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New rules for the setting of the prices and the supply of pharmaceuticals? - proposals from Wallström's inquiry regarding price and supply issues on the pharmacy market

The special investigator, Sofia Wallström, submitted her inquiry on 31 October 2012 (part of the full report to be presented at a later date) with the title "Price, supply and service – continued development of the pharmaceutical and pharmacy market" (SOU 2012:75) to the Government.

The proposal, which many parties on the pharmaceutical and pharmacy markets have awaited for a long time, has caused quite a stir in the industry and in the media. The proposal is divided into three parts that we consider important to report on: a proposal for a new pricing model for original pharmaceutical without generic competition, access in the pharmacies and substitution of pharmaceuticals in pharmacies. Elisabeth Eklund, partner, and Oscar Jansson, associate, present and comment below on the proposal.

Introduction

The inquiry is divided into three parts that we consider important to highlight: a proposal for a new pricing model for original pharmaceuticals without generic competition, availability at pharmacies and substitution of pharmaceuticals at pharmacies.

1. Proposal for a new pricing model for original pharmaceuticals without generic competition

The inquiry's main proposal is that the current value based pricing for new pharmaceuticals should be retained, but it states that there is a need to develop the application in respect of the link price-volume and that an international reference pricing (IRP) should be implemented after five years, with further amplification after ten years. It is further suggested that:

- The county councils and the pharmaceutical industry should be able to enter into collaboration agreements for in-patient pharmaceuticals. The cooperation should be used where the treatment cost per patient or the product cost per package is high and where there are several therapeutic alternatives or for new, innovative pharmaceuticals that are identified within the framework of the national introduction process which is being drawn up within the context of the national pharmaceutical strategy. It is stressed that a precondition is that

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such agreements are drawn up for sufficiently large regions, on the basis of a broad community perspective, as well as in close collaboration with the Dental and Pharmaceutical Benefits Agency (TLV) in respect of prioritisation and cost effectiveness analyses. Such agreements must not result in negative effects for the pharmacies' changeover to parallel-imported products.

- To introduce a de minimis threshold limit of 10 MSEK (where the sum is the estimated total sales to patients per year for the pharmaceutical in question) for the reimbursement system in order to simplify and facilitate for companies as well as to release investigative resources (up to 30 %) to benefit all kinds of pharmaceuticals and medical technology products.
- New rules shall be introduced as to enable pharmacies to negotiate the purchase price of so-called non-substitutable generic products (typically so-called biosimilars) in the same way as with other substitutable pharmaceuticals and thereby expand the parallel imports.

The inquiry's proposal is to utilise the savings that arise through reduced prices to stimulate innovation and well-developed collaboration between the health care sector and the pharmaceutical industry, an improved follow-up and evaluation, improved use of pharmaceuticals etc.

The Government states that in sum the inquiry's proposals will result in savings of 2.4 billion SEK by reducing the cost for pharmaceutical for the public authorities.

2. Availability at pharmacies

One of the greatest aspects that the inquiry highlights is the extent of backorders for prescription pharmaceuticals. Since the reregulation of the pharmacy market over 300 additional pharmacies have been established in Sweden. At the same time several investigations show that consumers are of the opinion that the pharmacies' keeping of stocks have decreased. It affects among others the following groups: elders, rheumatics, individuals with psychic problems and individuals with Alzheimer's disease. The inquiry also show that the available material suggest that provision of pharmaceuticals at pharmacies only has been affected marginally. However, there are an unknown number of customers that leave the pharmacy empty-handed. The reregulation of the pharmacy market has resulted in several changes that may have affected consumers' experience of supplies and servicing negatively, among others that new pharmacies have needed time to build up their stocks and that the pharmacy operators switched to new IT systems. The inquiry considers that there are reasons to clarify and strengthen the regulatory framework in order to create conditions for further improvement of the supply and delivery.

The inquiry proposes that the Medical Products Agency (MPA) should be given the task of describing the extent of backorder listings amongst the pharmaceutical companies which supply pharmaceuticals in Sweden which should include how

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often backorder lists lead to serious shortages in the pharmacy supply chain and what the backorder lists are due to. This survey should then form the basis for a new assessment of a possible supply obligation on the pharmaceutical manufacturers. The MPA should consult with the TLV in this respect.

The inquiry further suggested that:

- A requirement is introduced for reasonable stock keeping at pharmacies in order to ensure satisfactory access for the consumers to those pharmaceuticals and products that are covered by the supply obligation.
- A clarification is made that the obligation for the pharmacies to supply within 24 hours does not apply in certain situations. These situations were also exempted from the so-called 24-hour rule during the pharmacy monopoly period and was also indicated in connection with the reregulation.
- Enhanced possibilities are given for pharmacies to dispatch pharmaceuticals between each other in emergency situations with the object of improving the availability for the consumer.
- An obligation should be introduced for pharmacies to the effect that where a pharmacy does not have the pharmaceutical demanded in stock, the consumer is informed at which pharmacy the pharmaceutical is available.
- It is proposed that Apotekens Service AB should develop a joint electronic search system showing which pharmacy/ies that hold a particular pharmaceutical in stock. The search system shall be open to everyone to use, e.g. consumers, pharmacy personnel and prescribing individuals. An obligation is instituted for pharmacies to report to Apotekens Service AB whether they hold in stock a certain requested pharmaceutical.
- Assurance of improved preconditions for the authorities concerned to carry out proper supervision.
- TLV should review the regulations concerning the gross margin. The inquiry also considers that the pharmacy operators should develop industry guidelines with the object of improving conditions for the right of return, storage/shelf-life etc.

All in all, the inquiry adjudges that these proposals will lead to a better service for the pharmacy customers and that more customers will receive their pharmaceuticals and products within a reasonable time.

3. Substitution at the pharmacies for pharmaceuticals that are no longer protected by patents

In 2002 Sweden introduced a system of generic substitution of pharmaceuticals. The system includes so-called generic pharmaceuticals and original pharmaceutical which has been determined to be interchangeable by the MPA and results in that the pharmaceutical that currently has the lowest price will be the pharmaceutical dispensed by the pharmacist in a pharmacy.

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The inquiry does not suggest any major changes regarding substitution of pharmaceuticals at pharmacies, the cheapest product will continue to be handed out as the general rule. If the patient chooses to pay the difference, he or she is entitled to receive the original pharmaceutical, unless the doctor has indicated that the exchange may not be made due to medical reasons which only occur in exceptional cases. Then the patient receives the original pharmaceutical without having to pay the additional cost.

The inquiry notes that the exchange system has been criticized since too frequent exchanges can cause problems, in the worst case errors, especially for the elderly and patients with many drugs. Also the pharmacy operators have criticised the system as it increases the costs for stock keeping and handling. To improve the system the inquiry proposes that:

- Currently the prescriber only has the option to refuse exchange of the product on medical grounds by ticking a box on the prescription. It is however very uncommon. It is proposed that a pharmacist, out of regard for patient safety, can block product substitution. Where special reasons apply, the pharmacist has the possibility of substituting the prescribed pharmaceutical against a pharmaceutical that has previously been handed out based on the prescription.
- Extended periods in the substitution system, so that the new 'product of the period' (i.e. the cheapest substitutable generic for the respective original pharmaceutical) is designated for two months at a time instead of one month as at present. This is then combined with a longer preparation period for the suppliers.
- Demand that suppliers actively register/apply for their particular product being designated as 'product of the period'.
- Differentiated sell-off periods (between products with high respectively low volume) which can lead to longer sell-off periods for low volume products.
- The survey that the MPA, in consultation with TLV, should make in respect of backorder listings should form the basis a renewed assessment of a possible supply obligation for pharmaceuticals, including generic pharmaceuticals.
- Administrative fines for pharmacies that fail to comply with the provisions concerning substitution.
- Strengthened information efforts concerning generic substitution directed at the patients.
- Marking of packages with information on what is prescribed and what is issued as well as the name of the active substance (ingredient). Furthermore, it is proposed that the Government continues to work for changes in the European regulatory framework for pharmaceutical packaging as well as investigating the possibilities for a voluntary national agreement.
- Developed IT systems at pharmacies and wholesalers as well as at TLV in order to achieve the positive effects to which the proposals described are expected to lead.

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Comment to the above mentioned proposals

One of the questions that are worth some attention is the question regarding how agreements between the county councils and pharmaceutical companies should be managed. This question is highly complex and is, as you may know, the subject of several legal reviews. If the courts do not put an end for the rebate agreements the inquiry does not suggest that these shall be legally regulated through legislation but only through agreements. It is an odd solution to let the county councils enter into agreements with the pharmaceutical companies without a legal basis – it is important that transparency and equal treatment is prioritized and it is difficult without an underlying clear legal framework.

Another large part of the proposal that is of importance is the funds the Government proposes to save on pharmaceutical costs. An analysis of how innovation should be encouraged must be made when the original manufacturers are the real losers as regards the proposed savings for pharmaceutical costs of 1.8 billion SEK in the form of lower prices. The inquiry's proposal to set aside a part of the savings to encourage innovation is hardly enough. It should be remembered that it is the original pharmaceutical manufacturers' revenues that forms the basis of funds that finance the development of new pharmaceuticals. Do we risk to miss out on new pharmaceuticals because of these savings?

It is possible to submit opinions on the inquiry and over a hundred market actors are requested through the review process to submit their opinions, but there is also a possibility to make your opinion heard. The opinions must be submitted before 25 February 2013. Thereafter the Government will draft a legislative suggestion in the form of a Governmental Bill. We will revert when the bill has been published.

Elisabeth Eklund,
Partner / Advokat

Oscar Jansson,
Associate