Agreement between the Danish Association of the Pharmaceutical Industry (Lif), the Danish Regions and the Ministry of Health and Elderly Affairs on a cap on the prices of medicinal products between 1 July 2016 and 15 December 2018

Pricing of medicinal products is unrestricted in Denmark.

The Danish Association of the Pharmaceutical Industry (Lif), the Danish Regions and the Ministry of Health and Elderly Affairs have made the present agreement on a cap on the prices of medicinal products for the period to 15 December 2018. The agreement has been made as an extension to the agreements of 15 December 2006, 19 December 2008, 20 December 2011 and an extension to the latter on 15 December 2014.

The parties agree that the agreement will help remove uncertainty about the impact of pricing trends on the development of spending on medicinal products and reimbursement by the Regions during the term of the agreement since the agreement sets a price-cap over all reimbursable prescription medicinal products marketed by Lif's member companies. The price-cap applies to areas with limited competition as a result of the patents of original products as well as areas subject to competition in which Lif's members market generic products.

The parties agree that the agreement will help provide the space for ongoing introduction and spread of new improved therapeutic options in the field of pharmaceuticals.

Main points of the agreement

The agreement relates to prescription medicinal products with general reimbursement and general condition reimbursement, also including generic products marketed by Lif's member companies. The agreement constitutes an extension of the price-caps in the agreements of 15 December 2006, 19 December 2008, 20 December 2011 and 15 December 2014. This means that the price-caps for individual medicinal products between 1 July 2016 and 15 December 2018 shall generally be the prices ruling on 30 August 2006 with subsequent adjustments in accordance with previously concluded price-cap agreements.

The agreement means that price-caps should to all intents and purposes fundamentally not be adjusted during the term of the agreement. As a result of the length of time covered by the four agreements, and hence the price-caps, the agreement does however provide that companies can exceptionally in individual cases undertake limited price-rises with the consent of the Ministry and solely in extraordinary circumstances to address significant distortions in the pricing structure. The parties to the agreement assume that the number of applications will be of the same order as hitherto:

Lif has stated 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. 3.

Terms of the Agreement

Scope of the agreement, etc.

1. The agreement relates to setting a price-cap for prescription medicinal products with general reimbursement, including general condition reimbursement, for companies that are members of Lif.

2. All prices in the agreement refer to pharmacy purchase prices, AIP.

Price-cap determination

3. The price of prescription medicinal products with general reimbursement, including general conditional reimbursement, shall not be raised from the effective date of this agreement and until 15 December 2018 above the price for individual packs on 30 August 2006 with subsequent adjustments in accordance with previous agreements.

3.2 Medicinal products marketed for the first time between 30 August 2006 and 15 December 2006

Medicinal products marketed for the first time between 30 August 2006 and 15 December 2006 shall continue during the term of the agreement not to exceed the price notified on first marketing, with subsequent adjustments in accordance with previous agreements.

3.3 Medicinal products marketed for the first time before 30 August 2006, but not priced by 30 August 2006

During the term of the agreement, prescription medicinal products marketed for the first time before 30 August 2006, but not priced by 30 August 2006, shall continue to not exceed the latest notified price before 30 August 2006 with subsequent adjustments made in accordance with previous agreements.

3.4 New medicinal products

Prescription medicinal products with new active agents, new combination products, new (non-substitutable) pharmaceutical forms or medicinal products that in some other way differ significantly from existing products (e.g. significant differences in strengths or medicinal products used for a new indication or a new group of patients) which are or will be marketed for the first time during the term of the agreement, shall not during the term of the agreement exceed the price notified to the Danish Medicines Agency when applying for general reimbursement.

3.5 New variants (strength and pack sizes, et.) of medicinal products

3.5.1. New pack sizes or strengths of already marketed products that are or will be marketed for the first time during the term of the agreement 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 from the same company. Packs that are not currently being marketed, but which had previously been allocated a price-cap, shall be included in the basis for comparison.

When comparing variants, the following order shall be used when prioritising:

1. Identical pharmaceutical form or substitutable pharmaceutical forms, strength and pack size - to be compared

2. Identical pharmaceutical form or substitutable pharmaceutical forms and strength, but other pack size – proportionate comparison by pack size per unit (e.g. numbers, ml, doses, etc.)

3. Identical pharmaceutical form or substitutable pharmaceutical forms and pack size but differing strength – proportionate comparison by strength per unit (e.g. mg, ml, mg/ml, etc.)

4. Identical pharmaceutical form or substitutable pharmaceutical forms but differing strength and pack sizes – proportionate comparison by pack size and strength per unit.

3.5.2. In instances when the Danish Medicines Agency has granted reimbursement for a medicinal product that falls within sec. 3.5.1., the price-cap shall be the price on which the reimbursement decision was based.

3.6 New medicinal products where the company already markets a similar medicinal product (generic products).

The price of medicinal products marketed for the first time during the term of the agreement with the same active agent as products from the same company that have already been marketed and which are not covered by sec. 3.4., shall not exceed the price-cap for the products that have already been marketed.

3.7 New medicinal products where the company does not already market a similar medicinal product (generic products).

3.7.1. The price of medicinal products marketed for the first time during the term of the agreement in which the company has not already marketed a comparable product, but where other companies market a similar generic product with general or general conditional reimbursement, shall not exceed the highest notified price in the pack substitution group for the six pricing periods prior to the introduction of the product pack on the market. Pricing periods shall only be included, in which at least two generic products have been on the market. The price of the original product shall not be considered in determining the price-cap.

3.7.2. In instances where it is not possible to set the price-cap in accordance with sec. 3.7.1., the basis for comparison shall be extended to include pack substitution groups with other pack sizes. The price-cap shall be determined according to the principles in sec. 3.7.1. of the agreement. The price-cap shall however be determined on a comparative basis according to the number of units of the active agent in the packs concerned.

3.7.3. In instances where there is no basis for determining the price-cap in accordance with secs. 3.7.1. or 3.7.2. of the agreement, the price-cap shall be set as the introduction price.

3.7.4. Price-caps set in accordance with sec. 3.7 of the agreement shall not exceed the price-cap for the original medicinal product.

3.7.5. Generics shall be taken to mean products in the same ATC code (Level 5), pharmaceutical form or substitutable pharmaceutical forms and strength.

3.8 Changes to the reimbursement status of a medicinal product

If the status of a medicinal product that has already been marketed changes during the term of the agreement from being non-reimbursable to being reimbursable, the price of the product shall not exceed the price at which the product was notified on the date of the Danish Medicines Agency's decision on reimbursement.

Possibility of single price-cap changes (price-cap dispensation)

4. During the term of the agreement, Lif's member companies may exceptionally apply in extraordinary circumstances to the Ministry of Health and Elderly Affairs for permission to notify prices that exceed the price-cap, cf. sec. 3 of the agreement.

In such rare situations, the Ministry may on application grant dispensation for increases in the price-cap for individual medicinal product packs compared to the applicable price-cap when the product is felt to be of of considerable importance for treating patients, and where:

1. The price of the product compared to comparable products on the Danish market and in relation to other comparable countries is significantly distorted and where the company can demonstrate that there would be a danger of the medicinal product concerned being withdrawn from the Danish market, or
2. There is not a suitable alternative to the product and where the price of the product compared to other comparable countries is distorted and the company can demonstrate that with the current pricing structure, there would be a danger of the medicinal product concerned being withdrawn from the Danish market, or
3. There are extraordinary production issues and the company can demonstrate that with the current pricing structure, there would be a significant danger of the medicinal product concerned being withdrawn from the Danish market.

The company applying for dispensation shall give an account of, and document, the special grounds for submitting the application. The price-cap shall only be raised for medicinal products (packs) that have been marketed in Denmark for the first time before 31 December 2014.

Applications are to be processed by the Ministry of Health and Elderly Affairs within three weeks of full details having been submitted.

Compliance with the agreement

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

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.

Termination and accession, etc.

6. During the term of the agreement, the Ministry of Health and Elderly Affairs shall give Lif prior notice of the introduction of significant changes in the area of reimbursable prescription medicinal products.

If the assumptions for the agreement or trading conditions for the pharmaceutical industry in the area of reimbursable prescription medicinal products change significantly, any of the parties to the agreement may terminate it with immediate effect.

7. The Ministry of Health and Elderly Affairs will take the initiative to ensure that suppliers of reimbursable hospital medicine that are not members of Lif accede to the principles of the agreement or are covered by other measures. In so doing, the Ministry will write to, and hold meetings with, companies that are not members of Lif and have significant sales on the Danish market.

Miscellaneous

8. Immediately after signing the agreement, the Ministry of Health and Elderly Affairs shall notify the competition authorities and the EU Commission of the present agreement. Lif shall receive a copy of the notification documents. The Ministry of Health and Elderly Affairs will also monitor ongoing price developments in the area of pharmaceuticals.

9. The agreement shall apply from 1 July 2016 to 15 December 2018. The parties shall hold a mid-way review of the agreement before year-end 2017. At least three months before the expiry of the agreement, the parties shall hold discussions on the situation associated with the end of the agreement.

Copenhagen 30 May 2016

Danish Association of the Pharmaceutical Industry, Lif

Ministry of Health and Elderly Affairs

Danish Regions