Danish Life Science News January 2025

Anette Moll Berg
Partner

Ulrik Bangsbo Hansen
Partner

DLA Piper's experienced Life Science team presents an overview of notable Danish Life Science news from January 2025. In this article, you will find the following news.

- New medicine types added to the list of critical medicines subject to the mandatory stock requirement
- EU moving closer to advances towards electronic package leaflets
- Pharmaceutical companies to ensure labelling on medicine packages cannot be removed

New medicine types have been added to the list of critical medicines subject to the mandatory stock requirement

The new Danish regulations concerning required pharmaceutical stock levels entered into force on June 1, 2024, and the requirement to maintain these stock levels became mandatory on January 1, 2025.The obligation applies to companies marketing any of the listed critical medicines in the Danish market. The obligation does not extend to parallel importers or distributors. However, marketing authorization holders, parallel distributors, and parallel importers are obliged to report their stock levels.

Consequently, companies marketing critical medicines in Denmark must build up a safety stock covering six weeks of the expected sales of the critical medicine by January 1, 2025. Additionally, they are required to report their stock levels of the critical medicine every two weeks.

A new executive order updated the list of critical medicines to include 581 medicines now. This executive order does not come into force until January 1, 2025, which means that the stock to be built up by January 1, 2025,

includes only the previously included 263 medicines. The newly added medicines must be reported starting April 1, 2025, and meet the mandatory stock requirement from July 1, 2025.

Companies may apply for full or partial exemption from the six-week stock requirement but not from the reporting obligation.

Non-compliance with these obligations may result in fines and companies may incur criminal liability under the Danish Criminal Code.

EU moves closer to electronic package leaflets

European medicines agencies have been considering replacing hard-copy package leaflets in favor of electronic ones to reduce paper consumption and costs. In addition, the change would ensure that consumers always have access to the most up-to-date version of package leaflets. However, it may pose challenges for individuals lacking basic IT skills, IT equipment, or internet access.

In 2023-2024, Denmark participated in a pilot project with the Netherlands, Sweden, Spain, and the European Medicines Agency to test electronic package leaflets in a standardized format. The resulting report concluded that the EU is generally well prepared to phase in electronic package leaflets, but further IT development and integration are needed and will continue in 2025. The report recommends starting implementation alongside hard-copy package leaflets on a voluntary basis, with each country proceeding based on its IT readiness.

Denmark is participating in a Nordic pilot project that allows pharmaceutical companies to supply medicines to all Nordic countries with a hard-copy package leaflet in English and an electronic package leaflet in the respective national languages.

Pharmaceutical companies must ensure labelling on medicine packages cannot be removed

It is a requirement for labelling on medicine packages to be indelible. Among other things, it must not be possible for the expiration date and batch number to be erased. There are no standardized methods or guides on how to test this. The Danish Medicines Agency regularly tests that printed texts meet the requirement. The Danish Medicines Agency's laboratory published a description of how they check the indelibility of packaging on their website on January 7, 2025. They check it by holding at sample in their hands while covering the batch and expiration date for 20 seconds. Then they rub it 10 times. The test is documented with pictures and observations are noted down. In addition, the color of a print can also be tested through pantone color cards. Any color change will be visible here. In general, the label must be able to withstand being rubbed.

Services	Life Sciences