



Australian Government

Department of Education, Employment and Workplace Relations

HLTPH307A Pack pharmaceutical products

Release: 1

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Modification History

HLT07 Version 4	HLT07 Version 5	Comments
HLTPH306C Package pharmaceutical products	HLTPH307A Pack pharmaceutical products	Unit updated in V5 Competency outcome changed to include additional essential knowledge from unit HLTPH301C

Unit Descriptor

This unit of competency describes the skills and knowledge required to package and/or pre-package pharmaceutical products according to Pharmacy Board of Australia's Guidelines on specialised supply arrangements and national guidelines / legislation on the filling of dose administration containers

Application of the Unit

The application of knowledge and skills takes place around standards, guidelines / legislation, organisation policies and procedures and under the supervision of a qualified person
Individuals may take responsibility for their own outputs
Work performed requires a range of well developed skills where some discretion and judgement is required

Licensing/Regulatory Information

Not applicable.

Pre-Requisites

Not applicable.

Employability Skills Information

This unit contains Employability Skills

Elements and Performance Criteria Pre-Content

ELEMENT

Elements define the essential outcomes of a unit of competency.

PERFORMANCE CRITERIA

The Performance Criteria specify the level of performance required to demonstrate achievement of the Element. Terms in italics are elaborated in the Range Statement.

Elements and Performance Criteria

- 1) Prepare *packaging process*
 - 1.1 Comply with dress code, safety requirements and personal hygiene procedures prior to entering the packaging area
 - 1.2 Clean and *prepare work area* according to batch work sheet or equivalent
 - 1.3 Obtain packaging person and according to packaging specifications documentation and interpret instructions from authorised
 - 1.4 Identify, clean, prepare and set *packaging equipment*
 - 1.5 Identify and report discrepancies in equipment functioning and take corrective action according to the instructions of an authorised person
 - 1.6 Obtain appropriate and sufficient *packaging materials* according to stock issuing procedures
 - 1.7 Obtain approved *medicine*
 - 1.8 *Prepare labels according to legal requirements*
 - 1.9 Check for, and rectify, discrepancies in labels

- 2) Pack *products*
 - 2.1 Operate packaging equipment to pack products
 - 2.2 Attach correct label to container
 - 2.3 Apply in-process controls and record results
 - 2.4 Report deviations to authorised person and take corrective action according to instructions from an authorised person

- 3) Conduct quality control
 - 3.1 Obtain approval from authorised person at designated points in the packaging process according to batch record
 - 3.2 Obtain relevant documentation and check product specifications according to batch documentation
 - 3.3 Reconcile and verify packaging materials under supervision of an authorised person
 - 3.4 Submit sample where appropriate

- 4) Complete packaging process
 - 4.1 Reconcile number of labels printed with number

used and report discrepancies to the pharmacist

4.2 Alert authorised person of excess materials

4.3 Complete packaging documentation and forward according to standard operating procedures

4.4 Obtain final approval from the pharmacist before releasing packed medicines/product to storage areas

4.5 Clean equipment

Required Skills and Knowledge

This describes the essential skills and knowledge and their level required for this unit.

Essential knowledge:

The candidate must be able to demonstrate essential knowledge required to effectively do the task outlined in elements and performance criteria of this unit, manage the task and manage contingencies in the context of the identified work role

This includes knowledge of:

- Awareness of indemnity issues in relation to Commonwealth/State regulatory and legislative requirements
- Identification and handling of products, including
 - formulary medicines and non-formulary medicines e.g. clinical trial medicines and Special Access Scheme medicines
 - products with the required integrity as well as those whose integrity has been compromised e.g. damaged, contaminated or deteriorated stock
 - routine handling of products and products requiring special handling, e.g. cytotoxics and their spill management, refrigerated and frozen items, light sensitive materials and flammables
- Infection control principles
 - maintaining a clean working environment and equipment, including the principles of cleaning and disinfection
 - personal hygiene and the use of protective clothing when handling and packaging pharmaceutical products
- Knowledge of and the rationale for applicable legislation, organisation policy and in-house standard operating procedures (SOPs), relating to packaging of pharmaceuticals
- Knowledge of the legal responsibilities of providers of health care in relation to confidentiality, client rights, duty of care and implications of negligence
- Legal requirements and principles of pharmaceutical product labelling e.g. product

This describes the essential skills and knowledge and their level required for this unit.

name, batch numbering and expiry date

- Pharmacy Board of Australia's Guidelines on specialised supply arrangements and guidelines/legislation on the filling of dose administration containers
- specific labelling requirements for filling dose administration aids (DAAs) and other containers
- Limitations of own work role including identification and referring of issues outside scope of practice to the authorised person
- Work Health and Safety (WHS) policies, guidelines and symbols and their relevance to packaging pharmaceutical products
- Operation, cleaning and maintenance of various types of equipment, in accordance with manufacturers' guidelines specifications and standard operating procedures, including:
 - counting trays
 - irons
 - heat sealing equipment
 - measures
 - scales
 - tweezers
- Packaging principles and processes, including:
 - calculations, weights and measures
 - properties of container types and selection for use
 - various pack sizes and selection for use
- Principles and practices of ethical and professional codes of conduct
- Standard pharmaceutical references including Australian Pharmaceutical Formulary (APF), MIMs, AMH and Micromedex
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Essential skills:

It is critical that the candidate demonstrate the ability to:

- Identify issues outside scope of practice and refer to the authorised person
- Maintain effective quality control during the packaging process
- Package and label pharmaceutical products in accordance with all requirements
- Work in accordance with Pharmacy Board of Australia's Guidelines and relevant organisation policy, legislative requirements, industrial awards and agreements and in-house standard operating procedures (SOPs) for pharmaceutical product packaging including labelling
- Work in accordance with relevant work health and safety, and infection control guidelines

In addition, the candidate must be able to effectively do the task outlined in elements and performance criteria of this unit, manage the task and manage contingencies in the context

This describes the essential skills and knowledge and their level required for this unit.

of the identified work role

This includes the ability to:

- Clean, operate and maintain the specified equipment according to manufacturer specifications and WHS requirements
- Enter and access data on pharmacy computer system
- Maintain packaging documentation
- Take into account opportunities to address waste minimisation, environmental responsibility and sustainable practice issues
- Use available resources and prioritise workload
- Use literacy, numeracy and oral communication skills required to fulfil the position in a safe manner as specified by the health care facility
- Use problem solving skills

Evidence Guide

The evidence guide provides advice on assessment and must be read in conjunction with the Performance Criteria, Required Skills and Knowledge, the Range Statement and the Assessment Guidelines for this Training Package.

Critical aspects for assessment and evidence required to demonstrate this competency unit:

- The individual being assessed must provide evidence of specified essential knowledge as well as skills
- Observation of workplace performance is desirable for assessment of this unit
- Consistency of performance should be demonstrated over the required range of situations relevant to the workplace
- Where, for reasons of safety, space, or access to equipment and resources, assessment takes place away from the workplace, the assessment environment should represent workplace conditions as closely as possible

The evidence guide provides advice on assessment and must be read in conjunction with the Performance Criteria, Required Skills and Knowledge, the Range Statement and the Assessment Guidelines for this Training Package.

Context of and specific resources for assessment:

- Assessment should replicate workplace conditions as far as possible
- Simulations may be used to represent workplace conditions as closely as possible. Acceptable simulation requires:
 - Scope to determine that work is conducted within legislative and regulatory requirements
 - Scope to determine that work is conducted within WHS and infection control requirements
- Resources essential for assessment include:
 - Access to relevant workplace or a simulated environment where assessment can take place
 - Relevant legislation, regulations and guidelines
 - Weighing and measuring equipment
 - Relevant packing machinery
 - Instructions on the use of equipment

Method of assessment may include:

- Formal appraisal systems
- Interviewing and questioning
- Observation in the work place
- Supporting statement of supervisor(s)
- Written assignments/projects, eg for fundamentals of microbiology and principles of cleaning and disinfection

The evidence guide provides advice on assessment and must be read in conjunction with the Performance Criteria, Required Skills and Knowledge, the Range Statement and the Assessment Guidelines for this Training Package.

Access and equity considerations:

- All workers in the health industry should be aware of access and equity issues in relation to their own area of work
- All workers should develop their ability to work in a culturally diverse environment
- In recognition of particular health issues facing Aboriginal and Torres Strait Islander communities, workers should be aware of cultural, historical and current issues impacting on health of Aboriginal and Torres Strait Islander people
- Assessors and trainers must take into account relevant access and equity issues, in particular relating to factors impacting on health of Aboriginal and/or Torres Strait Islander clients and communities

Range Statement

The Range Statement relates to the unit of competency as a whole. It allows for different work environments and situations that may affect performance. Add any essential operating conditions that may be present with training and assessment depending on the work situation, needs of the candidate, accessibility of the item, and local industry and regional contexts.

Packaging process includes:

- Packaging
- Pre-packaging

Prepare work area includes but is not limited to checking and correcting the following:

- Humidity, light
- Security
- Temperature
- Ventilation

Packaging equipment may be operated manually or automatically and may include but is not limited to:

- Counting trays
- Gloves
- Irons, heat sealing equipment
- Scales, measures
- Tweezers

Packaging materials may include but is not limited to:

- Dosage administration aids/containers
- Tamper proof dose administration containers

Medicines include:

- Bulk products
- Other medicines

Prepare labels according to legal requirements specifically for filling dose administration aids (DAA) and other containers may include but are not limited to:

- Date on which the container was filled
- Directions for use of each medicine as prescribed
- Inclusion of ancillary labels, where required
- Name of client
- Name, strength, form and quantity of all medicines supplied in the container
- Pharmacy details

Products may include:

- Formulary medicines and non-formulary medicines e.g. clinical trial medicines and Special Access Scheme medicines
- Products with the required integrity as well as those whose integrity have been compromised e.g. damaged, contaminated or deteriorated
- Routine handling products and products requiring special handling e.g. cytotoxics and their spill management, refrigerated and frozen items, light sensitive material and flammables

Unit Sector(s)

Not applicable.

Custom Content Section

Not applicable.