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Ministry of Health
The Swedish Trade Association for the Research-based Pharmaceutical Industry (*Läkemedelsindustriföreningen*)

Agreement on development of the Swedish ceiling-price model for pharmaceuticals 15 years after marketing authorisation

Background

Pharmaceuticals are part of everyday life for many people, and access to efficient medicines is a prerequisite for providing modern healthcare. Rapid development of medical care has continuously increased the benefits of medicines for the patient and for healthcare. The society's ability to finance medicines are, however, not unlimited, which underlines the importance of clear priorities and reaching the highest possible cost-effectiveness.

Pricing of medicines is free in Sweden, although in order for a medicine to be included in the pharmaceutical benefits system, the company has to demonstrate that the price the company wishes to charge is cost-effective when compared with alternative treatments which are already available. This pricing model is called value-based pricing (VBP) and means that medicines are priced on the basis of the value they contribute to patients, to healthcare, and to society in general.

In connection with the pharmacy re-regulation, the innovative pharmaceutical industry proposed and carried out substantial changes to the pricing system in order to render the Swedish model for generic substitution even more efficient. These price decreases helped to implement the reform without increased costs for patients and society. The principles of the voluntary price decreases have been incorporated in the regulations of *Tandvårds- och Läkemedelsförmånsverket* (TLV). Under these regulations, the prices of all medicines subject to generic competition shall be decreased with 65 per cent in case the price level has lowered with 70 per cent as an effect of generic competition. In this agreement, this ceiling-price structure is developed for the purpose of ensuring a good balance between the interests of the patients and the parties in the long-term perspective.

For the Swedish Government and the County Councils, it is important to ensure that the highest level of health can be achieved with available resources, and that the development of pharmaceutical expenditure is controlled and predictable.

Pharmaceutical industry and research are important interests for Sweden

The parties agree that Sweden for a long time has had a strong position in medical research, and that continued efforts are required in order to maintain and further strengthen the Swedish position. The Swedish Government has already taken actions to further strengthen Sweden as a nation for research and to develop the Swedish structures for innovation. The Government has presented the Research and Innovations Bill where e.g. special initiatives in the pharmaceutical field are included. In addition, the Government invests in increasing the number of clinical trials and has appointed a committee with the task of e.g. proposing a system for national coordination of clinical studies. Moreover, the Government has presented an Innovation Strategy. These efforts contribute to improvement of the research-based pharmaceutical industry´s conditions in Sweden.

Developed pricing model for medicines which are not covered by TLV's "65% rule"

The Pharmaceutical and Pharmacy Inquiry has in its report (SOU 2012:75) presented a proposal for a new pricing model for original pharmaceuticals without competition from generics. One of the proposals from the Inquiry is to supplement the value-based pricing model (VBP) in Sweden with international reference pricing (IRP). According to the Inquiry, the purpose with introducing IRP would be to ensure that Swedish pharmaceutical pricing would be at par with other comparable countries.

This agreement presents an alternative model to achieve the objectives the Government presented in

the directives to the Inquiry (Dir. 2011:55). This agreement contributes to achieving the objectives of both a reasonable cost control and a healthcare given the opportunity to remain at the forefront of healthcare outcomes. These have been starting points in the discussions which form the basis for this agreement. This agreement means that international reference pricing (IRP) will not be introduced in Sweden, provided that the savings presented in this agreement are realized. If the savings do not materialise,the Government will reconsider this matter. *Tandvårds- och Läkemedelsförmånsverket* will be instructed to continuously monitor price developments in Sweden in relation to other comparable countries. In addition, TLV is given a more active role in its work to develop the value-based pricing model in order to achieve greater cost-efficiency.

The purpose of this model is to create a pricing model for medicines within the pharmaceutical benefit system which is simple, predictable, and easy to communicate. The model takes into account the need to ensure continued access to medicines in the Swedish market and to enhance the appearance of natural price competition. The agreement covers all medicines except those deemed substitutable and have had a ceiling-price set by TLV.

The main principles of the agreement

The developed price model for medicines included in the pharmaceutical benefits system which is presented herein, is a straight percentage reduction in price by 7.5 per cent - the same for all products for which TLV has not set a ceiling price in accordance with the "65-per cent" model regardless of any competition - 15 years after the medicine received marketing authorisation.

The developed ceiling-price model will be implemented in two steps. January 2014, the price reductions will be implemented by an undertaking from the innovative pharmaceutical industry in respect of all products which received marketing authorisation the year 1998 or earlier. As of 1 January 2015, price decreases will be implemented continuously and annually - based on changes in TLV's regulations - for all additional products which will have passed the deadline of 15 years after marketing authorisation.

Since the purpose of the patent and SPC systems is to secure that products will have an effective market exclusivity for 15 years, it is of great importance that the price-setting authority, TLV, continuously works to streamline its case handling. TLV will be instructed to continuously monitor processing times. TLV should also investigate the possibility to start the investigation of pricing issues already at a "positive opinion" from the European Medicines Agency (EMA).

In cases where there are special reasons, individual companies shall, on a well-founded basis, be able to apply to TLV for adjustments to the percentage reduction for the individual product. This possibility should be handled restrictively.

There may be a value in maintaining the percentage level of the decreased ceiling-price the same throughout the term covered by this agreement, 2014-2017. However, it is impossible for any party to an estimate what the exact savings will be from the introduction of this pricing model, since the market is continuously evolving.

For this reason, the parties agree on the need for an ongoing dialogue on the development of the ceiling-price model. TLV will be instructed to annually evaluate the agreement to ensure that prices are reduced in a way that corresponds to the savings presented above. The calculations shall be based on prices and volumes within the pharmaceutical benefits system as per October 31, 2012, measured in AIP. Based on the market dynamics that are created when various new types of medicines lose their market exclusivity, reasons may occur to develop the ceiling-price model further, and it cannot be excluded that some adjustment or differentiation in the percentage rate may be necessary to ensure price dynamics and continued good access to medicines in Sweden.

Based on additional analyses performed on the basis of the information presented by the Pharmaceutical and Pharmacy Inquiry, the parties agree that a reasonable change of the level of

savings as a result of the developed price model over the period 2014-2017 is 800 million SEK in AIP (400 million in 2014 and an additional average of over 130 million per year in savings increase over the period 2015-2017, ie. an additional 400 million in savings). Based on this objective, the Parties agree that the price of each package shall be reduced by 7.5 per cent with effect from 1 January of the 16th year after the approval (defined on the basis of substance and form).

The parties agree that Sweden, with the proposed pricing model, will have a simple, predictable, and long-term pricing system for medicines within the pharmaceutical benefits, with value-based pricing at introduction, a developed ceiling-price model 15 years after marketing authorisation, and maintaining pricing according to "periodens vara" for drugs that are substitutable. By considering patents and SPC systems, this pricing model is also well in line with the Government's Research and Innovation Policy, while ensuring price dynamics and continued good access to medicines in Sweden.

This agreement will be valid subject to approval by the Government and by the board of *Läkemedelsindustriföreningen.*

Stockholm 5 September 2013

For the State	For *Läkemedelsindustriföreningen*	
Karin Johansson	Robert Ström	Marine Quienart Stojanovic
State Secretary	Chairman	Vice Chairman