



SUBMISSION 52



Commonwealth Department of  
Health and  
Ageing

**SUBMISSION BY THE OFFICE OF CHEMICAL SAFETY, THERAPEUTIC GOODS ADMINISTRATION, COMMONWEALTH DEPARTMENT OF HEALTH AND AGEING**

**TO THE**

**JOINT STANDING COMMITTEE ON THE NATIONAL CAPITAL AND EXTERNAL TERRITORIES- ANNUAL REPORT REVIEW (EXTERNAL TERRITORIES)**

**ON THE**

***PROCESSESSING OF EXPORT APPROVALS FOR CONTROLLED MEDICATIONS BY THE THERAPEUTIC GOODS ADMINISTRATION FOR THE INDIAN OCEAN TERRITORIES***

## **1. LEGISLATIVE FRAMEWORK**

### *International Convention*

Australia is signatory to the three International Drug Treaties:

- *Single Convention on Narcotic Drugs 1961,*
- *Convention on Psychotropic Substances 1971 and*
- *United Nations Convention Against Illicit Traffic in Narcotic Drugs and Psychotropic Substances 1988,*

under which countries are required to impose controls on the import and export of certain drugs and precursor substances as identified in the Schedules to these Treaties.

Two categories of drugs, narcotic drugs and psychotropic substances are controlled by the international drug control treaties. At present, control is exercised over more than 116 narcotic drugs under the 1961 Convention. They include mainly natural products such as opium and its derivatives, morphine, codeine and heroin, but also synthetic narcotics such as methadone and pethidine, as well as cannabis and cocaine. Some 111 psychotropic substances are controlled by the 1971 Convention. Most of them are contained in pharmaceutical products acting on the central nervous system. Broadly speaking, these are the hallucinogens, the stimulants and the depressants and some analgesics.

### *Australian Controls*

Responsibility for authorising manufacture and export of narcotics and other substances, as established under the *Single Convention*, is vested in the Secretary of the Department of Health and Ageing and is exercised through the authority of the *Narcotics Drugs Act 1967* and the *Customs Act 1901* and the associated *Customs (Prohibited Exports) Regulations 1958*.

In Australia these requirements are enacted through the *Customs Act 1901* and its associated *Customs (Prohibited Imports)* and *(Prohibited Exports) Regulations*.

### *External Territories Controls*

The *Customs Act 1901* does not extend to Australia's External Territories (Section 6(1) refers). For this reason the export of goods controlled under the *Customs (Prohibited Exports) Regulations 1958* to the External Territories (including Christmas Island) is subject to the full requirements of the *Customs Act 1901* and its associated regulations.

- Under Regulation 10 of the *Customs (Prohibited Exports) Regulations 1958* the exportation of a drug defined in the relevant schedule to these Regulations is prohibited unless the drug is exported by a licensed exporter and permission has been granted for the licensed exporter to export the drug to a specified country. (ie the Australian exporter is required to have both a Licence and Permit to Export).
- The granting of licences and permits to export goods from Australia that are controlled under the *Custom (Prohibited Exports) Regulations 1958* is administered by the Therapeutic Goods Administration (TGA).

The import of goods controlled under the *Customs (Prohibited Exports) Regulations 1958* to the External Territories (including Christmas Island) is subject to the full requirements of the *Customs Act 1901* and its associated regulations.

- Under Regulation 5 of the *Customs (Prohibited Imports) Regulations 1956*, as applied to the Territory of Christmas Island, the importation of a drug defined in the relevant schedule to these Regulations is prohibited unless the drug is imported by a licensed importer and permission has been granted for the licensed importer to import the drug from a specified country. (ie the Christmas Island importer is required to have both a Licence and Permit to Import).
- The granting of licences and permits to import goods to Christmas Island that are controlled under the *Custom (Prohibited Imports) Regulations 1956* is administered by the Christmas Island Administration.

## 2. PROCEDURE FOR EXPORT OF CONTROLLED SUBSTANCES TO CHRISTMAS ISLAND.

The procedure by which an export of a controlled substance is carried out between Australia and Christmas Island, is as follows:

- The intending importer on Christmas Island applies to the Christmas Island Administration for a permit to import controlled substances.
- An import permit once granted is forwarded by either the Territory Administration or the importer to the Australian Exporter.
- The Australian Exporter applies via fax to the Office of Chemical Safety for a permit to export which has an agreed target processing time in the Office of Chemical Safety of 10 working days for non-urgent permit applications and 3 working days for urgent permit applications. In the case of an Urgent permit application this is accompanied by a faxed copy of the Import permit issued to the Importer on Christmas Island.

In the case of an Urgent Export Permit application the Australian Exporter is asked to contact the Office of Chemical Safety via a specific phone number to confirm that the faxed application has been received. This confirmation is important to ensure any special arrangements in place (eg during periods of office closure where an alternate contact number is used) can be ascertained by the exporter to ensure that the permit application is received and processed within the target time of 3 working days.

- Upon receipt of the application the Office of Chemical Safety processes and issues an export permit to the Australian Exporter.
- In the case of an urgent permit application the export permit is faxed and the original express posted to the Australian Exporter.
- The goods to be exported are dispatched by the Exporter and released through Customs on the basis of the faxed copy of the export permit. Once the original copy of the export permit is received by the exporter it is endorsed for the amount of goods exported and returned, within five working days to the Office of Chemical Safety for finalisation of the export record.

## 3. PROVISION BY THE OFFICE OF CHEMICAL SAFETY, OF URGENT EXPORT PERMITS FOR CONTROLLED SUBSTANCES TO BE EXPORTED TO THE EXTERNAL TERRITORIES:

The Table below details the number and type of export permits issued for Christmas Island over the past few calendar years.

Year	Non Urgent	Urgent	TOTAL
2001	19	17	36*
2002	4	31	35*
2003 (YTD 30 April )	3	2	5

\* Six and two additional applications were received in 2001 and 2002, respectively, which were cancelled following processing.

In cases where the importer on Christmas Island has designated an urgent medical need for the supply of controlled substances from Australia the following arrangements and concessions have been put in place by the Office of Chemical Safety to expedite permit issue:

- A special application form for 'Urgent Request For a Permit to Export a Controlled Substance to an Australian Territory Island' is made available to the exporter for use in cases for which there is a recognised urgent medical need (eg. acute pain management in cancer patient).
- This application form must be faxed directly to the Office of Chemical Safety for urgent attention. The application form includes a written request that the Office of Chemical Safety should be contacted on a specified phone number to confirm that the faxed permit application has been received.
- Normally an original of the accompanying export permit is required to accompany an export permit application. However in the case of urgent request a concession is made whereby a faxed copy of the corresponding import permit is accepted.
- Once issued, the export permit is both faxed and express posted to the exporter on the date of issue, and export is authorised to proceed on the basis of the faxed copy, not as per usual only on the basis of the original export permit.

### **Timeframe performance**

The target turnaround time for issue of urgent export permits to Christmas Island by the Office of Chemical Safety is three (3) working days. In a total of 40 applications received from 1 January 2002 to 30 April 2003, thirty three (33) or 83% were for urgent permits.

- Of these 33 urgent applications:
  - 7 permits were issued on the day of application;
  - 16 within 1 working day;
  - 6 within 2 working days;
  - 3 within 3 working days; and
  - 1 within 4 working days.
- Of the remaining 7 non-urgent applications:
  - 2 permits were issued on the day of application;
  - 3 within 1 working day;
  - 2 within 4 working days.

#### **4. SPECIFIC DETAILS OF PERMITS RAISED IN EARLIER EVIDENCE**

In relation to the application/permit instances mentioned by Mr Baldock in his statement to the Joint Standing Committee on 11 March 2003, the following details pertain:

- Export permit CSH02E1876 was issued on Thursday 28 November 2002 against import permit No. 2711. This urgent application was received on Wednesday 27 November 2002 (turnaround time of 1 working day).

- Export permit CSH02E1942 was issued on Monday 9 December 2002 against Import Permit No. 0312. This urgent application was received on 5 December 2002 (turnaround time of 2 working days).
- The issue of Export permit CSH03E0040 was delayed. The circumstances contributing to this delay are:
  - a. An application for this permit was originally sent by the Australian Exporter by facsimile on 27 December 2002. The Office of Chemical Safety opened on 2 January 2003 to find this application (the exporter failed to contact the Office of Chemical Safety by phone as required for an urgent permit application. Consequently, this request was not processed via the special arrangements put in place by the Office of Chemical Safety to cover the Christmas /New Year period).
  - b. As this application was being processed, the Office of Chemical Safety noticed that the export permit was accompanied by an import permit No. 2312, which had expired on 3 January 2003. This meant the Territory Administration was required to reissue an import permit before an export permit could be issued. The Exporter was not contacted until 6 January 2003, the next working day. In addition, the Exporter's Licence to export had expired (31 December 2002) and an application for renewal was being processed by the Office of Chemical Safety.
  - c. The new Import Permit No. 2315, was issued in the Territory, faxed directly to the Office of Chemical Safety by the importer on Christmas Island and formally received by the Office of Chemical Safety all on 6 January 2003.
  - d. The Licence to Export and the Export permit CSH03E0040 were issued on 8 January 2003.

Office of Chemical Safety  
Therapeutic Goods Administration (Group Of Regulators)  
Department of Health and Ageing

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