Process for obtaining diphtheria antitoxin (DAT) in Queensland

Background

Diphtheria antitoxin (DAT) is an injection used to counter the effects of the diphtheria toxin produced by the bacteria *Corynebacterium diphtheriae*. 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).

Queensland holds a limited supply of *VINS Diphtheria Antitoxin B.P* (one type of DAT). 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. The forms can be downloaded from the TGA website: [http://www.tga.gov.au/form/special-access-scheme#forms](http://www.tga.gov.au/form/special-access-scheme#forms)

The process for the release of DAT in Queensland involves an approval stage and a dispatch stage:

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

Approval stage

- Diphtheria is a Notifiable Condition at both provisional and pathological diagnosis. The treating Medical Officer and/or Infectious Diseases Physician (MO/IDP) must notify a Public Health Physician (PHP) regarding the case and the possible requirement for DAT. Discussion points include:
  - requirements for using an unregistered product; and
  - requirements for completion of the SAS Category A form and a patient consent form

**Note** it is the responsibility of the treating MO/IDP to complete the SAS forms and return a copy of the Category A form to TGA in line with their Hospital and Health Service (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.

- Approval from the Executive Director or Medical Director on-call (ED or MD), Communicable Diseases Branch (CDB) can be sought by either the PHP or the MO/IDP¹
  - The PHP or the MO/IDP contacts the ED or MD CDB to request approval.
  - the ED or MD CDB will send a confirmation of approval email to the PHP and the MO/IDP.
  - MO/IDP liaises internally with their HHS Director of Pharmacy or pharmacist-on-call.

¹ MO/IDP to confirm to Executive Director/Medical Director on-call that they have discussed the case with their Public Health Physician
The Director of Pharmacy/Pharmacist-on-call emails a copy of the approval and completed SAS Category A form to Central Pharmacy and calls to arrange the dispatch of the DAT.

Dispatch stage

- 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 provides an after-hours service which can be accessed by contacting the Central Pharmacy On-Call Pharmacist via the Royal Brisbane and Women’s Hospital switch on (07) 36468111.
- Central Pharmacy will dispatch the antitoxin and the product information sheet.

Usage and disposal of DAT

- DAT product information (PI) that includes 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.
- 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 of locally by following proper local disposal procedures and documented accordingly.
- Disposal of expired diphtheria antitoxin, originally procured on behalf of CDB, requires approval by the Medical Director, Communicable Diseases and Infection Management, CDB. Once approved, send confirmation of disposal and the disposal number to the Communicable Diseases Branch.
- Director of Pharmacy/Pharmacist-on-call will notify the Central Pharmacy regarding usage and/or disposal of DAT. The Central Pharmacy will relay this information to CDB.
- CDB will work with Central Pharmacy and Link Healthcare to replenish the current stock level of 10 vials (10 x 10,000 IU).

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

- Communicable Diseases Branch on (07) 332 89753, email: ndpc@health.qld.gov.au
- Central Pharmacy (07) 31208500, 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) 36468111.
Authorisation and Dispatch Procedure for Diphtheria Antitoxin

MO/IDP consults with Public Health Physician (PHP)

PHP or MO/IDP discusses cases with Executive Director or Medical Director-on-Call (ED/MD CDB) and requests approval for dispatch of DAT

ED/MD CDB sends approval email to PHP and MO/IDP

MO/IDP emails approval from CDB to their Hospital and Health Service (HHS) Director of Pharmacy or Pharmacist-on-call.

HHS Director of Pharmacy or Pharmacist-on-call forwards these documents to Central Pharmacy along with a copy of the completed SAS Cat A form and calls to arrange the dispatch of the DAT.

Note:
MO/IDP completes SAS Cat A form and patient consent form and returns a copy of the Cat A form to TGA as per HHS procedures.