Agreement between the Danish Association of the Pharmaceutical Industry (Lif), the Danish Regions and the Ministry of Health on a cap on the prices of prescription medicine between April 1, 2019 – March 31, 2022

Pricing of medicinal products is unrestricted in Denmark.

The Danish Association of the Pharmaceutical Industry (Lif), the Danish Regions and the Ministry of Health have made the present agreement on a cap on the prices of prescription medicine for the period April 1, 2019 to March 31, 2022. The agreement has been made as an extension to the agreements of December 15, 2006, December 19, 2008, December 20, 2011, December 15, 2014 and the latest agreement from July 1, 2016 – December 15, 2018 with extension until March 31, 2019.

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

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 hospital medicines and on July 1, 2020 for eligible prescription drugs.

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 medicine with general reimbursement and general conditional reimbursement, also including generic products marketed by Lif's member companies. The agreement constitutes an extension of the price-caps in the agreements of December 15, 2006, December 19, 2008, December 20, 2011, December 15, 2014 and July 1, 2016. This means that in general the price-caps for individual medicine between April 1, 2019 and March 31, 2022 are the prices in place on August 30, 2006 with subsequent adjustments in accordance with previously concluded price-cap agreements.

The agreement means that price-caps should to all intents and purposes not be adjusted during the term of the agreement. Because of the length of time covered by the four agreements, and hence the price-caps, the agreement does however provide for the companies in exceptionally and individual cases to 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, if this is permissible under competition rules, comply with the terms of the price-cap agreement, cf. sec. 3.

Terms of the Agreement

1. The agreement relates to setting a price-cap for prescription medicines 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 medicines with general reimbursement, including general conditional reimbursement, shall not be raised from the effective date of this agreement and until March 31, 2022 above the price for individual packs on August 30, 2006 with subsequent adjustments in accordance with previous agreements.

3.2 Medicines marketed for the first time between August 30, 2006 and December 15, 2006.
Medicines marketed for the first time between August 30, 2006 and December 15, 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 Medicines marketed for the first time before August 30, 2006, but not priced by August 30, 2006.
During the term of the agreement, prescription medicines marketed for the first time before August 30, 2006, but not priced by August 30, 2006, shall continue to not exceed the latest notified price before August 30, 2006 with subsequent adjustments made in accordance with previous agreements.

3.4 New medicines
Prescription medicines with new active agents, new combination products, new (non-substitutable) pharmaceutical forms or medicines 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 medicines

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 based on 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 prioritizing:

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 medicine that falls within sec. 3.5.1., the price-cap shall be the price on which the reimbursement decision was based.

3.6 New medicines where the company already markets a similar medicine (generic products).

The price of medicines 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 medicines where the company does not already market a similar medicine (generic products).

3.7.1. The price of medicines 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 medicine.

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 medicine 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 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 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 medicine 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 medicine 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 medicine 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 medicines (packs) that have been marketed in Denmark for the first time before December 15, 2018.

Applications are to be processed by the Ministry of Health 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, Lif shall seek to regulate the situation as rapidly as possible and within four 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.

6. During the term of the agreement, the Ministry of Health shall give Lif prior notice of the introduction of significant changes in reimbursable prescription medicinal products.
If the assumptions for the agreement or trading conditions for the pharmaceutical industry in reimbursable prescription medicinal products change significantly, any of the parties to the agreement may terminate it with immediate effect.

7. The Ministry of Health 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 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 will also monitor ongoing price developments in pharmaceuticals.

9. The agreement shall apply from April 1, 2019 to March 31, 2022. The parties shall hold a mid-way review of the agreement before year-end 2020. 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 March 19, 2019

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Danish Association of the Pharmaceutical Industry, Lif

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Ministry of Health

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Danish Regions