

# POSITION STATEMENT

# **Health Screening and Condition Management in Community Pharmacy**

## **Position**

The Pharmacy Guild of Australia (the Guild) believes that health screening and condition management through community pharmacies can facilitate early diagnosis and intervention, enhance the monitoring of chronic conditions, improve therapeutic control and Quality Use of Medicines (QUM), and improve patient self-management. This will not only improve the health autonomy, literacy and empowerment of patients, but contribute to better health outcomes and quality of life for patients and improve the efficiency and effectiveness of our health system.

Community pharmacy is the optimal environment to provide patient education and support in the ongoing self-management of diagnosed conditions that can be assisted by monitoring:

- health markers such as blood pressure, blood lipids, blood glucose/HbA1c or lung function
- the response to medicines to manage treatments or adverse effects such as International Normalised Ratio (INR) for anticoagulant therapy, electrolyte levels or liver and kidney function

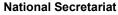
Community pharmacy is ideally placed to also assist in the screening for conditions including, but not limited to, cardiovascular disease (CVD), asthma, chronic obstructive pulmonary disease (COPD), diabetes, sleep apnoea and blood borne diseases such as human immunodeficiency virus (HIV) and hepatitis C. Community pharmacy in Australia is also taking a greater role in screening for and diagnosing urinary tract infections (UTI) and respiratory diseases such as influenza, SARS CoV2 (COVID) and Human Respiratory Syncytial Virus (RSV).

Community pharmacies could also be better used as part of a patient's health care team to assist in:

- identifying and managing deficiencies such as vitamin D, vitamin B12, iron, calcium or magnesium
- testing for and administration of vitamin B1 (thiamine) for heavy alcohol users, accompanied by promoting the safe reduction/cessation of alcohol for high-risk people, including during pregnancy
- national cancer screening programs, making tests more accessible and/or acting as collection points e.g. cervical screening self-collection kits.

## **Staff Education**

The Guild believes that all community pharmacists providing any clinical service, including health screening or condition management services, must be appropriately trained and work within their scope of practice. The Guild also recognises that support staff within a pharmacy may be trained to manage administrative and/or non-complex service functions (e.g. obtaining a sample for an in-pharmacy test,



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conducting a blood pressure test), noting that the pharmacist is responsible for any clinical assessment and decision.

The Guild supports the provision of evidence-based clinical services and products focused on improved outcomes for the patient. The Guild believes patients must be fully informed about the clinical services available to them from a community pharmacy. It is important that pharmacists clearly explain to the patient the difference between an indicative **screening test** (which requires further testing or advice) and a **diagnostic test** (which confirms whether the disease is present).

## **Diagnostics**

The Guild supports the use of pathology services and point-of-care testing (PoCT) technologies, including in-vitro diagnostic (IVD) medical devices as part of health screening and condition management services within a community pharmacy. Having been available for many years in Australia in the tertiary health setting and increasingly within general practice<sup>1</sup>, PoCT technology offers patients convenient access to fast, reliable and evidence-based testing which will lead to earlier presentation and management of a person's health conditions. Because of its ease of access and convenience, there is increasing access to PoCTs through community pharmacy, including for tests for which people may have privacy concerns such as HIV or drug screening self-testing kits.

The Guild strongly believes in patients having access to Government-subsidised pathology tests irrespective of the clinician ordering the test, including from community pharmacists managing pathology requests within their scope of practice. This would assist patients with more affordable health care and has been recognised within the final report for the Government's Scope of Practice Review<sup>2</sup>. The Guild recognises that while community pharmacists may have some familiarity with ordering and reviewing pathology tests, more training is needed in this area, including at the undergraduate level. With these supports, the Guild looks forward to pathology requests becoming a routine service option in community pharmacy, consistent with contemporary clinical guidance.

The Guild believes that community pharmacy should only use or supply to the patient for home use, products that have been approved as an IVD medical device by the Therapeutic Goods Administration (TGA), assuring that such a device is appropriate, accurate, reliable and included in the Australian Register of Therapeutic Goods (ARTG) as a basis for legal supply.<sup>3</sup>

Community pharmacies or other health centres should be the primary outlet for the supply of IVD medical devices for use in the community setting in preference to internet supply to provide the opportunity for counselling with a clinician, such as a community pharmacist. The Guild does not believe such devices should be supplied from a non-health retail outlet such as grocery stores or service stations.

Utilising a pharmacist's diagnostic skills also supports changes to enable easier access to treatments from a person's preferred community pharmacy. Community pharmacists in all States and Territories can diagnose urinary tract infections for women and supply the appropriate antibiotic treatment. The Guild believes similar arrangements should be in place to allow community pharmacists to supply antimicrobial treatments for confirmed diagnosis of other conditions such as influenza, COVID and chlamydia, including as a pharmaceutical benefit where appropriate, consistent with patient eligibility criteria.

## **Genetic Tests**

The Guild supports the availability of genetic testing kits within community pharmacy as a pharmacogenomic tool for home use or assessment by a pharmacist or external specialist to inform a person's health care. As a therapeutic product, these testing kits must be quality assured and listed on the ARTG. In addition, the Guild highlights the importance of appropriate training for pharmacy staff or the availability of a clinician with expertise in the area to reinforce the application of the testing and pre and post-test counselling.

## **Clinical Governance**

The Guild believes that community pharmacies providing health screening and condition management services and products must ensure they have the necessary clinical governance structures and quality assurance processes in place. This will ensure patients have access to high-quality, safe and clinically appropriate health care from their preferred community pharmacy. The AS85000.2024 - *Australian Community Pharmacy Standard* supports community pharmacies to apply the principles of clinical governance and continuous quality improvement. Pharmacies accredited under the Quality Care Pharmacy Program (QC2020) are required to develop and maintain a structured quality management system that supports the provision of safe, consistent and high-quality health care, and contributes to positive health outcomes for all Australians. QC2020 aligns with clinical governance principles for Australian community pharmacy and the requirements outlined in the Australian Commission for Safety and Quality in Health Care (ACSQHC) National Model Clinical Governance Framework<sup>5</sup>.

With the appropriate clinical governance, required under AS85000.2024, including infection control and cold chain processes, community pharmacy could also be utilised as a drop-off/collection point for specimens intended for laboratory-based analysis. Similarly, community pharmacy could be an option for providing health services requiring venepuncture, using suitably qualified providers. These options may be of particular use in rural and remote areas and other under-serviced communities where access to services and delays in receiving results is impeding patient health. It is especially relevant to our First Nations people in remote areas who experience a greater burden and severity of disease.

### **Team Care**

The Guild recognises community pharmacy as an integral part of a patient's health care team and supports communication involving other members of the team to optimise the patient's health outcomes. The Guild recognises that digital health records are a crucial element to the effective management of a person's health. They enable more effective and efficient sharing of health records, including any screening or monitoring tests undertaken and can also reduce the duplication of tests ordered or provided by different clinicians. This must be supported by community pharmacists having access to secure communication channels with other clinicians.

## Remuneration

The Guild supports community pharmacy being appropriately remunerated for providing health screening and condition management services. Ideally, a full patient subsidy for services would be available for eligible patients from the Commonwealth or state or territory government or by private health insurance. In the absence of full subsidisation, community pharmacies should always have the discretion to apply private fees for their services in addition to Government subsidies, and where a patient is not eligible for a service, pharmacies should be able to choose to provide the service for an appropriate private fee.

# **Background**

Recent years have highlighted many communities around Australia are underserviced with reduced or delayed access to health services<sup>6</sup>. People in regional, rural and remote areas have a higher incidence of health risk factors, a greater prevalence of chronic conditions and a greater burden of disease.<sup>7</sup> People living in rural and remote areas face barriers to accessing health care, due to challenges of geographic spread, low population density, limited infrastructure, and the higher costs of delivering rural and remote health care.<sup>8</sup> Other groups who would benefit from improved access to health screening and condition management services in community pharmacy include First Nations people as well as people with a disability, culturally and linguistically diverse people and people from lower socioeconomic households.

## Point of Care Testing and use of In-vitro diagnostic medical devices

IVD medical devices include pathology tests for laboratory testing as well as devices for use by a clinician at the point of care or by lay persons for self-testing. IVDs do not include products that are not intended for therapeutic use, including tests for parentage and kinship, drug tests used in sport, and tests for alcohol or the detection of illicit drugs 10.

PoCT is performed by a clinician at their site of practice, such as within a community pharmacy.

Examples of in-pharmacy PoCT include testing for blood glucose, HbA1c or blood lipids. Examples of self-test kits for home use include HIV self-test kits that have been approved for community pharmacy supply<sup>11</sup>, pregnancy tests, urinalysis sticks, and blood glucose meters and testing strips. Community pharmacies have been a major provider of COVID rapid antigen tests as part of the management response for COVID-19 and now also provide tests for influenza and RSV, all of which can be used for inpharmacy testing or for self-testing at home.

Internationally, tests for hepatitis C<sup>12</sup> and sexually transmitted infections such as chlamydia<sup>13</sup>, gonorrhoea and syphilis are available through community pharmacy, either by using in-pharmacy testing or self-tests purchased in-store or online.<sup>14</sup> Evidence shows that such services are feasible, accessible, convenient and accepted by the public<sup>15</sup>.

The increasing availability and use of PoC and home test kits from community pharmacy, with access to health professional advice, supports the ethical principle of a patient's right to exercise their preference for the kind of care they want.

Whether supplied as a supervised PoCT or sold over the counter for home use, the community pharmacy setting provides an opportunity for patients to seek advice on correct test use, and counselling on what to do if the test returns a reactive result. It also enables a prompt response to manage outbreaks of transmissible illnesses in timely manner.

# **Pathology Tests**

Pathology provides accurate and timely information that directly affects population health by providing clinicians with the insights to manage patients appropriately. <sup>16</sup> The subsidisation of pathology tests by the Commonwealth Government is legislated under the *Health Insurance Act 1973* and subordinate regulations. Pharmacists are not recognised as a 'practitioner' for subsidised pathology services under the *Health Insurance Act 1973*.

The ordering of pathology tests by community pharmacist is not yet a universal service, due in part to the lack of Government subsidies but also the limited availability of pharmacy-related pathology training to support pharmacists to work to their full scope.

## Pharmacogenomics testing for condition management

Pharmacogenomic testing at community pharmacies is a growing area with enormous potential to improve medicine efficacy through personalised treatment. Traditionally medicines have been prescribed to treat a condition without the ability to know whether that medicine will be effective for an individual patient. Pharmacogenomic testing offers the means of prescribing and dispensing medicine at doses appropriate to individual patients' genetic profile. To identify the right treatments for individual patients and minimise the risk of adverse drug reactions, pharmacogenomic testing can be carried out prior to initiation of treatment or during treatment in response to adverse effects being experienced. Commonly used medications with 'risk' gene variants include allopurinol, amitriptyline, azathioprine, carbamazepine, citalopram, clopidogrel, codeine, escitalopram, ondansetron, oxycodone, paroxetine, simvastatin, tamoxifen, tramadol and warfarin<sup>18</sup>.

## **Related Statements**

Nil

# **Authority**

### **Endorsed**

National Council - March 2025

National Council - November 2022

National Council - November 2012 (Disease Screening and Condition Management in Community Pharmacy)

#### Review

Policy and Regulation Sub-Committee - February 2025

Policy and Regulation Sub-Committee – November 2022

Policy and Regulatory Affairs Committee - October 2012 (Disease Screening and Condition Management in Community Pharmacy)

# References

<sup>1</sup> St John. A (2010) 'The Evidence to Support Point of Care Testing' Clin Biochem Rev Vol.31(3):111-119 [accessed online 27 September 2012]

<sup>&</sup>lt;sup>2</sup> <u>Unleashing the Potential of our Health Workforce – Scope of Practice Review | Australian Government Department of Health and Aged Care</u>

<sup>&</sup>lt;sup>3</sup> Therapeutic Goods Administration 'Overview of the regulatory framework for in-vitro diagnostic medical devices' (July 2011)

<sup>&</sup>lt;sup>4</sup> UTI prescribing nationwide | Pharmacy Daily; 29 Oct 2024

<sup>&</sup>lt;sup>5</sup> National Model Clinical Governance Framework | Australian Commission on Safety and Quality in Health Care

<sup>&</sup>lt;sup>6</sup> Patient Experiences in Australia: Summary of Findings, 2020-21 financial year | Australian Bureau of Statistics (abs.gov.au)

<sup>&</sup>lt;sup>7</sup> https://www.aihw.gov.au/reports/rural-remote-australians/rural-and-remote-health; updated April 2024

<sup>&</sup>lt;sup>8</sup> ibid

<sup>&</sup>lt;sup>9</sup> Overview of medical devices and IVD regulation | Therapeutic Goods Administration (TGA); July 2024

<sup>&</sup>lt;sup>10</sup> Regulation of In Vitro Diagnostic Medical Devices; June 2015

<sup>&</sup>lt;sup>11</sup> HIV self-tests available in Australia | Therapeutic Goods Administration (TGA)

<sup>&</sup>lt;sup>12</sup> London Drugs Launches Potentially Life-Saving Hepatitis C Screening at Pharmacies - London Drugs Blog

<sup>&</sup>lt;sup>13</sup> A pharmacy-based private chlamydia screening programme: results from the first 2 years of screening and treatment - PubMed (nih.gov)

<sup>&</sup>lt;sup>14</sup> https://onlinedoctor.lloydspharmacy.com/uk/sti-tests

<sup>&</sup>lt;sup>15</sup> (PDF) Chlamydia screening interventions from community pharmacies: A systematic review (researchgate.net)

<sup>&</sup>lt;sup>16</sup> The Centre for International Economics; Economic-value-of-pathology June-2019

<sup>&</sup>lt;sup>17</sup> HEALTH INSURANCE ACT 1973

<sup>&</sup>lt;sup>18</sup> RACGP - Pharmacogenomics in general practice