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## Swedish government proposes fines between SEK 25k - 100m for late backorders by pharmaceutical companies



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The Swedish government has on 24 January 2023 proposed a bill with actions aimed at improving the availability of medicines. The bill proposes fines ranging from SEK 25,000 to 100 million (approximately EUR 2,500 – 10 million) for pharmaceutical companies that backorder medicines too late.

The lack of access to medicines is a growing issue for patients and healthcare, due to reliance on global value chains at the same time as efficiency improvements having been made in the form of reduced inventories. This has created a vulnerability in the supply of medicines and reduced the ability of the healthcare system to withstand disruptions in supply flows. To address these challenges, the government has presented proposals in a government bill that will contribute to strengthening preparedness during peacetime crises and in case of a heightened state of alert, but also to better prevent and manage the shortage situations that arise in everyday life.

The proposals include:

- Fines for companies failing to inform about future shortages.
- Stockholding requirement for outpatient pharmacies adapted to the needs of the consumers in the market in which the pharmacy operates.
- Clarification that healthcare products required to be able to provide good care must be available. The Government also stresses the importance of Swedish regions and municipalities having good stockpiling and the Government may, if necessary, consider a statutory obligation to have healthcare products in stock.
- Expansion of Apotek Produktion & Laboratorier AB's (APL) mission to produce individualized drugs (so-called extempore drugs) and stock preparations also in peacetime crises and in case of a heightened state of alert.
- Extending wholes alers' obligation to supply medicines to outpatient pharmacies to also include an obligation to supply medicines to hospital pharmacies.

If adopted by parliament, the proposed amendments will take effect on 1 July 2023.

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