

Agreement of price reductions and a cap on the prices of hospital-only medicinal products for the period April 1, 2019 – March 31, 2023

This agreement has been made between the Danish Association of the Pharmaceutical Industry (Lif), the Ministry of Health and the Danish Regions.

Background

Medicine prices are unrestricted in Denmark with respect to medicines sold to the public in the primary health sector and those sold to hospitals. In parallel with this, for some years price-cap agreements have been made between the Ministry of Health, the Danish Regions and Lif. Since June 4, 2009, hospital-only medicines were regulated by a price-cap and price reduction agreement for hospital medicines made by Lif and the Ministry of Health in June 2009.

In the autumn of 2018, the Government launched the establishment of a statutory external reference price system (ERP). The ERP will apply to eligible, prescription and hospital-only medicines not covered by voluntary price-caps. The ERP system is expected to enter into force on January 1, 2020 for hospitalized medicines and July 1, 2020 for eligible prescription drugs.

In addition, hospital-only medicines have in the period January 1, 2013 – December 31, 2015, January 1, 2016 - April 1, 2016 and April 1, 2016 - March 31, 2019 been regulated in an agreement on price-cap and price reduction for medicines for the hospitals concluded between Lif, the Ministry of Health and Danish Regions. With the present agreement on price reduction and price-cap on the prices for hospital-only medicines in Denmark during the period April 1, 2019 – March 31, 2023, Lif, the Ministry of Health and the Danish Regions extend and reduce the price-caps set by the agreement of June 4, 2009 and subsequent agreements.

This agreement provides a cap on list-prices for hospital medicine to help society get more health for the money.

Lif wishes to emphasize the core issue that the agreement has been made in the light of the general economic situation characterizing Denmark and the other European economies. Lif would also wish to emphasize the key fact that the present agreement has been made to combine consideration for equal, easy access for patients to innovative, medicinal treatment while ensuring that the researching pharmaceutical industry has stable, predictable trading conditions.

The purpose of the price-cap agreement is to ensure predictability and a list price level for hospital medicine in Denmark leveling with prices in nine comparable countries: Sweden, Norway, Finland, UK, the Netherlands, Belgium, Germany, Ireland and Austria. The Danish list prices in 2018 are higher in some reference countries and lower in others. The agreed price-cap reductions totaled 12.5% is carried out with a view to ensuring that the Danish list prices during the contract period come in line with the list prices in comparable countries.

The parties will, in connection with the agreed mid-term review and no later than three months before the expiry of the agreement evaluate whether the predicted effect is realized.

Mechanisms in the hospital medicines market

On June 4, 2009, Lif and the Ministry of Health agreed on a price-cap for hospital medicines. It was also agreed that the list prices for hospital medicines were to be reduced by 5% on January 1, 2010. The prices for hospital medicines introduced during the term of the agreement were set using reference prices in nine countries that are comparable with Denmark (Sweden, Norway, Finland, UK, Ireland, Germany, the Netherlands, Belgium and Austria). The prices of hospital medicines could not be raised above the price-cap until December 31, 2012. Price-caps were to be regarded as maximum prices. In the agreement of December 18, 2012, Lif, the Ministry of Health and the Danish Regions agreed on further price reductions totaling 5% until January 2016. These price-caps were extended in the agreement to April 1, 2016 and again in the agreement from April 1, 2016 – March 31, 2019, which also contained a price reduction of 10%.

Lif, the Ministry of Health and Danish Regions agree that the actual pricing on hospital medicines is increasingly taking place under the price-caps because of the competitive situation, that happens regionally, among other things through the regional purchasing organization Amgros. The purchases are, among other things, based on the Medicines Council's recommendations for standard treatment.

Actual procurement prices depend on the starting point (list price), competition in the marketplace and how procurement is organized. The actual price for hospital medicines thus reflects an official list price (AIP) and the discount achieved.

It is expected that changes in list prices are followed by changes to current purchase prices and that the prices of medicines that are only subject to limited competition approximately reflect the official list price.

Lif, the Ministry of Health and the Danish Regions have made the present agreement on price-reductions and a price-cap on the list prices for hospital medicines to ensure the basis for continuing positive developments in the treatment of patients in the Danish hospitals.

Main principles of the agreement

The agreement extends the price-cap in the agreement of June 4, 2009 on a price-cap and price reductions for hospital medicines and the agreement of December 18, 2012. This means that during the period between April 1, 2019 – March 31, 2023, the price-cap for individual hospital medicines will generally be the prices on May 18, 2009 as subsequently adjusted under the price-cap agreement of June 4, 2009 and this agreement.

The price-cap is to be reduced by 2.5% on December 1, 2019, 2.5% on October 1, 2020, 2.5% on October 1, 2021, 2.5% on October 1, 2022 and 2.5% on February 2023. In all cases, the price-cap reduction will take effect in the first pricing period after the listed dates.

The prices of hospital medicines are not to be increased more than these prices up until March 31, 2023. In this agreement, hospital medicines shall be construed as those restricted for supply by hospitals and specialists.

The price of medicines introduced during the term of the agreement shall not exceed the average price in the European countries with which we in Denmark normally compare ourselves. The parties agree that the

group of comparable countries are: Sweden, Norway, Finland, UK, Ireland, Germany, the Netherlands, Belgium and Austria.

Terms of the Agreement

Lif states that its members have informed the Association that they will, if this is permissible under competition rules, comply with the terms of the price-cap agreement, cf. Sec. 1.

1. Price-cap and reductions

A1. From the effective date of this agreement and/or until March 31, 2023, the prices of hospital medicines shall not exceed the price applicable to individual packs on May 18, 2009 with subsequent adjustments in accordance with the price-cap agreement of June 4, 2009 and the agreement of December 18, 2012, although see Sec. B.

The price of products subject to a price-cap set on another date in the preceding agreement, including products for which the price-cap was initially set by notification of European prices, shall not be raised above the price-cap applicable on March 31, 2019, although see Sec. B.

A2. The price of hospital medicines marketed for the first time before May 18, 2009 but without having a notified price on May 18, 2009, shall not exceed the latest notified price notified before May 18, 2009, as subsequently adjusted in accordance with the price-cap agreement of June 4, 2009 and the agreement of December 18, 2012, although see Sec. B.

A3. The price of new hospital medicines marketed for the first time between April 1, 2019 and March 31, 2023 shall not exceed the price on first marketing, although see Secs. B and C.

B. The price-cap is to be reduced by 2.5% on December 1, 2019, 2.5% on October 1, 2020, 2.5% on October 1, 2021, 2.5% on October 1, 2022 and 2.5% on February 2023. In all cases, the price-cap reduction will take effect in the first pricing period after the listed dates.

C1. The price of new hospital medicines introduced between April 1, 2019 – March 31, 2023 must not exceed the average price in Sweden, Norway, Finland, UK, the Netherlands, Belgium, Germany, Ireland and Austria when the product is introduced on the Danish market (price-cap). The average is to be calculated regardless of how many of the countries concerned have marketed the products at the date concerned, although see Sec. C2. Companies are responsible for submitting pricing data to the Danish Health Data Authority with a view to determining the price-cap.

C2. If on introduction in Denmark a new hospital medicine has not been marketed in at least three of the above countries, a provisional price-cap (introduction price) is to be determined. When the product has been marketed in three countries, a provisional price-cap is to be calculated and set based on the average introduction price in the three countries. If the product is subsequently marketed in further three countries, a new provisional price-cap is to be calculated as the average introduction price of the product in the six countries although the price-cap cannot exceed the hitherto provisional price-cap, cf. Sec. 1. If the product is subsequently marketed in the remaining three countries, the final price-cap is to be calculated as the average of the introduction price of the product in the nine countries although the price-cap cannot exceed the provisional price-cap applicable hitherto.

C3. New hospital products in accordance with C1 and C2 are covered by the price reductions in Sec. B insofar as they have been marketed in Denmark prior to the cut-off dates noted in Sec. B.

C4. The price of new pack sizes and strengths of hospital medicines already marketed and where there are no significant differences compared to existing products, shall not during the term of the agreement exceed

the price per unit calculated proportionately based on the price-cap for the nearest comparable pack marketed by the same company.

D. All medicines covered by Secs. A-C shall be subject to dispensing provisions BEGR, AP4BG, NBS and AP4NB, although this shall not apply to products subject to general reimbursement or general conditional reimbursement.

E. All prices in the agreement refer to the (AIP) medicine list prices notified to the Danish Medicines Agency.

F. The parties to the agreement shall draw up guidance for interpreting its provisions.

2. If a member of Lif raises prices above the price-cap set in accordance with Sec. 1 without the prior consent of the Ministry of Health and Elderly Affairs, cf. Sec. 3, Lif shall seek to regulate the situation as rapidly as possible and within three weeks at the latest.

a) The parties to the agreement may transfer information on price-caps for specific pharmaceutical packages to Amgros, provided that a price-cap is not terminated no later than four weeks after the price-cap exceeded.

b) The parties to the agreement monitor the compliance of the agreement in cooperation.

c) The parties to the agreement lay down further guidelines for monitoring and the procedure for remedying any excess of the price-cap. The procedures are set out to provide for as fast and smooth as possible any overruns.

3. The agreement provides the option of individual price-cap changes. In exceptional cases, Lif's members may, because of extraordinary changes in trading and other conditions for a given product during the term of the agreement, apply to the Ministry of Health for authorization to notify prices more than the price-cap, cf. Sec. This shall apply for example to extreme fluctuations in foreign exchange rates. This exception shall also apply in the event of obvious errors in notified prices. Applications shall specify the very special reasons for their submission. Applications are to be processed by the Ministry of Health and Elderly Affairs within three months.

4. If the assumptions for the agreement or trading conditions for the pharmaceutical industry or the hospital sector change significantly, any of the parties to the agreement may terminate it with immediate effect.

5. Immediately after signing the agreement, the Ministry of Health shall notify the competition authorities and the EU Commission of the present agreement. Lif shall receive a copy of the notification documents.

6. The agreement applies to the rates applicable from April 1, 2019 until March 31, 2023. A mid-term discussion and possible renegotiation of the agreement will take place between all the parties before the end of October 2021. By January 5, 2023 at the latest, discussions will be held between parties on the situation in connection with the termination of the agreement. In this connection, the effects of the present agreement are assessed.

7. In connection with the mid-term discussion, the parties jointly establish an analysis design for comparing the list price development for hospital-only medicines in Denmark compared to the nine reference countries. This is to qualify and strengthen the basis for comparing Danish list prices with the reference

countries' list prices and thus increase the transparency of list price developments across countries. The documentation basis is included in connection with the parties' discussion on the status of the Danish list price level in relation to the reference countries' list price level at the end of the agreement.

Copenhagen, March 19, 2019

Ministry of Health

Danish Association of the Pharmaceutical Industry, Lif

Danish Regions