AUSTRALIAN

Code of Good Wholesaling Practice For Veterinary Ethical Products

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1. INTRODUCTION

100 **Wholesalers distribution forms part of the supply chain of manufactured therapeutic goods. Wholesalers are responsible for the effective, efficient and safe handling, storage and distribution of such products. This Code of Practice sets out appropriate steps for meeting this responsibility.**

101 **Except for a brief mention under "storage", the Code does not deal with either 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.**

2. INTERPRETATION

201 **In this Code, the word "should" indicates requirements that are expected to apply unless shown to be inapplicable or replaced by an alternative demonstrated to provide at least an equivalent level of quality assurance.**

3. BUILDINGS AND GROUNDS

301 **Warehousing of therapeutic goods should be carried out in buildings or parts of buildings that have been built for, or adapted to, this purpose.**

302 **The grounds should be established and maintained so as to minimise ingress into the buildings of dust, soil, or other contaminants and should be maintained in an orderly condition. They should be free of accumulated waste, dirt and debris. Waste should be collected in designated closed containers and disposed of at frequent intervals.**

303 **Buildings should be kept free of rodents, vermin, birds, pests and pets.**

304 **Buildings should provide protection for the goods from contamination and deterioration, including protection from excessive local heating or undue exposure to direct sunlight. The goods received or dispatched at receiving or dispatch bays, docks, platforms or areas should also be protected from dust, dirt and rain.**

305 **Buildings must be secured with a minimum of:**

- **perimeter alarm**
- **movement detector**
- **back to base alarm**

306 **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.**

307 **Buildings and fixtures should be kept clean and well maintained. Cleaning equipment should be stored under hygienic conditions.**

4. FACILITIES

401 **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.**

402 **All products must be stored according to manufacturer's label.**

a)

Controlled storage, e.g. freezers, refrigeration:

i.
Monitored, including back to base alarms.

ii.
Maintain records.

iii.
No sale or disposal without manufacturer's approval if temperature storage conditions are breached.

b)

Other storage areas other than controlled storage:

i.
Monitor using minimum/maximum thermometer/s.

ii.
Record daily.

iii.
Maintain records.

403 **If any temperature deviates and a product is found to be stored in an unsuitable area that product must be moved to an area complying with manufacturer's label.**

404 **Special storage facilities should be provided for poisons, drugs of addiction, "dangerous goods" or other classes of goods as required by applicable State or Territory legislation.**

405 **Incompatible activities such as manufacturer (including repackaging) or the handling of toxic chemicals should be avoided in areas in which therapeutic goods are handled by wholesale.**

5. PERSONNEL

501 **Key personnel bearing the responsibility for ensuring that products and materials are correctly handled, stored and distributed, should be identified,**

should have the education, training, experience or combination of these elements that will allow them to effectively discharge this responsibility.

502 **Operating personnel should be trained to perform assigned duties and functions at an acceptable level.**

503 **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 drugs coming into unauthorised possession.**

5A. CUSTOMER/SUPPLIER POLICY

504 **Wholesalers will:**

i.
Only supply to authorised persons or organisations as defined under relevant legislation.

ii.
Have in place a procedure to verify the authorised status of each customer and maintain a copy of relevant documentation.

iii.
Comply with manufacturers' distribution policies provided:
a)
The policies are legal

b)
The policies are compatible with the wholesaler's own business policy.

6. STOCK HANDLING AND STOCK CONTROL

601 **Handling and storage of therapeutic goods should be in accordance with established procedures designed to prevent contamination or deterioration of the goods, damage to packs, or confusion of products. Particular care should be taken to maintain the integrity of seals on packs of sterile goods. Attention should be paid to any special instructions from the manufacturer relating to handling or storage of the goods.**

602 **Importers should take all reasonable measures to ensure that goods are not mishandled or exposed to adverse storage conditions at wharves or airports.**

603 **Storage, supply, distribution and recording of all products must be in accordance with applicable State or Territory legislation.**

604 **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. Particular care should be taken to avoid mould growth in refrigerated areas.**

605 **There should be a system to ensure stock rotation, with frequent regular checks that the system is operating correctly.**

606 **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.**

607 **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.**

Inwards Goods - from Suppliers

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

609 **There should be a system for the recognition and prompt handling of drugs of addiction, of those products requiring specific temperature storage, of products that have a short shelf life and of any other products that require special care.**

610 **Goods from suppliers 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.**

Damaged Goods form Stock

611 **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.**

612 **Stocks of products with broken seals, damaged packaging or suspected of possible contamination must not be sold or supplied. Special attention should be given to the integrity of packages containing sterile devices.**

Returned Goods from Customers

613 **Returned goods from customers should only be accepted if:**

a)
They are in their original unopened containers, in good condition and bear a valid expiry date.

b)
There is no evidence that they have been subjected to adverse conditions.

c)
Each item is packed separately from other goods and accompanied by a separate returns note.

d)
They have been examined and assessed by an authorised person. Such assessment should take into account the nature of the goods, and any special storage conditions that may be required. If necessary, advice should be sought from the person responsible for the quality assurance of the manufactured product.

614 **Reconditioning or repackaging (including relabelling) of therapeutic goods must not be carried out by wholesalers.**

Returned Goods from Recall

615 **The document "Guidelines for Recall of Agricultural and Veterinary Chemicals" stipulates that recalled goods are the responsibility of the Registrant. Wholesalers should act in accordance with the instructions of the Registrant in matters of Recall.**

7. TRANSPORT

701 **Containers for delivery of goods should be clean and provide adequate protection for the goods delivered.**

702 **Goods labeled with a requirement for refrigerated storage should, where appropriate, be transported in insulating containers with ice or other cooling agent. The agent should not cause freezing of goods marked "refrigerate - do not freeze". Goods labeled with a requirement for frozen storage should be transported in such a way that they remain frozen.**

703 **Delivery of other goods requiring controlled temperatures should be carried out by the fastest practical means. These goods 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 labeled storage requirements.**

8. COMPLAINTS

801 **Complaints regarding products or packaging, as distinct from those relating solely to matters within the wholesaler's control, must be notified promptly to the manufacturer or registrant/supplier of the goods. Complaints relating to the wholesaler's own activity should be evaluated and measures taken, where appropriate, to prevent their recurrence.**

9. RECORDS

901 **Invoices or packing slips should be issued for each delivery and accompany the goods.**

902 **Clear and readily available records should be maintained showing the receipt and disposal of all products purchased and sold. Such records should be kept in an accessible form and place for the period in force under applicable legislation.**