



ACT
Government

ACT Health

Dear Pharmacists and Prescribers

National Coordination of Serious Medicines Shortages

I write to update you on an important initiative to support continued access to medicines during the COVID-19 public health emergency.

The Therapeutic Goods Administration (TGA), in consultation with state and territory health departments and national stakeholders, has developed a national protocol for enabling pharmacists to substitute medicines during serious medicines shortages.

In the event of a serious medicines shortage, the TGA will coordinate stakeholder advice on whether a pharmacy-level substitution is warranted. The decision to confirm a serious medicines shortage and allow substitution would be made by the TGA and will be published as a Serious Shortage Medicine Substitution notice (Notice) on the TGA website.

There is a range of situations where substitution by a pharmacist could be undertaken by a Notice, such as dispensing of:

- a lower or higher strength of a product (such as two 20mg tablets in place of 40mg tablet),
- another dose form of the same medication (e.g. capsule instead of tablet),
- a combination of individual medicines when a fixed dose combination is not available, or
- an immediate release form in lieu of a sustained / extended release version and vice versa.

Under the TGA protocol, substitution will not be permitted for another product containing a different active ingredient or for Schedule 8 (controlled) medicines.

A pharmacist is not required to check with the patient's prescriber before substitution in accordance with a TGA Notice, however they should advise the prescriber as soon as practicable.

On 1 May 2020, Dr Kerryn Coleman, ACT Chief Health Officer issued a temporary Standing Order for the supply of medicines during a public health emergency under the Medicines, Poisons and Therapeutic Goods Regulation 2008. The Standing Order adopts the TGA Serious Shortage Medicines Substitution protocol in the ACT by enabling pharmacist substitution of any medicine in accordance with a TGA Notice.

This decision has been made to reduce the impact of a serious medicines shortage in the ACT and prevent or mitigate any resulting public health harms.

The Standing Order is in force for the duration of the ACT declared public health emergency, unless revoked earlier. ACT Health Directorate will consider options to adopt the TGA scheme in the longer term. A copy is attached for your information.

More information about the TGA Serious Medicine Shortage Substitution protocol, including Questions and Answers, is available on the [TGA website](http://www.tga.gov.au) www.tga.gov.au.

Further information about medicines management during COVID-19 in the ACT may be accessed on the [Medicines Matters](#) page on the ACT COVID-19 website www.covid19.act.gov.au.

If you have further queries, please do not hesitate to contact the Pharmaceutical Services Section at the Health Protection Service on 02 5124 9208 or hps@act.gov.au.

Yours sincerely,



Vivien Bevan
Chief Pharmacist
Health Protection Service
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