RACGP
Royal Australian College of General Practitioners

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21 July 2022

Mr Shaun Drummond
Acting Director-General
Queensland Health
Level 37
1 William St Brisbane Q 4000

Via email: DG_Correspondence@health.qld.gov.au
Cc: Ms Liza-Jane McBride

Dear Mr Drummond,

Re: Consultation paper – Proposed amendments to Part 2 Urinary Tract Infection Pharmacy Pilot – Queensland (UTIPP-Q Circumstances and conditions) of the Extended Practice Authority – Pharmacists Version 1

Thank you for your letter 7 July 2022 to the Royal Australian College of General Practitioners (RACGP) inviting feedback on the proposed amendments to the Extended Practice Authority – Pharmacists Version 1 ('the Pharmacists EPA). This letter and detailed appendices form our response to Queensland Health's consultation paper and survey questions.

The RACGP has significant concerns regarding the consultation process undertaken by Queensland Health as the feedback platform is very restrictive. The form included a single question with a 'yes/no' answer and limited options for 'no' responses with field character restrictions for free text answers. The feedback form has severely limited the ability of industry stakeholders to contribute meaningfully to the consultation. The RACGP believes this feedback should have been undertaken prior to Queensland Government announcements about making this arrangement permanent.

The RACGP remains opposed to the decision by Queensland Government to permanently allow pharmacists to prescribe antibiotics (Schedule Four medicines) for uncomplicated urinary tract infections in women aged 18 years and older. We have reviewed the Urinary Tract Infection Pharmacy Pilot – Queensland (UTIPP-Q) final report ('the report'), the consultation paper and the proposed amendments to the Pharmacists EPA Part 2 and include our detailed and evidence-based objections in Appendix 1.

In short, the RACGP does not support any of the proposed changes to the Pharmacist EPA. The pilot did not demonstrate that pharmacists can safely treat UTI and in fact demonstrated there is a risk pharmacists will not adhere to the required protocols. We are very concerned that the proposed reforms to health policy have been decided on such poor quality evidence and will result in poor health outcomes for patients.

We strongly urge the Queensland Government to reconsider this decision as a matter of priority, so that patient safety is not further compromised. So that these concerns and questions can be discussed further, we request a meeting with the Queensland Government and Queensland Health. Please contact James Flynn, RACGP Queensland State Manager on (07) 3456 8962 or james.flynn@racgp.org.au for further information or to arrange a meeting.

Yours sincerely,

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Appendix 1: RACGP Concerns and questions regarding the UTIPP-Q pilot and proposed changes to Pharmacist EPA

1. *Disregard for Commonwealth medicines policy, Inquiry and regulatory recommendations, and the specially designed mechanisms to ensure quality prescribing.*

1.1 Establishment of a protocol that is outside of current regulatory processes

The Therapeutic Goods Administration (TGA) already has a process in place for medications to be safely down regulated from Schedule Four prescription-only medications to Schedule Three pharmacist-only medications. The Queensland Government's use of the *Extended Practice Authority – Pharmacists Part 2* ('Pharmacists EPA Part 2') bypasses these processes to create the same effect.

Will the Queensland Government and the UTIPP-Q Consortium provide a copy of the documented processes (equivalent to TGA process) that were used to assess the clinical risk-benefit and patient safety of effectively down-scheduling these medications?

Antibiotic resistance is one of the greatest challenges facing the current health system, and reducing antibiotic use is a national and international priority. The use of the Pharmacists EPA Part 2 to effectively down-schedule trimethoprim, nitrofurantoin and cefalexin (or any systemic or topical antimicrobial) from prescription only medicine to over-the-counter is against the fundamental principles of antimicrobial stewardship, and contradicts the holistic approach required for antimicrobial prescribing as highlighted by the Australian Commission on Safety and Quality in Health Care (ACSQHC), in the Antimicrobial Stewardship Clinical Care Standard.

The NSW Antimicrobial Stewardship Pharmacist Network stated in their submission to the TGA that infectious disease groups would recommend strengthened rather than weakened protections on antimicrobial prescribing.[1] The report states that the UTIPP-Q pilot included an 'infectious diseases representative/sexual health' (sic) on the steering and advisory group and therefore it is assumed there would have been discussion about these concerns.

However, it is not mentioned in the report. The section about antimicrobial stewardship on page 12 of the report references studies related to the pharmacist's role in supporting antimicrobial stewardship when they are dispensing medicines prescribed by medical practitioners. This is an important role; however, the pharmacist will not be performing this role if they are prescribing.

Management of UTIs in an antimicrobial stewardship era supports getting the diagnosis right and not prescribing antibiotics when there is no UTI. This involves waiting for confirmation in equivocal cases and getting the right antibiotic the first time by knowing the local microbial aetiologies and resistance patterns. The protocol which did not include urinalysis or other assessment delivered high rates of antibiotic prescribing and high failure rates. This is out of step with Commonwealth, ACSQHC and other state and territory strategies which are in place to counter antibiotic resistance - a future major risk to humanity.

How will the Queensland Government monitor prescribing habits of pharmacists to protect against antibiotic over-prescribing?

1.2 Compliance and monitoring

The Professional Services Review Director Professor Julie Quinlivan expressed concerns about the lack of external independent regulatory or compliance oversight and highlighted inconsistencies with Commonwealth legislation when commenting on the North Queensland Pharmacy Scope of Practice Pilot.

Her comments hold true for the UTIPP-Q prescribing arrangements.

The Queensland Government has not provided a legislative mechanism to provide external regulatory oversight for pharmacists prescribing, meaning there is no pathway by which inappropriate prescribing can be reviewed. While we understand pharmacists are prescribing outside of the Pharmaceutical Benefits Scheme (PBS), they should be held to the same standards as doctors if they intend to increase their areas of professional responsibility.

How will the Queensland Government address the lack of external independent regulatory compliance oversight as there is already evidence (see 1.3) for pharmacist over-prescribing of antibiotics and potential for more in the future?

The Pharmacists EPA states that pharmacists must keep a record of patient information including the name and address of the patient, date the medicine is sold, description and quantity of the medicine and the directions given for the use of the medicine. Pharmacists should be held to the same standard as GPs if providing similar services.

Can the Queensland Government confirm that record keeping requirements will also include the below, and outline the plans for audit activities on record keeping associated with UTI prescribing?

- Pharmacists document the patient history and the service provided according to the Professional Practice Standards
- Documentation of referral
- Any education or counselling provided to the patient is also advised.

Fragmentation of care is a significant risk. Pharmacists should upload all information about the encounter to the patient's my health record and connect with the patient's usual GP. Instead GPs were dealing with treatment failures and in most cases, without communication from the pharmacist.

Can the Queensland Government advise how they will enforce maintenance of the patient's health record and outline what measures will be taken to ensure that the patient's usual GP is updated?

Cefalexin is used in a variety of other illnesses.

Can the Queensland Government advise what monitoring of cefalexin prescriptions will be undertaken to ensure these medicines are not being prescribed for other conditions?

1.3 Evidence of over prescribing

The report, *page 38, Table 11: Number of UTI Services Provided by UTIPP-Q Pharmacy* provides evidence of early indications of future problems with Queensland pharmacist prescribing. By RACGP's calculations, less than 1% (5) pharmacies provided about 10% of the scripts for antibiotics during the pilot duration. In other words, at least 640 of the 6751 (9.48%) services were provided by five pharmacies. **This is certainly an outlier group to which the report offers little to no explanation,** stating:

> *'A total of 817 pharmacies enrolled in the UTIPP-Q pilot over the study period. Table 10 and 11 provides data on the number of services offered by pharmacies enrolled in the UTIPP-Q pilot. However, while there was a broad offering of services across the sites as indicated above, 34.3% (280/817) of pharmacies offered no services at all with most pharmacies (53.9%, 441/817) providing up to twenty services. Only five pharmacies provided more than 100 services.'*[2]

1.3.1 Learning from overseas and local experience of over-prescribing by pharmacists:

- Following the reclassification of chloramphenicol, there were significant increases in the supply of the ophthalmic antibacterial in both England and Wales.[3,4,5]
- In New Zealand, the most commonly prescribed medicines by non-medical providers were antibiotics and analgesics.[6] An analysis of New Zealand community pharmacy prescribing habits found that use of trimethoprim was high and norfloxacin use could also be reduced further and many prescriptions were for a dose or duration outside those recommended in New Zealand guidelines.[7]
- In the United Kingdom, when the number of pharmacist prescribers tripled it coincided with a five-fold rise in the number of items prescribed by pharmacists outside of hospitals in England in the same timeframe.[8]
- In Canada, pharmacists prescribed seven times more antibiotics than physicians did for urinary tract infection.[9]
- In 2018, the opioid codeine was up-scheduled from over the counter (Schedule Three) to prescription only (Schedule Four) following long-term increases in opioid-related hospital admissions and overdoses in Australia.[10] Up-scheduling of codeine products in Australia in 2018 appears to have been associated with a near halving of Australia's national codeine supply.[11]

The direct relationship between volume of sales and business sustainability generates a conflict of interest, whereby commercial interests can influence the health advice provided by pharmacists. The report stated that half of the pharmacist respondents found charging a $19.95 service fee difficult when they did not supply the antibiotic. If pharmacists can only feel comfortable to recoup their service costs when prescribing this significantly risks overprescribing (the report shows 96% of women received antibiotics). This cannot be ignored and demonstrates potential for further over-prescribing now that this has been made permanent. This issue does not exist in general practice where there is a separation between prescribing and dispensing. A 2019 GP registrar study showed that only 86% were given immediate antibiotics in a higher complexity cohort.[12]

What process will the Queensland Government put in place to identify and monitor over-prescribing, such as in the case of the five pharmacies in the UTIPP-Q pilot without independent compliance oversight?

1.4 Clarification of protocol prescribing arrangement without a medical diagnosis and future workforce mobility

The Inquiry into the establishment of a pharmacy council and transfer of pharmacy ownership in Queensland Recommendation 2 specified that the risk-minimisation framework should include consultation with a GP, utilising 13HEALTH or have regard to the patient's medical record and also on-site testing. The UTIPP-Q final report demonstrates that neither of these recommendations have been adopted.

The Pharmacy Board of Australia ('the Pharmacy Board'), during the public consultation phase and in the subsequent position statement on pharmacist prescribing, has made several statements and recommendations for consideration if states and territories were to authorise pharmacists to prescribe.

The pilot outcomes stated in the report do not demonstrate compliance with the Pharmacy Board recommendations in the following areas:

1.4.1 The Pharmacy Board noted in their public consultation prescribing discussion paper that a prescribing under a structured prescribing arrangement model "*would need an established*

diagnosis by an appropriately trained healthcare professional, usually a medical practitioner. Protocols would need to be developed collaboratively and clearly define the roles of each member of the team, with clear referral responsibilities and pathways."[13]

The Pharmacy Board states in their position statement that prescribing under this model requires changes in state and territory medicines and poisons legislation to authorise pharmacists to prescribe and these are matters to be determined by state and territory governments.[14]

Concerningly, the RACGP suggests that the UTIPP-Q pilot prescribing model is somewhere in between a structured prescribing arrangement and autonomous prescribing due to the lack of an established diagnosis by a medical practitioner.

The Pharmacy Board states that "*autonomous prescribing by pharmacists requires **additional regulation via an endorsement for scheduled medicines***."[14] Before the Pharmacy Board can assess and consult on the regulatory need to pursue an endorsement, extensive preparatory work is needed. The Pharmacy Board is not making an application for approval of endorsement for scheduled medicines at this time.

Can the Queensland Government confirm that pharmacists are prescribing lawfully, given pharmacists are prescribing for a condition that they must first diagnose?

1.4.2 The Pharmacy Board states, "*to facilitate workforce mobility, a key objective of the National Registration and Accreditation Scheme, the Board encourages national consistency in the approach to any legislative changes to authorise pharmacists to prescribe*." Given legislation in each state and territory provides for particular health professionals to prescribe medicines, it is desirable to establish nationally consistent regulatory requirements for pharmacist prescribing. The variation in vaccination authorities between the states and territories is an example of why the use of the Pharmacist EPA Part 2 will not achieve a nationally consistent approach.

1.5 Adherence to Pharmacy Board recommendations regarding pharmacist prescribing

The Pharmacy Board pharmacist prescribing position statement[14] asked the pharmacy profession and stakeholders to consider the following points if progressing any further work relating to pharmacist prescribing:

1.5.1 Evidence of public health need

"*Evidence that pharmacist prescribing would address a public health need not currently met through existing prescribing practices must be enough to support the development of proposals for pharmacist prescribing."*

The RACGP does not believe that the UTIPP-Q Pilot was developed to meet a public health need. The pilot was not able to confirm that each of the patients had a urinary tract infection as there was no urinalysis. The report has not identified a reduction in hospital emergency department presentations/admissions.

1.5.2 Body of evidence to inform the development of pharmacist prescribing models

"While trials of pharmacist prescribing have been or are being conducted in some practice settings, further trials conducted by jurisdictions in collaboration with service providers may be required to inform the development of pharmacist prescribing models."

This is the only pilot undertaken to date in Australia. It is very unusual and dangerous to make permanent decisions about non-medical prescribing based on one poorly designed pilot study.

1.5.3 Management of conflict of interest in prescribing and supplying in retail setting

"Conflicts of interest need to be managed such as the capacity for a service provider to generate additional income by prescribing and supplying the prescribed medicines and/or pharmacists prescribing medicines when treatment by another health practitioner is in the patient's interest."

Can the Queensland Government explain how the UTIPP-Q pilot met this criterion for pharmacist prescribing? There is not a separation between prescribing and dispensing in the community pharmacy setting and therefore there is a direct link between prescribing and generating additional income?

1.5.4 Independent checks and balances

"Separation of prescribing from the supply of medicines to ensure that an independent check of the prescribing occurs needs to be addressed in the development of any model of pharmacist prescribing."

Can the Queensland Government explain how this criterion will be met, given some pharmacy locations have only one pharmacist, or during periods of illness pharmacy capacity can be reduced to a single pharmacist?

1.5.5 Patient records

"Access to patient records is needed to prescribe effectively and to ensure patient safety."

Can the Queensland Government explain how this criterion is being met, particularly in the case of excluding previous trimethoprim failure/hypersensitivity, renal impairment, or sexually transmitted infections?

1.5.6 Consideration of model setting appropriateness

"Models of prescribing in various practice settings (hospital, community pharmacy, GP clinics, and/or residential aged care facilities etc) must be clearly articulated to determine what would be needed for successful implementation and sustainability of prescribing models in different settings."

Despite requests from the medical community (in particular the RACGP), asking for the pilot to be moved from community pharmacy to medically supervised settings, the Queensland Government and UTIPP-Q Consortium did not contemplate another setting other than community pharmacy.

The report stated that a service fee of $19.95 was payable by the patient (in addition to the cost of any prescribed antibiotics). Half of the pharmacist respondents found charging the fee difficult when they did not supply the antibiotic. The pressure to only charge a service fee if also prescribing an antibiotic to a patient, creates an unsustainable model for pharmacy if the pharmacist cannot recoup their time providing this service. It also increases the risk of overprescribing (the report shows 96% of the women received antibiotics).

Can the Queensland Government publish a risk/benefit assessment of UTIPP-Q for various practice settings that clearly articulates the decision to locate the model in a retail pharmacy setting?

1.5.7 Education, training and registration

"Appropriate education needs to be developed to support pharmacist prescribing if authorised by jurisdictions. In the case of autonomous prescribing, which is likely to require an endorsement for scheduled medicines (if approved by Ministerial Council), education providers would need to develop and deliver accredited and approved education programs to provide the qualification required for the endorsement of pharmacists' registration."

This assumes that the pharmacist has completed their full training including their internship and will still require further education.

The Pharmaceutical Society of Australia and the Pharmacy Guild of Australia, Queensland stated that:

'*Pharmacists complete a minimum five years of training as well as on-going, mandatory professional development and have specialist training prior to participating in the UTI Pilot.'*

The footnote stated that:

'All participating pharmacists are required to undertake mandatory training prior to administering the service. The education is independently accredited with a Continuing Professional Development (CPD) accrediting organisation that adheres to the Australian Pharmacy Council's (APC) Standards and Guidelines.'

The report also stated:

"A clear bimodal distribution was seen in the period of enrollment in the UTIPP-Q by pharmacists participating in the pilot (Figure 12). There is an almost equal number who joined when the pilot began in June 2020, with those who began their participation in early 2021. This second cluster aligns with the intake of pharmacists as new graduates at the beginning of 2021."

Pharmacist requirements for the UTIPP-Q pilot included registration with the Australian Health Practitioner Regulation Agency (Ahpra), appropriate indemnity and completion of the UTIPP-Q education/training module. According to Figure 11 in the report, almost half of the pharmacists were interns and 'new graduates' and were providing prescribing services and collecting clinical information from patients.

Can the Queensland Government provide clarification on the 'second cluster', and whether this group were interns with provisional registration or registered pharmacists?

Internationally, pharmacists often require postgraduate training and additional prescribing authorisation to prescribe antibiotics for a UTI and in many cases, patients have an existing diagnosis from a medical practitioner or pharmacists are working in collaboration with another medical professional. In many cases the pharmacists must communicate information about the dose, duration, quantity and name of the medication prescribed to the patient's doctor. The UTIPP-Q pilot did not communicate these details to a patient's usual GP. The pharmacist is working in isolation from the GP.

The RACGP is concerned by the number of interns, new graduates or 1st year pharmacists with limited pharmacy experience, let alone patient assessment and prescribing experience, who will be prescribing for UTIs and collecting clinical information.

Can the Queensland Government outline what the minimum hours of experience working in a community pharmacy patient facing role are required to be considered competent in prescribing for UTI?

Can the Queensland Government outline what ongoing Continuing Professional Development the pharmacists will be required to undertake to maintain competency?

2. *Concerns with UTIPP-Q research design, outcomes and lack of adherence to the protocol.*

2.1 Lack of confidentiality

The UTIPP-Q pilot protocol states that the pharmacist is the ONLY person who should have involvement in all aspects of patient contact when a patient presents with UTI symptoms to the pharmacy.

However, *Figure 18: Tasks and responsibilities associated with UTIPP-Q service implementation in pharmacy* on p52 of the report shows that pharmacist assistants, intern pharmacists and other staff were involved in collecting clinical information such as symptoms, past medical history, allergies etc and obtaining patient consent for the research.

Also, *Figure 11: Number of years practicing as a pharmacist* indicated that there was only one intern pharmacist; this intern appears to have been involved in a lot of services given the percentage allocations in tasks appears to be between 5% and 10% of each of the services indicated.

Non-pharmacists were also explaining the research component of the service. Given pharmacists did not follow the protocol during the research phase where engagement was monitored, there is a high degree of likelihood that this would continue to occur and possibly in larger volume when rolled out more broadly and without external oversight.

Can the Queensland Government clarify how they will continue to monitor and audit these services to ensure patient confidentiality and adherence to protocol in the absence of external, independent regulatory oversight?

2.2 Unacceptably high loss to follow-up rate

The report states that a total of 35.7% (2,409/6751) participants were available for follow-up at 7 days. It is important to recognise that because the protocol allowed women to opt in or out of the data collection (and 805 women completed the service but declined consent to have their data included in the analysis), the actual number of women treated in the pilot was 7556,

Therefore just 32% (2409/7556) women who received the service were followed up by pharmacists**. Representing a 68% loss to follow-up rate**. Patients lost to follow-up tend to have different outcomes to those who are followed up. In some instances, patients lost to follow-up have had a bad outcome or serious complication.

In addition, only 68 women completed the anonymous Clinical Service Evaluation Survey (CSES) out of the 7556 women who were treated, making the follow up rate of the online survey 0.89% overall, or 2.8% for those who were sent the link to the survey.

In the report summary the claim is made that this evaluation "*Demonstrated that pharmacists have delivered safe and appropriate care that align (sic) to clinical protocols*".

Queensland University of Technology conceded that the evaluation was not designed to be able to demonstrate that pharmacists can deliver safe and appropriate care. It was claimed this was because the protocols under which the pharmacists were prescribing had already been 'proven' safe and effective.

> *"This particular project is a service evaluation. It's not a clinical trial…In this case, the evaluation was really about the experience of service provision by pharmacists and patients"*

However, less than 1% of those treated in the service pilot gave feedback on their experience of the service provision (the pharmacy follow up did not ask questions about patient experience only the online CSES).

Can the Queensland Government explain how these outcomes demonstrate that the experience of service provision by pharmacists and patients was adequately achieved based on such low completion rates (<1%)?

Can the Queensland Government provide clarification on what internal assessment criteria and standards were used by Queensland Government and UTIPP-Q Consortium to determine that these poor outcomes (unacceptably high loss to follow up rates) provided sufficient evidence of ongoing good patient care to qualify this as a permanent service?

2.3 Patient outcomes concerns

The protocol did not require urinalysis (dipstick testing) nor urine cultures. Therefore, there is no accurate way of measuring whether there was a urine infection in the first place, whether an antibiotic was needed at all, and if there was a UTI, whether the appropriate antibiotic had been prescribed. This is a major failing of the pilot design. The failure to resolve UTI symptoms in 13% of 'uncomplicated' cases is clinically significant.

The report also demonstrates numerous instances where the protocol was not followed:

- 43 patients were not referred to a GP, even though they had reported to the pharmacist they had not had a resolution of their symptoms and had not sought further care.
- 40 patients sought further care which was not through their GP; the study has not provided information on where these women sought care, though it appears that at least four have volunteered the information that they attended an emergency department, and presumably many, if not all, of the remaining women also attended an emergency department.
- 112 patients who had unresolved UTI symptoms who attended a GP received another antibiotic. The study claims this is in keeping with normal UTI management, however, the study does not state what type of antibiotics were given or their indication. Many, if not all, of these antibiotics may have been given to treat STIs or other non-UTI conditions that were undiagnosed by the pharmacist. If this is the case, then the **research was incomplete and did not appropriately identify adverse outcomes.**
- Six women were prescribed repeat antibiotics by a pharmacist within 14 days of a first prescription of antibiotics by a pharmacist. At least one patient had only three days interval between repeat antibiotic prescriptions by a pharmacist (per p31 Table 4, this information was not highlighted). None of these six individuals were recorded as having a recurrent UTI or as having been provided a referral to a GP.

In Appendix 3 (p81) the UTIPP-Q initial service protocol question 6 shows that pharmacists were instructed to ask if the patient had a UTI in the last 2 weeks and if so, they were deemed ineligible for treatment.

- At least ten individuals had received 3 services within 1 year (there was a discrepancy in the report on p31 where the text indicated the number was 10, yet Table 4 showed the number as 13). These women should have been referred to GP instead as they required a urine microscopy culture sensitivities test (urine MCS).

The report also mentioned that *"a urine test was not performed in 52/144 patients who attended a GP with unresolved symptoms after being prescribed antibiotics for UTI by a pharmacist"*. This suggests 36.1% who went on to see their GP may have had an obvious non-UTI cause for their symptoms and were inappropriately prescribed antibiotics by the pharmacist. The GP was left to manage the treatment failures.

2.4 UTIPP-Q report inadequacies.

- The report definition of an uncomplicated UTI is incomplete. The report states that '*Uncomplicated UTIs occur in a structurally and functionally normal urinary tract'*.

  The actual definition of an uncomplicated UTI is as follows:

  Uncomplicated UTI occurs in patients who have a normal, unobstructed genitourinary tract, who have no history of recent instrumentation, and whose symptoms are confined to the lower urinary tract.

- On page 18 of the UTIPP-Q report, the two options proposed for the management of UTIs by community pharmacists both stated, "*If a patient was commenced on antimicrobial therapy, their preferred GP would be notified by the pharmacist*.", however this step was not included in the protocol. In the protocol, GPs were only notified if their patient was able to be followed up by the pharmacist and they noted that they had ongoing symptoms. The pharmacist then opted to send the GP a letter. However, the evaluation states that 86 patients were verbally referred to their GP (suggesting no letter was sent to the GP) and that 43 patients who ought to have been referred as they had ongoing symptoms were not referred at all.

- The UTIPP-Q protocol asked women if they were pregnant or if they were 'at risk of STI' as 'yes or no' questions. This is inadequate to assess for undiagnosed pregnancy and sexually transmitted infection (STI). There are clear protocols for questions to ask to be reasonably sure a woman is not pregnant, and these were not followed. Asking about STI requires clinical training and experience to ensure the questioning occurs in a safe and acceptable way, it is not enough to ask someone 'are you at risk of STI?'

- The report evaluation noted "*A recent investigation found Australian pharmacists displayed variable adherence to guidelines when supplying medicines for the treatment of conjunctivitis and emergency hormonal contraception*."

  The use of the word 'variable' minimises the reality. The study referenced found that:

  "57.6% of pharmacies followed dispensing behaviour compliant with the protocol, while 31.3% involved some form of overtreatment or overselling of medication."

  It is RACGP's view that the UTIPP-Q pilot has demonstrated what other evidence has already shown; community pharmacists do not adhere to protocol and overtreat or oversell medicine.

3. Concerns with the Pharmacists EPA

3.1 Lack of transparency for future PSA guideline updates

The Pharmacists EPA states that the '*pharmacist at a community pharmacy to provide empirical treatment, in accordance with the Pharmaceutical Society of Australia Guidance for provision of antibiotics for acute uncomplicated cystitis in women' and* includes a link to this document that is not publicly available https://my.psa.org.au/s/training-plan/a110o00000A62cEAAR/urinary-tract-infectionpharmacy-pilot-queensland-utippq. Therefore, there is a lack of transparency about the protocols being followed by pharmacists and the ability to monitor for updates.

What protections will the Queensland Government put in place to ensure transparency of consultation and notifications on future amendments to this guideline?

3.2 Clinical and legal governance concerns based on Queensland Government's existing performance with maintaining up-to-date vaccination authorities and clear websites.

The Pharmacists EPA does not remain up to date regarding the vaccination authority for pharmacists.

- At present, the Public Health Emergency Pandemic Response to Coronavirus Disease Emergency Order permits pharmacists to vaccinate children 5 years and older for influenza and COVID-19 vaccinations.
- The Pharmacists EPA Version 1 (and the proposed Version 2) state the minimum age for influenza vaccine is 10 years and COVID-19 vaccines are 16 years.
- The Queensland Health immuniser registration and qualifications webpage states that the Pharmacists EPA outlines the scope and conditions of vaccination activities for pharmacists but makes no mention of the need to check for Emergency Orders, nor does it link to the current vaccine-related emergency order.
- The Chief Health Officer Public Health Directions webpage also does not mention Public Health Emergency Pandemic Response to Coronavirus Disease emergency order.
- The authority for pharmacists to administer influenza to children 5 years and older is not found on the influenza immunisation pages, and instead is found on the COVID-19 vaccination services policies and plans webpage.
- The Pharmacist EPA includes specific reference to the COVID-19 vaccines; hence it is implied that a separate pandemic response emergency order would not be required.
- Other states regularly update their pharmacist vaccination authorities for influenza and COVID-19 vaccines to ensure consistent information.

The vaccination space is rapidly changing and the RACGP is concerned that if the Queensland Government has not been able to maintain clear information for relatively straight forward vaccinations, that there is potential for more to fall through the cracks with the addition of more complex prescribing.

3.3 Appendix 3 – community pharmacy requirements, 1d states:

'has sufficient space and appropriate surfaces for the patient to lie down in the event of an adverse reaction; and for staff to safely perform resuscitation procedures.'

RACGP does not believe that all pharmacies (performing vaccinations) comply with this criterion, nor the requirement to conduct private conversations related to the UTI screening within a screened or private consulting area. The current Pharmacists EPA does not specify the privacy requirements for the UTI prescribing.

What auditing processes will the Queensland Government put in place to ensure compliance with these requirements?

Appendix 2: Summary of key questions

1.1 Will the Queensland Government and the UTIPP-Q Consortium provide a copy of the documented processes (equivalent to TGA process) that were used to assess the clinical risk-benefit and patient safety of effectively down-scheduling these medications?

1.1 How will the Queensland Government monitor prescribing habits of pharmacists to protect against antibiotic over-prescribing?

1.2 How will the Queensland Government address the lack of external independent regulatory compliance oversight as there is already evidence (see 1.3) for pharmacist over-prescribing of antibiotics and potential for more in the future?

1.2 Can the Queensland Government confirm that record keeping requirements will also include the below, and outline the plans for audit activities on record keeping associated with UTI prescribing?

- Pharmacists document the patient history and the service provided according to the Professional Practice Standards
- Documentation of referral

Any education or counselling provided to the patient is also advised

1.2 Can the Queensland Government advise how they will enforce maintenance of the patient's health record and outline what measures will be taken to ensure that the patient's usual GP is updated?

1.2 Can the Queensland Government advise what monitoring of cefalexin prescriptions will be undertaken to ensure these medicines are not being prescribed for other conditions?

1.3.1 What process will the Queensland Government put in place to identify and monitor over-prescribing, such as in the case of the five pharmacies in the UTIPP-Q pilot without independent compliance oversight?

1.4.1 Can the Queensland Government confirm that pharmacists are prescribing lawfully, given pharmacists are prescribing for a condition that they must first diagnose?

1.5.3 Can the Queensland Government explain how the UTIPP-Q pilot met this criterion for pharmacist prescribing? There is not a separation between prescribing and dispensing in the community pharmacy setting and therefore there is a direct link between prescribing and generating additional income?

1.5.4 Can the Queensland Government explain how this criterion will be met, given some pharmacy locations have only one pharmacist, or during periods of illness pharmacy capacity can be reduced to a single pharmacist?

1.5.5 Can the Queensland Government explain how this criterion is being met, particularly in the case of excluding previous trimethoprim failure/hypersensitivity, renal impairment, or sexually transmitted infections?

1.5.6 Can the Queensland Government publish a risk/benefit assessment of UTIPP-Q for various practice settings that clearly articulates the decision to locate the model in a retail pharmacy setting?

1.5.7 Can the Queensland Government provide clarification on the 'second cluster', and whether this group were interns with provisional registration or registered pharmacists?

1.5.7 Can the Queensland Government outline what the minimum hours of experience working in a community pharmacy patient facing role are required to be considered competent in prescribing for UTI?

1.5.7 Can the Queensland Government outline what ongoing Continuing Professional Development the pharmacists will be required to undertake to maintain competency?

2.1 Can the Queensland Government clarify how they will continue to monitor and audit these services to ensure patient confidentiality and adherence to protocol in the absence of external, independent regulatory oversight?

2.2 Can the Queensland Government explain how these outcomes demonstrate that the experience of service provision by pharmacists and patients was adequately achieved based on such low completion rates (<1%)?

2.2 Can the Queensland Government provide clarification on what internal assessment criteria and standards were used by Queensland Government and UTIPP-Q Consortium to determine that these poor outcomes (unacceptably high loss to follow up rates) provided sufficient evidence of ongoing good patient care to qualify this as a permanent service?

3.1 What protections will the Queensland Government put in place to ensure transparency of consultation and notifications on future amendments to this guideline?

3.3 What auditing processes will the Queensland Government put in place to ensure compliance with these requirements?

References

[1] Shahabi-Sirjani A. Submission Proposed criteria for appendix M of the Poisons Standard to support rescheduling of substances from Schedule 4 (Prescription only) to Schedule 3 (Pharmacist only).2019. NSW Antimicrobial Stewardship Pharmacist Network. Available from: https://www.tga.gov.au/sites/default/files/submissions-received-and-tga-response-consultation-proposed-criteria-appendix-m-poisons-standard-nsw-aspn.pdf
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