2021-04-20

Greatest possible health for tax money spent

– central government reimbursement of medicines

Summary and recommendations

The Swedish National Audit Office (Swedish NAO) has audited the work of the Dental and Pharmaceutical Benefits Agency (TLV) to assess which medicines will be subsidised and included in the high-cost threshold scheme. The audit also included the Government's efforts to provide the conditions for this work. The overall conclusion of the Swedish NAO is that the Government and the TLV could do more to get the greatest possible health for the tax revenues spent by the public sector on medicines. In 2020, the cost of medicines within the pharmaceutical benefits scheme amounted to approximately SEK 34.3 billion, including patient fees.

Audit findings

It is difficult for TLV to include certain types of new medicines in the benefits scheme with the "reasonable cost criterion" that currently applies to pricing. This applies in particular to medicines for severe rare chronic conditions where treatment will be lifelong. These products often have a high price and sometimes an uncertain treatment effect. It is important that there are provisions that allow these medicines to be included in the benefits scheme and be brought into use in health care. At the same time, it is important that the Government takes measures to moderate cost increases in the pharmaceutical benefits scheme and to make the use of medicines effective. Central government costs for subsidised medicines are expected to increase by several billion kronor over the next few years.

Good models for risk-sharing between companies and central government/regions can compensate for uncertainty in treatment effects, for example by making payment gradual in pace with the ability to verify treatment outcomes. At the same time, risk-sharing requirements mean a greater necessity for good data access. However, some new medicines with a good treatment effect still remain at a high price. To compensate for expected cost increases for new medicines, there is a need to reduce the cost of older medicines. For example, there is a need for greater scope to reduce prices for biological medicines.

The willingness and ability of the regions to enter into side agreements with rebates, and to steer doctors' prescribing, are crucial to ensure cost-effective use of medicines and to mitigate future cost increases in pharmaceutical benefits. The Government needs to investigate how the State can make it easier for the regions and strengthen their incentives to enter into side agreements and to steer the use of medicines.

The continued development of value-based pricing requires close collaboration between key stakeholders in the pharmaceutical sector. The Government needs to create conditions for one or more agreements with the industry and the regions on new criteria for pricing and reimbursement, which are adapted to the development of the pharmaceutical market. The agreements need to be accompanied by supplementary legislative amendments in the area.

Follow-up of the reimbursement decisions is in general terms a neglected area in TLV's operations. Lack of data is a partial explanation for this, but follow-up can also be improved with the data that TLV already has access to. A more systematic follow-up of the reimbursement decisions is a prerequisite for TLV to be able to develop pricing and contribute to more cost-effective use of medicines.

TLV needs to clarify its communication about which social costs and benefits underlie its reimbursement decisions. TLV also needs to clarify its principles for how the agency assesses the severity of disease. Otherwise, there is a risk of unjustified differences in TLV's reimbursement decisions.

Recommendations

The Government should:

- initiate new discussions between central government, industry and the regions in order to reach agreements with mutual commitments that may form the basis for legislative amendments. We believe that all three parties need to participate at least in the initial phase.

  The discussions should particularly focus on:

  1. how the basis for pricing and reimbursement of different types of medicines in different phases of the life cycle can be developed
  2. how the National Board of Health and Welfare's National Patient Register and Prescribed Drug Register can be developed to better support the appropriate pricing and reimbursement of medicines
  3. how central government can facilitate and provide incentives for regions to guide prescribing more clearly towards medicines that offer good value within the limitations of the benefits scheme.

- ensure that TLV can systematise the follow-up of decisions based on the data that TLV currently has access to.

TLV should:

- communicate more clearly how they take social costs and benefits into account.
- develop clearer frameworks for assessing the severity of disease.