



Australian Government

HLTPHA002 Pack pharmaceutical products

Release: 1

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Modification History

Release	Comments
Release 1	This version was released in <i>HLT Health Training Package release 2.0</i> and meets the requirements of the 2012 Standards for Training Packages. Minimal changes to the elements and performance criteria. New evidence requirements for assessment, including volume and frequency. Significant changes to knowledge evidence.

Application

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

This unit applies to pharmacy assistants and technicians working under the supervision of a pharmacist.

The skills in this unit must be applied in accordance with Commonwealth and State/Territory legislation, Australian/New Zealand standards and industry codes of practice.

Elements and Performance Criteria

ELEMENT

PERFORMANCE CRITERIA

Elements define the essential outcomes

Performance criteria describe the performance needed to demonstrate achievement of the element

1. Prepare for packaging

1.1 Comply with dress code, safety requirements and personal hygiene procedures prior to entering the packaging area

1.2 Obtain packaging documentation, work sheet and interpret instructions from authorised person and according to packaging specifications

1.3 Clean and prepare work area according to pre-determined work sheet or equivalent

1.4 Identify, clean, prepare and set packaging equipment

ELEMENT**PERFORMANCE CRITERIA**

Elements define the essential outcomes

Performance criteria describe the performance needed to demonstrate achievement of the element

- 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 and check labels according to work sheet and legal requirements
- 1.9 Submit work sheet and labels to pharmacist for approval

2. Pack products

- 2.1 Operate packaging equipment to pack products
- 2.2 Label container/units according to labelling specifications on the work sheet
- 2.3 Apply in-process controls and record results accurately
- 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 work sheet
- 3.2 Obtain relevant quality control documentation and check product specifications according to work sheet
- 3.3 Reconcile and verify packaging materials under supervision of an authorised person
- 3.4 Submit sample

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 batch documentation and forward according to standard operating procedures

ELEMENT

Elements define the essential outcomes

PERFORMANCE CRITERIA

Performance criteria describe the performance needed to demonstrate achievement of the element

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

4.5 Clean equipment according to manufacturer instructions

Foundation Skills

The Foundation Skills describe those required skills (language, literacy, numeracy and employment skills) that are essential to performance.

Foundation skills essential to performance are explicit in the performance criteria of this unit of competency.

Unit Mapping Information

No equivalent unit.

Links

Companion Volume implementation guides are found in VETNet -

<https://vetnet.gov.au/Pages/TrainingDocs.aspx?q=ced1390f-48d9-4ab0-bd50-b015e5485705>

Assessment Requirements for HLTPHA002 Pack pharmaceutical products

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Performance Evidence

The candidate must show evidence of the ability to complete tasks outlined in elements and performance criteria of this unit, manage tasks and manage contingencies in the context of the job role. There must be evidence that the candidate has:

- followed workplace procedures and safe packaging practices for at least 10 different product batches, including at least 5 dose administration aids (DAAs)/dose administration containers for an individual client
- identified issues outside scope of own practice and referred to the authorised person

Knowledge Evidence

The candidate must be able to demonstrate essential knowledge required to effectively complete tasks outlined in elements and performance criteria of this unit, manage tasks and manage contingencies in the context of the work role. This includes knowledge of:

- legal and ethical requirements (national, state/territory) for pharmacy work, and how these are applied in organisations, including:
 - codes of conduct
 - duty of care (and implications of negligence)
 - privacy, confidentiality and disclosure
 - records management
 - rights and responsibilities of workers, employers and clients
 - specific legislation:
 - medicines and their use
 - the practice of pharmacy
 - different schedules of medicines and pharmaceutical products

- work role boundaries – responsibilities and limitations
- work health and safety
- legal requirements and principles of pharmaceutical product labelling (product name, batch numbering and expiry date):
 - Pharmacy Board of Australia's *Guidelines on specialised supply arrangements*, national guidelines and legislation on the filling of dose administration containers
 - specific labelling requirements for filling DAAs and other containers
 - key information for inclusion:
 - date on which the container was filled
 - directions for use of each medicine according to work sheet
 - inclusion of ancillary labels, where required
 - name, strength, form and quantity of all medicines supplied in the container
 - pharmacy details
- Pharmacy Board of Australia *Guidelines for dispensing medicines*, that apply to individual workers
- key information in standard pharmaceutical references and their use by pharmacy assistants, including:
 - *Australian pharmaceutical formulary and handbook* (APF)
 - MIMs
 - *Australian medicines handbook* (AMH)
 - Micromedex
- infection control principles and their relevance to pharmaceutical packaging
- features of packaging equipment including their operation, cleaning and maintenance, 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
 - types of packaging materials
- environmental conditions required for pharmaceutical packaging related to:
 - humidity, light
 - security
 - temperature
 - ventilation
- product identification and handling, including those for:

- formulary medicines and non-formulary medicines
- products with the required integrity as well as those whose integrity has been compromised
- routine handling of products and products requiring special handling

Assessment Conditions

Skills must be demonstrated in the workplace or in a simulated environment that reflects workplace conditions. The following conditions must be met for this unit:

- use of suitable facilities, equipment and resources, including:
 - weighing and measuring equipment
 - packaging equipment and materials, including DAAs and containers
 - pharmaceutical stock management procedures
- modelling of industry operating conditions, including time constraints for completing packaging activities

Assessors must satisfy the Standards for Registered Training Organisations (RTOs) 2015/AQTF mandatory competency requirements for assessors.

Links

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<https://vetnet.gov.au/Pages/TrainingDocs.aspx?q=ced1390f-48d9-4ab0-bd50-b015e5485705>