The background of the entire page is a close-up, slightly blurred photograph of numerous white, oval-shaped pills. The pills are scattered across the frame, with some in sharp focus and others blurred in the foreground and background. The overall color palette is a soft, muted blue-grey, which serves as a backdrop for the white text and pills.

# *The Swedish Pharmaceutical Reimbursement System*

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# The Swedish Pharmaceutical Reimbursement System - A brief overview

Sweden made some major changes to its reimbursement system in 2002. Earlier almost all prescription drugs were automatically approved for reimbursement. Today applications are thoroughly scrutinized and cost-effectiveness is a crucial decision-making criteria.

In October, 2002, a new Pharmaceutical Reimbursement system took effect in Sweden and the Pharmaceutical Benefits Board (LFN) was consequently appointed by the Government to decide whether or not a medicine should be reimbursed.

## Three reasons for the change

One reason for the change was, as in most of the rest of Europe, that the cost of reimbursed drugs had increased rapidly during the 1990s.

Secondly, Sweden had a very generous reimbursement-system. For instance, all prescription drugs which received a fixed sales price were automatically approved for reimbursement.

Thirdly, we did not know if we got value for money. There were unclarities concerning if the increase in costs was balanced by, for example, added therapeutic value.

The overall aim of changing the system was that a new law and a new agency would lead to a more rational and cost-effective public use of medicines.

**Table 1. The situation before the new law (then), and after (now)**

Then	Now
Almost all medicines accepted	All medicines subject to 3 main criteria and carefully scrutinized
Civil servants decided on reimbursement	LFN expert Board decides based on recommendations from civil servants
Costs sky-rocketing on an annual basis	Cost development stabilized on a low level
Negotiation major part of work	Cost-effectiveness central criterion and no negotiations.
Many blockbuster drugs on market	Many patents expired, generics take their place
Pharmacies dispensed brand name drugs	Generic substitution mandatory; if an identical generic exists, it must be dispensed

## How are medicines financed in Sweden?

Medicines have three financial sources in Sweden. These are the county councils, the state and patients.

### In-patient

The county councils pay all costs for medicines for in-patient care. They are responsible for providing healthcare to the population in Sweden. And they have the right to levy taxes to finance their duties.

### Out-patient

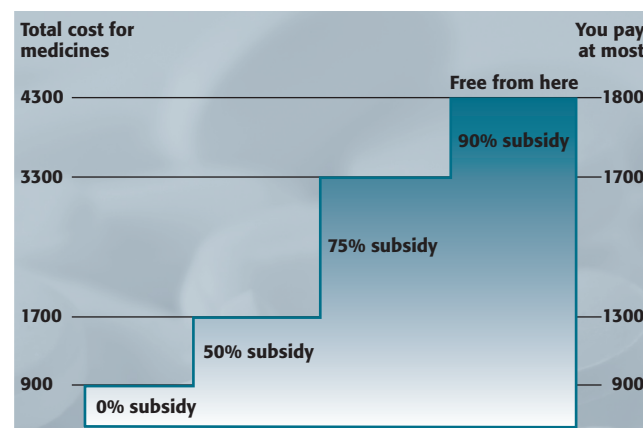
For prescription drugs for out-patient care, the county councils receive a specific government grant. In the year 2005 the state paid 19.8 billion Swedish crowns – approximately 2.2 billion Euros. This more than covered the costs.

### By patients

Some of the cost for medicines for out-patient care is paid privately by the patients. The most an individual patient pays in this co-payment during a year is about 200 Euro. On average the patients pay 21 percent of the costs for out-patient medicines.

Costs for all children under 18 years of age within a family may be added together. The use of insulin is fully reimbursed.

**Table 2. No co-payment allowed below 900 kronor, about 100 euro.**



## **Criteria decide reimbursement**

The LFN's task is to decide whether a prescription drug for out-patient care should be reimbursed or not.

There are three criteria which must be fulfilled if a medicine should be reimbursed:

The *human value principle*; which underlines the respect for equality of all human beings and the integrity of every individual. We may not discriminate against people because of sex, race, age and so on when making decisions on reimbursement.

The *need and solidarity principle*; which says that those in greatest need take precedence when it comes to reimbursing pharmaceuticals. In other words, people with more severe diseases are prioritised over people with less severe conditions.

The *cost-effectiveness principle*; which states that the cost for using a medicine should be reasonable from a medical, humanitarian and social-economic perspective.

These three criteria should all be considered and weighed together by the Board when making its decisions.

## **Cost effectiveness is a crucial aspect**

Cost-effectiveness is one central principle in the Swedish reimbursement system and is analyzed from a societal perspective. This means that all relevant costs and revenues for treatment and ill health should be considered, regardless of who pays – be they state, county council, local authority or patient.

### **How do we do it?**

When we evaluate the cost-effectiveness of a drug we first pool all of the costs associated with using the drug; such as costs for the drug, costs related to visits to the doctor, costs for possible further healthcare measures, and costs due to the side-effects of the drug.

Then we balance total costs against the benefits from using the drug. The benefits come in two forms: effects on health and cost savings. And the beneficial effects on health show up either as a longer life expectancy or a higher health-related quality of life.

## **Societal perspective**

We also need to do more to get a full societal perspective. So we take into account if the drug means that the patient can work and support himself or herself instead of being sick-listed and perhaps forced into early retirement. Here the benefits go to the individual, the employer and to the state which avoids the costs for sick-listing and early retirement. If the patient is older perhaps the treatment means that he or she can manage better without as much help from the municipality's elderly care services or relatives.

This kind of analysis is done to show whether or not the use of a drug costs citizens a reasonable amount of money in relation to the health gains it offers the patients. The actual size of the health bill is not a good measure of

whether we are using the right amount of drugs or even the right kind of drugs. The crucial aspect here is instead that the drug is cost-effective, and not just for the healthcare sector, but for society as a whole.

And that is why Sweden has chosen to consider cost-effectiveness rather than cost-containment as an instrument to get as much value for our tax-money as possible when reimbursing pharmaceuticals.

Sometimes the good effects of a medicine are so great that they easily compensate for all costs. Then the treatment is considered as cost saving.

But we do not make such high demands in order to consider if the use of a medicine is cost-effective. That people get well, do not experience pain and can live a more normal life through using a medicine is important enough for society to be willing to pay for it.

## **No price negotiations**

Another important aspect of the Swedish reimbursement system is that we do not negotiate prices. We look upon the price as an integrated part of the cost-effectiveness analysis. If the price is too high there will be no cost-effectiveness. Then the Board will reject the application in question. And the company will have to decide if they should apply again and suggest a lower price.

## **Why is it that we do not negotiate prices?**

Why are we not eager to force the price down as much as possible? There are mainly three reasons:

### ***Not possible to efficiently set prices***

We don't believe that it really is possible for a government agency to efficiently set prices as the pharmaceutical companies will soon learn to adjust their prices accordingly. For example, if the reimbursement agency always tries to get a 30 percent lower price, the companies will learn to start the negotiation with a price 30 percent higher than they actually want.

### ***Let the market work as freely as possible***

Secondly, the pharmaceutical market is very regulated. But we do not want to regulate it more than necessary. We want to allow the market to work as freely as possible by letting the companies set the price and then decide whether or not we as taxpayers and patients are willing to buy that particular drug.

### ***Stimulate innovations***

And thirdly, a reimbursement system which uses cost-effectiveness from a societal perspective can play an important role when it comes to stimulating innovations.

If the pharmaceutical industry can rely on us being ready to pay a high price for drugs which are beneficial to society, then they will probably deliver more new drugs for urgent treatments.

## A product-oriented system

The Swedish reimbursement system is mainly product-oriented. This means that medicines are either granted reimbursement status for the whole of its approved area of use or not at all.

However, in exceptional cases the LFN can restrict the reimbursement of a medicine to a limited area of use or to a special patient group.

### Two examples of restricted reimbursement:

\* Levemir, a medicine against diabetes was reimbursed but only for patients with type 1 diabetes, not type 2.

\* The medicine Crestor against high cholesterol was approved for reimbursement but only for patients who did not achieve the desired result with the use of generic simvastatin, as Crestor is not cost-effective compared with generic simvastatin on a general basis. Crestor is, in other words, only reimbursed if it is used as a second-line drug.

Moreover, the Board can make a decision dependent on certain conditions. So far, the Board has used four different types of conditions. Here are two examples:

1. The reimbursement can be limited in time to make it possible for the company to provide the LFN with more data, for example on long-term effects on morbidity and mortality or with a follow up report on the product to see if it is used according to the restrictions for reimbursement.
2. The company has to specify the restrictions set by the Board in their marketing of the product.

## Expert Board makes decisions

The decisions on pricing and reimbursement are made by an expert Board within the agency. There are ten Board members and a chairperson, all appointed by the government to serve for a period of two years. They all have personal substitutes. Collectively the members of the Board have a broad theoretical and practical competence in the area of medicine and health economics. Additionally, two members have their background in user groups – organisations for patients and for senior citizens. And the chairperson is a legal advisor.

When necessary, the Board can temporarily co-opt one or more experts with particular expertise. Co-opted experts do not take part in the decisions.

## Companies can appeal

In accordance with the so-called Transparency directive the Board is to announce its decision on reimbursement and pricing within 180 days after receiving a fully completed application.

The Swedish government has set a tighter target when it comes to the time-limit for decisions on reimbursement and pricing in Sweden. We have to announce our decisions within 120 days.

A company has the possibility to appeal the Board's decision to a public administrative court.

## Generic substitution mandatory

One of the major changes four years ago was that generic substitution became mandatory between medically equivalent drugs. Now the pharmacy dispenses the least expensive generic drug or parallel-imported drug available regardless of what the doctor has written on the prescription. However doctors can, for medical reasons, oppose the substitution. But this happens very rarely. Patients are allowed to refuse a generic product, but only if they are willing to pay the difference between it and the more expensive branded pharmaceutical.

### Patient rejects generic drug:

If a patient for some reason rejects the fact that the pharmacy dispenses the cheapest generic simvastatin, which is against high cholesterol, instead of the branded drug Zocor, he or she has to pay the difference. If the price for simvastatin is 40 SEK and the price of Zocor is 220 SEK the patient has to pay 180 SEK.

The companies have to apply to the LFN if they want to increase or decrease a price on a drug which is subjected to generic competition. To boost competition between the pharmaceutical companies the LFN has introduced a simplified process for price-decisions concerning substitutable drugs.

If the new price, which the company in question is applying for, is lower or similar to the highest price within a group of substitutable medicines, we allow both price cuts and price rises without further investigation.

The LFN has made over 25 000 such decisions so far.

We make decisions on price changes once a month and of course a company does not know which price its competitors have applied for. The company which can offer the lowest price will get the majority of the sales which creates robust price competition.

## Savings of 700 billion Euro

Generic substitution has been very successful in Sweden. Off-patent drugs have fallen more than 40 percent on average in price from the reform in 2002 until the end of 2005. Or in other words, we pay a price that is 40 percent less today for the same health-effect as in 2002. As a whole, pharmaceutical prices in Sweden have dropped by about 15 per cent as a consequence of the reform. The accumulated savings have been some 700 million Euro.

Furthermore the introduction of generic substitution coin-



cided with the fact that several blockbuster drugs went off patent. If that had not been the case then the effect of the reform would not have been as pronounced.

And here are some examples of sharp drops in prices for drugs losing their patent:

**Table 3. Sharp drop in prices for drugs losing their patent. (Average price Skr per DDD)**

Substance	Brand name	Therapeutic area	Price reduction in percent
Simvastatin	Zocor	High cholesterol	-92
Citalopram	Cipramil	Depression	-83
Omeprazole	Losec/Prilosec	Ulcer	-65
Sertraline	Zoloft	Depression	-62
Felodipine	Plendil	High blood pressure	-61

#### **The review of 2 000 medicines in the “old system”**

Besides taking decisions on pricing and reimbursement for new drugs we are also carrying out a review of the entire list of pharmaceuticals eligible for reimbursement. The reason for this is that it was not practically possible to review all medicines overnight, when the new reimbursement system took effect four years ago. Therefore the medicines which had been reimbursed in the old system were allowed to maintain their reimbursement status until further notice.

Consequently, the LFN is now carrying out a review to ascertain whether these some 2 000 medicines satisfy the new conditions or not. And we use the same decision-making criteria for new and old medicines.

The medicines are reviewed one therapeutic area after the other. In total there are 49 such therapeutic groups. We will go through them in the order biggest first, based on the size of the sales value for each group.

We published the results from the first review, medicines against migraine, in February 2005 and from the second one, medicines against diseases caused by stomach acid, in January 2006.

**Table 4. Reimbursement Review**

<b>The six ongoing reviews (Jan 07)</b>
- High blood pressure
- Asthma and coughing
- Depression
- High cholesterol
- Pain
- Diabetes

#### **Big savings from reviews**

In the review of drugs for treatment of migraine, we carried out a deeper analysis of the most modern of these medicines, known as triptans, because they account for a whole 93 percent of the market. The result of the review was that we saved some 3.5 million Euro.

In the review of drugs against stomach acid the Board decided to withdraw the reimbursement for a couple of PPI's. One drug that will not retain its reimbursement status is Losec Mups (omeprazole). The reason is that Losec Mups has the same clinical effect as generic omeprazole, but at a price which is much higher. In other words, it is not cost-effective.

The Board also decided on discontinued reimbursement for a group of drugs named H2 antagonists. They concluded that H2 antagonists could be a cost-effective choice for some milder symptoms like heartburn, but these diseases give so small losses in quality of life that the treatment should not be reimbursed by society. Instead, patients should bear the full cost. In this case the Board let the need and solidarity principle take precedence over the cost-effectiveness principle. Those decisions saved some 20 million Euro.

*For more information please contact us using the details provided below.*



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