

Counterfeit drugs: an Australian perspective

A recent report on counterfeit drugs and online pharmacies highlighted the global impact of falsified or substandard drugs.¹ In countries with stringent legislation, governance and customs, such as Australia, the prevalence of counterfeit medications is low and estimated by the World Health Organization to be less than 1% of market value.² Substandard medications are a greater issue globally, with reduced efficacy and potential for contamination.³ All may have serious and unpredictable risks (Box).

Globally, there are about 36 000 active internet pharmacies, of which less than 5% are estimated to be legitimate. In the United States and the European Union, consumers have access to a list of authorised websites, such as LegitScript (<https://www.legitscript.com>) and the EU common logo (via national websites listed with the European Medicines Agency). In contrast, in Australia, there is currently no government-endorsed safe list of Australian internet pharmacies. In June 2015, 115 countries including Australia participated in Operation Pangea, an international week of action targeting the online sale of counterfeit and illicit medicines; over 20 million falsified medicines were seized, 429 investigations were launched, and 2414 websites were taken offline.⁴ This and other initiatives, including the WHO global surveillance and monitoring system and an EU directive (2011/62/EU) aiming to limit supply, address the growing issue of falsified medications.

Patients use online pharmacies for convenience, cost savings, and access to medications without a prescription. In Australia, medications purchased online are often lifestyle medications targeted at improving a person's quality of

Common risks of falsified or substandard medications

Issue	Consequences
Excess active ingredient	Increased adverse drug reactions
Reduced or no active ingredient	Reduced efficacy
Incorrect ingredient	Adverse drug reactions and unpredictable effects
Toxic additives or contaminants	Potential for significant injury or death
Past use-by date or poor packaging	Reduced efficacy

life. These include medications for weight loss, hair growth, and treatment of erectile dysfunction. There have been recent reports in Australia of these medications being contaminated with sulfonyleureas⁵ and sibutramine⁶ with significant adverse effects. The Therapeutic Goods Administration (TGA) issues advisories and safety alerts when counterfeit and illegal medications are detected (available at <https://www.tga.gov.au/alerts>).

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For Australian travellers, the WHO and the Northern Territory Department of Health advise travellers to purchase antimalarial and prescription medications before departure. This is based on studies in Africa and Asia that have reported treatment failure due to insufficient or inactive ingredients in locally purchased medications.³ Adverse effects associated with toxic additives present because of substandard quality control have also been reported with medications purchased overseas. For example, mass poisonings have resulted in death secondary to contamination with diethylene glycol.⁷ Although localised to specific countries, with

the rise of unregulated online pharmacies, this is a potential risk even in countries with adequate pharmaceutical controls and quality assurance such as Australia.

In the era of increasing globalisation of pharmaceutical products, Australia must remain vigilant, and clear guidelines for monitoring, regulation and education are needed. Suggestions to implement this include:

- All Australian online pharmacies should be accredited through the Quality Care Pharmacy Program. From this, the TGA in conjunction with the Pharmacy Guild of Australia should release a safe list of Australian online pharmacies.
- Public awareness campaigns should utilise NPS Medicine Wise and Australian Prescriber — resources widely accessed by consumers, pharmacists and prescribers.
- The Australian Customs and Border Protection Service should continue to work with global agencies to optimise the identification of counterfeit medications.

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