Denmark

Recent and planned developments in pharmaceutical policies 2025

CHANGES IN PRICING

Re-negotiation of price cap agreements

The Danish Regions, the ministry of the interior and Health of Denmark and the Danish pharmaceutical industry association are re-negotiating the price cap agreements for both primary and secondary health care medicines. The price cap agreement for secondary health care medicines was completed in December 2024, ending with an agreed price cap for 2025-2027. The price caps will be reduced by 2.1% as of July 1, 2025, by 2.1% as of February 1, 2026, and by 0.8% on February 1, 2027. The negotiations are still in progress for primary care products as of march 2025. The current agreement on primary care medicines expires September 30th 2025.

Price negotiation on primary care product: Trial period

On November 15th 2024, a proposal to update the Health Act were sent for public consultation. This update is focusing on the addition of the possibility of negotiating confidential prices for primary sector medicines (by Amgros). A trial period is to be established, where applications for full or limited reimbursement can be assessed on the basis of a confidential price. Products eligible to be included in the trial period is new expensive medicinal products, medicinal products that are subject to reassessment of reimbursement status, or medicinal products that are to be changed from primarily hospital use to out-patient use (Primary care sector use). The trial period is set to start on July 1st 2025 and run until June 30th 2028. In the trial period it is expected that 3-5 medicines are included in the negotiations annually.

CHANGES IN REIMBURSEMENT

Updated reimbursement conditions for diabetic medicines excluding insulin

On April 30th 2024 a re-evaluation of the reimbursement status for diabetic medicines excluding insulin, was announced. This re-evaluation meant, among other things, that the reimbursement conditions for GLP-1 analogues was strengthened. The updated reimbursement conditions were valid from November 25th 2024.

OTHER CHANGES

Mandatory stockpiling

As of January 1st, mandatory stockpiling of critical medicines is implemented. The new policy entails that companies that market selected critical medicines in Denmark, are obliged to have a stock corresponding to a minimum of 6 weeks use, based on national sales data. Stocks must be physically placed in Denmark. In addition, the companies are obliged to continuously report their stock on critical medicines to the Danish Medicines Agency. The list of selected critical medicines can be found here; https://www.retsinformation.dk/eli/lta/2024/1421

SPECIAL TOPIC:
Current advances in HTA
(for EU Member States: Implications from EU-HTA Regulation)

The HTA system in Denmark

Sector	HTA organisation and decision-maker	Basis of decisions
Outpatient sector	The Danish Medicines Agency both conducts the HTA, and acts as decision-maker. If general or conditional reimbursement is granted, the level of reimbursement Is based on the patients yearly medical expenses.	Decision is based on pharmacological, therapeutic area and pricing information. Health economic evaluations can be included in the HTA if the applicants include an economic assessment in their reimbursement application.
Inpatient sector	The Danish Medicines Council conducts the HTA and makes a recommendation based hereon. The final decision-maker on whether the medicine is used in the hospitals is the Danish regions. Regardless of the recommendation status, there is no co-payment on inpatient medicines.	Recommendations is based on pharmacological, therapeutic area and economic assessments. It is possible to negotiate prices during the HTA process. All negotiations on inpatient products is facilitated by AMGROS.

The implications of the EU-HTA regulation

From January 2025 the Danish Medicines Council, which focus on the inpatient sector, will include the European Joint Clinical Assessments (JCAs) in their national evaluations. The JCAs will be an integrated part of the clinical assessment, and the Danish Medicines Council will focus on the national aspect of the clinical assessment, as well as the economic evaluation and social/organisational aspects.
The Danish medicines agency are currently working on their implementation plan, but expect to align with the implementation approach of the Danish Medicines Council.