



National Unit specification: general information

Unit title: Pharmaceutics: Legal and Ethical Controls

Unit code: FH28 12

Superclass: PA

Publication date: December 2012

Source: Scottish Qualifications Authority

Version: 04

Summary

This Unit has been designed to develop knowledge, understanding and problem solving skills in relation to the legal and ethical control of dispensing practice. This Unit is a mandatory Unit of the National Certificate in Pharmacy Services but can also be taken as a free-standing Unit.

It is designed primarily for staff working within the pharmacy sector. However it may also be suitable for somebody with an interest in the subject area.

Outcomes

- 1 Demonstrate knowledge and understanding of legal controls over the sale and supply of medicines.
- 2 Demonstrate knowledge and understanding of professional and contractual responsibilities which determine pharmacy practice.
- 3 Solve problems related to current legislation affecting health and safety in the pharmacy workplace.

Recommended entry

While entry is at the discretion of the centre, candidates would normally be expected to have some knowledge and understanding and skills relating to English. This could be demonstrated by attainment of:

- ◆ Standard Grade English at a minimum of Grade 3 or equivalent
- ◆ Pharmaceutics: Good Dispensing Practice

National Unit specification: general information (cont)

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Credit points and level

1 National Unit credit at SCQF level 6: (6 SCQF credit points at SCQF level 6*)

**SCQF credit points are used to allocate credit to qualifications in the Scottish Credit and Qualifications Framework (SCQF). Each qualification in the Framework is allocated a number of SCQF credit points at an SCQF level. There are 12 SCQF levels, ranging from Access 1 to Doctorates.*

Core Skills

Opportunities to develop aspects of Core Skills are highlighted in the Support Notes of this Unit specification.

There is no automatic certification of Core Skills or Core Skill component in this Unit.

National Unit specification: statement of standards

Unit title: Pharmaceuticals: Legal and Ethical Controls

Acceptable performance in this Unit will be the satisfactory achievement of the standards set out in this part of the Unit specification. All sections of the statement of standards are mandatory and cannot be altered without reference to SQA.

Outcome 1

Demonstrate knowledge and understanding of legal controls over the sale and supply of medicines.

Performance Criteria

- (a) The requirements of current legislation regarding the sale, supply, storage of licensed and unlicensed medicines and the licensing of medicines are described correctly.
- (b) The requirements of current legislation regarding controlled drugs, poisons and methylated spirits are described correctly
- (c) The requirements of current legislation relevant to consumer and data protection in the sale and supply of medicines are described correctly.

Outcome 2

Demonstrate knowledge and understanding of professional and contractual responsibilities which determine pharmacy practice.

Performance Criteria

- (a) The major functions of the pharmacy regulatory and professional bodies are described correctly.
- (b) The relative professional responsibilities of pharmacists, pharmacy technicians and other pharmacy staff are described correctly.
- (c) The requirements of the community pharmacy contract with NHS Scotland are described correctly.

Outcome 3

Solve problems related to current legislation affecting health and safety in the pharmacy workplace.

Performance Criteria

- (a) Current legislation affecting health and safety at work is interpreted correctly in terms of a pharmacy workplace.
- (b) Potential hazards are identified correctly in terms of a pharmacy workplace.
- (c) Corrective measures for identified hazards are described correctly.

National Unit specification: statement of standards (cont)

Unit title: Pharmaceuticals: Legal and Ethical Controls

Evidence Requirements for this Unit

Evidence is required to demonstrate the candidates have achieved all Outcomes and Performance Criteria.

Outcomes 1 and 2 should be assessed under controlled conditions by a single holistic closed-book assessment of one hour duration covering all of the above Performance Criteria

Outcome 1

- ◆ Candidates must correctly describe the requirements of current legislation regarding the sale, supply and storage of medicines.
- ◆ Candidates must correctly describe the requirements of current regulations regarding controlled drugs, poisons and methylated spirits.
- ◆ Candidates must correctly describe the requirements of current legislation regarding consumer and data protection.

Outcome 2

- ◆ Candidates must correctly describe major functions of the pharmacy regulatory body.
- ◆ Candidates must correctly describe relative professional responsibilities of pharmacy staff.
- ◆ Candidates must correctly describe requirements of the community pharmacy contract with NHS Scotland.

National Unit specification: statement of standards (cont)

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Outcome 3 should be assessed by a written and/or oral report the equivalent of approximately 1000 words, covering all of the Performance Criteria, of a research activity into a specific application of health and safety legislation. A minimum of four reference sources should be used and be listed in a bibliography.

Outcome 3

The teacher/lecturer responsible must attest that the report is the work of the candidate which should:

- (a) Correctly interpret current Health and Safety at work legislation in terms of the pharmacy workplace.
- (b) Correctly identify a minimum of three potential hazards in terms of a pharmacy workplace.
- (c) Correctly describe the appropriate corrective measures for the identified potential hazards.

National Unit specification: support notes

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This part of the Unit specification is offered as guidance. The support notes are not mandatory.

While the exact time allocated to this Unit is at the discretion of the centre, the notional design length is 40 hours.

Guidance on the content and context for this Unit

Outcome 1

- (a) The requirements of the Medicines Act and the Veterinary Medicines Regulations are described correctly in terms of the sale, supply and storage of:
- ◆ POM, P and GSL medicines.
 - ◆ POM-V and POM-VPS medicines.
 - ◆ Unlicensed and off-label use of medicines.
- (b) The requirements of current legislation are described correctly in terms of the supply and storage of:
- ◆ Schedules 1 to 5 Controlled Drugs.
 - ◆ CD prescription requirements.
 - ◆ CD register and cabinet, safe management of Controlled Drugs.
 - ◆ Non-medicinal Poisons, Methylated Spirits.
- (c) The requirements of current legislation relevant to consumer protection are described correctly.
- ◆ Generic and proprietary medicines, extemporaneous preparations, Trade Descriptions Act.
 - ◆ Patient Medications Records (PMRs), Data Protection Act, Freedom of Information Act, Access to Health Records Act.
 - ◆ Adult and child protection, patient confidentiality eg discretion in dealing with patients, access to services and inclusion, Consumer Protection Act, Equality and Diversity legislation.

Outcome 2

- (a) The role of the pharmacy regulatory body and related professional bodies is described correctly.
- ◆ Inspection of premises and documentation, Scottish Drug Testing Scheme.
 - ◆ Regulation and registration of pharmacy technicians, including code of conduct/ethics, educational standards and reflective practice.

National Unit specification: support notes (cont)

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- (b) The relative professional responsibilities of pharmacists, pharmacy technicians and other pharmacy staff are described correctly.
- ◆ Pharmacist, responsible pharmacist, pharmacy technician, other pharmacy support staff.
 - ◆ Colleagues as customers, other healthcare professionals, other organisations within pharmacy.
 - ◆ Principles of effective team working including styles of interactions between team members, handling problem relationships within teams.
- (c) The requirements of the community pharmacy contract with NHS Scotland are described correctly.
- ◆ Pharmacy contract-opening hours, rotas, dispensing.
 - ◆ Pharmacy contract- core services and additional services.
 - ◆ Structure of the NHS in Scotland, NHS (Pharmaceutical Services) Scotland Regulations 2003.

Outcome 3

- (a) Current legislation affecting health and safety at work is interpreted correctly in terms of a pharmacy workplace.
- ◆ Health and Safety at Work Act (HASWA), lifting and handling, Visual Display Units (VDUs).
 - ◆ Control of Substances Hazardous to Health (COSHH), Chemical Hazards and Information Packaging (CHIP).
- (b) Potential hazards are identified correctly in terms of a pharmacy workplace.
- (c) Corrective measures for identified hazards are described correctly.

Guidance on learning and teaching approaches for this Unit

The learning and teaching of pharmaceutics is most effective when concepts, principles, and theories are set in a relevant context eg by making reference to applications of pharmaceutics in real life situations.

Learning and teaching approaches should include lectures, individual and group work reinforced by handouts and worksheets which should incorporate problem-solving exercises. Worksheets should be designed to encourage students to use a wide range of textbooks and reference sources to solve problems. Student-centred practical exercises and the use of case studies and role-play should be incorporated when appropriate to reinforce teaching.

National Unit specification: support notes (cont)

Unit title: Pharmaceuticals: Legal and Ethical Controls

This Unit must be taught by either a pharmacist or pharmacy technician.

Opportunities for developing Core Skills

The Reading Communication Core Skill component at SCQF level 5 may be developed in all three Outcomes while candidates are reading materials on aspects of pharmacy law and ethics, and health and safety at work.

The Written Communication Core Skill component at SCQF level 5 may be developed in all three Outcomes while candidates are preparing written responses to formative and summative assessments, and during the production of the Outcome 3 report.

Guidance on approaches to assessment for this Unit

Outcomes 1 and 2 should be assessed under controlled conditions by a single holistic closed-book assessment of one hour duration covering all of the above Performance Criteria.

Achievement of Outcomes 1 and 2 could be demonstrated by use of a cut-off score. Any cut-off score must be commensurate with the minimum evidence requirements of the Unit Specification.

A suggested structure for Outcome 3 could be:

Title

Contents Page

Introduction

Content: Structured under appropriate headings

Summary

Bibliography

A minimum of 4 reference sources, eg texts, journals and websites should be used.

The report may be prepared in the candidate's own time. Centres should make every reasonable effort to ensure that the report is the candidate's own work. Where copying or plagiarism is suspected candidates may be interviewed to check their knowledge and understanding of the subject matter.

Opportunities for the use of e-assessment

E-assessment may be appropriate for some assessments in this Unit. By e-assessment we mean assessment which is supported by Information and Communication Technology (ICT), such as e-testing or the use of e-portfolios or e-checklists. Centres which wish to use e-assessment must ensure that the national standard is applied to all candidate evidence and that conditions of assessment as specified in the Evidence Requirements are met, regardless of the mode of gathering evidence. Further advice is available in *SQA Guidelines on Online Assessment for Further Education (AA1641, March 2003)*, *SQA Guidelines on e-assessment for Schools (BD2625, June 2005)*.

National Unit specification: support notes (cont)

Unit title: Pharmaceuticals: Legal and Ethical Controls

Disabled candidates and/or those with additional support needs

The additional support needs of individual candidates should be taken into account when planning learning experiences, selecting assessment instruments, or considering whether any reasonable adjustments may be required. Further advice can be found on our website www.sqa.org.uk/assessmentarrangements.

History of changes to Unit

Version	Description of change	Date
02	Amendments to wording within the 'Guidance on learning and teaching approaches in this unit', bottom paragraph.	10/10/2011
03	Cut-off score sentence added under 'Guidance on approaches to assessment for this unit'.	03/02/2012
04	Inconsistency across units in Recommended entry Clarification of the wording to avoid ambiguity and over/under assessment. Correction of typos and editing (cut and paste) errors in text.	10/12/2012

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