

Critical shortages of obstetric medicines put pregnant women at risk in Australia, warn experts

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Supplies of several crucial obstetric medicines are running short in Australia, putting the health of pregnant women at risk and highlighting

systemic issues impacting reliable access to safe and effective treatment in pregnancy, according to a new assessment published in the [Medical Journal of Australia](#) (MJA).

"Australia's supply and access issues in [prescription medicine](#) during [pregnancy](#) are significant concerns, and caused by several converging problems," said lead author A/Prof Stefan Kane, Director of Maternity Services (Medical) at the Royal Women's Hospital in Melbourne. "We urgently need to address these and build a system that puts the health of pregnant women and their babies first."

The authors say an urgent fix is needed to stem and prevent shortages and call for the government to create a publicly-funded entity dedicated to registering, importing and manufacturing critical medications for use during pregnancy. This would reduce the current reliance on off-label prescribing and ensure a continuous supply of essential pharmaceutical treatments for conditions including pre-eclampsia (high blood pressure during pregnancy), post-partum hemorrhage (bleeding after delivery), and nausea.

Additionally, the article calls for reforms in the way regulators assess and categorize medicines to provide more clinically relevant information on safety and efficacy, and to explore novel and safe strategies to include pregnant women in [clinical trials](#).

Co-author Prof Amanda Henry, Program Head of Women's Health in Australia for The George Institute for Global Health, Professor of Women's Health at the School of Clinical Medicine, UNSW Medicine and Health, and Councilor for the Royal Australian and New Zealand College of Obstetricians and Gynecologists (RANZCOG), says pregnant women are significantly underrepresented in pharmacological clinical trials, primarily due to historical biases creating a reluctance to study the effects of medications in this population.

This exclusion results in clinicians having limited evidence on the safety and efficacy of drugs during pregnancy, leading to undertreatment for conditions both related and unrelated to pregnancy, and potential harms from inappropriate dosing or from newer, more effective treatments not being approved for this population.

The authors welcome the recent statement by the National Health and Medical Research Council (NHMRC) advocating for sex, gender, variations of sex characteristics and sexual orientation to be routinely considered in health and medical research as an important initial step to addressing this imbalance.

"The exclusion of pregnant women and women of reproductive age from clinical trials not only puts them at risk but also denies them the benefits of medical advancements that other populations enjoy," Prof Henry says. "It's time to reframe the system so it proportionately considers the risks of including these women in trials AND factors in the inequity and risks of NOT including them."

The review highlights that many essential medications used in pregnancy are old, off-patent, or prescribed off-label. This makes them commercially unattractive for [pharmaceutical companies](#), resulting in regular supply constraints and frequent discontinuation.

"We are in a perilous situation where pregnant women are vulnerable to the whims of market forces," A/Prof Kane says. "The lack of incentive for pharmaceutical companies to register and maintain the supply of older, off-patent drugs used in pregnancy is putting lives at risk."

The Royal Australian and New Zealand College of Obstetricians and Gynecologists (RANZCOG, the College) supports the article's recommendations and has already called for urgent intervention to prevent worsening shortages. Earlier this year, the college convened a

roundtable bringing together key stakeholders to workshop possible solutions.

"Medicine and device shortages in pregnancy and women's health are longstanding issues that continue to impact patient care. Solutions may not be simple, but we must be fully committed to working together to overcome these challenges," said Dr. Anna Clare, Co-Chair of the roundtable.

The Perspective article in *MJA* serves as a call to action for health care professionals, policymakers, and pharmaceutical companies to collaborate and prioritize the needs of [pregnant women](#). By implementing the suggested strategies, Australia can pre-empt the supply issues in prescription medicine and safeguard the health of expectant mothers and women of reproductive age.

More information: Stefan C Kane et al, Pharmaceuticals in pregnancy: a multifaceted challenge in Australia, *Medical Journal of Australia* (2024). [DOI: 10.5694/mja2.52421](https://doi.org/10.5694/mja2.52421)

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