

**NATIONAL COORDINATING COMMITTEE ON  
THERAPEUTIC GOODS**

**Australian**

**CODE OF GOOD WHOLESALING PRACTICE**

**FOR THERAPEUTIC GOODS**

**FOR HUMAN USE**

**Draft Revision – June 2006**

This Code supersedes the November 1991 edition of the Australian Code of Good Wholesaling Practice for Therapeutic Goods for Human Use. The provisions of this Code are applied through applicable State and Territory therapeutic goods / drugs and poisons legislation, and/or State or Territory wholesaler licensing arrangements.

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## INTRODUCTION

Wholesaler distribution forms part of the supply chain for therapeutic goods. Wholesalers (sometimes referred to as distributors) are responsible for the effective, efficient and safe handling, storage and distribution of such products.

This Code of Practice is concerned with ensuring that product quality is maintained during wholesaler warehousing and distribution and it sets out appropriate standards to be applied by, or required of, wholesalers in meeting this responsibility. In short, wholesalers are responsible to ensure that medicines and/or other therapeutic goods are stored and distributed within the label requirements of the manufacturer and in accordance with this Code. This includes the distribution of temperature sensitive medicines (if stocked) via the cold chain.

The Code of Practice applies to all classes of therapeutic goods – including medicines, medical or therapeutic devices and any other goods declared to be therapeutic goods under section 7 of the *Therapeutic Goods Act 1989* (the Act).

This Code does not negate or supersede other Codes or common or statute law requirements such as the obligations of contractors, Occupational Health and Safety, Customs and Excise, Poisons (including narcotics), Dangerous Goods, or the many legal requirements surrounding building construction. These must be understood and met by the wholesaler.

## INTERPRETATION

In this Code:

The words “**should**” and “**shall**” mean “**must**” and the activities, descriptions or specifications accompanied by the word “**should**” or “**shall**” are to be read as mandatory, unless the wholesaler is able to demonstrate that the activity, description or specification is inapplicable or can be replaced by an alternative which must be demonstrated to provide at least an equivalent level of quality assurance.

“**Controlled Drugs**” means any substances specified in Schedule 8 of the Standard for the Uniform Scheduling of Drugs and Poisons (SUSDP) and any other substances included in Schedule 8 of an applicable State or Territory Poisons List.

“**Goods with High Illicit-Value**” means all Controlled Drugs, and any other goods containing any substance (or salts, esters or derivatives thereof) specified in Appendix 1 *List of Other Goods with High-Illicit Value*.

“**Scheduled medicines**” means any medicine classified as a ‘Pharmacy Medicine’, a ‘Pharmacist Only Medicine’, a ‘Prescription Only Medicine’ or a ‘Controlled Drug’ in the Standard for the Uniform Scheduling of Drugs and Poisons (SUSDP) or an applicable State or Territory Poisons List.

“**Supply**” includes supply by way of sale, exchange, gift, lease, loan, hire or hire-purchase.

“**Therapeutic goods**” has the same meaning as in subsection 3(1) of the Act.

[NOTE: the definition as at the date of the Code of Practice is as follows:

*therapeutic goods* means goods:

- (a) that are represented in any way to be, or that are, whether because of the way in which the goods are presented or for any other reason, likely to be taken to be:
  - (i) for therapeutic use; or
  - (ii) for use as an ingredient or component in the manufacture of therapeutic goods; or
  - (iii) for use as a container or part of a container for goods of the kind referred to in subparagraph (i) or (ii); or
- (b) included in a class of goods the sole or principal use of which is, or ordinarily is, a therapeutic use or a use of a kind referred to in subparagraph (a)(ii) or (iii); and includes medical devices and goods declared to be therapeutic goods under an order in force under section 7, but does not include:
  - (c) goods declared not to be therapeutic goods under an order in force under section 7; or
  - (d) goods in respect of which such an order is in force, being an order that declares the goods not to be therapeutic goods when used, advertised, or presented for supply in the way specified in the order where the goods are used, advertised, or presented for supply in that way; or
  - (e) goods (other than goods declared to be therapeutic goods under an order in force under section 7) for which there is a prescribed standard in the Australia New Zealand Food Standards Code as defined in subsection 3(1) of the Australia New Zealand Food Authority Act 1991; or
  - (f) goods which, in Australia or New Zealand, have a tradition of use as foods for humans in the form in which they are presented.]

**“Therapeutic use”** has the same meaning as in subsection 3(1) of the Act.

[NOTE: the definition as at the date of the Code of Practice is as follows:

*Therapeutic use* means use in or in connection with:

- (a) preventing, diagnosing, curing or alleviating a disease, ailment, defect or injury in persons or animals; or
- (b) influencing, inhibiting or modifying a physiological process in persons or animals; or
- (c) testing the susceptibility of persons or animals to a disease or ailment; or
- (d) influencing, controlling or preventing conception in persons; or
- (e) testing for pregnancy in persons; or
- (f) the replacement or modification of parts of the anatomy in persons or animals.

**“Wholesaler”** means a person who sells or supplies by wholesale and includes centralised purchasing authorities and pharmacy buying groups conducting wholesaling operations. A “Full Line Wholesaler” distributes a full range of medicines and/or other therapeutic goods, while a “Short Line Wholesaler” trades in a limited range of products only.

Unless the contrary intention occurs in relevant State or Territory legislation, the term

**“Wholesaling”** in relation to therapeutic goods and the requirements of this Code means:

- (a) supply for the purposes of resale or resupply; or
- (b) supply for the purposes of use in connection with a trade, business, profession or industry, including supply of an ingredient for the purposes of incorporation in therapeutic goods, and includes:
  - (c) supply of a substance or goods in wholesale quantities for use in a public institution; and
  - (d) the transportation of the goods from the wholesale premises to the customer.

## SECTION 1

### BUILDINGS AND GROUNDS

#### Principle

Policies and Procedures should be in place to provide:

- Adequate protection for all goods stored within the building;
- Safe and secure access to the property;
- Safe and secure access to the goods stored; and
- Security of the property and the goods stored.

#### Practice

- 1.1 Warehousing of therapeutic goods should be carried out in buildings or parts of buildings that have been built for, or adapted to, this purpose.
- 1.2 The grounds should be established and maintained so as to minimise ingress into the buildings of dust, soil or other contaminants and should be free of accumulated waste, dirt and debris. Waste should be collected in designated closed containers and disposed of at frequent intervals. Waste collection and disposal must be carried out by a licensed waste collector.
- 1.3 Buildings should be kept free of rodents, vermin, birds, pets and pests.
- 1.4 Buildings should provide protection of the goods from contamination and deterioration, including protection from excessive local heating, cooling or dampness, or undue exposure to direct sunlight. The goods received or despatched at receiving or dispatch bays, docks, platforms or areas should also be protected from dust, dirt, rain, vermin and birds.
- 1.5 The facility should have appropriate perimeter fences, gates, lighting, signage and other systems that discourage attempted site penetrations and ensure security of the grounds and buildings. Suitable surveillance and detection systems should be installed to detect any security breach on the site or buildings.
- 1.6 Sufficient space should be provided for the orderly receipt, warehousing and dispatch of goods and, in particular, a quarantine area for isolation of goods when necessary, including isolation of faulty packs and recalled goods.
- 1.7 Buildings and fixtures should be kept clean and well maintained. Cleaning and house-keeping equipment should be stored and maintained to effect adequate hygienic control and condition.

## SECTION 2

### FACILITIES AND SECURITY

#### Principle

Policies and Procedures should be in place to provide:

- A safe and secure work environment;
- An appropriate level of protection for stored goods to prevent theft, product misuse and possible subsequent illegal distribution;
- For the correct security and management of the facility; and
- For the correct reporting any material theft and/or product theft and/or product misuse.

#### Practice

- 2.1 Storage facilities should protect goods from deterioration. The conditions of storage for the goods should be compatible with the storage conditions specified on their labels.
- 2.2 Controlled storage environments such as deep-freeze and refrigeration, should be monitored using suitable temperature recording devices and the records reviewed and filed. Refrigerated and freezing storage environments should be fitted with both an alarm and a visual signal to indicate if refrigeration has failed. The signal should permit resetting only by an authorised person. All refrigeration and freezers shall be connected to a backup power supply such as a generator, or backup refrigeration and freezer facilities shall be available.

**For specific storage and distribution requirements for temperature sensitive goods, refer to Section 5.**

- 2.3 Temperatures in other areas where goods requiring specific storage conditions are held should be monitored and the results tabulated and analysed so as to demonstrate the suitability of these areas for their purposes.
- 2.4 If any temperature is found to have deviated outside the relevant recommended conditions for an extended time, the manufacturer of the goods should be contacted and the suitability of the product for use resolved.
- 2.5 Instruments or equipment used for monitoring temperature should be calibrated on a regular basis to ensure their accuracy and appropriate records kept of calibration tests and results.
- 2.6 Special storage facilities should be provided for poisons, Controlled Drugs, other goods with high illicit-value, dangerous goods and other classes of goods as required by applicable State or Territory legislation or licensing conditions.
- 2.7 All special storage facilities should be linked to the overall facility security system with a reliable 24-hour communication link to monitored controls.
- 2.8 All special storage facilities should have detection devices against tampering, with procedures for testing and maintenance in place to ensure continuous operation.

- 2.9 The systems should be monitored as remotely as appropriate and provide an access audit trail. High-risk areas should have additional access deterrents such as caged enclosures and/or CCTV, and/or dual custody and/or time delay locks as appropriate.

**For further detail on the management of Controlled Drugs and Other Goods with High Illicit-Value, refer to Section 7.**

- 2.10 Incompatible activities such as manufacture (including repackaging) or the handling of toxic chemicals shall be avoided in areas in which therapeutic goods are handled by wholesale.
- 2.11 Fork lifts and other materials handling equipment should be secured at the end of daily operations. All ignition keys should be removed from the equipment and kept in a locked area that is separated from the area where the equipment is held.

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## SECTION 3

### PERSONNEL

#### Principle

Policies and Procedures should be in place to provide for:

- Employees and other persons having access to the facility, to minimise the possibility of scheduled medicines coming into unauthorised possession; and
- The selection of staff, sub-contractors and contractors, and the administration and ethical conduct requirements for these staff and contractors.

#### Practice

- 3.1 An organisational structure clearly identifying management responsibilities should be in place and properly documented.
- 3.2 Individual responsibilities should be clearly understood by individuals and recorded.
- 3.3 Appropriate policies and procedures should be in place for the selection of staff and contractors, as well as requirements for ethical conduct of staff and contractors.
- 3.4 Operating personnel should be trained to perform assigned duties and functions at an acceptable level.
- 3.5 Procedures and conditions of work for employees and other persons having access to the products must be designed and administered to minimise the possibility of scheduled medicines coming into unauthorised possession.
- 3.6 Additional training should be provided for personnel with responsibility for special storage conditions such as refrigerated areas and Controlled Drugs. Training should cover security and safety risks involved.
- 3.7 Standard operating procedures should be developed and enforced for correct security and handling methods and for correct procedures for reporting material theft and/or product theft and/or product misuse.

## SECTION 4

### STOCK HANDLING AND STOCK CONTROL

#### Principle

Policies and Procedures should be in place to provide for:

- Correct stock rotation controls;
- Any required full stock counts;
- Correct return controls for any damaged or returned goods; and
- Correct actions required in recalling goods on behalf of their manufacturer or sponsor.

#### Practice – Stock Handling and Control - General

- 4.1 Importers should take all reasonable measures to ensure that goods are not mishandled or exposed to adverse storage conditions at wharves or airports.
- 4.2 Storage, supply, distribution and recording of Controlled Drugs and other scheduled medicines must be in accordance with applicable Commonwealth, State or Territory legislation.
- 4.3 Storage areas should be adequate and organised to permit segregation and identification of the various materials and products stored and should enable stored goods to be easily maintained in a clean, dry and orderly condition. Goods should be stored off the floor on pallets or shelves to reduce dust and moisture exposure, and to help facilitate cleaning. Particular care should be taken to avoid mould growth in refrigerated rooms or cabinets.
- 4.4 There should be a system to ensure stock rotation, with frequent regular checks that the system is operating correctly.
- 4.5 Spilled substances should be cleaned up promptly and rendered safe as quickly as practicable and under the supervision of a responsible person. A written procedure for dealing with spillage of items of special hazard, such as cytotoxic drugs, should be available and training provided to responsible staff. Spill kits should be conveniently located within the storage area.
- 4.6 Measures should be taken to demonstrate that scheduled medicines are not misappropriated. Regular and formal audit of required procedures and full stock counts of goods with high-illicit value held in special storage areas should occur. Significant losses should be reported to licensing authorities and/or the police.
- 4.7 Goods bearing an expiry date must not be received or supplied after their expiry date or so close to their expiry date that this date is likely to occur before the goods are used by the consumer. Such goods must be withdrawn from sale and quarantined pending disposal in accordance with agreements between wholesaler and supplier.

#### Practice – Stock Handling and Control - Inwards Goods from Suppliers

- 4.8 Stock should be received and examined for correctness against order, expiry date and absence of damage.

- 4.9 There should be a system for the recognition and prompt handling of Controlled Drugs and other goods with high illicit-value, those products requiring specific temperature storage, products that have a short shelf-life and any other products that require special care.
- 4.10 Goods rejected by the wholesaler because of error, breakage, leaking containers or other faults should be placed in quarantine until the matter is resolved with the supplier.
- 4.11 To ensure that the quality of stock has not been compromised prior to receipt, scheduled medicines should be sourced only from the relevant product sponsor, or another wholesaler licensed under applicable State or Territory legislation.

### **Practice – Stock Handling and Control – Supply of Scheduled Medicines**

- 4.12 Wholesalers must have in place an adequate customer validation protocol to ensure that persons or corporate entities supplied with Controlled Drugs and/or other scheduled medicines are authorised appropriately under State or Territory legislation to obtain, use, supply or be in possession of those substances.
- 4.13 An invoice, made out in the name of the authorised person or corporate entity, as appropriate, must be issued to the authorised person or corporate entity, reflecting the date of supply, the name and address of the person or corporate entity supplied, and the name and the quantity of the product supplied on each occasion a supply is made.
- 4.14 Records of supply must be maintained by the wholesaler in accordance with State and Territory legislation.

**For further detail on the supply of Controlled Drugs and Other Goods with High Illicit-Value refer to Section 7.**

### **Practice – Stock Handling and Control - Damaged Goods from Stock**

- 4.15 Stock which has been damaged or withheld from sale and which is not immediately destroyed should be placed in quarantine until disposal so that it cannot be sold in error or, in the case of liquid leakage, cause contamination of other goods.
- 4.16 Formal procedures should be in place to ensure all returned and/or damaged goods are correctly accounted for until disposals occur.
- 4.17 Special attention should be given to the integrity of all packages including those requiring special storage conditions. Products with broken seals, damaged packaging or suspected of possible contamination must not be sold or supplied.

## SECTION 5

# TEMPERATURE SENSITIVE THERAPEUTIC PRODUCTS (TSTPS)

### Principle

- Policies and Procedures should be in place to ensure that throughout the receipt, storage and distribution of TSTPs, the integrity of the cold chain is maintained.

### Practice - General

- 5.1 Special refrigerated areas for the storage of TSTPs should be correctly set up and operational continuously.
- 5.2 New equipment used for the storage of TSTPs providing low temperature storage (for example, within range of +2°C to +8°C) or other specified temperatures (for example, < 0°C) shall be validated according to the manufacturer's written procedure before it becomes operational.
- 5.3 Recording devices shall be installed within equipment used to store products at low temperature to enable humidity, and air and product temperature to be recorded at regular intervals.
- 5.4 Temperature monitoring equipment shall be installed that is capable of alerting staff in the event that the defined temperature has been compromised.
- 5.5 Arrangements shall be made for nominated staff to examine and record temperature readings at least once in every 24-hour period, with the supervisor reviewing records once a month. Such records should be kept for at least one year.
- 5.6 Suitable training shall be provided to staff who are required to record and maintain temperature records.
- 5.7 Regular maintenance shall be carried out on all refrigeration plants in accordance with the manufacturer's instructions. Maintenance records should be kept.
- 5.8 An approved contractor shall check the calibration and function of all recording and monitoring devices on an annual basis, including alarms and other associated equipment (in conjunction with requirements of clause 5.5).
- 5.9 Refrigerated storage areas shall be linked to uninterrupted power supply (UPS) devices to ensure a continuous power supply in the event of interruptions. Where a UPS device is unavailable or impractical the wholesaler shall be able to provide alternative temporary refrigerated storage such as mobile transport vehicles or mobile refrigerated containers (see also clause 2.2).
- 5.10 Procedures should be in place detailing the actions to be taken in the event of continued power failure or an excursion outside set temperature parameters.

## Practice - Inwards TSTPs from Suppliers

- 5.11 Goods with a manufacturer-specified temperature range should not be stored in a temporary stock location that could expose them to temperatures outside the specified range.
- 5.12 Goods requiring storage within a specified temperature range should be moved as a matter of priority to the temperature area corresponding to the manufacturer's label requirements.

## Practice - Order Assembly and Dispatch of TSTPs

- 5.13 TSTPs should be packed in an area specially set aside for the assembly and packaging of these products. Preferably, this should be immediately next to the refrigerated area.
- 5.14 Temperature containment packaging shall be used to ensure integrity of the cold chain is maintained between wholesaler and customer.
- 5.15 For each delivery, due account should be taken of the time required for delivery, weather conditions, and any foreseeable exposure risks in assessing delivery method and temperature containment packaging to be used.
- 5.16 Special delivery procedures, transport and packaging should be established for TSTPs likely to be exposed to unfavourable environment.
- 5.17 Goods requiring temperature maintenance in the range of +2°C to +8°C should be labelled refrigerate – do not freeze. Goods requiring temperature maintenance in the range below 0°C should be labelled keep frozen.
- 5.18 Goods required to be kept within a specified temperature range should be clearly identifiable from other goods in the same delivery.
- 5.19 On delivery, the attention of the receiver should be drawn to the order containing TSTPs and reasonable efforts be made to ensure the receiver places these goods into appropriate storage facilities.

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## SECTION 6

### TRANSPORT

#### Principle

Policies and Procedures should be in place to provide:

- Adequate methods of transportation to achieve safe and secure delivery of all goods from their point of collection to their point of delivery.

#### Practice - General

- 6.1 Containers for delivery of goods should be clean and provide adequate protection for the goods delivered.
- 6.2 Delivery of goods requiring controlled temperatures should be carried out by the fastest practical means.
- 6.3 Goods labelled to require refrigerated storage should, where appropriate, be transported in temperature containment packaging or insulated containers with ice or other cooling agent. The agent used for packaging should not cause freezing of goods marked 'Refrigerate – do not freeze'. Goods labelled to require frozen storage should be transported in such a way that they remain frozen.
- 6.4 Other goods requiring controlled temperatures may, in suitable circumstances, remain temporarily outside the specified temperature range while delivery is in progress. However in assessing suitable conditions for delivery in any particular case, due account should be taken of the time required for delivery, prevailing or likely weather conditions and the nature of the goods and their labelled storage requirements. Special procedures should be established for goods likely to be exposed to unfavourable environments over holiday periods or during transport to far Northern destinations.
- 6.5 Consideration could be given to the use of temperature logging devices to monitor temperature in transit.

#### Practice – Transport of Controlled Drugs and Other Goods with High Illicit-Value

Refer to Section 7 for details on the transport of Controlled Drugs and Other Goods with High-Illicit Value.

## SECTION 7

### MANAGEMENT OF CONTROLLED DRUGS AND OTHER GOODS WITH HIGH ILLICIT-VALUE

This Section covers wholesale activities relating to all Controlled Drugs (Schedule 8 medicines), and to those other goods that have potential to be diverted for illicit use or trafficking, or for illicit conversion to other products that have a high illicit-value.

Goods with high illicit-value include pseudoephedrine and pseudoephedrine containing products.

The requirements of this Section do not supersede or negate requirements relating to Controlled Drugs or other scheduled medicines that are specified in applicable State or Territory legislation. Rather, this Section augments the requirements of the relevant State or Territory legislation, and provides clarification as to how some of the legislated requirements may be met by wholesalers.

#### Principle

Policies and Procedures should be in place to provide:

- Correct and adequately controlled storage and handling methods for all goods that are encompassed under this Section; and
- Control and administration of all transport movements from wholesalers to product recipients.

#### Practice – Personnel Handling Controlled Drugs and Other Goods with High Illicit-Value

- 7.1 Where possible, before commencing employment, all employees required to have access to goods with high illicit-value should be cleared through a Police Name Check, Criminal Record Check or equivalent.
- 7.2 Regular documented training and review should be instituted and carried out for all staff with unsupervised access to goods with high illicit-value.

#### Practice – Secure Storage of Controlled Drugs and Other Goods with High Illicit-Value

- 7.3 The general level of security required for individual facilities should be commensurate with State or Territory legislative requirements relating to Controlled Drugs, stock levels of high illicit-value stock and the location and amenity of the premises.
- 7.4 A security report should be obtained from an independent security consultant with appropriate industry knowledge. The recommendations included in that report should be acted upon after consultation with State or Territory licensing authorities.
- 7.5 All facilities storing Controlled Drugs and/or other goods with high illicit-value should be protected by 24hr back-to-base monitored electronic alarm system or equivalent.
- 7.6 Controlled Drugs must be stored in a vault or safe, in accord with applicable State or Territory legislation. A vault or safe used for the storage of Controlled Drugs should be located in a

secure area of the building, out of public view, and kept locked except when in immediate use.

- 7.7 Where Controlled Drugs are stocked, the vault or safe should have a caged area surrounding the entrance, with a door that will be locked whilst activities in the vault are taking place, so as to restrict access to authorised staff. Alternately, the vault or safe may be situated in an area of the premises to which access is limited to authorised staff.
- 7.8 All external doors to the premises that are not regularly in use should be fitted with audible alarms to alert staff when opened.
- 7.9 Procedures should be in place to prevent unauthorised persons gaining access to areas where Controlled Drugs or other goods with high illicit-value are stored, for example, through the inwards goods reception area or the dispatch area.
- 7.10 In addition to requirements applying to Controlled Drugs, stocks of other goods with high illicit-value should be stored separately from other goods in a locked facility with access limited to authorised staff.
- 7.11 Provision shall be made to secure all pick face fixtures that contain goods with high illicit-value. Bulk stocks of goods with high illicit-value should be stored in pallet racking and wherever possible, be located in the upper levels of pallet racking.
- 7.12 An audit of all high-risk stock should be regularly undertaken, with the reports of those audits made available for review by the responsible authority on request.

### **Practice – Supply of Controlled Drugs and Other Goods with High Illicit-Value**

**Refer to Section 4 for general requirements relating to the supply of all scheduled medicines (including Controlled Drugs and other goods with high-illicit value)**

- 7.13 “Calling orders” (where the person purported to have ordered the stock attends the wholesaler’s premises to collect the stock) should be discouraged, but if these occur then a protocol should be in place to ensure the bona fides of the person obtaining the products. Cash sales should be unavailable for high illicit-value stock.
- 7.14 The packaging of orders containing Controlled Drugs and/or other goods with high illicit-value should be undertaken in a manner so that the outer package does not indicate that it contains a Controlled Drug and/or other goods with high illicit-value, and is properly addressed to the person to whom it is being supplied.

### **Practice – Transport of Controlled Drugs and Other Goods with High Illicit-Value**

- 7.18 The delivery service contracted should maintain an appropriate and stable workforce that has undertaken (where possible) a Police Name Check report, or equivalent.
- 7.19 All delivery drivers should be issued with and display an official identity card, including a photograph of the person, when calling to warehouse premises to collect goods for delivery. Should a delivery driver present without photo identification, adequate steps must be taken to determine and confirm the bona fides of the person.

- 7.20 Delivery drivers should be instructed that the delivery vehicle must be locked at all times when unattended, including the circumstances when a delivery is taking place.
- 7.21 Each delivery vehicle should be fitted with a suitable alarm system that is activated when access is attempted to any part of the vehicle.
- 7.22 A system should be in place with delivery drivers to enable the return of signed receipts obtained from the authorised recipients of the goods. The system should also allow for the tracking of deliveries from dispatch to receipt by the intended recipient.
- 7.23 Record keeping and receipting of goods taken by the delivery service and delivered to the required destination should be such that all personnel handling the goods throughout the delivery chain are recorded and identifiable.

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## SECTION 8

### MANAGEMENT OF COMPLAINTS, RETURN OF UNUSED AND/OR DAMAGED GOODS AND PRODUCT RECALLS

#### Principle – Complaints Handling and Control

Policies and Procedures should be in place to provide:

- Formal methods of receiving and recording complaint details;
- Adequate methods of handling and communicating complaint content; and
- Adequate methods of measuring and evaluating complaint content.

#### Practice – Complaints Handling and Control

8.1 Complaints regarding a product or its packaging as distinct from those relating solely to matters within the wholesaler's control, must be notified promptly to the manufacturer or sponsor of the goods.

8.2 Complaints relating to the wholesaler's own activity should be evaluated and measures taken, where appropriate, to prevent their recurrence. Records of these complaints and the remedial measures taken should be maintained.

#### Principle – Return of Unused and/or Damaged Goods from Customers

Policies and Procedures should be in place to ensure:

- All unused and/or damaged goods returned from customers are correctly accounted for until correct disposal occurs; and
- Detailed product recording occurs at time of receipt and follows through to quarantine storage and physical dispatch or disposal.

#### Practice – Return of Unused and/or Damaged Goods from Customers

8.3 Goods which have left the care of the wholesaler should only be returned to saleable stock if:

- (a) they are in their original unopened containers, in good condition and bear a valid expiry date;
- (b) it is not evident that they have been subject to adverse conditions;
- (c) on receipt, they are packed separately from other goods and accompanied by a separate Returns Note; and
- (d) they have been examined and assessed by a person authorised to do so. Such assessment should take into account the nature of goods, and any special storage conditions they may require. If necessary, advice should be sought from the authorised person responsible for the quality assurance of the manufactured product.

8.4 Any returned temperature sensitive product should not be returned to saleable stock but quarantined in a suitable temperature controlled area until written advice from supplier/manufacturer is received.

- 8.5 Reconditioning or repackaging (including relabelling) of therapeutic goods must not be carried out by wholesalers unless such activity is specifically exempted from the requirements to hold a manufacturer's licence.

### **Principle – Product Recall**

Policies and Procedures should be in place to provide for actions to be taken:

- In the event of a recall of product held in stock; and
- In recalling goods on behalf of a sponsor.

### **Practice – Product Recall**

- 8.6 Procedures should be consistent with the “Uniform Recall Procedure for Therapeutic Goods” issued by the Therapeutic Goods Administration.
- 8.7 Wholesalers should be able to facilitate a recall relevant to the area to which goods have been supplied.
- 8.8 Full Line Wholesalers should have the necessary systems in place to carry out (if required) any recall on behalf of a sponsor.
- 8.9 Recalls carried out should be documented and records of all recalled goods received into the warehouse should be kept.
- 8.10 Stock that has been recalled and is not immediately destroyed should be placed in quarantine until disposal so that it cannot be sold in error or, in the case of liquid leakage, cause contamination of other goods.
- 8.11 Formal procedures should be in place to ensure all recalled goods are correctly accounted for until disposals occur.

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## SECTION 9

# MANAGEMENT OF RECORDS, DOCUMENTATION AND STANDARD OPERATING PROCEDURES

### Principle

Policies and Procedures should be in place to ensure:

- All records are kept in accordance with legislative requirements;
- All records are maintained in accordance with the general requirements of the Company, this Code of Practice and all relevant Statutory Authorities; and
- All documentation is adequate to achieve the designed and desired level of recording and control.

### Practice – Management of Records

- 9.1 All records should be stored and maintained in such a way that they are accessible and readily retrievable. Records should be appropriately labelled, dated and suitably contained for easy identification.
- 9.2 Records should be stored in facilities that provide a suitable environment to minimise damage or deterioration and to prevent loss through inadequate storage and/or control. Computer records must be secure and protected from unauthorised access.
- 9.3 Procedures should be established for identification, collection, indexing, access, filing, storage, maintenance and disposition of records.
- 9.4 Responsibility for maintaining records should be clearly defined and documented.
- 9.5 In determining the retention period for particular records, customers' requirements, legislative requirements, and Company policy should all be taken into account. If the required retention period differs, whichever is the longer period should apply. Retention periods should be documented in Procedures.

### Practice – Management of Documentation

- 9.6 Documents should be designed, prepared, reviewed and distributed with appropriate care. All documents should be approved, signed and dated by appropriate authorised persons and not be changed without due authorisation.
- 9.7 Documents should have unambiguous contents, and the title, nature and purpose should be clearly stated. They should be laid out in an orderly fashion and be easy to check.
- 9.8 Records of Controlled Drug activities should be maintained as required by State or Territory legislation and, where required, should include batch numbers of distributed stock to ensure full traceability.

- 9.9 Reports and records of audits relating to scheduled medicines and stock counts of goods with high-illicit value, undertaken in accordance with paragraph 4.6, should be made and maintained on file for two years.
- 9.10 Where applicable, full Material Safety Data Sheets (MSDS) should be kept and maintained.
- 9.11 The original sponsor of the goods should always be traceable and the approved Product Information should be available to authorities and end-users, downstream and upstream.
- 9.12 Mechanisms should exist to allow for transfer of information.

### **Practice - Policies**

- 9.12 Policy documents should detail: who developed the policy; date policy endorsed; who endorsed the policy; where the original is held; the version number; date approved; review date; responsibility for review; and date last updated.
- 9.13 Policy documents should identify the scope and purpose (overview) of the policy, and provide details of topic/s addressed.

### **Practice – Standard Operating Procedures (SOPs)**

- 9.14 A register should be kept, detailing Standard Operating Procedures (SOPs).
- 9.15 SOPs should be numbered, dated, have a title, identify the name or position of the person responsible for the SOP, and include detailed instruction on the subject and a date for review.

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**OTHER GOODS WITH HIGH ILLICIT-VALUE**

**Products that contain the following substance:**

Pseudoephedrine (including all salts, esters or derivatives thereof), alone or in combination with any other therapeutically active substance.

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