30 June 2023

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The Hon Shannon Fentiman MP
Minister for Health, Mental Health and Ambulance Services
Minister for Women

Mr Shaun Drummond
Director-General
Queensland Health

By email: [redacted]

Subject: Urgent cessation of UTI Community Pharmacy Service

Dear Minister and Director-General

AMA Queensland remains extremely concerned about the threat posed to patients during the Urinary Tract Infection Pharmacy Pilot – Queensland (UTIPP-Q) and currently as part of the Urinary Tract Infection Community Pharmacy Service (UTICPS).

Attached is a copy of new and alarming findings made by general practitioner and AMA Queensland Councillor Dr Stephanie Dawson-Smith about both programs. Dr Dawson-Smith's concerns are based on recent information released by Queensland University of Technology and following discussions with Queensland Health. They show the threat posed to patients is serious and ongoing given the UTIPP-Q was made permanent under the UTICPS.

We again call for the urgent cessation of the UTICPS and a thorough review of the UTIPP-Q to address the multiple concerns raised by Dr Dawson-Smith and in previous correspondence by her and AMA Queensland. In addition, the North Queensland Community Pharmacy Scope of Practice Pilot must be immediately abandoned given it was justified by Queensland Health on the basis of the UTIPP-Q and UTICPS. None of these programs can continue without posing a grave and real threat to patient safety.

We are willing to meet with you to discuss these concerns at your convenience.

Yours sincerely

Dr Maria Boulton
President
AMA Queensland

Dr Brett Dale
Chief Executive Officer
AMA Queensland

27 June 2023

[redacted]
Executive Director, Assessment & Resolution
Office of the Health Ombudsman
Email: [redacted]

Dr Stephanie Dawson-Smith
Email: [redacted]

Dear [redacted],

Thank you for your recent email correspondence. I am writing to outline the rationale that an RTI document from Qld Health pertaining to the UTIPP-Q which, when viewed with the data contained in the UTIPP-Q Service Evaluation Report, demonstrates that over the period 19th June 2020 to 30th September 2022 between 3,280-3,897 women appear to have been supplied antibiotics illegally via Queensland Health's UTIPP-Q service.

Key points:

- Pharmacists providing antibiotics for empirical treatment of urinary tract infection (UTI) as part of the UTIPP-Q (UTI Pharmacy Pilot - Queensland) were legally required to act in accordance with both 'The Pharmaceutical Society of Australia Guidance for provision of antibiotics for acute uncomplicated cystitis in women' (PSA Practice Standard) and 'the treatment protocol established under the UTIPP-Q' (Steering Group Protocol).

- The Steering Group Protocol was not consistent with the PSA Practice Standard due to multiple omissions and alterations. The Steering Group Protocol was comparatively lax and inadequate to the task of identifying those patients who were unsuitable for the service due to risk of complicated infection and resistant UTI.

- The Software Workflow that pharmacists were mandated to use as part of the UTIPP-Q (Final GuildLink Module) was not consistent with the PSA Practice Standard.

- The inconsistencies between the PSA Practice Standard, the Steering Group Protocol and the Final GuildLink Module are clinically important, and threaten patient safety.

- The UTIPP-Q Evaluation findings indicate that pharmacists appear to have generally followed the Steering Group Protocol but did not follow the PSA Practice Standard when providing the UTIPP-Q service. However, for 'risk of sexually transmitted infection (STI)', the report findings suggest neither protocol was followed.

- Per the Steering Group Protocol, patients with 'any STI risk' were ineligible for treatment. Per the PSA Practice Standard, age ≤29 was a 'clinically relevant risk factor for STI'. Of the total of 10,270 UTIPP-Q study participants only 9 (<0.1%) were identified as having 'any STI risk'. This was despite 3,633 of those patients being aged ≤29. Per the PSA Practice Standard these 3,633 patients should have been deemed ineligible for treatment due to STI risk.

- In the UTIPP-Q Outcomes Report, which Queensland parliamentarians relied upon when deciding to make the UTIPP-Q permanent, the authors reported and analysed data using a definition for recurrent UTI that the Queensland Health Deputy Director-General has acknowledged was not consistent with the Steering Group Protocol or the PSA Practice Standard. The use of this false definition reduced the reported treatment protocol deviation rate for the relevant ineligibility criterion by more than 20 fold.

- Following my complaint to Queensland Health regarding the UTIPP-Q Outcomes Report, the authors have released a new report omitting the claim that, "the UTIPP-Q has successfully demonstrated the implementation and evaluation of a service that has … demonstrated that pharmacists have delivered safe and appropriate care that align (sic) to clinical protocols". However, despite the Queensland Health Chief Allied Health Officer previously advising that the UTIPP-Q Outcomes Report would be retracted if it had reported data in a way that was not consistent with the PSA Practice Standard, the original report containing false information remains published on the QUT website.

1. <u>The legal framework for pharmacists to supply prescription-only medication through the UTIPP-Q</u>

To allow pharmacists to legally supply and sell antibiotics without a valid prescription as part of the UTIPP-Q, regulatory approval was required.

Initially this authority came in June 2020 via a Drug Therapy Protocol under the Health (Drugs and Poisons) regulations of 1996. That legal document was later replaced on the 27th September 2021 by an Extended Practice Authority "Pharmacists" under section 232 of the Medicines and Poisons Act 2019 (EPA 'Pharmacists').

These documents stated the scope of the regulated activities with the regulated substances which a pharmacist is authorised to carry out.

These authorisations were relevant over the trial period which commenced on 19 June 2020 and concluded on 31 December 2021. A pharmacist could sell and supply antibiotics only if it was in accordance with the treatment protocol established under the UTIPP-Q and in accordance with 'The Pharmaceutical Society of Australia Guidance for provision of antibiotics for acute uncomplicated cystitis in women' (PSA Practice Standard). For instance, the EPA 'Pharmacists' states that:

'*The endorsed model of care for the trial enables a community pharmacist to provide empirical treatment,* ***in accordance with the Pharmaceutical Society of Australia Guidance for provision of antibiotics for acute uncomplicated cystitis in women****.'*

AND

'For participating in the UTIPP-Q, a pharmacist may sell [an antibiotic for empirical treatment of urinary tract infection] … to a patient without the requirement for a prescription:

a. *subject to the restrictions for the medicine stated opposite in Appendix 4, Column 2 (if any); and*
b. ***in accordance with the treatment protocol established under the UTIPP-Q****.'*

Thus, legally, pharmacists were required to act in accordance with both the PSA Practice Standard and the Steering Group Protocol whenever they supplied and/or sold antibiotics without a valid prescription for the treatment of UTI.

<u>2. The Steering Group Protocol was not consistent with the PSA Practice Standard. The Software Module that pharmacists were mandated to use as part of the UTIPP-Q (Final GuildLink Module) was not consistent with the PSA Practice Standard.</u>

In March I met with Queensland Health representatives (the Deputy Director-General, Chief Allied Health Officer and Chief Medical Officer) along with the AMA Qld President and CEO. In this meeting the Chief Allied Health Officer, Ms Liza-Jane McBride stated that the PSA Practice Standard was the same as the UTIPP-Q Protocol. In follow-up correspondence to me, the Queensland Health Deputy Director-General, Dr Helen Brown, has stated that the treatment

protocol established under the UTIPP-Q (Steering Group Protocol) is presented on p24 of the UTIPP-Q Outcomes Report (https://eprints.qut.edu.au/232923/). Dr Brown provided the below screenshot of the 'actual final GuildLink Module'* Software Workflow Eligibility Criteria for the UTIPP-Q (Figure 1.)

It is important to note that:
1. the Steering Group Protocol was not consistent with the PSA Practice Standard (see Table 1);

2. the UTIPP-Q Outcomes Report published a version of the PSA Practice Standard (https://eprints.qut.edu.au/232923/ Appendix 1. p62-74) that was not consistent with the actual PSA Practice Standard (see attached RTI document** p25-30, see also https://www.psa.org.au/wp-content/uploads/2022/12/Treatment-guideline-for-pharmacists-cystitis.pdf, and see also the hyperlink referenced in the EPA 'Pharmacists': https://my.psa.org.au/s/training-plan/a110o00000A62cEAAR/urinary-tract-infection- pharmacy-pilot-queensland-utippq) due to multiple clinically significant omissions and alterations.

Figure 1. Software Workflow Eligibility Criteria for the UTIPP-Q

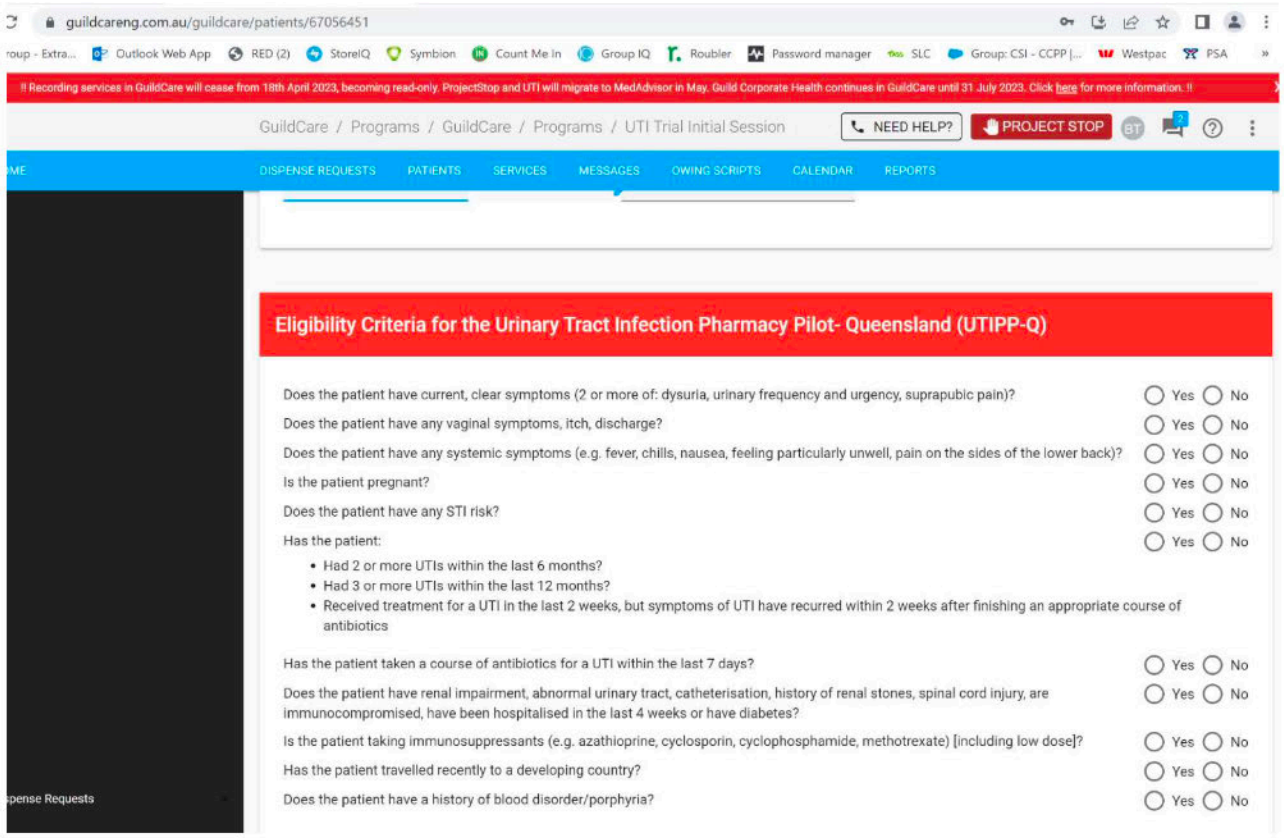

Table 1. Examples of inconsistencies between the PSA Practice Standard (referenced in the Extended Practice Authority 'Pharmacists' — Version 1), the modified version of the PSA Practice Standard published as Appendix 1 to UTIPP-Q Outcomes Report June 2022 (p62-74), the Steering Group Protocol and the Final GuildLink Module Software Workflow.

PSA Practice Standard	Modified version of the PSA Practice Standard published as Appendix 1 to UTIPP-Q Outcomes Report	Steering Group Protocol	Final GuildLink Module Software Workflow
Ineligibility criteria for treatment, requires referral to a medical practitioner			
Fever >38*C (**sign**)	Fever >38*C (**sign**)	Fever (**symptom**)	Fever (**symptom**)
Vomiting	Vomiting	Vomiting	**Omitted**
Previous episodes of pyelonephritis	Previous episodes of pyelonephritis	**Omitted**	**Omitted**
Postpartum	Recent birth, miscarriage or abortion	**Omitted**	**Omitted**
History of urinary tract abnormality or obstruction	History of urinary tract obstruction	**Omitted**	**Omitted**
Antibiotics within the last **3 months**	Antibiotics within the last **3 months**	**Omitted**	Antibiotics **for a UTI** in the last **7 days**
Inpatient/resident of a healthcare facility or other care facility in last **3 months**	Hospitalisation within the previous **4 weeks**	Hospitalisation in last **4 weeks**	Hospitalisation in the last **4 weeks**
Intrauterine device in situ	Intrauterine device in situ	**Omitted**	**Omitted**
Overseas travel within last **3 months**	Travel to a **developing** country within the previous 3 months	**Omitted**	**Recent** travel to a developing country
Risk factors for STI "Relevant risk factors for STI in females include: -age ≤29 years -previous STI -sexual contact without a condom/dental dam outside a mutually monogamous relationship -a new sex partner in last 60 days -multiple sex partners -a sex partner with multiple other sex partners -a sex partner recently treated for an STI -sexual contact with a sex worker. Refer patients with relevant risk factors for STI to a medical practitioner for further investigation."	**Omitted**	Any STI risk	Any STI risk

*Dr Brown has acknowledged that wording related to recurrent UTIs in the Example GuildCare Software Workflow (p81) published in the UTIPP-Q Outcomes Report is not consistent with the Steering Group Protocol (p24) and PSA Practice Standard (p62) in the published UTIPP-Q Outcomes Report. The Software Workflow the authors published as an appendix to the UTIPP-Q Outcomes Report was not the actual Software Workflow (Figure 1. Final GuildLink Module Software Workflow) that was used in the UTIPP-Q.

**Mr James Lake, a Cairns-based General Practice Director, made a Right to Information application for documents related to the UTIPP-Q, including the clinical protocol for the UTIPP-Q. "Third party consultation extended the due date significantly, as the consulted third party lodged objections to the release of the documents. Numerous emails were exchanged and meetings were conducted with the third party to discuss their rationale for objecting to the release."

3. The inconsistencies between the PSA Practice Standard, the Steering Group Protocol and the Final GuildLink Module are clinically important and threaten patient safety.

The Steering Group Protocol was lax when compared with the PSA Practice Standard and was clearly inadequate to the task of identifying those patients who were unsuitable for the service due to the presence of complicated UTI and resistant UTI. The Steering Group Protocol and Final GuildLink Module omitted the following PSA Practice Standard ineligibility criteria: previous episodes of pyelonephritis, postpartum period, history of urinary tract abnormality or obstruction, and intrauterine device in situ. The Steering Group Protocol and Final GuildLink Module significantly altered the ineligibility criteria related to fever, recent prior antibiotics, recent prior hospitalisation/resident of a healthcare facility or other care facility, and recent overseas travel.

The UTIPP-Q Service was not equipped to provide safe healthcare to patients with complicated UTI, resistant UTI, and STI and therefore it was essential that patients at risk of these conditions should not have been treated as part of the service. Severity of complicated UTI could not be assessed as no examination was performed, complicated UTI could not be treated empirically with the available antibiotic regimens, resistant UTI could not be appropriately managed as no urine testing was performed and STIs could not be diagnosed or treated through this service. Delay in treatment of these conditions can have permanent ramifications, including sepsis, chronic pelvic pain and infertility.

4. The UTIPP-Q Evaluation findings indicate that pharmacists did not follow the eligibility criteria defined in the PSA Practice Standard when providing the UTIPP-Q service.

In March I raised concerns with Queensland Health representatives that an incorrect definition of recurrent UTI was used in the Example GuildCare Software Workflow published with the UTIPP-Q Outcomes Report. I was told by the Queensland Health representatives that if the software workflow was incorrect they were confident pharmacists would have relied on their training and ignored the software prompts in front of them, using the software as a recording tool not a clinical prompt. The training provided to pharmacists to allow them to provide the UTIPP-Q service consisted of a 1.5 hour online module with a multi-attempt, multi-choice quiz and therefore was unlikely to be adequate to provide such robust training that pharmacists would be confident to ignore the mandated software's prompts. The same concern that it would have been difficult for pharmacists to ignore the software prompts applies to the inconsistencies between the Final GuildLink Module eligibility criteria and the PSA Practice Standard eligibility criteria, as outlined in Table 1 above.

The published data indicates that pharmacists providing the UTIPP-Q service did not follow the elements of the eligibility criteria that were in the PSA Practice Standard but not in the Steering Group Protocol.

Of 10,270 women who consented to participate in the UTIPP-Q evaluation, under the 'summary of reasons for consumers deemed ineligible to participate' published in the final UTIPP-Q Service Evaluation Report (available at https://eprints.qut.edu.au/239310/):
0 were deemed ineligible due to having fever as a sign (only symptoms listed),
0 were deemed ineligible due to being in the postpartum period,

0 were deemed ineligible due to having had antibiotics within the last 3 months,
0 were deemed ineligible due to being an inpatient/resident in a non-hospital care facility in the last 3 months, and
0 were deemed ineligible due to having an intrauterine device in situ.
These criteria were all present in the PSA Practice Standard and omitted in the Steering Group Protocol. The statistical improbability that these risk factors all occurred at a rate of 0% in the study population strongly suggests the greater likelihood that none of these ineligibility criteria were included in the implementation of the service.

Furthermore, of 10,270 women, under the 'summary of reasons for consumers deemed ineligible to participate' in the final UTIPP-Q Service Evaluation Report:
9 women (<0.1%) were found to be at "any risk of STI".
The incongruence between the rate of risk of STI that was detected in the pilot and the rates of risk of STI in the Australian community raises serious questions regarding the safety of the service that was provided.

5. Per the Steering Group Protocol, patients with 'any STI risk' were ineligible for treatment. Per the PSA Practice Standard age ≤29 was a 'clinically relevant risk factor for STI'. Of the total of 10,270 UTIPP-Q study participants, only 9 (<0.1%) were identified as having 'any STI risk'. This was despite 3,633 of those patients being aged ≤29. Per the PSA Practice Standard these 3,633 patients should have been deemed ineligible for treatment due to STI risk.

Clearly, the Steering and Advisory Group and the Consortium for the UTIPP-Q had identified that the service was not suitable or safe for patients at risk of STI. The Steering Group Protocol ineligibility criterion "any STI risk" was somewhat vague and presumably the intended meaning was that patients with any STI risk factor (as listed in the PSA Practice Standard explanatory notes) was ineligible for the service. The alternative is that the Steering Group Protocol literally meant "any STI risk", in which case all patients who had ever been sexually inactive would have been ineligible, for an average Australian adult female population this would have been expected to translate to >80% of participants being ineligible due to STI risk. 97% of Australian's aged 15-29 understand that anyone who is sexually active is at risk of STI. Over 80% of Australians aged 15-29 report sexual activity.[1]

The PSA Practice Standard listed relevant risk factors for STI (see table 1) including: age ≤29, or multiple sex partners / partner with multiple sex partners, or unprotected sex outside a mutually monogamous relationship. The PSA Practice Standard stated that patients with 'relevant' risk factors for STI were to be referred to a medical practitioner and were not eligible for the service.

It is important to clarify that in the PSA Practice Standard "patient**s** with risk factor**s**" (plural) for STI was to be read as "a patient with a risk factor" (singular). This is clear when looking at the earlier ineligibility criteria in the list. For example "sign**s** and symptom**s** of pyelonephritis" appropriately required only one sign or symptom to meet the ineligibility criteria and this was reflected in the Steering Group Protocol. The use of the plural form was stylistic as it would have been dangerous to require that patients only be deemed ineligible if they had multiple signs and symptoms of pyelonephritis which would be the literal translation of what the authors later wrote "refer the patient to a medical practitioner if sign**s and** symptom**s** of pyelonephritis are present".

Whilst the PSA Practice Standard stated pharmacists were expected to exercise professional judgment in adapting the guidance to presenting circumstances, that patients aged ≤29 were to be deemed at risk of STI and ineligible was clearly delineated in the explanatory notes and therefore no adaptation was required. For instance, the PSA Practice Standard states that a pharmacist should consider whether the guidance applies to a transgender patient and this would be an example of a situation where professional judgment would need to be applied.

If the PSA Practice Standard's list of relevant risk factors for STI was applied, at minimum, the 3,633 women aged 18-29 were ineligible for the UTIPP-Q (~35% of participants). Legally, pharmacists were obliged to act in accordance with both the PSA Practice Standard and Steering Group Protocol. In practice, it is clear that neither protocol has been followed in relation to the STI risk ineligibility criteria.

Even if the PSA Practice Standard that age ≤29 alone made a patient ineligible due to STI risk were ignored and instead we considered that other risk factors should be present, the data would still indicate that STI risk was not adequately identified in the study. 78% of Australian women aged 15-29 report having had unprotected sex in the past 12 months, 83% of Australians aged 15-29 reported multiple sexual partners in the past 12 months, and 24% reported having unprotected sex with casual partner/s in the past 12 months.[1]

It is not plausible that the rate of any STI risk detected was <0.1% merely due to selection bias, the most likely explanation for the low rate of participants identified to be at risk of STI is that the service failed to adequately identify participants at risk of STI.

If a sexual health history cannot be reliably obtained through this service and is critical to the safe provision of the service, it is obvious that the service is not safe. This is important because of the implications for women's health at both individual and public health levels. Research shows that in young women seeking care for urinary symptoms, 9-28% had a proven STI[2]. STI symptoms can be transient and resolution of symptoms does not equate to resolution of disease. Therefore, advising patients to see a GP if symptoms have not resolved is not adequate to capture all cases of STI. Failure to promptly treat STIs can lead to catastrophic, irreversible health impacts for women and these include infertility, significantly increased risk of ectopic pregnancy and chronic pelvic pain; as well as the ongoing risk of transmission of STI to sexual partners and missed opportunity to track and treat previous partners.

5. In the UTIPP-Q Outcomes Report which Queensland parliamentarians relied upon when deciding to make the UTIPP-Q permanent, the authors reported and analysed data using a false definition for recurrent UTI. The use of this false definition reduced the reported treatment protocol deviation rate for the relevant ineligibility criterion by more than 20 fold.

In the aforementioned March meeting with Queensland Health representatives I raised that the UTIPP-Q Evaluation had analysed and reported data in a way that was not consistent with the PSA Practice Standard. During the meeting the Chief Allied Health Officer stated that if it were found by Queensland Health that this were the case then there would be a formal retraction of the UTIPP-Q Outcomes Report.

In the UTIPP-Q Outcomes Report,
"Recurrent infections were defined as more than 3 UTIs within the previous year".

Whereas in the PSA Practice Standard and the GuildCare Software Protocol,
"Recurrent UTI is defined as two or more UTIs within 6 months or three or more UTIs within 12 months"
The UTIPP-Q Outcomes Report went on to analyse data using the incorrect definition for recurrent UTI. The UTIPP-Q Outcomes Report contained false statements that were based on these false data findings.

Following the meeting with Queensland Health representatives I provided written correspondence which demonstrated that the authors of the UTIPP-Q Outcomes Report reported and analysed data using an incorrect definition for recurrent UTI. The Queensland Health Deputy Director-General has since acknowledged that the definition that was used by the UTIPP-Q Outcomes Report for recurrent UTI was not consistent with the Steering Group Protocol or the PSA Practice Standard. Subsequent to this, QUT published the UTIPP-Q Service Evaluation Report on the 26th April 2023. In this updated report, the authors made a number of noteworthy changes. For example, the authors removed the incorrect definition of recurrent UTI and instead used the correct definition for recurrent UTI to analyse data. As a result of using the correct definition it has been identified that 192 individuals received treatment inappropriately when they had a recurrent UTI. In the prior report the authors had claimed the number of individuals treated inappropriately when they had a recurrent UTI was 6, when at that time the actual number was greater than 120. The original UTIPP-Q Outcomes Report containing false reporting has not been retracted and remains published on the QUT website.

This falsely reported outcomes paper was relied on by Members of Queensland Parliament in deciding to make the UTIPP-Q permanent through legislative change.

The updated UTIPP-Q report has admitted that the number of patients who received treatment when they had recurrent UTI and were therefore ineligible is “evidence of treatment protocol deviation”.

The updated report has also now commented on the 22 patients who were inappropriately supplied cefalexin because the “patient requested it”. This issue of patients being supplied cefalexin inappropriately (cefalexin was the third line antibiotic which could legally be supplied only where the first and second line antibiotics were both inappropriate for the patient) was raised in my August 2022 Issues Paper and has not previously been acknowledged.

I will note that the data in both reports demonstrates far more than 22 patients were supplied cefalexin without legal justification***. In any case, the following statement in the UTIPP-Q Outcomes Report was noticeably absent in the final Service Evaluation Report,

“This reported treatment approach used by pharmacists in the pilot aligns to first-line therapy according to the recommended evidence based empiric treatment guideline.”

There was another striking and inaccurate statement in the original Outcomes Report that the UTIPP-Q Evaluation authors chose not to include in the final Service Evaluation Report:

“The UTIPP-Q has successfully demonstrated the implementation and evaluation of a service that has:

1 Reinforced the value provided to the health care system and accessibility of community pharmacy...

2 Demonstrated that pharmacists have delivered safe and appropriate care that align (sic) to clinical protocols...

3 Concluded that pharmacists have the appropriate skills, competencies and training to manage the empiric treatment of uncomplicated UTIs in the community pharmacy.”

***The Drug therapy protocol and Extended practice authority stated the second-line antibiotic could be prescribed only where the first-line was inappropriate for the patient and the third line could only be prescribed where both the first and second-line therapies were inappropriate for the patient. These are as follows (from table 4 of the outcomes report):
—22 were given the third-line therapy because ‘patient requested it’
—31 were assessed as appropriate to receive second-line therapy but then received third-line therapy instead without cause#
—19 cases were not supplied either first-line therapy or second-line therapy because they were “pregnant, trying to conceive or breastfeeding”.
—-If they were pregnant they should have been identified in the earlier part of the service as ineligible. If they were trying to conceive and possibly pregnant then they also were ineligible for the service. If they were trying to conceive and definitely not pregnant then second-line therapy was certainly not contraindicated as it is category A safe in pregnancy. If they were breastfeeding then first-line therapy was not contraindicated. In most cases second-line therapy is also safe in breastfeeding.

#217 found to be inappropriate for second-line therapy out of total of 362 patients (bottom row); 362-217= 145; however 114 (row 17) were given second-line therapy (=31 patients given third-line therapy who were determined by pharmacist as being appropriate for second-line therapy).
217 were found to be inappropriate for second-line therapy and therefore 217 should have been given third-line therapy. However, the number was actually 248 (row 18) (217+31).

In summary, there is evidence that thousands of women have been provided a service that does not appear to have been consistent with legal restraints on the provision of that service. These legal restraints were designed to act as safeguards for women. An evaluation of the service that contained false information was provided to Members of Queensland Parliament. Queensland Parliament moved to make the service permanent following receipt of this information. Since that time an updated evaluation report has re-reported the data with significant amendments that

disprove claims made in the original report's 'key recommendations and findings' section. These issues have not been investigated appropriately. Meanwhile, the UTIPP-Q service poses an ongoing serious threat to the health of women in Queensland.

Yours sincerely,
Dr Stephanie Dawson-Smith

References:

1) Adam, P. C. G., de Wit, J. B. F., Ketsuwan, I., Treloar, C. (2019). Sexual health-related knowledge, attitudes and practices of young people in Australia. Results from the 2018 Debrief Survey among heterosexual and non-heterosexual respondents. Sydney: Centre for Social Research in Health, UNSW Sydney. http://doi.org/10.26190/5c5128aac57e5

2) Olson E, Gupta K, Van Der Pol B, Galbraith JW, Geisler WM. *Mycoplasma genitalium* infection in women reporting dysuria: A pilot study and review of the literature. Int J STD AIDS. 2021 Nov;32(13):1196-1203. doi: 10.1177/09564624211030040. Epub 2021 Jul 6. PMID: 34229513; PMCID: PMC8858599.