



PROFESSIONAL PRACTICE PROFILE FOR PHARMACISTS UNDERTAKING COMPLEX COMPOUNDING

Prepared by the Pharmacy Board of Australia
on behalf of the pharmacy profession

Published March 2015

PharmBA1502 03

CONTENTS

Introduction3
Complex compounding4
Prerequisite competency standards4
Complex compounding training programs5
Competency standards for complex compounding5
Domain 1: Professional and ethical practice8
Standard 1.1 Practise legally8
Standard 1.2 Practise to accepted standards	11
Standard 1.3 Deliver 'patient-centred' care	13
Standard 1.4 Manage quality and safety	15
Standard 1.5 Maintain and extend professional competence	16
Domain 2: Communication, collaboration and self-management	18
Standard 2.1 Communicate effectively	18
Standard 2.2 Work to resolve problems	20
Standard 2.3 Collaborate with members of the health care team	22
Standard 2.4 Manage conflict	24
Standard 2.5 Commitment to work and the workplace	25
Standard 2.6 Plan and manage professional contribution	27
Standard 2.7 Supervise personnel	29
Domain 4: Review and supply prescribed medicines	31
Standard 4.1 Undertake initial prescription assessment	31
Standard 4.2 Consider the appropriateness of prescribed medicines	33
Standard 4.3 Dispense prescribed medicines	34
Domain 5: Prepare pharmaceutical products	38
Standard 5.1 Consider product requirements	38
Standard 5.2 Prepare non-sterile drug products	44
Standard 5.3 Aseptically prepare sterile drug products	45
Standard 5.4 Prepare cytotoxic drug products	47
Domain 6: Deliver primary and preventive health care	50
Standard 6.1 Assess primary health care needs	50
Standard 6.2 Deliver primary health care	52
Standard 6.3 Contribute to public and preventive health	55
Domain 8: Critical analysis, research and education	56
Standard 8.1 Retrieve, analyse and synthesise information	56
Standard 8.2 Engage in health, medicines and pharmacy practice research	59

INTRODUCTION

1. This professional practice profile has been developed by the Pharmacy Board of Australia (the Board) on behalf of the pharmacy profession. Outlining the competencies required for complex compounding provides a tool to help pharmacists acquire and maintain the required competence for any type of complex compounding. It may also help course providers to develop complex compounding training programs. In undertaking this work the Board recognises that changes in professional practice necessitate regular review of the competency standards for the profession. The Board therefore acknowledges that this profile, which is based on the competencies of the National Competency Standards Framework¹ (the National Framework), is also subject to change.
 2. The profile has been created by selecting all competencies in the National Framework relevant to complex compounding and customising the evidence examples where necessary to show the behaviour expected of a competent pharmacist whose professional function is to undertake complex compounding. The competencies in Domains 1 and 2 of the National Framework are universally applicable to all professional activities so are automatically included in all practice profiles. The other selected competencies are intended to encompass complex compounding in all professional practice settings. Pharmacists can use the profile to select those complex compounding competencies relevant to their own practice setting.
 3. The competencies required to undertake complex compounding can be attained through training and workplace experience. This profile does not explicitly define a training
- curriculum for complex compounding. However, course providers should be able to demonstrate a link from their curriculum and course learning objectives to the complex compounding competencies of this profile. Primary sources such as professional codes, guidelines and practice standards will also be of assistance in guiding curriculum design.
4. Pharmacists wishing to develop their competence in complex compounding can use this profile to:
 - identify the competency standards relevant to their practice/practice setting
 - reflect on their continuing professional development needs
 - develop a learning plan, and
 - undertake activities to address their learning needs.
 5. It is acknowledged that many pharmacists will have a scope of practice that is broader than that encompassed in this profile. Those pharmacists wishing to create a personalised profile relevant to their particular scope of practice and practice setting can do so by combining relevant competencies from this profile. They can then undertake the process described in Section 1.8 *Developing a professional practice profile* of the National Framework to select additional relevant competencies from the National Framework. For example, those pharmacists whose professional role includes managerial oversight of a complex compounding service will need to select relevant competencies from Domain 3 *Leadership and management* of the National Framework.
 6. It is assumed pharmacists using this or any other profile are aware of their professional obligations and practise in a manner that is consistent with professional codes, standards and guidelines.

¹ Pharmaceutical Society of Australia 2010, Competency standards, Pharmaceutical Society of Australia, viewed 20 January 2015, www.psa.org.au/supporting-practice/national-competency-standards

COMPLEX COMPOUNDING

7. The following definitions of the terms ‘simple compounding’ and ‘complex compounding’ have been adopted and included in the Board’s *Guidelines on compounding of medicines*.

Simple compounding means the preparation and supply of a single ‘unit of issue’ of a therapeutic product intended for use by a specific person in response to an identified need. It routinely involves the compounding of products from formulations published in reputable references such as the *Australian Pharmaceutical Formulary and Handbook* (excluding the preparation of sterile products from these formulations, which is considered complex compounding), or using other formulations for which information confirming quality, stability, safety, efficacy and rationality is available.

Complex compounding means the preparation and supply of a single ‘unit of issue’ of a therapeutic product that is intended for immediate use by a specific patient and that requires or involves specific competencies, equipment, processes or facilities. Examples include sterile products and preparations containing ingredients which pose an occupational health and safety hazard such as cytotoxics or hormones, monoclonal antibodies, micro-dose single unit dosage forms containing less than 25mg of active ingredient, tablets, capsules, troches and modified release preparations.

8. These guidelines state that a ‘compounded product should be prepared only in circumstances when an appropriate commercial product is unavailable or unsuitable’.
9. The growth in recent years in the number and type of compounded products provided by

pharmacists to Australian consumers² has occurred in response to a need for customised medicines to meet the unique health care requirements of individual consumers. Circumstances giving rise to the need for customised medicines include discontinuation or lack of availability of a suitable commercial product, consumer allergies to components of available products (e.g. preservatives, flavouring or colouring agents) or tailoring of product form or strength to facilitate accurate dosing (e.g. in children or those with swallowing difficulty). Compounded products are also in demand in veterinary medicine because of the diversity of the animals and ailments for which treatment is required. These factors have been a driver for the range of compounded products being expanded to include complex compounded products, the change facilitated by the availability of relevant training programs and by technological advances.

PREREQUISITE COMPETENCY STANDARDS

10. Pharmacists are required to demonstrate competency in simple compounding at the time of entry to the profession. The particular compounding competencies expected to be demonstrated are described as entry-level requirements in the National Framework (refer to page 80 and the shaded sections of standards 5.1 – 5.4). These same simple compounding competencies would be the minimum expected of pharmacists wishing to gain the expertise required to prepare complex compounded pharmaceutical products through undertaking additional training. Thus the entry-level/simple compounding competency standards in Domain 5 *Prepare pharmaceutical products* are prerequisite foundation competencies for undertaking a complex compounding training program.

² In this document the term ‘consumer’ refers to any individual provided with a complex compounded product for either human or veterinary use.

Inevitably, there will be a significant overlap in the competencies expected for simple compounding and those required for complex compounding. This is due to complex compounding requiring the acquisition of additional knowledge and skills primarily in the areas of compounding technique, equipment and facilities, risk management, pharmaceuticals and pharmacotherapy with complex compounded products.

COMPLEX COMPOUNDING TRAINING PROGRAMS

11. Pharmacists who wish to engage in complex compounding must acquire and build the requisite knowledge and expertise through participation in formal training programs and ongoing workplace training and experience. Pharmacists should satisfy themselves that any education and training done to acquire competence for complex compounding addresses and assesses core complex compounding competencies and/or directly related learning objectives. They should also try to ensure they have achieved competence in simple compounding before participating in a complex compounding training program and that they are able to access relevant experiential learning opportunities on completion of training.
12. All pharmacists will have carried out simple compounding activities but their experience in this area of professional practice may not be current. It is therefore expected that complex compounding training programs for pharmacists will be initiated with an introduction to simple compounding principles and processes. Thereafter, they will be focused on building upon the prerequisite competencies to enhance the pharmacist's knowledge, skills and expertise in the areas of:
 - Compounding techniques and the use of specialised compounding equipment and facilities.
 - Compounding conventions and principles, and chemical compatibilities.
 - Use of specialised information sources for identifying suitable formulations and clarifying issues relevant to the stability, efficacy and safety of products.
 - Safe handling and waste disposal procedures for hazardous materials and contaminated equipment to control exposure of self, other personnel, consumers and the environment.
 - Pharmacotherapeutic and pharmacokinetic considerations impacting on indications for use, precautions and contraindications, potential adverse effects, and safe and informed use by the consumer to whom the products are recommended and/or supplied.
13. The range of pharmaceutical products encompassed within the definition of complex compounding is quite diverse. For this reason it is likely that complex compounding training programs will be structured to allow pharmacists to complete core units of training and then select from a range of extension units (e.g. cytotoxic (linked to Standards 5.1 and 5.4) or sterile products (linked to Standards 5.1 and 5.3)) based on their preferred areas of practice. As for other continuing professional development (CPD) activities, it is expected that course providers are able to provide potential course participants with information demonstrating that their course encompasses the core competencies for complex compounding and, where relevant, the competencies required for selected extensions to compounding practice.
14. This professional practice profile is a tool for showing the competencies required for specific roles, services or positions that involve complex compounding. The process

COMPETENCY STANDARDS FOR COMPLEX COMPOUNDING

for building a professional practice profile is described in 1.8 *Developing a professional practice profile* of the *National Competency Standards Framework for Pharmacists in Australia (2010)*.

15. Table 1 shows a summary of the professional practice profile for a pharmacist undertaking complex compounding. The subsequent pages show an expanded version of the profile with customisation of the evidence examples, where appropriate, to reflect the performance expected to be observed in a pharmacist undertaking complex compounding³. It should be noted that the profile and the evidence examples encompass any or all of the types of products that may be prepared in complex compounding. Not all of these will be relevant to individual pharmacists because of the choices they have made about the types of products they will be involved in preparing. The profile reflects the fact that products involving complex compounding may be supplied on prescription or order, or may be recommended and initiated by the pharmacist as a component of the primary health care services they provide.

³ Within the expanded profile the convention of shading entry-level/simple compounding requirements has been maintained. However, while the performance criteria are unchanged, the evidence examples may have been customised for complex compounding.

Table 1: Professional practice profile – Complex compounding pharmacist

Domain (* = universally applicable competencies)	Standards	Elements	Performance criteria
1 – Professional and ethical practice*	All	All	All
2 – Communication, collaboration and self-management*	All	All	All
4 – Review and supply prescribed medicines	All	All	All
5 – Prepare pharmaceutical products	5.1	All	All
	5.2	All	All
	5.3	All	All
	5.4	All	All
6 – Deliver primary and preventative health care	6.1	All	All
		1	All
	6.2	2	All
		3	1 – 2, 4
		5	All
	6.3	3	All
8 – Critical analysis, research and education	8.1	1	1 - 5
		2	All
		3	All
		4	All
	8.2	All	All

Domain 1: Professional and ethical practice

Standard 1.1 Practise legally⁴

Performance criteria	Evidence examples
Element 1 – Comply with statute law, guidelines, codes and standards	
1 Understands the requirements of statute law, professional guidelines, codes and standards that comprise the legislative environment for practice.	<ul style="list-style-type: none"> • Ability to describe the key legislative instruments impacting on professional practice, including those specifically relating to compounding. • Ability to describe the limited conditions of exemption from regulation that apply to complex compounding under the Therapeutic Goods Act 1989 (Cth), Therapeutic Goods Regulations 1990 and Agricultural and Veterinary Chemicals Code Act 1994 (AgVet Code). • Ability to describe the key requirements of the AgVet Code and product registration requirements as they apply to complex compounded products for veterinary use. • Ability to describe requirements of professional codes (e.g. The Code of Ethics for Pharmacists), guidelines and standards adopted as part of the legislative framework for practice.
2 Applies legislative requirements directly applicable to the provision of pharmacy services.	<ul style="list-style-type: none"> • Ability to promptly access and correctly interpret the requirements of statute law in relation to complex compounding. • Ability to describe examples of how complex compounding services are carried out to comply with legislative requirements (e.g. storage and documentation of controlled substances, labelling of prescription medicines). • Ability to describe how legislative requirements have influenced operational policies and procedures.

⁴ Legislation referred to in this Standard includes the latest editions and amendments of:

- *Health Practitioner Regulation National Law Act 2009.*
- State/territory legislation controlling the ownership and approval of pharmacies.
- State/territory legislation controlling medicines, drugs, poisons and controlled substances.
- *National Health Act 1953.*
- The Commonwealth Privacy Act and relevant state/territory privacy legislation.
- The Commonwealth Therapeutic Goods Act and Regulations.
- Commonwealth and state/territory legislation controlling health care.
- Disability and equal opportunity legislation.
- Relevant sections of Occupational Health and Trade Practices legislation.
- *Agricultural and Veterinary Chemicals Code Act 1994.*

Performance criteria

Evidence examples

3	Understands the obligations created by codes of conduct/ethics for professional practice adopted by the registering authority.	<ul style="list-style-type: none">• Ability to describe and explain the obligations created by codes of conduct/ethics.• Ability to interpret the obligations created by relevant codes in terms of the complex compounding services provided.
4	Interprets and applies the requirements imposed by guidelines and standards adopted by the registering authority.	<ul style="list-style-type: none">• Ability to describe the key requirements of relevant guidelines and standards (e.g. Pharmacy Board of Australia guidelines for dispensing of medicines, CPD, mandatory notifications and advertising of regulated health services).• Ability to describe the process required for mandatory notification of the conduct or impairment of a health practitioner.• Ability to practise in a manner consistent with the requirements of professional guidelines and standards relevant to complex compounding.
5	Understands the issues relevant to maintaining workplace safety.	<ul style="list-style-type: none">• Ability to explain the key areas of responsibility under occupational health and safety legislation for maintaining a safe workplace in the premises where complex compounding is conducted, particularly in relation to containment of risks to personnel, consumers and the environment.• Ability to describe features of the work environment that may impact on workplace safety (e.g. fumes, aerosols, hazardous substances, sharps and waste management, equipment design and use).
6	Accepts shared responsibility for maintaining a safe working environment.	<ul style="list-style-type: none">• Ability to describe and/or promptly access risk management protocols such as those for emergencies, threats or injury (e.g. exposure to a hazardous substance, cytotoxic spill, needle stick injury).• Ability to comply with policies and procedures intended to improve safety in the workplace (e.g. hazardous waste management and workplace access policies).• Ability to maintain immediate work environment in a clean, tidy, hygienic and hazard free state (e.g. halls and doorways free of obstacles, garbage regularly disposed of, spills promptly cleaned, equipment maintained according to manufacturers' recommended maintenance schedule).
7	Considers the responsibilities in the workplace that arise from more general statute law.	<ul style="list-style-type: none">• Ability to discuss the general implications of occupational health, industrial relations and trade practices legislation (e.g. equal opportunity and fair trading provisions, obligations to provide for disabled access to facilities and services).

Performance criteria

Evidence examples

Element 2 – Respond to common law requirements

- | | | |
|---|--|---|
| 1 | Understands the pharmacist's duty of care to consumers and other clients of the service. | <ul style="list-style-type: none">• Ability to discuss the concept of professional 'duty of care' and the legal implications of professional actions being considered 'unsatisfactory professional conduct', 'professional misconduct' or 'negligence'.• Ability to explain the purpose of professional indemnity insurance and demonstrate currency of indemnification for the complex compounding services provided. |
| 2 | Considers the rights, responsibilities, duty of care and/or legislative obligations applicable to other health professionals/facility personnel. | <ul style="list-style-type: none">• Ability to describe factors relevant to delivery of complex compounding services that arise from the legislative obligations, rights and responsibilities or duty of care of collaborating professionals (e.g. medical practitioners and veterinarians). |
| 3 | Responds promptly to situations of uncertainty in regard to professional conduct. | <ul style="list-style-type: none">• Ability to describe the timing and order of steps to be taken in the event of an error, potential misadventure and/or claim of professional misconduct or negligence.• Ability to describe circumstances where the professional conduct or impairment of a health professional may warrant intervention or mandatory notification. |

Element 3 – Respect and protect the consumer's right to privacy and confidentiality

- | | | |
|---|---|---|
| 1 | Considers the impact of privacy legislation on professional practice. | <ul style="list-style-type: none">• Ability to describe the key features of relevant federal and state/territory privacy legislation impacting on the provision of complex compounding services (e.g. disclosure, consent to collect, requests for own health records).• Ability to describe the legislative limitations on collection, use and disclosure of personal information (including health information). |
| 2 | Understands the consumer's expectations and rights in relation to maintenance of privacy and confidentiality. | <ul style="list-style-type: none">• Ability to describe the types of information that must be kept confidential.• Ability to describe the likely impact on consumer dignity and trust of breaches to privacy and confidentiality. |
| 3 | Takes all reasonable steps to assure consumer privacy is maintained and to avoid unauthorised or accidental disclosure of confidential information. | <ul style="list-style-type: none">• Ability to describe circumstances in practice, including during disposal of records, where consumer privacy or confidentiality could be compromised.• Ability to explain the steps taken to protect consumer privacy and maintain confidentiality of personal information (including health information). |

Performance criteria

Evidence examples

- | | | |
|---|---|--|
| 4 | Takes appropriate action to advise the consumer and prevent a recurrence of a breach of consumer privacy. | <ul style="list-style-type: none">• Ability to describe circumstances that warrant advice to consumers that a breach of privacy has occurred.• Ability to describe corrective actions taken to prevent a recurrence of a breach of privacy. |
|---|---|--|

Element 4 – Support and assist consumer consent

- | | | |
|---|--|--|
| 1 | Accepts the importance of gaining consumer consent. | <ul style="list-style-type: none">• Ability to explain the importance of the consent process as the means by which consumers exert autonomy and grant or withhold permission. |
| 2 | Understands the nature of consumer consent. | <ul style="list-style-type: none">• Ability to describe the essential elements of valid consent (e.g. capacity to consent, clear and accurate explanation, confirming the consumer understands, absence of coercion, explicit statement of right to decline).• Ability to explain that consent is an ongoing process rather than an event and that it can be withdrawn by the consumer at any time. |
| 3 | Obtains consumer consent as required for professional services, including those where personal health information will be collated and shared with other health professionals. | <ul style="list-style-type: none">• Ability to describe services or situations where consent is required prior to supply of a complex compounded product.• Ability to obtain consent from consumers and/or carers or guardians.• Ability to describe the documentation required to record informed consumer consent. |
| 4 | Understands procedures to follow in the event that consent is denied or withdrawn. | <ul style="list-style-type: none">• Ability to describe documentation and/or actions required where consent is denied or withdrawn. |

Standard 1.2 Practise to accepted standards

Performance criteria

Evidence examples

Element 1 – Demonstrate personal and professional integrity

- | | | |
|---|--|---|
| 1 | Understands the position of trust in which the profession is held. | <ul style="list-style-type: none">• Ability to describe the fundamental obligations of pharmacists to behave and practise in a manner that upholds the reputation and standing of the profession. |
| 2 | Understands the scope of practice of a pharmacist in relation to that of other health professionals. | <ul style="list-style-type: none">• Ability to describe roles and activities carried out compared to the roles and expectations of collaborating health professionals. |

Performance criteria

Evidence examples

3	Understands pharmacists are accountable for the services provided and the associated outcomes.	<ul style="list-style-type: none">• Ability to accept responsibility for the actions and decisions taken in the course of providing complex compounding services and the associated outcomes (direct and indirect).• Ability to promptly respond to poor or potentially poor outcomes (e.g. in the event of error or misinformation).
4	Works within the limits of professional expertise.	<ul style="list-style-type: none">• Ability to recognise and describe the limitations in their knowledge, skills and experience in relation to the range and types of complex compounded products and related information provided.
5	Accesses additional information and/or expert advice and assistance when needed.	<ul style="list-style-type: none">• Ability to recognise and describe the limitations in expertise and/or interpretive ability that would necessitate additional support being sought.• Ability to describe how additional information or clarification can be or is obtained.
6	Contributes to the ongoing development of the profession.	<ul style="list-style-type: none">• Ability to explain the benefits of participating in professional organisations and/or committees.• Ability to actively participate in professional organisations and/or committees.

Element 2 – Contribute to enhanced service quality

1	Understands the consumer's right to receive safe and high quality pharmacy services.	<ul style="list-style-type: none">• Ability to explain the obligation to apply professional care and expertise to deliver high quality pharmacy services.• Ability to lead by example and promote consistent high quality work from others.
2	Understands the means by which the quality of pharmacy services can be maintained and improved.	<ul style="list-style-type: none">• Ability to explain the difference between quality control, quality improvement and quality assurance.• Ability to describe quality control, quality assurance and quality improvement methodologies, including the types of measures that can be used in a complex compounding service.
3	Accepts responsibility for assuring the quality of professional services provided.	<ul style="list-style-type: none">• Ability to describe the tools and methods available for monitoring the quality of complex compounding services provided (e.g. consumer feedback, self-audit against quality standards).• Ability to assess or self-audit the quality of professional services provided against endorsed standards and guidelines to identify where change would be beneficial.

Performance criteria

Evidence examples

- | | | |
|---|--|---|
| 4 | Seeks continuous improvement in service quality. | <ul style="list-style-type: none">• Ability to describe and/or demonstrate quality improvement and/or quality assurance activities for complex compounding in which they are or have been participants. |
| 5 | Shows initiative in implementing and evaluating changes to practice. | <ul style="list-style-type: none">• Ability to describe or demonstrate changes in service delivery or professional practice that are a direct result of a quality improvement activity.• Ability to describe ways in which the outcomes of practice change can be evaluated. |

Standard 1.3 Deliver 'patient-centred' care

Performance criteria

Evidence examples

Element 1 – Maintain primary focus on the consumer

- | | | |
|---|--|--|
| 1 | Understands the primacy of consumers and their needs. | <ul style="list-style-type: none">• Ability to describe an approach to service delivery that, as far as practicable, accommodates the wishes and needs of consumers.• Ability to discuss the rights of consumers to access professional services and advice regardless of their health status (including disease state or level of disability). |
| 2 | Respects the rights of consumers to participate in decision-making, control their personal information and make choices about their health care. | <ul style="list-style-type: none">• Ability to discuss the importance of consumer involvement/engagement in health service delivery (e.g. make their own choices about who to involve in their care and whether to accept or decline advice, services or products). |
| 3 | Accepts and supports the consumer's rights to be informed and make autonomous decisions. | <ul style="list-style-type: none">• Ability to explain the scope of information that might be covered to clearly and openly inform consumers about complex compounding services (e.g. service description, place of products compared to commercially available products, and product and service costs).• Ability to support and accept consumer decisions and choices about the health care services they receive, including when it is at odds with the pharmacist's view. |
| 4 | Recognises and respects the values, beliefs, personal characteristics, and cultural and linguistic diversity of consumers.- | <ul style="list-style-type: none">• Ability to discuss how the different values, beliefs and cultural backgrounds of consumers may influence the way in which professional services are provided.• Ability to describe ways in which flexibility in service delivery may be provided to, as far as practicable, accommodate the values, beliefs and cultural backgrounds of consumers. |

Performance criteria

Evidence examples

- | | | |
|---|---|--|
| 5 | Understands the impact on practice of a culturally diverse consumer population. | <ul style="list-style-type: none">• Ability to discuss areas of care likely to be impacted by a culturally diverse consumer population (e.g. illness behaviour, preferred treatment modalities, attitudes to dress and gender of health professionals, role of the family in care).• Ability to discuss ways in which the pharmacist's cultural and linguistic background influences the assumptions made about consumer needs and the delivery of services and advice. |
|---|---|--|

Element 2 – Address consumer needs

- | | | |
|---|--|---|
| 1 | Adopts a respectful and empathic attitude to consumers. | <ul style="list-style-type: none">• Ability to show respect, dignity and consideration for consumers.• Ability to maintain composure, to communicate and behave in a respectful manner, even during difficult situations. |
| 2 | Partners with consumers in the delivery of professional services. | <ul style="list-style-type: none">• Ability to describe the means by which consumers are able to participate in the planning and delivery of complex compounding services.• Ability to engage the consumer as an active participant in the delivery of complex compounding services. |
| 3 | Adapts service delivery, as far as practicable, to satisfy the needs of consumers. | <ul style="list-style-type: none">• Ability to anticipate and/or recognise consumer need within the limits of their expertise and experience.• Ability to describe circumstances where complex compounding service delivery may need to be adapted because of the health status or disability of a consumer.• Ability to elicit information relating to values, beliefs and cultural backgrounds of consumers that may influence the way in which professional services are provided. |
| 4 | Encourages consumers to seek and use information relevant to their health needs. | <ul style="list-style-type: none">• Ability to support consumers to make therapeutic and lifestyle decisions in relation to the use of complex compounded products that are consistent with achieving good or improved health.• Ability to describe the information sources through which consumers are informed about the complex compounding service and products provided (e.g. information sheets, cautionary and advisory labels and, where available, CMI). |
| 5 | Responds to consumer comment and feedback about the services and advice provided. | <ul style="list-style-type: none">• Ability to describe issues upon which consumer feedback may be used to improve service delivery.• Ability to receive and respond to consumer complaint or comment about the services and/or advice received. |

Performance criteria

Evidence examples

- | | | |
|---|---|--|
| 6 | Accepts responsibility for advocating on behalf of consumers consistent with the professional role and expertise of a pharmacist. | <ul style="list-style-type: none">• Ability to describe areas where the rights or needs of consumers might be presented and/or supported with other health professionals and/or public authorities (e.g. advocacy on behalf of a consumer group for access to specific compounded products). |
|---|---|--|

Standard 1.4 Manage quality and safety

Performance criteria

Evidence examples

Element 1 – Protect and enhance consumer safety

- | | | |
|---|---|--|
| 1 | Understands the concept of a continuum of care. | <ul style="list-style-type: none">• Ability to discuss the risks to consumer safety posed by care that extends between care settings (e.g. hospital to community, hospital to hospital) and/or is delivered by multiple health care providers (GP to specialist, GP to pharmacist).• Ability to discuss ways in which continuum of care with complex compounded products can be enhanced. |
| 2 | Understands the potential sources of error in professional service delivery and their likely consequences. | <ul style="list-style-type: none">• Ability to describe factors which increase the likelihood of error and/or misadventure with complex compounding (e.g. interruptions, excessive workload, inadequate supervision, working beyond limits of expertise, personal impairment, transfer of care).• Ability to discuss ways in which risk factors can be identified and managed. |
| 3 | Ensures appropriate professional services documentation is completed for identifying and managing risks to consumers. | <ul style="list-style-type: none">• Ability to describe documentation that should be completed to protect consumer safety.• Ability to maintain relevant, accurate and up-to-date records. |
| 4 | Recognises the importance of maintaining a 'no blame' culture in the workplace. | <ul style="list-style-type: none">• Ability to discuss the impact of a 'no blame' culture on reporting and preventing recurrence of incidents. |

Element 2 – Respond to identified risk

- | | | |
|---|---|--|
| 1 | Participates in prompt withdrawal of stock or equipment that is subject to a product recall notice. | <ul style="list-style-type: none">• Ability to describe and/or demonstrate recall procedures to be used in response to a product recall notice or to access the information promptly. |
| 2 | Accepts responsibility for reporting and following up medication incidents. | <ul style="list-style-type: none">• Ability to explain the importance of reporting and following up medication incidents with complex compounded products.• Ability to describe the reporting and follow-up processes in use. |

Performance criteria

Evidence examples

3	Accepts responsibility for identifying and responding to personal circumstances that could impair professional performance.	<ul style="list-style-type: none">• Ability to describe personal factors that could impair performance.• Ability to describe sources of support where impaired performance is suspected or confirmed.
4	Acts promptly in the event of a medication incident to minimise harm and/or prevent recurrence.	<ul style="list-style-type: none">• Ability to describe the course(s) of action available to minimise harm.• Ability to identify follow-up strategies likely to be effective in preventing recurrence (e.g. root cause analysis).• Ability to describe changes made to policies, procedures and/or the workplace to prevent recurrence of incidents related to complex compounded products.
5	Understands the responsibility to inform consumers of medication incidents likely to impact on their health or wellbeing.	<ul style="list-style-type: none">• Ability to describe the principles of open disclosure as they apply to health care incidents.• Ability to discuss the requirements for open disclosure and how these relate to the expectations of professional indemnity insurance providers.
6	Documents medication incidents including actions taken to minimise the impact on consumers and/or prevent recurrence.	<ul style="list-style-type: none">• Ability to describe and/or use an appropriate recording system for incidents related to complex compounded products.• Ability to demonstrate compliance with workplace procedures or guidelines for documenting and responding to medication incidents.

Standard 1.5 Maintain and extend professional competence

Performance criteria

Evidence examples

Element 1 – Accept the importance of life-long learning

1	Understands the concept of life-long learning for pharmacists.	<ul style="list-style-type: none">• Ability to discuss life-long learning (continuously striving to gain knowledge and maintain competence) in the context of career development and the pharmacist's professional role in delivering health care services.
2	Encourages and supports the professional development of colleagues.	<ul style="list-style-type: none">• Ability to maintain a positive attitude to continuous learning and professional development.• Ability to provide complex compounded products, professional advice and guidance to others consistent with the limits of own expertise.

Performance criteria

Evidence examples

- | | | |
|---|--|--|
| 3 | Understands the expectations of the registering authority and professional associations in relation to maintenance of competence and ongoing professional development. | <ul style="list-style-type: none">• Ability to discuss the role the Pharmacy Board of Australia has for protecting the public and the scope of professional development activities/opportunities provided by professional associations and other organisations. |
| 4 | Understands the importance of self-assessment, reflective learning, peer review and performance review as sources of feedback on professional capability. | <ul style="list-style-type: none">• Ability to describe the reflective learning and peer review processes.• Ability to participate in self-assessment processes.• Ability to describe preparation process for performance review (e.g. identify goals, training needs and achievements (expected and unexpected) and identifying support needs from supervisor). |

Element 2 – Undertake self-directed learning

- | | | |
|---|---|---|
| 1 | Develops a professional development plan (that includes goals and strategies) to maintain and/or improve professional capability. | <ul style="list-style-type: none">• Ability to describe the process for defining a competency grid relevant to a specific role and applying it to develop a personal learning plan.• Ability to describe how performance feedback, reflective learning and/or peer review has influenced development plan. |
| 2 | Accepts responsibility for achieving learning and professional development goals. | <ul style="list-style-type: none">• Ability to explain a plan of action for addressing professional development and learning needs (for new knowledge, skills or attributes).• Ability to identify potential sources of activities, their quality and relevance, to address identified learning and professional development needs.• Ability to participate in a range of activities (e.g. experiential learning, academic courses, presentations, clinical audits and workshops) that address learning and professional development needs. |
| 3 | Regularly monitors learning and development achievements against the plan. | <ul style="list-style-type: none">• Ability to compare learning and development achievements with established goals. |
| 4 | Applies learning to improve performance and/or extend professional practice. | <ul style="list-style-type: none">• Ability to apply new knowledge and/or experiences to enhance problem-solving abilities, change professional practice or deliver new services.• Ability to describe the training done to develop the knowledge, skills and professional expertise required to undertake complex compounding.• Ability to implement and describe practice change subsequent to reflective review process. |

Domain 2: Communication, collaboration and self-management

Standard 2.1 Communicate effectively

Performance criteria	Evidence examples
Element 1 – Adopt sound principles for communication	
1 Maintains open lines of communication.	<ul style="list-style-type: none">• Ability to exchange and share information with others.
2 Values the input of others.	<ul style="list-style-type: none">• Ability to demonstrate respect for the opinions and views of others.
3 Understands that non-verbal elements can exert a significant impact on the effectiveness of communication.	<ul style="list-style-type: none">• Ability to describe key non-verbal factors impacting communication (e.g. presentation, posture, gestures, facial expression).
4 Recognises barriers to effective communication must be addressed.	<ul style="list-style-type: none">• Ability to describe barriers to effective communication (e.g. emotional status (distress, anger or aggression), culture, values and beliefs, sensory impairment (hearing or vision), disabilities (mental or physical), personality conflict, socioeconomic or educational status, communication through a third party).• Ability to demonstrate or describe strategies and/or resources to address barriers to effective communication (e.g. revised communication pathways, tools for third party communication).
Element 2 – Adapt communication for cultural and linguistic diversity	
1 Understands the likely impact of the pharmacist's values, beliefs and cultural and linguistic background on communication with consumers.	<ul style="list-style-type: none">• Ability to demonstrate insight into personal background issues that may impact on communication with consumers from a variety of cultural and linguistic backgrounds.
2 Recognises the special communication needs of consumers and/or carers with different cultural and linguistic backgrounds.	<ul style="list-style-type: none">• Ability to demonstrate sensitivity to the needs, values, beliefs and cultural backgrounds of others.• Ability to describe the barriers to communication that exist for consumers and/or carers with different cultural and linguistic backgrounds.

Performance criteria

Evidence examples

- | | | |
|---|--|---|
| 3 | Responds, as far as practicable, to the needs of those from diverse cultural and linguistic backgrounds. | <ul style="list-style-type: none">• Ability to describe strategies and/or resources for communicating effectively with people from different cultural backgrounds, including Indigenous Australians (e.g. use of appropriate interpreters, revised communication pathways). |
|---|--|---|

Element 3 – Manage the communication process

- | | | |
|---|--|--|
| 1 | Establish rapport and empathy with the consumer. | <ul style="list-style-type: none">• Ability to actively listen, empathise and engage with the consumer and understand their position/needs.• Ability to express opinions and provide information in written and/or verbal form in a manner that does not elicit concern, anger or other adverse response. |
| 2 | Establishes communication pathways necessary to achieve desired work outcomes. | <ul style="list-style-type: none">• Ability to describe the communication network established to achieve work outcomes. |
| 3 | Ensures communication is appropriate to the audience and the material. | <ul style="list-style-type: none">• Ability to select a vocabulary, communication style and form for both written and verbal communications that is appropriate for the situation, the audience and the material being communicated (e.g. avoids unnecessary jargon, clearly explains medical and pharmaceutical terminology). |
| 4 | Expresses thoughts and ideas clearly, consistently and unambiguously. | <ul style="list-style-type: none">• Ability to discuss the importance of consistency of message for achieving credibility and attitudinal change.• Ability to formulate and express ideas and opinions clearly in written and verbal form.• Ability to communicate information accurately, concisely and confidently in writing and verbally.• Ability to clarify and elaborate ideas, opinions and information to enhance understanding. |
| 5 | Explores the needs of consumers and communicates relevant information. | <ul style="list-style-type: none">• Ability to elicit needed information and identify the information needs of a particular audience/consumer.• Ability to ask relevant questions, listen attentively and respond to verbal and non-verbal cues and use an interpreter if necessary to clarify communication needs. |

Performance criteria

Evidence examples

- | | | |
|---|--|--|
| 6 | Verifies that the information provided has been received and understood. | <ul style="list-style-type: none">• Ability to describe or demonstrate the use of a systematic process for following up that demonstrates written reports have been received and understood.• Ability to follow up, ask questions and/or use visual or other aids to confirm that the intended 'message' has been received and is understood. |
| 7 | Recognises the importance of responding to feedback for improving - communication. | <ul style="list-style-type: none">• Ability to explain how response to feedback enhances communication.• Ability to describe ways in which communication has been altered in response to feedback. |

Element 4 – Apply communication skills in negotiation

- | | | |
|---|--|---|
| 1 | Recognises circumstances where a negotiated outcome is required. | <ul style="list-style-type: none">• Ability to describe circumstances in the workplace where conflicting interests must be or were addressed to achieve an outcome. |
| 2 | Recognises the importance of research and preparation in the negotiation process. | <ul style="list-style-type: none">• Ability to identify and describe relevant information which will be necessary for a successful negotiation. |
| 3 | Understands the importance of finding a position that satisfies the objectives of each party to the negotiation. | <ul style="list-style-type: none">• Ability to describe the benefits of a negotiated outcome.• Ability to describe acceptable outcomes for particular situations associated with the provision of complex compounding services. |
| 4 | Addresses circumstances requiring a negotiated outcome. | <ul style="list-style-type: none">• Ability to be assertive and use supportive and persuasive communication to achieve a desired outcome.• Ability to describe or demonstrate an appropriate negotiation strategy for particular situations associated with the provision of complex compounding services. |

Standard 2.2 Work to resolve problems

Performance criteria

Evidence examples

Element 1 – Analyse the problem/potential problem

- | | | |
|---|---|--|
| 1 | Accepts responsibility for addressing problems. | <ul style="list-style-type: none">• Ability to demonstrate that problems are addressed in a timely manner as they arise. |
|---|---|--|

Performance criteria

Evidence examples

- | | | |
|---|---|---|
| 2 | Identifies and clarifies the problem and its likely causes. | <ul style="list-style-type: none">• Ability to identify and fully describe (verbally or in writing) the nature of a problem and probable causes or causative factors. |
| 3 | Identifies possible approaches for resolving the problem. | <ul style="list-style-type: none">• Ability to document the identified problem(s), causative factor(s) and options for resolving the problem. |

Element 2 – Act to resolve the problem/potential problem

- | | | |
|---|--|--|
| 1 | Understands when to seek assistance or guidance. | <ul style="list-style-type: none">• Ability to discuss the types of circumstances where assistance should be sought (e.g. impaired performance, suspected misconduct). |
| 2 | Uses a collaborative approach for addressing problems. | <ul style="list-style-type: none">• Demonstrated ability to identify individuals or groups whose input is essential for addressing the identified problem.• Ability to engage the cooperation of relevant personnel to implement the plan for addressing the problem.• Ability to encourage and accept input by others into problem-solving. |
| 3 | Uses initiative to formulate a plan for resolving an identified problem. | <ul style="list-style-type: none">• Ability to describe a preferred approach for addressing the problem and justify the choice in terms of causes and intended or expected outcomes (e.g. review of formulations either to improve products or in response to lack of availability of ingredients / changes in source of ingredients). |
| 4 | Completes relevant documentation as required. | <ul style="list-style-type: none">• Understands the types of problems requiring documentation (e.g. medication incidents, personnel disputes, injuries in the workplace).• Ability to accurately complete required documentation. |
| 5 | Recognises the need for regular review of the results achieved to identify any further action(s) required. | <ul style="list-style-type: none">• Ability to discuss the purpose of reviewing the results achieved (e.g. incomplete resolution, other problems created).• Ability to demonstrate or describe how the results of review have been used to determine what further action, if any, is required. |

Standard 2.3 Collaborate with members of the health care team

Performance criteria	Evidence examples
Element 1 – Support team development and cohesion	
1 Accepts the value of partnerships and teamwork to improve consumer care.	<ul style="list-style-type: none"> Ability to demonstrate a positive attitude to working collaboratively with others.
2 Engenders trust for the role of a pharmacist and cooperation from other team members.	<ul style="list-style-type: none"> Ability to maintain respect and confidence in the pharmacist's contribution. Ability to provide feedback, encouragement and support to team members.
3 Understands the role, responsibilities and expertise of the pharmacist in relation to that of other members of the health care team.	<ul style="list-style-type: none"> Ability to describe role and responsibilities in relation to a pharmacist's expertise and the expectations of collaborating team members.
4 Recognises and respects the professional rights, skills and contributions of other team members.	<ul style="list-style-type: none"> Ability to describe the complementary roles and responsibilities of members of the health care team.
5 Respects and preserves the relationships that other members of the health care team have with consumers.	<ul style="list-style-type: none"> Ability to discuss the role of other members of the health care team (including with consumers) in a way that engenders understanding and confidence in the team and its members.
Element 2 – Promote effective teamwork	
1 Accepts responsibility for fulfilling the role expected of a pharmacist within the team.	<ul style="list-style-type: none"> Ability to respond to the demands and expectations of collaborative team members. Ability to share information and expertise to facilitate a shared understanding.
2 Identifies opportunities for collaboration on common goals and interests.	<ul style="list-style-type: none"> Ability to describe the types of issues that can be addressed within a collaborative team (e.g. adherence, standard protocols and procedures, research).
3 Shows leadership in responding to pharmaceutical or therapeutic issues.	<ul style="list-style-type: none"> Ability to demonstrate a proactive approach to responding to pharmaceutical or therapeutic issues that arise within the team.

Performance criteria

Evidence examples

- | | | |
|---|--|---|
| 4 | Collaborates with other health care professionals to enable consumers to achieve the best health outcomes. | <ul style="list-style-type: none">• Ability to maintain rapport and work in partnership (share information with consumer consent, and work cooperatively on consumer health goals) with other professionals to achieve therapeutic goals.• Ability to actively contribute a pharmacist's perspective and make a positive contribution to team based problem-solving and decision making. |
| 5 | Participates in evaluations of team effectiveness. | <ul style="list-style-type: none">• Ability to describe ways in which the effectiveness of the team and the individuals within it can be assessed. |

Element 3 – Maintain an effective professional role

- | | | |
|---|---|--|
| 1 | Ensures that the pharmacist's professional rights and values are not compromised. | <ul style="list-style-type: none">• Ability to describe requests of colleagues that might be regarded as unreasonable in the context of providing safe, effective and defensible complex compounding services.• Ability to apply assertiveness skills to deal with unreasonable requests and/or refusals that would compromise practice or consumer care. |
| 2 | Upholds professional practice standards and conventions within the team. | <ul style="list-style-type: none">• Ability to provide clear, concise and confident explanation and/or justification of a position.• Ability to initiate discussion on possible alternate courses of action to achieve a desired outcome. |

Standard 2.4 Manage conflict

Performance criteria	Evidence examples
Element 1 – Understand the importance of preventing and managing conflict	
1 Understands the need to maintain productive professional relationships and a constructive work environment.	<ul style="list-style-type: none"> • Ability to identify the means by which rapport and/or cooperation is maintained. • Ability to describe the means by which responses to input to the work environment are monitored.
2 Understands the need to act promptly to prevent conflict arising.	<ul style="list-style-type: none"> • Ability to describe situations where prompt action can prevent the development of conflict (e.g. inability to provide a requested product, timeliness of product or service delivery).
3 Understands the need to address conflict in a timely manner.	<ul style="list-style-type: none"> • Ability to describe the impact of conflict in the workplace (e.g. tension, low morale, absenteeism, system or service failure, and aggressive or uncooperative behaviours).
4 Understands the need to work in an impartial and fair manner.	<ul style="list-style-type: none"> • Ability to describe the importance of adopting a 'no blame' approach to understanding conflict in the workplace.
Element 2 – Clarify the nature of the conflict	
1 Understands when to seek assistance or guidance.	<ul style="list-style-type: none"> • Ability to discuss circumstances where assistance should be sought (e.g. claimed bullying or discrimination).
2 Works with colleagues to gather information relevant to identifying the source(s) and/or nature of the conflict.	<ul style="list-style-type: none"> • Ability to undertake enquiry in a sensitive and non-confrontational manner. • Ability to identify the key issues and key participants in the conflict.
3 Understands the need to work in an objective manner when gathering information.	<ul style="list-style-type: none"> • Ability to describe the nature and source(s) of the conflict without apportioning blame.
4 Applies analytical skills to identify a range of approaches that might be used for resolving conflict.	<ul style="list-style-type: none"> • Ability to describe a range of possible approaches/strategies that are effective for resolving conflict in the workplace (e.g. negotiation, collaborative problem-solving, mediation, arbitration).
5 Identifies situations where onward referral is warranted.	<ul style="list-style-type: none"> • Ability to describe situations where referral is warranted (e.g. severe emotional distress, intractable dispute).

Performance criteria

Evidence examples

Element 3 – Act to address conflict

1	Works with colleagues to identify and agree a preferred approach.	<ul style="list-style-type: none">• Ability to explain and justify the preferred method for resolving the conflict.• Ability to discuss preferred method (and other options if necessary) with those involved in the conflict.
2	Initiates onward referral as required.	<ul style="list-style-type: none">• Ability to identify and access contact details for relevant support services (e.g. counselling and mediation services, human resources expert).
3	Adopts a collaborative approach to reviewing the impact of actions taken to identify any further action required.	<ul style="list-style-type: none">• Ability to describe the means by which the success of the approach taken will be assessed.• Ability to discuss how those involved in the conflict will be engaged in the assessment and follow-up process.

Standard 2.5 Commitment to work and the workplace

Performance criteria

Evidence examples

Element 1 – Adopt a conscientious approach

1	Uses a systematic and well organised work process.	<ul style="list-style-type: none">• Ability to demonstrate a rigorous and systematic work process.• Ability to demonstrate efficient work practices.• Ability to use time productively.
2	Accepts responsibility for and can account for professional judgments, acts and omissions.	<ul style="list-style-type: none">• Ability to account for actions, omissions and outcomes associated with professional contribution.
3	Displays diligence and care.	<ul style="list-style-type: none">• Ability to demonstrate care and attention to detail in undertaking work activities.• Ability to deliver accurate and complete work output.
4	Adopts a responsible attitude and professional image in the workplace.	<ul style="list-style-type: none">• Ability to demonstrate punctuality.• Ability to demonstrate flexibility in extending working hours where needed to meet consumer needs.• Ability to demonstrate appropriate attire and presentation for the role and situation.

Performance criteria

Evidence examples

5 Copes with emotions in a functional manner.

- Ability to recognise and take responsibility for emotions.
- Ability to integrate emotions with intellect and will.
- Ability to deal positively with negative emotions such as anger.

Element 2 – Understand the work environment

1 Understands the structure in which the pharmacist works.

- Ability to clearly describe the structure of the organisation, environment and/or pharmacy service in which they work.
- Ability to describe where their position fits in the structure and their responsibilities and accountabilities.

2 Verifies the pharmacist's role and responsibilities within the organisation.

- Ability to describe their roles and responsibilities in terms of the position statement/duty statement applicable to the position held.

3 Understands the conditions of employment.

- Ability to describe the key conditions of employment, including specific inclusions or exclusions (e.g. award entitlements, contractual conditions, special arrangements).
- Ability to demonstrate compliance with conditions of employment.

Element 3 – Contribute to maintaining a safe working environment

1 Contributes to maintenance of workplace security systems.

- Ability to describe the key security systems for the workplace (e.g. for cash, narcotics and other controlled substances, investigational drugs, consumer records, entry and exit points) and levels of access and/or authority applicable to each.

2 Promotes maintenance of a safe and secure workplace by others.

- Ability to clearly describe to supervised staff those work practices expected of them that are intended to maintain a safe and secure workplace.

Standard 2.6 Plan and manage professional contribution

Performance criteria	Evidence examples
Element 1 – Assure the adequacy of resources	
1 Understands the need to assess the adequacy of available human resources.	<ul style="list-style-type: none"> • Ability to describe the adequacy of the available compounding expertise for undertaking the required work. • Ability to discuss the link between excessive workload and fatigue, stress, performance impairment and error.
2 Establishes the communication pathways necessary to achieve desired work outcomes.	<ul style="list-style-type: none"> • Ability to describe the communication network established to achieve work outcomes.
3 Assesses the adequacy of resources available to undertake work activities.	<ul style="list-style-type: none"> • Ability to assess required resources for usual presenting workload. • Ability to assess specific requirements for undertaking work (e.g. information, raw materials, specialised facilities and equipment, relevant complex compounding expertise) and to ensure those requirements are, or can be, met.
4 Works with colleagues to ensure resources are adequate for the usual workload.	<ul style="list-style-type: none"> • Ability to initiate action (e.g. advice to supervisor, recruitment activity) when available resources and usual workload are poorly correlated.
5 Works with colleagues to ensure adequate and appropriate stock and equipment is available.	<ul style="list-style-type: none"> • Ability to assess required levels of raw materials and/or equipment for the range and number of complex compounded products prepared. • Ability to maintain a supply chain for required materials of appropriate quality for the complex compounded products prepared.
6 Contributes to stock management and equipment maintenance in a manner consistent with local policy and procedures.	<ul style="list-style-type: none"> • Ability to describe requirements and/or comply with local policies for materials management (e.g. acquisition, storage and quarantine arrangements) and equipment maintenance. • Ability to accurately maintain a log of equipment testing/certification that is consistent with relevant Australian Standards or manufacturers specifications.

Performance criteria

Evidence examples

Element 2 – Plan and prioritise

1	Accepts responsibility for completing tasks in a timely manner.	<ul style="list-style-type: none">• Ability to discuss ways of managing multiple and/or conflicting demands on their time.
2	Understands the need for careful planning.	<ul style="list-style-type: none">• Ability to discuss the approaches/strategies for delivering outputs/outcomes in a timely manner (e.g. through productive and efficient work habits, prioritisation).
3	Assigns priorities to tasks in accordance with known circumstances.	<ul style="list-style-type: none">• Ability to justify assigned priority in terms of consumer need, difficulties to be resolved and timelines.• Ability to identify factors and/or criteria (e.g. urgency, importance, possibility of using alternative products or personnel) that impact on the priority assigned to tasks.• Ability to adjust priorities in response to changing circumstances.

Element 3 – Manage work activities

1	Allocates resources according to established priorities.	<ul style="list-style-type: none">• Ability to use initiative and a flexible approach to manage human and other resources consistent with work demands.
2	Uses available resources to assist and support work effort.	<ul style="list-style-type: none">• Ability to describe the personnel and other support systems that are available in the work environment to facilitate and support various activities associated with the complex compounding service.• Ability to use systems (e.g. a 'day book' for noting issues for follow-up, computer programs, and electronic communication and stock ordering systems) that facilitate and support work effort.
3	Seeks additional information and guidance required to complete tasks in a timely manner.	<ul style="list-style-type: none">• Ability to understand and apply information, guidance and instructions provided by others to progress work activities.• Ability to recognise situations where additional information or expertise is needed from other personnel (e.g. manager/senior pharmacist, human resources manager, business manager) to complete tasks.
4	Ensures work practices comply with local policies and procedures.	<ul style="list-style-type: none">• Ability to apply and/or promptly access policies and procedures specific to the workplace that impact on own work practices (e.g. stock management, complaints handling, and waste disposal).
5	Determines which, if any, of the tasks may be safely delegated.	<ul style="list-style-type: none">• Ability to identify and justify tasks or elements of tasks that may be appropriately delegated to other available personnel.

Performance criteria

Evidence examples

- | | | |
|---|---|--|
| 6 | Manages problems/issues that may act as barriers to the timely completion of tasks. | <ul style="list-style-type: none">• Ability to manage interferences (e.g. telephones, interruptions) that consume time without contributing to task completion.• Ability to use problem-solving skills to identify corrective action needed to resolve specific problems/issues that may impede work progress.• Ability to manage normal work and contingencies/unplanned events or demands to meet work deadlines.• Ability to adhere to pre-arranged schedules for completion of tasks. |
|---|---|--|

Standard 2.7 Supervise personnel

Performance criteria

Evidence examples

Element 1 – Accept the supervisory role

- | | | |
|---|--|---|
| 1 | Understands the nature of supervision. | <ul style="list-style-type: none">• Ability to describe the nature of the supervisory role, what is meant by direct supervision, and where responsibility for outputs and outcomes rests. |
| 2 | Accepts responsibility for supervising the work of colleagues. | <ul style="list-style-type: none">• Ability to discuss key issues for effectively supervising the work of colleagues.• Ability to contribute to revision of the duty statements /job descriptions of supervised personnel. |

Element 2 – Delegate tasks

- | | | |
|---|---|---|
| 1 | Ensures supervised personnel work within the limits of their competence | <ul style="list-style-type: none">• Ability to describe the limitations in an individual's skill or aptitude compared to the task requirements.• Ability to recognise and describe the limitations applicable to delegation of specific tasks. |
| 2 | Defines and communicates delegated tasks and the expected performance to the personnel to whom it is delegated. | <ul style="list-style-type: none">• Ability to use effective communication to clearly describe the task to be carried out and the expected performance. |
| 3 | Confirms that supervised personnel understand task requirements. | <ul style="list-style-type: none">• Ability to confirm understanding of task requirements (e.g. using questioning, listening and non-verbal cues). |

Performance criteria

Evidence examples

Element 3 – Assist the work of supervised personnel

1	Understands when supervised personnel may make autonomous decisions.	<ul style="list-style-type: none">• Ability to describe situations where autonomous decision-making by supervised personnel would be appropriate/legally defensible.
2	Works with supervised personnel to establish priorities and organise work flow.	<ul style="list-style-type: none">• Ability to establish a clear priority order of work activities in the short term (daily to weekly) and medium to long term (monthly to annually) with supervised personnel.
3	Recognises situation where additional support and/or guidance is needed for supervised personnel.	<ul style="list-style-type: none">• Ability to identify situations where supervised personnel are experiencing difficulties in completing work activities and/or where a mandatory notification obligation exists.• Ability to describe signs/cues from supervised personnel that indicate additional guidance or support is needed (e.g. hesitancy, distress, seeks clarification from less authoritative sources).• Ability to use initiative and apply professional expertise to resolve problems encountered by supervised personnel.
4	Ensures work practices of supervised personnel are consistent with their roles and comply with local policy and procedures.	<ul style="list-style-type: none">• Ability to promptly access and explain policies and procedures applicable to or impacting on supervised work (e.g. acquisition and management of raw materials and equipment, complaints handling, and waste disposal).• Ability to describe the defined roles of supervised personnel.• Ability to clearly explain policy and procedure changes to supervised personnel.

Element 4 – Support improved performance of supervised personnel

1	Understands the performance assessment and management processes of the organisation.	<ul style="list-style-type: none">• Ability to describe the performance assessment and management process within their organisation.
2	Monitors performance and contributes to the performance assessment of supervised personnel.	<ul style="list-style-type: none">• Ability to discuss the key communication factors (e.g. sensitivity, tact and clarity), content issues (e.g. positive feedback, constructive comment, goals and strategies) and process issues (e.g. fair dealing and due process) relevant to providing performance feedback.• Ability to describe the performance assessment documentation used for supervised personnel.
3	Provides constructive feedback to improve motivation and performance.	<ul style="list-style-type: none">• Ability to discuss performance and offer constructive criticism and advice without engendering an adverse response.

Performance criteria

Evidence examples

- | | | |
|---|---|--|
| 4 | Assists the work performance of supervised personnel. | <ul style="list-style-type: none">• Ability to identify resources, training or personal support that can be provided to facilitate performance improvement in supervised personnel.• Ability to contribute to workplace training programs relevant to complex compounding for supervised personnel. |
|---|---|--|

Domain 4: Review and supply prescribed medicines

Standard 4.1 Undertake initial prescription assessment

Performance criteria

Evidence examples

Element 1 – Validate prescriptions

- | | | |
|---|--|---|
| 1 | Confirms that prescriptions are authentic and comply with legal requirements and professional conventions. | <ul style="list-style-type: none">• Ability to explain the key legal requirements of a valid prescription as specified by relevant state or territory legislation.• Ability to describe and/or promptly access information on the professional conventions and obligations applicable to dispensing prescriptions, including those for medicines that are subsidised under the Pharmaceutical Benefits Scheme (PBS).• Ability to describe or demonstrate a verification/confirmation process for prescriptions received orally (e.g. by telephone) or electronically. |
| 2 | Acts to ensure fraudulent or illegal prescriptions are not dispensed. | <ul style="list-style-type: none">• Ability to describe substances/medicines that are known to be subject to abuse or intentional misuse.• Ability to recognise or describe signs of prescription fraud.• Ability to describe and/or demonstrate use of a system to respond where a prescription is suspected of being fraudulent or is deemed illegal. |

Element 2 – Clarify medication orders

- | | | |
|---|--|---|
| 1 | Ensures prescriptions are accurate and complete and clearly communicate the prescriber's intended treatment. | <ul style="list-style-type: none">• Ability to identify and justify the need for additional information (e.g. age or weight of consumer, dose or dosing instructions) to be obtained from consumer/carer or prescriber. |
|---|--|---|

Performance criteria

Evidence examples

- | | | |
|---|---|--|
| 2 | Liaises with the prescriber and/or the consumer/carer to obtain additional information as required. | <ul style="list-style-type: none">• Ability to clarify the prescribers intended treatment through liaison with the prescriber.• Ability to maintain professional rapport with the consumer/carer and prescriber when making enquiries relevant to the prescription. |
| 3 | Annotates prescriptions in accordance with legal requirements and professional conventions. | <ul style="list-style-type: none">• Ability to describe legal requirements and professional conventions for annotating prescriptions for complex compounded products (e.g. annotations clearly distinguishable from the writing of the prescriber and their source identified).• Ability to clearly annotate prescriptions to show information that has been obtained from the prescriber and/or consumer/carer and any decisions taken in relation to the compounded product to be provided. |

Element 3 – Confirm availability of medicines

- | | | |
|---|--|---|
| 1 | Establishes any special circumstances or supply arrangements impacting on availability of the prescribed medicine. | <ul style="list-style-type: none">• Ability to describe the requirements applicable to medicines with specific supply arrangements (e.g. the supply and pricing of private prescriptions for complex compounded products). |
| 2 | Identifies suitable products held in stock or available from a supplier. | <ul style="list-style-type: none">• Ability to use authoritative reference sources and supplier catalogues to clarify required product ingredients and their availability. |
| 3 | Liaises with prescribers to identify suitable alternative products where supply difficulties are apparent. | <ul style="list-style-type: none">• Ability to identify and justify the choice of a therapeutic alternative where a prescribed product cannot be obtained.• Ability to discuss suitable alternative medicines/therapies with prescribers. |
| 4 | Accepts responsibility for advising consumers/carers of reasons for any delay in supply of medicines and the actions taken to assure continuity of care. | <ul style="list-style-type: none">• Ability to clearly explain to consumers/carers the cause of, and actions underway to minimise, delays in supply.• Ability to describe the documentation and processes used to follow up on deferred supply prescription medicines and keep the prescriber and consumer informed.• Ability to describe measures or options for working with the consumer/carer to assure continuity of care consistent with clinical need. |

Standard 4.2 Consider the appropriateness of prescribed medicines

Performance criteria	Evidence examples
Element 1 – Gather relevant information	
1 Uses a systematic approach to access and review the consumer medication record or notes.	<ul style="list-style-type: none"> • Ability to access consumer medication records, including those that are stored electronically. • Ability to elicit changes to therapy, patterns of usage and adherence, previous allergies, adverse effects and drug interactions and any relative or absolute contraindications from the consumer medication record or notes.
2 Obtains additional essential medication related information from the consumer/ carer and/or the prescriber.	<ul style="list-style-type: none"> • Ability to identify and justify additional information needed to confirm the safety and/or appropriateness of the prescribed compounded product. • Ability to maintain professional rapport with consumer/carer and/ or prescriber when seeking additional health and/or medication related information.
3 Uses relevant information sources to clarify or confirm information or meet additional information needs.	<ul style="list-style-type: none"> • Ability to identify relevant information sources for different types of information. • Ability to use information resources to obtain or confirm required information.
Element 2 – Review the prescribed medicines	
1 Understands the therapeutic use(s) or pharmacological rationale for use of prescribed medicines.	<ul style="list-style-type: none"> • Ability to describe the therapeutic uses and/or pharmacology of the prescribed compounded product, or to readily access this information. • Ability to explain why the particular compounded product is likely to have been prescribed for a specific consumer.
2 Considers consumer, drug and dosage form factors likely to impact on the efficacy or safety of treatment.	<ul style="list-style-type: none"> • Ability to describe the types of consumer factors (e.g. medical conditions/disease states, age, weight, allergies, pregnancy and lactation), drug factors (e.g. bioavailability, pharmacokinetics, efficacy, toxicity) and formulation factors (e.g. use of preservatives, stability, sterility) that are likely to impact on efficacy and safety of treatment.
3 Identifies clinically significant potential or actual drug related problems likely to be associated with use of the prescribed medicines.	<ul style="list-style-type: none"> • Ability to use professional judgement to identify clinically significant potential or actual medication related problems associated with use of the prescribed compounded product.

Performance criteria

Evidence examples

- | | | |
|---|--|---|
| 4 | Identifies factors likely to adversely affect adherence to the intended treatment. | <ul style="list-style-type: none">Ability to describe consumer or lifestyle factors or characteristics of the compounded product that are likely to adversely impact on adherence (e.g. language, literacy and numeracy skills, manual dexterity, vision, racial, religious and cultural background, dosing regimen, side-effect profile and cost). |
| 5 | Uses professional judgement to determine whether any changes in prescribed medicines are warranted to promote enhanced safety and/or efficacy. | <ul style="list-style-type: none">Ability to identify changes in the prescribed compounded product, dosage form and dosing regimen that are thought necessary in the interests of consumer safety and/or enhanced treatment efficacy. |

Element 3 – Promote optimal medicines use

- | | | |
|---|---|---|
| 1 | Liases with the prescriber regarding suggested changes in therapy to resolve or minimise issues likely to adversely impact on adherence. | <ul style="list-style-type: none">Ability to justify to the prescriber the rationale (based on evidence or professional expertise) behind recommended changes in the complex compounded product or to discuss alternative therapeutic options where necessary. |
| 2 | Initiates action, in consultation with prescribers and/or consumers, to address issues impacting on adherence. | <ul style="list-style-type: none">Ability to discuss with the consumer and the prescriber characteristics of the compounded product which may impact on its ease of use or acceptability to the consumer and to identify strategies to assist adherence with therapy. |
| 3 | Understands the need to accurately code and record clinical interventions consistent with professional standards or conventions and workplace policy. | <ul style="list-style-type: none">Ability to use a systematic classification and recording system for clinical interventions.Ability to describe the process by which data on clinical interventions is captured, analysed and used. |

Standard 4.3 Dispense prescribed medicines

Performance criteria

Evidence examples

Element 1 – Apply a systematic dispensing procedure

- | | | |
|---|--|--|
| 1 | Uses professional judgement to determine the priority order in which prescription medicines are dispensed. | <ul style="list-style-type: none">Ability to decide a priority order for dispensing prescribed compounded products, taking account of factors such as the urgency of clinical need, consumer safety and legal requirements, and the time and care needed for recording, preparing and checking all aspects of the complex compounding process and final product. |
|---|--|--|

Performance criteria

Evidence examples

2	Maintains a logical, safe and disciplined dispensing procedure.	<ul style="list-style-type: none">• Ability to operate computerised dispensing and bar code scanning systems to accurately select ingredients and maintain consumer medication records.• Ability to describe factors known to be associated with dispensing or compounding errors (e.g. inaccurate or incomplete master worksheets, frequent interruptions).• Ability to apply a systematic process to preparation and dispensing of complex compounded products which incorporates sequential checks for accuracy.• Ability to accurately select product, dosage form and required quantity.
3	Considers factors likely to compromise product efficacy and stability when repackaging medicines out of their original containers/packaging.	<ul style="list-style-type: none">• Ability to describe factors (e.g. light sensitivity, deliquescence, possible contamination) that may impact on the advisability of using ingredients in a complex compounded product that have to be removed from the original unit of use packaging (e.g. proprietary creams, capsules or eye or ear drops)
4	Applies legible, comprehensible and complete labels to dispensed medicines.	<ul style="list-style-type: none">• Ability to produce labels in which the type face is large enough and dark enough to be easily read, instructions are expressed in readily understandable English, are adapted to meet specific consumer needs (e.g. poor sight) and include all the information required by law/professional convention and for safe and effective use of the product by the consumer.• Ability to select a site for the label that does not cover important information provided by the sponsor company such as expiry date, batch number, storage requirements or dosing information.
5	Incorporates relevant cautionary and advisory directions into the labelling of dispensed medicines consistent with legal requirements and professional conventions.	<ul style="list-style-type: none">• Ability to use ancillary labels or cautionary and advisory statements as specified in legislation, the <i>Australian Pharmaceutical Formulary and Handbook</i> (APF) and otherwise as considered appropriate.
6	Ensures dispensed medicines and the applied labels directly correlate to the prescribed medicines and dosing regimen.	<ul style="list-style-type: none">• Ability to use the prescription as the primary source for checking that both the label and dispensed compounded product correlate to the product prescribed or subsequently confirmed with the prescriber.• Ability to demonstrate a rigorous and systematic process for checking medicines dispensed by others including non-pharmacists.

Performance criteria

Evidence examples

- | | | |
|---|--|---|
| 7 | Accepts responsibility for ensuring dispensed medicines are issued (and administered for supervised dosing in the pharmacy) to the correct consumer. | <ul style="list-style-type: none">• Ability to demonstrate the use of a checking process of consumer/closing details with those on the prescription at the time a compounded product is supplied. |
| 8 | Takes prompt action to minimise the impact of dispensing errors and reduce the risk of recurrence. | <ul style="list-style-type: none">• Ability to describe the steps necessary to minimise the impact of dispensing errors on consumers and minimise the risk of recurrence. |

Element 2 – Manage records

- | | | |
|---|--|--|
| 1 | Completes prescription records for dispensed medicines, including controlled substances, consistent with legal requirements. | <ul style="list-style-type: none">• Ability to describe the recording requirements for prescribed compounded products.• Ability to demonstrate maintenance of prescription records that include prescription annotations and comply with legal requirements. |
| 2 | Maintains accurate and up-to-date consumer medication records consistent with professional standards and conventions. | <ul style="list-style-type: none">• Ability to describe and/or demonstrate compliance with professional conventions in relation to maintenance of consumer medication records.• Ability to promptly access additional guidance from professional guidelines and standards. |
| 3 | Accurately records details of medication incidents (including 'near misses') including the actions taken to minimise their effects and prevent recurrence. | <ul style="list-style-type: none">• Ability to describe appropriate recording and response requirements for dispensing errors such as provided in <i>Procedure to follow in case of a dispensing error</i> (Pharmaceutical Defence Limited).• Ability to demonstrate compliance with workplace procedures for documenting and responding to medication incidents. |

Element 3 – Assist consumer understanding and adherence

- | | | |
|---|--|--|
| 1 | Liaises with the consumer/carer to clarify their information needs. | <ul style="list-style-type: none">• Ability to communicate with consumers/carers to confirm their knowledge and understanding of their disease/condition and medications and clarify the level, type and form of information required. |
| 2 | Identifies additional information needs arising from changes in the medicines or medication treatment. | <ul style="list-style-type: none">• Ability to identify circumstances where a change in appearance of compounded product or its packaging needs to be discussed with the consumer/carer. |

Performance criteria

Evidence examples

3 Provides advice on the medicine, dosing regimen, precautions, possible adverse effects and any specific storage requirements.	<ul style="list-style-type: none">• Ability to describe, in terms appropriate for informing the consumer, the therapeutic indications, pharmacological actions and precautions for dispensed compounded products.• Ability to identify and describe the most relevant adverse effects and to discuss these with consumers/carers without causing alarm.
4 Reinforces and clarifies verbal advice by demonstrating administration technique and using written consumer information resources as required.	<ul style="list-style-type: none">• Ability to use written consumer information, where available, to tailor information relevant to specific consumers and/or circumstances.• Ability to describe additional sources of information provided to consumers (e.g. Consumer Medicines Information (CMI) or product information sheets) to facilitate the safe and effective use of a compounded product.• Ability to describe and/or demonstrate specific use or administration technique for complex compounded products.
5 Checks that consumers understand why the medicines have been prescribed and how they are to be used/administered and stored.	<ul style="list-style-type: none">• Ability to check that advice and information provided about a complex compounded product has been understood (e.g. uses questions to confirm understanding, interprets cues that information has not been understood).
6 Works with the consumer/carer to positively impact on adherence with prescribed treatment regimen.	<ul style="list-style-type: none">• Ability to discuss with consumers/carers the importance of adherence and possible courses of action that may improve their ability or willingness to adhere to prescribed treatment.• Ability to demonstrate the use of aids/appliances intended to assist the use of complex compounded products.

Domain 5: Prepare pharmaceutical products

Standard 5.1 Consider product requirements

NOTE: Standard 5.1 underpins all of the Standards in this Domain and must be used in conjunction with each of Standards 5.2, 5.3 and 5.4.

Performance criteria	Evidence examples
Element 1 – Consider legislative and professional obligations	
1 Understands specific codes and regulations that apply to the preparation of pharmaceutical products.	<ul style="list-style-type: none">• Demonstrated understanding of relevant codes (e.g. <i>Pharmaceutical Inspection Convention and Pharmaceutical Inspection Co-operation Scheme (PIC/S)</i>, <i>Guide to Good Manufacturing Practice for Medicinal Products</i>) and legislative requirements.• Ability to describe the quality management obligations associated with all aspects of complex compounding (e.g. audit trail on raw materials and final products, quarantine and sterility testing requirements, operator training and validation procedures),
2 Complies with workplace practices and professional conventions for product preparation.	<ul style="list-style-type: none">• Ability to describe professional standards and conventions as well as workplace policies and procedures for the preparation of pharmaceutical products, including complex compounded products.• Ability to describe the types of clothing required (e.g. safety glasses, latex gloves, gowns and overshoes) for compounding various types of complex compounded products (e.g. products that contain irritants or which release fumes, are hazardous or contain cytotoxic drugs) that will protect the product, environment, preparer and other personnel.• Ability to describe the key features of a quality assurance program for compounded products.
3 Maintains currency of information on legislative, professional and workplace policy requirements applicable to the preparation of pharmaceutical products.	<ul style="list-style-type: none">• Ability to describe and/or demonstrate systems or processes established to capture new information on standards and conventions applicable to the preparation of pharmaceutical products (e.g. latest editions of <i>Australian Pharmaceutical Formulary and Handbook (APF)</i> and <i>Professional Practice Standards</i>, circulars from the Therapeutic Goods Administration (TGA), Australian Pesticides and Veterinary Medicines Authority and Health Department and changes in OH&S legislation).

Performance criteria

Evidence examples

- | | | |
|---|---|---|
| 4 | Ensures processes to protect consumer safety are applied. | <ul style="list-style-type: none">• Ability to describe checking processes required to assure consumer safety (e.g. double check of calculations, weights and measurements, quarantine of products prior to final check and release, label reconciliation, and check and release of final products).• Ability to describe how the application of safety procedures is documented for all prepared products.• Ability to describe procedures and processes required to specifically protect the consumer from hazards in the workplace (e.g. fumes, particulates or aerosols) or those associated with use of the product. |
|---|---|---|

Element 2 – Confirm the need for the product

- | | | |
|---|--|---|
| 1 | Understands the therapeutic context in which the product has been requested. | <ul style="list-style-type: none">• Ability to promptly access standard treatment protocols or individual consumer treatment plans.• Ability to clarify the context of treatment from the consumer's medication record or other sources such as consumer notes. |
| 2 | Obtains additional clinical or medication related information as needed. | <ul style="list-style-type: none">• Ability to identify and justify additional information needed to confirm the safety and/or appropriateness of providing the requested product.• Ability to access and interpret test results relevant to the product requested (e.g. white cell count for chemotherapy, biochemistry for total parenteral nutrition (TPN)).• Ability to maintain professional rapport with consumer/carer and/or prescriber when seeking additional clinical or medication related information. |
| 3 | Uses evidence-based decision-making in determining what changes, if any, are warranted in the requested product. | <ul style="list-style-type: none">• Ability to describe and/or promptly access evidence-based information on treatment protocols and preferred treatment options or formulations.• Ability to apply clinical information to determine if requested product will meet consumer needs. |

Performance criteria

Evidence examples

- | | | |
|---|---|--|
| 4 | Provides advice on the selection of a suitable product. | <ul style="list-style-type: none">• Ability to describe the nature of a range of pharmaceutical formulations and provide advice on their appropriate selection and use.• Ability to advise on issues such as infusion diluents, strength, volume and rate, and TPN composition and caloric value for specific consumers taking account of their clinical status (e.g. hydration, catabolic state, renal function).• Ability to describe and justify the choice of an alternative product, including where an individualised complex compounded product is indicated and recommended. |
|---|---|--|

Element 3 – Confirm the required formulation

- | | | |
|---|---|---|
| 1 | Selects a standard formulation to correspond to a specified product where one exists. | <ul style="list-style-type: none">• Ability to use standard reference sources (e.g. master manufacturing sheets or databases) to access required formulations for complex compounded products.• Ability to select the correct standard formulation for a specific product. |
| 2 | Identifies circumstances that might warrant adjustments being made to a formulation. | <ul style="list-style-type: none">• Ability to recognise the potential in a formulation for physicochemical incompatibilities (e.g. acid-base reactions, precipitation, flocculation, oxidation, hydrolysis and colour change).• Ability to identify situations where a formulation requires adjustment to ensure adequate stability, compatibility and suitability for its intended use (e.g. use of pH buffers, alteration of vehicle, addition of suspending agent, preservative or antioxidant). |
| 3 | Uses reference sources to modify the formulation in a manner consistent with consumer needs, and professional guidelines and conventions. | <ul style="list-style-type: none">• Ability to use a range of reference sources (e.g. APF, IV additive compatibility and caloric intake guides) relevant to compounding to correctly identify the nature and/or magnitude of the required adjustment to a complex compounded product.• Ability to promptly access additional guidance on professional conventions relating to modification of formulations to identify the specific means by which the required modification may be achieved.• Ability to appropriately adjust TPN formulation, infusion diluents, strength, volume and rate based on changes in consumer's clinical status (e.g. hydration, catabolic state and renal function). |

Performance criteria

Evidence examples

- | | | |
|---|--|---|
| 4 | Discusses and confirms required modifications with prescriber and/or consumer as required. | <ul style="list-style-type: none">• Ability to describe situations where legislation or professional conventions require the prescriber (e.g. change in concentration of active ingredient(s) or dosage) and/or the consumer (e.g. change in colour or flavour) to be notified of a change.• Ability to explain and confirm required modifications with the prescriber or consumer. |
| 5 | Uses databases and other evidence-based reference sources to research formulations where no standard formulation exists. | <ul style="list-style-type: none">• Ability to use evidence-based information sources relevant to complex compounding to identify suitable formulation options for addressing therapeutic needs where no standard formulation exists.• Ability to identify expertise (e.g. pharmacists within hospitals or pharmaceutical companies) and information sources (e.g. medical or pharmaceutical journals) from which non-standard formulations/ advice may be obtained. |
| 6 | Develops an appropriate formulation where no standard formulation exists. | <ul style="list-style-type: none">• Ability to develop a formulation to meet the needs of individual consumers (e.g. paediatric powders) or prescribers by reference to peer reviewed or other substantive information sources or by consultation with other expert sources.• Ability to support the safety and compatibility of all ingredients and the quality, safety efficacy and rationality of the formulation using sound clinical and pharmaceutical evidence. |

Element 4 – Determine if production requirements can be met

- | | | |
|---|--|---|
| 1 | Understands the formulation instructions, including preparation methods. | <ul style="list-style-type: none">• Ability to interpret and explain the terminology, abbreviations and instructions for preparing specific products. |
| 2 | Understands issues impacting on stability that are likely to influence preparation technique and selection of final storage container. | <ul style="list-style-type: none">• Ability to describe the effects of moisture, oxygen, light, heat and microbiological contamination on product stability, efficacy and shelf-life.• Ability to identify or promptly access information on any issues impacting on the stability/shelf-life of particular compounded products. |

Performance criteria

Evidence examples

3 Confirms the active ingredients and excipients required for preparing the product and their suitability for use.	<ul style="list-style-type: none">• Ability to accurately identify ingredients by trade, generic or common name and to differentiate their quality on the basis of the certificates of analysis or ingredient specifications, including where these are provided by external contractors.• Ability to differentiate active ingredients from excipients and to explain the purpose of each ingredient present in the formulation (e.g. therapeutic agent, vehicle, flavouring or suspending agent, buffer, antioxidant, preservative).• Ensures storage conditions for ingredients and materials are optimal for protecting their integrity and quality.
4 Understands the requirement to assess any risks associated with handling and/or manipulating the product and/or product ingredients.	<ul style="list-style-type: none">• Ability to use Safety Data Sheets or other resources to undertake a risk assessment and identify any sources of risk (e.g. cytotoxic or teratogenic agents, biologicals, hormones, irritants) posed to personnel, the product or the environment.• Ability to differentiate products that may be prepared at an open manufacturing workstation from those that require aseptic dispensing (e.g. eye drops, injections and instillations) in an isolator cabinet or laminar air flow work station in a cleanroom.• Ability to describe and/or demonstrate safe handling techniques (e.g. order of addition, use of specialised equipment/facilities) for ingredients that are potentially harmful (e.g. strong acids and alkalis, podophyllin, cytotoxic agents).• Ability to describe required practices for the safe and effective cleaning of equipment used and for the safe disposal of waste materials generated from the compounding process (e.g. sharps, consumables and hazardous materials).
5 Confirms availability and suitability of required equipment/environment.	<ul style="list-style-type: none">• Ability to identify equipment/environment appropriate for the preparation of a specific product (e.g. pharmaceutical isolator cabinet, laminar air flow workstation in a cleanroom, powder mill, capsule machine, pH meter, high precision measures and electronic balances).• Ability to confirm the required equipment/environment is clean and has been properly maintained (e.g. recalibrated or recertified according to manufacturer's instructions or local policy).
6 Identifies an appropriate course of action where preparation requirements cannot be met.	<ul style="list-style-type: none">• Ability to use problem-solving skills to identify a course of action or make a recommendation that addresses consumer need where a product cannot be made in the workplace.

Performance criteria

Evidence examples

Element 5 – Prepare and maintain product documentation

1	Understands the value of using a worksheet, logbook or register for recording details of prepared products.	<ul style="list-style-type: none">• Ability to describe the reasons for completing a product worksheet/logbook/register (e.g. tracking batches of ingredients in the event of a recall, checking of involved personnel, quantities and ingredients in the event of consumer complaint or misadventure).
2	Calculates the required quantities for each of the ingredients in the final product.	<ul style="list-style-type: none">• Ability to accurately calculate requirements for the final complex compounded product (e.g. weights, volumes, percentages, displacement values, strengths, aliquots and dilutions).
3	Ensures product worksheet, logbook or register is legible, accurate and complete.	<ul style="list-style-type: none">• Ability to demonstrate the use of a worksheet, logbook or register as appropriate to document the details of routinely and ad hoc prepared products, including ingredients and their batch number and expiry dates, compounding process, and expiry date and labelling of the final product.• Ability to create master manufacturing worksheets and to recognise calculation errors and/or inconsistencies between a worksheet/logbook/register and a master manufacturing sheet or product order/prescription.
4	Seeks additional information or guidance about any issue of concern or uncertainty before proceeding to preparation of the product.	<ul style="list-style-type: none">• Ability to describe or demonstrate ways in which additional guidance or enhanced certainty can be achieved (e.g. double checking of calculations by another individual, reviewing preparation methods described in master worksheet, use of reference texts to confirm strengths, doses or dilutions).
5	Applies a systematic process for assigning batch numbers and storing records of prepared products.	<ul style="list-style-type: none">• Ability to demonstrate and/or describe a system for creating batch numbers and storing and retrieving records of complex compounded products.• Ability to describe the way in which the product documentation provides an audit trail for the ingredients used and the final product that can be used in the event of an adverse effect or recall.• Ability to undertake recording and record storage functions consistent with local policies and procedures.

Performance criteria

Evidence examples

Element 6 – Optimise packaging and labeling

1	Prepares legible, comprehensible and complete final product labels in accordance with worksheet/logbook/register, legislative requirements and professional conventions.	<ul style="list-style-type: none">• Ability to promptly access information on legal requirements and professional conventions applicable to the labelling of complex compounded products.• Ability to generate accurate, unambiguous and complete labels consistent with the details on the worksheet/logbook/register and with professional conventions and legal requirements (e.g. including name of consumer, name and contact for the pharmacy, strength/amount of all ingredient(s), dosing information, batch number, expiry and storage requirements).
2	Chooses packaging for prepared products that promotes safe use and addresses factors likely to compromise product stability.	<ul style="list-style-type: none">• Ability to describe and/or use information sources to identify factors (e.g. light, moisture, temperature, container type) impacting on stability and shelf-life.• Ability to choose containers appropriate for the intended use of the product (e.g. dropper bottles for eye and ear drops, Toomey syringe for bladder instillations) and for addressing factors known to impact on product stability/shelf-life (e.g. amber bottles, aluminium foil outer wrapping).
3	Applies labels to prepared products to optimise their stability and promote their correct storage and use.	<ul style="list-style-type: none">• Ability to describe additional labelling requirements for specific products that will promote their correct storage and use (e.g. supplementary labels such as 'Shake the bottle', 'Refrigerate' and 'Discard after.....days', or special administration instructions).• Ability to label prepared products without obscuring the manufacturer's information relevant to the correct storage and/or use of the final product.

Standard 5.2 Prepare non-sterile drug products

(To be used in conjunction with Standard 5.1 Consider product requirements.)

Performance criteria

Evidence examples

Element 1 – Assemble ingredients and materials

1	Selects ingredients of appropriate quality.	<ul style="list-style-type: none">• Ability to select ingredients of appropriate quality/standard for inclusion in products intended for human therapeutic or veterinary use (e.g. pharmaceutical grade, in date, stored according to storage advice on label, visually free of contamination and/or signs of degradation such as colour change, crystallisation or deliquescence).
---	---	---

Performance criteria

Evidence examples

- | | | |
|---|---|---|
| 2 | Selects ingredients and equipment accurately. | <ul style="list-style-type: none">• Ability to select ingredients (form and strength) and final container that exactly match the descriptions on the worksheet. |
| 3 | Reduces the potential for other activities and/or materials to impede, cross contaminate or cause error in the preparation process. | <ul style="list-style-type: none">• Ability to organise an area of suitable size in the workplace that provides for the segregation of compounding of one product from other products and from other professional activities, and containment of any risks posed to personnel, consumers and the environment. |

Element 2 – Apply compounding principles and techniques

- | | | |
|---|--|---|
| 1 | Measures quantities required according to the worksheet. | <ul style="list-style-type: none">• Ability to accurately weigh and measure ingredients. |
| 2 | Adopts a systematic process for combining ingredients that is consistent with sound pharmaceutical compounding practice. | <ul style="list-style-type: none">• Ability to demonstrate preparation techniques and use of equipment (e.g. grinding, mixing, blending)• Ability to demonstrate the use of equipment and relevant complex compounding techniques consistent with the range of product types prepared.• Ability to demonstrate a systematic technique for making a variety of pharmaceutical products, including complex compounded products. |
| 3 | Uses techniques that avoid contamination of the product. | <ul style="list-style-type: none">• Ability to demonstrate technique and personal hygiene measures (e.g. hand washing, use of gloves, caps or gowns) that limit the opportunities for contamination of the product. |

Standard 5.3 Aseptically prepare sterile drug products

(To be used in conjunction with Standard 5.1 Consider product requirements.)

Performance criteria

Evidence examples

Element 1 – Understand the work environment and work practices

- | | | |
|---|---|---|
| 1 | Understands the operation of a cleanroom environment. | <ul style="list-style-type: none">• Ability to describe the function of the cleanroom, including pressure differentials, airflow, use of High Efficiency Particulate Air (HEPA) filters and placement of the cabinet and other equipment. |
|---|---|---|

Performance criteria

Evidence examples

2	Understands the principles of aseptic dispensing in a HEPA filtered horizontal laminar airflow cabinet.	<ul style="list-style-type: none">• Ability to describe the basis for use of aseptic dispensing technique in a horizontal laminar airflow cabinet in a cleanroom.• Ability to differentiate and describe products that require aseptic dispensing to ensure sterility (e.g. TPN, narcotic and antibiotic infusions, eye drops and injections).
3	Understands the issues important to the selection of correct equipment for aseptically prepared products.	<ul style="list-style-type: none">• Ability to discuss issues (e.g. needle gauge, minibag volume, types of plastic infusion bags, luer lock syringes, sterilising and venting filters) relevant to correct selection of equipment for aseptic product preparation.
4	Participates in activities/programs intended to assure sound aseptic technique and the quality of aseptically prepared products.	<ul style="list-style-type: none">• Ability to describe a validation/certification program for maintaining sound aseptic technique (e.g. validation of technique using media testing).• Ability to demonstrate sound aseptic dispensing technique for the types of sterile complex compounded products provided.• Ability to describe the key features of a quality assurance program for aseptic preparation of compounded products.

Element 2 – Prepare and supply sterile products

1	Selects and assembles materials and equipment required for specific product.	<ul style="list-style-type: none">• Ability to describe the uses of different pieces of equipment used in aseptic dispensing (e.g. sterilising, venting and particulate filtration filters, additive ports, minibag entry port closures).• Ability to correctly assemble all materials required to aseptically prepare complex compounded products.
2	Uses appropriate scrub and gowning techniques before entering the cleanroom.	<ul style="list-style-type: none">• Ability to demonstrate correct scrub and gowning technique (e.g. by ensuring maintenance of sterility of gloves during gowning).
3	Uses appropriate setup and manipulative technique for aseptic preparation of products in a laminar airflow cabinet.	<ul style="list-style-type: none">• Ability to demonstrate correct equipment setup and aseptic dispensing technique for preparation of sterile compounded products in a laminar airflow cabinet (e.g. by media fill testing of prepared products).
4	Complies with local policies and procedures for cleaning the cabinets between products and at the end of work sessions.	<ul style="list-style-type: none">• Ability to describe policies and procedures applicable to maintaining the operation and cleanliness of the laminar airflow cabinet.

Performance criteria

Evidence examples

- | | | |
|---|---|---|
| 5 | Maintains the integrity of the cleanroom environment. | <ul style="list-style-type: none">• Ability to describe procedures for transfer of products and materials between the cleanroom and general work areas.• Ability to describe work practices intended to maintain cleanroom integrity, including the correct and safe disposal of consumables and sharps. |
| 6 | Contributes to maintenance of an audit trail on all ingredients used and on final products. | <ul style="list-style-type: none">• Ability to describe the way in which records support maintenance of an audit trail on ingredients and final products. |
| 7 | Provides advice to others on the correct use/application of aseptically prepared products. | <ul style="list-style-type: none">• Ability to describe how aseptically prepared products should be used to limit the opportunity for product contamination. |

Standard 5.4 Prepare cytotoxic drug products

(To be used in conjunction with Standard 5.1 Consider product requirements.)

Performance criteria

Evidence examples

Element 1 – Understand the work environment and work practices

- | | | |
|---|---|---|
| 1 | Understands the importance of preparing cytotoxic drug products in environments and using equipment specifically provided for that purpose. | <ul style="list-style-type: none">• Ability to explain the toxic potential of cytotoxic/teratogenic drugs.• Ability to describe how features of the equipment and environment contribute to protection of product, environment and people, including the preparer.• Ability to differentiate products requiring preparation in a cleanroom and cytotoxic drug safety cabinet or isolator cabinet.• Ability to describe how the specialised techniques used in manipulation of cytotoxic drugs contribute to the protection of the product, environment and people. |
| 2 | Understands the operation of the cleanroom and cytotoxic drug safety cabinet and/or isolator cabinet. | <ul style="list-style-type: none">• Ability to describe the operation of an isolator cabinet and/or the airflow and venting systems of the cleanroom and cabinet (including the way in which the air pressure differentials work and the changes in pressure that occur in the event of the spill alarm system being activated). |
| 3 | Understands the safety procedures applicable in the event of a spill or accidental exposure to a cytotoxic drug. | <ul style="list-style-type: none">• Ability to describe or demonstrate emergency procedures for a spill or accidental exposure. |

Performance criteria

Evidence examples

- | | | |
|---|---|---|
| 4 | Understands the principles to be applied for the safe transportation of cytotoxic products and disposal of waste. | <ul style="list-style-type: none">• Ability to describe risks posed by cytotoxic products and waste and how correct packaging and disposal reduces the risks. |
|---|---|---|

Element 2 – Prepare cytotoxic drug products

- | | | |
|---|--|--|
| 1 | Scrubs and gowns appropriately before commencing preparation of the product. | <ul style="list-style-type: none">• Ability to describe and/or demonstrate correct scrub and gowning technique.• Ability to select correct gowning apparel for preparation of cytotoxic products (e.g. moisture impervious coveralls and mask). |
| 2 | Understands how to arrange ingredients and equipment within the preparation cabinet. | <ul style="list-style-type: none">• Ability to demonstrate the desired layout of ingredients and equipment in the preparation cabinet.• Ability to explain the way in which the arrangement of ingredients and equipment minimises the risk of contamination of the product, personnel and the environment. |
| 3 | Uses sound technique to prepare cytotoxic drug products in a cytotoxic drug safety cabinet or isolator cabinet. | <ul style="list-style-type: none">• Ability to demonstrate sound technique for manipulating cytotoxic drugs/drug products using the variety of equipment required for preparing compounded products. |
| 4 | Takes prompt action to clean up cytotoxic spills in the cabinet or cleanroom. | <ul style="list-style-type: none">• Ability to describe and/or demonstrate the correct use of a spill kit and procedures to be observed in the event of a spill inside the cabinet. |
| 5 | Disposes of waste materials generated during the preparation of products according to established protocols. | <ul style="list-style-type: none">• Ability to describe and/or demonstrate disposal of waste materials such as used needles, syringes and primary containers consistent with established policy and procedures. |
| 6 | Packages each product in a manner that allows its safe transportation from the preparation area to consumer treatment areas. | <ul style="list-style-type: none">• Ability to describe and/or demonstrate the sealed impervious packaging required before the product leaves the cleanroom environment.• Ability to describe any additional packaging required to minimise the risk of product contamination and unintended exposure of the environment or people during its transportation. |
| 7 | Contributes to maintenance of an audit trail on all ingredients and final products. | <ul style="list-style-type: none">• Ability to describe the way in which records support the maintenance of an audit trail on ingredients and final products. |

Performance criteria

Evidence examples

Element 3 – Assist the safe use of cytotoxic drug products

1	Applies product labels that clarify the method of administration, storage requirements and expiry for product users.	<ul style="list-style-type: none">• Ability to produce clear, unambiguous labels that provide user information, including information on administration, storage and expiry.• Ability to describe the professional labelling (e.g. the specific purple symbol used to denote a cytotoxic drug) and storage conventions (e.g. segregation from other products) used for products that contain cytotoxic drugs.
2	Provides advice on administration techniques and equipment required for the safe administration of cytotoxic drug products.	<ul style="list-style-type: none">• Ability to describe precautions and/or demonstrate the use of equipment (e.g. special purpose gowns and gloves, luer lock connectors and luer lock connector giving sets) needed for the safe handling and administration of cytotoxic drug products.
3	Explains equipment and processes required for the safe handling and disposal of cytotoxic waste, including affected body fluids.	<ul style="list-style-type: none">• Ability to describe or promptly access information on the correct disposal equipment and processes required for different types of contaminated waste.

Element 4 – Protect personal health

1	Understands circumstances that would preclude personal involvement in the preparation of cytotoxic drug products.	<ul style="list-style-type: none">• Ability to describe circumstances which would preclude personal involvement in the preparation of cytotoxic drug products (e.g. pregnancy, immunosuppression).
2	Participates in activities/programs intended to assure sound technique and the quality of aseptically prepared products.	<ul style="list-style-type: none">• Ability to describe a validation/certification program for maintaining sound aseptic technique.• Ability to demonstrate sound aseptic technique and procedures for preparing non-sterile cytotoxic drug products through participation in a quality assurance program.• Ability to describe key features of the quality assurance program.
3	Maintains accurate and complete records of exposure to cytotoxic drugs/drug products.	<ul style="list-style-type: none">• Ability to describe and/or demonstrate the use of a systematic recording system for products made, time spent in preparing each and unusual incidents such as spills or needlestick injuries.
4	Reports spill and exposure incidents consistent with local policies and procedures.	<ul style="list-style-type: none">• Ability to describe or promptly access policies and procedures for reporting and follow-up of spill and exposure incidents.

Domain 6: Deliver primary and preventive health care⁵

Standard 6.1 Assess primary health care needs

Performance criteria	Evidence examples
Element 1 – Elicit relevant clinical information	
1 Undertakes consultation with the consumer/carer in a manner that protects their privacy and confidentiality.	<ul style="list-style-type: none"> • Ability to discuss ways in which consumer privacy and confidentiality may be protected during a clinical consultation. • Ability to describe circumstances where the consumer's right to receive primary health care services anonymously should be protected. • Ability to use a structured 'patient-centred' consultation with the consumer/carer without engendering concern, resistance or other adverse reaction. • Ability to clarify the nature and duration of the symptoms/condition, other associated symptoms or signs, current or recent medications and actions/treatments already used and their effectiveness, asking appropriate questions where the required information is not readily volunteered.
2 Uses the consumer medication record where this is available to confirm health information relevant to the presenting condition/symptoms.	<ul style="list-style-type: none"> • Ability to access individual consumer's electronic or hard copy medication records to clarify current or recent medication treatment. • Ability to select information from the consumer medication record that is relevant to the condition or symptoms under consideration.
3 Obtains additional required clinical information from other health professionals and/or information sources (with consumer consent).	<ul style="list-style-type: none"> • Ability to describe and justify additional clinical information required (e.g. concurrent medical conditions, laboratory test results) to form an opinion about the treatment options. • Ability to identify and access (with consumer consent) sources of clinical information about a consumer other than those available within the pharmacy.
4 Maintains a network with individuals and organisations that are able to provide complementary input in the provision of primary health care services.	<ul style="list-style-type: none"> • Ability to describe the complementary roles or expertise of the contacts in their primary health care network (e.g. other pharmacists, medical practitioners or veterinarians with an interest in, or commitment to, complex compounding).

⁵ In this Domain it is assumed a complex compounded product would be recommended and any adjustments to use or formulation made in the context of a medication history, initial assessment of primary health care needs and ongoing medication management. It is therefore also assumed that the pharmacist will be able to satisfy competencies for obtaining a medication history, recommending treatments and advising ways in which the treatment regimen, including the compounded product and non-medicinal treatments, should be adjusted to achieve desired health outcomes. Elements and performance criteria relating to delivery of direct care in acute or emergency situations have been excluded.

Performance criteria

Evidence examples

Element 2 – Identify management options

1	Assesses the potential seriousness of the presenting symptoms/condition in the context of the clinical information gathered and the particular consumer.	<ul style="list-style-type: none">• Ability to describe clinical circumstances where particular care is needed (e.g. babies or infants, pregnant or breastfeeding women) or onward referral should be considered (e.g. persistent or potentially serious symptoms).• Ability to integrate and interpret clinical information to identify possible contributing or confounding factors.
2	Determines the goal of treatment and considers consumer, drug and dosage form factors likely to impact on treatment options.	<ul style="list-style-type: none">• Ability to describe the intended therapeutic goal or outcome expected (e.g. amelioration or cure of symptoms, prevention of complications).• Ability to identify consumer factors (e.g. language, literacy and numeracy skills, manual dexterity) and drug factors (e.g. potential for abuse, complex dosing regimen) that may limit the choice of therapeutic options.• Ability to identify factors which may preclude the use of some treatment options (e.g. treatment with warfarin, pregnancy or breastfeeding).
3	Identifies possible medicinal and non-medicinal treatment strategies or options.	<ul style="list-style-type: none">• Ability to identify a range of medicinal and non-medicinal treatment options/strategies, including those for which there may be a relative or absolute contraindication.• Ability to discuss treatment options in terms of coexisting diseases/conditions and current medication treatment regimen, presenting symptoms, their duration and the extent to which previous efforts have been successful.
4	Assesses the potential for inappropriate use or abuse of selected medicinal treatments.	<ul style="list-style-type: none">• Ability to make and justify a decision on whether or not to provide a medicine, including a complex compounded product that has potential for misuse or abuse.
5	Considers the need to involve other health professionals or services.	<ul style="list-style-type: none">• Ability to identify and/or describe circumstances where the intervention of another health professional (e.g. medical practitioner, nurse, physiotherapist, podiatrist) would be of benefit.• Ability to identify and/or describe circumstances where an immediate rather than a conditional referral to a medical practitioner would be warranted (e.g. failure of therapy, acute deterioration of condition, symptom/condition outside the area of expertise/professional role of a pharmacist).

Performance criteria

Evidence examples

Element 3 – Initiate collaboration or onward referral

1	Explains the need to seek advice/ assistance from other health professionals where self-care is considered inappropriate.	<ul style="list-style-type: none">• Ability to provide an explanation of the need for onward referral.• Ability to gain the consumer's agreement for liaison with and/or referral to a health practitioner of the consumer's choice without engendering concern or other negative reactions.
2	Undertakes onward referral of consumers in a manner consistent with professional standards and conventions.	<ul style="list-style-type: none">• Ability to demonstrate and/or describe the professional standards and conventions applicable to onward referral of consumers or to promptly access that information.• Ability to demonstrate use of a written and/or oral referral process that informs another health professional of the basis for the onward referral, advice or treatment already provided and pharmacist contact details.
3	Liaises and/or collaborates with other health professionals to whom consumers have been referred.	<ul style="list-style-type: none">• Ability to describe collaborative efforts with other health professionals for the delivery of primary health care services.
4	Acts to ensure consumers in need of emergency medical care are promptly directed to the most appropriate source of care.	<ul style="list-style-type: none">• Ability to describe and/or promptly access information on appropriate lines of referral for medical emergencies (e.g. cardiac arrest, epileptic seizure, asthma attack, poisonings and overdose).

Standard 6.2 Deliver primary health care

Performance criteria

Evidence examples

Element 1 – Ensure the clinical appropriateness of medicines and health care products

1	Establishes whether selected medicines or health care products are suitable for intended use.	<ul style="list-style-type: none">• Ability to clarify the clinical need for which a medicine or health care product has been requested or selected.
2	Assists consumers/carers to make informed choices on the selection of appropriate medicines or health care products.	<ul style="list-style-type: none">• Ability to provide explanation and/or justification for clinical intervention where medicines or health care products may not be appropriate or are contraindicated.• Ability to differentiate circumstances where a complex compounded product is the most appropriate means of satisfying the consumer's health care needs.• Ability to provide explanation/justification for advice provided to consumers/carers on medicines or health care product selection.

Performance criteria

Evidence examples

- | | |
|---|---|
| <p>3 Recommends medicines (including dosing regimen and form) or health care products that will satisfy the consumer's need and which are suitable and safe to use.</p> | <ul style="list-style-type: none">• Ability to recommend medicines (including dosing regimen and form) or health care products that will satisfy the consumer's therapeutic need, taking into account their health beliefs and preferences.• Ability to justify the decision to recommend the use of a complex compounded product in terms of consumer factors (e.g. medical conditions/disease states, age, weight, allergies, pregnancy and lactation), drug factors (e.g. bioavailability, pharmacokinetics, interactions, toxicity) or other factors that are likely to impact on its safety or suitability for use. |
|---|---|

Element 2 – Promote safe and effective use of medicines and health care products

- | | |
|---|--|
| <p>1 Assesses the consumer's need for information about the selected or recommended medicine or health care product.</p> | <ul style="list-style-type: none">• Ability to ask questions, listen and watch to determine the consumer's level of understanding and their need for additional information or demonstration of technique for use or care. |
| <p>2 Provides advice about the selected/ recommended medicine or health care product, using written consumer information resources as required for further clarification.</p> | <ul style="list-style-type: none">• Ability to explain, in terms appropriate for informing the consumer, about the complex compounded product and its use and place in overall treatment regimen, the expected outcomes and actions to take should these outcomes not be achieved.• Ability to use written information resources (e.g. cautionary and advisory labels, equipment instruction leaflets) to clarify or reinforce advice provided. |
| <p>3 Ensures that the consumer/carer understands how the medicine or health care product is to be used/ administered.</p> | <ul style="list-style-type: none">• Ability to check that the information provided has been understood (e.g. uses questions to confirm understanding, interprets cues that information has not been understood, and restates information in a different way to improve clarity).• Ability to check the consumer's technique for using the recommended complex compounded product and any other associated health care product, aid or device. |
| <p>4 Works with the consumer/carer to positively impact on the benefits derived from use of a recommended medicine or product.</p> | <ul style="list-style-type: none">• Ability to identify other factors (e.g. fluid intake, dietary measures) that may assist the therapeutic actions of the recommended treatment or reduce exacerbations of symptoms/conditions. |

Performance criteria

Evidence examples

- | | | |
|---|--|---|
| 5 | Undertakes follow-up of consumers where indicated to monitor progress and/or outcomes. | <ul style="list-style-type: none">• Ability to discuss criteria by which consumers may be selected for follow-up (e.g. anxiety and/or poor capacity to understand medicines or dosing information, further information to be provided or referral to a medical practitioner).
• Ability to undertake follow-up in a manner that is consistent with consumer expectations and/or consent. |
|---|--|---|

Element 3 – Support non-medicinal management options

- | | | |
|-------|--|---|
| 1 | Explains reasons for advising against the use of medicines. | <ul style="list-style-type: none">• Ability to identify and describe situations where the use of complex compounded products and other medicines is either not indicated or is likely to be of limited benefit.
• Ability to explain/justify decisions for advising against medicines treatment. |
| <hr/> | | |
| 2 | Recommends non-medicinal interventions or actions to assist management of symptoms/conditions. | <ul style="list-style-type: none">• Ability to identify and describe non-medicinal actions or interventions that may have a positive impact on the severity, frequency or duration of the symptoms/condition (e.g. dietary and sleeping habits or exercise routines or other lifestyle factors). |
| <hr/> | | |
| 4 | Offers suggestions for other possible sources of support or assistance. | <ul style="list-style-type: none">• Ability to describe or promptly access information on relevant services, organisations or health programs that may offer support or assistance. |

Element 5 – Manage records for primary health care services

- | | | |
|---|--|--|
| 1 | Ensures primary health care services, including progress and/or outcomes, are recorded accurately in the consumer medication record consistent with legislative requirements and professional standards and conventions. | <ul style="list-style-type: none">• Ability to describe or promptly access information on legal and professional requirements for updating the consumer medication record.
• Ability to describe a system of documentation that captures details of the primary health care service provided, including advice, product and product use recommendations, actions and interventions and progress or health outcomes achieved.
• Ability to demonstrate compliance with legal and professional requirements for recording primary health care services, including those involving the recommended use of a complex compounded product. |
|---|--|--|

Standard 6.3 Contribute to public and preventive health

Element 3 – Support consumer health literacy and self-management

- | | | |
|---|--|--|
| 1 | Encourages and supports consumers to enhance their health literacy. | <ul style="list-style-type: none">• Ability to discuss a partnership approach with consumers for building health literacy.• Ability to discuss options for enhancing consumer access to reliable resources and information for maintaining health and wellness.• Ability to discuss the importance of providing consumers with effective and relevant choices for maintaining their health. |
| 2 | Identifies consumers likely to benefit from provision of specific health and lifestyle advice. | <ul style="list-style-type: none">• Ability to explain the behaviours that reflect readiness to respond to preventive health advice.• Ability to describe consumer groups likely to benefit from targeted educational advice. |
| 3 | Delivers responsible, consistent, evidence-based advice to consumers about the potential benefits of preventive health activities. | <ul style="list-style-type: none">• Ability to provide relevant evidence-based preventive health/lifestyle advice (e.g. diet, smoking, exercise) to consumers without engendering resistance or other adverse reaction.• Ability to provide information and advice in a form, format and language that promotes understanding.• Ability to reinforce preventive health messages in a manner consistent with that provided to consumers by other members of the health care team.• Ability to use electronic aids (e.g. PowerPoint presentation) and/or print materials (e.g. newsletters, posters, brochures) to support the delivery of public health information. |
| 4 | Confirms consumers' understanding of risk factors and strategies for reducing the risk of disease. | <ul style="list-style-type: none">• Ability to ask questions and seek feedback to assess consumer understanding.• Ability to modify the form, format and/or language used to deliver information and advice to enhance understanding. |
| 5 | Supports and reinforces consumers' efforts at self-management of their risk factors for disease. | <ul style="list-style-type: none">• Ability to describe and/or demonstrate the use of a system for follow-up of consumers counselled about the need to modify their risk factor exposure.• Ability to discuss strategies proven to be effective in motivating consumers to continue with preventive health activities/lifestyle choices. |

Domain 8: Critical analysis, research and education

Standard 8.1 Retrieve, analyse and synthesise information

Performance criteria	Evidence examples
Element 1 – Manage information resources and systems	
1 Ensures information resources are sufficient and appropriate for the types of information usually requested/ provided.	<ul style="list-style-type: none"> • Ability to justify the adequacy (e.g. relevant, current, accurate, evidence-based) of information resources held in terms of the volumes and types of information usually sought or requested. • Ability to explain and justify the criteria (e.g. quality of content, application and limitations, and cost) applied to evaluate the likely value of potential new information resources relevant to complex compounding.
2 Establishes search strategies for the most common types of information requested/needed.	<ul style="list-style-type: none"> • Ability to produce a search strategy for various types of information needed or requested. • Ability to explain the logic in the cascade of information resources cited in specific search strategies.
3 Establishes conventions for setting information retrieval priorities.	<ul style="list-style-type: none"> • Ability to explain conventions applicable to information retrieval priorities in terms of factors such as urgency of need, complexity of information sought, coexisting work requirements and available resources.
4 Develops a medicines and health information contact network.	<ul style="list-style-type: none"> • Ability to describe the role/uses of information network contacts (e.g. government departments and agencies, educators and other professionals involved in complex compounding, pharmaceutical companies, raw material and equipment suppliers).
5 Ensures accurate and complete records are securely stored and can be promptly retrieved.	<ul style="list-style-type: none"> • Ability to demonstrate the use of a standardised format for recording information searches, findings and how these were used for complex compounded products. • Ability to describe the conventions applied for storage of records. • Ability to apply a logical system for secure storage of records. • Ability to promptly and conveniently access securely stored records

Performance criteria

Evidence examples

Element 2 – Retrieve information

1	Clarifies the nature and urgency of the required information.	<ul style="list-style-type: none">• Ability to establish the urgency with which a compounded product or related information is required.• Ability to ask questions, listen and restate requirements to ensure clarity and agreement on information needs.• Ability to concisely describe the nature, level of complexity and form in which information is required.
2	Considers the adequacy of available information resources for meeting information needs.	<ul style="list-style-type: none">• Ability to differentiate types of information resources (e.g. advertorial/promotional materials, objective/independent reference texts, peer-reviewed journal articles/research papers) on the basis of their quality, suitability and reliability.• Ability to discuss the scope and usefulness (applications and limitations) of a range of information resources, including indexing and abstracting services and electronic database relevant to complex compounding.
3	Accesses additional information sources where those in the workplace are found to be inadequate.	<ul style="list-style-type: none">• Ability to identify circumstances where available information resources are inadequate for responding to information needs.• Ability to select and justify the choice of other information sources (e.g. drug information centres, government agencies, pharmaceutical manufacturers or other pharmacists) for meeting information needs.
4	Applies a systematic search strategy for responding to information needs.	<ul style="list-style-type: none">• Ability to apply a defined search strategy for a specific type of information.• Ability to develop and apply a logical and appropriate search strategy for required information in the absence of a defined search strategy.
5	Selects relevant information/literature from a variety of resources, including electronic databases.	<ul style="list-style-type: none">• Ability to demonstrate the use of a variety of electronic and hard copy resources to retrieve relevant information/literature.• Ability to select and justify the selection of material considered relevant for satisfying information needs.

Performance criteria

Evidence examples

Element 3 – Review and analyse information

1	Understands basic concepts and terminologies required to critically analyse clinical information.	<ul style="list-style-type: none">• Ability to describe the differences between ‘levels of evidence’ that apply to clinical research such as those applied by the National Health and Medical Research Council (NHMRC) (e.g. Level II – well designed randomised controlled trial (RCT), Level IV – case series).• Ability to explain the meaning of statistical terms and/or methods commonly used in scientific/medical literature (e.g. relative and absolute risk, statistical significance, confidence intervals (CI), number needed to treat (NNT), cost-effectiveness and cost-benefit analysis).
2	Establishes the extent to which confidence may be placed in the content of clinical papers.	<ul style="list-style-type: none">• Ability to discuss the quality and reliability of information in primary sources (e.g. RCT in peer-reviewed journal versus unreferenced statement).• Ability to discuss the validity of methods used (e.g. avoidance of bias, sampling methods, inclusion/exclusion criteria, use of surrogate markers).• Ability to explain the clinical significance or impact on product use of new information from primary sources.
3	Understands and interprets the retrieved information.	<ul style="list-style-type: none">• Ability to explain the content of clinical papers, including those relating to comparative efficacy and safety of medicines, cost effectiveness and the pharmacokinetics of different dosage forms.
4	Uses professional judgement to reconcile divergent or conflicting information and/or form a view where there is a paucity of information.	<ul style="list-style-type: none">• Ability to identify situations where retrieved information is inconsistent or in conflict.• Ability to determine and justify a course of action/recommendation in the face of divergent or conflicting information or where there is a paucity of information.

Element 4 – Synthesise information

1	Integrates retrieved information into a clear, cohesive, objective and succinct response.	<ul style="list-style-type: none">• Ability to integrate information from diverse sources to reach a decision or provide an objective and unambiguous response/summary.• Ability to clearly relate the retrieved information to the request/information need, presenting circumstances and/or consumer or drug factors.
2	Constructs the response in a professionally defensible and responsible manner.	<ul style="list-style-type: none">• Ability to describe issues (professional, ethical and legal) impacting on the way findings, advice, opinions and recommendations can or should be presented or used.

Performance criteria

Evidence examples

3	Applies a standardised referencing technique to link information to the evidence base.	<ul style="list-style-type: none">• Ability to produce a fully referenced information summary and use a referencing technique of the type used in scientific writing (e.g. the Vancouver System).
4	Explains the evidence base underpinning the response clearly and concisely.	<ul style="list-style-type: none">• Ability to clearly explain the evidence-based content of the response making reference, where appropriate, to the request/information need, presenting circumstances and consumer or drug factors.
5	Substantiates professional advice, opinions and recommendations contained within the response.	<ul style="list-style-type: none">• Ability to differentiate professional opinion, advice or recommendations from literature findings.• Ability to justify opinions, advice and recommendations by reference to the evidence base, pharmacological knowledge, consumer or drug factors and/or presenting circumstances.

Standard 8.2 Engage in health, medicines and pharmacy practice research

Performance criteria

Evidence examples

Element 1 – Understand research principles and concepts

1	Understands research ethics and methods and key issues impacting on the design of research protocols.	<ul style="list-style-type: none">• Ability to discuss ethical principles relevant to undertaking research (e.g. avoidance of conflict of interest, respect of participating individuals, maintenance of integrity and beneficence).• Ability to describe key factors to be considered in the design of research protocols (e.g. sample size, duration, inclusion and exclusion criteria, avoidance of bias, analysis technique).• Ability to describe the differences in core features of common research methods (e.g. case control study, cohort study, RCT, qualitative research methods).
2	Understands statistical terms and techniques used to analyse research data.	<ul style="list-style-type: none">• Ability to describe statistical terms and techniques (e.g. t-test, p-value, confidence intervals, regression analysis).• Ability to discuss how statistical issues (e.g. sample size) impact on research design.• Ability to describe key economic concepts such as cost-effectiveness and cost benefit.
3	Understands the relationship that must be maintained between the research question, the findings and conclusions.	<ul style="list-style-type: none">• Ability to describe the direct and logical connection between the research question, what the research has shown and the conclusions drawn.

Performance criteria

Evidence examples

4 Understands the importance of consumer involvement in research.

- Ability to discuss the means by which consumer involvement in research is encouraged and facilitated.

Element 2 – Conduct research

1 Adopts a rigorous and systematic approach to identifying areas where there is a gap in the evidence base.

- Ability to apply a systematic approach to identify and prioritise areas where there are gaps in the evidence base.
- Ability to describe and justify a research need.
- Ability to clearly articulate the research question intended to be answered by the proposed research.

2 Critically analyse and review literature to establish existing knowledge in the area of research interest.

- Ability to undertake a literature review of the area of research interest.
- Ability to discuss the evidence gap demonstrated by the literature review.

3 Develops and defines the research concept and methodology or protocol.

- Ability to develop a research concept and proposal to explore the area of research interest.
- Ability to explain how the research proposal addresses the identified gap in evidence.
- Ability to justify the appropriateness of the research method for exploring the research question.

4 Ensures required approvals are secured.

- Ability to describe approvals required as prerequisites for commencement of research (e.g. institutional or ethics committee approvals, grant application approval for funding).
- Ability to complete documentation required to gain relevant approvals.

5 Conducts the research according to the research proposal, explicitly accounting for any variations.

- Ability to collect and document quantitative and/or qualitative data relevant to the research question.
- Ability to describe any variations to methodology, their impact and how these have been addressed to assure the validity of the research.

6 Analyses and interprets the research results to clarify findings.

- Ability to accurately undertake calculations and statistical analysis on grouped data, including costs.
- Ability to apply analytical and clinical reasoning skills to results to establish the research findings.
- Ability to discuss research findings in terms of the research question.

Performance criteria

Evidence examples

7	Formulates discussion and conclusions that are supported by the research findings.	<ul style="list-style-type: none">• Ability to explain and justify the discussion and conclusions in terms of the research findings.• Ability to recognise and describe the limitations of the research methodology and/or findings.• Ability to describe the clinical significance of the findings and/or the extent to which they may be generalised or applied to other settings.
8	Accepts responsibility for the management and retention of research data and materials.	<ul style="list-style-type: none">• Ability to discuss the data and primary materials that should be retained.• Ability to describe or demonstrate use of a secure and accessible data storage system.
9	Documents research findings, including negative findings, accurately and completely.	<ul style="list-style-type: none">• Ability to write a scientific paper that accurately reports methods, findings and conclusions.

Element 3 – Disseminate and apply findings

1	Identifies the most appropriate dissemination strategies for sharing findings with colleagues and the wider community.	<ul style="list-style-type: none">• Ability to describe a range of dissemination strategies for sharing research findings (e.g. web-based publication, in-service presentation in the workplace, publication in professional journal, national or international conference presentation).
2	Promotes practice change and enhanced knowledge by responsibly sharing research findings.	<ul style="list-style-type: none">• Ability to justify the choice of dissemination strategy.• Ability to apply dissemination strategies to responsibly share research findings.
3	Integrate research evidence into professional practice.	<ul style="list-style-type: none">• Ability to describe and justify required adjustments to workplace systems or practices in response to research findings.• Ability to demonstrate the application of research evidence into systems or policies and procedures.• Ability to describe practice changes initiated as a result of application of research evidence.