

## Medication Shortages

### Context

*Australia imports over 90% of its pharmaceutical products<sup>1</sup> leaving the country particularly vulnerable to international drug shortages. Medication shortages in Australia have increased by 300% since the COVID-19 pandemic.<sup>2</sup> Currently, there is an international shortage of a number of essential medicines that are affecting Australians.*

**Medication shortages and supply instabilities of essential medications can potentially worsen health inequities for the Aboriginal and Torres Strait Islander population. Access to essential medications is necessary to reduce the burden of disease, hospitalisations and premature death that adversely affects this population.**

These medication shortages are now disproportionately affecting the Aboriginal and Torres Strait Islander population.

The Queensland Aboriginal and Islander Health Council (QAIHC), the peak body for Aboriginal community-controlled health services (ACCHSs) in Queensland, has reviewed a range of policy instruments that act to minimise the impact of these medications shortages on the Australian health system. These instruments include federal and state-based levers. There is compelling evidence these levers do not offer a complete solution to the problem, leading to clinician confusion and other adverse impacts on equitable access to treatment, particularly for clinical conditions that disproportionately impact on Aboriginal peoples

and Torres Strait Islanders. Importantly, Aboriginal community-controlled health services (ACCHSs) alone cannot avoid nor shape the market forces that are worsening medication access inequities faced by their patients. A whole of health system response is needed.

QAIHC makes a number of recommendations in this Position Statement to guide Queensland Health and Federal bodies towards systems that may mitigate compounding health inequities from these medication shortages. In this Position Statement, two examples of critical medication shortages are presented, and these include:

- The shortage of benzathine benzylpenicillin (Bicillin LA) prefilled syringes due to a disruption at the point of manufacturing, as well as increased global demand for the product.<sup>3</sup> This medication is a compelling example of an essential medicine, particularly for Aboriginal and Torres Strait Islander people.
- The shortage of 5% permethrin cream which is the current first-line treatment of scabies. Scabies is a known risk factor for Group A streptococcal skin infections which increases the predisposition to acute rheumatic fever (ARF) and rheumatic heart disease (RHD).

1. Therapeutic Goods Administration. Management and communication of medicine shortages and discontinuations in Australia. Version 11. Canberra, May 2019. Accessed Nov 20, 2023. <https://www.tga.gov.au/sites/default/files/2023-02/managementand-communication-medicine-shortages-and-discontinuations-australia.pdf>

2. Cameron EE, Bushell M-JA. Analysis of drug shortages across two countries during pre-pandemic and pandemic times. Res Social Adm Pharm Sept 2021;17(9):1570-1573. doi: 10.1016/j.sapharm.2020.12.001

3. Martyn K (Pfizer Inc.). Letter to: Customers. Jun 12, 2023. Accessed Nov 20, 2023. <https://www.fda.gov/media/169427/download>

There are a number of Australian schemes that aim to assist medication supply at time of shortages. In particular, the Therapeutic Goods Administration (TGA) has an important role in managing medicine shortages. The TGA can identify safe, suitable substitute medicines to ensure patients have continued access to important medicines through Section 19A of the Therapeutic Goods Act (1989).<sup>4</sup>

However, if the TGA approved substitute medication is not approved for the Pharmaceutical Benefits Scheme (PBS), patients are required to pay the full cost when it is sourced from community pharmacy. This cost can be considerably higher than the price paid for the original medication that was substituted.<sup>5</sup> A substantial price mark-up in times of product shortages is an inevitable consequence.

The Close the Gap (CTG) PBS Co-Payment measure for Aboriginal peoples and Torres Strait Islanders reduces or eliminates the cost of medications for the Aboriginal and Torres Strait Islander population and has played a critical role in enhancing health equity for Indigenous Australians. However, this measure cannot take effect if a substitute medication is not PBS approved. Expedited TGA registration of substitute medications make no difference to patient access if the cost of the medication for patients is prohibitive.

There will be ongoing global challenges associated with medication shortages and these will continue to disproportionately affect the Aboriginal and Torres Strait Islander population. A sustainable policy solution is needed.

## Impact of this shortage on Queensland Aboriginal community-controlled health organisations

Nationally, Aboriginal and Torres Strait Islander people account for 92% of the diagnoses of **acute rheumatic fever (ARF)** between 2017 and 2021.<sup>6</sup> Group A Streptococcal (GAS) non-invasive infections are the cause of ARF and rheumatic heart disease. These infections include preventable and treatable GAS pharyngitis/tonsillitis and GAS impetigo (skin infections) arising from scabies, and other predispositions for skin infections.

In northern Australia, Aboriginal and Torres Strait Islander people experience **invasive Group A Streptococcal infections** at 6-10 times the rate of non-Indigenous Australians.<sup>7</sup>

Notification rates for **non-congenital syphilis** in Aboriginal and Torres Strait Islander people were 5.8 times the rate for non-Indigenous Australians nationally but goes up to 27 times in remote and very remote areas.<sup>8</sup>

**Acute post-streptococcal glomerulonephritis** has only recently become notifiable in Queensland, and there are already reports of clusters of APSGN in North Queensland.<sup>9</sup>

QAIHC refers to medications for these conditions as 'essential medicines' as they highlight the inequitable impact of medication shortages on Aboriginal peoples and Torres Strait Islanders disproportionately affected by these conditions.

4. <https://www.tga.gov.au/resources/resource/guidance/section-19a-guidance-industry>

5. Therapeutic Goods Administration. Prescribe an unapproved therapeutic good (health practitioners). Canberra. Accessed Nov 20, 2023. <https://www.tga.gov.au/products/prescribe-unapproved-therapeutic-good-health-practitioners>

6. Australian Institute of Health and Welfare. Acute rheumatic fever and rheumatic heart disease in Australia, 2017-2021. May 2023. Accessed Nov 20, 2023. <https://www.aihw.gov.au/reports/indigenous-australians/arf-rhd/summary>

7. Hla TK, Cannon JW, Bowen AC, Wyber R. Getting to grips with invasive group A streptococcal infection surveillance in Australia: are we experiencing an epidemic? Med J Aust. Aug 21, 2023. doi: 10.5694/mja2.52056

8. Australian Institute of Health and Welfare. Aboriginal and Torres Strait Islander Health Performance Framework. 1.12 HIV/AIDS, hepatitis and sexually transmissible infections. Feb 15, 2023. Accessed Nov 20, 2023. <https://www.indigenoushpf.gov.au/measures/1-12-hiv-aids-hepatitis-sex-transmissible-infect>

9. Townsville Public Health Unit. Public health alerts: APSGN, measles, pertussis, shortage of Bicillin LA. Nov 13, 2023. Accessed Nov 20, 2023. <https://nqphn.com.au/index.php/news/public-health-alerts-apsgn-measles-pertussis-shortage-bicillin-lar>

## Current schemes to assist medication supply at times of shortages

In Queensland, there are currently no Department of Health sponsored schemes to support Aboriginal community controlled health services (ACCHSs) to access essential medications in short supply.

Other Australian schemes that aim to assist medication supply at time of shortages are listed below.

### Serious Scarcity Substitution Instruments (SSSIs)

In the event of serious medication shortages, community pharmacists can substitute specific medicines with another dosage form or strength **of the same medicine**, without prior approval from the prescriber. This relies on the availability of an alternate formulation **of the same product**.<sup>10</sup> A PBS subsidy can be allocated to the TGA registered substitution of the same medicine according to certain criteria.<sup>11</sup> This instrument has not yet been proven to solve the medication shortages faced by ACCHSs for the priority health issues under consideration.

### National Medical Stockpile

The National Medical Stockpile is a strategic reserve of supplies, including medicines, vaccines, personal protective equipment (PPE), for national health emergencies and supplements the stock held by state and territory health authorities.<sup>12</sup> The supply of products is only possible when commercial supply is unavailable and there is a demonstrated need for its use. For security reasons, details about the content of the stockpile are not released publicly.<sup>12</sup> To QAIHCs knowledge, this stockpile does not include products for ARF/RHD, syphilis, or scabies and release approvals are neither clear to state or federal health authorities.

### Special Access Scheme

Prescribers can use the *Special Access Scheme* (SAS) *Category A pathway and the Authorised Prescriber* (AP) scheme to access 'unapproved' medicines from overseas.<sup>13</sup> However, accessing an unapproved product requires consideration of the patient's informed consent, adherence to relevant standards of good medical practice, and poses risks of treatment with an alternative product. This is not a safe nor suitable alternative method for ACCHSs to access essential medications. This scheme has not been proven to solve the medication shortages faced by ACCHSs for the priority health issues under consideration.

### Minimum Stockholding Requirements

From 1 July 2023, the amendments to the *National Health Act 1953* took effect and imposed requirements for manufacturers ('Responsible Persons') to keep four or six months of 'usual demand' **PBS listed** medicines (known as 'designated brands') as stock in Australia. These medications must meet certain criteria but are generally the mainstay of treatment for some of the most prevalent health conditions in Australia.<sup>14</sup>

These measures cannot prevent shortages at a manufacturing level. However, they can support supply of essential medications during shortages until stock is available again. Once stock is depleted, community pharmacy cannot access supply unless the TGA has registered a product from an alternative supplier. PBS subsidy may not be available, meaning this is not a viable solution to medication shortages faced by ACCHSs.

The examples below pertain to 5% permethrin cream for the treatment of scabies, and benzathine benzyl penicillin to illustrate how this scheme does not offer a solution to medication shortages faced by ACCHSs.

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10. Therapeutic Goods Administration. Serious Scarcity Substitution Instruments (SSSIs). Canberra. Sept 29, 2023. Accessed Nov 20, 2023. <https://www.tga.gov.au/resources/resource/guidance/serious-scarcity-substitution-instruments-sssis>
  11. The Pharmaceutical Benefits Scheme. PBS subsidy for medicines subject to a Serious Scarcity Substitution Instrument FAQs. Canberra. Nov 2, 2023. Accessed Nov 20, 2023. <https://www.pbs.gov.au/files/serious-shortage-medicine-substitution-files/PBSsubsidy-for-medicines-subject-to-a-Serious-Scarcity-Substitution-Instrument-FAQ.pdf>
  12. Australian Government Department of Health and Aged Care. National Medical Stockpile. Canberra. Jun 2, 2023. Accessed Nov 20, 2023. <https://www.health.gov.au/our-work/national-medical-stockpile>
  13. National Aboriginal Community Controlled Health Organisation. Shortages of medicines in Australia. Aug 12, 2021. Accessed Nov 20, 2023. <https://www.naccho.org.au/shortages-of-medicines-in-australia/>
  14. The Pharmaceutical Benefits Scheme. Minimum stockholding guidelines. Canberra. Oct 21, 2022. Accessed Nov 20, 2023. <https://www.pbs.gov.au/industry/pricing/medicines-supply-security-guarantee/Pharmaceutical-Benefits-Scheme-Minimum-Stockholding-Guidelines-published-21-Oct-2022.pdf>

### **Example 1: Permethrin (5% cream) is a designated brand, but this doesn't guarantee supply**

The treatment of scabies is a priority for First Nations health for the prevention of secondary skin infections and the prevention of ARF and RHD.

5% permethrin (TGA and PBS approved as Lyclear, 30g) is first-line treatment for scabies and is a 'designated brand', but is no longer available in Australia from community pharmacy due to a global shortage. Encube (60g) is now approved by the TGA as a replacement. However, Encube is not PBS approved. This product is therefore costing patients between \$60 to \$150 per tube, dependant on the community pharmacy.<sup>15</sup>

There are secondary alternatives for the treatment of scabies.

Therapeutic Guidelines and the National Healthy Skin Guideline 2nd edition offer alternative treatments. Oral ivermectin can be used first line for scabies in most patient groups, which is on the PBS.

- "Oral ivermectin 200micrograms/kg for children over the age of 5 years (or over 15kg) and for nonpregnant/non-breastfeeding adults. Repeat the dose in 7 days."

Ivermectin cannot be used for the treatment of children less than 15kg, nor pregnant or breastfeeding women, which is often required to treat whole households for scabies.

Benzyl benzoate (Benzemul, Ascabiol) is a second line treatment due to potential skin reactions but is also currently in shortage.

### **Example 2: Pfizer's benzathine benzylpenicillin (Bicillin LA) is a designated brand, but supply was only possible with PBS listing of an alternative**

Intramuscular benzathine benzylpenicillin (Pfizers designated brand) is indicated in the treatment of acute rheumatic fever and prevention of rheumatic heart disease, syphilis, including congenital syphilis, invasive Group A Streptococcal Infections, streptococcal pharyngitis and tonsillitis, and impetigo (as risk factors for ARF/RHD), including acute post-streptococcal glomerulonephritis.<sup>16,17</sup>

Recently, a limited or completely depleted stock of Bicillin LA led to expedited PBS listing of a substituted product (Extencilline) after nearly 6 months of waiting.<sup>18</sup> In light of the shortage, the Queensland Statewide Antimicrobial Stewardship Program made recommendations for clinicians to conserve stock for priority indications and consider alternative agents.<sup>19</sup>

Substitute formulations (alternative manufacturers<sup>20,21</sup>) were made available, with clinicians having to deal with differing clinical formulations, constituents including potential allergens, more shortages, and subsequent lapsed approvals. There were delays in Pharmaceutical Benefits Scheme (PBS) approvals, with each vial requiring a payment of approximately \$44.60 to be paid by the patient.<sup>22</sup> This medication is now PBS approved and due for listing in June 2024, making it accessible and affordable. However, ACCHSs faced uncertainties and medication rationing during a period of many months with no clear lines of communication from relevant authorities.

15. Personal communication, Aboriginal community controlled health service, May 2024.

16. Therapeutic guidelines Limited. Therapeutic guidelines. Accessed Nov 20, 2023. <https://tgldcdp.tg.org.au/>

17. Western Australia Country Health Service. Public health management of acute post-streptococcal glomerulonephritis guideline. Jun 2019. Accessed Nov 20, 2023. <https://www.wacountry.health.wa.gov.au/~media/WACHS/Documents/Aboutus/Policies/Public-Health-Management-of-Acute-Post-Streptococcal-Glomerulonephritis-Guideline.pdf>

18. Pfizer Hospital. Pfizer injectables product availability report. Nov 2023. Accessed Mar 4, 2024. [https://www.pfizerhospitalus.com/injectables\\_availability\\_report](https://www.pfizerhospitalus.com/injectables_availability_report)

19. Queensland Statewide Antimicrobial Stewardship Program. Clinical care alert: benzathine benzylpenicillin (Bicillin LA) shortage. Oct 2023. Accessed Nov 20, 2023. [https://www.childrens.health.qld.gov.au/\\_data/assets/pdf\\_file/0018/191205/Benzathine-Benzylpenicillin-shortage-communicate.pdf](https://www.childrens.health.qld.gov.au/_data/assets/pdf_file/0018/191205/Benzathine-Benzylpenicillin-shortage-communicate.pdf)

20. Therapeutic Goods Administration. Benzylpenicillin benzathine 1.2 million I.U powder and solvent for suspension for injection (Brancaster Pharma, UK). Accessed Mar 4, 2024. <https://www.tga.gov.au/resources/section-19a-approvals/benzylpenicillinbenzathine-12-million-iu-powder-and-solvent-suspension-injection-brancaster-pharma-uk>

21. Electronic Medicines Compendium. Benzylpenicillin benzathine 2.4 Million I.U. powder and solvent for suspension for injection – summary of product characteristics. Jul 17, 2023. Accessed Nov 20, 2023. <https://www.medicines.org.uk/emc/product/11044/smpc>

22. ORSPEC Pharma team, internal communication, Nov 6, 2023.

## Medication shortage reports database

To assist clinicians in dealing with medication shortages, the TGA has published lists of medications affected. This database does not assist with the supply and access to medications.

Medication shortages in Australia considerably complicates clinician options for the management of ARF, GAS skin infections, and syphilis treatment. There are no clear lines of communication to assist

prescribers with decision making nor about the formulation of substitute agents.

Examples of relevant proposed alternative agents for the management of these conditions and their availability is shown in the table below as per the Therapeutic Guidelines<sup>5</sup> and the TGA Medicine shortage reports database [current as of 28 May 2024].<sup>23</sup>

| Alternative agent  | Current availability   | Notes   |
|--|--|---|
| <b>Treatment of acute rheumatic fever</b>  |  |   |
| Oral cefalexin for 10 days<br>(125mg/5mL powder for oral liquid bottle)                                    | Limited availability   | Formulation for children. Alternative but penicillin is the drug class of choice to treat residual Group A strep infection and to eliminate carriage. |
| Oral azithromycin for 5 days<br>(200mg/5mL powder for oral suspension bottle)                              | Limited availability   | Formulation for children. Alternative but penicillin is the drug class of choice to treat residual Group A strep infection and to eliminate carriage. |
| <b>Treatment of early syphilis</b>   |  |   |
| Oral doxycycline for 14 days   | Limited availability of 100mg tablets                          | Alternative but doxycycline cannot be used in pregnant patients, and benzathine benzylpenicillin is the drug of choice for early syphilis.            |
| <b>Treatment of streptococcal pharyngitis and tonsillitis</b>  |  |   |
| Oral amoxicillin for 10 days<br>(500mg/5mL powder for oral suspension bottle; 1000 mg tablet blister pack) | Limited availability or unavailable depending on manufacturer. | Alternative, for situations where phenoxymethylpenicillin is not tolerated, noting it is not preferred as first-line treatment.                       |

## PBS listing of alternative medications

The National Aboriginal Community Controlled Health Organisation (NACCHO) is a member of the TGA 'Medicine Availability Working Group' (WG) which includes state and territory health department representatives to share information and model the availability of important medicines used in hospitals. The Group can advocate for speedy PBS listing of substitute medications in

shortages, but this process can take months and is wholly independent of the recommendations of the WG which meets infrequently. The WG may be more effective if it is expanded to include NACCHO Affiliates such as QAIHC to ensure collaboration with Queensland Health medication services functions to ensure primary health care experiences are considered.

23. Therapeutic Goods Administration. Medicine shortage reports database. Canberra. Accessed Mar 4, 2024. <https://apps.tga.gov.au/Prod/msi/search>

## Role for Hospital and Health Services medication access for priority populations during medication shortages

There are currently no mechanisms at a Queensland State Government level to assist ACCHSs facing medication shortages.

However, Hospital and Health Services (HHSs) could play a role to assist ACCHSs to access medication stock held in Central Pharmacy. Central Pharmacy provides medicines for patients in HHSs, dental clinics, Qld Ambulance service sites and private patients of hospitals within Queensland.<sup>24</sup> Central Pharmacy is also a commercialised business unit of Queensland Health. HHSs purchase stock of medicine from Central Pharmacy to supply to their patients.

ACCHSs cannot currently access medication stock from Central Pharmacy. However, HHSs could provide stock to ACCHSs under a purchasing arrangement with them, at times of shortages, for priority health conditions, and in circumstances where substitute medications are not yet PBS listed. Such a process could serve to redistribute essential medicines to ACCHSs through a state government sponsored supply mechanism.

Currently, medication supply to ACCHSs from the HHS in times of shortages (via Central Pharmacy) may be approved, but this is subject to individual HHS discretion. It is QAIHCs understanding that such arrangements have already occurred in local

negotiations with ACCHSs, and these are to be commended. Such arrangements would be consistent with the legislated Health Equity commitments of HHSs (see below).

Any local Health and Hospital Service (HHS) or Queensland Health related actions to benefit Aboriginal peoples and Torres Strait Islanders should be linked to Health Equity Strategy efforts required under the Making Tracks Together — Queensland's Aboriginal and Torres Strait Islander Health Equity Framework- actions required by legislation.<sup>25</sup>

A state-wide agreement and Directive, underpinned by a clear process for the supply of medications under critical situations where access to medications for ACCHSs through other means is not possible, will serve to streamline access, avoid the need for individual HHS negotiations, and help meet HHS equity obligations.

The redistribution of essential medicines and health supplies has been used in other countries to mitigate overstocking, wastage and stockouts by moving unused stock to locations where it is required.<sup>26</sup> Such a process is urgently required in Queensland.

## Alternative schemes at a national level

There are currently no federal mechanisms to prioritise access to medications during a shortage to priority populations, such as Aboriginal peoples and/or Torres Strait Islanders. However, a federal scheme for the redistribution and supply of medications to ACCHSs that was co-designed with NACCHO could be created to solve crises associated with essential medication shortages.

Stakeholders at multiple levels, from primary care to the national level, could collaborate to implement efficient

and real-time inventory management surveillance tools to aid in the redistribution of essential medications.

A real-time surveillance tool could assist in the effective channelling of excess stock or soon-to-expire medicines to health services with high consumption rates of the product or high prevalence rates of the specific treatable condition.

24. <https://www.legislation.qld.gov.au/view/pdf/published.exp/sl-2021-0143/lh#:~:text=Central%20Pharmacy%20conducts%20bespoke%20manufacturing,the%20repackaging%20of%20some%20medicines>.

25. Queensland Health. Making Tracks Together — Queensland's Aboriginal and Torres Strait Islander Health Equity Framework. Available from: <https://www.health.qld.gov.au/public-health/groups/atsihealth/making-tracks-together-queenslands-atsihealth-equity-framework>

26. Mabizela S, Nakambale HN, Bangalee V. Predictors of medicine redistribution at public healthcare facilities in King Cetshwayo District, KwaZulu-Natal, South Africa. BMC Health Services Research. Oct 17, 2023;23 (1108). doi: 10.1186/s12913-023-10096-4.

## Recommendations

Medication shortages can have drastic effects on the health of Aboriginal and Torres Strait Islander patients leading to suboptimal care and delays to treatment with downstream consequences including increased healthcare costs. Rural and remote communities in Queensland face even more challenges with long distances to transport stock, and a lack of community pharmacy.

There are no strategies to improve the stability of supply and procurement of essential medicines in Australia for Aboriginal peoples and Torres Strait Islanders at times of medication shortages. This on a background of current and a gross underutilisation of medications by this population.<sup>27</sup>

The costs required to introduce systems to minimise Aboriginal and Torres Strait Islander health inequities arising from such medication shortages are more than offset by the underutilisation of medications-related expenditure at a state and federal level.

QAIHC makes the following recommendations for State and Federal health systems as a way to avoid further medications-related inequities:

### Recommendation 1:

The TGA and Queensland Health adopt systems that can recognise when medication shortages are likely to disproportionately affect the Aboriginal and Torres Strait Islander population. This is to trigger timely and bespoke policy responses to pre-empt and minimise healthcare related harms. By their nature, the impact of such medication shortages will be most evident by primary health care service providers and therefore will require collaboration with NACCHO and QAIHC to enable the Department of Health and Ageing and Queensland Health to have a line of sight to the problem.

### Recommendation 2:

The TGA and PBAC establish mechanisms to fast-track the PBS approval processes for TGA approved substitute medications whenever medication shortages disproportionately and adversely impact on equitable primary health care delivery to the Aboriginal and Torres Strait Islander population.

### Recommendation 3:

That federal and State health authorities create and formalise a process for the redistribution of specified essential medications to Aboriginal community-controlled health organisations to assist patients during times of medication shortages whenever medication supply cannot be guaranteed from a community pharmacy.<sup>28</sup> Such processes may include:

- a. A direct subsidy scheme that permits ACCHSs to order TGA approved alternative medications directly from a central federal supplier. Such a system could be co-designed with NACCHO and support ACCHSs to order medicines that have been secured for use and distribution specifically to Aboriginal community-controlled health organisations at times of medication shortages.
- b. Qld HHS Directives in collaboration with individual ACCHSs, where clinical need arising from TGA informed medication shortages triggers the HHS to approve the release and supply of TGA approved substitute medications sourced from Central Pharmacy, directly to the ACCHS.
- c. The development of a real-time inventory management surveillance tool to aid in the redistribution of essential medications to where shortages will adversely impact health equity efforts.

27. Aboriginal and Torres Strait Islander Health Performance Framework.

28. Shuka S, Zahoor F, Hayat K, Saeed A, Gillani AH, Omer S et al. Drug shortage: causes, impact, and mitigation strategies. *Front Pharmacol*. 2021;12:693426. doi: 10.3389/fphar.2021.693426.

## Recommendations Continued

### Recommendation 4:

The TGA provide readily available and clear information to prescribers on the substitute medication including ingredients, method of administration, labelling, storage information, transport requirements with comparisons to the original product to reduce the need for individual prescribers to carry out this work themselves.<sup>29</sup>

For further information:

Associate Professor Sophia Couzos

[sophia.couzos@qaihc.com.au](mailto:sophia.couzos@qaihc.com.au)

29. Ryan MJ. Medicine shortages: there are solutions! Actions to take to reduce medicine shortages. Aust Health Rev. 2021 Aug;45(4):504-506. doi: 10.1071/AH20306.