

## Denmark

### Recent and planned developments in pharmaceutical policies 2025/2026

#### CHANGES IN PRICING

##### Price negotiation on primary care products: 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). In July 2025 a trial periode was started, where applications for full or conditional reimbursement can be assessed on the basis of a negotiated, 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). Since the new arrangement came into effect, eight companies have approached Amgros to initiate price negotiations for their medicines. We have successfully completed negotiations with three of these companies, while discussions with the remaining companies are either underway or scheduled to begin soon.

The trial period is set to run for a three-year period from 1 July 2025 until June 30th, 2028.

#### CHANGES IN REIMBURSEMENT

##### Reassessment of reimbursement status

Continuous reassessment of the reimbursement status of prescription drugs are carried out by the Danish Medicines Agency. In 2025 the group of opioids have been reassessment, and going forward none of this will be eligible for general reimbursement, only conditional reimbursement.

Current therapeutic areas under reassessment include allergy treatments, anticoagulant medications and fertility treatments.

#### OTHER CHANGES

##### Mandatory stockpiling

As of January 1st, 2025, mandatory stockpiling of critical medicines was implemented in Denmark. 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 places in Denmark. In addition, the companies are obliged to continuously report their stock on critical medicines to the Danish Medicines Agency. The mandatory stockpiling of critical medicines is set to be evaluated before the end of 2026.

##### AMR

As of April 10th, 2025, The Nordic Council of Ministers has been working on a joint Nordic procurement model for narrow-spectrum antibiotics to strengthen supply security and support prudent antibiotic use. On June 11th, 2025, the Danish Ministry of Health published a national action plan on antimicrobial resistance in humans, focusing on prudent antibiotic use, surveillance, and prevention.

##### Biosimilar substitution

In order to increase competition for biological medicines on the Danish market, the Danish Medicines Agency has introduced substitution of biosimilar medicines. Biosimilar substitution is expected to increase the availability of biological medicines for patients, thereby increasing price competition and reducing the risk of supply difficulties. As of November 10th, 2025, medicines containing teraparotide was introduced for biosimilar substitution as the first in Denmark. Other medicines are currently being assessed, and it is expected that more medicines are included during 2026.

#### SPECIAL TOPIC:

##### Regulation, pricing and reimbursement of pharmaceutical combination products

Definition

Regulation exists?

Special HTA requirements?

Pricing policy

Reimbursement policy