

## THE DEREGULATION OF THE SWEDISH PHARMACY MONOPOLY

### Background:

The deregulation of the pharmacy monopoly has been a long process. Mr Lars Reje, the Government inquirer, presented his findings and his proposals in spring 2008, but this has now largely been abandoned. The Ministry of Social Affairs has put forward a new model, which is still inspired by Reje's fundamental proposals, but with new elements.

### Over-all structure

The government proposes to allow both horizontal and vertical integration of pharmacy chains. Industry will not be allowed to own pharmacies. It is expected that the new regulation will lead to the emergence of few chains. De-regulation of OTC sales will be announced later. Please note that nicotine replacement therapies (NRTs) are already allowed to be sold in the general trade.

### Sell-off

In order to secure availability of pharmacies also in remote and sparsely populated areas of Sweden, the government intends to sell off 50 % of the current pharmacies in clusters, probably 3 to 4. Each cluster will include pharmacies both in urban and rural areas. The 50 % that will remain in state ownership will be split in two parts; the first part, with about 250 pharmacies, will be kept by Apoteket AB. It is also expected that Apoteket AB will be allowed to go international and compete with foreign pharmacy chains in other countries. The remaining 200 pharmacies in state ownership will be put in a separate entity and run as a franchise, in which individual pharmacists will eventually have the possibility to buy out their own pharmacy. The franchise operation will most likely be tightly linked to Apoteket AB, and use its systems and processes.

### Pricing

The remuneration of pharmacies and the corresponding pricing model for pharmaceuticals has been a contentious issue. The government now proposes a mixed model. First, TLV (previously known as LFN) will maintain responsibility for approving drugs for reimbursement, based on the established criteria (including cost-effectiveness). The government has announced that it intends to strengthen TLV, and that they will present a Bill to this regard during spring of 2009. It is expected that TLV will also be asked to review hospital drugs, which today are excluded from national reimbursement as they are tendered instead. TLV will also get new instruments, to allow more flexibility in decision-making and possible risk-sharing with companies. It is also expected that TLV will become more active when patents have expired in established therapeutic groups. For generics, the government proposes a national contracting model. Even if it does not say so, it has been inspired by recent developments in the Netherlands and in Germany. However, the details of the suggested contracting system are different, and is unlikely to function in practice.

Pharmacy chains will be allowed to carry out parallel imports themselves, or negotiate directly with direct importers on rebates. Pharmacy chains are also allowed to negotiate rebates on other originator medicines, but it is expected that this will not deliver any significant revenue for pharmacies as TLV maintains its national role.

### What now?

The proposals have already been heavily criticized by a number of stakeholders. The pharmacists association is very critical on a number of accounts. First, they mean that the way that the government intends to sell off the pharmacies will make it impossible for individual pharmacists to acquire a pharmacy. Secondly, the suggested pricing model makes it very difficult for individual pharmacies to be competitive versus negotiating pharmacy chains. The pricing model, have been heavily criticized by all parties in the pharmaceutical industry. The view is that the model is flawed and will open up for illicit behavior.

The proposal has now been reviewed by the Legal Committee of the Swedish Parliament. They only had some minor comments. Thus it is likely that it will be accepted, and will be put as a proposal to the parliament with an expected vote in March 2009.

One additional uncertainty for all players, and in particular for potential pharmacy chains, is the stand taken by the opposition (Social Democrats, Green party and Left party). The spokesperson for the Social Democrats, former Minister of Social Affairs Ms Ylva Johansson, has said that they will roll back the deregulation as far as possible should they come to power in 2010. The opposition, however, is open to franchising and OTC liberalization. In the debate in Sweden there is some uncertainty about the fate of the proposal, and what will happen in practice, as the target date of July 1<sup>st</sup> 2009 seems very unrealistic.