Summary

The remit

At present, Apoteket AB (the National Corporation of Swedish Pharmacies) has exclusive rights to conduct retail trade in medicinal products to consumers. The Inquiry's remit has primarily been to present proposals that make it possible for actors other than Apoteket AB to conduct retail trade in medicinal products. The remit has also included examining how distance commerce with medicinal products is to be designed and to present proposals to guarantee that certain services and functions that are currently performed by Apoteket AB will also be available in the future.

Under the terms of reference, the aim of re-regulation is to achieve efficiency gains, better accessibility for consumers, price pressure, and safe and appropriate use of medicinal products.

The Inquiry's proposals, under the terms of reference, are to contribute to lower consumer prices for medicinal products without this leading to increased expenses for public authorities. One important aspect has been to review the pricing model for medicinal products.

In the terms of reference, it is emphasised that the Inquiry's work is to be based on a patient and consumer perspective and that the high level of expertise, safety and quality that currently characterise trade in medicinal products is to be maintained. It is also emphasised that it is important that accessibility to medicinal products in rural and other areas is safeguarded, that supply of medicinal products is conducted rationally and promotes safe and appropriate use of medicinal products, and that proposals that concern individual companies are drafted so that the administrative burden on these companies is as little as possible.

Precautionary principle

Approach to change

The terms of reference have left the Inquiry with a complex assignment and a tight time schedule. This situation has to a great extent shaped the Inquiry's broad and comprehensive approach.

The view of how the proposals should be drafted has also been affected by the general viewpoints expressed in the evaluation of previous re-regulation processes presented in the Regulation Inquiry's report *Liberalisation, regulations and markets* (SOU 2005:4).

The Inquiry has also studied with great interest experience gained from changing systems in the pharmacy service in other countries; this has provided valuable insights regarding strategies for change. At the same time, this experience is of limited use due to the unique initial situation in Sweden: nowhere else in the OECD area is there, or has there been, a situation where a nationwide, state-owned pharmacy chain is to be transformed into a market with a balanced structure of actors.

The terms of reference do not address issues concerning the state's ownership policy regarding Apoteket AB. Since the company's market share has a major impact on the implementation of the Inquiry's proposals regarding statutory regulations for a re-regulated pharmacy market, the Inquiry is working with several tentative scenarios that form the outcome of different ownership policy approaches.

Together, the above starting points and restrictions form the following choices in the Inquiry's overall approach to change:

- As far as possible, build on previous systematic stages in the development of the pharmacy service.
- Do not change that which is considered to be working in a re-regulated environment.
- Be radical in proposals where introduction of a reorganisation is necessary.
- Base proposals on evidence, where such is available.

Experience from other re-regulation processes show that it is difficult to predict the impact at all stages of a reorganisation. The effectiveness of the proposed regulations, the establishment of new practices, and the number and actions of the actors can only be

assessed once the re-regulation is in place. The Inquiry therefore considers that in a first stage, the re-regulation should be conducted subject to review through continuous and structured evaluation, after which adjustments, amendments and restrictions can be made in the regulations. The Inquiry therefore proposes that a precautionary principle be applied, which means that:

- During an implementation phase of two years, it is proposed that models be used for pricing medicinal products and compensation to pharmacies that give primary consideration to control of society's costs for medicinal products and where increased market dynamism can later be introduced based on results of evaluations and the actual actor situation in the market.
- During the same period an independent evaluation process should be established to monitor the build-up and development of the pharmacy market with regard to the goals stated in the terms of reference and other essential conditions for a functioning market. Based on the results of the evaluation process, proposals can be made regarding the need for adjustments and supplementary measures.
- The Inquiry expects that after this kind of implementation phase and an evaluation process, proposals can be drafted for a more dynamic price model concerning medicinal products with functioning generic competition, open-ended transparency mechanisms and discount sharing models between the pharmacy industry and public authorities.

As far as possible, build on previous systematic stages in the development of the pharmacy service

The reasons for the reforms that led to the establishment of the Pharmaceutical Benefits Board, the participation of medical services in the price-setting process and county councils' responsibility to pay for pharmaceutical benefits are also valid in a re-regulated market. The Inquiry bases its proposals on these established institutions, and in this main report proposes that measures be considered to, in the long term, further strengthen the role of the Pharmaceutical Benefits Board and the participation of medical services in the price-setting process. In the Inquiry's interim report on the provision of medicinal products to hospitals,

county councils are given broader opportunities to make use of competition based on the opportunities they already have within the framework of the Public Procurement Act.

Do not change that which is considered to be working in a re-regulated environment

The current cost/utility value principle for pricing medicinal products with patents should be retained. These medicinal products represent the substantially largest portion of society's costs of the benefits scheme. The requirement of changing to cheaper parallel imports of medicinal products where such are available should be retained.

The obligation to provide prescribed medicinal products should be retained, as should the opportunity for generic substitution.

The construction of the high cost protection system should be retained. This entails equal treatment of consumers that is nationally uniform.

The uniform pricing of medicinal products and products that are included in the benefits scheme should remain.

Current principles for calculating the difference between a product's purchase price and retail price should be retained in all essentials. This means that the relative price levels will not change because of technical reasons that follow from the Inquiry's proposals concerning new ways to replace pharmacies.

The service that the Swedish Poisons Information Centre provides to medical services and the public will be safeguarded both through a new organisational position outside the competitive arena and through continuation of current financing.

Be radical in proposals where introduction of a reorganisation is necessary

One condition for the idea of re-regulation to become a reality is that various pharmacy actors are able to start up in the Swedish market under reasonably long-term and stable conditions and with reasonably foreseeable risks.

These conditions are defined by such matters as:

- Terms of ownership,

- Rules for setting up pharmacies,
- Fundamental business conditions,
- Access to infrastructure on competitively neutral terms.

The conditions are also affected by the framework for Apoteket AB's initial market share and the opportunities for business development in this phase. This is defined by the state's ownership policy.

It is the Inquiry's assessment that the only current actor, Apoteket AB, will initially have a very strong position due to over twenty-five years of exclusive rights, its ownership situation and its generally good reputation among the public.

In light of this, the Inquiry considers that there should be few obstacles and low entry barriers for new actors, equal and competitively neutral access to the infrastructure and a business model with opportunities for negotiating logistics services and purchase prices for medicinal products.

The infrastructure of databases and information systems are important for efficient operations, control and overview of the use and costs of medicinal products and as background data for research and development. The proposal calls for these to be detached from Apoteket AB and operated under state ownership with a competitively neutral approach to all pharmacy actors.

The Inquiry also recommends that the state limit Apoteket AB's initial market share by selling some pharmacies. The aim is to facilitate a rapid establishment of a market situation with a functioning actor composition from a competition perspective.

Start up phase under evaluation

The Inquiry proposes a review in 2011, i.e. after a two-year start up phase. It is proposed that the Government draft a commission for an evaluation, to be assigned to an independent examiner, to follow developments and evaluate the realisation of objectives and other strategic aspects.

The period up until the review is intended to be used to evaluate the actual results of the new legislation, the freedoms, the restrictions, the functionality of the new regulatory system, etc. and to gain knowledge as to whether they are efficient and sustainable.

This can then be done in light of actual knowledge of the state's ownership strategy regarding Apoteket AB, where the Inquiry presents various scenarios. Further, in this phase it should be possible to see enough contours of which actors start up in the market after regulatory reforms and thereby reach conclusions regarding the realisation of objectives, functions in the transparency system, division of discount margins between public authorities and pharmacies, etc.

In this way necessary adjustments and additions in legislation can be made in light of actual developments, evaluation results and proposals from supplementary inquiries.

In addition, this approach creates scope for building up learning and expertise at the government agencies with decision-making, supervision and control functions in a re-regulated pharmacy market.

The need for subsequent inquiries

Today's pharmacy system contains a number of solutions that are considered to have shortcomings, applications and practices that require clarification etc., which have been under discussion for varying lengths of time. Several issues are complex and in certain cases there is no common view as to how to formulate a new proposal.

A number of these kinds of issues have been channelled to the Inquiry in the hope that it will be able to present proposals.

In view of the time frame at its disposal, the Inquiry has chosen to give priority to the most central issues. This means that the issues mentioned will be carried over into the re-regulated system to be solved there by subsequent inquiries. Priority has been given to issues considered to be of crucial importance to re-regulation.

Confidence regarding cost control during the start up

Substantial changes should not be made to regulations and decision-making processes for pricing in the patent-protected pharmaceutical segment. This segment is the substantially largest cost item of the pharmaceutical benefit scheme.

Regarding the pharmaceutical segment without patent protection with generic competition, it is proposed that a robust model, tested in a competitive environment, be introduced and used during the start up phase. The model will allow adjustments and can be set so that the profits realised by society through the generic reform are retained, which is verified through the simulations carried out by the Inquiry.

The model also means that the current monthly changes in the generic selection can be replaced by a selection strategy that provides greater continuity, so that the extra compensation for additional costs regarding the changes that Apoteket AB currently receives can immediately be dispensed with. This also means fewer changes for customers.

Proposals will be presented on price pressure, transparency regarding purchase discounts and the division of these between pharmacies and public authorities, which is expected to lead to reduced costs for public authorities as early as during the implementation phase. The overall cost reduction during the first year is estimated at SEK 110 million, and during the second year an additional SEK 80 million is expected to be saved.

The Inquiry proposes a system for compensation to pharmacies that allows good predictability and control over costs for the services financed by society that pharmacies are required to carry out.

The Inquiry has paid considerable attention to the price pressure goal contained in its terms of reference and proposes following a cautious strategy with robust tools for cost controls during the implementation phase.

International industry trends

A number of interesting changes are occurring in the international pharmacy and wholesale markets. On the one hand, this development is characterised by an increased abundance of variety with regard to forms of distribution, such as direct sales from industry to pharmacies and medical services, specialised wholesalers and pharmacies, providing deliveries from a distance and new logistical solutions. On the other hand, the market is characterised by larger concentrations in both the pharmacy and wholesaler segments and integration in commercial chains.

It is becoming more common for pharmacies to receive compensation from both negotiated discounts on generic and parallel imports, and to receive compensation for each prescription filled or for each package sold.

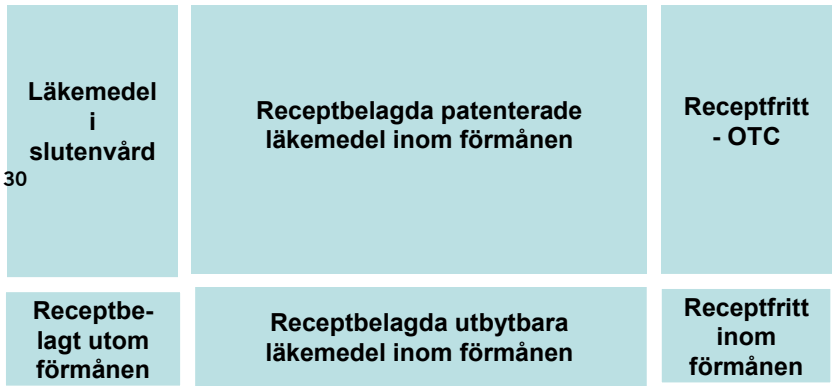
In Europe, consolidation among wholesalers is taking place. From 1990 to 2004, the number of wholesalers with complete selections fell from 600 to 150. In 2004, the three largest wholesalers had 46 per cent of the market in the EU as it was at that time (22 countries). At the same time, it is becoming more common for wholesalers to build up pharmacy chains of their own with pharmacies that they either own or are linked to through franchising or other contract-related models. This development means that more pharmacies are owned by companies and that both horizontal and vertical integration is growing in scope.

Mail order solutions, which stand for about 20 per cent of the American market, are now growing in Europe as well. In some countries, such as the Netherlands, Germany and Switzerland, the market share is 5–8 per cent.

Medicinal products market segment

In all, sales of medicinal products amounted to some SEK 31 billion in 2006. Price formation works according to completely different kinds of logic in different segments of the supply of medicinal products. The largest segment by far is made up of medicinal products with active patents that are prescription products. In 2006, this segment stood for some SEK 20 billion. The next largest segment was the use of medicinal products in inpatient care, which spent nearly SEK 6 billion. Generically interchangeable products accounted for over SEK 3 billion and non-prescription sales covered nearly SEK 3 billion. In addition, there are two smaller segments, one made up of prescription medicinal products that are not included in the benefits scheme and are therefore paid in full by the consumer, and finally non-prescription medicinal products that are prescribed and therefore are covered by the pharmaceutical benefits scheme.

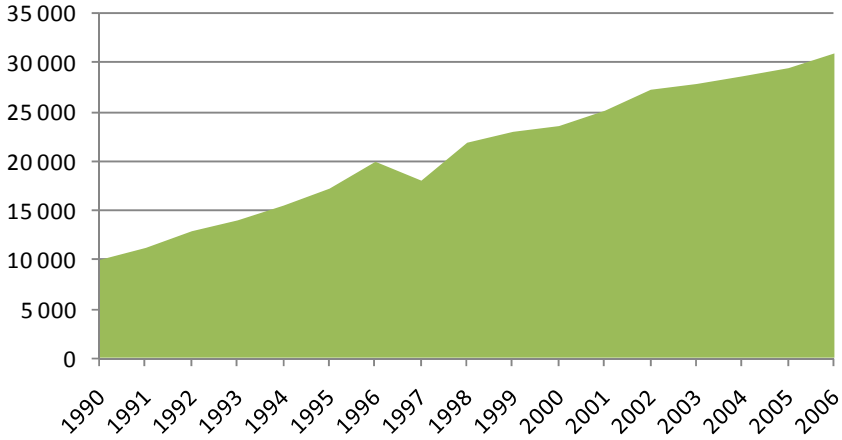
Figure 1



Costs of medicinal products in Sweden

The overall costs for Swedish medicinal products increased rapidly during most of the 1990s, but the rate of increase levelled off from 2002 and onwards.

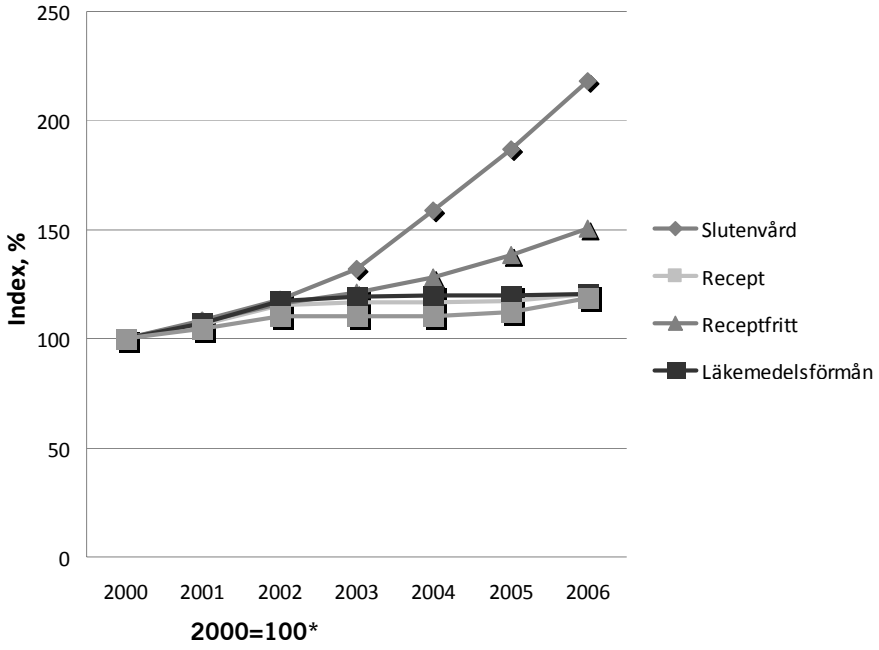
Figure 2 **Costs for medicinal products 1990–2006, SEK million**



Studies of which factors were behind the sharp increase in costs for medicinal products during the 1990s indicated two important components: an increasing volume of medicinal products consumed and a shift from using older, cheaper medicinal products to new, innovative products. The shift in the selection to more expensive medicinal products was the factor that drove the cost increase the most.

Since 2002, sales in the prescription medicinal products segment have remained relatively stable, while sales of non-prescription medicinal products and inpatient care have continued to increase.

Figure 3 Changes in costs for medicinal products 2000–2006, where



*) The graph displays the cost growth in variable prices as an index since 2000.

In the next few years, the costs for pharmaceutical benefits are expected to increase more rapidly than in recent years. The National Board of Health and Welfare estimates that the rate of cost increases will rise by 3.5 per cent in 2007. During 2008–2009 the cost increase is expected to be about 4.5 per cent and somewhat higher in 2010 and 2011.

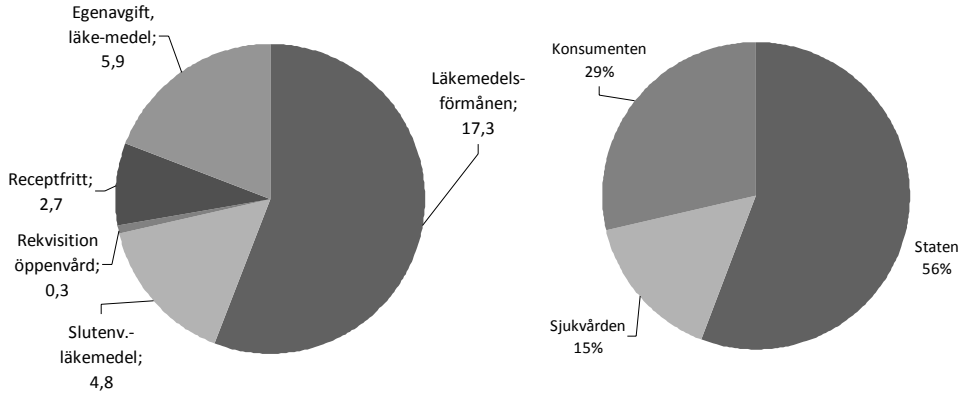
The National Board of Health and Welfare gives the following as the primary reasons as to why the costs are being pushed up:

- fewer major patents expire,
- more medicinal products are expected to be introduced,
- the volume is expected to increase in light of underlying factors such as the age structure and living habits of the population,
- fewer medicinal products are expected to be transferred to inpatient care.

Financing costs of medicinal products

Public funds, from the state and county councils, cover about 71 per cent of the total costs for medicinal products in Sweden. This is a higher percentage than the average in the OECD, which was 61 per cent in 2006. All of the Nordic countries except Iceland are close to or under the OECD average regarding tax-financed medicinal products. Of the 29 öre of the 'medicinal products krona' that the public is responsible for, 21 öre (70 per cent) go to prescription medicinal products and 9 öre (30 per cent) go to self-care products.

Figure 4

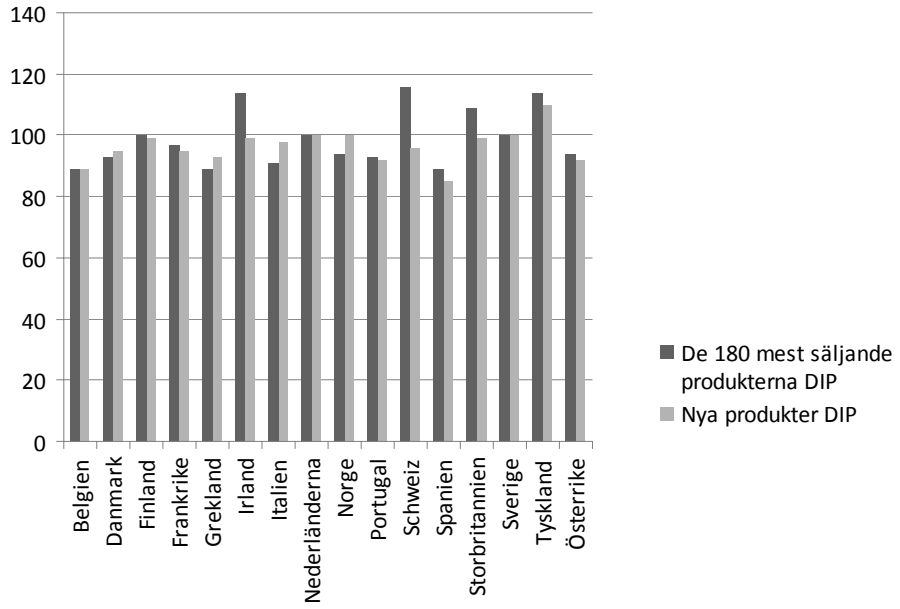


Price comparisons with other countries

For many reasons, it is technically difficult to make exact price comparisons between countries. There are a number of systems used to establish prices and the systems have changed considerably in recent years. The patterns of using medicinal products also differ dramatically from one country to another – different preparations are prescribed, and there are different strengths and different package sizes for one and the same preparation. The Inquiry has had access to several analyses, and this summary refers to an OECD analysis published in 2007.

The OECD concludes that the prices obtained by manufacturers in the Swedish market are, by European standards, high within the market segment subject to patents, and that it is only in Germany that manufacturers receive higher prices than in Sweden for new medicinal products.

Figure 5 **Differences in the drug trade's average purchase prices (DIP) for medicinal products in 16 European countries (Sweden=100)**



The varying results in the different ways of making international price comparisons invite the use of caution regarding conclusions.

The following sums up the Inquiry's point of departure, which forms the basis of the analyses and proposals:

Original medicinal products with active patents

Sweden has low, among the lowest, prices for medicinal products on the customer side, or AUP.

Purchase prices to Apoteket AB, called AIP, are average when compared to European standards.

The medicinal products industry's sales prices, or DIP, are comparatively high.

Generically interchangeable medicinal products

Sweden has relatively low prices for medicinal products on the customer side, AUP

When it comes to AIP and DIP, Sweden is at an average European level.

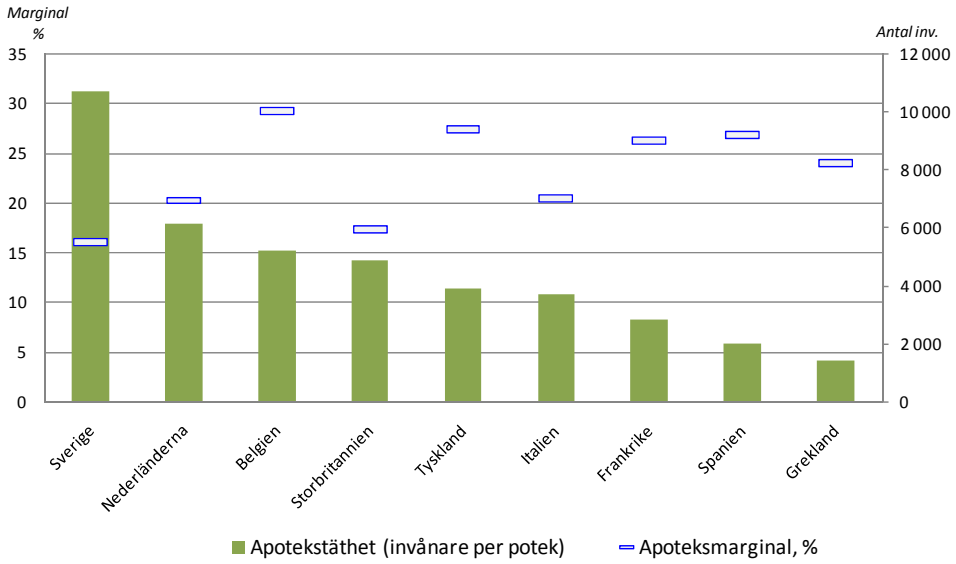
The retail trade

According to Apoteket AB, there were 870 outpatient pharmacies in Sweden in 2006. The 870 pharmacies' sales in AUP (income) varied from SEK 0.9 million to SEK 245.7 million. The average sales figure per pharmacy was SEK 32 million. In 2006, sales figures for the median pharmacy were just over SEK 25 million.

The total margin (compensation from the pharmaceutical benefits scheme) for all pharmacies amounted to SEK 3.6 billion for medicinal products and almost SEK 0.3 billion for other products covered by the benefits scheme.

In 2006, the margin for pharmacies in Sweden was 16.4 per cent measured as a percentage of the purchasing price for prescription products. This is low from an international perspective. The following comparison is based on a European study from 2007.

Figure 6 Pharmacy margin and pharmacy density



This comparison is to be interpreted with a good deal of caution since information from pharmacies can vary greatly from one country to another. On the surface, the graph could be interpreted to mean that pharmacy margins tend to rise with increased pharmacy density. Sweden, with the lowest pharmacy density, also has the lowest pharmacy margin of these countries. Other factors also play a part. In the UK for example, pharmacies are to carry out certain expanded healthcare services, but have insignificantly higher margins than in Sweden, and pharmacy density is twice as high.

In Sweden there are 10 700 persons per pharmacy. Only Denmark has lower coverage (16 800 persons per pharmacy). The median of the 25 European countries that submitted data is 3 900 persons per pharmacy. In the UK, the figure is nearly 5 000 persons per pharmacy. After re-regulation of the Norwegian pharmacy market, the number of persons per pharmacy dropped from 11 540 to 8 098.

Price formation mechanism

General requirements

In a study on price regulations in the UK published in 2007, the British Office of Fair Trading (OFT) summarised that the following criteria and requirements should be established for effective pricing.

- The system should produce economic efficiency.
- It should be functional, adaptable and strike a reasonable balance between flexibility and stability for stakeholders.
- It should be transparent and provide society and stakeholders with good insight into price formation.

The Inquiry agrees with this view and, further, considers that criteria to be fulfilled include:

- creating mechanisms that give public authorities control over the development of costs for medicinal products,
- creating incentives for global manufacturers to supply medicinal products in Sweden,
- creating incentives for research and development in cooperation with Swedish basic and clinical research and development,
- creating scope for new, more effective and probably more expensive medicinal products within a limited socio-economic framework,
- creating a balance between costs for medicinal products and other health and medical care resources, and
- creating stimulus for the safe use of medicinal products based on patient benefit and good management.

Mechanisms for price pressure

The Inquiry's terms of reference and goals include elements that generate pressure on increased costs for the distribution of medicinal products, such as greater accessibility, a better range of services and, possibly, increased costs for supervision in a more dynamic market with more actors. The patient and consumer perspective should be strengthened.

The Inquiry's assessment is that the factors that generate costs can be managed.

Several international studies indicate that there is value in giving pharmacies a mandate to constitute a commercial counterweight to the medicinal products industry and to be able to negotiate their purchase prices. The OECD report and others also show there is potential for lower purchase prices. The Inquiry has chosen to provide pharmacies in the re-regulated market with this instrument so as to achieve increased price pressure.

For the negotiations to be successful, it is of vital importance to be able to link prices to guaranteed volumes, to be able to approach different suppliers, to have access to an efficient logistics service and to have knowledge of the European price and supplier situation. For these and other reasons, the Inquiry sees no reasons for setting obstacles for pharmacy actors that have these capabilities, but instead sees them as a necessary commercial counterweight to pharmaceutical companies.

Pricing and business logic

The pricing model is based on the classification that the Medical Products Agency assigns to medicinal products in exchange groups. This classification is based on medical criteria and concerns the possibility of exchanging medicinal products with one another. There are a large number of these kinds of groups while the number of medicinal products included in them varies.

On the basis of this classification, two price models are defined that are based on the business logic created:

a. existing active patents,
b. expired patents and stable generic competition.

Competition and price pressure occurs in segment *a* when parallel imported or parallel distributed medicinal products that are interchangeable with the original exist.

Competition and price pressure occurs in segment *b* when patents expire and stable access to generic copies is available on the market.

Interchangeability is based on medical criteria while patent/non-patent is the business logic dimension of the price model.

Pricing models in summary

The Inquiry proposes that some of the key cornerstones of the current price model be left unchanged. These include:

- The role of medical services in the pricing system and the responsibility of county councils for costs should be maintained. Even though the OECD considers that there is no clear evidence regarding effects, the Inquiry feels that additional time must be given to develop clear control mechanisms in healthcare. The Inquiry considers that the county councils' responsibility for costs and its role in the pricing process will improve the conditions for the qualitative control and appropriate use of medicinal products.
- The Pharmaceutical Benefits Board should set the pharmacies' retail prices (AUP) for all medicinal products covered by the benefits scheme. The prices of medicinal products that the Pharmaceutical Benefits Board decides are to be covered by the benefits scheme should be uniform throughout the country. As before, the Pharmaceutical Benefits Board should decide if a medicinal product is to be covered by the pharmaceutical benefits scheme.
- The current high-cost protection scheme for consumers should be maintained and thus remains unchanged by the Inquiry's proposals.
- Prices for medicinal products with active patents should be set by the Pharmaceutical Benefits Board on the basis of a cost-benefit principle. A government price agency would enable pricing with a uniform price model and price level across the country.
- The obligation to supply should be retained for all prescription medicinal products.
- Pricing of non-prescription medicinal products that are not covered by the benefits scheme should, as before, be free.

The following are new central mechanisms whose introduction is proposed with regard to the re-regulation of the pharmacy market:

- When a medicinal product has stable generic competition, the Pharmaceutical Benefits Board should lower the pharmacies'

retail price (AUP) by a specified percentage according to a *benefits price model for exchange groups*. In the first stage of re-regulation, when a new pharmacy market is being established, pricing should be done with consideration to society's need of security as regards control of the overall costs. In a second stage, when a new pharmacy market is established, more dynamic pricing should be introduced.

- The Inquiry's proposals would allow pharmacies to develop a business model that includes negotiation of purchase price with manufacturers/wholesalers, which will mainly have an impact on medicinal products that are interchangeable, i.e. medicinal products with stable generic competition and parallel imports.
- Part of the larger trading margin that results from the right of pharmacies to negotiate purchase prices, to be set by the Government, should be transferred to public authorities and consumers by means of lower AUP prices and/or adjustments to compensation to pharmacies.
- Price formation should therefore also be transparent by means of obligatory reports to the Pharmaceutical Benefits Board concerning manufacturers' prices to wholesalers/pharmacies (DIP) regarding prescribed medicinal products covered by the benefits scheme.
- Compensation to pharmacies should be changed. It should be replaced by a set compensation per customer served. Pharmacies should also be compensated through a set annual basic compensation. This will create a neutral compensation system regardless of a product's price.

In the system for pricing proposed by the Inquiry, compensation to pharmacies also acts as a regulator to transfer some of the results of streamlining and price negotiations between pharmacies and manufacturers to public authorities. So as not to disturb the current balance between social security contributions and benefits, the Inquiry proposes that the compensation received by pharmacies for filling prescriptions and other services be decoupled from the pharmacy surcharge that is to be included in the consumer price (AUP).

As previously mentioned, the Inquiry recommends that the re-regulation be carried out in two stages. During a first, two-year

introductory stage, the Inquiry proposes a number of robust, tested mechanisms that will provide public authorities with good control over developments. During this phase, when the new market is being established, more sustainable and dynamic mechanisms should be developed that take note of the actual market situation that is evolving.

This kind of mechanism is a model that is sustainable over time, which means that some of the larger trading margin that pharmacies can negotiate should be of benefit to public authorities and consumers. The Inquiry presents some recommendations that can be put to use during a two-year introductory stage, but suggests that the Government commission a report and take a decision on a general mechanism to be used after that period.

Permission to conduct retail trade in medicinal products

The Inquiry proposes that business operators who intend to conduct retail trade in medicinal products should apply to the Medical Products Agency for a licence for the enterprise. A licence of this kind should be valid indefinitely and entail a general right to conduct retail trade in medicinal products. Accordingly, a licence for each individual pharmacy should not be required. There should, however, be an obligation for the licence holder to report where pharmacies will be located to the Medical Products Agency. Reports should also be made as to who will be responsible for medicinal products and when significant changes are made in the enterprise.

It is the Inquiry's assessment that a person who applies for a licence to conduct retail trade in medicinal products should not be required to have pharmaceutical qualifications. There should, however, be staff with pharmaceutical qualifications on the pharmacy premises during opening hours, and all pharmacies should have access to someone who is responsible for medicinal products and who sees to it that the enterprise is conducted in accordance with the regulations that apply to the sale and handling of medicinal products. The person who is responsible for medicinal products should be a pharmacist or someone with pharmaceutical training who has sufficient qualifications and experience for the task. As a rule, a person who is responsible for medicinal products should have responsibility for at most three pharmacies.

The Inquiry considers that, in connection with a re-regulation of the pharmacy market, there is a risk that there may be a shortage of pharmacists and that measures should be taken to avoid a shortage of this kind.

Under certain conditions, it should be possible to revoke a licence. Conducting retail trade in medicinal products without a licence and neglecting to submit an application to the Medical Products Agency should be punishable. A person who applies for a licence should pay an application fee, in an amount determined by the Government.

Obstacles to ownership of a pharmacy

For various reasons, primarily in the interest of protecting public health and maintaining low costs for medicinal products, there should be restrictions as to who should be eligible for a licence to conduct retail trade in medicinal products. The Inquiry proposes that the following should not be eligible for a licence:

- manufacturers of medicinal products, except where manufacturing refers to mechanical dose dispensing, manufacturing of extemporaneous preparations or manufacturing of preparations to be kept in stock,
- the marketing authorisation holder of a medicinal product, and
- prescribers.

Nor should some legal persons who, typically, have strong common interests with the aforementioned actors, such as parent and subsidiary companies, be eligible for a licence to conduct retail trade in medicinal products. The Government, or an authority designated by the Government, should be allowed to grant exemptions from these restrictions if there are special grounds for doing so.

Supervision and control

The Medical Products Agency should have supervision over retail trade in medicinal products. As is presently the case, pharmacy staff should be under the supervision of the National Board of

Health and Welfare. Supervision by the Medical Products Agency should be financed by an annual fee charged to licence holders.

With the aim of both facilitating and streamlining supervision by the Medical Products Agency and ensuring the quality of the sale and the handling of medicinal products, the Inquiry proposes that each licence holder should exercise their own supervision of the sale and handling of medicinal products and implement a control programme of their own that is suitable to their enterprise.

Requirements concerning pharmacy premises, equipment etc.

Pharmacy premises should be designed, furnished and equipped so that they are suitable to their purpose and in such a way as to secure a high level of security and good quality in the enterprise. The Government or the Medical Products Agency may issue further regulations on this issue.

Supply of medicinal products (accessibility)

The Inquiry proposes that pharmacies should have an obligation to be able to provide all prescribed medicinal and other products. When it is possible to exchange a medicinal product, the pharmacist should fill a prescription with an interchangeable product instead of the product prescribed. The pharmacist should provide the prescribed medicinal product if the prescriber opposes an exchange or if the consumer chooses to purchase the product prescribed.

Pharmacies should not be obligated to provide all non-prescription medicinal products. Nor should there be an obligation for pharmacies to be able to deliver medicinal products from a distance throughout the country or to have pharmacy agents.

As long as no part of Apoteket AB has been sold and the company has a completely dominant position in the market, the company should be required to maintain the national pharmacy coverage at its present level. In connection with the sale of parts of Apoteket AB, new actors in the market should be required to assume responsibility for pharmacy coverage. The responsibility for pharmacy coverage should be limited in time for both Apoteket

AB and other actors. After a certain period of time consideration should again be given to whether special measures are required in order to satisfy the supply of medicinal products.

The Inquiry does not propose any regulations on the longest acceptable period of time for pharmacies to provide medicinal products or on pharmacy opening hours, range of products or stock capacity.

IT infrastructure

In 2008, a transitional solution should be set up that involves separating the databases, registers and systems that are proposed to be accessible to all pharmacies from Apoteket AB and temporarily placing them in a newly-formed subsidiary. Before the end of 2008, the subsidiary should be detached from Apoteket AB so that as of 1 January 2009 it is an independent wholly state-owned company, here called Apotekens Servicebolag AB. Further consideration should be given to the specific details as to how this should be done.

Apotekens Servicebolag AB should assume responsibility over personal data for the prescription register and the list of medicinal products from Apoteket AB. Apotekens Servicebolag AB should also assume responsibility for the high-cost protection database, the prescription mailbox for electronic prescriptions, the prescription register for electronically saved prescriptions, the dose database and the consent register. The company should also assume Apoteket AB's responsibility for the register of workplace codes.

The field of application for the Prescription Register Act (1996:1156) should be expanded to include all medicinal products and other products that are prescribed for people, regardless of whether or not they are covered by the Act on Pharmaceutical Benefits, etc. (2002:160). The personal data in the prescription register should also be available for use in dispensing medicinal products and other products that are prescribed. Further, the prescription register should be available for use when registering electronic prescriptions.

As regards purchases of prescription medicinal products, each pharmacy should instantly provide information electronically regarding such matters as the day of purchase, product, amount, dose, cost and cost reduction according to the Act on

Pharmaceutical Benefits etc., reason for the prescription, the patient's name and personal identity number. Every pharmacy should have the technical equipment necessary so that the information can be transferred in this manner. If a pharmacy does not report this information or if it does not have the technical equipment necessary for submitting reports in the prescribed manner, the licence to operate a pharmacy may be revoked.

The provisions on the obligation to provide information regarding Apotekens Servicebolag AB should be included in the Prescription Register Act. Dispensing staff at pharmacies should have direct access in the prescription register to information on dispensing medicinal products and other products that have been prescribed, background data for high cost protection and dose prescriptions, iterative prescriptions and electronic prescriptions. Regarding the list of medicinal products, information should only be provided to a pharmacist at a pharmacy, as is the case at present.

It is proposed that special provisions be set for Apotekens Servicebolag AB and pharmacies regarding assigning authorisation and access controls. Special obligations to observe confidentiality are proposed for Apotekens Servicebolag AB staff.

Each pharmacy should deliver statistics regarding all sales of medicinal products and certain other products. Anyone who sells medicinal products to those responsible for medical services, hospitals or other medical institutions should provide statistics of this. The same should apply to all sales of vaccines and serums. If the obligation to provide information is not fulfilled the licence to conduct trade in medicinal products may be revoked.

Apotekens Servicebolag AB should take over responsibility for the compilation of national pharmaceutical statistics which at present rests with Apoteket AB. The obligation to supply information to authorities and county councils which at present is the responsibility of Apoteket AB should instead rest with Apotekens Servicebolag AB.

The Inquiry considers that the establishment of a special law on internal handling of personal data at pharmacies should be considered.

Some services and functions that are currently provided by Apoteket AB

Apoteket AB is currently responsible for certain services and functions that will also be needed in a re-regulated pharmacy market. The Inquiry has presented proposals as to how these are to be provided and how to ensure that these services are available even after the pharmacy market has been changed.

Every pharmacy should be able to offer customers part payment of medicinal products and other products covered by the Act on Pharmaceutical Benefits, etc. Pharmacies should be able to determine the details of how the system of part payments is to be designed, with the stipulation that the client must have the right to pay off the debt in regular instalments over a one-year period. The part payment systems should be financed by the pharmacies.

Each pharmacy and wholesaler should have a printed method for processing complaints and an effective system for discontinuation of medicinal products.

Upon request, pharmacies should be able to issue 'Schengen certificates', i.e. a certificate to allow the transport of narcotic preparations for medical treatment in the Schengen area.

As is the case at present, each pharmacy should provide information and advice on medicinal products, the use of medicinal products and self-care products to private customers that is adapted to the needs of the individual and producer-independent. Unlike today, however, the Inquiry considers that there should not be an obligation for pharmacies to provide information to prescribers. It is considered that information of this kind can be provided through channels other than pharmacies.

Every pharmacy should accept discarded medicinal products from the public and arrange for their transport to processing facilities. Every pharmacy should also provide information to the public on why discarded medicinal products should be handed in and where this can be done.

Apoteket AB should no longer have the task of operating the Swedish Poisons Information Centre. It should instead be operated in the form of a limited company as a subsidiary to SOS Alarm Sverige AB, of which the state owns one half and municipalities and county councils own the other half. The activities of the Swedish Poisons Information Centre should be regulated in an

agreement between the state and the company, and financed through compensation from the state.

In a re-regulated pharmacy market, the responsibility of Apoteket AB for the provision of certain vaccines and antidotes, and the provision of medicinal products to Sweden's total defence, should be procured by the National Board of Health and Welfare, the Swedish Armed Forces or other relevant government agencies.

Dose dispensing

The basic requirement for carrying out mechanical dose dispensing is a manufacturing licence issued by the Medical Products Agency. The Inquiry proposes that, if certain requirements are met, parties who conduct retail trade in medicinal products should instead be eligible for a special licence for mechanical dose dispensing at pharmacies, issued by the Medical Products Agency. Neither a manufacturing licence nor a special licence is required for mechanical dose dispensing.

A licence should entail the general right to conduct mechanical dose dispensing. It should be valid indefinitely. The licence holder should report to the Medical Products Agency where mechanical dose dispensing will be conducted and any significant changes in the enterprise. Failure to submit a report of this kind within the prescribed period of time should possibly lead to the revocation of the licence to conduct mechanical dose dispensing. It should also be possible to revoke the licence when certain other conditions exist. It should be punishable to intentionally or through negligence conduct mechanical dose dispensing without a licence, or to neglect to report where mechanical dose dispensing will be conducted and any significant changes in the enterprise.

Provision of extemporaneous and licensed medicinal products

Every pharmacy should be able to provide all prescribed extemporaneous and licensed medicinal products. It should not be required that every pharmacy be able to manufacture extemporaneous medicinal products on their own.

Within the framework of what is regulated by the Medical Products Agency, pharmacies should be able to decide on their own how the organisation of production, distribution and provision of extemporaneous and licensed medicinal products is to be arranged. Pharmacies themselves should be responsible for financing.

So as to ensure access to extemporaneous medicinal products in a re-regulated market, Apoteket AB should be obligated to manufacture and, at cost price, deliver extemporaneous medicinal products to pharmacies during a transitional period.

Distance commerce with medicinal products

It is proposed that no restrictions be established as to which medicinal products may be the object of distance commerce. Accordingly, both prescription and non-prescription medicinal products should be available for purchase from a distance.

Pharmacies should be responsible for ensuring that processing of distance commerce is conducted in such as way that the preparation does not harm people, property or the environment, and that the quality of the preparation is not impaired.

The pharmacy should be responsible for ensuring that the dispensing of medicinal products following a distance order is arranged so that it is equally as secure as dispensing of medicinal products at pharmacies.

Age limits for purchasing non-prescription medicinal products and authorisation certification

An age limit regulated by law should not be introduced for the purchase of non-prescription human and veterinary medicinal products. The primary reasons for this are that an age limit would infringe upon the possibilities for young people to engage in self-care and involve the risk of young people not having access to treatment when necessary or that treatment is unnecessarily delayed. The need to protect young people whose intention is take an overdose of medicinal products should be met in another manner.

In a second stage of its work, the Inquiry will present proposals on allowing the sale of a limited range of non-prescription

medicinal products at locations other than pharmacies. When presenting proposals at that stage, the Inquiry will again analyse the issue of age limits for the purchase of non-prescription medicinal products.

Section 22 of the Medicinal Products Act makes it evident that there is an obligation upon whoever dispenses a medicinal product to ensure that it is dispensed to an authorised person. A provision on how authorisation is to be established should not be introduced.