AUSTRALIAN MEDICAL ASSOCIATION
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Why pharmacists must not prescribe medications for women's UTIs in South Australia

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The AMA strongly opposes expanding the practice of pharmacists to enable them to prescribe antibiotics for UTIs.

The primary reason is that this will compromise patient safety and demonstrate that it is acceptable to legislate for substandard care for women.

The Queensland model fails to address how a retail pharmacy business will manage their actual conflict of interest in diagnosing/prescribing and selling. The amendments fundamentally conflict with the long-standing and essential separation of drug prescribing and selling functions, fragments medical care, and undermines team-based, collaborative healthcare.

Consistent with the views of the Pharmaceutical Society of Australia, AMA(SA) considers the separation between dispensing and prescribing activities to be critical, and pharmacist-prescribing requires 'adequate checks and balances and auditing to ameliorate conflict-of-interest risk'.

Why UTIs?

AMA(SA) has asked why it is UTIs that have been the subject of these pilots in other states. We have been told the reason is that they are a usually a low-risk 'women's problem'.

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Women who have had a few UTIs before and recognise the symptoms immediately may want to obtain antibiotics as quickly as possible.

In fact, many GPs in Queensland believe UTIs have been chosen because ‘simple’ UTIs only affect women. UTIs in men are more complicated, which is why they are not included in these experiments.

Women who have had a UTI before that did clear up with antibiotics may be persuaded that a quick trip to the pharmacist is preferable to waiting for a GP. However, this approach overlooks the possibility of other causes of the symptoms, other complications and history of antibiotic use.

A pharmacy diagnosis can be wrong. Those women who repeatedly seek antibiotics for UTIs may be those at greatest risk of missed diagnoses of cancer or a serious STI, or pregnancy. And some women who may think they have UTIs may actually be pregnant – and some antibiotics may be dangerous for the foetus.

Some women who have additional symptoms may not want to discuss them with a pharmacist and may withhold pertinent information to avoid awkward conversations. It would be usual for a doctor to ask about sexual activity and vaginal pain or discharge, questions that should be asked in private and with an understanding of what the answers mean.

What is presented as a means of empowering women is really an affront: ‘you’re not even to be given the dignity of privacy and a confirmed diagnosis’.

Patient safety – some Queensland numbers

- The QUT report into the Queensland pilot demonstrates a 65% attrition rate in patient follow-up.
- Contrary to basic research standards, this follow-up was conducted by the same pharmacy that delivered the service.
- The scarce data that was collected showed there were multiple instances where pharmacists did not follow the protocol provided (including prescribing treatment to patients who were ineligible, not referring patients to a GP when they ought to have been referred, and allowing pharmacy assistants to handle the patient interactions when this was expressly prohibited).
- Only 68 of 6,751 participants in the pilot completed an independent evaluation of the service experience, the Clinical Service Evaluation Survey (CSES). The methodology introduced significant risk of selection bias, as not all women who consented to take part in the evaluation were given the opportunity to complete the CSES. Only those who had follow up with a pharmacists received a non-standardised verbal offer from the pharmacists to receive the link to the CSES.

- Despite the Pharmacy Guild in Queensland changing its protocols to meet Pharmaceutical Society of Australia (PSA) safety requirements, pharmacists still failed to follow the protocols – after the training that was implemented to make the 'trial' safe.

The report by the numbers:

- The Queensland Government's Urinary Tract Infection (UTI) prescribing pilot started in 2020, with the Queensland University of Technology commissioned to manage and evaluate the pilot.
- During the pilot, pharmacists were allowed to diagnose and prescribe antibiotics for women with 'uncomplicated' UTIs without medical oversight or the use of basic urine dipstick tests.
- An AMA Queensland survey of doctors in March 2022 identified at least 240 cases of women who needed further treatment, including one ectopic pregnancy, a missed cancer diagnosis and antibiotic resistance.
- The QUT evaluation reported:
    - About 8,000 women took part in the pilot
    - Only 3,500 had contact details for follow-up
    - Follow-up was done by the pharmacist who provided the service
    - 12 women agreed that they might have considered going to an ED – the Pharmacy Guild is using this figure to claim 1,000 ED presentations were prevented
    - 97 per cent of women were prescribed antibiotics
    - One in two pharmacists said they would have found it difficult to charge the consultation fee ($19.95) without also selling antibiotics.

The vast majority of services were delivered in cities and major regional towns in business hours, not after hours or in rural and remote areas.

Now the Queensland Government is expanding the pilot to include more, serious conditions.

Two case studies (shared with patient permission)

On a weekend morning in December, Dr Bridget Sawyer saw a woman who sought an urgent appointment as the woman thought that she had a UTI.

A specific history was suggestive but not conclusive of urine infection. A dipstick urine test quickly revealed that the woman did not have a UTI. (The dipstick test can determine the presence of blood, protein, sugar, white cells – found in infection – and nitrites in a graded amount.)

A clinical examination identified the problem as a gynecological diagnosis often seen in post-menopausal women due to a lack of oestrogen that can masquerade as a UTI. Treatment provided was of topical oestrogen cream and reassurance that she did not have a UTI.

Dr Sawyer and the patient discussed her presentation. The woman agreed that if the opportunity had been available, she would have seen her pharmacist and accepted antibiotic treatment because she was confident that she did indeed have a UTI. She is otherwise well and has no medical history of note.

The second case, during the same weekend, was an older woman who has a complicated history including diabetes, weight issues, multiple medications and a past history of UTI. The woman called Dr Sawyer concerned she had a UTI. With the patient's detailed history, Dr Sawyer determined a UTI was likely.

Dr Sawyer provided an e-prescription for an antibiotic that is not the one usually prescribed for UTIs, due to the woman's medical history. A UTI was later confirmed. However, the woman's complex history means she would not have recovered with the 'standard' antibiotic and could have been very unwell. A follow-up appointment has been booked.

International comparisons

It is not true to claim – as has occurred interstate – that schemes operate under similar conditions in New Zealand, Canada and the United Kingdom. In New Zealand, pharmacist prescribers must train in a specific clinical area – paediatrics for example – and then they work within a hospital paediatrics ward, not in a retail pharmacy.

New Zealand

- Pharmacists must have a postgraduate clinical diploma or equivalent and have several years of clinical experience in a specialised area before applying for the 12-month postgraduate course.
- The course involves a 250-hour practical along with an academic component.
- Qualified pharmacy prescribers work within their specific clinical area of practice in a hospital ward.

United Kingdom

- Minimum standard learning time of 26 days' worth of structured learning and a 90-hour practical.
- Most work in general practices.

Canada

- Limited **emergency** prescribing and prescription extension powers in 10 of 13 provinces.

- One province (Alberta) allows pharmacists to apply for additional prescribing authorisation. All information must be relayed back to the patient's doctor. If it is a new condition, the pharmacist must refer the patient to a doctor for formal diagnosis and treatment.

Six questions for the South Australian Government

- What will you do to ensure there's no potential conflict of interest in the pilot?
- Why do you think it will be acceptable to shift the cost of paying for medicines from the government to the patient, especially as those who can't afford the care won't capitalise on this 'opportunity'?
- Why are you ignoring the advice of Australia's medicines regulators in deciding what can be prescribed in a pharmacy?
- Why are you ignoring the position of the Pharmacy Board, which is that pharmacists cannot autonomously prescribe the medications they sell?
- When did you determine that South Australian women no longer deserve world-class care?
- Will you ensure that in South Australia, the 'pilot' is a real trial, with results recorded, measured and assessed? Ethics approval must be sought.
- If any 'trial' is implemented, will it cease immediately if serious impacts on health are discovered and reported?

Requirements of any South Australian trial

If such an expansion of pharmacists' scope of practice was to be introduced on a trial basis in South Australia, we require for patient safety:

- appropriate clinical governance for pharmacist-prescribing of antibiotics. This must include –
    - a requirement that the pharmacist check the patient's My Health Record (MHR) prior to selling the antibiotics, and upload an event summary with consultation details to the patient's MHR
    - data collection and monitoring of antibiotic sales in a central registry that is accessible by regulatory bodies to check for appropriate practice and prescribing patterns (comparable to the scrutiny, recording and collection of data for GP prescribing)
    - a requirement to advise a patient's general practitioner of the treatment
    - a mechanism to identify and track patient complications
- that the fee-for-service consultation conducted by the pharmacist be undertaken in a private consultation room. This is essential to ensure patient confidentiality

and candour in the discussions necessary to exclude pregnancy and STI. 'Offering' a private space is not sufficient to ensure patients will provide information about their sexual history and health, vaginal symptoms and any information about antibiotic use that may be essential in correct, safe prescribing.

- that SA Health undertakes a comprehensive communications campaign with general practitioners to ensure that doctors know how and where to report patient complications associated with inappropriate antibiotic use, complications, adverse reactions, misdiagnoses, and delayed and missed diagnoses. This requires establishing a central mechanism to record doctors' experiences of dealing with patients who have experienced these outcomes, including hospital presentations.

Best practice in patient care and antibiotic stewardship requires comprehensive medical history taking, physical examination including vital signs, abdominal examination and examination for costovertebral able tenderness, urinalysis and access to pregnancy testing prior to antibiotic prescription. These cannot be conducted in a retail pharmacy.

Enabling pharmacists to prescribe antibiotics without reference to a patient's medical history undermines efforts to monitor and enforce compliance with best-practice approaches for appropriate and judicious antimicrobial use, as required in *Australia's National Antimicrobial Resistance Strategy 2020 and Beyond*.

Summary

These pilots and legislation to expand pharmacists' scope of practice are an erosion of healthcare standards and jeopardise patient safety.

Developments in patient care require measures that strengthen, not fracture, healthcare and that prioritise patient safety, not retail pharmacy profits.

Despite what some big pharmacy owners say, this prescribing does not happen anywhere else in the world, and should not happen in Australia. GPs train for 12-15 years to have the expertise to diagnose these conditions.

Patients will have to pay for the consultation and the prescription, for which there is no MBS number for the consultation or PBS support if the medication is prescribed by a pharmacist. This increases inequity, with those able to afford payment having more access to services.

We understand that access to GPs is an issue. We propose a model in which nurses and nurse practitioners within GP practices are the answer.