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New bill requires companies to maintain emergency stocks and report their stock of critical medicines



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A new bill to the Danish Medicines Act has been sent out for consultation by the Ministry of Interior and Health. This is in continuation of the government's decision to create stocks of critical medicines for the winter of 2023-2024 at wholesale level, which expires in April.

The bill aims to ensure that patients are less affected by supply difficulties. This is a problem, which has been increasing in Europe in recent years and in Denmark, the total inventory can only cover the need for a limited time in case of supply difficulties. This is as manufacturers and importers do not operate with large inventories, rather they carefully plan production based on demand to keep their costs down. Therefore, the proposed bill will ensure that the need is covered for a longer period while necessary actions can be taken.

The proposal contains amendments to section 75 applicable to companies bringing critical medicines for humans on the market in the primary care sector in Denmark. Should the bill pass, these companies will have an obligation to set up and maintain a safety stock of this medicine in Denmark, equivalent to 8 weeks of pharmacy and retail sales.

According to the bill, the same actors will be obligated to report their stock of the medicine to the Danish Medicines Agency. The Danish Medicines Agency can issue penalty fines if companies do not comply, amounting to DKK 500 per each commenced week.

The bill is expected to enter into force on 1 July 2024.

The bill can be read <u>here</u> (Only in Danish).

The Danish Medicines Agency's news on the matter may be read <u>here</u> (Only in Danish).

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