Sweden

Recent and planned developments in pharmaceutical policies 2017/2018

Special topic: patient involvement in pricing and reimbursement of medicines

CHANGES IN PRICING

Information about prices for pharmaceuticals included in benefits are generally available online, see www.tlv.se/beslut/sok/lakemedel/

Risk-sharing via Managed Entry Agreements (MEA´s) is an important tool to manage uncertainties for pharmaceuticals included the benefits scheme.

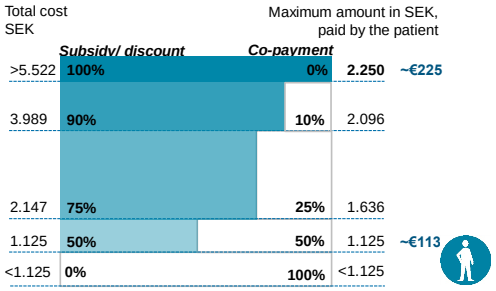
The County Councils and the pharmaceutical companies' had 24 ongoing MEA's in 2017 to ensure cost effectiveness for out-patient pharmaceuticals in the benefits scheme.

The total expenditure for products with MEA amounted to approx.15 percent of the benefits scheme in 2017. Total refund amounted to 947 million SEK for the year.[1] The refund is equivalent to 3.5 percent of the total expenditure of all products in the benefits scheme.

For 2018, the refund is shared 60/40 between the County Councils and the government (70/30 in 2017).

CHANGES IN REIMBURSEMENT

Patient co-payment in 2018



The maximum co-payment for patients is SEK 2 250 (approx.€ 225) per year for pharmaceuticals included in the benefits scheme from January 2018. An increase by SEK 50, ~ € 5, from 2017.

Children under 18 years are exempt from co-payment for reimbursed pharmaceuticals.

Young adults (under 21) receive free contraceptives included in the benefits scheme.

OTHERS CHANGES

Revised substitution groups for pharmaceuticals with competition (Product of the month)
Pharmaceuticals subject to competition are grouped according to number of units, volume or weight from March 1st, 2018. Parenteral administrated pharmaceuticals, approx. different 215 products, have been regrouped and may be substituted at the pharmacy.

Increased focus on quality and safety at the pharmacy / in the dispensing process
A recent government bill (Prop 2017/18:157) regarding the quality and safety in the dispensing process, highlights the need to measure the performance of basic services performed at the pharmacies and the development of specific pharmacy services. Among other matters, the responsibility for the pharmaceuticals ordered for a specific customer is transferred from the pharmacy to the wholesalers. The amendments will be implemented in different phases, starting in August 2018 (but no later than July 2020).

Full information on the pharmaceutical treatment of individuals
The government has adopted a resolution to introduce a National Medication List that contains information, available to all physicians that threats the patient about what medicines a patient is prescribed and has collected. The list will be up and running in June 2020 and will replace the Prescription registry and the Medicine list.

New dialogue between pharmaceutical companies and agencies in three Scandinavian countries
A joint health technology assessment (HTA) pilot project, known as FINOSE, was launched by FIMEA, NoMA and TLV in March 2018. The objective is to explore ways of collaborating in the assessment of pharmaceutical technologies. Each pilot will result in a joint assessment report that later may be the basis for national decisions or recommendations corresponding to each agency's remit.

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SPECIAL TOPIC: Patient Involvement in Pricing and Reimbursement of Medicine

The involvement of patients in the pricing and reimbursement process is important to achieve better use of medicines – for the benefit of patients and society.

TLV's aim with involving patient and interest/user groups in the reimbursement process is to further improve dialogue, reach an enhanced, mutual understanding of needs, work methods and challenges. It is further to achieve better conditions for a sustainable use of pharmaceuticals at a reasonable cost in relation to the benefit.

Patients, interest and user groups are represented in several forums.

Patient representation in the Pharmaceutical Benefits Board

- The government appoints a representative for patient/user/consumer groups to the Pharmaceutical Benefits Board. The board decides whether a pharmaceutical product should be eligible for reimbursement and included in the benefits scheme.

A Board of Advisors observe and provide guidance to the Director General

- A Board of Advisors, consisting of representatives from different organisations and user groups, are appointed by the government to have an observatory role as representatives for the public and to provide guidance to TLV´s Director General.

Dialogue forum meetings between patient organisations and TLV two times per year

- Several patient and interest/user organisations participate in the recurring TLV Dialogue Forum (two times per year) that is a forum for discussing current issues, for instance ostomy products, biosimilars, generic substitution as well as pricing policies.

Dialogue and collaboration

Patient and interest/user groups participate in specific issues.

- TLV has had dialog with representatives of several patient and user organisations regarding specific products, e.g. for treatment of Hepatitis C, Hemophilia A (Factor VIII), ostomy, diabetes and different forms of cancer.

- Round table discussions with both patient and professional representatives have been conducted in the field of e.g. diabetes to aim for an increased dialog related to both pharmaceuticals and medical technology.

- During 2017, a pilot project was initiated with a patient organisation, with the aim of getting a further understanding of patients', in this case, ostomy patients´ view of quality.