Should pharmaceutical costs be curbed?*

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Summary

Pharmaceuticals account for almost a fifth of total health spending in OECD-countries. Both pharmaceutical innovations and the aging of the population explain the increasing importance of pharmaceuticals in health care. Due to the importance of patent protection and insurance coverage, pharmaceutical markets are subjected to economic regulation – both on the supply-side and the demand-side. In this paper, we briefly review the Nordic pharmaceutical market, before explaining the main regulatory policy measures taken by governments in these countries. Empirical research has been undertaken to investigate regulation and competition, and we provide a review of some of the findings.

Keywords: pharmaceutical markets, pharmaceutical costs, reference pricing, price cap, health insurance.
JEL classification numbers: I11, I13, I18, L51.

* We are grateful for comments from participants at the Nordic Economic Policy Review Conference on Economics of Health Care (May 2012, Reykjavik) and at the Norwegian Health Economic Conference (May 2012, Oslo). Financial support from the Norwegian Research Council is acknowledged.

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Pharmaceuticals have become an important part of health care, both in terms of treatment outcomes and in terms of public spending. Pharmaceuticals now account for almost a fifth of total health spending in OECD-countries.[1] Both pharmaceutical innovations and the aging of the population explain the increasing importance of pharmaceuticals in health care. Cancer, high blood pressure and cholesterol, and depression are examples of diseases where pharmaceutical innovations have improved the treatment, but also triggered increased costs for public health insurance schemes in Nordic countries. In Norway, the consumption of anti-cholesterols per inhabitant increased by close to 340 percent from 2000 to 2009. Both Finland and Denmark have seen similar growth rates. The growth rates in Sweden and Iceland have been lower, but also these countries have seen a sharp increase in the consumption of anti-cholesterols.

The life-cycle of a new drug entering the market can be divided into two phases. The first phase is the one in which a patent protects the innovating company from direct competition from other companies. The patent holder has exclusive rights to produce and sell the drug. The second phase begins when the patent expires and other firms are free to produce and market the exact same – generic – drug.

The abilities of governments to control – or curb – costs in these two phases are very different. When a new drug is approved and enters the market, the main mechanism for controlling costs is by setting requirements for prescription and reimbursement (restricting the use) and by setting price-caps. In addition, parallel import of pharmaceuticals within EU restricts the ability of the innovating company to increase prices in one single country – competition between direct import and parallel import to some extent hinders third-degree price discrimination in the European market. In Sweden and Denmark, parallel import is actively used when determining the patients' copayment (see Section 3.3).

For a patented drug, cost control is closely linked to the quality of the drug relative to other treatment options for the same disease. Reducing spending on innovative drugs (phase one) involves a tradeoff with quality of health care. If a new drug enables a considerably improved treatment compared to other available drugs, curbing the costs for this patient group may be welfare-reducing. If instead the new drug is less innovative ("me-

[1] Health at a Glance (2011).

too-drug"), the cost can be curbed with therapeutic competition without hurting the patient.

With the entry of generic drugs (phase two), large cost savings can be realized if the insurance schemes are able to trigger price competition among the producers. A successful implementation of generic competition can generate a cost saving without lowering the quality of treatment.

The rest of this paper is organized as follows. In Section 1, we briefly review the Nordic pharmaceutical market. In Section 2, we continue by explaining the main regulatory policy measures used by governments in these countries. Section 3 provides a review of some of the findings in the empirical research that has been undertaken to investigate regulation and competition in these markets. We conclude the paper in Section 4 by returning to the question raised by the title of our paper.

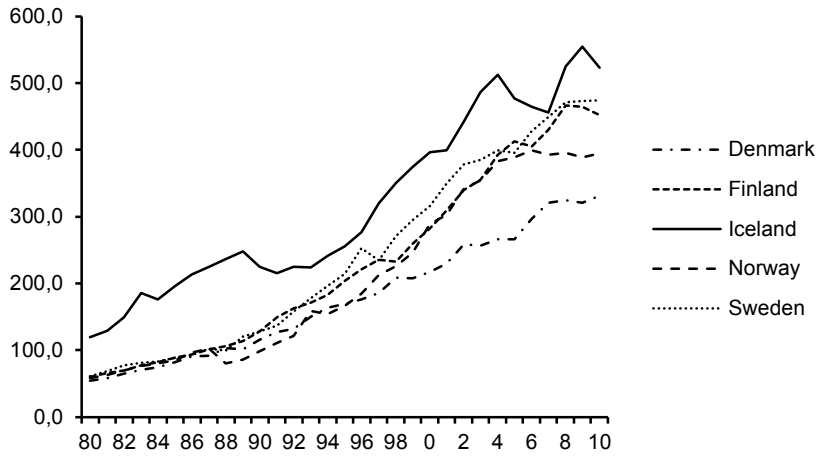
1. Nordic pharmaceutical markets

In this section, we take a closer look at the pharmaceutical market in the Nordic countries. We first describe the level and development of pharmaceutical expenditure in the national markets. Then, we consider the price and the consumption levels of pharmaceuticals in order to explore sources of variation in pharmaceutical spending across countries.

1.1 Pharmaceutical sales/expenditures

The figure below shows the development of pharmaceutical expenditure per capita, measured in USD (OECD-purchasing power parity), from 1980 to 2010. There is a significant variation across the Nordic countries. Iceland has the highest level of pharmaceutical expenditure with USD 523 per capita in 2010, whereas Denmark has the lowest expenditure level with USD 331 per capita. Thus, pharmaceutical expenditure in Iceland is almost 60 percent higher than in Denmark, when making the OECD-purchasing power adjustment. We also see that Finland, Norway and Sweden experienced higher growth rates than Denmark during the 1990's.

Figure 1. Pharmaceutical expenditure (USD-PPP) per capita, 1980-2010



Source: OECD Health Data.

The average annual growth in pharmaceutical expenditure (measured in USD-PPP) from 1990 to 2004 was as high as 12 percent for Norway and 10 percent for Sweden. The annual growth rate in Denmark was 7 percent. In Norway, pharmaceutical expenditure has been stable, or even slightly declining, since 2004.

International comparisons of consumption levels are difficult and controversial (see Almås, 2012). A simple exchange rate conversion changes the picture dramatically by turning Denmark into a country with high pharmaceutical consumption as compared to other Nordic countries. The expenditure levels in 2011, measured with euro per capita, are as follows:

Table1. Pharmaceutical expenditure per capita. Euro. 2011

	Denmark	Finland	Norway	Sweden
Euro per capita, 2011	400	360	310	360

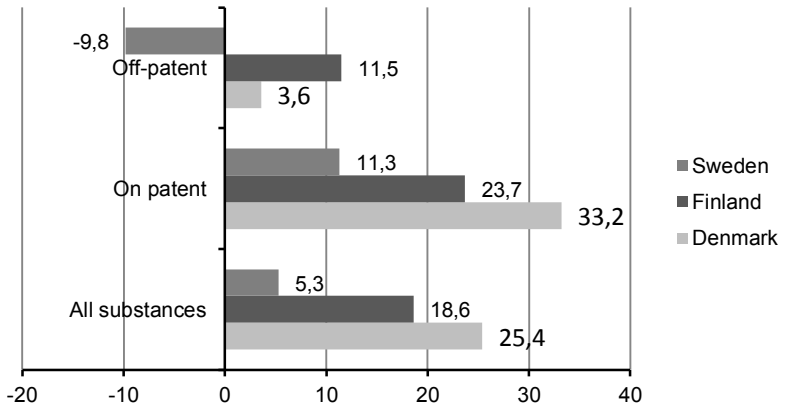
Source: LMI. Facts and figures.

The difference between the two measures in Figure 1 and Table 1 is due to the PPP-adjustment.

1.2 Prices of pharmaceuticals

Pharmaceutical expenditure (sale) is the product of prices and volumes. In this section, we consider the prices in the Nordic countries, whereas in the next section we consider the volumes. Comparing the prices of pharmaceuticals across countries is a challenge, since these products are by nature heterogeneous.[2] There have been a couple of recent studies on the pharmaceutical price levels including the Nordic countries. Brekke et al. (2011b) compare the prices of pharmaceuticals in Norway with nine European countries. They use a sample of the 300 most selling substances as the basis for comparison, and compute a wide set of price indices in order to measure the price levels for all substances and for various submarkets such as the on-patent and off-patent market segments. The figure below reports the price indices for the Nordic countries with Norway as the base country with a price index normalized to zero.

Figure 2. Bilateral price indices based on average substance prices at pharmacy levels, 2010



Source: Brekke et al. (2011b).

We see that the Norwegian price level tends to be the lowest among the Nordic countries. If we look at all substances in the sample, importing the Swedish price level would result in a 5.3 percent increase in the pharmaceutical expenditures in Norway assuming that the consumption is

[2] Danzon (1999) gives a detailed discussion of challenges related to cross-country price comparisons.

unchanged. Importing the Finnish and Danish price levels results in even higher expenditure increases of 18.6 and 25.4 percent, respectively. The price differences are higher in the on-patent market segment, while for substances in the off-patent market segment with generic competition Sweden does, in fact, have a lower price level than Norway.

Note that if the price indices show that the Norwegian consumption of pharmaceuticals would be 10 percent more expensive if using, say, Swedish prices, the reverse is not necessarily true. The reason is that we then need to replace the Norwegian consumption weights with the Swedish consumption weights, implying that although the prices are the same, the price indices would be different. In a recent report, Brekke and Holmås (2012) have computed the Swedish price indices for the on-patent market segment and contrasted these with the price indices obtained in Brekke et al. (2011b). The results show that there is a weak tendency for the base country to become cheaper, but the results are not qualitatively altered. This is also confirmed in a recent study by the Swedish regulatory body TLV written by Arnberg et al. (2012). Thus, cross-country price differences might partly explain the differences in pharmaceutical sales (expenditures) per capita between the Nordic countries.

1.3 Consumption of pharmaceuticals

The second source of differences in pharmaceutical sales across the Nordic countries is the consumption of pharmaceuticals. Since drugs are sold in different pack sizes with different strengths and formulations, we need a measure to make consumption comparable across substances. The most common measure is defined daily doses (DDDs).[3] The figure below shows the consumption of pharmaceuticals (in DDDs) normalized by per 1 000 capita for the Nordic countries.

[3] This is a measure developed by the World Health Organization (WHO) that allows for a comparison of consumption across products with different substances, dosages, and formulations. A DDD is based on the recommend treatment for the main indication of the specific drug. For instance, if the DDD is 20mg of a given substance, then a pack with 10 tablets of 10mg would yield a volume of 5 DDDs.

Figure 3. Consumption, DDD per 1 000 capita

Source: OECD Health Data: Pharmaceutical market.

We see that the consumption of pharmaceuticals in Denmark, Iceland and Norway is low as compared to in Finland and Sweden. Finland has the highest consumption level in 2010 with close to 2 800 DDDs per 1 000 capita. This is about 20 percent higher than the consumption level in Norway, Denmark and Iceland. The variation in the consumption of pharmaceuticals across the Nordic countries is substantial, but they have all experienced a high consumption growth with an accompanying increase in pharmaceutical costs.

2. Pharmaceutical regulations in Nordic countries

The pharmaceutical market is characterized by numerically low price elasticities on the demand side and market power on the supply side.[4] An unregulated market would in this situation be likely to yield high pharmaceutical prices and correspondingly high expenditures of drug consumption. Most countries therefore use several regulatory instruments to con-

[4] See Scherer (2000) for an overview of specific features of the pharmaceutical market. Brekke (2009) also offers a similar overview with a focus on the Norwegian market.

trol prices and total consumption of prescription drugs.[5] In this section, we describe some of the most important regulations, and discuss briefly how they are expected to affect prices and the demand for pharmaceuticals. We also categorize the Nordic countries with respect to the regulatory instruments used.

2.1 Regulatory instruments

We can make a fundamental distinction between supply-side and demand-side regulation. Supply-side regulation attempts to directly control drug prices and can apply to different levels of the vertical supply chain; manufacturers, wholesalers and retailers (pharmacies). Demand-side regulation attempts to control prices and the consumption of pharmaceuticals indirectly through the design of the reimbursement system. Therefore, we can distinguish between the regulation of the price (or the margin) that the suppliers of drugs receive (supply-side regulation), and the regulation of the price that consumers actually pay (demand-side regulation).

Demand-side regulations

Health insurance implies that patients (potentially also doctors) are not very responsive to prices of alternative drugs. Insurers therefore usually do not offer a 100 percent coverage of medical expenses, but impose cost sharing on patients through copayments. The structure of the copayments is a key issue for making patients more conscious of the pharmaceutical costs. In this section, we first discuss the more regular copayment schemes that are used, and then describe a more recent and increasingly popular copayment scheme called reference pricing. Finally, we will discuss a couple of other (non-price) instruments that are employed by insurers.

The regular copayment schemes usually take two different forms: deductibles or coinsurance. Formally, we may write these two copayment schemes as follows:

[5] Danzon (1997) offers an overview of pharmaceutical price regulations with examples from various countries.

$$c = \begin{cases} d & \text{if deductible scheme} \\ a \times p & \text{if coinsurance scheme} \end{cases}$$

where $c \in (0, p)$ is the copayment, $d \in (0, p)$ is the deductible, $a \in (0,1)$ is the coinsurance rate, and $p > 0$ is the price of the prescribed drug. In the case of $c = 0$, there is full insurance coverage, whereas if $c = p$ there is no insurance coverage.[6] A deductible is simply a flat fee (say EUR 5) that patients have to pay when purchasing the prescribed drug. Deductibles impose demand-side cost sharing, but the cost-sharing is regressive in the sense that more expensive drugs face a higher coverage than cheaper drugs.

A disadvantage of deductibles is that the copayment is not linked to the price of the drug. This implies that patients (or prescribing doctors) would not be responsive to the relative prices of alternative drugs. Thus, demand is likely to be price inelastic under a deductible scheme, enabling the pharmaceutical firms to charge high prices. Some insurers (countries) have therefore introduced more refined schemes with higher (lower) deductibles for expensive (cheaper) drugs. However, the correspondence between the price of the drug and the price patients face (the copayment) is still weak, so demand is not likely to be very price elastic even under multi-tiered deductible schemes.

Many insurers (countries) have therefore adopted *coinsurance* schemes, which introduce a direct link between drug prices and copayments. Under this scheme, patients pay a defined share (say 30 percent) of the price of the drug. Copayments of alternative drugs would reflect the price differences only adjusted by the coinsurance rate. Coinsurance is therefore likely to induce more price responsiveness on the demand-side and, in turn, some degree of price competition between alternative therapeutic drugs.

One issue with coinsurance schemes is that the copayments for expensive drugs can be considerable. Some insurers (countries) therefore offer a higher coverage for costly drug therapies. This can be done in several ways. One way is to impose lower coinsurance rates for more expensive drugs. Another way is to impose caps on the copayments and then offer a 100 percent coverage for additional expenditures. The disadvantage of

[6] The latter applies to over-the-counter drugs, as well as prescription drugs that are not on the insurer's reimbursement list.

these adjustments is, of course, that they make demand less price elastic and therefore counteract the intention of coinsurance regimes.

If cost-sharing were the main concern for the insurers, then (a refined) deductible scheme could do equally well as coinsurance. However, insurers tend to prefer coinsurance to deductibles, because of the direct link to the drug price that makes demand more price elastic and increases the potential for price competition between alternative pharmaceuticals.

Let us illustrate the potential effects of coinsurance schemes on the pricing and cost-sharing between patients and insurers. In the below table, we have constructed an example with an increase in the coinsurance rate from 0.2 to 0.3. This is assumed to make demand more price elastic and trigger a price reduction by the pharmaceutical companies. In Case A the response is weak and the price is only reduced by EUR 1, whereas in Case B, the response is strong and results in a price reduction of EUR 4.

Table 2. Copayments and coverage when price responses to coinsurance rates

	Coinsurance rate	Drug price	Copayment	3rd-party payment
Case A:	0.2	€ 10	€ 2.0	€ 8.0
Weak price response	0.3	€ 9	€ 2.7	€ 6.3
Case B:	0.2	€ 10	€ 2.0	€ 8.0
Strong price response	0.3	€ 6	€ 1.8	€ 4.2

Source: Own construction.

In Case A with a weak price response, a higher coinsurance rate is mainly shifting the costs from the insurer (third-party payer) to the patient. Increasing the coinsurance rate is therefore almost equivalent to offering a lower insurance coverage. However, in Case B with the strong price reduction, a higher coinsurance rate does not only reduce the payment for the insurer, but in fact also for the patient. In this case, a higher coinsurance rate is actually *increasing* the insurance coverage to the patients, since the *de facto* copayment has become lower. This example illustrates the two effects of coinsurance: (i) the direct effect is to shift costs from payer to patient; (ii) the indirect effect is to lower the prices of pharmaceuticals and thus, the total payment for pharmaceuticals.

Reference pricing, sometimes also called internal referencing, is a co-payment scheme that has become increasingly popular in recent years. This scheme introduces high-powered incentives for patients to choose cheaper alternative medicines. Under reference pricing, drugs are classified into different reference groups based on therapeutic effect. For each reference group, the regulator sets a reference price, which is the maximum reimbursable price for all drugs in the reference group. Any positive difference between the actual drug price and the reference price is not reimbursable. Formally, we can write the copayment under reference pricing (with coinsurance) as follows:

$$c = \begin{cases} a \times r + (p - r) & \text{if } p > r \\ a \times p & \text{if } p \leq r \end{cases}$$

where $r \in (0, p)$ is the reference price. The effect of reference pricing is to increase the price elasticity of demand for drugs priced above the reference price. The lower the reference price is set, the more price elastic demand is likely to be. Under this scheme, the insurance coverage is lower for expensive drugs, which is in contrast to deductible and coinsurance schemes. The aim of reference pricing is to induce consumers to select cheaper alternatives and stimulate price competition between producers of therapeutically related drugs.

The reference pricing schemes vary according to (i) how broadly the reference groups are defined, and (ii) how the reference price is determined. The most narrow, but also most common, definition of reference groups only includes therapeutically equivalent drugs (i.e., same substance) for which the patent protection has expired. This scheme, often called *generic reference pricing*, has the aim of inducing patients to select cheaper generic versions instead of high-priced brand-names. A less narrow definition is also based on therapeutically equivalent drugs, but extends the scheme to also including patent-protected drugs. This scheme aims at stimulating competition from parallel-imported drugs in the on-patent market segment. The more broadly defined reference pricing schemes include therapeutically related drugs (with different substances) in the reference groups. The intention of *therapeutic reference pricing* schemes is to stimulate competition from therapeutic substitutes. However, the therapeutic reference pricing schemes are also likely to limit the

profits (patent rent) of the patent-protected drugs, and are therefore more controversial from a policy perspective.[7]

Finally, the reference pricing schemes vary according to how the reference price is defined. Generally, the reference price is set somewhere between the highest priced and the lowest priced drug in the reference group. The strict regimes define the reference price equal to the cheapest drugs, implying that the patient faces a surcharge on every other drug in the reference group. In most regimes, the reference price is updated over time according to price changes by the pharmaceutical producers, and is therefore endogenously determined by market prices.[8]

There are also non-price demand-side instruments that affect the pricing and consumption of drugs. First, most insurers (countries) require the pharmaceutical firms to report cost-efficiency or a cost-benefit analysis before placing the drug on the reimbursement list. These analyses would include a suggested price by the pharmaceutical companies. Obviously, suggesting a very high price would imply a low cost-efficiency ratio, and therefore a lower probability for reimbursement. Thus, there is an implicit trade-off for the pharmaceutical companies in their price setting between a lower margin and a higher probability of getting on the reimbursement list. Some insurers use the reimbursement listing procedure actively as a negotiation tool, and exclude drugs that do not have a favorable pricing relative to the existing therapeutic alternatives.

Second, the allocation of physician's budgets for prescription drugs is an instrument that some insurers (countries) have implemented. This instrument has been used in the UK and Germany. The insurer computes a budget for each physician based on her list of patients and the cost of drugs. If the physician only prescribes high-cost drugs, the budget will quickly be spent and the patient would need to go to another physician to obtain her drug. The idea is that these budgets should induce the physicians to take into account the cost of drugs, and prescribe cheaper alternatives (e.g., generics) when available.

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[7] Brekke et al. (2007) study theoretically the effects of different reference pricing schemes, and find that therapeutic reference pricing induces stronger price competition and lower profits than generic reference pricing (or regular coinsurance).

[8] Brekke, Holmås and Straume (2011) set up a model with endogenous and exogenous reference pricing and show that endogenous reference pricing gives generic firms a strategic incentive to lower their prices, not just to capture market shares from brand-names, but also to manipulate the reference price and make the brand-name more costly for patients.

Supply-side regulations

The supply side in pharmaceutical markets consists of a set of vertically related providers. Upstream we have the pharmaceuticals companies. These firms can be divided into two groups; brand-name and generic producers. The brand-name producers are typically innovating firms that invest in R&D and marketing, whereas the generic producers copy the original drugs and once the patent protection has expired, may enter the market with these copy products. Downstream, there are distributors (wholesalers and parallel traders) and retailers (pharmacies). There is a wide set of supply-side regulations that restrict the behavior and trade of the vertically related firms. Here, we focus on the restrictions that are aimed at affecting the pricing and demand for pharmaceuticals. This includes regulations of prices, margins, and entry into national markets.

Many insurers (countries) directly control the pricing of drugs. The most common way of controling prices is to impose a price cap that defines the maximum price a provider can charge for a specific drug on the market. Price cap regulation obviously curbs the market power of pharmaceutical firms, but could be harmful to innovation as the profit is reduced. The interesting question is therefore how the price cap is set by the insurer.

An increasingly popular price cap scheme is *international reference pricing* (external referencing). Under this scheme, the price cap for a given drug is determined by the prices of the same drug in a set of reference countries. The exact formula for the price cap varies from country to country, but is usually a weighted average of the prices of the drug in the foreign countries. The strictness of the price cap scheme would therefore depend on the countries selected in the reference group, and whether the formula imposes a price cap at the lower end of the price distribution in the foreign countries.

International reference pricing is a simple procedure for fixing the price cap and ensures that the price level in a given country is not at the higher end. However, this scheme relies on foreign countries setting drug prices that offer optimal returns on the R&D investments. The most obvious effect of international reference pricing is that is contributes to an international harmonization of drug prices. The more countries that apply this instrument, the stronger is the effect. This scheme would therefore prevent international price discrimination by the pharmaceutical firms.

The incentives for innovation are not likely to be optimal under international reference pricing.

Price cap regulation is usually imposed at either the manufacturer or the wholesale level. To make the price cap binding at the retail level, most insurers (countries) impose a mark-up regulation on the downstream firms. One interesting issue is that different mark-up schemes could affect the final consumer prices through the pharmacies' dispensing incentives. More specifically, if pharmacy mark-ups are set as a percentage add-on to wholesale prices, pharmacies would have a financial incentive to increase their (absolute) mark-up by dispensing more expensive drugs. This incentive can be eliminated by setting the mark-up as a flat fee, implying that the pharmacies would be indifferent between dispensing a cheap or an expensive drug profitwise. However, a regressive mark-up scheme, where for instance the percentage mark-up is lower for more expensive drugs, gives incentives for pharmacies to dispense cheaper rather than expensive drugs. As we will see below, all these alternatives are currently in use in the Nordic countries.

There are also non-price instruments on the supply-side that are likely to affect the pricing and consumption of pharmaceuticals. G*eneric substitution* regulation allows or requires pharmacies to substitute a prescribed brand-name drug with a cheaper generic version. This regulation is often combined with reference pricing to facilitate the sales of generics. However, the pharmacies' incentives for generic substitution depend on their financial gains from this costly activity. If the mark-up regulation is progressive (e.g., the percentage add-on on the wholesale price), then pharmacies will benefit from dispensing the prescribed high-priced brand-name. Thus, for generic substitution regulation to be effective, a regressive mark-up regulation would most likely be needed.[9]

2.3 Regulatory schemes in Nordic countries

Let us now consider the regulatory schemes in the Nordic countries according to the different instruments used in demand-side and supply-side regulation. When making this classification, it is important to bear in

[9] Brekke et al. (2012) study the pharmacies' incentive to substitute generics for brand-names, and show that this relies on the relative product margins and copayments. Using Norwegian register data, they find that a higher margin on generics relative to brand-names is associated with a higher generic market share.

mind that many real-world regulatory schemes combine elements from the more stylized regulatory models presented above. We start by describing the demand-side regulations. Table 3 classifies the various instruments used to affect the demand in the Nordic countries.

Table 3. Demand side regulations in Nordic countries

Country	Reference pricing	Reference pricing applies to	Coinsurance	Regressive coverage
Denmark	Yes	Same substance	Yes	Yes
Finland	Yes	Same substance, off-patent only	Yes	Yes
Iceland	Yes	Same substance	Yes	Yes
Norway	Yes	Same substance, off-patent only	Yes	Yes
Sweden	Yes	Same substance	Yes	Yes

Source: Brekke et al. (2011b).

The Nordic countries make use of reference pricing schemes to limit the reimbursement and induce patients to choose cheaper versions of drugs with the same chemical ingredient. In Norway, this is not the official name given to the scheme.[10] The system nevertheless has the fundamental ingredients of a reference pricing system. The same argument applies to Sweden, which does not officially use generic reference pricing. However, since it is compulsory for pharmacies to perform generic substitution, unless the patient chooses to pay the price difference between the brand-name drug and the cheapest available generic drug, the system is a *de facto* generic reference pricing scheme.

The reference pricing schemes in Denmark and Sweden are more extensive. In Norway and Finland, this scheme only applies to substances where the patent has expired and generic products have been introduced. However, in Denmark and Sweden, the reference pricing scheme also applies to patent protected products when parallel imported drugs with the same substance are introduced. In this sense, the Danish and Swedish schemes do not only exploit generic competition, but also competition from parallel trade in the on-patent market segment.

[10] The scheme in Norway is called «Trinnpris», and implies a step-wise cut in the reference price (trinnpris) over time after generic entry.

Another difference between the Nordic countries is the formula for the reference price. Denmark and Sweden practice a strict scheme where the reference price is set equal to the lowest price of the drugs in a given reference group. In Norway, the reference price is a fixed discount on the brand-name price when generic entry took place. The Danish and Swedish reference prices are updated frequently (every 14 days) and endogenously determined by the price setting of the pharmaceutical firms. The Norwegian reference price is, however, exogenous and not dependent on the price setting by the firms after being exposed to reference pricing.

In addition to reference pricing, all Nordic countries have copayments based on coinsurance, but there are some significant differences. In Norway, the coinsurance rate is 38 percent. However, this is combined with copayment caps both per prescription and per year. The yearly cap also includes copayments on other health care services such as physician visits, etc. For medical expenses exceeding the cap, there is 100 percent coverage. Thus, the *de facto* cost sharing is much lower than 38 percent. Notably, the surcharges under reference pricing are not subject to the copayment caps, and have to be paid out-of-pocket irrespective of the cap. In Sweden, the coinsurance rates vary according to the price of the drug. Expensive drugs face a lower coinsurance rate than cheaper drugs. This scheme is similar to the copayment cap scheme in Norway, but less discrete in its nature.

Regarding the use of supply-side regulation, Table 4 summarizes the instruments used in the Nordic countries.

Table 4. Supply side regulation in Nordic countries

Country	Price Cap regulation	Mark-up regulation	
		Wholesalers	Pharmacies
Denmark	No	No direct regulation	Linear (% + flat fee)
Finland	Yes	No direct regulation	Regressive (% + flat fee)
Iceland	Yes	No direct regulation	Regressive (% + flat fee)
Norway	Yes	No direct regulation	Regressive (% + flat fee)
Sweden	No	No direct regulation	Regressive (% + flat fee)

Source: Brekke et al. (2011b).

First, we see that Denmark and Sweden allow free price setting on pharmaceuticals, while Finland, Iceland and Norway resort to direct price control. The *price cap scheme* in Finland and Norway is based on interna-

tional reference pricing. Norway uses a basket of nine European countries as a benchmark.[11] Finland uses a much wider set of countries, and includes most countries in the EEA. The price cap in Norway is fixed at the average of the three lowest prices in the reference countries. The Finish price cap formula is less transparent, and it is based more on a "reasonable" price relative to the reference countries. Thus, it is less clear whether the Finish system is a strict price cap regime. Iceland bases the price caps on the average Nordic prices. A specific feature of the price cap regulation in Iceland is that separate caps are set for the original product and generic drugs. Denmark and Sweden do not control prices through price cap regulation, but rely more on their extensive reference pricing scheme to stimulate price competition from parallel trade and generic producers. However, they have some degree of price negotiations when it comes to the inclusion of drugs on the reimbursement list due to the requirements related to cost-effectiveness.

The table shows that all Nordic countries practice *mark-up regulation* at the downstream level. The mark-up regulation is imposed at the pharmacy level, leaving the wholesaler margins unregulated. The regulated mark-up is based on the wholesale prices (pharmacy purchasing prices) and consists of two parts; (i) a percentage add-on and (ii) a flat fee. In Denmark, the percentage mark-up is linear (8.6 percent) irrespective of the price level. In the rest of the Nordic countries, the percentage mark-up that pharmacies are allowed to add is lower for expensive drugs, and therefore regressive. However, all Nordic countries allow the pharmacies to add a flat fee for each pack sold. Interestingly, Sweden offers a higher flat fee (SEK 10) on generics and parallel-imported drugs than on brand-names, yielding the pharmacies a financial incentive for generic substitution. In Norway, the regulation of pharmacy margins is not very effective, since more than 80 percent of the pharmacies are owned by the wholesalers. The main purpose of the mark-up regulation is therefore to set the maximum price (price cap) at the retail level.

Finally, we would like to mention that the taxation of pharmaceuticals varies across the Nordic countries. Some countries indirectly subsidize consumption of pharmaceuticals by charging a lower value-added tax (VAT) rate than on other products or services. The table below shows the

[11] These countries are Belgium, Denmark, Finland, Germany, Ireland, the Netherlands, Norway, Sweden and United Kingdom.

regular VAT and the VAT imposed on pharmaceuticals in the different Nordic countries.

Table 5. Value added tax rates in Nordic countries, 2011

	Regular VAT %	VAT % on pharmaceuticals	
		Prescription drugs	Non-Prescription drugs
Denmark	25.0	25.0	25.0
Finland	23.0	9.0	9.0
Iceland	25.5	25.5	25.5
Norway	25.0	25.0	25.0
Sweden	25.0	0.0	25.0

Source: EFPIA/EU (2011).

The table shows that the VAT rates vary across the Nordic countries. The governments in Denmark and Norway impose the regular VAT of 25 percent on pharmaceuticals. However, Finland and Sweden subsidize pharmaceutical consumption by charging a lower VAT than the regular one. In Finland, there is a 9 percent VAT on both prescription and over-the-counter drugs. There is no VAT on prescription drugs in Sweden, but OTC drugs are charged the regular VAT of 25 percent.

To sum up, there is a considerable variation in the regulatory schemes in the Nordic countries, perhaps surprisingly large, despite the similarities between countries in this region.

3. Do economic incentives matter?

In this chapter, we will discuss how regulatory schemes and economic incentives matter in the choice of pharmaceuticals. We first look at generic substitution, and then therapeutic substitution, based on a recent study by Dalen, Locatelli, Sorisio and Strøm (2011).

3.1 Generic substitution

From March 2001, Norwegian pharmacies were allowed to substitute a branded drug for a generic version, independent of the product name prescribed by the doctor. Being permitted to intervene between the physician and the patient, the pharmacies got an active role in the market for

generics. The doctor can still guard against substitution, but this requires an explicit reservation to be added to the prescription note ("active substitution method").[12] If the doctor refuses to substitute on behalf of a patient who is covered by the social insurance scheme, the brand-name price mark-up (as compared to the cheapest generic version) is paid by the social insurance scheme. Even without such a reservation by the physician, the patient may insist on the branded drug, in which case the pharmacy is obligated to hand out the brand-name drug. In this case, the insurance scheme does not cover the price difference between the branded drug and the reference price. The difference has to be paid by the patient himself.

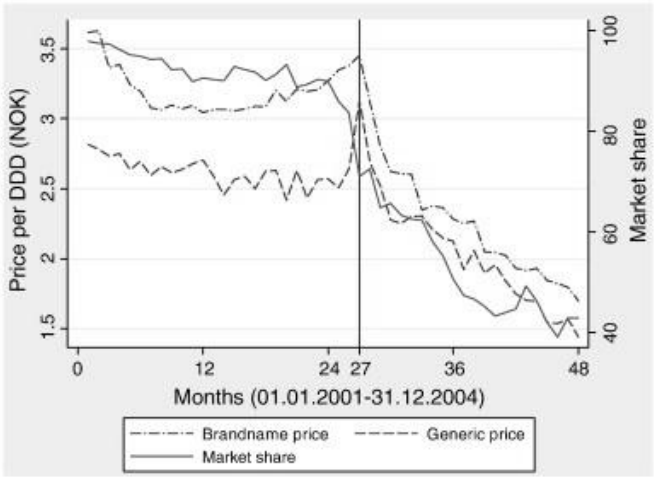
Price comparisons with other Nordic countries showed, however, that the generic substitution introduced in 2001 was not sufficient to trigger price competition and lower retail prices. The weak price response of generic substitution motivated a new regulatory scheme – "index pricing" – introduced in March 2003. The index price scheme was established for six different drugs: omeprazol (ulcer), enalapril and lisinopril (high blood pressure and heart failure), citalopram (depression), cetirizin and loratadin (allergy). Simvastatin (high cholesterol) was added in June 2004.

For these drugs, the regulator set a reimbursement price (the index price) to be paid to the expediting pharmacy, irrespective of what the chain paid for the chosen drug. This gives the pharmacies strong incentives to facilitate fierce price competition between producers of generic drugs. The index price on a drug (chemical substance) was updated every third month, and set equal to the sales-weighted average of all prices reported by the pharmacy chains, plus a fixed distribution (wholesale and retail) margin. If a retailer selected a producer with a price exceeding the average of the sales-weighted average of all prices, the net margin of the integrated retailer-wholesale pharmacy firm drops below the fixed distribution margin, whereas a retailer selecting a producer with a lower producer price experiences an increase in his net margin. This way of regularly updating the index price, based on observed producer prices from previous months, ensured that the index price tracked the development in producer prices over time.

[12] Another doctoral procedure would be the "two-line method". Here the doctor signs either on a line that reads "brand-name necessary" or on a line that reads "substitutions allowed". Both methods have been in use in the US, and prove to have an impact on the number of refusals. The two-line method generates more refusals than the active substitution method (Hellerstein, 1998).

The index price scheme was expected to stimulate generic substitution in pharmacies, thereby triggering price competition between producers. Brekke et al. (2009) investigated to what extent the index price scheme was successful in stimulating price competition compared to the price cap regulation. They found that index price regulation significantly reduced both brand-name (by 18-19 percent) and generic prices (by 7-8 percent). Figure 4 shows the average price of brand-name drugs and generics from January 2001 to December 2004. The vertical line indicates the introduction of the index price scheme. The price drop following the index price scheme goes together with a substantial drop in the market share of brand-name drugs.

Figure 4. Price per DDD for brand-name and generic, and brand-name market share in Norway



Source: Brekke et al. (2009).

In a follow up paper, Brekke et al. (2011a) showed that the index price regulation also triggered a significant shift in market shares towards generic drugs, which together with the price reductions resulted in substantial cost savings of about 30 percent.

In January 2005, the index price scheme was replaced with a new price regulation scheme that abandoned the direct use of economic incentives to bring down pharmaceutical prices after patent expiration. The new scheme – called the *step-wise* (no. "Trinnpris") model – consists of a predefined, stepwise reduction of the reimbursed price, starting from the

time of generic entry into the market. The pharmacies are instructed to have the drug available at the reimbursable retail price.

The scheme gives the pharmacy chains strong incentives to lower their purchasing prices. The model does not prescribe any future price reviews based on the development of these prices. All cost savings – in terms of reduced purchasing prices – are kept by the pharmacies themselves. This scheme illustrates the fundamental trade-off that often has to be made in the regulation of prices. Maximum incentives to minimize costs (here to put pressure on the producer prices of generic drugs) are obtained by offering fixed retail prices. However, in order to be credible, these prices must be set at sufficiently conservative levels. If the government is too eager in reducing the cost of drug reimbursement – by setting the post-generic prices at very low levels – the pharmacies will report economic problems which, in turn, will make it necessary for the government to increase the prices. When such a scheme could be enforced without protests from the pharmacy chains, there are good reasons to expect the predetermined prices to be pleasantly higher than the purchasing prices.[13]

Dalen, Furu, Locatelli and Strøm (2011) investigate how prices, different regulatory schemes, and characteristics of patients, doctors and pharmacies affect the substitution between brand-name and generics. The choices of patients/doctors and pharmacies are modeled as a bilateral comparison between the utilities of using brand-name and generics.

The analysis is not able to disentangle the doctors' prescriptions and the choices made by the pharmacies, given that the doctor has not blocked for a generic substitute. The choice probabilities in the model are thus the product of the prescription probability and the choice probability of the pharmacies. In the empirical model, unobserved heterogeneity in the choice probabilities is allowed for.

Data used in the estimation of the model was extracted from the Norwegian Prescription Database (NorPD) at the Norwegian Institute of Public Health. NorPD was established on January 2004. All drugs in Norway are classified according to the Anatomical Therapeutic Chemical (ATC) classification system. From this database, Dalen, Furu, Locatelli and Strøm (2011) extracted the entire population of prescriptions in February 2004 and 2006 for 23 different drugs (chemical substances) subjected to generic competition. This amounts to 313 078 observations (102 201 in

[13] The step-wise model was proposed by the pharmacy chains.

February 2004 and 210 877 in February 2006). Between 2004 and 2006, several drugs were opened for generic entry, and this explains the increase in the number of observations. The reason for adding February 2004 as well as February 2006 was to capture the two regulatory schemes: the "index price" and "the step-wise price" model.

With up to 23 chemical substances, they are able to cover a broad set of indications, such as blood pressure and heart failure, cholesterol, depression, ulcer, antibiotics, and allergy. Several of the drugs in the study are among the most selling drugs in Norway, which was also the motivation for selecting these drugs. The drugs include simvastatin (cholesterol), cetirizin (allergy), and enalapril (blood pressure).

Their empirical results imply that the larger the difference is between the price of the brand-name and generics, the less likely it is that the brand-name is purchased. Thus, generic substitution works.

Patients with prescriptions covered by the national insurance scheme (No. "Blåresept") are more likely to use the brand-name drug. Moreover, older patients are less likely to end up with a generic and older doctors are more likely to prescribe brand-names. They also find that time after generic entry matters: The probability of generic prescription increases with time after generic entry – generic substitution is less likely for young off-patent molecules.

Of particular interest is the result of the impact of the index price scheme on the choice of brand versus generics. As mentioned above, in 2004 this scheme should give the pharmacy an incentive to dispense cheaper versions. In Dalen, Furu, Locatelli and Strøm(2011), there are four chemical substances that were covered by this scheme in 2004. For these substances, the probability of choosing brand-names turns out to be lower than for other substances. The impact is strong, with a 26 percent lower probability of choosing brand-name versions instead of a generic drug.

This result is in line with the results derived by Brekke et al. (2009). As mentioned above, they find that the index-price scheme had a significant and strong impact on prices, both for generic and brand-name versions. Note that although the prices dropped and more so for the brand-name, the price of the brand-name was still higher than for the generics.

Another study of generic substitution in the Norwegian market is Brekke et al. (2012). This paper uses register data to compute the gross

margins that the pharmacy chains have on selling brand-names and generics. The study reveals that the pharmacy chains obtain higher margins on generics, and find a strong, positive relationship between relative margins and the products' market shares. They also show that this effect is stronger for the products under reference pricing. The results indicate that the pharmacies are more likely to promote a generic substitute to patients, the larger is the generic margin relative to the brand-name margin. Thus, financial incentives are important for pharmacies' incentives to engage in generic substitution.

Sweden introduced generic substitution in October 2002. Pharmacies were required to substitute the cheapest available generic for the brand-name prescribed by the doctor. As in Norway, patient copayment increased if the cheapest drug was not chosen. Granlund (2010) investigates the effect of the reform on prices and demand using panel data from 1997 to 2007. He finds that the introduction of generic substitution on average lowered the prices by 10 percent. The price drop was strongest for brand-name drugs that faced generic competition prior to the reform. For these drugs – the price-drop was 14 percent.

A Finnish study reveals similar price responses to generic substitutions, introduced in March 2003. Aalto-Setälä (2008) finds that the reform led to an average price drop of 10 percent.

3.2 Therapeutic substitution: The market for Tumor Necrosis Factor (TNF) alpha inhibitors[14]

Using a unique natural policy experiment in Norway, Dalen, Locatelli, Sorisio and Strøm (2011b) have investigated to what extent the price responsiveness of prescription choices is affected when the identity of the third-party payer changes and the choices are made between different drugs developed for the same diagnoses (therapeutic competition). The case in point is the Norwegian market for Tumor Necrosis Factor (TNF) alpha inhibitors.

When the market for TNF-inhibitors opened in Norway in 2000, the first entrant *Enbrel* was fully covered by the obligatory national insurance plan. Treatment with Enbrel is initiated by the hospital doctor, but the

[14] Dating TNF-alpha inhibitors representing the most important way of treating arthritis and other autoimmune diseases (Feldmann and Maini, 2003).

cost was automatically covered by the national insurance plan. The second entrant *Remicade* did not obtain the same type of coverage. Instead, the treatment cost had to be fully covered by the doctor's affiliated hospital. Importantly, the hospitals' budget did not include any earmarked grants for these patients. The cost of treatment with Remicade, therefore, competed with other expenses within the hospital. This sharp asymmetry in funding schemes reflects a quality attribute of the two drugs. Enbrel is administrated by the patients themselves (pump injections), while Remicade requires several hours' infusion at hospitals. In the fall of 2002, the government modified the plan for Remicade. The government required a copayment of 20 percent from the doctor's affiliated hospital. Enbrel maintained its full insurance plan coverage. The third entrant *Humira* is also administrated by pump injections by patients, and received the same funding plan as Enbrel when the drug entered in January 2003.

An important policy change took place in 2006. Then, the asymmetry of financing among Enbrel, Humira, and Remicade was entirely removed by returning the entire funding responsibility to the hospitals for all three drugs. Since then, all costs of treatment with TNF-alpha inhibitors have to be covered by the doctors' affiliated hospital.

When estimating how economic incentives affect the choices of medical doctors and patients, one has to take into account that it is not only economic incentives that matter for the choices. The quality of the pharmaceuticals as well as side effects may have an impact on the choices. It is then important to consider the obvious fact that these quality and side effects may be priced out in the market by the producers of the drugs.

To deal with this problem, Dalen, Locatelli, Sorisio and Strøm (2011) jointly estimated the market share and price-setting equations, assuming monopolistic competition. The estimated coefficients imply that doctors appear to be significantly more price-responsive when the costs are covered by the hospitals as compared to when the costs are covered by national insurance.

As expected, the numerical values of the own price elasticities increase when quality aspects are accounted for (demand and price setting model) compared to when they are not (the market share model). The mean value of the own-price elasticities is given in the table below.

Table 6. Mean own-price elasticities

	The market share model	Demand and price setting approach
Enbrel	-0.59	-2.19
Humira	-0.92	-3.39
Remicade	-0.29	-1.02

Source: Dalen, Locatelli, Sorisio and Strøm (2011).

Thus, when quality and side effects are accounted for in the model, the numerical values of the own-price elasticities become much higher. In this case, therapeutic substitution between patented drugs therefore seems to be highly price-responsive.

4. Should pharmaceutical costs be curbed?

We end this paper with a discussion of the problem raised by the title of our article – should pharmaceutical costs be curbed? Especially if we look at the Norwegian case, we see that pharmaceutical expenditure stopped increasing around 2005. Since then, we have even seen a slight drop in expenditure. This is not caused by a drop in the volume of pharmaceuticals taken by Norwegian patients. The number of defined daily doses has been increasing after 2005.

The main explanation for this combination of reduced expenditure levels and increased consumption of medicines is the increasing number of drugs that went off patent. For many years, The Association of the Pharmaceutical Industry in Norway (LMI) reported the market share of innovative drugs in Norway in their annual report "Facts and figures".[15] During the 1990's, innovative drugs represented an increasing part of the total sales volume. Since then, however, the innovation rate has declined with few new drugs and an increasing number of drugs that went off patent. In 2000, the market share of innovative drugs was reported to be close to 38 percent. In 2005, the market share was as low as 10 percent.
The flattening expenditure curve in Norway is therefore explained by a more mature pharmaceutical market in combination with a regulatory

[15] Innovative drugs are here defined as drugs that have entered the market during the last five years.

policy that has enabled a strong price competition on off-patent drugs (generics). Lowering the pharmaceutical costs by implementing fierce generic competition is welfare-improving and comes without any severe negative side-effects.

However, it is of more interest to return to the political debate in the early 1990's. During these years, pharmaceuticals costs were steadily increasing and caused increasing costs for the social insurance scheme. The government repeatedly expressed concerns for the expenditure growth, which was higher than the overall growth rate in health care cost.

Since the growth rate was to a large extent caused by the introduction of new drugs, it is less clear if this is something to curb. New drugs improve treatment which is to the benefit of patients, and these benefits should be compared with the costs of funding pharmaceuticals.

In a series of papers, Frank Lichtenberg has empirically investigated the health effects of new drugs. Lichtenberg (2012a) shows that about one-third of the increase in German life-expectancy during 2001-2007 can be explained by the replacement of older drugs with newer drugs. Lichtenberg (2012b) investigates the effect of new drugs on functional limitations of elderly Americans in nursing. Functional limitations are significantly lowered by the use of newer drugs at nursing homes.

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Comment on Brekke, Dalen and Strøm: Should pharmaceutical costs be curbed?

Helgi Tómasson*

The paper by Brekke, Dalen and Strøm starts by reporting some facts on pharmaceutical sales in Denmark, Finland, Norway and Sweden in the year 2011. It is stated that the pharmaceutical cost per capita ranges from 310 to 400 euros. The authors mention growth of sales, and correctly state that not much can be inferred on data for only two years. The sales are decomposed into price and volume and it is stated that Norway tends to have the cheapest drugs. They correctly cite that exchanging, say, Swedish prices and Norwegian prices would affect price indices as the consumption weights differ between the two countries. The authors also discuss the impact of packaging. The drugs are packed differently among the countries which adds to the heterogeneity. The volume of the consumption is highest in Sweden but lowest in Denmark. The low consumption and high sales in Denmark are due to the high price of drugs in Denmark. All these facts support the claim that an international comparison is difficult.

The authors characterize the nature of the pharmaceutical market as a low price elasticity on the demand side and strong market power on the supply side. These oligopolistic characteristics result in widespread regularization systems around the world. The authors summarize some important regulatory instruments. The arsenal of instruments is large both on the demand- and the supply side, as well as for price-based and non-price-

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based instruments. The Nordic countries seem to use most of these instruments. The authors review some differences in how the Nordic countries implement the instruments, e.g., how they treat on-patent drugs, what kind of mark-up is allowed, taxes, etc.

Next, the authors turn to the questions, "Do economic incentives matter?" and "What is a good policy?". The econometric toolbox seems quite similar to what is described in Train (2009) and what the authors have used in other publications. Dalen et al. (2011) is cited and a model from this reference is described. To fully understand the econometrics in this paper, it is necessary to look up the formulas and concepts in these references. A large data set containing all Norwegian prescriptions from February 2004 to February 2006 is described. A scenario of the behaviour of doctors and patients is drafted. Even here, the paper would benefit from a formal statement of the model. Perhaps a graph showing the timing of the events could be helpful.

The authors report an interesting experiment, the *index pricing*, introduced in 2003. The idea of the index pricing strategy is to fix the reimbursement for some popular categories of drugs irrespective of what the pharmacy paid for each brand of drug.

In 2005 a new experiment, the *stepping price model*, replaced the index pricing model. The authors conclude that the regulatory instruments seem to have an impact, in particular they favour the index pricing model. The question of the impact on health seems to be left open. That question might be a much more challenging one.

The authors have used a large data set. The quality of the information of such a data set, and any data set, depends on the exact definition of the scientific model and the corresponding statistical model.

The paper is essentially a literature overview of, first, the regulatory environment of pricing of pharmaceutical products in the Nordic countries and, second, a discussion of a few econometric results that the authors have derived in earlier research (Brekke et al., 2009; Brekke et al., 2011) on responses and preferences in the pharmaceutical market. The conclusion seems to be that the pharmaceutical costs can be curbed, but it is less clear whether they should be.

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