Sweden reviews financing and pricing

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Introduction

In mid-November 2016 the government issued directives to review the pricing and reimbursement system and the national financing system for medicinal products. The government declared that the existing system is complex and complicated and must be improved in order to operate a modern healthcare system.

Among other things, the review seeks to find a clear division of responsibilities between the national government and local county councils and regions and to establish foreseeable processes for stakeholders.

The report from the review will be presented to the government on December 1 2018.

Financing system

In 1998 the reimbursement costs for medicinal products were transferred from the national government to the county councils. After a transition period the county councils were supposed to be compensated for the increased costs with a general government grant to each county council. However, this was never implemented. Instead there has been a specific grant for the reimbursement costs, which has been negotiated and agreed between the central government and the county councils for specific periods. The grant agreements have, among other things, divided the grant between the county councils according to population. There is also a solidarity agreement in place between the county councils regarding costs for treatment of rare diseases that are unevenly spread over Sweden. The latest grant agreement stated that there is a need for a review of the financing of medicinal products to make it more long term and predictable. However, the agreement expired on December 31 2016, with negotiations throughout 2016 failing to reach a new arrangement.

Review

The system of acquiring medicinal products for patients within the healthcare system has become increasingly complex. Apart from the standard model where medicinal products are included in the reimbursement system with a certain co-payment from patients, there are defined contagious diseases for which there is no patient co-payment. There are also medicinal products (eg, orphan drugs and oncology products) that have not been granted reimbursement by the Dental and Pharmaceutical Benefits Agency (TLV) due to not having been deemed cost effective on a patient group level, although they may be cost effective for certain patient sub-groups. Such products may be paid for by the county councils outside the reimbursement system.

The directives for the review for an improved financing system include:

- analysis of whether a specific grant for reimbursed medicinal products is effective or whether a change is needed;
- consideration of whether the specific grant system should be kept or be subsumed into the

general government grant;
- analysis and consideration of whether there is a need for change in the division of responsibilities between central government and county councils regarding the financing of new effective medicinal products and, if so, the proposal of measures; and
- analysis of the need for cost compensation between county councils.

Pricing and reimbursement system

The pricing and reimbursement system is generally aimed at medicinal products sold and dispensed at retail pharmacies. For medicinal products ordered and used within the hospital system, pricing is free and the hospital access to such medicinal products is normally established through public procurements. Pricing is also free for prescription medicinal products sold and dispensed at retail pharmacies which have not been granted reimbursement.

The current pricing and reimbursement system was implemented in 2002 and requires that a product pass a health technology assessment to be granted reimbursement. The medicinal product applying for reimbursement is compared to one or more alternative medicinal products used within the healthcare system in order to assess its cost effectiveness. The evaluations may, for instance, describe whether a new treatment that is more effective than an existing treatment is also cost effective. The result is often presented as a cost per quality adjusted life year (QALY) gained. If the cost per QALY gained is below a certain threshold value, the new medicinal product is deemed cost effective.

The current system is product based, not indication based (ie, unless the TLV specifically limits the reimbursement due to certain indications not having been deemed cost effective, all indications under the marketing authorisation are reimbursed).

Review

Under the current pricing and reimbursement system, medicinal products aimed at smaller patient groups (eg, orphan drugs) will have difficulty proving cost effectiveness within QALY thresholds used by the TLV, due to high research and development costs and a very high price per patient ratio. The effectiveness of such a medicinal product is also often uncertain due to difficulties in conducting conclusive clinical trials on the severe and chronic conditions for which they are indicated.

Advanced therapy medicinal products (eg, gene therapy, which is predicted to increase in the future) are problematic to handle under the pricing and reimbursement system – including whether they should be classified as medicinal products that can apply for reimbursement or treatment methods within the healthcare system.

Pricing and reimbursement for medicinal products under adaptive licensing or other types of licensing (eg, accelerated assessments of marketing authorisations) make up another topic which the government believes should be covered in the review, since there is a clear benefit for certain patients getting early access to new effective medicinal produtcts, while simultaneously patient risk is increased.

The review will compare a product-based pricing and reimbursement system with an indication-based pricing and reimbursement system. The review will also address the fact that Sweden is one of the few countries not using international reference pricing. As a result, pharmaceutical companies have an incentive to try to maintain high prices for medicinal products within the Swedish reimbursement system.

Finally, the TLV's so-called 'Trialogue Project' – which concerns negotiations between pharmaceutical companies, the TLV and the county councils on risk-sharing or discount agreements – will be reviewed to ensure that the process is clear, predictable and transparent.

Directives include:

- thorough analysis of the pricing and reimbursement system and development to date, including the Trialogue Project;
- evaluation of access to and actual prices of medicinal products in Sweden compared to other

similar countries;

- evaluation of accumulated effects on pricing and access to medicinal products in Sweden when Sweden is used as a pricing reference by other countries and, if needed, a proposal of new measures to minimise possible negative effects;
- analysis, consideration and, if required, a proposal of new measures for price control for all publicly financed medicinal products;
- analysis and consideration of different pricing models before proposing measures; and
- proposal of a pricing and reimbursement system based on equality, which creates good access to and use of effective medicinal products in Sweden, while simultaneously not increasing costs when compared to the current system.

Comment

Although a government review regarding the pricing and reimbursement system was conducted as recently as 2011 to 2014, it has since become clear that a more thorough review is needed. The system has not been updated to cover changes and developments.

The out-of-date system has resulted in the TLV and other stakeholders developing ordinances and procedures to an extent where it is possible to question the legal basis for certain developments. Consequently, disputes have also increased.

The outcome of the review will likely change the pricing and reimbursement system substantially. However, there will be a general election in September 2018, and if a new government is elected it may decide not to act on the review or to give new or amended directives.

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