Drug shortages: tougher financial penalties in France

● In 2024, the French authorities fined 11 pharmaceutical companies a total of €8 million for failing to comply with their obligation to hold contingency stocks to prevent drug shortages.

In France, the annual number of reports of potential or actual shortages of "critical medicines" increased from 871 in 2018 to 3825 in 2024, and peaked at 4925 in 2023 (1,2).

In 2024, the French Health Products Agency (ANSM) imposed 36 fines totalling €8.2 million on pharmaceutical companies that had not complied with their obligation to hold contingency stocks to prevent drug shortages (2). The published details of 33 of these penalties show that they concerned 11 companies and 19 drugs, including blood pressure-lowering drugs, anti-epileptics, anti-infective drugs, anti-neoplastics, injectable corticosteroids and antidepressants. Half of the penalties were imposed on Biogaran and Sandoz, and accounted for three-quarters of the total fines (3). The fines were set at 20% of the company's 2023 sales revenue for each of the products in question. In 2024, French regulations limited fines to 30% of sales revenue, with a ceiling of €1 million (3,4).

For "critical medicines", the French authorities require companies to hold a minimum contingency stock of 2 months, calculated on the basis of sales in France over the previous 12 months. The ANSM can increase this requirement to 4 months if the drug has "*been affected by potential or actual shortages on a regular basis in the two previous calendar years*" (our translation). The fines handed out in 2024 sanctioned companies that had failed to hold 4 months' worth of stocks. According to our calculations, on average, their contingency stocks barely covered 2.5 months (3).

In October 2024, the future ANSM director appeared to favour introducing tougher penalties when asked about the regulations during her hearing at the French National Assembly as a candidate for the directorship, but did not repeat this statement at her Senate hearing (5). When one of the sanctioned firms appealed its fine through the Paris Administrative Court in 2022, the latter upheld the authority of the ANSM to impose such sanctions (6).

In 2025, France's Social Security Financing Act increased the maximum fine to 50% of the sales revenue for the product in question, and raised the ceiling to €5 million. The length of time for which the penalty decisions are published on the ANSM website was extended from 1 month to 1 year. However, plans to increase the ANSM's powers by enabling it to require companies to hold 6 months' worth of contingency stocks were scrapped at the end of the legislative procedure, and temporarily low stocks are even permitted if they are "*appropriate*" for market supply (4,7).

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Countering the influence of the pharmaceutical and medical devices industry in Europe

● Prescrire signed joint letters to the British, Irish and European authorities calling on them to prioritise the interests of patients over those of industry.

Healthcare policy

In March and June 2025, Prescrire signed joint letters to the British and Irish health ministers, calling for them to tackle conflicts of interest by establishing robust, state-run transparency systems for the mandatory disclosure of payments from pharmaceutical and medical device companies to individuals and organisations in the healthcare sector (1,2).

In May 2025, in the face of moves by the Trump administration to reform drug pricing in the US, and the potential impact of this on other countries, including in Europe, Prescrire also signed an open letter to European Commission president Ursula von der Leyen. This letter urged the Commission not to give in to pressure from pharmaceutical companies, in the wake of their ultimatum warning of a risk of "*exodus*" to the US unless Europe adopts more industry-friendly policies.

In the view of the letter's signatories, this threat represents an opportunistic attempt to exploit current geopolitical instability in order to promote the interests of the pharmaceutical sector to the detriment of the public interest (3).

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