

Standard Operating Procedure

Guidance for Accessing Diphtheria Antitoxin

June 2022

Guidance for accessing diphtheria antitoxin from the Queensland Medical Stockpile

BACKGROUND

Diphtheria antitoxin (DAT) is an injection used to counter the effects of the diphtheria toxin produced by the bacteria *Corynebacterium diphtheriae*. The Queensland Medical Stockpile is managed by Central Pharmacy on behalf of the Communicable Diseases Branch (CDB). The Stockpile includes a limited supply of diphtheria antitoxin (DAT), 10,000 IU/10mL. This stock is held and supplied for use at zero cost to Hospital and Health Services (HHS).

DAT is not on the Australian Register of Therapeutic Goods (ARTG), so must be accessed using the Special Access Scheme (SAS) of the Therapeutic Goods Act 1998 (TGA Act). Release of the antitoxin for treatment can only be made in accordance with SAS arrangements, which mandates the completion of a "SAS Category A Form" along with a patient consent form. Additional information can be accessed via the Central Pharmacy SAS ordering website

<https://qheps.health.qld.gov.au/central-pharmacy/products/special-access-scheme>

Diphtheria antitoxin is a Schedule 4 drug and requires medical officer authorisation.

SCOPE

The following procedures will assist with the prompt approval and dispatch of DAT.

INSTRUCTIONS

Notification

- Diphtheria is a notifiable condition, as per the *Public Health Act (2005)*, at both provisional and pathological diagnosis. The treating Senior Medical Officer and/or Infectious Diseases Physician (SMO/IDP) must notify a Public Health Physician (PHP) regarding the case and the possible requirement for DAT. Notification to the PHP can occur by email (at all hours), with follow-up notification via phone during daylight hours.

Approval process

- Approval for DAT is to be given by the HHS IDP.
 - The SMO contacts the IDP to request approval.
 - The IDP will send confirmation of approval via email to the SMO.

Note: it is the responsibility of the treating SMO/IDP to complete the SAS Category A Form and return a copy of the form to the TGA in line with their HHS procedure (for example, this may be done via the HHS Director of Pharmacy).

The patient consent form should be kept in the patient's medical record.

Requesting DAT

- SMO/IDP liaises internally with their HHS Director of Pharmacy or Pharmacist on-call to obtain DAT

Note: Some HHSs may have prepositioned DAT at a dedicated HHS Pharmacy that can be used.
- The HHS Director of Pharmacy/Pharmacist on-call emails the completed SAS Category A form to Central Pharmacy (cc a copy to NDPC@health.qld.gov.au).
- The HHS Director of Pharmacy/Pharmacist on-call phones Central Pharmacy (07 3120 8500) to arrange the dispatch of the DAT, if there is no prepositioned stock.

Dispatch stage

Where there is no prepositioned stock:

- The HHS Director of Pharmacy/Pharmacist on-call is responsible for arranging supply with Central Pharmacy using the normal order placement and dispatch process established for SAS items.
- Central Pharmacy will dispatch the antitoxin and the product information (PI) sheet.

Usage and disposal of DAT

- Directions for use and storage requirements will accompany the drug.
- Store at 2 °C to 8 °C. Once the vial is opened, the preparation must be used immediately. Diphtheria antitoxin should not be used if it has been exposed to freezing temperatures.
- Director of Pharmacy/Pharmacist on-call will notify the Central Pharmacy regarding usage and/or disposal of DAT.
- Any unused vials of DAT at the HHS must be returned to the relevant HHS Hospital Pharmacy. The HHS pharmacy will contact the Central Pharmacy for advice on whether to return unused vials to Central Pharmacy. Vials that are not accepted by Central Pharmacy for return are to be disposed by following local disposal procedures and documented accordingly.
- Disposal of expired diphtheria antitoxin should only be undertaken following discussion with and consent from Central Pharmacy.

Queensland Medical Supply stock of DAT and prepositioning

- CDB will have oversight of DAT stock levels held by Central Pharmacy.
- Central Pharmacy will liaise with CDB to review remaining stockholdings and purchase replenishment stock as deemed necessary by CDB.
- Ten vials of DAT can be prepositioned by both Cairns and Hinterland HHS and Townsville HHS at a dedicated HHS pharmacy.
 - The HHS Director of Pharmacy/Pharmacist on-call is responsible for arranging supply with Central Pharmacy using the normal order placement and dispatch process established for SAS items.
 - Central Pharmacy will dispatch the antitoxin and the product information (PI) sheet

CONTACT

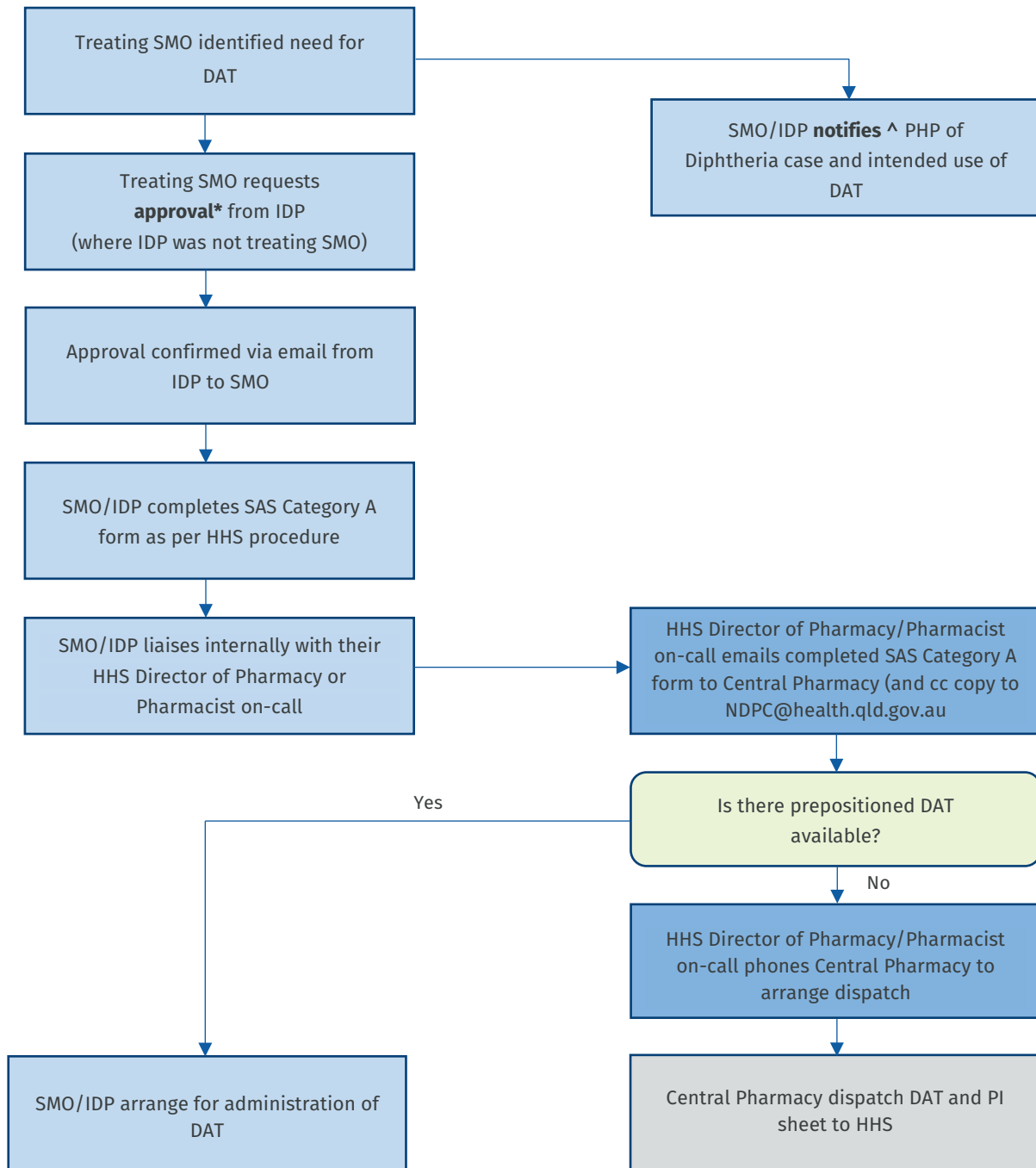
For further information on the release of DAT from Central Pharmacy please contact:

- Public Health Units: <https://www.health.qld.gov.au/system-governance/contact-us/contact/public-health-units/>
- Communicable Diseases Branch: (07) 332 89753, email ndpc@health.qld.gov.au
- Central Pharmacy: (07) 3120 8500, email CentralPharmacy@health.qld.gov.au.
After hours: please contact Central Pharmacy On-Call Pharmacist via the Royal Brisbane and Women's Hospital switch on (07) 3646 8111
- Infectious Diseases Physician: via local hospital switch.

REVIEW

This Standard Operating Procedure remains valid until 30 June 2024 and should be reviewed on a bi-annual basis or as required.

PROCESS FLOWCHART



*approval for DAT is through the IDP only. CDB and the PHP do not need to provide approval, as the need for treatment is based on clinical decision.

^notification to the PHP can occur immediately via email, with follow-up phone call during daylight hours only.

DAT = Diphtheria antitoxin
 IDP = Infectious Diseases Physician
 SMO = Senior Medical Officer
 PHP = Public Health Physician
 CDB = Communicable Diseases Branch