Pfizer will withdraw the antiagastic and duodenal ulcer drug Cytotec (misoprostol) from the French market next March 1. This follows a number of reports of serious side-effects from off-label use of the drug to induce childbirth and medical abortions.

The French branch of the US pharmaceutical manufacturer did not explain why it is taking the drug off the market in France or whether it plans to do the same elsewhere. The company takes its “decisions on a case-by-case basis” and “made [this] decision for France in full agreement with the ANSM [the French National Agency for Medicines and Health Products Safety]”, a company spokesperson said in an email to The Lancet. They added that misoprostol is sold in 79 countries, but refused to disclose any sales figures.

The ANSM issued warnings about the gynaecological risks of Cytotec in 2005 and 2013, and the French National Authority for Health and its independent advisory body on health regulation, issued recommendations along similar lines in 2010 and 2015.

The problem is that “doctors ignored [all of them]”, says ANSM Director General Dominique Martin.

In many cases, practitioners opted for vaginal, rather than oral, administration of Cytotec. This is “debatable” as the drug is indicated for oral use only, Martin told reporters on Oct 20. “From today, the use of Cytotec is no longer available, and to introduce a 25 μg-dosed misoprostol drug for inducing labour called Angusta in 2018, Martin says. Manufactured by Danish pharmaceutical firm Azanta, Angusta was launched in the five Nordic countries—Denmark, Finland, Iceland, Norway, and Sweden—in April, 2017. But “this is not a solution”, says Anne Loirette, vice president of the association Timéo et les Autres, which was founded by Joux. “The molecule is exactly the same as Cytotec. In Denmark, there are cases of women being sent home after taking the drug, and suffering such severe contractions that their uterus is ruptured before they can reach hospital”, she adds.

The ANSM aims to ensure there are sufficient stocks of alternatives to replace Cytotec when it is no longer available, and to introduce a 25 μg-dosed misoprostol drug for inducing labour called Angusta in 2018, Martin says. Manufactured by Danish pharmaceutical firm Azanta, Angusta was launched in the five Nordic countries—Denmark, Finland, Iceland, Norway, and Sweden—in April, 2017. But “this is not a solution”, says Anne Loirette, vice president of the association Timéo et les Autres, which was founded by Joux. “The molecule is exactly the same as Cytotec. In Denmark, there are cases of women being sent home after taking the drug, and suffering such severe contractions that their uterus is ruptured before they can reach hospital”, she adds.

The ANSM will hold a meeting on Nov 20 with patients associations, health-care professionals, and academic bodies to discuss any further steps to be taken in the Cytotec case.

Barbara Casassus