Sagas

Metamizole (also known as *dipyrone*) is an analgesic and antipyretic drug that exposes patients to a risk of fatal agranulocytosis of unpredictable onset. In late 2024, the European Commission decided to maintain *metamizole*-containing medicines on the European market.

Metamizole has had an eventful history. It was withdrawn from the US market in 1976 because of this serious adverse effect. It was withdrawn from the Swedish market in 1975, then reinstated before it was definitively withdrawn in 1999, both times for this same adverse effect. It has also been withdrawn from the market of other countries. *Metamizole* has not been marketed in France since the 2000s, but in 2025, the French Health Products Agency (ANSM) continues to authorise compassionate access to two *metamizole*-containing products (see also "Metamizole: European marketing authorisations maintained despite the risk of fatal agranulocytosis", p. 100 of this issue).

In 2024, it was Finland's turn to go *metamizole*-free. This followed the realisation that deaths attributed to this drug were still being reported despite the numerous national measures taken since 2015: restrictions on treatment duration, discontinuation of boxes containing 100 units, a letter to health professionals, a patient card, and amendments to the summaries of product characteristics (SmPCs) and patient leaflets. Numerous measures, but all insufficient to make this analgesic less dangerous, an analgesic that, furthermore, has not been shown to be better than others.

The lesson learned from this saga is clear: to eliminate a risk, nothing beats removing the cause. Finland's drug regulatory agency and the pharmaceutical company concerned put this into practice in 2024.

A second saga is rumbling on, as of early 2025. *Pseudoephedrine* is a sympathomimetic decongestant used in the common cold, with serious adverse effects that have been known for decades. The European Commission recently chose to keep this drug on the European market, too. After numerous amendments to the SmPCs and patient leaflets for *pseudoephedrine*-containing medicines, as well as other measures that had little effect, *pseudoephedrine* was made a prescription-only medicine in France, a move that will undoubtedly decrease the number of patients exposed to this drug. A small step forward, granted, but the risk has not yet been eliminated.

Prescrire