NATIONAL COORDINATING COMMITTEE
ON THERAPEUTIC GOODS

Australian
CODE OF GOOD WHOLESALING PRACTICE FOR MEDICINES IN SCHEDULES 2, 3, 4 AND 8

Effective date 1 April 2011

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.

CODE OF GOOD WHOLESALING PRACTICE FOR MEDICINES IN SCHEDULES 2, 3, 4 AND 8

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INTRODUCTION

This Code is applicable to wholesalers who, for the purposes of this Code, are defined as persons or organisations, including manufacturers, wholesalers, manufacturer's agents, importers and distributors who store and/or supply by wholesale substances and preparations (referred to in this document as "medicines") included in Schedules 2, 3, 4 and 8 of the *Standard for the Uniform Scheduling of Drugs and Poisons* or other applicable State or Territory poisons legislation. The term "wholesaler" also includes providers of third party logistics and distribution. The code applies to substances in Schedules 2, 3, 4 and 8 from raw materials to finished goods.

Wholesaling forms part of the supply chain for medicines in Schedules 2, 3, 4 and 8. Wholesalers are responsible for the effective, efficient and safe handling, storage and distribution of those medicines.

This Code of Practice is concerned with ensuring that quality is maintained during wholesaling and it sets out appropriate standards to be applied. In short, medicines in Schedules 2, 3, 4 and 8 need to be stored and distributed in accordance with the label requirements of the sponsor, State and Territory legislation and this Code.

Although it is a Code of Practice and not legislation, compliance with it may be made mandatory in States and Territories. Compliance with the Code is considered to be attained if alternative practices to those set out in this document that achieve an equivalent or better outcome are adopted. However, if an alternative practice is adopted, the wholesaler should be prepared to demonstrate that the alternative practice achieves an outcome that is equivalent to, or better than, the provisions of the Code.

This Code does not negate, detract from 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. This Code does not, in any way, diminish the obligations of wholesalers to comply with these and other legal requirements.

The structure of this Code reflects an increasing level of responsibility for higher risk practices as follows:

Sections 1–9 - applies to all medicines included in Schedules 2, 3, 4 and 8;

Section 10 - sets out additional requirements applicable to the wholesale of medicines classified as Controlled Drugs (Schedule 8 or "CD") and goods with high illicit value ("GHIV").

A program of auditing at regular intervals to ensure compliance with all aspects of this Code and relevant legislation should be established and maintained. Intervals between audits should be risk based.

The National Coordinating Committee on Therapeutic Goods acknowledges the contribution of stakeholders, including law enforcement agencies, to the development of this Code of Practice. In particular, the National Pharmaceutical Services Association contributed significantly to the development and modernisation of this document.

INTERPRETATION

In this Code:

"AS/NZS" means Australian/New Zealand Standard published jointly by Standards Australia and Standards New Zealand.

"Cold chain" means a temperature-controlled supply chain. An unbroken cold chain consists of an uninterrupted series of storage and distribution activities which maintains a given temperature range, based on the sponsor's recommended conditions for product stability integrity stated on the TGA approved product packaging. A common temperature range for a cold chain is 2 to 8°C. A **"cold chain"** medicine is a medicine that requires cold chain controls.

"Controlled Drugs" (CD) means substances included in Schedule 8 of the *Standard for the Uniform Scheduling of Drugs and Poisons* and any other substances included in Schedule 8 of an applicable State or Territory poisons legislation.

"Dangerous Goods" means goods classified as such according to the *Australian Code for the Transport of Dangerous Goods by Road and Rail* (ADG Code) as amended from time to time.

"Goods with High Illicit Value" (GHIV) means medicines specified in Appendix 1 - *Goods with High Illicit Value.*

"Material Safety Data Sheet" (MSDS) means detailed information documented by the manufacturer or importer of a substance. The MSDS describes the physical and chemical properties of the product and contains useful information such as flash point, toxicity, procedures for spills and leaks, and storage guidelines.

"Medicines" means any substance or preparation included in Schedules 2, 3, 4 and 8 in the *Standard for the Uniform Scheduling of Drugs and Poisons* or other applicable State or Territory poisons legislation. The term includes raw materials and finished goods.

"Recalled Medicines" means medicines with respect to which the sponsor or health authorities have issued a notice for their permanent removal from supply or use for reasons relating to deficiencies, quality, safety or efficacy.

"Repackaging" means the application of supplementary labelling such as the name and address of the sponsor, or relabelling a product to comply with the labelling requirements of the applicable State or Territory poisons legislation.

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

"Security Risk Assessment" means a risk assessment required under section 9.1.

"Standard Operating Procedures" means documents that detail operating processes, including a description of the operations to be carried out, the precautions to be taken, and record keeping for the performance of the procedure.

"Temperature sensitive medicines" (TSM) means medicines which must have their temperature maintained within a specified temperature range in order for quality, safety and/or efficacy to be maintained. The term includes:

- "Cold chain medicines" which are medicines requiring refrigeration or freezing and cold chain transport and storage, and
- "Medicines other than cold chain medicines requiring controlled temperatures".

"Wholesaler" means a person or organisation, including a manufacturer, wholesaler, manufacturers' agent, importer and distributor who stores and/or supplies by wholesale substances and preparations (referred to in this document as "medicines") included in Schedules 2, 3, 4 and 8 of the *Standard for the Uniform Scheduling of Drugs and Poisons* or other applicable States and Territory poisons legislation. The term also includes providers of third party logistics and distribution.

"Wholesaling" and "supply by wholesale" means:
(a) supply of medicines for the purposes of resale or resupply; or
(b) the supply of medicines for use in connection with a trade, business, profession or industry.

SECTION 1

BUILDINGS AND GROUNDS

Principle	Practice
Policies and procedures should be in place to provide: A. good housekeeping and protection for all medicines stored within the building B. safe and secure access to the property C. safe and secure access to the medicines stored D. security of the property and the medicines stored therein.	1.1 Warehousing of medicines should be carried out in buildings or parts of buildings that have been built for, or adapted to, this purpose. 1.2 Sufficient space should be provided for the orderly receipt, warehousing and dispatch of medicines and, in particular, a quarantine area should be available for isolation of medicines when necessary, including isolation of faulty packs, returned and expired goods and recalled medicines. 1.3 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. 1.4 Buildings and storage facilities, including bays, docks and platforms used for the receipt or despatch of goods, should protect the medicines from contamination and deterioration, including protection from excessive local heating, cooling or dampness, or undue exposure to direct sunlight. 1.5 Buildings should be kept free of rodents, vermin, birds, pets and pests, and records should be kept relating to pest control measures. 1.6 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. 1.7 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 and detection of site penetrations if they occur. **For specific security requirements for medicines generally, see Section 9, and for Controlled Drugs and Goods with High Illicit Value, see Section 10.**

SECTION 2

STORAGE FACILITIES	
Principle	**Practice**
Policies and procedures should be in place to provide storage conditions that ensure the maintenance of quality and safety of stored medicines.	2.1 Storage facilities for medicines should protect the medicines from deterioration. The conditions of storage should be in accordance with the storage conditions specified on their labels and their Material Safety Data Sheets (MSDS) where relevant. 2.2 Temperatures in facilities where TSM are held should be monitored using suitable temperature recording devices and the results recorded and analysed so as to demonstrate the suitability of these areas for their purposes. Such records should be kept for at least one year. 2.3 Facilities need to be provided that allow for temperature monitoring and recording in case of power failures. 2.4 Instruments or equipment used for monitoring temperature should be calibrated on a regular basis to ensure their accuracy and appropriate records should be kept of calibration tests and results. 2.5 If TSM storage temperature is found to have deviated from the sponsor's recommended conditions specified on the label for an extended time, the sponsor of the goods should be contacted and the suitability of the product for use resolved. The meaning of extended time is to be determined in consultation with the sponsor of the product. **For specific storage and distribution requirements for cold chain medicines, see Section 8.** 2.6 Incompatible activities, such as manufacturing, must be avoided in areas in which medicines are handled by wholesale. **For specific storage requirements for Controlled Drugs and Goods with High Illicit Value, see Section 10.**

SECTION 3

PERSONNEL	
Principle	**Practice**
Policies and procedures should be in place to provide staff with the necessary skills and knowledge to ensure the maintenance of the quality, safety and security of the medicines stored and handled.	3.1 An organisational structure clearly identifying staff and their key roles, including management, should be in place and documented. 3.2 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. 3.3 Standard operating procedures should be developed for use by all staff. Staff should be trained in the operating procedures relevant to their responsibilities in such a way that individual responsibilities are clearly understood. 3.4 Personnel should be trained to perform assigned duties and functions at an acceptable level. Training records should be kept and training should be repeated or reinforced at appropriate intervals. Adequacy of training should be audited. Approval for staff to perform assigned duties and functions should be recorded. 3.5 Specific training should be given for medicines with specific risks, e.g. medicines requiring special storage conditions, fragile products or medicines containing substances that pose high risk to personnel and/or to product quality if package integrity is breached or spillage occurs, e.g. dangerous goods, cytotoxic drugs. 3.6 Specific training should be given for tasks requiring the evaluation of goods, (e.g. evaluation of complaints about damage during delivery to the customer (see Section 6.2), return to saleable stock of returned unused goods (see Section 6.3)) or the evaluation of process deviations (e.g. internal audits).

SECTION 4

STOCK HANDLING AND STOCK CONTROL

Principle	Practice
Policies and procedures should be in place to provide for stock handling and stock control.	**General** 4.1 Storage areas should be adequate and organised to enable segregation and identification of the various materials and products stored, and should enable stored medicines to be easily maintained in a clean, dry and orderly condition. 4.2 Medicines should be stored off the floor (e.g. on pallets or shelves) to reduce exposure to dust and moisture, and to help facilitate cleaning. Particular care should be taken to prevent mould growth in refrigerated rooms and cabinets. 4.3 Handling and storage of medicines should be in accordance with established procedures designed to prevent contamination or deterioration of the goods, damage to packs or confusion of products. Particular attention should be paid to maintaining the integrity of seals on packs of sterile goods. Attention should also be paid to any special instructions indicated on the TGA approved product packaging relating to handling or storage of the goods. 4.4 There should be a system to ensure stock rotation, with regular checks that the system is operating correctly, such as a stock cycle counting program. 4.5 Spills should be cleaned up promptly and rendered safe as quickly as practicable in accordance with instructions in the MSDS where applicable. Spill kits should be conveniently located within the storage area. 4.6 A written procedure for dealing with spillage of items of special hazard, such as dangerous goods or cytotoxic drugs, should be available and training provided to responsible staff. 4.7 Medicines bearing an expiry date should 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 medicines are used by the consumer. Such medicines should be withdrawn from sale and quarantined pending disposal in accordance with agreements between wholesaler and supplier or sponsor. 4.8 Repackaging (including relabelling) of medicines must be carried out only by wholesalers who hold an appropriate licence or authority under State and Territory and/or Commonwealth legislation, unless the activity is exempt from these requirements and only with the express approval of the sponsor. **Inwards Goods from Suppliers** 4.9 Upon stock arrival at the wholesaler, it should be inspected and examined for correctness against order, acceptable period of time before stock expiry date and absence of damage or evidence of tampering.

	4.10 There should be a system for the recognition and prompt handling of medicines that require special handling or care. 4.11 Medicines rejected by the wholesaler on receipt because of error, breakage, leaking containers or other faults should be placed in quarantine until the matter is resolved with the supplier. 4.12 Importers should take all reasonable measures to ensure that goods are not mishandled or exposed to adverse storage conditions at wharves or airports.

SECTION 5

TRANSPORT	
Principle	**Practice**
Policies and procedures should be in place to provide adequate methods of transportation to achieve safe, secure and timely delivery of all medicines from their point of collection to their destination. Transportation conditions should maintain the quality of the medicines being transported.	5.1 Containers for delivery of medicines should be clean and provide adequate protection from damage or deterioration for the medicines delivered. 5.2 Medicines other than cold chain medicines requiring controlled temperatures may remain temporarily outside the specified temperature range while delivery is in progress. However in assessing circumstances for delivery in any particular case, due account should be taken of the time required for delivery, prevailing or likely weather conditions and the medicines' labelled storage requirements. 5.3 A system should be in place to give assurance of the trustworthiness of employed and contracted delivery personnel, for example, through proof of identity and criminal records, employment history and reference checks. 5.4 A system of identification of employed and contracted delivery personnel should be in place. 5.5 Employed and contracted delivery personnel should be required to keep vehicles secured when unattended. 5.6 A system should be in place to enable the return of signed receipts obtained from the authorised recipients of the goods in paper or electronic form. 5.7 There should be standard operating procedures for employed delivery personnel to ensure safe, secure and timely delivery of medicines and for dealing with incidents such as accidents which result in loss or destruction of a load, or part of a load, of medicines in transit. Where delivery is carried out by a contractor, agreements should include procedures to be adopted by the contractor. 5.8 When deliveries are performed by delivery personnel other than those directly employed by or contracted to the wholesaler (subcontractors), scheduled medicines should be packed in a manner that prevents identification of the contents. Systems should be in place to promptly follow up on any undelivered packages. Wholesalers should only utilise subcontractors for non-metropolitan, emergency, small or irregular deliveries. **For transport of cold chain medicines, see Section 8.**

SECTION 6

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

Principle	Practice
Policies and procedures should be in place to provide: A. receipting and recording of complaint details B. adequate methods of handling and communicating complaint content C. adequate methods of measuring and evaluating complaint content D. resolution of complaints and prevention of a recurrence.	**Complaints Handling and Control** 6.1 Complaints regarding a medicine or its packaging, as distinct from those relating solely to matters within the wholesaler's control, should be directed promptly to the supplier or sponsor of the medicine. 6.2 Complaints relating to the wholesaler's own activity, including transport, should be evaluated. Unless the evaluation indicates that the problem is trivial or outside the wholesaler's control, measures should be taken to remedy the problem and prevent its recurrence. Records of these complaints and the remedial measures taken should be maintained.
Policies and procedures should be in place to ensure all unused and/or damaged medicines returned from customers other than through the Return of Unwanted Medicines (RUM) Program are accounted for until disposal occurs.	**Return of Unused and/or Damaged Goods from Customers** 6.3 Medicines which have left the care of the wholesaler should only be returned to saleable stock if examined and assessed by a person authorised to do so and: (a) they are in their original unopened containers, with intact labels and packaging and bear a valid expiry date; and (b) there is no reason to believe that they have been subject to adverse environmental conditions; and (c) there is no reason to believe the goods have been tampered with or are contaminated; and (d) on receipt, they are packed separately from other goods and accompanied by a separate Returns Note; and (e) if necessary, advice is sought from the sponsor of the medicines Medicines not returned to saleable stock should be quarantined pending disposal, or returned in accordance with the agreement between the wholesaler and the supplier or sponsor.

Policies and procedures should be in place to provide for actions to be taken: A. in the event of a recall of medicines held in stock B. in recalling medicines on behalf of a sponsor C. to generate records of recalled medicines.	**<u>Product Recall</u>** 6.4 Procedures should be consistent with the *Uniform Recall Procedure for Therapeutic Goods* issued by the Therapeutic Goods Administration. 6.5 Recalls carried out should be documented and records of all recalled medicines received into the warehouse should be kept. 6.6 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 leak and contaminate other goods. 6.7 Standard operating procedures should be in place to ensure all recalled medicines are accounted for until disposal occurs.

Policies and procedures should be in place to ensure that damaged products and products otherwise unsuitable for sale are quarantined and accounted for.	**<u>Damaged Stock and Stock Unsuitable for Sale</u>** 6.8 Stock which has been damaged or is otherwise deemed unsuitable for sale, temporarily or permanently, should be placed in quarantine so that it cannot be sold in error, misappropriated or stolen or leak and contaminate other goods. Quarantine may be achieved through physical isolation from saleable stock or electronically through a warehouse management system or stock control system. 6.9 Standard operating procedures should be in place to ensure all quarantined medicines are correctly accounted for and are unavailable for sale

SECTION 7

MANAGEMENT OF RECORDS, DOCUMENTATION AND STANDARD OPERATING PROCEDURES

Principle	Practice
Policies and procedures should be in place to ensure: A. all records are kept in accordance with legislative requirements B. all records are maintained in accordance with the general requirements of the wholesaler, this Code of Practice and relevant Statutory Authorities C. all documentation is adequate to achieve the required standard of recording and control, including that relating to the quarantining of stock.	**Management of Records** 7.1 An accurate record of all receipts and sales transactions must be kept. 7.2 All records should be stored and maintained in such a way that they are accessible and readily retrievable. 7.3 Records should be stored in facilities that provide a secure environment which minimises damage or deterioration and prevents loss through inadequate storage and/or control. 7.4 Computer records must be secure and protected from unauthorised access and tampering. Procedures should be in place to ensure data integrity of computer records. 7.5 Procedures should be established for identification, collection, indexing, access, filing, storage, maintenance and disposition of records. 7.6 Responsibility for maintaining records should be clearly defined and documented. 7.7 In determining the retention period for particular records, customers' requirements, suppliers' and sponsors' requirements as set out on the TGA approved product packaging, legislative requirements, and the wholesaler's policy should all be taken into account. If the required retention periods differ, whichever is the longer period should apply. Retention periods should be documented in standard operating procedures. **Management of Documentation** 7.8 Systems should be in place for the design, preparation, review and distribution of standard operating procedures ("documents"). All documents should be approved or signed and dated by appropriate authorised persons and not be changed without authorisation. Documents may be in electronic or paper form. 7.9 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. 7.10 Where applicable, full MSDS should be accessible. 7.11 There should be a system to prevent the inadvertent use of superseded documents.

	Policies 7.12 Policy documents should detail: • who developed the policy; • the date the policy was endorsed; • who endorsed the policy; • where the original is held; • the version number; • review date; • responsibility for review; and • date last updated. A register of policy documents should be kept. 7.13 Policy documents should identify the scope and purpose (overview) of the policy, and provide details of topic/s addressed. **Standard Operating Procedures** 7.14 A register of standard operating procedure documents should be kept. 7.15 Standard operating procedures should be: • clear, concise, comprehensible and readily available to those needing to use them; and • numbered, dated, have a title, identify the name or position of the person responsible for the standard operating procedures; and • include detailed instruction on the subject and a date for review.

SECTION 8

COLD CHAIN MEDICINES	
Principle	**Practice**
Policies and procedures should be in place to ensure that throughout the receipt, storage and distribution of cold chain medicines, the integrity of the cold chain is maintained, according to the sponsor's recommended conditions in regard to product stability integrity as set out on the TGA approved product packaging.	**General** 8.1 Refrigerated areas for the storage of cold chain medicines should be correctly set up and operate continuously. 8.2 Any new equipment used for the storage of cold chain medicines should be commissioned according to the manufacturer's written procedure and the storage conditions validated before becoming operational. 8.3 Temperature monitoring equipment should be installed within facilities used to store cold chain medicines to enable air and/or product temperature as appropriate to be recorded. Such devices should be able to operate in the event of a mains power failure. 8.4 Temperature monitoring equipment should be capable of alerting staff in the event that the defined temperature range has been compromised. There should be appropriate alert systems for any temperature deviation outside of the set range. 8.5 Maximum and minimum temperatures should be recorded, either electronically or manually at least once in every 24-hour period, with the supervisor reviewing records on a regular basis as appropriate for the medicines stored. Such records should be kept for at least one year. 8.6 Regular maintenance should be carried out on all refrigeration plants in accordance with the manufacturer's instructions. Maintenance records should be kept. 8.7 The calibration and function of all temperature monitoring equipment, , including alarms and other associated equipment, should be checked on an annual basis. 8.8 Procedures should be in place detailing the actions to be taken in the event of continued power failure or an excursion outside the defined temperature range. 8.9 If cold chain medicine storage temperature is found to have deviated from the sponsor's recommended conditions, the sponsor of the medicines should be contacted and the suitability of the medicine for use should be resolved and the outcome recorded.

	Inwards Cold Chain Medicines from Suppliers 8.10 Cold chain medicines with a defined temperature range should not be stored in a temporary stock location that could expose them to temperatures outside the specified range, unless authorised by the sponsor and with monitoring of the conditions to which the medicine is exposed. 8.11 Cold chain medicines requiring storage within a defined temperature range should be moved as a matter of priority to the temperature area corresponding to the medicines' label requirements. **Order Assembly and Dispatch of Cold Chain Medicines** 8.12 Packaging of cold chain medicines should be undertaken in an area specifically set aside for this purpose and be performed under conditions (temperature and time) that minimise the risk of medicine temperature excursions outside the conditions prescribed on the TGA approved product packaging. 8.13 Validated temperature-control systems (e.g. thermal packaging, temperature-controlled containers, refrigerated vehicles) shall be used to ensure integrity of the cold chain is maintained between wholesaler and customer. 8.14 For each delivery, assessment of the delivery method and validated temperature-controlled system to be used should consider the time required for delivery, weather conditions and any foreseeable exposure risks. 8.15 Special delivery procedures, transport and packaging should be established for cold chain medicines likely to be exposed to an unfavourable environment. 8.16 The external packaging/shippers containing cold chain medicines should be labelled: ▪ "Refrigerate – do not freeze" – for medicines requiring temperature maintenance in the range of + 2ºC to +8ºC; or ▪ "Refrigerate contents on receipt" - for medicines transported in packaging that should be removed before the medicine is placed inside refrigeration; or ▪ "Keep frozen" - for medicines requiring temperature maintenance in the range below 0ºC. 8.17 Cold chain medicines should be clearly identifiable from other goods in the same delivery. 8.18 The packaging and handling of cold chain medicines should seek to alert the receiver that the order contains cold chain medicines and that the receiver should place these medicines in appropriate storage facilities as soon as possible. **Transport of Cold Chain Medicines** 8.19 Cold chain medicines should be transported under conditions that have been validated or are monitored to ensure that the relevant temperature range is maintained during transport, according to the sponsor's recommended conditions in regard to product stability documented on the TGA approved product packaging. The cooling agent should not cause freezing of medicines marked "Refrigerate – do not freeze". Medicines labelled "Keep frozen" should be transported in such a way that they remain frozen.

SECTION 9

SECURITY ARRANGEMENTS AND PROCEDURES

Comment – This section covers the base level security requirements for medicines (i.e. other than for CD and GHIV which require additional security measures to those outlined in the section - see Section 10.)

Principle	Practice
Policies and procedures should be in place to provide for: A. an appropriate level of protection for stored medicines to prevent pilferage, diversion, theft, misuse and illegal distribution B. the security and management of the facility C. reporting of theft or misuse of raw ingredient or product.	**<u>Security/Facilities</u>** 9.1 Management should carry out a security risk assessment and maintain a security risk management plan for the wholesale business, taking into account relevant matters including the type (e.g. the different security risks associated with drugs subject to dependence and abuse such as benzodiazepines and anabolic steroids, compared with antibiotics) and quantities of medicines, the premises and their location, the operational aspects of the wholesale business and the loss history of the facility (the Security Risk Assessment and Security Risk Management Plan). 9.2 Wholesalers should review the Security Risk Management Plan for adequacy at least annually and, if they find the plan to be inadequate, implement improvements and update the plan. 9.3 Wholesalers should undertake regular security audits of the premises against the Security Risk Management Plan and act promptly on any non-compliance encountered. The frequency of audits should be commensurate with risk but should be carried out not less frequently than once every twelve months. 9.4 Suitable surveillance and detection systems should be installed to monitor points of vulnerability identified in the Security Risk Assessment. 9.5 The surveillance and detection systems used should be commensurate with the assessed risk and be linked to the overall facility security system with a reliable after-hours communication link to monitored controls. 9.6 Access to storage facilities and other security-sensitive areas should be limited to those personnel who are required to have it. 9.7 Adequate overall site security measures need to be in place to prevent unauthorised persons gaining access to the site and areas where medicines are stored. **<u>Personnel</u>** 9.8 A senior manager should be appointed to have overall responsibility for the security of the premises, including the Security Risk Management Plan and audits to ensure compliance with it.

	9.9 Procedures and conditions of work for employees and other persons having access to medicines should be designed and administered to minimise the possibility of pilferage, diversion or theft. 9.10 Standard operating procedures for security, handling methods and reporting of theft or misuse of medicines should be developed and enforced. The procedures should be maintained in a manner that is consistent with the Security Risk Management Plan and, subject to security restrictions, should be readily accessible to staff. **Stock Handling and Control – Supply of Medicines** 9.11 Systems should be in place to prevent theft of medicines. Theft, loss, suspected tampering or suspicious unresolved discrepancies in records other than minor handling losses must be reported to the police and licensing authorities, in accordance with all State, Territory and Commonwealth requirements, or in the absence of any legislative requirements, within seven days of discovering such unexplained circumstances. 9.12 Wholesalers must have in place an adequate validation protocol that ensures that persons supplied with medicines are authorised appropriately under State or Territory legislation to be supplied with those medicines. Procedures should be in place to validate opening of new accounts and amendments to account details. 9.13 In the case of "Calling orders" (where the person purported to have ordered the stock or another person acting on his or her behalf attends the wholesaler's premises to collect the stock), a protocol should be in place to ensure the bona fides of the person calling for the products. **Waste Management** 9.14 Medicines for destruction should be enclosed in secure, opaque and sealed packaging or container. The packaging or container must not identify the contents of the packaging from the outside. The packaging or container must identify the content as waste. For example, labelling on the external packaging that is visible should be removed, expunged or painted over. Alternatively, destruction of waste medicines may be carried out under the personal supervision of personnel authorised by the wholesaler. 9.15 Collection and destruction of waste medicines must be carried out by a waste collector or other person who is licensed or permitted to do so under relevant State or Territory legislation.

SECTION 10

ADDITIONAL MEASURES FOR MANAGEMENT OF CONTROLLED DRUGS (CD) AND OTHER GOODS WITH HIGH ILLICIT VALUE (GHIV)

This Section covers wholesale and associated activities relating to all Controlled Drugs (CD) and Goods with High Illicit Value (GHIV). CD and GHIV are attractive targets for diversion for illicit use or trafficking, including illicit conversion to other products that have a high illicit value.

Goods with high illicit value, for the purposes of this Code, are listed in Appendix 1.

The measures described in this Section are additional to existing requirements relating to CD or other medicines that are specified in relevant State or Territory legislation. Rather, this Section gives direction to wholesalers on how to manage the additional risks of goods with high illicit value.

Principle	Practice
Policies and procedures should be in place to provide: A. a Security Risk Assessment of the wholesale business, taking into account the type and quantities of CD and/or GHIV, the premises and their location and the operational aspects of the wholesale business B. a Security Risk Management Plan which details: ▪ secure storage and handling methods for all CD and/or GHIV commensurate with the risk, and ▪ control and administration of all transport movements of CD and/or GHIV from wholesalers to product recipients, and ▪ detailed records of transactions in respect of CD and/or GHIV.	**Wholesaler Risk Rating** Wholesalers handling CD and/or GHIV need to assess whether their additional risk is high, moderate or low. Wholesalers at high risk would be those that store raw active ingredient as well as large quantities (e.g. multiple pallets of a single medicine) of manufactured product, including as bulk tablets or capsules to be packaged, and expect to always hold these substances on site. Typically, wholesalers that manage this volume of CD and/or GHIV are manufacturers of these products or third party logistics bulk storage facilities supplying to wholesalers). Wholesalers at moderate risk would be those storing a wide range of wholesale quantities of CD and/or GHIV most of the time, typically larger wholesale distribution centres. Wholesalers that hold wholesale quantities of GHIV seasonally would be considered to be at moderate risk during the period wholesale quantities are kept. Wholesalers at low risk would be those storing CD and/or GHIV in small quantities. **Security Risk Assessment and Security Risk Management Plans** • All wholesalers should take into consideration the increased risk of handling CD and/or GHIV when preparing the Security Risk Assessments and Security Risk Management Plans required in Section 9. Specifically, in the Security Risk Assessment and the Security Risk Management Plan, wholesalers need to address the increased risks and address vulnerabilities in the areas set out below. The extent to which they are addressed should be dependent on the level of risk of diversion of CD and/or GHIV.

- Risk areas to be addressed are:
    - Probity, and training of staff handling CD and/or GHIV.
    - Access by staff, contractors and visitors to premises, especially areas where CD and/or GHIV are stored.
    - Location of storage facilities for CD and/or GHIV within premises.
    - Premises perimeters including electronic security systems, landscaping, layout, lighting, signage, staff and visitor entry and exit and car parking.
    - Construction of buildings, including doors and windows.
    - Stock control measures for handling CD and/or GHIV.
    - Supply, dispatch and receipt arrangements.
    - Arrangements for delivery, including security and accountability of delivery services.

Wholesalers with Moderate or High Risk:

In the case of wholesalers with moderate or high risk, the Security Risk Management Plans referred to in Section 9 should be in accordance with AS/NZS ISO 31000:2009, Risk management - Principles and guidelines (Note: AS/NZS HB 167:2006 Security Risk Management Handbook provides guidelines for the application of risk management to security risks).

The services of a consultant who has registration or licensing in security in at least one State/Territory and appropriate industry knowledge should be engaged to assist in the preparation of the Security Risk Management Plan in compliance with AS/NZS ISO 31000:2009, and review of the plan when the plan is updated to reflect operational changes that result in a significant increase in risk.

It is appropriate for the security consultant to be directed to take into account the need for timely medicines supply to communities, including those in rural and remote areas across Australia to remain affordable.

The Security Risk Management Plan and the security consultant's report should be made available for inspection by State/Territory health authorities.

Wholesalers with Low Risk

While wholesalers with low risk should have a Security Risk Management Plan, the plan need not conform to AS/NZS ISO 31000:2009.

All wholesalers

Personnel

10.1 Procedures and conditions of work for employees and other persons having access to CD and/or GHIV should be designed and administered in accordance with the Security Risk Assessment and Security Risk Management Plan.

10.2 An application for a Police Name Check, Criminal Record Check or equivalent should be lodged on or prior to commencement of

	employment of all new warehouse employees and employee delivery drivers. Existing employees may be exempt from this process on the basis of their employment history. The same requirement applies to all regular casual staff or contractors employed in the warehouse or as delivery personnel under an equivalent process by their agency or employer. 10.3 Regular documented training and review should be instituted and carried out for all employed personnel with access to CD and/or GHIV covering security and safety risks involved. This training should be supported by a program of regular security checks, inspections and audits. **Specific Requirements for CD** 10.4 CD, including CD waste, should be stored in a vault or safe and in accordance with applicable State or Territory legislation. 10.5 In the case of wholesalers with high or moderate risk, the vault or safe should be fitted with an alarm, seismic detectors and should be video monitored. In the case of wholesalers with high risk, the locking mechanism for the vault or safe should require two persons to gain access and be time-delayed. 10.6 The safe or vault should be located in a secure area of the building, out of public view, and kept locked except when in immediate use. 10.7 Access to the safe or vault should be limited to authorised staff, controlled and monitored via appropriate measures to be determined by the Security Risk Management Plan. 10.8 A Controlled Drugs register should be maintained at each site in accordance with State and Territory legislation. These records should be subject to regular audits and verification by a responsible supervisor or manager. 10.9 As waste containing CD has the same illicit value as saleable goods, waste, including expired products or manufacturing rejects, should be stored and handled under similar security to raw materials and commercial stock. 10.10 CD must be destroyed in accordance with State/Territory requirements. 10.11 Waste containing CD should be disposed of as soon as reasonably possible. Regular small runs to disposal facilities are likely to reduce the risk of diversion from storage. 10.12 Discarded raw material packaging that contained CD should be de-identified. **Specific Requirements for GHIV** 10.13 Storage of any raw material comprising GHIV must be in a vault or safe. The vault or safe should be fitted with an alarm, seismic detectors and should be video monitored. The locking mechanism for the vault or safe should require two persons to gain access and be time-delayed. 10.14 Wholesalers should store medicines containing GHIV, other than picking stock or when it is necessary to carry out an essential operation in connection with them, in a secure manner that restricts

	access and allows for rapid detection of interference or diversion and ease of identification of offenders. Examples of satisfactory storage arrangements are: - an enclosed or caged area with restricted access, suitable alarms and video monitoring and recording, or - a structure that provides equivalent security to a cage such as a cage fitted on a pallet, a storage cabinet, or a fenced off structure inside pallet racking (all lockable) with restricted access, suitable alarms and video monitoring and recording 10.15 Wholesalers should undertake regular and documented formal stock counts of GHIV on hand. The frequency of stock counts is to be set out in the Security Risk Management Plan and based on the Security Risk Assessment. 10.16 As waste containing GHIV has the same illicit value as saleable goods, waste containing GHIV (other than when the GHIV is present in small quantities in a large volume of other waste), including expired products or manufacturing rejects, should be stored and handled under similar security, and accounted for in a similar manner to raw materials and commercial stock. 10.17 Waste containing GHIV, other than when the GHIV is present in small quantities in a large volume of other waste, must be destroyed in accordance with State/Territory requirements for destruction of CD. 10.18 Bulk quantities of waste containing GHIV should be disposed of as soon as reasonably possible. Regular small runs to disposal facilities are likely to reduce the risk of diversion from storage. 10.19 Discarded raw material packaging that contained GHIV should be de-identified before being disposed of in open waste bins.

APPENDIX 1

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.