The Pharmaceutical Benefits Board

- areas of responsibility and tasks

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Contents

Introduction

Why a new agency?

Subsidy conditions

Cost for pharmaceutical benefits
- Financing
- Pharmaceutical benefits – high-cost threshold

Pharmaceutical Benefits Board
- Organisation
- The Committee structure
- The Board’s tasks
- Processing times

Decision-making criteria for subsidised pharmaceuticals
- Product-based benefit scheme
- Criteria

Under investigation
**Introduction**

In April 2002, the Swedish Parliament decided to introduce a new law concerning pharmaceutical benefits, etc. (bill 2001/02:63, the New Pharmaceutical Benefits Reform). The new law will take effect as of 1 October 2002. A new independent government agency, the Pharmaceutical Benefits Board (Läkemedelsförmånsnämnden, LFN), will start operations at the same time. In addition to its main assignments, the new agency will replace the National Social Insurance Board in the task of pricing medicines and other medical items covered by the high-cost threshold for pharmaceutical purchases.

The new law concerning pharmaceutical benefits means that a new order will be introduced to the public system of subsidising medicines and other items covered by the pharmaceutical benefits scheme.

Pharmaceutical benefits will continue to be government regulated and thus are identical throughout the country. However, all prescription drugs will no longer receive a fixed sales price, and thus automatically be approved for subsidy.

After 1 October 2002, medicines and other medicinal products will only be included on the pharmaceutical benefit scheme if they fulfil the criteria set forth in the new law concerning pharmaceutical benefits.

The PBB will be responsible for determining if a drug or other items covered by the pharmaceutical benefits scheme is to be subsidised. This means that the PBB will replace the National Social Insurance Board in the task of pricing medicines. The PBB will also be in charge of reviewing all current medicinal products and determining whether the product will continue to be listed on the pharmaceutical benefits scheme.
Why a new government agency?

The fact that pharmaceuticals are in principle automatically subsidised can in time, from a social economic perspective, result in less space for other crucial measures in the areas of health and medical care. This is the reason for establishing the Pharmaceutical Benefits Board – its task is to systematically and continuously evaluate which pharmaceuticals should be subsidised from a social and medical/health-economic perspective.

The objective is that the PBB, through its operations, is to contribute to a rational and cost-effective public use of medicinal products. In a broader perspective, the Board will subsequently contribute to achieving the national goals for health and medical care and greater effectiveness of the priority-setting guidelines for health and medical care as set forth by Parliament.

Subsidy conditions

Medicines play an integral role in health and medical care and they are used as a valuable replacement for, or supplement to other medical care. It is imperative that resources consumed by medicinal products are part of the collective resources for health and medical care to ensure the best and most cost-effective care for the patient.

The Medicinal Products Act (SFS 1992:859) includes fundamental national regulations regarding control and surveillance of medicinal products. In addition, the EU has community legal procedures to supervise that medicinal products fulfil certain demands as regard to quality, safety and efficacy before being allowed on the market.

A medicinal product must be approved for sale before being offered for sale in Sweden. The Medical Products Agency may however make an exception (through a license) on behalf of an individual patient.
A fundamental condition for approving a cost-reduction of a medicinal product is that the PBB has recommended that the medicine in question be included on the pharmaceutical benefits scheme.

Furthermore, before a specific prescribed medication is made available on the pharmaceutical benefits scheme, thus entitling an individual user to reduced medicine costs four demands must be met. The medicinal product must be:

- a prescription drug, in principle
- prescribed by a person authorised to write a prescription
- intended for human beings with the intention of preventing, identifying, alleviating or curing an illness or the symptoms of an illness.
- prescribed on a prescription form labelled with a workplace code.

Under certain conditions, non-prescription drugs can also qualify under the scheme. A non-prescription drug can be covered by the benefit scheme if the product is needed for the treatment of a long-term illness demanding continuous treatment for a period of at least one year or recurrent treatment for a period of at least three months per treatment period. Exceptions are however:

- medicinal products to stop smoking
- medicinal products against hair loss
- certain medicinal products intended for external use (according to the recommendations of the Medical Products Agency)
- herbal products and homeopathic products

Persons under the age of 16 may also be entitled to subsidised foodstuffs. Oral contraceptives and certain consumables are also covered by the pharmaceutical benefits scheme. Other consumables are free of cost for the patient.
Costs for pharmaceutical benefits

Financing

Medicinal products are financed by three sources:
- publicly, by the county council through state subsidy (pharmaceutical benefits scheme)
- publicly, solely by the county (in-patient care) and
- privately through the patient co-payment

Formally speaking, the responsibility for the costs of the pharmaceutical benefits scheme was transferred to the county council as of 1 January 1998. At the same time, a special government grant was introduced specifically to the county councils for the costs of the pharmaceutical benefits. In 2000, the cost for pharmaceutical benefits was almost SEK 15.6 billion.

Pharmaceutical benefits – a high-cost threshold

All persons living in Sweden are entitled to a safety net that limits the cost of medicinal products for the individual. The high-cost threshold extends also to people from other Nordic countries and persons eligible for healthcare benefits in Sweden according to the EU Council’s ordinance (EEG) 1408/71.

This threshold means that the cost for medicinal products is gradually reduced for the individual patient over a 12-month period. The patient carries the full cost if the total cost for medicinal products does not exceed SEK 900 during a 12-month period.
Thereafter, subsidies reduce costs by:

- 50% if costs exceed SEK 900 though no more than SEK 1,700
- 75% if costs exceed SEK 1,700 though no more than SEK 3,300
- 90% if costs exceed SEK 3,300 though no more than SEK 4,300
- 100% if costs exceed SEK 4,300

Thus, the most an individual patient pays during a 12-month period is SEK 1,800.

The highest amount for families with children is a total of SEK 1,800.

The county council fully finances all medicinal products used by in-patient health facilities operated by the county council. In-patient health care is care that requires that a patient be admitted to a hospital.
The Pharmaceutical Benefits Board (PBB)

Organisation

The Pharmaceutical Benefits Board will commence operations on 1 October 2002 and be headed by a Director-General. The agency has a committee that makes recommendations on pricing and subsidy of medicines and other medical products covered by the pharmaceutical benefits scheme.

The Board will:

- monitor developments in the field of medicinal products
- follow-up and assess its recommendations
- monitor developments in other countries and benefit from the experiences of other countries
- inform concerned parties of its operations and the effects of recommendations regarding pricing and subsidies.

The Committee will:

- rule on general pricing guidelines
- rule on subsidy and price regulations for new medicines and products, with the exception of new strengths
- on its own initiative, decide whether a medicine or specific product should be included on the pharmaceutical benefits scheme.
- on its own initiative or after receiving an application, decide on a change in the conditions pertaining to whether a medicine or specific product should be included on the pharmaceutical benefits scheme
- in line with authorisation, rule on regulations to the law (2002:160) concerning pharmaceutical benefits and other such ordinances
- decide on general advice to sponsors or manufacturers of products that might be covered by the benefit scheme
- decide on other issues assigned to the Committee by the Director-General.

The Director-General decides which issues the Committee will not determine.
The Committee structure

The Committee consists of a chairman and ten committee members. The Government appoints the chairman and committee members (as well as personal replacements) to serve for a fixed period of time.

Of the ten committee members, four will be appointed from county councils, four from government agencies and other actors with expertise in the field of medicinal products, and two from users groups.

The Committee forms a quorum when the chairman and at least half of the other committee members are present. The Director-General will always participate in the Committee’s meetings, though not in its recommendations. If possible, all committee members shall be present when major issues are addressed. When necessary, the Committee can temporarily co-opt one or more experts with particular expertise. Co-opted experts do not partake in the recommendations.
The Board’s tasks

*The Pharmaceutical Benefits Board’s primary task is to recommend if a medicine or specific product is to be included on the pharmaceutical benefits scheme and set the price.*

The PBB shall, after receiving an application from the sponsor or manufacturer of a medicinal product, decide whether a medicinal product is to be included on the pharmaceutical benefits scheme. The applicant is to stipulate and motivate the preferred price. The Committee’s decision shall be based on the criteria stipulated in the regulations for pharmaceutical benefits.

Acting on the initiative of a sponsor or manufacturer of a specific medicinal product, the Board can rule on a price increase and price decrease respectively, as well as if a medicinal product available on the scheme should no longer be subsidised.

Furthermore, acting on its own initiative, the Board can eliminate a medicinal product from the benefits scheme, decide on a price increase and a price decrease respectively and revoke a subsidy.

Before the PBB announces its recommendation in a specific matter, both the sponsor and manufacturer of the medicinal product and the county council will be provided the opportunity to deliberate the matter with the Committee.

The sponsor or manufacturer of a medicinal product and the county council are entitled to request that the Board reassess a previous pricing recommendation. The applicant of the requested change is entitled to deliberate the issue with the Committee.

The PBB will review subsidy and sales price in a particular context and take a decision which may be appealed. An appeal against the Board’s recommendation can be made in a public administrative court.
If the Board rules that a medicinal product is no longer to be subsidised, the previously set sales price is no longer valid. A subsidy review encompasses also new pharmaceutical benefits, areas of use and packaging sizes for already approved medicinal products and certain consumables.

The PBB can also rule that extemporary medicinal products and license pharmaceuticals will be included on the benefits scheme though a sales price has not been set for these products.

The former reference-price system will be phased out and the Board will not adopt this system from the National Social Insurance Board.

The PBB will publish a schedule listing all medicinal products approved for subsidy under the pharmaceutical benefits scheme and information on what price can be extracted for these products. Moreover, this schedule will be submitted at least once a year to the European Commission.

In addition, the Board is to submit factual and objective information regarding its operations.
Processing times

Subsidy: 180 days  Price increase: 90 days

In the area of medicinal products, community legislative regulations govern access to measures that regulate pricing of medicinal products and how they conform to the national healthcare insurance system (Council terms of reference 89/105/EEG), so-called transparency directives.

The purpose of the terms of reference is to provide an overview of the methods utilised for national pricing and applied criteria, and to make these available to all actors operating on the medicinal products market within EU’s Member States. The terms of reference includes a stipulated turnaround time from when an application is submitted to when the agency has made a decision.

The rules for processing times are also included in the Pharmaceutical Benefits Ordinance (2002/687) issued by the Government 4 July 2002.

The PBB is to announce its recommendation on subsidy and pricing within 180 days after receiving a fully completed application for the inclusion of a medicine or product on the pharmaceutical benefits scheme.

A decision to increase a previously fixed sale price is to be announced within 90 days after the Board has received an application. If the information submitted in support of the application is insufficient, the Board is to immediately inform the applicant of what information is needed and take a decision within 90 days after receiving supplementary information.

If many applications for a price increase are submitted, the processing time can be extended for a single 60-day period. The applicant will be informed of such an extension before the deadline.

The applicant is entitled to implement the price increase in full if the Pharmaceutical Benefits Board has not announced its decision within the specified time period. The Board must immediately announce any decision to reduce previously fixed sales prices.
Decision-making criteria for subsidised pharmaceuticals

The Pharmaceutical Benefits Board shall give particular consideration to cost-effectiveness and marginal utility in its review process.

Product-oriented benefit scheme

The new subsidy system is primarily product-oriented. However, in exceptional cases, the Board can recommend that a medicinal product be included in the benefit scheme for a restricted area of use. Moreover, the Board can couple a recommendation with certain conditions. The Board will subsequently announce which areas of use and which particular conditions this may encompass.

Criteria

The general basis for the Board’s deliberations is the comprehensive health and medical care objective, namely good health and care on equal terms. The Board will also consider the basic ethical principles that apply to health and medical care. These ethical principles pinpoint a general position in priority-setting situations.

*The human value principle means that care is to be administered with respect for the equality of all human beings and the integrity of every individual.*

*The solidarity principle means that those in greatest need take precedence in medical care.*

The new law concerning medicinal products adds a further principle:

*The cost-effectiveness principle means that the cost for using a medicinal product should be reasonable and fair from a medical, humanitarian and social-economic perspective.*
The Board shall also consider:

*The suitability of the medicine, meaning that the medicine is suitable for an intended purpose without any unacceptable side effects in relation to the intended effect.*

Furthermore, the Board shall also consider:

*Marginal utility, which means that there are no other available medicines or methods of treatment deemed considerably more suitable. This is generally also referred to as addition patient utility.*

The Government states in the New Pharmaceutical Benefits Bill that, based on these criteria, it follows that a new medicinal product associated with higher costs than the equivalent current therapy should, in general, not be included on the benefits scheme. When the Committee takes a decision on whether a new medicinal product should be available on the scheme, it should assess if the costs are reasonable in relation to the achieved health advantages. If adequate alternative treatment is lacking, the cost should be reasonable in relation to the extra cost where the alternative is to administer no treatment.

It is the responsibility of the applicant to show that the criteria for subsidy as stipulated in the law concerning pharmaceutical benefits are fulfilled.

The Pharmaceutical Benefits Boards issues instructions for implementation and general advice that provides more detailed guidance as to the criteria considered by the Committee in making its recommendations. The Board will also draw up more detailed guidelines regarding what documentation should be enclosed with the application.

The existence of a government agency authorised to recommend if a medicine or product is to be included on the pharmaceutical benefits scheme is a new phenomenon in Sweden and praxis has subsequently yet to be set in this area. As the PBB becomes more experienced in its role, this praxis will gradually grow forth and develop. When appropriate, the Board will also take advantage of other countries’ experiences.
Under investigation

Pricing

A work group has reviewed the pricing of products available on the pharmaceutical benefits scheme. The group presented its results to the Government on 30 September 2002.

Apoteket AB’s trade margin

The agreement between the State and the National Co-operation of Swedish Pharmacists (Apoteket AB) is currently under review. This includes the task of determining trade margin, which PBB took over from the National Social Insurance Board.

Consumables

The Government has given the National Board of Health and Welfare, the Medical Products Agency and the National Social Insurance Board the task of conducting a collective review of the regulations for consumables needed for the self-administration of medicinal products and self-monitoring of medication. This assignment includes reviewing if it suitable to regulate these articles within the framework of the pharmaceutical benefits scheme and how the rules relate to the medical technical regulatory framework. The results of the assignment are to be presented in October 2003.

Follow-up in the area of medicinal products

A special investigator has been appointed to conduct a broad analysis of the current and future need for, and possibility of medical and economic follow-up within the area of medicinal products. (Directive 2002:38). The results of this assignment are to be presented 31 December 2002.
Environmental consideration

The government also intends to appoint the Medical Products Agency the task of reviewing how environmental consideration can figure in as a natural aspect of prescribing, using and pricing medicinal products.