

## Statements and comments on cost containment in the pharmaceutical sector

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In Finland outpatient pharmaceuticals are reimbursed by the statutory National Health Insurance (NHI) scheme run by the Social Insurance Institution. NHI covers all Finnish residents. In addition to outpatient pharmaceuticals it reimburses medical costs in the private sector, travel costs to health care units, sickness allowance, maternity leave allowance, occupational health care and some rehabilitation services. It does not cover public health services, but these are organized by the 400 or so municipalities, which are also responsible for paying for pharmaceuticals used in health care units.

Finland has several methods for containing the costs of outpatient pharmaceuticals. Finland does not control the price of drugs directly, although the reimbursability of a medicinal product and its reasonable wholesale price both need to be approved by the Pharmaceuticals Pricing Board (The PPB). The PPB is subordinate to the Ministry of Social Affairs and Health. The price control applies only to reimbursable pharmaceuticals. All reimbursed pharmaceuticals have a maximum wholesale price. -The PPB decides also on which reimbursement categories each pharmaceutical product belongs to. Other major tools in cost containment are cost-sharing and compulsory generic substitution, which has been in place since April 2003.

In 2006 maximum wholesale prices were reduced by law by 5 %. In practice this lowered the prices only of drugs which are sold at the maximum price approved by the Pharmaceutical Pricing Board. Generic products are usually already sold at much lower prices than the maximum and the reform therefore did not affect those prices.

Physicians do not have any financial incentives - such as budget holding - in the area of outpatient care and NHI as a payer has few opportunities to directly influence physicians. However, there are some other measures to influence prescription patterns. The Centre for Pharmacotherapy Development (Rohto) guides pharmacotherapy in Finland by disseminating independent drug information to physicians. The SII annually sends a letter to physicians reporting on the expenditure on drugs that the particular physician prescribed in the last year, and for comparison the average expenditure of all physicians of the same speciality. Prescribing is also informed by Current Care-guidelines, which are guidelines produced by the Finnish Medical Society Duodecim. However, with very few exceptions these guidelines do not include financial information. Prescription patterns are also regulated to an extent by limiting reimbursement. For example in 2006 the PPB decided that the most expensive statins would only be reimbursed after less expensive statins have first been tried and found to be inadequate.

# 1. Fair access for patients to drugs

## 1.1 Description of current situation

NHI guarantees that all Finnish residents have an equal chance to have outpatient drug expenses reimbursed. There are three levels of reimbursement for the patient: 42%, 72% and 100% of actual costs. The aim has been to grade the categories according to medical criteria based on the severity of the illness and the necessity of the drug treatment. The Higher Special Refund Category (100 %) covers 34 chronic illnesses and the Lower Special refund Category (72 %) consists of ten chronic illnesses. The illnesses included in the Special Refund Categories are set out in a Decree of the Council of State, and the decisions relating to choosing the medicinal products eligible for reimbursement in the 72 % and 100 % categories are made by the PPB. Thus the level of reimbursement depends on the type of or severity of the disease and the pharmaceutical product. There is also a maximum limit for out-of-pocket payments for reimbursed pharmaceuticals per calendar year (about 640 eur). Only a small proportion of prescription pharmaceuticals are not covered at all. On average NHI covers about 70% of the outpatient prescription drug expenses.

## 1.2 Questions raised and debated in Finland

- Reimbursement categories are graded according to medical criteria based on the severity of an illness and the necessity of drug treatment. Severe and chronic illnesses that entitle patients to reimbursement under the special refund categories are detailed in a Government Decree. To change the status of an illness listed in a decree is politically difficult because of strong opposition from patients and public opinion. The higher the reimbursement status, the more difficult it is to effect a change downwards.
- Is the annual limit for out-of-pocket payments at the right level? Should the annual payments be calculated per an individual or per household?
- Two channel funding (municipalities inpatient pharmaceuticals/NHI outpatient pharmaceuticals) creates some cost-shifting problems
- Are there too many reimbursement categories?

## 1.3 Key issues proposed for debate

- Polypharmacy is common among the elderly; patients with chronic diseases often have poor compliance; alternative therapies to medication are rarely used
- How could the limited resources be allocated in the most appropriate way in the reimbursement system? How can a balance be reached between cost containment, limiting the patient's share of costs and rewarding the innovative medicines?

## 2. Price negotiations and tendering procedures

### 2.1 Description of current situation

Officially there is no explicit method for price negotiations in the outpatient pharmaceutical reimbursement system. The Marketing Authorisation Holder should submit an application for basic reimbursement status and seek confirmation of a reasonable wholesale price. The application must include, in addition to the proposed wholesale prices, a well-grounded evaluation of the benefits and costs incurred should the product be included in the reimbursement system at the proposed price. Before a drug can move to one of the special refund categories, the company must submit evidence on therapeutic value and cost effectiveness. The expert group assigns drugs submitted for reimbursement to one of two special refund categories. Criteria used for the higher level of reimbursement include severity of the disease, the necessity and cost-effectiveness of the medicinal product, the proven therapeutic value of the medicinal product, and the funds available for special reimbursement products; and whether supportive evidence exists.

When a new pharmaceutical substance is submitted for reimbursement, the application must contain a pharmaco-economic evaluation. In the decision on price, the costs of the drug are compared to its benefits, and to the costs and benefits of alternatives and the prices of comparable medicinal products in Finland. In addition, the proposed price is compared to that in other EEA countries.

The PPB either accepts or rejects the application. Before the final decision the PPB usually submits a draft decision to the applicant. The applicant may give a response to it and (for instance) adjust the proposed wholesale price.

A decision issued by the PPB covering reimbursability and the reasonable wholesale price is valid for a fixed term only. The decision concerning a new active substance is valid for up to three years and other decisions for up to five years. To ensure the continuation of the reimbursability of a medicinal product the marketing authorization holder must submit a renewal application - including a wholesale price proposal - to the PPB. The PPB will re-evaluate the reasonableness of the maximum wholesale price (among other things) on the basis of new data.

There is no tendering process in Finland in respect of outpatient pharmaceuticals. However, a tendering process is frequently used when hospitals and other health care units purchase pharmaceuticals.

### 2.2 Questions raised and debated in Finland

- When a new medicine is launched there are usually many open questions regarding its therapeutic value. Seldom is there enough data about its long-term effects, relative efficacy and effectiveness or cost effectiveness. The unanswered question often is what are the benefits and risks for the patients, society and the industry.

### 2.3 Key issues proposed for debate

- The price decision depends on the therapeutic value of a medicine. What are the possibilities of EU level co-ordination in assessing the therapeutic value of a medicine and evaluating the evidence supporting it?

- What possibilities does an individual member state have to negotiate for a price when the aim of the companies is a common price at EU-level to avoid parallel trade?
- When submitting its application and negotiating the price the marketing authorization holder should be aware of the reimbursement system in the individual member state. How can this knowledge be improved among applicants?

### 3. Risk-sharing agreements

#### 3.1 Description of current situation

In Finland decisions concerning the reimbursement status and maximum wholesale price of a medicine are always made for a fixed term only. This gives the PPB a tool to re-evaluate the reimbursement status and the price periodically. The PPB can also restrict the eligibility of reimbursement to clearly defined indications. These tools can be considered as risk-sharing.

#### 3.2 Questions raised and debated in Finland

- PPB could have better resources to more efficiently reconsider reimbursement when situation changes.
- Pharmaceutical industry has proposed having risk-sharing for clinical outcomes in the reimbursement system (at macro-level). In this system reimbursement could be granted quickly and re-assessed when more knowledge has been accumulated on benefits, side-effects etc.
- It has proven difficult to remove the reimbursement status of a medicine once approved. What tools might there be to address this?

#### 3.3 Key issues proposed for debate

- What kinds of risk sharing methods on clinical outcomes exist in EU countries?
- How can uncertainty as to the cost effectiveness of new medicines be shared with the companies? What are the right tools and mechanisms for risk sharing?
- Would it be possible to implement this kind of system at patient level?

## 4. Agreements on budgets for the treatment of illnesses

#### 4.1 Description of current situation

The government has set a “growth target” for the period 2008–2011, announcing that annual growth in the budget for drug reimbursement should not exceed five percent. There is also a fixed budget for new products in the special reimbursement category (8.4 Million €/year).

There is also a type of a price-volume agreement system in the Finnish reimbursement system. If the product sales or the reimbursement expenses significantly exceed the estimate accepted as the basis for the price confirmation decision, the PPB can reconsider the maximum reasonable wholesale price. There is no payback system in Finland.

#### 4.2 Questions raised and debated in Finland

- This has not really been discussed in Finland

#### 4.3 Key issues proposed for debate

- Are these systems used in EU countries?