TGA Therapeutic Goods Administration

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SERVICES

AUSTRALIAN

Code of Good Wholesaling Practice

For Therapeutic Goods

For Human Use

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CODE OF GOOD WHOLESALING PRACTICE FOR THERAPEUTIC GOODS FOR HUMAN USE

1. INTRODUCTION

100 Wholesaler 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. It applies to both classes of therapeutic goods - medicinal products ('drugs' in terms of the regulations to the Therapeutic Goods Act) and medical devices.

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 by 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 & 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, pets and pests.

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 despatched at receiving or despatch bays, docks, platforms or areas should also be protected from dust, dirt and rain.

305 Buildings should have sufficient security to prevent misappropriation of the goods.

306 Sufficient space should be provided for the orderly receipt, warehousing and despatch 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 in 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 Controlled storage environments, e.g deep freeze, 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 that refrigeration has failed. The signal should permit resetting only by an authorised person.

403 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.

404 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.

405 Instruments or equipment used for monitoring temperature should be calibrated on a regular basis to ensure their accuracy.

406 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.

407 Incompatible activities such as manufacture (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/materials are correctly handled, stored and distributed, should have the education, training, experience or combination of these elements that will allow then 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.

6. STOCK HANDLING AND STOCK CONTROL

General

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 given to maintaining 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 drugs of addiction 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 rooms or cabinets.

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 Measures should be taken to demonstrate that restricted goods are not misappropriated.

608 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

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

611 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.

612 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 From Stock

620 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.

621 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 medical devices.

Returned Goods from Customer

630 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) 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 the goods, and any special storage conditions they may require. If necessary, advice should be sought from the person responsible for the quality assurance of the manufactured product.

631 Reconditioning or repackaging (including relabelling) of therapeutic goods (except for addition of name and address or registration numbers) must not be carried out by wholesalers unless such activity is specifically excepted from the requirement to hold a manufacturers licence.

Returned Goods - from Recall

640 There should be a written procedure detailing the action to be taken in recalling goods on behalf of their manufacturer or sponsor, subject to any amendment necessary in specific circumstances. This procedure should be consistent with the "Uniform Recall Procedure for Therapeutic Goods" issued by the Department of Health, Housing and Community Services. The wholesaler should be able to facilitate a recall procedure relative to the area to which goods have been supplied. Recalls carried out should be documented and records of all recalled goods received into the warehouse should be kept.

7. TRANSPORT

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

702 Goods labelled to require 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 labelled to require frozen storage should be transported in such away that they remain frozen. Where appropriate, the transport packaging should be fitted with devices to detect exposure to conditions outside specific limits.

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 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.

8. COMPLAINTS

801 Complaints regarding the product or its packaging, as distinct from those relating solely to matters within the wholesalers control, must be notified promptly to the manufacturer or sponsor of the goods. Complaints relating to the wholesalers' 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 Therapeutic Goods, Poisons or Trade Practices legislation.