



RIKSREVISIONEN

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Preparatory work for the pharmacy reform

Summary

The Swedish pharmacy market has undergone a comprehensive change as a consequence of the market liberalization on 1 July 2009. Through this liberalization, the Riksdag's goal was to give consumers increased access to medicine, better service, and a greater supply of services, as well as lower medicine costs for the benefit of the consumer and the public sector. Liberalization should be carried out so that both large and small actors should have an interest in, and the opportunity for, establishing themselves and operating for the long term on the Swedish pharmacy market.

The goal of the reform should be attained through exposing Apoteket AB to competition and creating a pharmacy market. To facilitate other actors coming into the new pharmacy market, parts of Apoteket AB have been sold off, and a state small business corporation has been formed.

Certain initial results could be seen on the market as early as autumn 2010, in the form of an increased number of newly established pharmacies. The Swedish National Audit Office has, however, aimed its review at the government's preparatory reform work. The actors concerned in the review are the government, Apoteket Omstrukturering AB (OAB), Apotekens Service AB, Apoteket AB, the Swedish Medical Products Agency (Läkemedelsverket), the Dental and Pharmaceutical Benefits Agency (TLV), and the National Board of Health and Welfare (Socialstyrelsen).

The purpose of the review is to analyse whether the preparatory work by the government, the authorities and the corporations concerned has created good conditions for meeting the goal of pharmacy reform during the intensive liberalization period.

Observations and conclusions

The Swedish National Audit Office is of the opinion that parts of the preparatory reform work have been handled appropriately. The government has, to a large extent, carried out extensive investigative work and identified early on, as an example, that the necessary IT structure should be separated from Apoteket AB and be made available for all actors on the market. The government has further reduced the market power of Apoteket AB in order to facilitate competition on the market, and prioritised guaranteeing the supply of medicine, and safety, during the restructuring.

At the same time, the Swedish National Audit Office's review has shown that there are deficiencies in important parts of the preparatory work, which run the risk of obstructing the rise of a pharmacy market and thereby the target achievements of the reform. The government's organization and operating method has also to some extent run counter to an effective use of the State's resources.

The Swedish National Audit Office understands that the time for implementing pharmacy reform was short. At the same time, it is important that the decision was made on a well-founded basis, as it is costly to adjust and redo afterward. The government has drawn lessons from earlier liberalizations, especially with an emphasis on certain economic aspects of implementation. The Swedish National Audit Office is, however, missing the following in its review:

- A documented analysis of which legal issues were considered and prepared before the choice of implementing organisation and the total structure of the reform. Also, aspects such as legal, stable, and predictable rules affect how well a market functions.
- An impartial analysis of the regulation of the pharmacy's retail mark-up. The regulation chosen starts largely from how the retail mark-up was regulated before the reform. On a market exposed to competition, this regulation runs the risk of leading to either high costs for taxpayers or a lower degree of target achievement.

The Swedish National Audit Office has responded to two questions from the purpose of the review.

Audit Question 1: Have the government, the companies and the authorities responsible created good conditions for a pharmacy market in accordance with the decision of the Riksdag?

According to the comprehensive assessment of the Swedish National Audit Office, there are deficiencies in the government's formation of important parts of the preparatory work. This runs the risk of obstructing the rise of a functional pharmacy market in accordance with the goal of the reform. The Swedish National Audit Office makes the following assessment:

- The choice of organisational form was not sufficiently prepared, as was the need for special regulation in this regard.
- Different, changeable conditions came to affect the restructuring process, since market conditions for pharmacy actors were not clarified for the market actors in advance.
- Long-term responsibility for the development of Apoteket AB was not taken into sufficient consideration. Apoteket AB was prevented, for example, from rationalising its operations because certain standstill regulations concerning the corporation's business conditions were not terminated *in time*. This despite the fact that large pharmacy buyers came onto the market at the beginning of 2010 and the corporation no longer had a dominant position.

- The pricing principle for Apoteket's IT transition solution (ATS) was not competition-neutral between large and small independent businesses. In pricing for the strategic infrastructure, on the other hand, a competition-neutral pricing principle was applied between various company sizes and thereby favours diversity on the market.
- The tasks for Apotekens Service AB have not been sufficiently clarified in the law. Nor has the company been given any obligations to fulfil general administrative regulations, despite the tasks of the company bearing the features of exercise of public authority to some extent.
- The profitability model applied in order to regulate the pharmacies' retail mark-up is not formed in a manner appropriate and effective for society.
- The current model for pharmacy service in rural areas does not create long-term predictability.

Audit Question 2: Have the government and Apoteket Omstrukturering AB created good conditions for an effective organisation and work process during liberalization?

According to the comprehensive assessment of the Swedish National Audit Office, an effective use of the State's resources risks being frustrated in some of the parts of the reform that have been researched through the way the organisation and operating methods have been applied by the government. The Swedish National Audit Office makes the following assessment:

- Supervision and licensing tasks in various government agencies and companies are, to some extent, overlapping and mutually dependent on each other, with a risk for problems in drawing boundaries. This can lead to unnecessarily high costs for the State at the same time as the regulations become difficult for market actors to predict and follow.
- There was no task from the government to gather up initial data on the market before the implementation of the reform. This reform therefore cannot be evaluated in all its parts.

Recommendations of the Swedish National Audit Office

Recommendations for the government

The Swedish National Audit Office submits the following recommendations against the background of the observations and conclusions made in the review.

- The government should immediately ensure that the TLV clarifies and publicizes which profitability principles are being used in determining the retail mark-up and how the margin will be adjusted in the future.

- The government should, moreover, ensure that a top-to-bottom analysis of the model which regulates the pharmacies' retail mark-up is carried out so that accessibility is neither too high nor too low in relation to consumer benefit. In this context, the need for formation of a predictable, cost-effective solution for pharmacy coverage in rural areas should also be analysed.
- The government should clarify and regulate the licensing and supervision tasks of Apotekens Service AB.
- The government should see to it that the conditions for creating a more effective organisation for licensing and supervision are investigated.
- The government should review the particular restrictions in the ownership directive that prevent Apoteket AB from rationalising its operations.
- The government should, at its earliest opportunity, take a position on whether the operations in Apodos and Apoteket Farmaci AB should be sold off from Apoteket AB so that the company and other actors can plan for future strategic steps within the economic areas.