

# PCP Sample Answers

## Poisons Control Plan for a **Licence**: To Sell or Supply by Wholesale **OR** to Manufacture and Sell or Supply by Wholesale **Part One – Sample Answers**

### 1. The Licence

#### Location of documents

##### *1.1 Indicate where the licence document is to be located;*

- Displayed in the office area.
- Filed in the office of the Warehouse Manager.

##### *1.2 Indicate where the approved version of the Poisons Control Plan is to be located;*

- In a clearly marked file in the office of the Warehouse Manager / Regulatory Affairs Officer.

##### *1.3 Indicate the position (or role) of the person(s) to be responsible for the periodic review of the approved Poisons Control Plan and the frequency with which the review is to occur;*

- The Operations Manager is required to review the PCP at least annually and to submit any proposed amendments for approval.

##### *1.4 Indicate the manner in which the review of the PCP is to be documented and where the corresponding records are to be retained;*

- The (DH approved) copy of the PCP is to be retained, as a controlled document in a clearly marked folder, with the date of review and the signature of the reviewer to be clearly recorded on each occasion.

## Licensed activities

### ***1.5 Indicate the type(s) of wholesaling activity to which the licence may apply;***

- supply of products manufactured on the premises
- supply of products manufactured elsewhere
- supply, by indent, of items sourced locally / from overseas
- supply of professional samples to medical practitioners

### ***1.6 Indicate the types of products to be supplied;***

- human therapeutic goods
- veterinary therapeutic goods
- agricultural chemicals
- automotive products for the domestic market
- cleaning chemicals for industrial use
- industrial raw materials

### ***1.7 Indicate the type(s) of manufacturing activity (if any) to which the licence may apply;***

- complete manufacture from raw materials
- blending liquids and/or powders
- manufacturing tablets/capsules
- repacking from bulk containers
- relabelling imported products
- manufacture of "own brand" products
- toll or contract manufacture

### ***1.8 Indicate whether a Therapeutic Goods (TGA) Licence is held in relation to all or some of the manufacturing activities to which this licence may apply;***

If a TGA Licence is held, please indicate the Licence Number and details of the manufacturing activities to which it relates.

- The company manufactures a limited number of products that fall under the jurisdiction of the TGA and a number that do not.

## 2. Reference Material

### ***2.1 Indicate whether a copy of the SUSDP is held and where it is to be located;***

- Retained by the Regulatory Affairs Officer
- SUSDP not held

### ***2.2 If the SUSDP is not held, indicate how the Poisons Schedules are to be determined for substances which are to be sold or supplied;***

- A limited number of scheduled poisons are to be supplied and the schedules are to be determined by reference to Material Safety Data Sheets.
- Before a product line is added to the computer database, the poisons schedule is to be verified by reference to the information provided by the manufacturer.
- A copy of the SUSDP is to be held at head office for periodic reference.
- A copy of the SUSDP is held by a company consultant for periodic reference.

- Poisons schedules are to be determined by reference to the signal headings of labels on containers.
- S2 = Pharmacy Medicine;
- S3 = Pharmacist Only Medicine;
- S4 = Prescription Only Medicine;
- S5 = Caution;
- S6 = Poison;
- S7 = Dangerous Poison;
- S8 = Controlled Drug.

***2.3 Indicate where The Act and The Regulations are to be accessed or located;***

- Retained by the Regulatory Affairs Officer.
- Held at head office.
- Accessed on the Internet when required.

### **3. Security & Storage**

***3.1 Indicate the general security measures that are to be taken to prevent misappropriation of scheduled poisons by external or internal agents (eg. burglars, staff, contractors);***

- High perimeter fence with barbed wire on top and lockable gates
- Deadlocks on all external doors
- After hours patrols by contracted security company
- Monitored alarm system with infra-red and movement detectors
- Audible alarm system

### **Storage**

***3.2 Indicate how Schedule 5 and 6 poisons (if any) are to be stored;***

- Floor to ceiling pallet racking
- Banks of metal shelving
- Flammable goods store
- External bunded enclosure with weather protection above
- Sales are by indent only and scheduled poisons are stored, on behalf of the licence holder, in a warehouse licensed under the *Dangerous Goods Act* and the *Drugs Poisons and Controlled Substances Act*.

### **Schedule 7 poisons [if any]**

***3.3 Indicate how Schedule 7 poisons are to be stored;***

- In a lockable cage in the warehouse.
- In an area where there is no public access.

## 4. Sale/Supply

### *4.1 Indicate the type(s) of customers to be supplied with scheduled poisons;*

- Medical practitioners
- Veterinary surgeons
- Pharmacists
- Automotive industry
- Textile industry
- Pharmaceutical wholesalers
- Retail outlets / Supermarkets / Hardware Stores
- Hospitals and/or nursing homes

### Listed Regulated Poisons in Schedule 7 [if any]

### *4.2 Indicate which Listed Regulated Poisons the licence holder is licensed and/or likely to supply;*

- Metallic cyanides for electroplating
- Arsenic in the form of copper chrome arsenate
- Dilute cyanide solutions for laboratory use
- Arsenic trioxide for use as a termiticide

The Act prohibits the supply, by wholesale, of Listed Regulated Poisons other than to a person authorised by the Act (medical practitioner, pharmacist, veterinary surgeon or dentist) in the lawful practice of their profession or to a person holding a licence or permit which allows purchase of the specified substance. Penalties for breach of this requirement can be severe.

### *4.3 Indicate how legal supply is to be ensured in relation to Listed Regulated Poisons in Schedule 7:*

- Cyanide is to be supplied only to permit holders who will be required to provide a copy of their current permit each year.
- Arsenic is to be supplied to a limited number of clients whose authorisation will be checked by reference to the Poisons Licence Register.
- All orders for such substances are to be referred to the Supply Manager who will be required to verify a current permit is held.

### Activities of representatives and/or agents [if any]

### *4.4 Indicate the extent and nature of agent activities and the means by which their orders are to be processed;*

- The company may have a small number of agents to visit clients and obtain orders that are to be transmitted to the licensed premises for despatch.
- The company may have a small number of agents to obtain orders (for sample stock) and deliver the consigned stock, after the order has been processed at the licensed premises.
- The company may have **approximately** twenty agents (or brokers) to obtain orders that are to be transmitted to another licensed wholesaler, for despatch.

## Labelling and packaging of “own brand” and/or imported products [if any]

***4.5 Indicate the means by which the licence holder will be able to ensure that the labelling and packaging of all schedules poisons, to be supplied, complies with the requirements of the legislation;***

- The company designs its own labels by reference to the standards of the SUSDP. These labels are to be attached by the contract manufacturer / by the overseas supplier.
- The contracted manufacturer is required to confirm that labels comply with SUSDP specifications.
- The contracted manufacturer is required to confirm that containers comply with SUSDP specifications – in relation to embossed warning statements and in relation to child-resistant closures (where necessary).
- Imported products are intended **solely** for industrial / laboratory use and are to be labelled and packaged in accordance with other standards.
- The company reviews any new products to ensure labelling and packaging complies.

## 5. Records of Transactions

***5.1 Indicate how records of transactions are to be retained;***

- Computerised records with back-up copies to be stored off-site.
- Copies of invoices are to be filed chronologically, on the premises, in a secure cabinet.
- Copies of invoices are to be filed in customer files.

## 6. Staff Training

***6.1 Indicate how staff training and information are to be provided to employees;***

- Staff members are to be personally instructed by experienced personnel and supervised until a satisfactory level of competence is achieved.
- Formal classes are to be conducted initially, with all staff involved in an annual review.
- All procedures are to be documented, in accordance with ISO 9002 accreditation / TGA Licence documented procedures, with staff instructed in the implementation of those procedures.

***6.2 Identify key areas, specific to the licence holder (if any), where there is a greater risk of unlawful supply and/or a greater vulnerability to loss or pilferage;***

- Drugs of dependence (eg. anabolic steroids) – refer to Part Two of the PCP.
- Verifying the identity of a person collecting a “calling order” – refer to Part Two of the PCP.
- Expensive medications (eg. Viagra)
- Chemicals that can be used as precursors for the manufacture of illicit drugs.
- Verifying the qualifications or authorisation of a person who wishes to open an account.
- Failing to identify the restricted nature of a chemical sourced from an overseas supplier (eg. listed carcinogens)

***6.3 Indicate how relevant staff members are to be supervised and periodically re-trained to address the noted risk areas;***

- Relevant staff members are to be involved in re-educational activities, at least annually, to ensure they are aware of the noted risk areas.
- All staff members are to be required to review the company's documented procedure manual annually. High-risk issues are to be prominently flagged to ensure they are not overlooked.

***6.4 Indicate the manner in which complaints or other undesirable incidents are to be documented and addressed;***

- Any complaints are to be recorded, for prompt review by the QA Department, in order to identify any possible problems with product integrity or content.
- Discrepancies noted during physical stock checks of drugs and poisons are to be recorded on incident sheets and, if not resolved, are to be reported to the Operations Manager for further investigation and/or mandatory reporting to the authorities.

## **7. Returned Goods [other than therapeutic goods]**

***7.1 Indicate how returned goods are to be handled and stored;***

- Returned goods are to be placed in a locked store, in the finished goods storage area, until they can be examined with a view to possible resupply.
- Damaged goods are to be set aside, in a locked cabinet, for waste disposal.

***7.2 Indicate what records are to be made in relation to returned goods;***

- Returned goods are to be credited, to clients' accounts, and will appear as negative entries in those records.
- Details of returned goods are to be recorded in a logbook. Stock will not be included in the inventory until it has been approved for resupply.

***7.3 Indicate what steps are to be taken to verify the integrity of returned goods that are to be resupplied;***

- Only goods contained in sealed containers are to be considered for resupply.
- Returned goods are to be examined, by the QC Manager, to confirm the integrity of the container and that the container's seal has not been opened.

## **8. Waste Disposal**

***8.1 Indicate the manner in which such waste material is to be handled;***

- Expired therapeutic goods are to be sent for high temperature incineration.
- Other waste material is to be collected periodically by contract carriers.