

## Sweden

Dental and Pharmaceutical Benefits Agency (TLV)

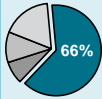
### Pharmaceutical pricing and reimbursement policies

#### OUT-PATIENT

#### IN-PATIENT

PRICING

##### Pricing of pharmaceuticals in the benefit scheme



**66%** of sales are within the benefits scheme (TLV; 2014). Companies apply to TLV in order to enter a product into the reimbursement scheme. By using the Value Based Pricing method, TLV determines whether the pharmaceutical, at a given price and effect, is cost-efficient and can be reimbursed. TLV decides both the pharmacy purchasing and retail price. Recently, TLV proposed a revised construction of the pharmacy margin, to better fit a changing market with increasing volume of high-cost pharmaceuticals. TLV decides neither ex-factory price, nor the wholesalers' margin.

##### Pricing policies for reimbursed pharmaceuticals



**High cost pharmaceuticals.** A new form of collaboration between county councils, pharmaceutical companies and TLV has been developed to establish national recommendations and a plan for coherent introduction of new high-cost pharmaceuticals. A result of this collaboration may lead to a risk sharing agreement between the county councils and the pharmaceutical companies.



**Pharmaceuticals subject to competition.** A tender auction system is applied to determine the available product at the lowest price for off-patent and interchangeable pharmaceuticals. The winning product in each group is the preferred product the following month. More than half of all dispensed packages are part of the system, and constitute one fifth of total expenditure for the benefit scheme.

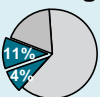


**Pharmaceuticals not subject to competition** and older than 15 years are imposed with a price reduction of 7.5%. This reduction was optional during 2014; however, as of 2015 it is enacted by law.



**Pharmaceutical reviews.** Reviews of pharmaceuticals approved for the benefit scheme are performed by TLV in therapeutic areas where there is reason to question whether the pharmaceuticals still provide sufficient cost-efficient use.

##### Pricing of pharmaceuticals not included in the benefit scheme

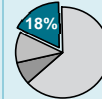


**15%** of sales are out-patient pharmaceuticals outside the benefit scheme, such as OTC (11%) and non-reimbursed Rx (4%). The price setting is unrestricted. The companies decide ex-factory price, the wholesaler decides the price to pharmacies and pharmacies set the retail price.



The standard VAT rate is 25%, and is applied to both OTC-pharmaceuticals and medical devices. There is no VAT on prescribed pharmaceuticals.

##### Pricing in the hospital sector



**18%** of pharmaceutical sales are made in the hospital sector.

Pharmaceuticals in the hospital sector are paid by 21 county councils providing healthcare. The county councils are responsible for the purchase of pharmaceuticals. The county councils are allowed to form partnerships and negotiate prices individually, or in clusters.



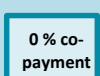
Drug and Therapeutic Committees within county councils act as advisory boards concerning the use, efficiency and cost of pharmaceuticals.

There is no VAT imposed on pharmaceuticals and medical devices purchased by the county councils.

REIMBURSEMENT



For pharmaceuticals included in the benefit scheme, the patient and the state share the costs of the pharmaceuticals. During a 12-month period, a patient pays the full amount of pharmaceuticals up to SEK 1 100 (€120). After paying SEK 2 200 (€240), the patient is fully subsidized. Between SEK 1 100 and SEK 2 200, the patient is subsidized 50%, 75% or 90%, depending on the accumulated costs.



Insulin, pharmaceuticals prescribed for preventing contamination of certain communicable diseases (i.e. HIV), and pharmaceuticals for persons lacking perception of their own state of illness, are always subsidized at 100%. There is a government proposal to offer children fully subsidized pharmaceuticals within the benefit scheme. At present time, children are included in the same benefit scheme as adults.

An adult patient pays a fee when visiting a hospital or primary care center. The maximum fee per patient is SEK 1 100 (€120) per year. Should the amount exceed SEK 1 100 (€120) during said period, the health care is fully subsidized. Patients pay a fixed fee for the medical appointment and no co-payment is required for pharmaceuticals used during a hospital stay.