower the price. However, under a given price cap there is no incentive to lower prices below the price cap since patients will always have to bear the same fraction of

the price cap. Comparable high price caps seem less likely to stir cost awareness on the demand side.

The effect from a change in the patients' perceived valuation of the two goods follows from the two following expressions:

$$\frac{\partial p_i^{prod}}{\partial \theta_i} = \frac{2b}{(2b+k)(2b-k)} > 0 \tag{5.25}$$

$$\frac{\partial p_i^{prod}}{\partial \theta_j} = \frac{k}{(2b+k)(2b-k)} > 0 \tag{5.26}$$

It follows from the two above expressions (5.25) and (5.26) that the relationship between consumer valuation and producer price is positive. A higher valuation of both goods means that the manufacturers set higher prices. This conclusion follows because a higher valuation is implying that consumers are willing to pay more for both goods. It is also observed that the effect under (5.25) is stronger than the effect under (5.26) since $0 < k < b$. Hence, the patients valuation of the own product i has a stronger influence on the price than the valuation of the counterpart j.

In the benchmark case, I find that with a common price cap and a common co-payment for brand-name as well as for generic goods, prices are higher than the marginal costs of production and are unequal in the equilibrium. The brand-name good has a higher producer price in the equilibrium than the generic good. With a similarity of the price regulatory policies for both goods, the incentive for pharmaceutical firms to price compete seems to be very limited. The dominant factor is the perceived difference in quality. Therefore, pharmaceutical firms producing generic substitutes cannot take advantage of their lower cost structures to attract more patients in this setting.

5.2   Differentiated price caps.

Now I will introduce differentiated price caps into the model in order to study the effects on demand and equilibrium prices.

The following assumption is imposed:

$$\bar{p}_B > \bar{p}_G \tag{5.27}$$

saying that each good has a price cap and that the price cap for the brand, $\bar{p}_B$, is strictly higher than the price cap for the generics, $\bar{p}_G$.

Following the same procedures as in the benchmark case, the price-level in equilibrium becomes:

$$p^*_B = \frac{2b[\theta_B - \bar{p}_B(\alpha-1)b + \bar{p}_G(\alpha-1)k + bc] + k[\theta_G - \bar{p}_G(\alpha-1)b + \bar{p}_B(\alpha-1)k + bc]}{(2b+k)(2b-k)} \quad (5.28)$$

$$p^*_G = \frac{2b[\theta_G - \bar{p}_G(\alpha-1)b + \bar{p}_B(\alpha-1)k + bc] + k[\theta_B - \bar{p}_B(\alpha-1)b + \bar{p}_G(\alpha-1)k + bc]}{(2b+k)(2b-k)} \quad (5.29)$$

Subtracting (5.28) from (5.29) yields the following expression:

$$p^*_B - p^*_G = \frac{(2b-k)(\theta_B - \theta_G) + (2b+k)(b+k)(1-\alpha)(\bar{p}_B - \bar{p}_G)}{(2b+k)(2b-k)} > 0 \quad ==> \quad p^*_B > p^*_G \quad (5.30)$$

It follows from (5.30) that the equilibrium price for the brand is strictly higher than the equilibrium price for the generics. This conclusion also mattered for the benchmark model.

Subtracting the two equilibrium quantities yields:

$$Q^*_B - Q^*_G = \theta_B - \theta_G + (b+k)[(\bar{p}_B - \bar{p}_G) + \alpha(\bar{p}_G - \bar{p}_B)] + (-b-k)\frac{[(2b-k)(\theta_B - \theta_G) + (2b+k)(b+k)(1-\alpha)(\bar{p}_B - \bar{p}_G)]}{(2b+k)(2b-k)}$$

$$Q^*_B - Q^*_G > 0 \quad ==> \quad Q^*_B > Q^*_G \quad (5.31)$$

From (5.31) it is observed that even for small $\Delta\theta = \theta_B - \theta_G$, the expression stays positive. In the equilibrium, the demand is highest for the brand. Brand loyalty might be stronger than the financial incentive of a lower price cap for generics.

I now want to study the relationship between the equilibrium producer prices and the price cap levels. This is done be differentiating (5.28) and (5.29) with respect to the price caps:

$$\frac{\partial p_i^{prod}}{\partial \bar{p}_i} = \frac{(2b^2 - k^2)(1-\alpha)}{(2b+k)(2b-k)} > 0 \quad (5.33)$$

$$\frac{\partial \, p_i{}^{prod}}{\partial \, \bar{p}_j} \quad = \quad \frac{kb \, (\alpha - 1)}{(2b+k)(2b-k)} \qquad < \quad 0 \tag{5.34}$$

with i;j = B;G and i≠j.

From the two above expressions, I find that the equilibrium price of each good increases in response to a higher price cap for its own good (see 5.33). Whereas there is a negative relationship between the equilibrium price of own good and the price cap of the rival (see 5.34). A lower price cap for the generic will lead to a higher equilibrium price for the brand. This finding follows because an increase in the rival's price cap makes the rivals good more expensive for consumers and more demand will be directed towards other firms supplying them with power to raise there prices somewhat.

Under differentiated price caps, I find that the brand-name good has still a higher producer price in the equilibrium than the generic good. The dominant factor is still the perceived difference in quality.

5.3 Differentiated co-payments rates.

Now I will introduce differentiated rates of co-payment into the model in order to study the effects on demand and equilibrium prices.

The following assumption is imposed:

$$\alpha_B \; > \; \alpha_G \tag{5.35}$$

saying that each good has a co-payment rate and that the co-payment for the brand, α_B, is strictly higher than the co-payment for the generic, α_G.

Following the same procedures as in the benchmark case, the price-level in equilibrium becomes:

$$p^*_B = \frac{2b[\theta_B - \bar{p}([\alpha_B-1]b-[\alpha_G-1]k)+bc] + k[\theta_G - \bar{p}([\alpha_G-1]b-[\alpha_B-1]k)+bc]}{(2b+k)(2b-k)} \tag{5.36}$$

$$p^*_G = \frac{2b[\theta_G - \bar{p}([\alpha_G-1]b-[\alpha_B-1]k)+bc] + k[\theta_B - \bar{p}([\alpha_B-1]b-[\alpha_G-1]k)+bc]}{(2b+k)(2b-k)} \qquad (5.37)$$

Taking the difference between (5.37) and (5.36) yields:

$$p^*_B - p^*_G = \frac{(2b-k)(\theta_B-\theta_G) + 2b(b+k)(\alpha_G-\alpha_B)\bar{p} + k(b+k)(\alpha_B-\alpha_G)\bar{p}}{(2b+k)(2b-k)} \qquad >/< \quad 0$$

$$p^*_B > p^*_G \quad \text{or} \quad p^*_B \leq p^*_G \qquad\qquad (5.38)$$

From (5.38) I find that the equilibrium price of the generic is no longer strictly lower than the equilibrium price of the brand. This is because the second term in the numerator of (5.38) is negative. The expression (5.38) can become positive or negative. This depends on the difference between the consumer valuation of both goods, $\theta_B-\theta_G$ and the difference between the co-payments, $\alpha_G-\alpha_B$. The closer the drug valuations and the bigger the difference between the co-payments, the more likely it will be that in the equilibrium the producer price of the generic is higher than the producer price for the brand. Firm G faces a lower cost burden for the patient, $0 < \alpha_G < \alpha_B < 1$, and can take advantage of a certain price scope of demand. For the very same producer price, the patient would have to pay less for generics. Firm G can exploit this advantage. As long as the price paid by the patient for the generic is smaller to the price paid for a brand, a price sensitive patient might demand the generic.

A numerical example shows that even with a relatively higher producer price, firm G can still offer its product to a less expensive consumer price than firm B. I denote a common price cap $\bar{p} = 6$ and the following differential co-payments, $\alpha_B = 0.4$ and $\alpha_G = 0.32$. The actual consumer price when both firms price their products according to the price cap are 2.4 for the brand and 1.92 for the generic. By exceeding the price cap slightly with a new producer price of 6.3, firm G can now charge a higher producer price than firm B. Although patients buying product G are charged an avoidable co-payment equal to the amount that exceeds the price cap (0.3). The consumer price of G is still lower than the price paid for B:

$$p_G{}^{cons} = \alpha\bar{p} + [p_G{}^{cons} - \bar{p}] = 0.32 * 6 + 0.3 = 2.32 \qquad (5.39)$$

Especially after modifying or changing a regulatory system, firms might utilize this price scope. For the patient the consumer price of generic medicines paid under a common price cap practically does not change, only the reasoning for the consumer price changes.

Subtracting the two equilibrium quantities yields:

$$Q^*_B - Q^*_G = \theta_B-\theta_G - b(\alpha_B-\alpha_G)\,\bar{p} + k(\alpha_G-\alpha_B)\,\bar{p} + (-b-k)(p^*_B - p^*_G) \quad >/\leq \quad 0$$

$$Q^*_B > Q^*_G \quad or \quad Q^*_B \leq Q^*_G \qquad\qquad (5.40)$$

From (5.40) I find that in the equilibrium, under differentiated co-payments the demand for generics can exceed the demand for brand-named goods. This is because the found expression can become positive or negative. The expression becomes negative if and only if the perceived valuation $\Delta\theta = \theta_B-\theta_G$ is sufficiently small enough and the co-payments α_B and α_G are different enough so that $\Delta\alpha = \alpha_B-\alpha_G$ is big, meaning that the demand is generics is higher than the demand for the brand. The more substitutable the goods are perceived, thus $\Delta\theta$ is very small, the more effective are differential co-payments in increasing to shift the demand to relatively lower priced generics.

As done before, I now want to study the relationship between the equilibrium producer prices and the co-payment levels. This is done be differentiating (5.36) and (5.37) with respect to the co-payments:

$$\frac{\partial p_i}{\partial \alpha_i} = \frac{(k^2 - 2\bar{p}b^2)}{(2b+k)(2b-k)} \quad < 0 \qquad\qquad (5.40)$$

$$\frac{\partial p_i}{\partial \alpha_j} = \frac{(k\bar{p}b - 2bk)}{(2b+k)(2b-k)} \quad > 0 \qquad\qquad (5.41)$$

From the above expressions, I find that the equilibrium price of each good decreases in response to a higher co-payment for its own good (see 5.40) whereas there is a positive relationship between the equilibrium price of the own good and the co-payment of the rival (see 5.41). A lower co-payment for the generic will lead to a lower equilibrium price for the

brand. This finding follows because an decrease in the rival's co-payment makes the rivals good cheaper for consumers and more demand will be directed towards this product.

Under differentiated co-payments I find that the in the equilibrium the producer price as well as the demand for the brand can be higher or smaller than the producer price and demand for the generic. With differentiated co-payments for both goods, the incentive for pharmaceutical firms to price compete seems more relevant than under the benchmark scenario. The dominant factor is no longer the perceived difference in quality alone. Higher cost-awareness becomes gains more importance.

5.4   Comparing the three scenarios

After identifying the the equilibrium prices in all three scenarios, I would now like to compare all three scenarios according to their level of profits for firm B which has been the former monopoly manufacturer. I do this to find out under which scenario producer prices are closest to the marginal costs of production in the equilibrium. I assume that the closer the producer price is to the marginal costs of production, the more effective the regulatory means have been.

Traditional market oriented models using Cournot or Bertrand competition, show that the entry and availability of new alternatives to a certain product will result in price competition and in the decrease of prices of the brand [see BOONE et al. (2007)]. WIGGINS and MANESS (2004) for example show in their study of anti-infectives that prices of the branded drug fall with the entry of generic competitors. Even more, prices decrease inverse in relation to the number of sellers.

Competitive pressure

Competitive pressure (CP) means a situation when a firm finds it more optimal to reduces prices as the competition increases. As seen in figure 4.2, in a situation under perfect competition the optimal producer price equals the marginal costs of production. High competition will reduce the profit of all firms in the market. In the following I will investigate what happens with the profit of producer B in the three scenarios. The intention is to identify in which scenario the competitive pressure is highest and thus the profit is lowest.

In the situation where the producer price equals the marginal costs of production, the profit of firm B would be zero. I denote competitive pressure as CP, the steepness of the firm's profit function is denoted by $\partial\pi/\partial c$[20]. The steeper the profit function, the less profitable is this profit function for the firm. In the following, the definition of competitive pressure is geared to my subject: price competition. I will use competitive pressure as the steepness of the profit function of firm B under the three previously derived scenarios, $CP^i = \partial\pi/\partial c$. CP^i ($i = 1, 2, 3$) refers to the scenario, as CP^1 is the competitive pressure found for the benchmark case and so on. I chose to analyze the competitive pressure for firm B, producing the brand, since I assume that the situation from monopoly to competition changes producer prices most. I aim to find the scenario where firm B's profit function is steepest meaning that this profit function is least profitable to firm B but closest to the optimal producer price under perfect competition respectively, which is the marginal cost of production c.

Deriving the firm's profit function with respect to its cost level for the benchmark scenario, I obtain:

$$\frac{\partial \pi_B}{\partial c}=(p_B^{prod}-c)[\theta_B-b(\alpha \bar{p}+[p_B^{prod}-\bar{p}])+k(\alpha \bar{p}+[p_G^{prod}-\bar{p}])] = 0$$

$$\Rightarrow \quad CP^1 = b(\alpha \bar{p}+[p_B^{prod}-\bar{p}])-k(\alpha \bar{p}+[p_G^{prod}-\bar{p}])-\theta_B \tag{52}$$

For scenario two and under differential price caps, I find:

$$\frac{\partial \pi_B}{\partial c}=(p_B^{prod}-c)[\theta_B-b(\alpha \bar{p}_B+[p_B^{prod}-\bar{p}_B])+k(\alpha \bar{p}_G+[p_G^{prod}-\bar{p}_G])] = 0$$

$$\Rightarrow \quad CP^2 = b(\alpha p_B+[p_B^{prod}-\bar{p}_B])-k(\alpha p_G+[p_G^{prod}-\bar{p}_G])-\theta_B \tag{53}$$

For scenario three and under differentiated co-payments, I find:

$$\frac{\partial \pi_B}{\partial c}=(p_B^{prod}-c)[\theta_B-b(\alpha_B \bar{p}+[p_B^{prod}-\bar{p}])+k(\alpha_G \bar{p}+[p_G^{prod}-\bar{p}])] = 0$$

$$\Rightarrow \quad CP^3 = b(\alpha_B \bar{p}+[p_B^{prod}-\bar{p}])-k(\alpha_G \bar{p}+[p_G^{prod}-\bar{p}])-\theta_B \tag{54}$$

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[20] See MARTIN (1993).

To compare the expressions found under (52), (53) and (54), I will substitute (53) from (52) and (54) from (52). By doing so, I intend to find out if one of the scenarios is stirring more competitive pressure on the firm's profit function. This is the case when producer prices decrease close to the marginal costs of production and the profit function is steepest.

Substituting (53) from (52), yields:

$$CP^1 - CP^2 \;=\; b(p - p_B)(\bar\alpha - 1) - k(p - p_G)(\bar\alpha + 1) \quad < \quad 0 \tag{55}$$

Substituting (54) from (52), yields:

$$CP^1 - CP^3 \;=\; b(\alpha - \alpha_B)\bar{p} - k(\alpha - \alpha_G)\bar{p} \quad < \quad 0 \tag{56}$$

Both expressions, (55) and (56) show that the effect when differentiating the policy instrument with respect to $\bar{p}$ or with respect to α, dominate the competitive pressure found under common price caps and common co-payments in the benchmark scenario. Both profit functions for firm B are steeper than firm B's profit function under the benchmark scenario.

Now, to find out which profit function is steepest (differentiated price caps or differentiated co-payments), I substitute (56) from (55), which yields:

$$CP^2 - CP^3 \;=\; b[p_B(\alpha - 1) + \bar{p}(\alpha_B - 1)] - k[p_G(\alpha - 1) + \bar{p}(1 - \alpha_G)] \quad < \quad 0 \tag{57}$$

From the expression in (57), I find that the effect on competitive pressure from different co-payments dominates the effect of different price caps. Competitive pressure seems highest under scenario three (differentiated co-payments). Firm B's profit function is steepest under differentiated co-payments, meaning that it's producer price is lowest and the profit function least profitable respectively.

5.5 Concluding remarks

Under the taken assumptions, in all three scenarios the equilibrium prices are found to be higher than the marginal costs of production, c. This is because consumers perceive the brand and the generic as being differentiated goods. This also explains why p^*_G is lower than p^*_B in

scenario one and two. Differentiated co-payments in scenario three allow firm G to exceed the producer price of firm B in the equilibrium.

Generally, increasing the co-payment and thus increasing the patient's cost burden may lead to a lower consumption since patients might substitute away from pharmaceutical products. By differentiating co-payment rates across brands and generics the overall demand for drugs might not change although the composition of the drug demand will. A relatively higher co-payment rate for brands and a relatively lower co-payment rate for generics will reduce the consumption of brands and increase the consumption for generics.

The lower the price cap, the stronger the downwards pressure on consumer prices. But the lower the maximum reimbursable amount, the more often and the higher the cost burden for the patient when firms do not set their prices according to the price cap. This can lead to a more limited choice of products because due to a more restricted ability to pay and willingness to pay on the demand side only products are chosen that do not exceed the price cap and thus avoid additional co-payments. For the supply side on the other hand an adaption to a relatively lower price cap would mean lower profit margins and decreases the incentive to invest in research and development of new innovative products. In the long run, this limits the future choice and supply of pharmaceutical products. Differential price caps can provide incentive for research intense firms by allowing a sufficiently high price cap and restricting low-cost generic products to a relatively lower price cap.

No setting was able to reach prices equal to the firms marginal costs. This is because the goods are perceived as differentiated goods. Although different price caps as well as different rates of co-payment work in the same direction of creating more price sensitivity on the demand side, the results suggest that the effect of differentiated co-payments for generic medicines range over the current system of common price caps and common co-payments. Different co-payments offer a more flexible regulatory spectrum than modified price caps alone. In addition, competitive pressure seems to be highest under differentiated co-payments also and supports this argument.

However, since economic theory predicts that differentiated products will result in prices that exceed marginal costs even in a Bertrand model and that these differences will increases as products become more differentiated, it might be wise for policy makers to invest in

consumer information systems when striving for pharmaceutical cost containment. Due to licensing, safety and other legal requisites, today's generic pharmaceuticals are perceived to be objectively from the same quality as their branded counterparts. But still, due to some quality believes on the demand side, both drugs might not be seen as equivalent and patients as well as prescribing physicians tend to be in favor for brand products. Therefore, influencing the consumers' perceived value for the generic drug, θ_G, is another way of tackling the problem. A better informed consumer will have a θ_G closer to the perceived brand quality, $\Delta\theta=\theta_B-\theta_G$ becomes very small or zero if the patient is indifferent between both goods.

5.6 Limitations of the model

Using a Bertrand price competition model, I have illustrated, that under certain assumptions, differentiated co-payments for branded and generic goods can lead to a more competitive market situation, rather than a common regulatory mean for both goods, once the patent for the active chemical ingredients has been expired.

The model assumes that there exist two firms, where firm B produces the brand-name originator and firm G the generic competitor. We assume that the products are perfect substitutes to their chemical formula, but we consider that consumers perceive them as vertically differentiated. Furthermore, I assume that the marginal costs of production are similar for both firms and independent from the products quality. The latter assumption might be controversial since it could be argued that firms producing generic goods might have relatively higher marginal costs of production. Brand-name originator firms are often long established in a market and thus can use technologies of already existing products, especially when offering an own branded-generic simultaneously to the innovative originator. However, literature often assumes constant and similar marginal costs of production [see e.g. SCOTT-MORTON 1998].

If we relax the previous assumptions, we could make the model more dynamic of course. For example we could introduce more firms into the market and not only observe firm B and G competing in prices. Firm G is no longer the only producer of a generic substitute, competition between more firms producing in this segment would be possible. In addition a scenario is possible where firm B can decide to not only produce the brand-name originator,

but simulataneously offer a so called brand-named generic to compete and possible try to drive firm G out of the market.

Furthermore, the model assumes linear demand and supply functions. Linear functions are also often used in literature because they are convenient and easy to derivate. A non-linear demand function could offer a more complex scenario.

6 Summary and conclusion

This thesis intended to give an overview of off-patent pharmaceutical pricing in dependence of the governmental regulations. It shows that the process of pharmaceutical price setting in this segment can be influenced by multiple determinants. Price competition can be observed in spite of insurance coverage. The degree of competition varies according to the product's life-cycle. During patent protection for an active chemical ingredient for example, competition can already be observed between products with similar therapeutic health effects. With patent expiry the degree of competition increases. From now on, generic copies of the beforehand legally protected chemical formulation be launched in the market. Paradoxically, the price of the originator does not necessarily decrease with generic competition. This phenomenon is for example been reasoned with the segmentation of the demand into a price sensitive and a less price sensitive side. Between the generic versions of an active chemical ingredient often exists a relatively grown competition. The price of a generic product generally decreases with the number of generic copies.

Since the ability to finance the social insurance system is wished for in most western countries, governments and other third-party payers aim to cost contain the expenditures for pharmaceutical products. Due to this, states engage with multiple policy instruments into pharmaceutical pricing. The regulation with reference pricing seems to be the most popular policy instrument. Price caps are more strict in their implementation. Theoretically pharmaceutical manufacturers are free in their product pricing. As the reference price, the pre-defined price cap only sets the maximum reimbursable amount. If the actual price exceeds the maximum reimbursable amount, the patient has to bear this difference completely alone. Many firms will now lower their prices to the price cap when the initial price was set higher to avoid a decrease in their sales volume. The difference to the reference price system which aims to control costs by stimulating competition, is that a price cap system is much tighter in setting the maximum reimbursable amount. This may help to contain costs but has the risk to drive out competition if set too low. The goal of price regulatory interventions is to control pharmaceutical pricing and to increase competition. To which degree these regulatory means succeed strongly depends on the design of the regulatory system. A reference price system depends on the clustering of products and a price cap system is strongly determined by the level of the capped price. Below the maximum reimbursable price, competition is limited though. These supply side policies are complemented by patient's co-payments on the demand side. Other demand side policies are positive lists that try to regulate the physicians

prescribing practice. Trading off the effects of demand side policies against the effect of supply side policies, it seems that increasing the cost-awareness among patients and physicians is more sufficient then tight supply sight policies in total. In terms of regulations, the state has to consider that in cases where he sets prices for new innovative medicines under a too strong negative price pressure, the incentive for manufacturers to invest in the research of diseases and the development of new drugs is reduced.

Since 1993 the Norwegian government regulates pharmaceutical prices. It implemented reference pricing to control costs. Other regulations such as patients' co-payments followed and underlined different developments later on. Furthermore, the state tried with generic substitution to give further financial incentives to the dispensing pharmacy. These regulations underly a dynamic process of permanent changes. In 2005, a modification of the Norwegian reimbursement scheme came to work. These changing regulations mean constantly new orientations for patients and physicians.

The research issue of this thesis was to analyze the effects on producer prices on drugs from introducing differentiated price caps and differentiated patient co-payment rates. To do so, it reviewed key studies and introduced a theoretical model into the discussion where price competition à la Bertrand was applied to the Norwegian market for off-patent medicines. Under certain assumptions, differentiated co-payments for branded and generic goods led to a more competitive market situation than that was the case under a common co-payment for both goods. The current rate for co-payment are 36% in Norway, both for generics and brands. Consumers' perceived value for generics was observed to determine producer prices. Due to licensing, safety and other legal requisites, generic medicines are objectively from the same quality as their branded counterparts. But due to certain quality believes on the demand side, brand and generic might not be seen as equivalent and patients might tend to be in favor for brand products. Influencing the consumers' perceived value for the generic drug is another way of tackling the problem with less regulatory involvement. Under perfect competition, consumer prices should be closest to the marginal costs of production.

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