

# Summary

The inquiry's remit has been to conduct a review of the pharmacy market. The emphasis has been on bringing about safe, efficient and equal supply of medicines and a pharmacy market notable for good availability and level of service. In accordance with the Terms of Reference, there has been a special focus on measures aimed at enhancing quality and patient safety in the pharmacy market.

## **Trends in the pharmacy market**

The inquiry has analysed how the community pharmacy market as such has developed since re-regulation, and has assessed ongoing trends in the market.

## **The pharmacy market has matured**

On 31 December 2016 there were 1 392 physical community pharmacies in Sweden, compared with 929 when the market was re-regulated in 2009. At the start of 2017, there were around 40 different players in the market, varying in size and orientation and with differing ownership.

Just over 30 of these players are small independent pharmacy companies with their own brands, which together run around 40 pharmacies. There are currently around 177 pharmacies in the small-business chain Apoteksgruppen. This can be compared with the situation in 2013, when there were 18 independent players in the market with 25 pharmacies, as well as Apoteksgruppen with 159 pharmacies.

The table shows the pharmacies' combined revenue in 2009–2016 in the community pharmacy market, broken down into three main categories.

**Community pharmacy market revenue 2009–2016, SEK billion**

	2009	2013	2014	2015	2016
Prescription-only medicines	24.6	25.7	26.8	28.7	30.0
Non-prescription medicines	3.6	3.7	3.7	3.8	4.0
Merchandise and services	3.2	4.5	5.2	5.6	6.1
<b>Total</b>	<b>31.4</b>	<b>33.9</b>	<b>35.7</b>	<b>38.1</b>	<b>40.1</b>

According to the inquiry, the pharmacy market today can be described as a market that, in many respects, has matured. The rate at which new pharmacies are established has stabilised at a level of just over two per cent per year, and all large pharmacy market players since 2015 have been engaged in e-commerce with medicines at national level. Following changes of ownership in 2013–2015, none of the market players are now owned by investment or venture capital companies. Nor does Apoteket AB occupy a special position in the market any longer.

### **Broadening of the product range and new services in pharmacies**

There has been steady broadening of the product range in the market since the re-regulation. Sales of merchandise by pharmacies have increased from SEK 3.2 billion in 2009 to SEK 6.1 billion in 2016. The share of merchandise in pharmacy sales has also risen. Today, there is a more extensive range of different types of merchandise and a higher proportion of own brands. Changes in store concepts and new pharmacy services can also be regarded as aspects of this trend. Supply, information and counselling on prescription-only and non-prescription medicines remain the core business of pharmacies, despite the broadening of the product range, and account for 85 per cent of sales.

In Sweden there are two types of licensed pharmacists, pharmacists and prescriptionists. In this summary the term pharmacist will be used for both unless otherwise stated. There are

many different types of services in pharmacies today: services provided by pharmacists, services linked to health and healthcare and services that can improve accessibility. Some services are provided on payment of a fee and some are free of charge. A new phenomenon is that pharmacies, in cooperation with companies that provide health care services, offer services with access to doctors. The total extent of such services is small, with sales estimated at a total of around SEK 10 million per year. Most services are offered at a limited number of pharmacies, but personal medication counselling is offered at many pharmacies. The inquiry takes the view that pharmacy services at the start of 2017 are still a relatively undeveloped area.

### **Ongoing trends in the pharmacy market**

The clearest trends in the pharmacy market, according to the inquiry, are rapid growth in e-commerce, a focus on merchandise and store profiling and recently started cooperation between pharmacies and companies that provide health care services. Pharmacies' e-commerce with medicines and other goods increased by almost 70 per cent in 2016, to SEK 1.7 billion. This is equivalent to 4.2 per cent of total revenue. The inquiry estimates that in 2020, e-commerce will account for roughly 8–15 per cent of combined pharmacy revenue.

### **Quality and safety in pharmacies**

The Government has stressed that the role of pharmacies in better use of medicines should become more pronounced. However, there is a lack of a cohesive description of the remit and responsibilities of pharmacies. The inquiry therefore considers there to be a need to define the basic remit of pharmacies more clearly.

## **Basic remit and principal tasks of pharmacies clarified**

The inquiry proposes that the basic remit of the pharmacies should be to supply medicines in a safe manner and promote good and cost-effective use of medicines. The principal tasks should be to

- ensure that consumers obtain access to medicines and other products as quickly as possible
- provide individually adapted information and advice
- where appropriate, carry out substitution of medicines and inform the patient that substitution is applicable and of the patient's right, in return for payment, to receive the prescribed medicine or some other substitutable medicine.

This creates a uniform picture of what requirements have to be met by pharmacies and what can be expected of the publicly funded portion of pharmacy operations.

## **Better quality in counselling on use of medication**

The inquiry has analysed reported shortcomings in counselling given at pharmacies, and proposes several measures to raise the quality of counselling provided and strengthen the role of pharmacies in improving the use of medicines.

Only pharmacists should be allowed to provide information and counselling when prescribed medication is dispensed. Dispensing of prescribed medication should be viewed as a cohesive process in which a pharmacist must take responsibility for all aspects. This improves quality and safety in dispensing and improves the prospects of appropriate counselling being given when prescribed medicines are dispensed. Pharmacies' responsibility for providing individualised information on substitution of medicines is clarified in law.

One of the pharmacies' important community tasks is to guide consumers in choosing between self-medication with non-prescription medicines or other products or to refer them to the appropriate level of care. The inquiry considers the present-day quality of advice on self-medication to vary widely between

pharmacies, and therefore proposes that at least expertise as a pharmacy technician or equivalent should be required for this task. This ensures a minimum level and standard for advice on self-medication.

The duty of a pharmacist to ensure, in dispensing prescribed medicines, that the consumer is able as far as possible to use the medication correctly should be raised from the regulatory level and made a statutory requirement. Regulations should consequently specify more closely what is required to fulfil this duty. The inquiry has described what should be included in the pharmacist's duty to check and advice. Special regulations should specify what is required of pharmacies engaged in e-commerce with regard to counselling, but a fundamental principle is that all pharmacies are covered by the requirements. This regulatory framework clarifies the advisory duty and the role of the pharmacies in how medication is used.

The dialogue between the pharmacist and the patient often takes place over a limited period of time. Also, patients are not receptive to inordinate amounts of information. These challenges make heavy demands on the ability of the pharmacist to communicate, and training courses for pharmacists today do not fully address the needs that exist. The inquiry therefore proposes that the requirements for awarding degrees to both pharmacists (*apotekare*) and prescriptionists (*receptarier*) should be supplemented by a requirement to be able to provide individualised information and counselling on medicines. This ensures provision of the necessary expertise and improves the prospect of pharmacies contributing to better use of medication. The inquiry also considers that the development of skills for pharmacy staff should tie in to a greater extent with the principal remit of the pharmacies, to ensure that the conditions necessary for safe dispensing and for providing counselling in connection with the dispensing of medicines and self-medication are met.

The design of the environment in which counselling is provided, in terms of protection of the consumer's personal privacy, is crucially important in enabling the pharmacist to fulfil the duties of dispensing and counselling. Regulations that lay down requirements for pharmacy premises have not been fully effective in practice. The inquiry therefore proposes that these requirements

be clarified in law. This would improve the prospects of the application of the rules having a practical effect, so that the pharmacies can improve the counselling they give and consequently make a greater contribution to better medication use.

### **Strengthening and clarifying the role of local quality manager**

The local quality manager (*läkemedelsansvarig*, LMA) has overall responsibility for quality in pharmacies. The inquiry has analysed the role of local quality manager and notes that it has not been fully effective in ensuring good quality and safety in the pharmacy market. It is therefore proposed that the role be clarified and strengthened. Both dispensers and pharmacists should be required to have professional experience and have completed local quality manager training in order to become local quality managers. The role should be regarded as senior and be staffed by pharmacists who have in-depth knowledge and expertise on the requirements to be met by pharmacies. A requirement should also be introduced for a local quality manager to have influence on how the pharmacy operation is organised. Taken together, this is expected to strengthen the significance of the role of the local quality manager in the quality and safety of the pharmacy operation.

### **Stricter requirements for pharmacy licences**

Several of the inquiry's proposals presented above mean that the requirements to be met in order to obtain a pharmacy licence will need to be stricter. However, the trend towards close cooperation between companies that provide health care services and community pharmacies being established necessitates a review of who is allowed to own a pharmacy and of the options for pharmacies to own and cooperate with care services companies. It is proposed that the Medical Products Agency be tasked with investigating this issue.

## **Indicators to measure and follow up pharmacy activities**

Further incentives are needed to encourage active work on quality and safety in the pharmacy market. It is therefore proposed that the Dental and Pharmaceutical Benefits Agency be tasked with developing indicators to measure and continuously monitor and analyse the pharmacy market on the basis of the expectations of the general public. This will increase the focus on development and quality in those elements that the indicators measure, which should be aspects of the operation that contribute benefit to the community.

## **Research, development and pharmaceutical services**

The inquiry considers research to be an important foundation on which to develop the role of pharmacies for better use of medication. Research and development activity focused on pharmacy operations and patients' use of medication from a broad societal perspective has decreased significantly since re-regulation. When the research and development activity of Apoteket AB was transferred to the Medical Products Agency, it became part of a broader operation, and the scope for research and development on the contribution of pharmacies to better medication use was consequently reduced. To compensate for Apoteket AB's pure research being closed down, the Swedish Research Council was allocated funds equivalent to SEK 4 million annually, starting from 2010, for research in pharmaceuticals. Over the period 2011 to 2015, the Swedish Research Council made a total of 20 grants from the special appropriation, but none linked to community pharmacy.

## **Strengthened research on the contribution made by pharmacies to safe and cost-effective medication use**

The inquiry proposes that the resources currently allocated by the Swedish Research Council to pharmaceuticals should instead be allocated to research in social pharmacy. This encourages research linked to the contribution made by pharmacies to safe and cost-effective medication use and improves the prospects of new

working practices in pharmacies being tried out and systematically evaluated. In the long term, it can make a valuable contribution to improving the role of the pharmacies in the use of medicines and collaboration between pharmacies and the healthcare system. The inquiry further considers that the Swedish Pharmaceutical Society should convene representatives of the pharmacy sector, relevant professions, the academic community and the county councils to set up a collaborative group that is to strengthen research on the contribution made by the pharmacies to safe and cost-effective medication use.

### **Remit on pharmaceutical services in pharmacies**

In addition to what the pharmacies are expected to supply under their basic remit, the contribution of pharmacists to better use of medication can be strengthened through pharmaceutical services, focusing for example on improving patient compliance with prescribed treatment. Despite pharmacy market players and pharmacists having clearly endeavoured, over a long period, to develop services, this activity to date has been limited and there is a lack of data on the effects under Swedish conditions. International research, on the other hand, suggests that pharmaceutical services can make a positive contribution to use of medication and be cost-effective for society. However, public funding of such a service necessitates evidence from conditions prevailing in Sweden. The inquiry considers there to be reason to speed up the development of pharmaceutical services in order to study whether the pharmacies in that way can make a greater contribution to safe and cost-effective medication use. It is therefore proposed that the Dental and Pharmaceutical Benefits Agency should be tasked with initiating and evaluating a trial activity with a pharmaceutical service in pharmacies.

### **Duty to supply and provide prescribed medicines and other products**

The inquiry presents proposals that will lead to improved provision of medicines and other products. More consumers will receive their



prescribed medication within a reasonable time and therefore be able to start their medicinal treatment more quickly. The level of service at pharmacies can also be expected to be enhanced.

### **Follow-up and analysis of the degree of direct dispensing**

Since re-regulation, it has become apparent in several follow-ups that consumers' experience of the provision of medicines by pharmacies has worsened, but there is no clear explanation for this. At the same time, it has emerged that what is referred to as the degree of direct dispensing is still around 95 per cent in pharmacies. Direct dispensing means that a customer who comes to a pharmacy without having ordered their medicine in advance has the medicine dispensed directly.

The inquiry proposes that the degree of direct dispensing should be monitored regularly and systematically. The reasons for any difference between the measured degree of direct dispensing and consumers' experience of dispensing should also be investigated and analysed. In the view of the inquiry, an independent party should be given responsibility for carrying out the measurements and analyses, and it is proposed that the authority determined by the Government should be allocated this remit.

### **The responsibility of the pharmacies for information and service**

The pharmacies can offer various services in situations where medicines cannot be dispensed directly. By law, the pharmacies firstly have to inform consumers at which other pharmacy or pharmacies the medicine or product is available to purchase. Secondly, the pharmacy staff have to order the medicine for the consumer for dispensing within 24 hours. There are also services that the pharmacies themselves have designed and that improve the prospects of consumers receiving their medicines and other products.

The picture conveyed to the inquiry is that the pharmacies in general could improve the information they provide to consumers, including on stock status at other pharmacies.

## **No justification for a duty on pharmacies to offer home delivery**

The inquiry takes the view that no statutory duty should be imposed on pharmacies to offer home delivery free of charge in situations where direct dispensing of a medicine is not possible. Most pharmacy chains already offer home delivery services as part of their e-commerce operation, which has improved the level of service.

## **A changed 24-hour rule that is safer and clearer**

The '24-hour rule' is largely complied with at present. However, the formulation of this rule with several exceptions leads to only a limited proportion of the orders placed at pharmacies being delivered to the consumer within 24 hours. In the case of around a million customer visits per year, consumers do not receive their medication within 24 hours. From a consumer perspective, there is therefore a great need to change the 24-hour rule so that more customers receive their medication the day after the order has been placed. The present-day rule is both unclear and unpredictable, which provides further justification for a change.

The inquiry proposes that medicines ordered by community pharmacies for an individual customer before 4 pm on a normal weekday should be delivered to the pharmacy no later than 4 pm on the next normal weekday, unless there are strong reasons why this cannot be done. This duty should apply to prescribed medicines and other products that are normally available at the wholesale distributor. Under the inquiry's proposal, the main responsibility for ordering medicines so that they can be dispensed to an individual customer within 24 hours would be transferred from the pharmacies to the wholesale distributors.

The proposal means that a significantly higher proportion of consumers than at present will receive their medication the day after ordering it. It will also become clearer for consumers from what time a medicine can be dispensed.

The requirement covers prescribed medicines and other products that consumers order at community pharmacies. Other medicines and articles that the pharmacies order regularly are not covered by the proposed rule. It is anticipated that they will be able

to be supplied in the same way as they are at present. The proposed rule is also to be regarded as a minimum level for when a consumer should be able to expect to receive the prescribed medicines it has not been possible to dispense directly at the pharmacy. The Medical Products Agency should also continue to supervise compliance with the rule, which is expected to have a positive impact in this respect.

### **Regulation of the right to return medicines**

The present-day system, with individual agreements for returns of medicines from community pharmacies, has been under discussion since re-regulation, and creates uncertainty and lack of clarity for all parties involved. The right to return also affects the degree of direct dispensing, as the pharmacies are unwilling to stock medicines for which there is rarely demand or which are expensive unless there is a possibility of returning them if no dispensing to consumers has been possible. The inquiry therefore proposes that statutory regulation of returns of medicines from pharmacies be introduced.

The inquiry considers that regulation of the options for returns, and what conditions are to apply in connection with returns, will improve the likelihood of pharmacies offering customers a better level of service in providing medication. It is also considered that this would lead to greater clarity for all parties concerned, more efficient handling of returns and more equal competition. In addition, it is important that the terms for right of return are clear so that the necessary quality is ensured for the medicines and other products returned.

The inquiry's proposal for the regulation of returns is based on the guidelines for returns prepared and agreed on by the industry. The regulatory framework should apply to those medicines and other products that are covered by the pharmacies' duty to provide, and it is proposed that the Medical Products Agency should supervise compliance with the regulations.

## **No proposal on expanded options to redistribute stocks**

It is possible at present for pharmacies to redistribute medicines in urgent situations, when a patient needs to have quick access to medicines. It is also possible to redistribute medicines when a pharmacy is closed down.

The inquiry deems the options that exist at present for pharmacies to redistribute medicines to be adequate, based on a patient safety perspective, and therefore does not present any proposal for expanded options for the redistribution of stocks.

## **Supervision of the pharmacy market**

The inquiry has reviewed the supervision of the pharmacy market and presents proposals aimed at enhancing supervision.

## **Collaboration between the supervisory authorities**

Responsibility for supervision of the pharmacy market is shared between several authorities that exercise supervision over the same activity, but from different perspectives. The supervisory responsibilities of the Medical Products Agency, the Dental and Pharmaceutical Benefits Agency and the Health and Social Care Inspectorate partially overlap. There is also evidence to suggest that the general public finds it difficult to navigate among these authorities.

The view of the inquiry is that the formal responsibilities of the authorities are clearly set out in laws and regulations. In practice, however, problems of demarcation and overlap can arise, and the authorities need to tackle these issues jointly. The inquiry therefore proposes that the Medical Products Agency, the Dental and Pharmaceutical Benefits Agency and the Health and Social Care Inspectorate be tasked with working together on supervision of the pharmacy market, with the aim of facilitating exchange of experience and knowledge and being better able to plan supervision. The supervisory authorities have partly differing methods of supervision and receive information about the market in different ways. By sharing knowledge and experience, the

authorities can contribute to each other's supervisory activity. Some areas in which it may be appropriate to cooperate are coordinated supervisory efforts, information to the general public and pharmacy market players about which authority does what and, in dialogue with the pharmacy market players, discussion of how results obtained in supervision can contribute to improved knowledge. The inquiry also considers that the Medical Products Agency and the Health and Social Care Inspectorate should jointly inform the pharmacy market players when an event has to be reported under the Patient Safety Act (as a *Lex Maria* case) or as a serious adverse event. The aim is to improve knowledge and harmonise the basis of assessment. This work can best be done as part of the collaboration between the authorities.

To enable a better exchange of information between the Medical Products Agency, Dental and Pharmaceutical Benefits Agency and Health and Social Care Inspectorate regarding supervision of pharmacies, and to enable outsiders to see some of the results, the inquiry proposes that the scope of protection for individual business and operating relationships be limited in the supervisory activity of the Medical Products Agency and Dental and Pharmaceutical Benefits Agency.

### **Enhancing supervision by the authorities**

The inquiry has reviewed supervision at the Medical Products Agency, Health and Social Care Inspectorate, Dental and Pharmaceutical Benefits Agency and the Swedish Data Protection Authority, and presents a number of proposals to enhance supervision undertaken by these authorities.

In 2015, the Medical Products Agency was tasked by the Government with reviewing how supervision of the pharmacy market by the authority can be enhanced. The Agency submitted a number of proposals and has also launched specific development activity in this area. The inquiry takes a positive view of this but considers that more can be done to enhance supervision. It proposes that the Medical Products Agency be tasked with developing the process for risk-based supervision and feedback to the pharmacy market players, so that the outcome of supervision

can lead to lessons being learnt and simplify anonymous notification to the authority. The Medical Products Agency should also describe how supervision of the pharmacy market has developed. The inquiry also proposes that the Medical Products Agency be given the right to receive further information from the Swedish e-Health Agency, with the aim of being able to undertake effective supervision.

Supervision of pharmacies by the Health and Social Care Inspectorate consists largely in handling complaints and notifications, that is to say reactive supervision. The inquiry takes the view that the Health and Social Care Inspectorate should become more proactive in the supervision of pharmacies and develop supervision of the pharmacy market in collaboration with the other supervisory authorities.

The Dental and Pharmaceutical Benefits Agency's supervision differs from that of the Health and Social Care Inspectorate and the Medical Products Agency in that it largely consists of continuously analysing the sales statistics of pharmacies. The Dental and Pharmaceutical Benefits Agency has launched development activity in the area of supervision and has identified three measures that need to be taken. These are supervision of more market players, consistent and faster administration, and earlier and more continuous follow-up of supervisory decisions. The inquiry proposes that the Dental and Pharmaceutical Benefits Agency be given expanded powers to levy sanction charges when pharmacies do not apply the prices set by the Agency in the pharmaceutical benefits scheme and when pharmacies substitute articles in contravention of the Act (2002:160) on Pharmaceutical Benefits, etc. The reason for doing so is that the Dental and Pharmaceutical Benefits Agency needs to be able to apply more effective sanctions in cases where the pharmacies systematically breach the regulatory framework and a decision on prohibition with imposition of a fine is not effective.

## **Geographical access to pharmacies and medicines**

There are five tools that together help ensure good access to pharmacies and medicines throughout the country: physical

community pharmacies, state grants to community pharmacy service, e-commerce by community pharmacies, pharmacy agents and sale of certain non-prescription medicines outside pharmacies.

### **Long-term sustainable conditions for pharmacy agents**

At present there are 643 pharmacy agents across Sweden in places where there are no physical community pharmacies. Only Apoteket AB runs pharmacy agent operations. The inquiry takes the view that pharmacy agents fulfil a function in maintaining good access to pharmacy services and medicines throughout the country, and therefore considers that agents should be retained. It presents a proposal for a regulatory framework by which long-term sustainable conditions for agent activity are created.

The inquiry proposes that all pharmacy market players be given an opportunity to establish and run pharmacy agent operations. Other parts of the proposal for a regulatory framework for agents are that:

- It should not be permissible to set up agent operations within five kilometres by car of a physical pharmacy.
- Whoever sets up agent operations should notify the Medical Products Agency of this before business commences.
- A single pharmacy should be responsible for the agent's activities.
- The pharmacy players should be able to sell all non-prescription medicines for humans and animals through stocks at the agents. There should be an age limit of 18 for such sales.
- There should be special requirements for the pharmacies' agent operations, for example with respect to how the medicines should be supplied.
- There should not be any fee for establishing and running agent operations.
- No support for pharmacies to establish agent operations should be introduced.

The inquiry proposes that Apoteket AB for the time being should continue to have owner instructions that involve the company running operations through agents, in so far as necessary to maintain good supply of medicines throughout the country. It may be necessary to adjust the wording of the present-day instructions.

### **Continued financial support for pharmacies in sparsely populated areas**

Access to physical pharmacies, depending on which part of the country is concerned, has either improved or remained almost unchanged since re-regulation. Today, almost 99 per cent of the population lives within a car journey of less than 20 minutes from the nearest pharmacy. The inquiry takes the view that access to pharmacies is generally good, although it varies between different parts of the country. It is not anticipated that there will be extensive closures of pharmacies in sparsely populated areas over the next few years. This assessment is based on financial support continuing to be provided for pharmacies in such areas. The inquiry considers the present-day support scheme for central government grants to pharmacies in sparsely populated areas to be an appropriate model that should be retained.

### **Pharmacy e-commerce with medicines a valuable complement**

The pharmacies' e-commerce is expanding strongly in terms of revenue, volume and organisation. There are six different players engaged in full-scale e-commerce with medicines at the national level, which means that they operate e-commerce with prescription-only medicines for humans and animals and have a delivery and collection service by which consumers are reached in the whole or large parts of Sweden. The inquiry takes the view that e-commerce is a valuable complement to physical pharmacies in terms of geographical access to medicines. For some consumers, this can also be a better alternative even when they are close to a physical pharmacy.



## **No need for further measures**

The inquiry's overall assessment is that the five tools analysed, taken together, ensure good access to pharmacy services and medicines throughout the country. Provided the proposal to retain and create sustainable conditions for pharmacy agents is implemented, and that there continues to be support for pharmacies in sparsely populated areas, there is no need for further measures to ensure geographical accessibility.

## **Sale of non-prescription medicines outside pharmacies**

Since 1 November 2009, sale of certain non-prescription medicines has been permitted at points of sale other than pharmacies under the Act (2009:730) on Trade in Certain Non-Prescription Medicines. It is the Medical Products Agency that decides which medicines may be sold outside pharmacies. The range that may be sold in this way is extensive, but in practice a limited number of products are available in stores.

Anyone wishing to sell non-prescription medicines outside pharmacies has to notify this intention to the Medical Products Agency before sale commences. There are currently around 5 500 notified points of sale. The Medical Products Agency has overall supervisory authority for ensuring that the points of sale comply with current regulations. The municipalities are responsible for operational checks on these points of sale and have to report serious shortcomings to the Medical Products Agency. At present only the Medical Products Agency is able to decide on sanctions against operators who fail to comply with the regulations.

## **The municipalities and the Medical Products Agency share supervisory authority**

The municipalities have expressed a strong wish to be allowed to decide, in their inspection activity, on administrative orders and prohibitions that can be combined with fines. At present they have equivalent powers to impose sanctions in their supervisory tasks relating, for example, to alcohol, tobacco, food and the

environment. The inquiry proposes that the supervisory authority under the Act on Trade in Certain Non-Prescription Medicines be shared between the Medical Products Agency and the municipalities. The municipalities should be given the right to decide on administrative orders and prohibitions that can be combined with fines in the event of failure to provide notification of the operation and when the requirements for the operation are not met. Municipalities that have come to a decision on such a case should send a copy of the decision to the Medical Products Agency. The municipalities should report serious shortcomings to the Medical Products Agency, which will then take over responsibility for pursuing the case. The Medical Products Agency is authorised to specify what is to constitute serious shortcomings.

### **Municipalities may transfer supervisory authority to another municipality**

In other areas, such as alcohol, tobacco and food, the municipalities have the option of purchasing services from another municipality to enable them to carry out the supervisory task. The municipalities have expressed a need to also be able to work together with other municipalities in carrying out the inspection of non-prescription medicines and regard this as essential in enabling all municipalities to have access to expertise in issues of this type.

The inquiry proposes that municipalities should be able to commission another municipality to carry out checks on the sale of non-prescription medicines under an agreement. A municipality should not, however, be able to transfer the right to make decisions on cases to another municipality.

### **Clearer distribution of roles between the Medical Products Agency and the municipalities**

Both the Medical Products Agency and the municipalities have argued that the present-day distribution of roles between the two parties regarding supervisory and inspection authority needs to be clarified, and that the mandate of the Medical Products Agency as an authority providing guidance must be made clearer. The

municipalities need to receive guidance on what the task of operational supervision of the sale of medicines outside pharmacies entails.

The inquiry proposes that it be clarified in the Act on Trade in Certain Non-Prescription Medicines that the Medical Products Agency should provide the municipalities with information and advice in their supervisory activity. The inquiry further proposes that the Medical Products Agency take the initiative to increase knowledge concerning what rules are applicable to the sale of non-prescription medicines outside pharmacies. This can be done by the authority preparing simple information materials that are also translated into several different languages. The knowledge that particularly needs to be spread among operators is that the Medical Products Agency must be notified of such sale, that self-inspection is important and that staff should refer the customer for pharmaceutical advice rather than providing advice on medication use themselves.

### **Medical Products Agency gains access to information from the Swedish e-Health Agency**

The inquiry proposes that the Medical Products Agency should receive information on sales under the Act on the Sale of Certain Non-Prescription Medicines from the Swedish e-Health Agency. The Medical Products Agency should be allowed to use the information to supervise that the point of sale is submitting the information required under the applicable regulatory framework and, where necessary, to check that the information submitted by the operator to the Medical Products Agency corresponds with the information provided to the Swedish e-Health Agency. It is also proposed that the Medical Products Agency have access to information from the Swedish e-Health Agency on deliveries by the wholesale distributors to those who sell non-prescription medicines.

## **Entry into force and transitional rules**

It is proposed that statutory amendments proposed by the inquiry enter into force on 1 July 2018. This applies to all statutory amendments except the requirement for pharmaceutical expertise in order to be allowed to dispense medicines, which it is proposed should enter into force at a later date. As this requirement may lead to redistribution of work duties in the pharmacies, and may affect the composition of the pharmacy workforce, the inquiry considers that the pharmacy market players should be given time to adjust their procedures relating to dispensing prescription medicines. It is therefore proposed that this requirement enter into force two years later than the other proposals, that is to say on 1 July 2020.

The inquiry also proposes a transitional rule regarding Apoteket AB providing notification of existing pharmacy agents. This will enable Apoteket and the Medical Products Agency to distribute the processing of these notifications over a period of six months after the rules on pharmacy agents start to apply.

## **Consequences of the inquiry's proposals**

The inquiry's proposals are aimed at improving quality and safety in the pharmacy market. The inquiry deems the proposals to be proportionate and not to go beyond what is necessary to achieve the envisaged purpose. It is not making any proposals that involve increased net public expenditure.

### **Cost-related consequences**

There are many stakeholders and players in the field of pharmacies and medicines. The stakeholders and players who may be affected by the inquiry's proposals are central government, the municipalities, consumers, the pharmacy market players, the pharmaceutical manufacturers, wholesale pharmaceutical distributors and points of sale outside pharmacies.

Some of the inquiry's proposals entail increased costs for the Medical Products Agency, the Dental and Pharmaceutical Benefits Agency and the Swedish e-Health Agency, most of which are non-recurring costs.

A number of the inquiry's proposals will have consequences for the pharmacy market players in terms of costs. These are principally proposals aimed at improving quality and protection of privacy in pharmacies, as well as better access to medicines. Wholesale distributors of medicines will face increased costs as a result of the inquiry's proposal for a change to the 24-hour rule. In the longer term it may also affect the pharmaceutical manufacturers.

Under the inquiry's proposals, the municipalities will in certain cases be able to decide on imposing administrative orders that can be combined with fines in the supervision of non-prescription medicines outside pharmacies. This will lead to increased administrative costs. As the municipalities themselves decide what charge they are to levy for supervision, they have an ability to fund this expense.

### **Other consequences**

The circumstances of small businesses will be affected by several of the inquiry's proposals; one proposal is considered to limit the prospects of small enterprises, while the other proposals are deemed to have a positive impact on their circumstances.

The inquiry's proposal to regulate pharmacy agents and assessment regarding grants to pharmacies in sparsely populated areas may have an impact on employment and public services in various parts of the country.

The inquiry's proposals on the sale of certain non-prescription medicines outside pharmacies signifies some expansion of state supervision of municipal activities. The principal purpose of the proposal is, however, to facilitate dialogue between the municipalities and the Medical Products Agency, whose task is to support the municipalities in their supervisory work.

Incorrect use of medication is, according to the National Board of Health and Welfare, the most common cause of injury to patients in the health care system after falls. This principally relates to side effects and interactions. Incorrect use of medication also leads to costs for the health service. Medication-related morbidity results in care costs of between SEK 12 and 19 billion every year, and approximately half these costs arise outside hospitals. The

inquiry's proposals largely focus on improving quality and safety in the pharmacy market. The view of the inquiry is that the proposals, taken together, will contribute to better use of medication. This, in turn, leads to reduced suffering for patients and reduced public expenditure, particularly in health care.

It is more common for women to visit pharmacies than men, and a substantial majority of those who work in pharmacies are women. It can therefore be assumed that some of the inquiry's proposals will generally affect women to a greater extent than men.