

I. Introduction and conclusion

1. This report is about the Danish hospitals' purchase of pharmaceuticals in the period 2007-2011. The study was initiated in May 2011 at the request of the Public Accounts Committee.

2. The report answers five questions concerning the regions' purchase of pharmaceuticals for the public hospitals that were put forward by the Public Accounts Committee on 16 March 2011. The questions are listed in the box below with reference to the sections of the report in which the individual questions are addressed.

BC	DX 1. THE QUESTIONS PUT FORWARD BY THE PUBLIC ACCOUNTS COM	MITTEE
1.	How much did the regions spend on hospital pharmaceuticals in the period 2005-2010?	Section III
2.	How were the prices of hospital pharmaceuticals set during that period?	Section IV
3.	How did the regions and Amgros ensure that hospital pharmaceuticals were purchased at the lowest possible prices?	Section VII
4.	What is the nature of the authority and obligation of the Ministry of Interior and Health (now the Ministry of Health and Prevention) to enter price agree- ments with the pharmaceutical industry, including the price-cap and price- reduction agreement entered with the industry in 2009?	Section VI
5.	Have other requirements than price been considered when the price agree- ment was entered?	Section V

The study is based on Rigsrevisionen's memorandum to the Public Accounts Committee of 2 August 2011 on the preparation of a major study of the regions' purchase of hospital pharmaceuticals.

3. The objective of the study is to assess whether the Ministry of Health and Prevention (Ministry of Health) and the regions ensure that hospital pharmaceuticals are purchased at the lowest possible price.

4. In this context the term hospital pharmaceuticals covers all medicines applied for the treatment of patients in the public Danish hospitals. The concepts of hospital medicines and hospital drugs are in this report synonymous with hospital pharmaceuticals.

5. The study comprises the Ministry of Health and the five regions.

Amgros is an association owned by the regions and is responsible for the procurement of pharmaceuticals for the Danish hospitals.

The pharmaceutical industry is an umbrella term for private companies that develop, research, manufacture and/or market hospital pharmaceuticals. Most of these companies are members of the Danish Association of the Pharmaceutical Industry (Lif). The members either have Danish headquarters, are subsidiaries of international companies, or they are companies, or they are companies doing research only or companies combining research and sales activities. In a **reference pricing system** the price of the individual pharmaceutical is determined on the basis of the price charges in selected countries. Reference pricing systems can be organised in many different ways.

MAIN CONCLUSION

The regions' costs for hospital pharmaceuticals are considerable and have for a number of years been on the increase. The costs cover a wide range of drugs with a few accounting for a large part of the expenses.

The Ministry of Health did not adopt a reference pricing system as recommended in the *Analysis of Hospital Pharmaceuticals* that was published in May 2009. Shortly after publication of the report, the ministry instead entered a price agreement with the Danish Association of the Pharmaceutical Industry (Lif) in order to reduce the price of products provided by the members of Lif. The ministry has emphasized that the price agreement was entered because the overall benefits of adopting a reference pricing system were subject to uncertainty, and Lif did not want such a system.

Rigsrevisionen has ascertained that the Ministry of Health has not taken any initiative to re-negotiate the price agreement in spite of the fact that the overall discount obtained turned out to be considerably lower than anticipated.

The Ministry of Health has stated that the other purpose of the agreement with Lif was to consider also the interests of the pharmaceutical companies that do research, and therefore reference is made to this aspect in the text of the agreement. Rigsrevisionen does not find it relevant to include this consideration in the price agreement.

Since 2007 the regions' procurement association has been responsible for purchasing pharmaceuticals for the public hospitals in Denmark. The association provides the regions with a satisfactory opportunity to obtain discounts through joint purchases and thereby achieve the lowest possible prices. Ensuring that the hospitals across regional borders all administer largely the same drugs to the patients is a prerequisite of increasing the procurement volume. Additional savings can be obtained for the regions if the impetus for standardization of the use of drugs across the regional borders is further sustained.

Overall, Rigsrevisionen is of the opinion that the initiatives taken by the Ministry of Health and the regions contribute to ensuring that pharmaceuticals are purchased at the lowest possible prices. Rigsrevisionen is, however, also of the opinion that additional savings could be achieved if efforts were further increased.

The Ministry of Health should analyse and consider its future policy to ensure lower prices of hospital drugs.

The main conclusion is based on the following sub-conclusions:

How much did the regions spend on hospital pharmaceuticals?

The regions' net expenditure for hospital pharmaceuticals amounted to approximately DKK 5.8 billion in 2010.

Costs increased from 2007 to 2010 by approximately 50 per cent. From 2010 to 2011 the growth has been more moderate, among other things, because the patents on certain drugs had expired.

Relatively few hospital drugs account for a large part of the expenditure; of the approximately 3,000 medicines that are administered in the hospitals, three of the most expensive drugs account for approximately 16 per cent of total costs, whereas 20 hospital drugs account for approximately 44 per cent of the total costs for hospital pharmaceuticals.

Has the Ministry of Health established a policy and entered agreements that ensure that the regions can purchase hospital pharmaceuticals at the lowest possible prices?

In a report published in May 2009, a work team including representatives from the Ministry of Health, the Danish Regions (interest organisation for the five regions) and the Ministry of Finance recommended the adoption of a reference pricing system as a measure to obtaining lower prices. In the report it was indicated that the price of selected products was approximately 7 per cent and 10 per cent lower in Norway and England, respectively, and in both these countries price-setting is based on reference pricing systems.

The estimated savings potential related to the adoption of a reference pricing system was subject to uncertainty due to the confidentiality of contractually determined prices. This served as an argument for the Ministry of Health's decision to enter a price agreement with Lif in June 2009. The agreement prescribes a five per cent discount on products provided by the members of Lif to the hospitals. These products account for approximately two-thirds of the hospitals' total costs for pharmaceuticals.

This agreement has financial implications for the regions which were informed of the agreement after signing. The Danish Regions would have appreciated an invitation to participate in the negotiations on the agreement.

In 2010, based on information provided by Amgros, the Ministry of Health established that the discount would be approximately three per cent instead of the originally estimated five per cent because the ministry, when signing the agreement, had not take en into consideration the discounts that the regions had already achieved through their joint procurement of hospital drugs. The ministry did not take action to have the agreement with Lif adjusted despite the fact that the expected discount was not achieved. Rigsrevisionen points to the fact that the ministry through a closer collaboration with the Danish Regions would have gained more detailed insight into the prices of hospital drugs, and thereby would have been in a better position to negotiate the agreement.

Prices referred to as contractually determined prices are fixed in a contract after a tender process and generally include discounts compared to the list prices.

Has the Ministry of Health taken other issues into consideration beyond that of ensuring that drugs are purchased at the lowest possible prices?

When entering the price agreement, the Ministry of Health decided to consider the interests of the pharmaceutical companies that do research, and they were not interested in a law-based reference pricing system but preferred a price agreement. In the agreement, reference is made to incorporating the research aspect in the running of the hospitals. It is, however, not clear why this issue is addressed in an agreement that is meant to ensure that the regions can purchase hospital pharmaceuticals at the lowest possible prices.

The Ministry of Health has only to a minor extent documented the negotiations on the agreement with Lif. Assessing the concrete process, including the considerations that formed part of the negotiations between the ministry and Lif, has therefore not been possible. Rigsrevisionen has established that a meeting was set up between the ministry and Lif two weeks before the report *Analysis of hospital pharmaceuticals* was published. The ministry has stated that no actual negotiations were conducted with Lif before the report was published, but has not been able to account for the purpose and contents of this meeting.

Has the Ministry of Health informed the Folketing of the price agreement?

On 26 May and 3 June 2009, the members of The Health and Prevention Committee asked the Minister of Health what initiatives the ministry would undertake following the report *Analysis of hospital pharmaceuticals*. The minister answered the questions on 14 July 2009, and on the same occasion the Committee was informed of the signing of the agreement with Lif on 4 June 2009.

The Ministry of Health is not under any obligation to enter price agreements with the pharmaceutical industry. The authority to do so is based on the practice of entering agreements with the pharmaceutical industry on medicine prices in the primary care sector, i.e. the medicine that is sold to the citizens through pharmacies, etc. The Folketing is familiar with this practice.

Have the regions and Amgros provided an adequate platform for procurement of hospital pharmaceuticals at the lowest possible prices?

The regions have centralised procurement of hospital pharmaceuticals in Amgros. Rigsrevisionen finds it satisfactory that the regions, through the tender policy pursued by Amgros, can obtain savings compared to the list prices of drugs that are determined by the manufacturers.

If the pharmaceuticals that are used in the hospitals are largely identical, the supply might increase and prices subsequently drop. The need for further standardisation has been known for years, and in 2009 the Danish Regions established *The Council for Use of Expensive Hospital Medicine* (RADS) with the aim of agreeing on the use of expensive hospital medicine across the regions. RADS has been authorised to work out recommendations for the 100 products that account for 80 per cent of total expenditure for hospital drugs. So far RADS has completed recommendations for 22 products. Rigsrevisionen has established that increased standardisation of the use of hospital drugs would benefit the efforts made by the regions to obtain the lowest possible prices.

Rigsrevisionen sees a potential for further savings if the use of hospital drugs across the regions is standardized even further.

List prices are the official prices that the manufacturers report to the Danish Medicines Agency. The official list prices may be adjusted by the manufacturer every fortnight.