

Agreement of price reductions and a cap on the prices of hospital-only medicinal products for the period 1 April 2016 – 31 March 2019

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. Between 4 June 2009 – 1 April 2012, 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.

Hospital-only medicines were also regulated in the period between 1 January 2013 – 31 December 2015 and between 1 January 2016 – 1 April 2016 by a price-cap and price reduction agreement for hospital medicines made between Lif, the Ministry of Health and Elderly Affairs and the Danish Regions.

Under this present agreement on price reductions and a cap on prices for hospital-only medicines in Denmark in the period between 1 April 2016 – 31 March 2019, Lif, the Ministry of Health and the Danish Regions have extended and reduced the price-caps set out in the agreement made on 4 June 2009 and subsequently.

This agreement provides a cap on list-prices for hospital medicine in order to help society get the greatest possible healthcare for the money.

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

The purpose of the price-cap agreement is to ensure predictability and a list price level on hospital medicines in Denmark that is at the same level as the nine comparable countries: Sweden, Norway, Finland, UK, the Netherlands, Belgium, Germany, Ireland and Austria. The agreed price-cap reductions of 10 per cent in total will be carried out with a view to decreasing the list prices of hospital medicines in Denmark, just as we also expect a decrease in the price trend in the comparable countries.

As part of the agreed midpoint review and at least three months before expiry of the agreement, the parties will assess whether the predicted effect has been achieved.

The Ministry of Health will take the initiative to ensure that suppliers of hospital medicine that are not members of Lif accede to the principles of the agreement or are covered by other measures.

Mechanisms in the hospital medicines market

On 4 June 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 1 January 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, Netherlands, Belgium and Austria). The prices of hospital medicines could not be raised above the price-cap until 31 December 2012. Price-caps were to be regarded as maximum prices. In the agreement of 18 December 2012, Lif, the Ministry of Health and the Danish Regions agreed further price reductions totalling 5% in the period to January 2016. These price-caps were extended in the agreement to 1 April 2016.

Lif, the Ministry of Health and the Danish Regions agree that the actual pricing of hospital medicines increasingly takes place below the price-caps as a result of the regional competitive situation, amongst other things by way of Amgros, the regional procurement organisation, which purchases medicinal products for hospitals. Purchases are made during centralised tenders, enabling Amgros to achieve discounts.

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 will be 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 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 4 June 2009 on a price-cap and price reductions for hospital medicines and the agreement of 18 December 2012. This means that during the period between 1 April 2016 and 31 March 2019, the price-cap for individual hospital medicines will generally be the prices on 18 May 2009 as subsequently adjusted under the price-cap agreement of 4 June 2009 and subsequent agreements.

The price-cap is to be reduced by 2.5% on 1 May 2016, by 2.5% on 1 April 2017, by 2.5 % on 1 April 2018 and 2.5 % on 1 February 2019. In all cases, the price-cap reduction will take effect in the first pricing period after the listed dates.

The prices of hospital medicines cannot be increased in excess of these prices until 31 March 2019. 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 is: Sweden, Norway, Finland, UK, Ireland, Germany, Netherlands, Belgium and Austria.

Terms of the Agreement

Lif states that its members have informed the Association that they will, provided that 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 until 31 March 2019, the prices of hospital medicines cannot exceed the price applicable to individual packs on 18 May 2009 with subsequent adjustments in accordance with the price-cap agreement of 4 June 2009 and the agreement of 18 December 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 31 March 2016, although see Sec. B.

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

A3. The price of new hospital medicines marketed for the first time between 1 April 2016 and 31 March 2019 shall not exceed the price on first marketing, although see Secs. B and C.

B. The price-caps shall be reduced by 2.5% on 1 May 2016, 1 April 2017, 1 April 2018 and 1 February 2019. 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 1 April 2016 and 31 March 2019 must not exceed the average price in Sweden, Norway, Finland, UK, 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 on the basis of 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 on the basis of 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 medicine list prices (AIP) notified to the Danish Medicines Agency ('Medicinpriser').

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, cf. Sec. 3, Lif shall seek to remedy the situation as rapidly as possible and within three weeks at the latest.

a) The parties to the agreement shall jointly monitor compliance with the agreement.

The parties to the agreement shall lay down detailed monitoring guidelines and procedures for remedying any non-compliance with the price-cap. These procedures are to be designed to ensure that remedial action is taken to rectify any non-compliance as quickly and flexibly as possible.

3. The agreement provides the option of individual price-cap changes. In exceptional cases, Lif's members may, as a consequence 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 authorisation to notify prices in excess of 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 within three weeks.

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 Ministry of Health will take initiatives to ensure that suppliers of hospital medicine that are not members of Lif accede to the principles of the agreement or are covered by other measures.

7. The agreement shall apply to the prices effective on 1 April 2016 until 31 March 2019. All the parties shall hold a review midway and possibly renegotiate the agreement before the end of October 2017. Discussions on the situation after the expiry of the agreement between the parties are to be commenced by 21 December 2018 at the latest. The effects of the present agreement shall be considered as part of this.

8. As part of the midway review and at least three months before expiry of the agreement, the parties shall jointly draw up documentation on the level of Danish prices for hospital-only medicinal products.

Copenhagen, 1 April 2016

Danish Association of the Pharmaceutical Industry, Lif

Ministry of Health and Elderly Affairs

Danish Regions