STANDARDS NEW ZEALAND
PAEREWA AOTEAROA

NZS 8134.7:2010

New Zealand Standard

Health and Disability Services Pharmacy Services Standard

NZS 8134.7:2010

MINISTRY OF HEALTH
MANATŪ HAUORA

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In particular, we wish to thank Alan Fraser for chairing the committee.

Permission has been obtained from the Pharmaceutical Inspection Co-operation Scheme (PIC/S) for the use of section 7.

COMMITTEE REPRESENTATION

This Standard was prepared under the supervision of the P 8120 Committee the Standards Council established under the Standards Act 1988.

The committee consisted of representatives of the following:

Nominating Organisation	Committee Member
Accident Compensation Corporation	Sunita Goyal
Association of Residential Care Homes (NZ) Inc.	Jessica Buddendijk
Clinical Advisory Pharmacists' Association	John Dunlop
Consumer NZ Inc.	Mark Bedford
DHBNZ Safe and Quality Use of Medicines Group	Avril Lee
Grey Power New Zealand Federation Inc.	Roy Reid
Healthcare Providers New Zealand	Jessica Buddendijk
Ministry of Health	Sue Scott
New Zealand College of Pharmacists Inc.	Chris Budgen
New Zealand Hospital Pharmacists' Association Inc.	William Allan
Pharmaceutical Society of New Zealand Inc.	Euan Galloway
Pharmacy Council of New Zealand	Barbara Moore
Pharmacy Guild of New Zealand Inc.	Rebecca Cheng
Pharmacy Industry Training Organisation	Jill Watt
NQIP Safe Medication Management Programme	Colette Burns
Royal New Zealand College of General Practitioners	Helen Moriarty
School of Pharmacy, University of Auckland	Sanya Ram

Compounding and Dispensing Working Group	Aseptic Dispensing Working Group
Chris Budgen (Chairperson)	Sue Scott (Chairperson)
Jason Gray	William Allan
Lillian Handey	Mark Bedford
Nish Vythilingham	Derryn Gargiulo
Sue Wiltshire	Maree Jensen

AMENDMENTS

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HEALTH AND DISABILITY SERVICES
PHARMACY SERVICES STANDARD

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REFERENCED DOCUMENTS

Reference is made in this document to the following:

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NZS 4121:2001	Design for access and mobility: Buildings and associated facilities
NZS 4304:2002	Management of healthcare waste
NZS 8134:2008	Health and disability services Standards
NZS 8134.1:2008	Health and disability services Standards – Health and disability services (core) Standards
NZS 8134.3:2008	Health and disability services (infection prevention and control) Standards

JOINT AUSTRALIAN/NEW ZEALAND STANDARDS

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SAA SNZ HB 436:2004	Risk management guidelines – Companion to AS/NZS 4360:2004

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New Zealand Building Code (NZBC) and Compliance Documents

New Zealand Public Health and Disability Act 2000

Privacy Act 1993

Resource Management Act 1991

Smoke-free Environments Act 1990

CODES

Code of Health and Disability Services Consumers' Rights 1996

Health Information Privacy Code 1994

New Zealand Code of Good Manufacturing Practice for Manufacture and Distribution of Therapeutic Goods, Part 3: Compounding and Dispensing 1993 (Code of GMP)

WEBSITES

Medsafe	http://www.medsafe.govt.nz
Ministry of Health	http://www.moh.govt.nz
New Zealand Legislation	http://www.legislation.govt.nz
Office of Health and Disability Commissioner	http://www.hdc.org.nz
Pharmacy Council of New Zealand	http://www/pharmacycouncil.org.nz

LATEST REVISIONS

The users of this Standard should ensure that their copies of the above-mentioned New Zealand Standards are the latest revisions. Amendments to referenced New Zealand and Joint Australian/New Zealand Standards can be found on http://www.standards.co.nz.

RELATED DOCUMENTS

Although not referenced in this Standard the following documents also contain helpful information:

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REVIEW OF STANDARDS

It is intended that NZS 8134.7:2010 is dynamic and reflects current accepted good practice. Regular reviews of the Standard will be undertaken to ensure that this is achieved, and that the Standard remains appropriate and applicable. Suggestions for improvement of this Standard will be welcomed. They should be sent to the Chief Executive, Standards New Zealand, Private Bag 2439, Wellington 6140.

FOREWORD

The *Health and disability services – Pharmacy services Standard* is generic in nature and forms part of the health and disability services Standards, which were revised and published in 2008.

NZS 8134.7 *Health and disability services – Pharmacy services Standard* is the foundation for describing good practice and fostering continuous improvement in the quality of pharmacy services.

Pharmacies and the services they provide have previously been required to meet the *Quality standards for pharmacy in New Zealand*. This document was published by the Pharmaceutical Society of New Zealand when it was the organisation with the statutory responsibility for pharmacists and pharmacies. It was used, with other documents, in the quality audits of pharmacies currently undertaken by the Ministry of Health.

To establish whether there was a need to develop a new Standard for pharmacy services in New Zealand, a scoping project was commissioned by the Ministry of Health. As a result, the committee of pharmacy sector experts agreed a new Standard was required to ensure pharmacy providers supplied good and safe services for consumers.

This Standard NZS 8134.7 is made up of introductory material in section 0, with core provisions on consumer rights and organisational management adapted from NZS 8134, in sections 1 and 2. Sections 3 and 4 contain material on the continuum of service delivery and safe and appropriate environments also from NZS 8134 but modified for the pharmacy setting. Section 5 outlines pharmacy dispensing, compounding, repackaging and batch preparation practice requirements based on the *New Zealand Code of good manufacturing practice for manufacture and distribution of therapeutic goods (GMP) – Part 3 Compounding and dispensing*. Material on the preparation of sterile products in community and hospital pharmacies has also been developed and incorporated as sections 6 and 7 on aseptic dispensing in the different settings.

NZS 8134.7 replaces the *Quality standards for pharmacy in New Zealand* and the *New Zealand Code of good manufacturing practice for manufacture and distribution of therapeutic goods, Part 3: Compounding and dispensing*.

0 GENERAL

0.1 SCOPE

The *Pharmacy services Standard* is designed to ensure that consumers are clear about their rights and providers are clear about their responsibilities for good and safe outcomes. This Standard defines the quality and safety requirements for the provision of community and hospital-based pharmacy services and clinical pharmacy services not provided from a pharmacy. The Standard more closely aligns with the wider health sector and forms part of the NZS 8134:2008 *Health and disability services Standards* suite of documents by aligning with the core Standards.

The *Pharmacy services Standard* aims to achieve the following outcomes:

(a) Consumers receive safe and appropriate services that comply with consumer rights legislation;

(b) Consumers receive timely services which are planned, coordinated and delivered in an appropriate manner;

(c) Services are managed in a safe, efficient and effective manner which complies with legislation; and

(d) Services are provided in a clean, safe environment which is appropriate for the needs of the consumer.

0.2 CONSUMER-ORIENTED SERVICES

This Standard incorporates the following principles of consumer-oriented pharmacy care set out in the ten principles of the *Pharmacy Council Code of Ethics*:

(1) The pharmacist shall promote consumer self-determination, respecting the consumer's right to understandable information, privacy, and confidentiality;

(2) The pharmacist shall optimise medicines-related health outcomes for the consumer according to their concerns, needs, cultural values, and beliefs;

(3) The pharmacist shall act to prevent harm to the consumer and the public;

(4) The pharmacist shall practise fairly and justly and promote family, whānau, and community health;

(5) The pharmacist shall actively seek and apply contemporary pharmacy knowledge and skills to ensure a high standard of professional competence;

(6) The pharmacist shall practise in a manner that does not compromise their own professional independence, judgement or integrity, or that of other pharmacists;

(7) The pharmacist shall act in a manner that promotes public trust in the knowledge and ability of pharmacists and enhances the reputation of the profession;

(8) The pharmacist shall provide information about professional services, medicines, and healthcare products in a dignified manner without making exaggerated or unsubstantiated claims;

(9) The pharmacist shall respect the skills and competencies of other healthcare providers and endeavour to work cooperatively with them to optimise the health outcomes of mutual consumers and the public;

(10) The pharmacist shall demonstrate a caring and compassionate manner.

0.3 MĀORI HEALTH

To achieve Māori health improvement and the reduction of Māori health inequalities, NZS 8134.7 focuses on:

(a) Ensuring accessible and appropriate services for Māori;

(b) Providing quality improvement systems that focus on Māori receiving health services commensurate with their health needs; and

(c) Enabling Māori and whānau involvement in health decisions.

NZS 8134.7 aligns with the strategies and goals of the *Māori health strategy for the pharmacy profession*, available on http://www.pharmacycouncil.org.nz.

NZS 8134 builds on the framework and principles for the public sector to take into account in supporting the health status of Māori as set out in *He korowai oranga: Māori health strategy*. Refer to http://www.moh.govt.nz.

0.4 INTRODUCTION

The delivery of optimal pharmacy services depends on both the competence of the pharmacist providing the service and the quality of the system through which that service is delivered. The intention of this *Pharmacy services Standard* is to set minimum quality Standards for the delivery of the service. Pharmacist competency is not covered by this *Pharmacy services Standard* but will continue to be covered by the *Pharmacy Council Competence Standards* for the *Pharmacist Scope of Practice*.

The broad diversity and uniqueness of the pharmacy sector has necessitated the use of generic phrases and terminology throughout the Standard which are to be interpreted according to the service setting. It is not the intention however, to standardise terminology throughout the different parts of the pharmacy sector. Rather it is expected that each service provider will interpret the intent of the statements used in the Standard for the service that they provide. In the development of NZS 8134.7, there has been a move away from extensively detailing specific inputs, instead concentrating on the outcome to be achieved. The exceptions to the outcome-focus of NZS 8134.7 are the prescriptive requirements of section 5 on dispensing, compounding, repackaging and batch preparation, and the sterile preparation requirements of sections 6 and 7. These exceptions are driven by the technical requirements of the activities.

Good practice is used in NZS 8134.7 and not the term 'best practice'. The use of the term 'best practice' implies that there is only one accepted approach to achieve a quality outcome whereas the use of the term 'good practice' allows for more than one accepted approach.

The definition of good practice is the current accepted range of safe and reasonable actions that result in efficient and effective use of available resources to achieve quality outcomes, and minimise risk for the consumer. Current accepted good practice should also reflect standards for service delivery where these exist.

Service provider, service and organisation are used throughout this Standard. All three terms are included in the definitions. Service provider refers to the individual delivering a service to the consumer. The term service is used to describe what is delivered by the service provider. The organisation is the entity legally responsible for and accountable for the services delivered.

0.5 INTERPRETATION

In NZS 8134.7 the word 'shall' refers to practices that are mandatory for compliance. 'Shall' is also used for practices that are already mandated in other documents. The word 'should' refers to practices that are advised or recommended. An exception to this usage occurs in section 7, *Aseptic dispensing of sterile products in hospital pharmacies*. In section 7 the words 'should' and 'shall' both refer to mandatory activities.

See Appendix A for an explanation of defined terms and abbreviations used in this Standard.

General guidance on how to meet the criteria in NZS 8134.7 is included throughout, and prefixed by the letter '**G**'. The purpose of the guidance is to assist with the interpretation of the criteria for each Standard by providing examples, which are general in nature, and do not necessarily include all methods that can be used to meet the criteria of each Standard.

The term 'normative' has been used in this Standard to define the application of the appendix to which it applies. A 'normative' appendix is an integral part of the Standard and contains requirements.

GUIDANCE

G 1 The purpose is to assist health and disability service providers to give effect to the Code of Health and Disability Services Consumers' Rights (the Code). Service providers will need to be able to demonstrate how their service, as well as their practice, complies with the Code. A provider is not in breach of the Code if the provider has taken reasonable actions in the circumstances to give effect to the rights, and comply with the duties, in this Code. The onus is on the provider to prove it took reasonable actions. For clarity, 'the circumstances' means all the relevant circumstances, including the consumer's clinical circumstances and the provider's resource constraints.

G 1.1.1 Education, including induction and ongoing professional development, is given to all service providers relevant to their role and level of contact with consumers.

G 1.2.1 The manner in which consumers are informed of their rights may vary according to the nature of the service.

G 1.2.2 Service providers may need to organise an interpreter to ensure a consumer is aware of their rights, so effective communication can occur and the consumer can be fully informed and able to make informed decisions. A summary of the Code is available in several languages on the website of the Health and Disability Commissioner (http://www.hdc.org.nz/theact/theact-thecode). The Code could be put into plain language (using graphics), talking book format, or printed in large text or in Braille (available from the Royal New Zealand Foundation of the Blind).

Other rights covered by NZS 8134.1 include those outlined in the:

(a) Human Rights Act;

(b) Privacy Act;

(c) Consumer Guarantees Act; and

(d) Health Information Privacy Code.

G 1.2.4 The manner in which the information is displayed may vary according to the nature of the service.

G 1.3.1 This may include, but is not limited to:

(a) An area for consultations to be undertaken in physical, visual and/or auditory privacy;

(b) Advice to consumers indicating that private areas are available for consultations.

G 1.3.2 Services need to be able to demonstrate how this is achieved. This may include, but is not limited to:

(a) Ensuring consumers unable to represent themselves, access input from family/whānau of choice where appropriate in order to maintain their cultural values and beliefs during service delivery;

(b) Specific training to prepare service providers to respond appropriately;

(c) Policy guidance for service providers on culturally competent practice, how to respond to culturally related requests, where to find relevant references and resources, and how to seek assistance when this is required;

(d) Access to a Māori advisory group to provide practical assistance to service providers to enable the service providers to achieve culturally competent practice with Māori consumers and whānau;

(e) The consumer, and when requested by the consumer, the family/whānau or other representatives, are consulted about individual values and beliefs.

G 1.3.4 Services need to be able to demonstrate how this is achieved. This may include, but is not limited to:

(a) Sexual health information pertinent to the consumer is readily available;

(b) No distinctions are made between consumers because of their sexuality;

(c) A policy defining how consumers seeking emergency contraception are referred for immediate care if the pharmacy does not provide this service.

1 CONSUMER RIGHTS – PHARMACY

Outcome 1 Consumers receive safe services of an appropriate standard that comply with consumer rights legislation. Services are provided in a manner that is respectful of consumer rights, facilitates informed choice, minimises harm, and acknowledges cultural and individual values and beliefs.

CONSUMER RIGHTS DURING SERVICE DELIVERY

Standard 1.1 **Consumers receive services in accordance with consumer rights legislation.**

Criterion The criterion required to achieve this outcome shall include the organisation ensuring:

1.1.1 Service providers demonstrate knowledge and understanding of consumer rights and provider's obligations, and incorporate them as part of their everyday practice.

Standard 1.2 **Consumers are informed of their rights.**

Criteria The criteria required to achieve this outcome shall include the organisation ensuring:

1.2.1 The *Code of Health and Disability Services Consumers' Rights* (the Code) is clearly displayed and easily accessible to all consumers.

1.2.2 Information about the Code and other rights is provided at the earliest opportunity in languages and formats suited to the needs of consumers who use the service.

1.2.3 Opportunities are provided for explanations, discussion, and clarification about the Code with the consumer, family/whānau of choice where appropriate and/or their legal representative during contact with the service.

1.2.4 Information about the Nationwide Health and Disability Advocacy Service and, where they exist, peer/consumer advocacy services is clearly displayed and brought to the attention of the consumer who may need the service.

INDEPENDENCE, PERSONAL PRIVACY, DIGNITY, AND RESPECT

Standard 1.3 **Consumers are treated with respect and receive services in a manner that has regard for their dignity, privacy, and independence.**

Criteria The criteria required to achieve this outcome shall include the organisation ensuring:

1.3.1 The service provider respects the physical, visual, auditory, and personal privacy of the consumer and their belongings at all times.

1.3.2 Consumers receive services that are responsive to the needs, values, and beliefs of the cultural, religious, social, and/or ethnic group with which each consumer identifies.

1.3.3 Consumers shall be addressed in a respectful manner by their preferred name.

1.3.4 Consumers' sexuality is respected in a manner that ensures the rights of the individual are protected.

GUIDANCE

G 1.3.6 Specific policies and procedures on abuse and neglect may include but are not limited to:

(a) Mechanisms to identify and respond in a timely manner to incidents of abuse or neglect. This could include physical abuse, emotional abuse, or signs of untreated health issues;

(b) Education programmes for service providers are repeated at appropriate intervals to maintain knowledge.

For further information refer to:

(i) *Family violence intervention guidelines – Child and partner abuse* (Ministry of Health)

(ii) *Family violence intervention guidelines – Elder abuse and neglect* (Ministry of Health)

(iii) Sections 15 and 16 of the Children, Young Persons, and Their Families Act, which authorise the reporting of suspected child abuse to a social worker or a member of the Police.

G 1.4.1 This may include but is not limited to:

(a) Recognising the cultural diversity and uniqueness of Māori and eliminating the risk of discrimination;

(b) Developing a monitoring strategy with iwi, hapū and whānau to evaluate services for Māori through the primary health organisation(s) or community pharmacy group the service provider affiliates within all areas of service planning, development and implementation affecting Māori;

(c) Recognising that spirituality is inextricably linked to Māori well-being;

(d) Actively recruiting service providers that reflect the consumer population;

(e) Utilising Māori models of health where possible when developing management plans.

G 1.4.2 This may be achieved by, but is not limited to:

(a) The use of printed material or media that will effectively inform Māori about the service(s) being provided;

(b) The use of Te Reo Māori where appropriate;

(c) Providing information to referral sources;

(d) Availability of service providers acceptable to Māori;

(e) Access to Māori support and advocacy services;

(f) Access to interpreters.

G 1.4.3 This may include, but is not limited to:

(a) Demonstration through a Māori health plan that is developed and implemented by the service provider;

(b) Developing working relationships with key Māori stakeholders where appropriate in order to meet the needs of Māori consumers;

(c) Establishing and maintaining links with Māori stakeholders when developing new services;

(d) Evaluating recommendations and the level of satisfaction with service delivery by Māori consumers and their whānau using the service.

G 1.4.4 This may be achieved by, but is not limited to:

(a) Ensuring consumers unable to represent themselves access input from whānau, hapū and iwi in order to maintain their cultural values and beliefs during service delivery;

(b) Documentation of specific Māori cultural needs of the consumer;

(c) Involvement of kaumātua/kuia and tohunga;

(d) Validation and observance of the Māori perspective of health which includes cultural, social, spiritual, whānau, environmental, and emotional factors in addition to physical health;

(e) Recognition that culture may include the practice of traditional healing and treatments.

G 1.4.5 This may be achieved by, but is not limited to:

(a) Identifying opportunities and implementing procedures to incorporate whānau support during service delivery;

(b) Identifying and eliminating barriers to whānau support and participation;

(c) Involving whānau and their knowledge of the individual during service delivery.

1.3.5 Services are provided in a manner that maximises each consumer's independence and reflects the wishes of the consumer.

1.3.6 Consumers are kept safe and are not subject to, or at risk of, abuse and/or neglect.

RECOGNITION OF MĀORI VALUES AND BELIEFS

Standard 1.4 **Consumers who identify as Māori have their health and disability needs met in a manner that respects and acknowledges their individual and cultural values and beliefs.**

Criteria The criteria required to achieve this outcome shall include the organisation ensuring:

1.4.1 Māori consumers receive services consistent with their cultural values and beliefs.

1.4.2 Māori consumers have access to appropriate services, and barriers to access within the control of the organisation are identified and eliminated.

1.4.3 The organisation plans to ensure Māori receive services commensurate with their needs.

1.4.4 Māori consumers' right to practise their cultural values and beliefs while receiving services is acknowledged by service providers.

1.4.5 The importance of whānau and their involvement with Māori consumers is recognised and supported by service providers.

GUIDANCE

G 1.5.1 This may be achieved by, but is not limited to:

(a) Developing a community profile to identify cultural mix, which may be achieved in conjunction with DHB or PHO health needs analysis;

(b) Knowing where and how to access local community support organisations;

(c) Developing relationships with key community groups and undertaking consultation on a regular basis.

G 1.5.2 This may include, but is not limited to demonstrating consultation with community groups.

G 1.6.1 Policies and procedures need to outline safeguards to protect consumers from discrimination, coercion, harassment and exploitation along with the actions that will be taken if there is inappropriate or unlawful conduct and the safety of a consumer is compromised or put at risk. This relates to discrimination that is unlawful under Part 2 of the Human Rights Act. As applicable, these policies should include, but are not limited to:

(a) Responsiveness to complaints of any form of impropriety;

(b) Management of consumer finances and personal accounts as they pertain to the service provider.

G 1.6.2 As applicable, these policies should include, but are not limited to:

(a) Conflict of interest (for example, policies and procedures address the accepting of gifts and personal transactions with a consumer);

(b) The appropriate code for the service provider. This may include the *Pharmacy Council Code of Ethics*.

G 1.7 Various sections of this Standard deal specifically with a consumer's right to receive services of an appropriate quality. This includes:

(a) Human resource management for employing competent service providers, ongoing education, supervision and mentoring arrangements;

(b) Policies and procedures for providing continuity of care and cooperation between providers;

(c) Incident reporting systems that are linked to open disclosure and quality improvement processes.

G 1.7.1 This may be achieved by, but is not limited to:

(a) The organisation supporting compliance with all legal, professional and ethical standards.

(b) The organisation making available to service providers a range of opportunities which may include, but are not limited to:

(i) Reference material and resources;

(ii) Conference attendance;

(iii) Study days;

(iv) Evidence-based guidelines;

(v) Clinical pathways;

(vi) Treatment protocols;

(vii) Access to mentoring, supervision and professional development;

(viii) Consumer developed and provided education;

(ix) Access to professional networking opportunities for service providers to share their knowledge.

Policies and procedures should be based on evidence-based rationales, which are monitored and evaluated.

RECOGNITION AND RESPECT OF THE INDIVIDUAL'S CULTURE, VALUES, AND BELIEFS

Standard 1.5 **Consumers receive culturally safe services which recognise and respect their ethnic, cultural, and spiritual values and beliefs.**

Criteria The criteria required to achieve this outcome shall include the organisation ensuring:

1.5.1 Consumers receive services in a manner that takes into account their cultural and individual values and beliefs.

1.5.2 The consumer and, when appropriate and requested by the consumer, the family/whānau of choice or other representatives, are consulted on their individual values and beliefs.

DISCRIMINATION

Standard 1.6 **Consumers are free from any discrimination, coercion, harassment, sexual, financial, or other exploitation.**

Criteria The criteria required to achieve this outcome shall include the organisation ensuring:

1.6.1 Policies and procedures are in place to ensure consumers are not subjected to discrimination, coercion, harassment, and sexual or other exploitation.

1.6.2 Service providers maintain professional boundaries and refrain from acts or behaviours which could benefit the provider at the expense or well-being of the consumer.

1.6.3 The organisation actively works to identify and address prejudicial attitudes and discriminatory practices and behaviours within its own service provision and any other service it has links with.

GOOD PRACTICE

Standard 1.7 **Consumers receive services of an appropriate standard.**

Criterion The criterion required to achieve this outcome shall include the organisation ensuring:

1.7.1 The organisation provides an environment that encourages good practice, which should include evidence-based practice.

GUIDANCE

G 1.8.3 This may be achieved by, but is not limited to service providers:

(a) Identifying themselves to consumers, using appropriate communication mediums;

(b) Wearing identification badges;

(c) Ensuring consumers are aware of the person(s) with whom they should discuss any aspect of their care.

G 1.8.4 This may include, but is not limited to:

(a) Accessing appropriately trained interpreter services where appropriate;

(b) Endeavouring to ensure that information, either given or received, is accurately understood.

G 1.9.1 Consent processes identified for the following situations, may include, but are not limited to:

(a) Routine situations appropriate to the service where informed consent is required, for example medicines use review (MUR) services;

(b) Consumers who are unable to consent;

(c) Children and young people;

(d) Involvement in teaching;

(e) Involvement in research;

(f) Meeting the needs of consumers.

G 1.9.2 The consumer is provided with understandable, written and verbal information on the potential benefits, adverse effects, alternatives, costs and predictable inconvenience associated with a particular treatment or therapy. With the consumer's informed consent, their family/whānau of choice may be provided with the same information where this is required. This may include, but is not limited to:

(a) Use of interpreters and advocates;

(b) Provision of information in a variety of languages and formats;

(c) A system of checking the information is understood;

(d) Provision of information suggesting other available methods of treatment or therapy, or the likely outcome of a 'no treatment' option.

G 1.9.5 This may be achieved by, but is not limited to ongoing training and education in the principles and practice of informed consent.

G 1.9.6 The choices and decisions recorded and acted on may vary according to the nature of the service. This may include but is not limited to:

(a) Identifying and recording consumer's desired outcomes;

(b) Identifying and recording the consumer's decisions about therapy.

COMMUNICATION

Standard 1.8 **Service providers communicate effectively with consumers and provide an environment conducive to effective communication.**

Criteria The criteria required to achieve this outcome shall include the organisation ensuring:

1.8.1 Consumers have a right to full and frank information and open disclosure from service providers.

1.8.2 Service providers allow sufficient time and an appropriate space for discussions to take place.

1.8.3 Consumers are assisted to identify service providers involved in their treatment.

1.8.4 Service providers use a range of communication tools suitable to the consumer's level of literacy and understanding.

INFORMED CONSENT

Standard 1.9 **Consumers and where appropriate their family/whānau of choice are provided with the information they need to make informed choices and give informed consent.**

Criteria The criteria required to achieve this outcome shall include the organisation ensuring:

1.9.1 Informed consent policies/procedures identify:

(a) Recording requirements;

(b) Information (including documentation) to be provided to the consumer by the service.

1.9.2 Service providers demonstrate their ability to provide the information that consumers need to have, to be actively involved in their recovery, care, treatment, and support as well as for decision-making.

1.9.3 Information is made available to consumers in an appropriate format and in a timely manner.

1.9.4 The service provider is able to demonstrate that written consent is obtained where required.

1.9.5 Service providers have a thorough knowledge and understanding of how to meet their duties to consumers under Rights 5, 6, and 7 of the Code of Health and Disability Services Consumers' Rights.

1.9.6 Consumer choices and decisions are recorded and acted on.

GUIDANCE

G 1.10.1 The information should be provided in a timely manner and in a way the consumer is able to understand.

ADVOCACY AND SUPPORT

Standard 1.10 **Service providers recognise and facilitate the right of consumers to advocacy/ support persons of their choice.**

Criteria The criteria required to achieve this outcome shall include the organisation ensuring:

1.10.1 Consumers are informed of their rights to an independent advocate, how to access them, and their right to have a support person(s) of their choice present.

1.10.2 The organisation has policies to facilitate the presence of advocates/support persons.

1.10.3 Service providers are educated to recognise this right to have an advocate/ support person present and identify and appropriately address circumstances where an advocate/support person is reasonable.

1.10.4 Consumers are supported to access services within the community when appropriate.

COMPLAINTS MANAGEMENT

Standard 1.11 **The right of the consumer to make a complaint is understood, respected, and upheld.**

Criteria The criteria required to achieve this outcome shall include the organisation ensuring:

1.11.1 An easily accessible, responsive, and fair complaints process, which is documented and complies with Right 10 of the Code of Health and Disability Services Consumers' Rights.

1.11.2 Information about a consumer's right to complain and the complaints process is available. Copies are provided for the consumer.

1.11.3 An up-to-date complaints register is maintained that includes all complaints, dates, and actions taken.

GUIDANCE

G 2.1.1 This may be achieved by, but is not limited to:

(a) The organisation's mission statement should be consistent with the philosophy of pharmacy practice as described in the preamble to the *Pharmacy Council Code of Ethics* and the requirements of the appropriate healthcare purchasers;

(b) Clearly identifying the goals, objectives and scope of service delivery including statements about quality activities;

(c) A written quality and risk management plan which may be separate or included in service/strategic/business plans.

G 2.1.2 This may include, but is not limited to:

(a) The organisation ensuring there are effective communication systems and working relationships in order to deliver coordinated services;

(b) The organisation's quality objectives reflect the need for both the provision of consumer-focused services and the continuous improvement of quality;

(c) The planning process incorporates research on pharmacy effectiveness, consumer outcomes, demographics and other relevant areas;

(d) The planning process identifies the human, financial and physical resources required for the service. This will influence the acquisition of resources and their allocation.

G 2.1.3 Management responsibilities are clearly specified by identifying a responsible person, for example the pharmacy licence holder and/or pharmacy manager who has overall responsibility for the quality management of the pharmacy.

G 2.2.1 In relation to a licence to operate a pharmacy, responsible persons include:

(a) The majority shareholder pharmacist(s);

(b) Person(s) responsible for the daily management of the pharmacy. At least one of these persons must be a pharmacist with a current Annual Practising Certificate.

G 2.2.3 Temporary absence includes, but is not limited to:

(a) Illness;

(b) Leave;

(c) Position vacancy.

2 ORGANISATIONAL MANAGEMENT – PHARMACY

Outcome 2 Consumers receive services that comply with legislation and are managed in a safe, efficient, and effective manner.

GOVERNANCE

Standard 2.1 **The organisation ensures services are planned, coordinated, and appropriate to the needs of consumers.**

Criteria The criteria required to achieve this outcome shall include the organisation ensuring:

2.1.1 The purpose, values, scope, direction, and goals of the organisation are clearly identified and regularly reviewed.

2.1.2 Organisational performance is aligned with, and regularly monitored against, the identified values, scope, strategic direction, and goals of the organisation.

2.1.3 The organisation is under the effective control of a suitably qualified and competent person with authority, accountability, and responsibility for the provision of services.

SERVICE MANAGEMENT

Standard 2.2 **The organisation ensures the day-to-day operation of the service is managed in an efficient and effective manner which delivers timely, appropriate, and safe services to consumers.**

Criteria The criteria required to achieve this outcome shall include the organisation ensuring:

2.2.1 The pharmaceutical services provided by the organisation are managed by a responsible person who is a pharmacist with authority, accountability, competency, and responsibility for the provision of services.

2.2.2 A charge pharmacist shall be identifiable at all times when pharmaceutical services are provided.

2.2.3 During a temporary absence of a manager a suitably qualified person performs the manager's role.

2.2.4 Services are planned to meet the specific needs of the consumer groups entering that service.

GUIDANCE

G 2.3.1 This may be achieved by, but is not limited to:

(a) A quality improvement and risk management policy;

(b) A quality and risk plan that is coordinated or integrated with the business or operational plan, and:

(i) Describes the quality and risk structure of the organisation

(ii) Demonstrates how key improvement activities link to quality and risk systems such as infection control, health and safety, compliance audits

(iii) Details the quality activities and projects for services

(iv) Describes the quality model in place in the organisation such as the PDSA cycle (Plan, Do, Study, Act), accreditation, or ISO certification;

(c) Reports of quality improvement activity that are communicated across the organisation;

G 2.3.3 This may be achieved by, but is not limited to:

(a) Identification and documentation of policies and procedures required by relevant standards and contracts;

(b) Documentation should cover all legislative, professional, and contractual requirements applicable to the operation of the service;

(c) Policies must specify that the holder of the pharmacy licence must not request or require any pharmacist who is employed or engaged in duties at the pharmacy to act in a way that is inconsistent with the applicable professional or ethical standards of pharmacy practice;

(d) Ensuring the quantity and detail specified in policies and procedures is relevant to the scope and complexity of the service provided;

G 2.3.4 This may be achieved by, but is not limited to:

(a) All documentation should be specific and unambiguous. Each document should state the version, date, title, nature, purpose and identify the pharmacy;

(b) Having processes to identify when and where new policies and procedures are required;

(c) Having processes to develop and approve new policies and procedures prior to implementation;

(d) Having systems for reviewing and updating policies and procedures regularly;

(e) Having processes to ensure service providers are educated on new/reviewed policies.

G 2.3.5 Complaints about individual products are examined, the causes of quality defects investigated, and appropriate measures taken on any defective products to prevent future recurrence.

G 2.3.6 This may be achieved by, but is not limited to:

(a) An internal audit/monitoring programme to measure achievement;

(b) Consumer/family/whānau, other representatives, service provider and referrer satisfaction surveys;

(c) Complaint and compliment management;

(d) Formal retrospective auditing of the documentation;

(e) Peer review, multidisciplinary team review;

(f) Developing a monitoring strategy with whānau, hapū and iwi to evaluate the extent to which Māori needs are being met.

QUALITY AND RISK MANAGEMENT SYSTEMS

Standard 2.3 **The organisation has an established, documented, and maintained quality and risk management system that reflects continuous quality improvement principles.**

Criteria The criteria required to achieve this outcome shall include the organisation ensuring:

2.3.1 The organisation has a quality and risk management system which is understood and implemented by service providers.

2.3.2 Management and service providers enable consumer participation and consultation wherever appropriate.

2.3.3 The organisation develops and implements policies and procedures that are aligned with current good practice and service delivery, meet the requirements of legislation, and are reviewed at regular intervals as defined by policy.

2.3.4 There is a document control system to manage the policies and procedures. This system shall ensure documents are approved, up to date, available to service providers, and managed to preclude the use of obsolete documents.

2.3.5 Key components of service delivery shall be explicitly linked to the quality management system. This shall include, but is not limited to:

(a) Event reporting;

(b) Complaints management;

(c) Infection control;

(d) Health and safety.

2.3.6 A process to measure achievement against the quality and risk management plan is implemented.

2.3.7 A corrective action plan addressing areas requiring improvement in order to meet the specified standard or requirements is developed and implemented.

2.3.8 Actual and potential risks are identified, documented, and where appropriate, communicated to consumers. This shall include:

(a) Identified risks are monitored, analysed, evaluated, and reviewed at a frequency determined by the severity of the risk and the probability of change in the status of that risk;

(b) A process that addresses/treats the risks associated with service provision is developed and implemented.

GUIDANCE

G 2.4.1 This may be achieved by, but is not limited to including a process for:

(a) Investigation;
(b) Analysis;
(c) Identification of trends;
(d) Planned corrective action;
(e) Review processes.

G 2.4.2 These requirements are contained in, but are not limited to the:

(a) Health Act;
(b) Medicines Act and Regulations;
(c) Misuse of Drugs Act and Regulations;
(d) Health and Safety in Employment Act;
(e) Health and Disability Services (Safety) Act;
(f) New Zealand Public Health and Disability Act;
(g) Health Practitioners Competence Assurance Act;
(h) Reporting requirements of the New Zealand Fire Service as specified in the Fire Safety and Evacuation of Buildings Regulations;
(i) Professional practice/legislation requirements.

G 2.4.3 This may be achieved by, but is not limited to recording/reporting:

(a) Accidents, incidents and near misses;
(b) Adverse clinical events including reports to Centre for Adverse Reaction Monitoring (CARM);
(c) Reports to the Intensive Medicines Monitoring Programme (IMMP);
(d) Complaints and suggestions;
(e) Infections/notifiable diseases;
(f) Other events as indicated by statute, regulation, or professional practice standards.

G 2.4.4 Consumers have the right to be fully informed of all adverse events in relation to the service they receive, the implications of those events and the outcomes of any reviews.

Open disclosure:

(a) Fosters open and honest professional relationships; and
(b) Enables systems to change to improve service quality and consumer safety.

The Health and Disability Commissioner has provided 'Guidance on open disclosure policies' to assist providers with this approach. Refer to http://www.hdc.org.nz for further information.

G 2.5.1 This may include, but is not limited to:

(a) A written job description available for each staff member. The job description should be regularly reviewed and updated;
(b) The manager should define the level of qualification, competence, experience, training and supervision required by a staff member to work in a particular area.

G 2.5.2 The organisation demonstrates effective systems for employing competent service providers with the required skills for each position. This may be achieved by, but is not limited to:

(a) Sighting and recording of practice registration/certificate renewal information;
(b) Credentialling of service providers;
(c) An internal process for evaluating competence;
(d) Sighting pharmacy technician qualification.

ADVERSE EVENT REPORTING

Standard 2.4 **All adverse, unplanned, or untoward events are systematically recorded by the service provider and reported in an open manner to affected consumers and, where appropriate, their family/whānau of choice.**

Criteria The criteria required to achieve this outcome shall include the organisation ensuring:

2.4.1 The event reporting system is a planned and coordinated process that is an integral part of the management system.

2.4.2 The service provider understands their statutory and/or regulatory obligations in relation to essential notification reporting and the correct authority is notified where required.

2.4.3 The service provider documents adverse, unplanned, or untoward events including service shortfalls in order to identify opportunities to improve service delivery, and to identify and manage actual and potential risk.

2.4.4 Adverse, unplanned, and untoward events are addressed in an open manner through an open disclosure policy.

HUMAN RESOURCE MANAGEMENT

Standard 2.5 **Human resource management processes are conducted in accordance with good employment practice and meet the requirements of legislation.**

Criteria The criteria required to achieve this outcome shall include the organisation ensuring:

2.5.1 The skills and knowledge required of each position are identified and the outcomes, accountability, responsibilities, authority, and functions to be achieved in each position are documented.

2.5.2 Professional qualifications are validated, including evidence of registration and scope of practice for service providers.

GUIDANCE

G 2.5.3 These processes may include, but are not limited to:

(a) Reference checking;

(b) Education/qualification checking;

(c) Police record checking;

(d) Recruitment and selection processes which encourage a wide range of applicants;

(e) Policies and processes accommodating the workplace needs of service providers with disabilities;

(f) Actively recruiting service providers who reflect the consumer population;

(g) Selection strategies which include assessment of the knowledge, attitudes, beliefs and skills of service providers required to meet the needs of the consumer.

G 2.5.4 This may be achieved by, but is not limited to:

(a) Appropriate orientation before a new practitioner provides care to consumers. Additional requirements may be imposed where the practitioner is new to the New Zealand health system;

(b) Service provider familiarity with:

(i) The quality improvement plan

(ii) Policies and procedures

(iii) Health and safety requirements

(iv) The authority and responsibility of the position

(v) Key functions and standards

(vi) Organisation's vision and values.

G 2.5.5 This may be achieved by, but is not limited to:

(a) Identifying opportunities to improve service delivery;

(b) Identifying education needs and associated time frames to meet these;

(c) Implementing a system of staff appraisal;

(d) Ensuring the competence of service providers;

(e) Giving feedback to service providers that is accurate and meaningful on consumer outcomes;

(f) Promoting a team approach;

(g) Implementing a system for service providers to give feedback on the performance of their management team;

(h) Ensuring effective performance management;

(i) Including in staff training and review sessions ways of improving understanding and implementation of quality assurance.

G 2.6.1 This may be achieved by, but is not limited to:

(a) Staff selection and placement policies should reflect the importance of assessing an individual's ability to perform a role;

(b) Performance is monitored and evaluated against position descriptions and agreed objectives;

(c) Personnel records containing professional and personal information which is essential for carrying out their job responsibilities are maintained for each staff member;

(d) Ensuring sufficient staff are available to provide safe delivery of services;

(e) Ensuring systems or processes promote a staffing mix that reflects consumer needs;

(f) A specified staff member is the designated workplace first aid provider and maintains competency as required by the Department of Labour.

2.5.3 The appointment of appropriate service providers to safely meet the needs of consumers.

2.5.4 New service providers receive an orientation/induction programme that covers the essential components of the service provided.

2.5.5 A system to identify, plan, facilitate, and record ongoing education for service providers to provide safe and effective services to consumers.

SERVICE PROVIDER AVAILABILITY

Standard 2.6 **Consumers receive timely, appropriate, and safe service from suitably competent service providers.**

Criterion The criterion required to achieve this outcome shall include the organisation ensuring:

2.6.1 There is a clearly documented and implemented process which determines service provider levels and skill mixes in order to provide safe service delivery.

GUIDANCE

G2.7.1 This may be achieved by, but is not limited to ensuring all relevant information is entered into the pharmacy information management system. Information should meet the legislative requirements for medicines and prescription information recording and be in line with Ministry of Health requirements.

G.2.7.2 This may be achieved by, but is not limited to:

(a) Date of the service;
(b) Full name;
(c) Preferred name;
(d) Alternative family names;
(e) Date of birth;
(f) Gender;
(g) Usual residential address;
(h) National Health Index (NHI) unique identifier;
(i) General practitioner (GP) and/or other prescribers;
(j) Eligibility for publicly funded services.

G 2.7.3 This may include but, is not limited to:

(a) Consumer records reflect the information requirements specified in the service policy;
(b) Consumer records contain adequate and appropriate information in order to facilitate the safe management of records.

G 2.7.4 Information about past consumers should be kept in compliance with the Health Information Privacy Code, Health (Retention of Health Information) Regulations, Medicines Act, and the Misuse of Drugs Act and Regulations.

G 2.7.5 This may include, but is not limited to the:

(a) Medicines Act and Regulations;
(b) Misuse of Drugs Act and Regulations;
(c) Health Information Privacy Code;
(d) Health (Retention of Health Information) Regulations;
(e) Health Act.

G 2.7.6 This may be achieved by, but is not limited to ensuring:

(a) Personal information on computer screens should not be visible to the public;
(b) Consumer records and service plans are protected from unauthorised access.

G 2.7.8 This may be achieved by, but is not limited to ensuring all entries are:

(a) Legibly documented;
(b) Objective and factual, using abbreviations which are listed and approved;
(c) Authorised/signed with time and date in a legible manner by the service provider (including their designation) making the entry;
(d) Made in ink, electronic or other mediums legally acceptable;
(e) Not defaced;
(f) Signed using a relevant signing register.

G 2.7.9 This may be achieved by, but is not limited to clear reference in the consumer's computer record to paper-based records (for example clozapine record or medicines use review record).

CONSUMER INFORMATION MANAGEMENT SYSTEMS

Standard 2.7 **Consumer information is uniquely identifiable, accurately recorded, current, confidential, and accessible when required.**

Criteria The criteria required to achieve this outcome shall include the organisation ensuring:

2.7.1 Information is entered into the consumer information management system in an accurate and timely manner, appropriate to the service type and setting.

2.7.2 The detail of information required to manage consumer records is identified relevant to the service type and setting.

2.7.3 Where the service provider is not required to meet the data requirements of the Information Directorate of the Ministry of Health adequate consumer detail is collected to safely manage consumer information.

2.7.4 The service keeps a record of past and present consumers.

2.7.5 Management of health information meets the requirements of appropriate legislation and relevant professional and sector standards where these exist.

2.7.6 Information of a private or personal nature is maintained in a secure manner that is not publicly accessible or observable.

2.7.7 Service providers use up-to-date and relevant consumer records.

2.7.8 All records are legible and the name of the service provider is identifiable.

2.7.9 All records pertaining to individual consumer service delivery are integrated.

GUIDANCE

G 3.1.1 This may include, but is not limited to:

(a) Location;

(b) Hours of service;

(c) Services and related services provided, for example, compliance packaging and delivery;

(d) Referral processes and criteria, for example medicine management services;

(e) Pre-entry information, for example waiting time, stock availability;

(f) Contact information;

(g) Out-of-hours contact information where applicable;

(h) Cost of services including information about all charges, given prior to commencement of dispensing.

G 3.1.2 This may be achieved by, but is not limited to:

(a) Ensuring the hours of service are appropriately communicated to facilitate consumer access to the service;

(b) Information is provided on how to access services in an emergency.

G 3.1.3 This may be achieved by, but is not limited to:

(a) The use of printed material or material appropriate to the communication needs/style of Māori and other consumers;

(b) Alternative formats such as Braille, large print;

(c) Interpreter policy, including the use of New Zealand sign language and the Pharmacy Guild translation kit;

(d) Website information.

G 3.1.4 This may be achieved by and is not limited to:

(a) Consumers fitting appropriate criteria for additional specialised services;

(b) Entry criteria, such as a prescription from an authorised prescriber, to access prescription medicines;

(c) Entry criteria, such as substantive consultation with a pharmacist to access pharmacist-only medicines;

(d) Entry criteria, such as appropriate recommendation from a suitable qualified staff member, to access pharmacy-only medicines.

G 3.1.5 Feedback to consumers/family/whānau, for example, if needle exchange, methadone, or clozapine services are not provided, should be in a format appropriate to the needs/condition of the consumer.

G 3.2.1 This may include, but is not limited to:

(a) The service provider having current knowledge and experience and a level of competence appropriate to the role being performed or being adequately supervised by a service provider with the necessary competence;

(b) The service provider ensuring that only personnel competent in the correct use of measuring equipment perform diagnostic tests or health screening;

(c) The requirements of all relevant Acts, Regulations and Codes for people handling medicines should be observed at all times;

(d) The certificate showing a licence to operate the pharmacy is displayed in a prominent position so it can be easily read by consumers.

G 3.2.2 This may include, but is not limited to:

(a) Consumers being able to access the assistance of a peer support service such as from the Asthma and Respiratory Foundation of New Zealand;

(b) Where appropriate offering the consumer and their family/whānau of choice opportunities to meet with service providers to provide advice/education on service delivery;

(c) Supporting the consumer and family/whānau to access community resources;

(d) Assisting the consumer, and where appropriate, their family/whānau of choice to identify specific goals if required.

3 CONTINUUM OF SERVICE DELIVERY – PHARMACY

Outcome 3 Consumers receiving pharmacy services, including dispensing, participate in and receive timely assessment, followed by services that are planned, coordinated, and delivered in a timely and appropriate manner, consistent with current legislation.

ENTRY TO SERVICES

Standard 3.1 **Consumers' entry into services is facilitated in a competent, equitable, timely, and respectful manner, when their need for services has been identified.**

Criteria The criteria required to achieve this outcome shall include:

3.1.1 Access processes are clearly documented, and are communicated to consumers, their family/whānau of choice where appropriate, local communities, and referral agencies.

3.1.2 The service operates at times most appropriate to meet the needs of the consumer group.

3.1.3 Adequate and accurate information about the service is made available.

3.1.4 Entry criteria, assessment, and entry screening processes are documented and clearly communicated to consumers, their family/whānau of choice where appropriate, local communities, and referral agencies.

3.1.5 When entry to the service has been declined, the consumer and where appropriate their family/whānau of choice are informed of the reason for this and of other options or alternative services.

SERVICE PROVISION REQUIREMENTS

Standard 3.2 **Consumers receive timely, competent, and appropriate pharmacy services in order to meet their assessed needs and desired outcomes/goals.**

Criteria The criteria required to achieve this outcome shall include:

3.2.1 Each stage of service provision (assessment, planning, provision, and evaluation) is undertaken by service providers who are competent to perform the function.

3.2.2 As appropriate each stage of service provision (assessment, planning, provision and evaluation) is developed with the consumer, and where appropriate, their family/whānau of choice or other representatives.

GUIDANCE

G 3.2.3 This may include, but is not limited to:

(a) Service provision time frames are documented in order to meet consumer needs in line with time frames specified in:

(i) The organisation's policies/procedures

(ii) Purchaser contracts/service requirements

(iii) Applicable standards/guidelines/legislation

(iv) Clinical pathways/desired clinical outcomes

(v) Negotiation with consumers, particularly where medicines are out of stock or for the delivery of medicines;

(b) A monitoring process to ensure time frames are met;

(c) A process to identify and respond to variances/trends.

G 3.2.4 This may include, but is not limited to:

(a) Adequate handover/briefing between changes of service providers;

(b) Promoting an interdisciplinary approach where possible;

(c) Cooperation between providers.

G 3.3.1 This may include, but is not limited to:

(a) Consumer preferences relating to their treatment, including brand preference and formulation preferences;

(b) Consumer's allergies, drug reactions and interactions of clinical importance;

(c) Where more than one service provider is involved (for example, in clozapine or methadone services, emergency contraceptive pill (ECP), and provision of pharmacist-only medicines) the assessment is coordinated;

(d) Where the service provider responsible for the assessment is different to the service provider responsible for service delivery, linkages between the two exist;

(e) Policies or protocols should be documented to ensure cooperation between service providers and continuity of service;

(f) Pharmacists should ensure they raise concerns with prescribers in a manner that is constructive and aims to reach the best decision for the consumer, following the guidance from the Pharmacy Council of New Zealand;

(g) Organisations have clear processes which encourage service providers to actively seek information from a range of sources, for example family/whānau, GP, referrer;

(h) Current reference resources and legislation should be accessible and service providers should know how to access and use them;

(i) The assessment is comprehensive, appropriate for the purpose, using evidence-based and culturally appropriate methods and tools.

G 3.3.2 Assessments are provided within time frames identified to safely meet the needs of the consumer. Assessments may include, but are not limited to:

(a) Assisting the consumer and/or family/whānau to identify specific goals if required;

(b) Supporting the family/whānau to access community resources.

G 3.3.3 This may include, but is not limited to, assessments in either a consultation room, or an appropriate area which gives privacy to the consumer.

G 3.3.4 Communication should be delivered in a manner that is understandable to the consumer. This may include, but is not limited to:

(a) Where a service provider is performing diagnostic tests or health screening, an explanation of results, and their significance and limitations, is based on current good practice;

(b) Results and records of diagnostic tests or health screening are completed in a manner that facilitates further follow-up where appropriate.

3.2.3 Each stage of service provision (assessment, planning, provision and evaluation) is provided within time frames that safely meet the needs of the consumer.

3.2.4 The service is coordinated in a manner that promotes continuity in service delivery and promotes a team approach where possible.

3.2.5 Where the service provider is unable to provide the service the consumer shall be assisted to obtain the service from another source.

ASSESSMENT

Standard 3.3 **Consumers' needs, support requirements and preferences are gathered and recorded where appropriate.**

Criteria The criteria required to achieve this outcome shall include:

3.3.1 Service providers seek appropriate information and access a range of resources to enable effective assessment.

3.3.2 The needs, outcomes and/or goals of consumers are identified in the assessment process and are documented to serve as the basis for service delivery planning.

3.3.3 Assessments are conducted in a safe and appropriate setting as agreed with the consumer.

3.3.4 Assessment and intervention outcomes are communicated to the consumer, referrers and relevant service providers.

GUIDANCE

G 3.4.1 Planning may include, but is not limited to:

(a) Consumers are supported to update their own service delivery plan where appropriate, for example a medication card or blood test results;

(b) Goals are identified by the consumer and, where appropriate, the family/whānau of choice and reviewed at regular times appropriate to the consumer's needs;

(c) Goals are measurable and achievable;

(d) The service having a direct emphasis on self-management as applicable.

G 3.4.2 Service delivery planning may also include interventions such as chronic diseases management and crisis information.

G 3.4.3 This may be achieved by, but is not limited to:

(a) Consumers and where appropriate their family/whānau of choice are informed of treatment and support options available;

(b) Interdisciplinary team involvement;

(c) Integration of primary and secondary services;

(d) Effective links between services;

(e) Service coordination;

(f) Minimising duplication and service fragmentation;

(g) Facilitating/ensuring access to regular primary care services;

(h) Medicine reconciliation.

G 3.5.1 This may include, but is not limited to:

(a) Clinical care/treatment;

(b) Direct support or interventions by the carer or service provider;

(c) Encouragement, direction, or supervision of a consumer completing an intervention themselves;

(d) Each person receiving the service is encouraged to develop and/or redevelop optimal levels of functioning to meet their own everyday living needs, within their community, using where possible community services and/or resources;

(e) Where appropriate the service attempts to re-engage the consumer who does not keep planned follow-up arrangements.

G 3.5.2 This includes consultation and liaison and may include, but is not limited to:

(a) Specialist and acute services;

(b) GPs;

(c) Allied health practitioners;

(d) Government agencies and non-government organisations;

(e) Māori health providers;

(f) Other relevant providers, including community services.

G 3.5.3 This may include, but is not limited to:

(a) The right to request change of service provider;

(b) Treatment and support in their home.

PLANNING

Standard 3.4 **Service delivery planning shall be consumer focused, integrated and promote continuity of service delivery.**

Criteria The criteria required to achieve this outcome shall include:

3.4.1 Service delivery planning is individualised to the consumer, accurate and up to date.

3.4.2 Service delivery planning describes the required support and/or intervention to achieve the desired outcomes.

3.4.3 Service delivery planning demonstrates service integration.

SERVICE DELIVERY

Standard 3.5 **Consumers shall receive adequate and appropriate services in order to meet their assessed needs and desired outcomes.**

Criteria The criteria required to achieve this outcome shall include:

3.5.1 The provision of services is consistent with, and contributes to, meeting the consumers' assessed needs, and desired outcomes.

3.5.2 Appropriate links are developed and maintained with other service providers and organisations working with consumers and their families.

3.5.3 The consumer receives services which:

(a) Promote health and well-being;

(b) Promote acceptance and inclusion.

This shall be achieved by working collaboratively with consumers, and if appropriate family/whānau, health, justice, and social services, and other community groups.

3.5.4 The consumer receives safe and respectful services in accordance with current accepted good practice, and which meet their assessed needs, and desired outcomes.

EVALUATION

Standard 3.6 **Consumers' service delivery outcomes shall be evaluated as appropriate in a timely manner.**

Criteria The criteria required to achieve this outcome shall include:

3.6.1 Where progress is different from expected, the service responds by initiating changes to the service delivery.

3.6.2 Evaluations are conducted at a frequency that enables regular monitoring of progress towards achievement of desired outcomes.

3.6.3 Evaluations are documented, consumer-focused, indicate the degree of achievement or response to the support and/or intervention and progress towards meeting the desired outcome.

GUIDANCE

G 3.7.1 This may include, but is not limited to referral to:

(a) GPs;
(b) After-hours services;
(c) Specialised therapy services;
(d) Allied health practitioners;
(e) Equipment providers;
(f) Community resources;
(g) Māori, or other culturally appropriate providers;
(h) Other services appropriate to the consumer.

G 3.8 This may include, but is not limited to:

(a) Acts, Regulations and Codes;
(b) Sector-related websites;
(c) Practice handbooks and guidelines;
(d) *Pharmacy Council of New Zealand Competence Standards.*

G 3.8.1 This may include but is not limited to:

(a) Detection and management of all medication errors and near misses;
(b) Recording of interventions;
(c) Compliance with all the legislative requirements pertaining to the recording, storage, disposal and stocktaking of medicines;
(d) Following the *Practice guidelines for opioid substitution treatment in New Zealand;*
(e) Complying with the Safe Medication Management Programme's Standards for medicine reconciliation;
(f) Monitoring of consumer requests for medicines which are prone to misuse – refer to *Pharmacy Council Code of Ethics;*
(g) Participation in research activities;
(h) Providing consumers with appropriate advice and counselling which may include written information.

G 3.8.2 This may include, but is not limited to:

(a) Service providers operating only within their scope of practice and competence;
(b) Documentation of medicines dispensed;
(c) Implementing a process to identify, record, and communicate a consumer's allergies, adverse drug reactions and respond appropriately;
(d) Ensuring both the measurement and recording of results of diagnostic tests or health screening are performed in accordance with documented procedures.

G 3.8.3 This may include, but is not limited to:

(a) Adequate information in a form that meets the needs of the consumer;
(b) Education on the purpose, actions, use, possible side effects and consequences of refusal/misuse;
(c) The evaluation of the need for aids such as compliance packaging.

REFERRAL TO OTHER HEALTH AND DISABILITY SERVICES

Standard 3.7 **Consumer support for access or referral to other health and/or disability service providers shall be appropriately facilitated, or provided to meet consumer choice/needs.**

Criteria The criteria required to achieve this outcome shall include:

3.7.1 Consumers are given the choice and advised of their options to access other health and disability services where indicated or requested.

3.7.2 The consumer's safety and right to be kept informed in a timely manner, is managed by service providers cooperating during the referral process.

PRACTICE REQUIREMENTS

Standard 3.8 **Consumers shall receive medicines in a safe and timely manner that complies with current legislative requirements and safe practice guidelines.**

Criteria The criteria required to achieve this outcome shall include:

3.8.1 A system or systems are implemented to manage safe and appropriate prescribing, dispensing, administration, review, storage, disposal and medicine reconciliation in order to comply with legislation, protocols and guidelines.

3.8.2 Policies and procedures clearly document the service provider's responsibilities in relation to each stage of service delivery.

3.8.3 The facilitation of safe self-administration of medicines by consumers where appropriate.

GUIDANCE

G 3.9.1 This may include, but is not limited to:

(a) Ensuring that sufficient information is obtained to enable a professional assessment of the consumer's needs to ensure the clinical appropriateness of any medicines recommended or advice given;

(b) Providing appropriate counselling or advice on the safe and effective use of the medicine to be supplied;

(c) Providing the capacity for a continuing dialogue with the consumer, for example a freephone number for additional information;

(d) Advising consumers to consult an appropriate healthcare provider whenever a request for a medicine or the symptoms described indicate that the consumer's interests would be better served by a face-to-face consultation;

(e) Ensuring there is the capability to contact the consumer's other healthcare providers if necessary;

(f) Giving advice or recommendations only for individual consumers.

G 3.9.3 This may include, but is not limited to:

(a) Compliance with security of consumer information;

(b) Education on the purpose, actions, use, possible side effects and consequences of refusal/misuse;

(c) The evaluation of the need for aids such as compliance packaging.

G 3.9.4 This may include, but is not limited to:

(a) Ensuring information relating to medicines includes all relevant details of adverse effects and contra-indications;

(b) Ensuring medicines of potential abuse, misuse, and dependence such as those containing pseudoephedrine or codeine are only made available in professionally considered circumstances;

(c) Preventing the sale of pseudoephedrine, codeine, or other medicines of potential abuse outside New Zealand where the classification of these medicines may differ;

(d) Ensuring the sale or supply of pharmacist-only medicines to treat chronic conditions follows the protocols developed by the Pharmacy Council of New Zealand;

(e) Ensuring services or promotions offered do not mislead or deceive consumers on any material detail or information about the pharmacy, pharmacy staff, medicines, or financial transactions;

(f) Extending responsibility for the medicine to the point of delivery to the consumer;

(g) Not dispensing prescription medicines for overseas consumers pursuant to prescriptions ordered by overseas prescribers whether or not they have been countersigned by New Zealand registered prescribers.

G 3.9.5 This may include, but is not limited to:

(a) The charge pharmacist responsible for the website being clearly identifiable so consumers can contact them if necessary;

(b) Maintaining records of the pharmacist assuming professional responsibility for any recommendation and identifying this pharmacist to the consumer;

(c) Providing details of how to make a complaint about the online pharmacy services provided;

(d) Ensuring advertisements comply with:

(i) All relevant legislation (Medicines Act sections 56 – 62; Medicines Regulations regulations 7 – 11)

(ii) The Advertising Standards Authority Therapeutic Products and Therapeutic Services Advertising Codes

(iii) The Pharmacy Council of New Zealand and Pharmaceutical Society *Guidance on advertising to the consumer and promotion of products of potential misuse*, March 2009. Refer to: http://www.pharmacycouncil.org.nz;

(e) Providing accurate, up-to-date generic healthcare advice that is of a high professional standard;

(f) Complying with the Statement set by the Pharmacy Council of New Zealand on the promotion and supply of medicines over the internet, August 2007. Refer to: http://www.pharmacycouncil.org.nz.

ONLINE PHARMACY SERVICES

Standard 3.9 **Consumers shall receive online pharmacy services in a safe and timely manner that complies with current legislative requirements and safe practice guidelines.**

Criteria The criteria required to achieve this outcome shall include:

3.9.1 The standard of advice and service available by electronic media shall be of the same level as that received by a consumer consulting with the pharmacist face-to-face.

3.9.2 The promotion and supply of medicines over the internet shall comply with the statement set by the Pharmacy Council of New Zealand on the *Promotion and supply of medicines over the internet*.

3.9.3 Pharmacists shall use caution whenever any medicines are supplied as a result of internet contact and comply with all legal requirements in these circumstances.

3.9.4 Pharmacists shall adhere to professional and ethical obligations that apply to online pharmacy services extending beyond the minimum legal requirements.

3.9.5 The charge pharmacist shall be responsible for the form and content of all information made available on the website.

GUIDANCE

G 4.1.1 This may be achieved by, but is not limited to, meeting the requirements of:

(a) The Resource Management Act;

(b) NZS 4304;

(c) NZS 8134.3;

(d) The Health Act; and

(e) The Hazardous Substances and New Organisms Act.

G 4.1.2 This may include, but is not limited to prompt action and early management (including prophylaxis) of waste and hazardous substances incidents such as:

(a) Biological waste;

(b) Cytotoxic waste;

(c) Hazardous waste;

(d) Pharmaceutical waste; and

(e) Sharps.

G 4.2.1 This may be achieved by, but is not limited to:

(a) The organisation demonstrating that the maintenance programme ensures all buildings, plant and equipment are maintained to an appropriate standard or specification where a Standard exists;

(b) Meeting manufacturers' specifications where a Standard does not exist;

(c) A process for upgrading and replacing equipment as required;

(d) Service providers receive training in the safe use of equipment by suitably qualified staff;

(e) Meeting the New Zealand Building Code requirements for disabled persons' access;

(f) Ensuring maximum reasonable protection against the entry of insects and animals.

G 4.2.3 This may be achieved by, but is not limited to ensuring:

(a) Pharmacy, amenities, fixtures, equipment and furniture meet infection control requirements, and are easy to clean and maintain;

(b) Non-slip surfaces or other safe effective means of minimising slipping are provided in areas frequently exposed to moisture or slippery substances;

(c) A product/equipment evaluation and implementation process;

(d) All equipment used for diagnostic tests or health screening meets relevant standards and is maintained according to the manufacturers' recommendations.

4 SAFE AND APPROPRIATE ENVIRONMENT – PHARMACY

Outcome 4 Services are provided in a clean, safe environment that is appropriate to the needs of the consumer, ensures privacy is maintained, is in a setting suitable for the consumer group, and meets the needs of people with disabilities.

MANAGEMENT OF WASTE AND HAZARDOUS SUBSTANCES

Standard 4.1 **Consumers, visitors and service providers shall be protected from harm as a result of exposure to waste, infectious or hazardous substances generated during service delivery.**

Criteria The criteria required to achieve this outcome shall include the organisation ensuring:

4.1.1 Service providers follow a documented process for the safe and appropriate storage and disposal of waste, infectious or hazardous substances that complies with current legislation and local authority requirements.

4.1.2 All incidents involving waste, hazardous substances, infectious material, or body substances are responded to which may include reporting, recording, investigating and reviewing.

4.1.3 Service providers involved in the management of waste and hazardous substances receive training and education to ensure safe and appropriate handling.

4.1.4 All hazardous substances are correctly labelled to allow for easy identification and safe use in line with the Hazardous Substances (Identification) Regulations and local authority requirements.

4.1.5 Protective equipment and clothing appropriate to the risks involved when handling waste or hazardous substances is provided, and used by service providers.

FACILITY AND EQUIPMENT SPECIFICATIONS

Standard 4.2 **Consumers and service providers shall be provided with an appropriate, accessible physical environment and facilities that are fit for their purpose.**

Criteria The criteria required to achieve this outcome shall include the organisation ensuring:

4.2.1 All buildings, plant and equipment comply with legislation.

4.2.2 Where there is a requirement under the New Zealand Building Code there is:

(a) A current Building Warrant of Fitness for older buildings;

(b) A code of compliance certificate and certificate of public use for new buildings.

4.2.3 Amenities, fixtures, equipment and furniture in the pharmacy are selected, located, installed and maintained with consideration of consumer and service provider safety, needs, and abilities, and meet the requirements of sections 5, 6, and 7.

GUIDANCE

G 4.2.4 This may be achieved by, but is not limited to:

(a) Demonstrating that all medicines and equipment are stored safely and appropriately in the pharmacy through:

(i) Storage in a logical and orderly manner which allows medicines, materials, and equipment to be separated and identified, and stock rotated

(ii) Storage in a way which protects against unauthorised access theft, adulteration, and/or any form of contamination at any stage of their use

(iii) Storage out of direct sunlight

(iv) Storage in conditions demonstrated to meet the temperature requirements specified by the medicine or material's manufacturer or supplier

(v) Storage in areas which provide appropriate and permitted public access to the medicine to meet the requirements of the Medicines Act and Medicines Regulations, the Misuse of Drugs Act and Misuse of Drugs Regulations and the *Pharmacy Council Code of Ethics*

(vi) Ensuring medicines that are awaiting collection or delivery or are returned by the consumer, or those requiring change are segregated from one another and clearly identified to avoid any ambiguity over their status;

(b) Demonstrating provision for the access of disabled persons to the pharmacy in accordance with the Building Code and applicable local authority bylaws;

(c) Demonstrating identification of known consumer safety hazards;

(d) Demonstrating appropriate storage for all hazardous materials;

(e) Demonstrating all equipment and any services used to provide pharmacy services are:

(i) Suitable for the purpose

(ii) Where appropriate, suitably calibrated and checked at defined intervals

(iii) Maintained in good repair

(iv) Thoroughly cleaned to prevent cross-contamination

(v) Suitably stored

(vi) Reserved for use in the provision of pharmacy services

(vii) Withdrawn from service and identified as such if no longer suitable for use;

(f) All personnel involved in diagnostic tests or health screening comply with relevant infection prevention guidelines where applicable.

G 4.2.5 This may include, but is not limited to:

(a) Floor surfaces and coatings are maintained in good order;

(b) Ramps and any facilities used by disabled people meet the requirements of NZS 4121;

(c) Floor surfaces likely to be slippery when wet are kept dry or clearly identified when wet.

G 4.3.1 This may include, but is not limited to meeting the requirements of the New Zealand Building Code:

(a) Toilet facilities do not directly open into the dispensary, compounding area, repackaging or batch preparation areas, of the pharmacy;

(b) Water for dispensing is neither drawn from sources in the toilet facilities nor is it stored there;

(c) Where the toilet facility is shared with other organisations, the pharmacy should have its own hand-washing facility which is separate from the dispensary sink;

(d) Disposable towels or hot air hand driers are provided for drying hands;

(e) A notice should be prominently displayed in the toilet facilities reminding service providers to wash their hands after using the toilet.

G 4.3.3 This includes but is not limited to hand-washing facilities in the dispensary area which are separate from the dispensary sink.

4.2.4 The physical environment minimises risk of harm, aids independence, and is appropriate to the needs of service providers and the consumer.

4.2.5 Fixtures, fittings, floor and wall surfaces are constructed from materials that can be easily cleaned, which are in line with infection prevention guidelines.

TOILET AND HAND-WASHING FACILITIES

Standard 4.3 **Service providers shall have access to adequate toilet and washing facilities. Service providers shall be assured privacy when attending to personal hygiene.**

Criteria The criteria required to achieve this outcome shall include the organisation ensuring:

4.3.1 There are adequate numbers of accessible toilets and hand-washing facilities conveniently located in proximity to each service area to meet the needs of service providers.

4.3.2 Hot water for hand-washing is provided at the tap at a safe and appropriate temperature that minimises the risk of harm to service providers.

4.3.3 Service providers and visitors are provided with adequate hand-washing facilities to ensure compliance with infection prevention guidelines.

GUIDANCE

G 4.4.1 This may be achieved by, but is not limited to:

(a) Meeting the requirements of the Fire Safety and Evacuation of Buildings Regulations;

(b) Ensuring emergency equipment is accessible, stored and serviced correctly, not expired and stocked to a level appropriate to the service setting;

(c) Closed-circuit television (CCTV), monitored alarms;

(d) Post-incident debriefing, and counselling where necessary;

(e) Regular annual refresher training should be provided to staff.

G 4.4.3 Refer to Regulation 20 and 21 of the Fire Safety and Evacuation of Buildings Regulations.

G 4.5.1 To ensure the interior environment is appropriately ventilated and temperature controlled, the service should meet New Zealand Building Code Clause G4 and G5.

EMERGENCY AND SECURITY SYSTEMS

Standard 4.4 **Consumers and service providers shall receive an appropriate and timely response during emergency and security conditions.**

Criteria The criteria required to achieve this outcome shall include the organisation ensuring:

4.4.1 Service providers receive appropriate information, training and equipment to respond to identified emergency and security conditions. This shall include fire safety, emergency procedures and armed hold-ups.

4.4.2 Service providers are able to provide a level of first aid and emergency treatment appropriate for the degree of risk associated with the provision of the service.

4.4.3 Where required by legislation there is an approved evacuation plan.

4.4.4 The service provider identifies and implements appropriate security arrangements relevant to the pharmacy setting.

LIGHT, VENTILATION AND HEATING

Standard 4.5 **Consumers and service providers shall be provided with adequate light, ventilation and an environment that is maintained at a safe and comfortable temperature.**

Criteria The criteria required to achieve this outcome shall include the service provider ensuring:

4.5.1 Areas used by consumers and service providers are ventilated, lit, and heated/cooled, appropriately.

4.5.2 Service providers shall meet the requirements of the Smoke-free Environments Act.

GUIDANCE

5 DISPENSING, COMPOUNDING, REPACKAGING AND BATCH PREPARATION

Outcome 5 Dispensing, compounding, repackaging and batch preparation practices in pharmacies have clearly defined procedures and are organised so that appropriate qualified staff, premises, equipment and materials are used according to the requirements of the individual preparation.

INTRODUCTION

Each and every aspect of dispensing, compounding, repackaging and batch preparation should be carefully considered and developed to ensure that appropriate standards are being achieved.

No person shall contemplate compounding a medicine unless they have a clear idea of the standard the finished medicine has to meet and can ensure that the appropriately qualified staff, equipment, materials and facilities are available in which to compound such a product.

This section replaces *The New Zealand Code of good manufacturing practice for manufacture and distribution of therapeutic goods, Part 3: Compounding and dispensing* 1993 (Code of GMP).

The Good Manufacturing Practice abbreviation GMP continues to be used in NZS 8134.7 as it has become a term that reflects a concept rather than just an abbreviation. The concept can be applied to dispensing, compounding, repackaging and batch preparation as well as manufacturing.

INTERPRETATION

Section 5 is only applicable to dispensing, compounding, repackaging and batch preparation practices provided by a licensed pharmacy.

This section applies to the preparation of a medicine for an individual person in sufficient quantity to fulfil an individual prescription. This section also applies to small-scale batch preparation and/or repackaging of a medicine by qualified staff in a pharmacy with the appropriate equipment, in the following situations:

(a) Where medicines **are not required** to be sterile, the requirements of (i) and (ii) shall be met:

  (i) The size of the batch shall not exceed:

    (A) Five litres of an oral or topical liquid
    (B) Five kilograms of a cream, ointment, or gel
    (C) 300 grams of loose powder blend or capsule powder blend
    (D) More than 300 grams and less than 5 kilograms of loose powder blend, or capsule powder blend for encapsulation only if there is demonstrated validation of the process (including testing) completed prior to the sale or supply of the product
    (E) 100 suppositories or other single solid dose forms, excluding capsules
    (F) 100 repackaged units. This applies to proprietary products only which are relabelled or repackaged into labelled containers as a batch operation, and

GUIDANCE

G 5.1 The basic concepts of quality assurance, good compounding and dispensing practice and quality control are interrelated. They are described here to emphasise their relationships and their fundamental importance to the dispensing, compounding, repackaging, and batch preparation and control of pharmaceutical products.

(ii) A batch of medicine is prepared not more than once a week, unless the previous batch has been dispensed or supplied in that period, or is expected to be dispensed or supplied in that period. A compounded batch quantity can be packed into any number of appropriately labelled containers at the time of compounding on the condition that the total size of the batch does not exceed the quantities listed in (i) above;

(b) Where medicines **are required** to be sterile, section 6 or section 7 of this Standard shall be followed. The dispensing pharmacist shall be familiar with the special requirements of the aseptic compounding of sterile preparations and have appropriate training.

Section 26 of the Medicines Act allows pharmacists in a community or hospital pharmacy to sell or supply compounded or repackaged medicines without a manufacturing or packing licence **only** if a request is made by the person to whom the medicine is to be sold or supplied or with reference to the needs expressed by that person. There is no allowance in the legislation for a pharmacist to store compounded or repackaged medicines on a shelf accessible to the public alongside other proprietary registered medicines.

QUALITY MANAGEMENT

PRINCIPLE

The pharmacist responsible for the dispensing, compounding, repackaging, or batch preparation of pharmaceutical products shall carry out these procedures so as to ensure that the products are fit for their intended use and do not place consumers at risk from inadequate safety, quality, or efficacy. The attainment of this quality objective is the responsibility of management and requires the participation and commitment of all qualified staff involved.

To achieve the quality objective reliably there shall be a comprehensively designed and correctly implemented system of quality assurance incorporating good dispensing, compounding, repackaging and batch preparation practice and quality control. This quality assurance system should be documented and its effectiveness monitored. All parts of the quality assurance system shall be adequately resourced with competent qualified staff, suitable and sufficient premises, equipment and facilities.

Standard 5.1 **Each pharmacy shall have a quality management scheme to ensure the safety, quality and efficacy of dispensed, compounded, repackaged and batch prepared products.**

Criteria The criteria required to achieve this outcome include:

5.1.1 Dispensing, compounding, repackaging and batch preparation procedures are clearly specified and documented.

5.1.2 Responsibilities of staff are clearly specified.

5.1.3 Arrangements are made for the supply and use of the correct starting and packaging materials.

5.1.4 All necessary validations of the equipment, procedures, starting materials and finished products are carried out and documented.

5.1.5 The finished product is correctly processed and checked, according to defined procedures.

GUIDANCE

G 5.2.4 In determining the appropriateness of the prescription, the pharmacist should undertake a clinical check which includes, but is not limited to, assessment of the prescription for:

(a) Appropriate dosage form and route of administration;

(b) Dosage within therapeutic range;

(c) Appropriateness according to consumer's parameters (such as age, weight, renal function) and previous medication. This is particularly important for treatments with a narrow therapeutic index, oncology preparations, or for babies and young children;

(d) Compatibility with other medication;

(e) Possible side effects;

(f) Risk of adverse drug reactions;

(g) Potential for non-concordance, inappropriate use and misuse by consumer;

(h) Contra-indications.

5.1.6 Pharmaceutical products are not sold or supplied before a pharmacist has checked that each product has been produced in accordance with any regulations relevant to the production, control and release of pharmaceutical products.

5.1.7 Satisfactory arrangements exist to ensure, as far as possible, that pharmaceutical products are stored and handled so that quality is maintained throughout their shelf life.

5.1.8 There is a procedure for self-inspection and/or quality audit which regularly appraises the effectiveness and applicability of the quality assurance system.

GOOD DISPENSING PRACTICE

Standard 5.2 **A disciplined dispensing procedure shall ensure that the appropriate product is selected and dispensed accurately and efficiently.**

Criteria The criteria required to achieve this outcome include:

5.2.1 Procedures for the dispensing and supply of pharmaceutical products are developed, documented and approved by the pharmacist(s) who has/have effective control of a community pharmacy, or the hospital pharmacy manager.

5.2.2 Procedures for dispensing and the supply of pharmaceutical products shall comply with statutory requirements.

5.2.3 Dispensing procedures must ensure:

(a) All dispensing activities are undertaken or directly supervised by a pharmacist;

(b) Original prescriptions to verify those received by telephone, fax, or other electronic means must be obtained promptly as required by legislation;

(c) Secure, accurate and orderly records of prescriptions must be maintained;

(d) Suitable and appropriate containers are used;

(e) Containers are labelled with information for the consumer that meets legal and professional requirements;

(f) All prescription forms clearly record who dispensed the prescription and the pharmacist responsible for the final check for completeness and accuracy;

(g) Proper controls are used to ensure that the medicines prescribed are received by the intended person;

(h) When a pharmacist is unable to dispense a prescription, the consumer is assisted to obtain the medicine from another source; and

(i) There is a medicine recall procedure which can be readily implemented.

5.2.4 Prescriptions are interpreted and evaluated for correctness, appropriateness and completeness, their authenticity verified and their priority for dispensing determined.

5.2.5 The dispensed medicine is correctly selected, packaged and stored by qualified staff and that sufficient information is given to the consumer to ensure its appropriate use.

5.2.6 The use of generic medicine substitution is controlled by agreed and documented policies.

GUIDANCE

G 5.3 Good compounding, repackaging and batch preparation practices are that part of quality assurance which ensures that products are consistently produced and controlled to the quality standards appropriate to their intended use.

GOOD COMPOUNDING, REPACKAGING AND BATCH PREPARATION PRACTICE

Standard 5.3 **Each pharmacy shall have robust compounding, repackaging and batch preparation practices.**

Criteria The following basic requirements shall be met:

5.3.1 All compounding, repackaging and batch preparation processes are clearly defined, reviewed, and known to be capable of consistently producing pharmaceutical products of the required quality and complying with their specifications.

5.3.2 Critical steps of compounding, repackaging and batch preparation processes and significant changes to processes are validated according to recognised good practice.

5.3.3 All necessary facilities for compounding, repackaging and batch preparation are provided including:

(a) Adequate and suitable premises and space;

(b) Suitable equipment and services;

(c) Correct materials, containers and labels;

(d) Approved procedures and instructions;

(e) Suitable storage and transport.

5.3.4 Instructions and procedures are written in clear and unambiguous language, specifically applicable to the services provided.

5.3.5 Appropriately qualified staff carry out procedures correctly.

5.3.6 Records are made, which demonstrate that all the steps required were taken and that the quantity and quality of the product was as expected.

5.3.7 Records of compounding and repackaging (including compliance, dose packaging and unit dose packaging) enable the history of a finished product to be traced. These records are to be retained in a comprehensible and accessible form.

5.3.8 A process is available to recall any product.

5.3.9 Complaints about products are examined and the causes of quality defects investigated. Appropriate measures are taken to prevent future recurrence.

STANDARD OPERATING PROCEDURES

Standard 5.4 **There shall be standard operating procedures (SOPs) for the dispensing, compounding, repackaging and batch preparation practices covered by sections 5, 6, and 7.**

Criterion The basic requirements are:

5.4.1 SOPs shall be in place, maintained and reviewed at least every 2 years.

GUIDANCE

QUALITY CONTROL

PRINCIPLE

Quality control involves sampling, specifications and testing and also documentation and procedures that ensure starting materials and packaging materials used, and finished products sold or supplied, are safe and of an acceptable quality. Quality control involves all decisions which relate to the quality of a product.

INTERNAL AUDIT

Standard 5.5 **Internal audit shall be conducted to monitor the implementation of and compliance with good dispensing, compounding, repackaging and batch preparation practices covered by sections 5, 6, and 7.**

Criteria The basic requirements are:

5.5.1 These audits shall be performed and recorded by an appropriately qualified staff member on a regular basis and shall be overseen by a pharmacist.

5.5.2 Internal audit records shall be recorded and signed off by a pharmacist.

5.5.3 Any action taken as a result of the audit shall be recorded, including the name of the pharmacist and the date.

DOCUMENTATION FOR QUALITY CONTROL

Standard 5.6 **Appropriate documentation shall be available to the pharmacist performing the quality control check on any starting materials, packaging materials and finished product.**

Criteria The basic requirements are:

5.6.1 The following details shall be available to the quality control pharmacist, where applicable:

(a) Specification for the materials and product;

(b) Testing procedures and records;

(c) Certificates of analysis and other analytical reports;

(d) Data from environmental monitoring;

(e) Procedures for and records of the calibration of instruments and maintenance of equipment;

(f) Compounding records.

5.6.2 Any documentation relating to batch preparation and repackaging shall be retained for a minimum of 3 years after the expiry date of the preparation.

GUIDANCE

G 5.7.1 It is fundamental when manufacturing medicines that the quality control function is independent from production. While this is also desirable for compounding, repackaging and batch preparation, this is often not possible. The pharmacists responsible for quality control are usually also involved in compounding. Thus it is vital that the quality aspects of compounding are not outweighed by other matters.

G 5.9.1 This may include but is not limited to:

(a) The opportunity for testing of the finished product is limited, therefore the competence of the staff is of crucial importance for the quality of the end product;

(b) Tasks and areas of responsibility should be clearly defined;

(c) Only qualified staff may dispense, compound, repackage and undertake batch preparation in accordance with Medicines Regulations 42 and 63.

PROCEDURES FOR QUALITY CONTROL

Standard 5.7 **Each pharmacy shall have a checking procedure to appropriately assess starting materials, packaging materials and finished products to ensure only acceptable products are released for sale or supply.**

Criteria The basic requirements are that:

5.7.1 A pharmacist responsible for quality control shall be involved in:

(a) Approval or rejection of starting and packaging materials and finished products;

(b) Evaluation of documentation;

(c) Ensuring appropriate testing is carried out;

(d) Approval of specifications, test methods and other quality control procedures;

(e) Ensuring that appropriate validation is carried out;

(f) Calibration of instruments, scales and other equipment;

(g) Recording these functions;

(h) Evaluating any deviations.

MATERIALS AND PRODUCT RELEASE

Standard 5.8 **Materials shall not be released for use, nor products released for sale or supply, until their quality has been judged to be satisfactory.**

Criteria The following basic requirements of quality control shall be met:

5.8.1 Adequate facilities, qualified staff and approved procedures are available for inspecting and assessing for use starting materials, packaging materials and finished products, and where appropriate, for monitoring environmental conditions for dispensing, compounding, repackaging and batch preparation purposes.

5.8.2 Records shall be made which demonstrate that all the required inspecting and assessing procedures were actually carried out. Any deviations are fully recorded and the finished products contain active ingredients of a quantity and quality required, and are enclosed within their proper container and correctly labelled.

5.8.3 No product is released for sale or supply prior to checking by a pharmacist to ensure it is in accordance with the requirements.

STAFF

STAFFING REQUIREMENTS

Standard 5.9 **Staff involved in dispensing, compounding, repackaging and batch preparation practice shall be qualified, have pharmaceutical training, practical skills and an appreciation of the importance of hygiene.**

Criteria The basic requirements are:

5.9.1 A pharmacist shall have overall responsibility for the quality management of the dispensing, compounding, repackaging and batch preparation practices.

GUIDANCE

G 5.10 This may include but is not limited to:

(a) The pharmacy manager should define the level of qualification, competence, experience, training and supervision required by a staff member to work in a particular area;

(b) Participation by staff in appropriate continuing education programmes should be encouraged and documented;

(c) The concept of quality assurance, GMP, and ways of improving their understanding and implementation should be included in staff training and review sessions.

G 5.11 This may include but is not limited to:

(a) Special attention should be paid to hand hygiene and appropriate clothing should be worn for the task being performed;

(b) External staff working in the pharmacy (for example, tradespersons or cleaners) or visitors to the pharmacy should be carefully supervised to ensure they do not compromise the hygiene procedures of the pharmacy.

G 5.11.3 This may include but is not limited to:

(a) Communicable diseases as defined in the Health Act and referred to in Medicines Regulation 27;

(b) Appropriate precautions that could be taken to minimise these hazards are appropriately covering any open lesion, and not being in contact with medicines during the infectious period of a disease;

(c) Staff who recognise they are at particular risk of a Human Immunodeficiency Virus (HIV) infection have a responsibility to be tested. Persons who test positive have a duty to seek and act on expert advice on occupational matters which may affect them and their colleagues or consumers;

(d) Only qualified staff may dispense, compound, repackage and undertake batch preparation in accordance with Medicines Regulations 42 and 63.

5.9.2 An adequate number of qualified and experienced staff is required to maintain a satisfactory dispensing, compounding, repackaging and batch preparation service.

5.9.3 The pharmacy manager/charge pharmacist shall ensure that responsibilities placed on any staff member are not so extensive as to compromise the quality of the pharmacy's products.

5.9.4 A staff policy and procedures manual shall be available. It shall be regularly reviewed and updated at least every 2 years.

5.9.5 A written job description shall be available for each qualified staff member. The job description should be regularly reviewed and updated.

TRAINING

Standard 5.10 **The organisation shall ensure that appropriate training is provided for all qualified staff to enable them to be competent in performing their particular tasks.**

Criteria The basic requirements are:

5.10.1 An introductory staff orientation and training programme shall be available for all new staff members.

5.10.2 All training of qualified staff shall be documented.

5.10.3 All qualified staff shall be familiar with relevant standard operating procedures (SOPs).

5.10.4 Qualified staff involved in aseptic dispensing, cytotoxic dispensing, compliance packaging, dose packaging, unit dose packaging, automated packing, compounding and dispensing shall receive specific training.

PERSONAL HYGIENE

Standard 5.11 **The pharmacy manager shall ensure that procedures for health, hygiene practices and protective clothing are established and followed.**

Criteria The basic requirements are:

5.11.1 Hygiene and infection prevention procedures shall be understood and practised by each staff member.

5.11.2 Any inappropriate practice (including, but not limited to eating, drinking, chewing and smoking or the storage of food, drink, smoking materials, and personal medication) shall not occur in the dispensing, compounding, repackaging, batch preparation and pharmaceutical storage areas of the pharmacy.

5.11.3 Staff members with a communicable or infectious disease, open skin lesions on exposed surfaces of the body, or a condition that would present abnormal microbiological hazards to products shall not be involved in compounding, repackaging and batch preparation or have direct contact with pharmaceutical products until the condition is corrected.

GUIDANCE

G 5.12 Layout and design should aim to minimise the risk of errors, contamination and cross-contamination.

G 5.12.10 This may include but is not limited to:

(a) If it is necessary to allow a person access to a restricted area, then that person should be escorted by a staff member;

(b) This restriction should be considered when designing access routes for goods delivery or public access to toilet facilities.

DISPENSING, COMPOUNDING, REPACKAGING AND BATCH PREPARATION AREAS AND EQUIPMENT

WORK AREAS

Standard 5.12 **Dispensing, compounding, repackaging and batch preparation areas and equipment shall be located, designed, constructed, adapted and maintained to suit the operations to be carried out.**

Criteria The basic requirements of dispensing, compounding, repackaging and batch preparation areas are:

5.12.1 The dispensing, compounding, repackaging and batch preparation areas shall be distinct identifiable areas separate from any sales or customer waiting areas.

5.12.2 These areas shall be designed and used only for dispensing, compounding, repackaging and batch preparation and shall enable a logical workflow and appropriate segregation of activities.

5.12.3 The areas shall be clean, orderly and well lit.

5.12.4 Each part of these areas shall be well maintained and in a hygienic condition.

5.12.5 There shall be written procedures and schedules available for cleaning all parts of these areas and appropriate cleaning records shall be maintained.

5.12.6 Environmental conditions including temperature, humidity and light shall be appropriately controlled for the operations being carried out.

5.12.7 Dispensing, compounding, repackaging and batch preparation areas shall be designed and equipped so there is maximum protection against the entry of insects or animals.

5.12.8 These areas shall be uncluttered and shall not contain anything that is not required for dispensing, compounding, repackaging, or batch preparation.

5.12.9 Products, starting materials and packaging materials shall be protected from theft, adulteration and contamination.

5.12.10 The public and unauthorised staff shall not have access to the dispensary, compounding, compliance packaging, repackaging, batch preparation, storage and quality control areas unless for a specific purpose authorised by the charge pharmacist.

5.12.11 The premises including wall junctions with other surfaces shall be properly constructed and kept in good repair. Walls, ceilings and floors shall be easy to clean.

5.12.12 All working surfaces, cupboards and shelves shall be finished with smooth, impervious and washable materials. Floors in any wet-compounding area shall be finished with a material that is smooth, impervious and washable.

5.12.13 Pharmaceutical products and starting materials shall be stored in a logical and orderly manner and away from direct sunlight.

GUIDANCE

G 5.13.2 Ambient room temperatures should not exceed 25°C.

G 5.13.4 Refrigerator temperatures should be maintained between 2 and 8°C.

G 5.14.4 Balances are legally required to be calibrated annually.

G 5.14.5 Validation should be by comparison with stamped certified glassware.

STORAGE AREAS

Standard 5.13 **Storage areas shall be sufficient to permit the effective separation and identification of the various stored materials and products and the environment appropriate to their storage.**

Criteria The basic requirements are:

5.13.1 Materials and products shall be protected from the adverse effects of temperature extremes, light and dampness.

5.13.2 The ambient maximum/minimum room temperature of the medicine storage areas (including the dispensary) shall be appropriately monitored and recorded to ensure maintenance of correct temperature. Corrective measures shall be taken when specified conditions have not been maintained.

5.13.3 Pharmaceutical materials and products shall be stored in a way which prevents cross-contamination. Particular attention shall be paid to items stored in the refrigerator.

5.13.4 The refrigerator maximum/minimum temperature shall be appropriately monitored and recorded to ensure maintenance of correct temperature. Corrective measures shall be taken when specified conditions have not been maintained.

EQUIPMENT

Standard 5.14 **Balances, measuring and other equipment and utensils shall be appropriate and adequate to carry out the operations of the pharmacy.**

Criteria The basic requirements are:

5.14.1 Dispensary equipment shall not be used for any other purpose than the preparation and dispensing of medicines.

5.14.2 Equipment and utensils shall be thoroughly cleaned, maintained and adequately stored.

5.14.3 Equipment and utensils shall be designed and constructed so that they are suitable for their purpose and easy to clean, to prevent contamination of products.

5.14.4 Measuring, weighing, recording and control equipment shall be calibrated and checked at defined intervals by appropriate methods. Adequate records of such tests shall be maintained.

5.14.5 Non-certified liquid measures shall be validated.

5.14.6 Defective equipment shall be clearly labelled as defective and removed from use.

5.14.7 Designated and separate equipment shall be used in the dispensing, compounding, repackaging and batch preparation of cytotoxic preparations.

GUIDANCE

G 5.15 Compounding should be carried out in accordance with systematic and precise routines, which support integrity in the operation. The aim of systematic routines is to achieve products that are safe and of an acceptable and consistent quality.

G 5.15.9 This may include but is not limited to:

(a) Visual evaluation of the end product;

(b) Testing of the end product;

(c) When powder or capsules are to be prepared in batch sizes greater than 300 grams of powder and up to five kilograms, then validation will be more comprehensive and completed before products are released.

COMPOUNDING

COMPOUNDING PROCEDURES

Standard 5.15 **Compounding procedures shall ensure that the medicines prepared are of the required quality.**

Criteria The basic requirements are:

5.15.1 Regularly used methods of preparation shall be documented in SOPs.

5.15.2 Regularly prepared formulas shall be written down in master batch documents.

5.15.3 Compounding shall be performed by competent qualified staff under the supervision of a pharmacist.

5.15.4 Only starting materials which have been approved for use and are within their expiry date shall be used.

5.15.5 The identity, and weight (or volume) of each ingredient shall be checked by a pharmacist.

5.15.6 Products and starting materials shall be identified at all times during preparation. Labels or indications on containers and equipment shall be clear and unambiguous.

5.15.7 The preparation of non-pharmaceutical products shall not take place in areas intended for the preparation of pharmaceutical products.

5.15.8 Equipment used in the preparation of non-pharmaceutical products shall not be used in the preparation of pharmaceutical products.

5.15.9 When a new method of preparation is adopted, steps shall be taken to demonstrate that it achieves the expected result.

DOCUMENTATION FOR COMPOUNDING

Standard 5.16 **Electronic or hard copy documentation shall be site specific, traceable, unambiguous and easy to read.**

Criteria The basic requirements are:

5.16.1 Each master document shall:

(a) State the title, nature and purpose of the document and identify the pharmacy;

(b) Have instructions that are clear, precise and unambiguous;

(c) Be prepared by an authorised person, who signs and dates the document;

(d) Be checked, dated and signed by a pharmacist;

(e) When requiring the entry of data, provide sufficient space for the data and for the signature or initials of the person making the entry.

5.16.2 All documents shall be kept up to date and be revised as necessary.

5.16.3 All amendments to any documents involved in the compounding, repackaging and batch preparation process shall be formally authorised and signed by a pharmacist.

GUIDANCE

G 5.17.2 This may include but is not limited to records about the facility, equipment, environment, materials and staff.

5.16.4 Outdated or superseded documents shall be cancelled, removed from active use, and the master archived for reference for a minimum of 3 years.

MASTER DOCUMENTS

Standard 5.17 Master document templates shall be created to record compounding and monitoring activities.

Criteria The basic requirements are:

5.17.1 A master batch document shall be prepared for frequently used standard formulas and shall include:

(a) The name of the product;

(b) A description of the pharmaceutical form and strength of the product;

(c) A list of the ingredients together with the amount of each;

(d) An area for the batch numbers and the expiry dates of the ingredients used;

(e) A step-by-step description of the compounding procedure;

(f) A list of the packaging material to be used;

(g) The storage conditions for the finished product;

(h) A sample of the label and any advisory/auxiliary labels;

(i) The assigned expiry date period;

(j) An area for recording the batch quantity;

(k) An area for recording the unit pack size;

(l) An area for the batch number to be assigned;

(m) An area for sign off by a pharmacist for the measuring and checking of the ingredients;

(n) An area for reconciliation of final yield and labels; and

(o) An area for sign off by a pharmacist for checking/release of the final product.

5.17.2 A master document shall be prepared for recording of cleaning/maintenance activities, calibrations, validations and other monitoring procedures. These records shall include the dates and identify the staff carrying out these operations.

5.17.3 A photocopy or reprint of the master document template shall be used as the record for these activities.

RECORD OF COMPOUNDING

Standard 5.18 A copy of the master batch document shall be used to make the record.

Criteria The basic requirements are:

5.18.1 The following information shall be recorded:

(a) The date of the preparation;

(b) The name of the compounder;

(c) Quantities of ingredients used;

(d) Total quantity prepared;

(e) Batch numbers and expiry dates of ingredients used;

GUIDANCE

G 5.19.1 If an active substance is not purchased from a licensed manufacturer or supplier (holding a packing licence) then the identity and purity of the substance should be established.

G 5.19.6 The assigning of an expiry date to a starting material should be based on reference to appropriate pharmaceutical resources or an understanding of the chemical properties of the starting material and whether the material has been subject to potential microbial or cross-contamination from frequent opening, or likely degradation from exposure to heat, light, air, or moisture.

(f) A unique identifying batch number;

(g) An expiry date of the finished product;

(h) A sample label and any auxiliary labels;

(i) Any deviation from usual practice in preparation or ingredients used;

(j) The signature or initials of the pharmacist checking/releasing the finished product.

5.18.2 In the case of individual compounding where a copy of a master batch document is not used as the record, a record shall be kept on the premises which enables the history of the finished product to be traced. This record shall include:

(a) The name of the preparation;

(b) Name and quantities of the ingredients used;

(c) The date of the preparation;

(d) A unique identifying number (usually the prescription number);

(e) The batch number and expiry date of each ingredient;

(f) The expiry date of the finished product;

(g) A copy of the product label;

(h) The signature or initials of the pharmacist checking/releasing the final product.

STARTING MATERIALS

Standard 5.19 **Starting materials shall be of a quality suitable for use in products intended for therapeutic use.**

Criteria The basic requirements are:

5.19.1 Starting materials shall be purchased from recognised suppliers who know the origin of the material and who supply pharmaceutical grade materials.

5.19.2 At the point of receipt, the containers of the starting materials shall be checked for integrity of package and seal, legibility of labelling, and for correlation between the order, delivery note and the supplier's labels. Any damage or contamination shall be considered by a pharmacist and appropriate action taken.

5.19.3 There shall be appropriate procedures or measures to assure the identity of the contents of each container of starting material.

5.19.4 A system shall be set up to ensure that all materials meet the required specifications at the time of purchase and on each and every occasion the material is used.

5.19.5 Incoming materials shall only be used if they meet predetermined specifications.

5.19.6 Starting materials received without an expiry date shall be assigned a suitable expiry date by the pharmacist. The date of receipt should be recorded on the package if received without an expiry date.

5.19.7 All starting materials shall be stored under the appropriate conditions established by the manufacturer and in an orderly fashion to permit batch segregation and stock rotation.

5.19.8 Special care is needed for handling penicillins and cytotoxics, hormones and highly active materials.

GUIDANCE

G 5.22 Special procedures are required for aseptic/sterile preparation. (See section 6 for aseptic dispensing of sterile products in community pharmacies or section 7 for aseptic dispensing of sterile products in hospital pharmacies.)

5.19.9 Potable water to be used as a starting material shall be of a quality appropriate for the finished product and be handled as other starting materials.

5.19.10 If a water filter is used it shall be maintained in compliance with the manufacturer's specifications.

MATERIALS AND FINISHED PRODUCT SPECIFICATION

Standard 5.20 Where appropriate there shall be written specifications for starting materials, packaging materials and finished products.

Criteria The basic requirements are:

5.20.1 There shall be specifications for starting materials and packaging materials. These shall include:

(a) A description of the material and the name and reference, if any, to a pharmacopoeial monograph;

(b) The storage conditions;

(c) The assignment of an expiry date by a pharmacist. Refer to appropriate resources when no expiry date has been issued by the producer.

5.20.2 There shall be specifications for finished products which include all the checks the product has to conform to before release for sale or distribution. These checks shall include:

(a) A description of the product with reference to an official compendium as needed;

(b) A suitable expiry date;

(c) A unique batch number;

(d) Packaging to be used;

(e) A sample label.

PACKAGING MATERIALS

Standard 5.21 Packaging materials shall be selected for their suitability for the products they will contain.

Criteria The basic requirements are:

5.21.1 The purchase and handling of packaging materials shall be accorded attention similar to that given to starting materials (see 5.19).

5.21.2 Containers shall be clean and dry before filling.

PREVENTION OF CROSS-CONTAMINATION

Standard 5.22 Adequate precautions shall be taken to prevent contamination, cross-contamination and product mix-up in all stages of preparation.

Criteria The basic requirements are:

5.22.1 Effective cleaning procedures shall be used before commencing and at completion of product preparation.

GUIDANCE

G 5.22.5 The significance of the risk of contamination varies with the type of contaminant and the product being made. Among the most hazardous contaminants are highly sensitising materials, biological preparations containing living organisms, certain hormones and other highly active materials.

Precautions should be taken when protective clothing is removed from areas where products with special risk of cross-contamination are processed.

G 5.23.1 In all cases dates should be based on knowledge of the product, materials and packaging materials as well as the pharmacist's knowledge of pharmaceutical science.

5.22.2 The compounding area shall only contain materials associated with the process being carried out, including the required documentation.

5.22.3 Products shall not be prepared simultaneously or consecutively in the same area unless there is no risk of mix-up or cross-contamination.

5.22.4 At every stage of compounding, preparation techniques shall be used which protect the starting materials and finished products from microbial and other contamination.

5.22.5 When working with dry materials and products, precautions shall be taken to prevent the generation and spreading of dust.

EXPIRY DATES OF COMPOUNDED PRODUCTS

Standard 5.23 An expiry date shall be assigned to the end product by a pharmacist with reference to pharmaceutical resources.

Criteria The basic requirements are:

5.23.1 The responsibility lies with the pharmacist to assess the expiry date and the storage conditions.

5.23.2 The expiry date assigned shall be stated on the label.

LABELS ON COMPOUNDED PRODUCTS

Standard 5.24 Labels that accurately describe the finished product shall be attached to the container.

Criteria The basic requirements are:

5.24.1 Labels of compounded medicines shall contain the following:

(a) Name of the pharmaceutical product;

(b) Dosage form and strength where applicable;

(c) Quantity in the container;

(d) Instructions for use and storage;

(e) Assigned batch number and expiry date;

(f) Date of compounding; and

(g) Name of pharmacy.

RELEASE OF FINISHED PRODUCT

Standard 5.25 There shall be a defined step where the finished product is compared with its specifications and released or rejected.

Criteria The basic requirements are:

5.25.1 The decision to release the finished product shall be made by the pharmacist taking responsibility for quality.

5.25.2 The assessment and decision shall be recorded.

GUIDANCE

G 5.26.2 A sign or label should be attached to these rejected materials or products so they are identified as not acceptable for use.

REJECTED AND RETURNED MATERIALS AND PRODUCTS

Standard 5.26 Rejected materials and products shall be identified and segregated.

Criteria The basic requirements are:

5.26.1 Rejected incoming materials and products shall be identified and segregated. They shall be returned to the supplier or destroyed.

5.26.2 Materials and products discarded or rejected during processing shall be stored in quarantine pending appropriate destruction.

5.26.3 Products returned from consumers/customers shall be destroyed.

REPACKAGING OF MEDICINES

PRINCIPLE

Repackaging is the process followed when a medicine is removed from its original labelled container as a batch operation and is at risk of losing its identity including batch number and expiry date.

Strip packed medicine that retains labelling, batch number and expiry date may be repackaged prior to dispensing without necessarily requiring repacking documentation, provided that a robust checking procedure is followed.

GENERAL REPACKAGING PROCEDURES

Standard 5.27 Repackaging shall maintain the quality and integrity of the medicine.

Criteria The basic requirements are:

5.27.1 The processing area shall only contain materials and documentation associated with the process being carried out.

5.27.2 Products shall be identified at all times during preparation. Labels or indications on containers and equipment shall be clear and unambiguous.

DOCUMENTATION FOR REPACKAGING OF MEDICINES

Standard 5.28 Where products are regularly repackaged there shall be a master batch document (repackaging instruction) for each product, pack size and type.

Criteria The basic requirements are:

5.28.1 The master batch document shall contain the following:

(a) Name of the product;

(b) Dosage form and strength;

(c) Pack size (repacked product);

(d) Instructions for the unpacking and repacking procedure (including any applicable in-process controls);

(e) A list of the packaging materials to be used;

(f) Storage conditions for the repacked product;

(g) Special precautions to be observed;

G U I D A N C E

(h) Labelling text or master reference label and any advisory/auxiliary labels.

(i) Assigned expiry date period (repacked product);

(j) An area for the original manufacturer's batch number and expiry date;

(k) An area for the in-house batch number and expiry date to be assigned;

(l) An area for sign off by a pharmacist for checking the label;

(m) An area for recording the product and packaging material quantities issued;

(n) An area for recording the product and packaging material quantities used or returned;

(o) An area for reconciliations of final yield, packaging materials and labels; and

(p) An area for sign off by the pharmacist for checking/release of the final product.

RECORDS FOR REPACKAGING OF MEDICINES

Standard 5.29 For regularly repacked products a copy of the master batch document shall be used to make the record.

Criteria The basic requirements are:

5.29.1 The following information shall be recorded:

(a) Date of processing;

(b) Name of the qualified staff member performing the operation;

(c) Name/strength/dose form and material names to be recorded;

(d) Quantities of all printed packaging materials, containers and bulk product, issued, used, destroyed, or returned to stock;

(e) Quantity of repackaged units prepared;

(f) A reconciliation for all components involved in the packaging procedure;

(g) Batch number and expiry date of original product;

(h) Assigned in-house batch number and expiry date of the repackaged product;

(i) A sample label and any auxiliary labels; and

(j) The signature or initials of the pharmacist checking/releasing the finished product.

PACKAGING MATERIALS FOR REPACKAGED MEDICINES

Standard 5.30 Packaging materials shall be selected for their suitability for the products they will contain.

Criterion **5.30.1** The requirements in 5.21 shall be met.

PREVENTION OF CROSS-CONTAMINATION FOR REPACKAGED MEDICINES

Standard 5.31 Adequate precautions shall be taken to prevent contamination, cross-contamination and product mix-up in all stages of preparation.

Criterion **5.31.1** The requirements in 5.22 shall be met.

GUIDANCE

EXPIRY DATES OF REPACKAGED PRODUCTS

Standard 5.32 An expiry date shall be assigned by a pharmacist to the repackaged products that does not exceed the manufacturer's expiry date.

Criteria The basic requirements are:

5.32.1 The pharmacist shall assign an appropriate expiry date with regard to the expected storage conditions.

5.32.2 The expiry date assigned shall be stated on the label.

LABELS ON REPACKAGED PRODUCTS

Standard 5.33 Labels that accurately describe the finished product shall be attached to the container.

Criterion **5.33.1** Labels of repackaged medicines shall contain the following:

(a) Name of the product;

(b) Dosage form and strength where applicable;

(c) Pack size;

(d) Assigned batch number and expiry date;

(e) Date of repackaging;

(f) Name of the pharmacy.

RELEASE OF FINISHED PRODUCT

Standard 5.34 There shall be a defined step where the finished product is compared with its specifications and released or rejected.

Criterion **5.34.1** The requirements in 5.25 shall be met.

REJECTED AND RETURNED MATERIALS AND PRODUCTS

Standard 5.35 Rejected materials and products shall be identified and segregated.

Criterion **5.35.1** The requirements in 5.26 shall be met.

GUIDANCE

G 5.36.2 Medicines should not be stored in compliance packs for extended periods of time, and for no longer than 8 weeks, unless a pharmacist considers a shorter period is appropriate, or recommended by the manufacturer.

COMPLIANCE PACKAGING, DOSE PACKAGING AND UNIT DOSE PACKAGING

The dispensing of medicines in separate dose compartments for day and time shall follow clearly defined procedures so as to produce packs that are accurately dispensed and of an acceptable and consistent quality.

REPACKAGING PROCEDURES

Standard 5.36 The repackaging procedure shall ensure that the final sealed pack meets the requirements of the prescription.

Criteria The basic requirements are:

5.36.1 Qualified staff involved in the compliance, dose and unit dose packing procedure shall be trained to do so and be competent in the procedure. Training shall be documented.

5.36.2 Only those medicines suitable for compliance, dose, or unit dose packing shall be put into packs. Procedures shall be in place to manage medicines not suitable for compliance, dose, or unit dose packs.

5.36.3 To reduce the risk of contamination the person packing the medication into the compliance, dose, or unit dose pack shall not come into direct contact with the medication. For example, handlers shall use gloves or forceps.

5.36.4 A protocol shall be in place describing the frequency for cleaning/disposing of the equipment used to place the medication into the unit dose pack.

5.36.5 Packs shall be checked and sealed as soon as practicable after filling.

5.36.6 Packs shall be sealed on the day of preparation.

PREPARATION AREA

Standard 5.37 A designated area shall be used for the packing process.

Criteria The basic requirements are:

5.37.1 The area shall be of a sufficient size to allow for separation of packing, checking and storage of finished packs.

5.37.2 Packs awaiting delivery, returned packs and packs awaiting change shall be stored in areas clearly labelled and distinct from one another to ensure there is no ambiguity over the status of a pack.

5.37.3 The area used shall be thoroughly cleaned before and after the operation.

5.37.4 Only equipment necessary for the repackaging process shall be kept in this area while packs are being prepared or checked.

GUIDANCE

G 5.39 This process involves the removal of medicines originally packed in foil strip packaging for addition to the automated dispenser reservoirs or for later use in compliance, dose, or unit dose packaging. Due to the risk of contamination and medicine selection error, this process should be strictly controlled and checked following repacked medicine procedures.

G 5.39.2 In all cases the assigned expiry date should be based on knowledge of the product, materials, packaging materials and the pharmacist's knowledge of pharmaceutical science.

G 5.39.4 The qualified staff performing the process should check that there are no foreign objects (foil, hair, desiccants) or poor quality products (for example, broken tablets) in the repacked container.

DOCUMENTATION

Standard 5.38 Completion of each stage of the packing process shall be documented and the records retained in the pharmacy.

Criteria The basic requirements are that:

5.38.1 Documentation related to the prescription and compliance packaging is completed before the packing operation is undertaken.

5.38.2 A record of the checking process is retained in the pharmacy.

5.38.3 Where a compliance, dose, or unit dose packing process involves de-blistering or repackaging of a medicine before it is placed into a pack, a batch packing record shall be kept (see 5.29 and 5.39).

DE-BLISTERING OF MEDICINES

Standard 5.39 Documented and systematic procedures shall be followed when medicines are removed from their original strip packaging.

Criteria The basic requirements are:

5.39.1 A batch record shall be kept for each medicine that is removed from its original blister packaging for later use in compliance, dose, or unit dose packaging.

5.39.2 The batch record shall include:

(a) The date of de-blistering;

(b) The name, strength and dosage form of the medicine;

(c) The original batch number and expiry date of the medicine;

(d) The identity of the person performing the procedure;

(e) The identity of the pharmacist checking the end product;

(f) The new assigned expiry date for the medicine in that container by the pharmacist.

5.39.3 Labels of de-blistered medicines shall contain the following:

(a) Name, strength and dosage form of the medicine;

(b) Date the medicine was de-blistered and packed into the container;

(c) Original batch number of the medicine;

(d) Assigned expiry date.

5.39.4 A check shall be made of the de-blistered medicines in the repacked container to ensure integrity of the medicines is maintained.

5.39.5 De-blistering of medicines shall only involve sufficient quantity for two week's use at a time.

5.39.6 Only one medicine shall be de-blistered at a time with the process finished and checked off by the pharmacist, before another medicine de-blistering process begins.

GUIDANCE

G 5.41.1 This may include but is not limited to:

(a) Checking against the original prescription;

(b) Checking against the prescriber-signed medication chart.

LABELLING

Standard 5.40 **Labelling of compliance packs, dose packs, or unit dose packs shall be easily read and understood by consumers and caregivers.**

Criteria The basic requirements are:

5.40.1 Packs shall contain the following details:

(a) Name of the consumer;

(b) Name and address of the pharmacy;

(c) Date of preparation of the pack;

(d) Strength and name of all medications in the pack;

(e) Prescription/reference number;

(f) Directions for use; dose and frequency of dose of medication in the pack written in English; and

(g) Cautionary and advisory labels.

5.40.2 Where a pack has perforations to enable separation of the individual dose units for each dose period, the labelling on each individual dose shall have:

(a) Consumer's name;

(b) Name and strength of each medication contained in the dose unit;

(c) Quantity of each medicine; and

(d) Dose time and day.

FINISHED COMPLIANCE, DOSE, OR UNIT DOSE PACK

Standard 5.41 **There shall be a defined step where the finished pack is checked by a pharmacist for quality and accuracy of dispensing, and released or rejected.**

Criteria The basic requirements are:

5.41.1 A final check shall be made against the appropriate authorisation following the normal checking procedure for dispensed medicines.

5.41.2 This final check shall be recorded both on the pack and on a document that contains the pharmacist identity and date, which remains on the pharmacy premises.

5.41.3 Any compliance pack rejected at the final check shall be quarantined until corrected and rechecked, or appropriately disposed of.

GUIDANCE

G 5.42.2 This may include but is not limited to:

(a) Written specification from the manufacturer;

(b) Documented procedures for filling canisters;

(c) Written checking procedures including dates and identification of staff involved.

AUTOMATED PACKING AND DISPENSING

PRINCIPLE

The use of an automated packing or dispensing device (automated device) should be carried out in accordance with systematic and precise routines, which support accuracy in the operation. The aim of systematic routines is to achieve packed products that are safe, accurate and of consistent quality. All good packing and dispensing practices shall be employed.

AUTOMATED DEVICES

Standard 5.42 **Good dispensing practices shall be established and followed for safe and accurate medicine packing and dispensing.**

Criteria The basic requirements when using an automated device are:

5.42.1 All processes involved are clearly defined, recorded, reviewed and known to be capable of consistently producing accurately dispensed packed medicines.

5.42.2 Critical steps of the process shall be validated including software systems.

5.42.3 At every stage of processing, products and materials shall be protected from microbial and other contamination.

5.42.4 Thorough checking of the end product shall be undertaken by a pharmacist before release of the product for supply.

5.42.5 Adequate and suitable space for the automated device to operate shall be available.

5.42.6 Entering of the profile (cycle date, medicines to be packed, frequency, and dose, if signing sheets are required) shall be performed by qualified staff only.

5.42.7 The automated device shall be calibrated according to the manufacturer's specifications.

STAFF

Standard 5.43 **Only appropriately qualified staff shall be involved in any part of the automated packing and dispensing processes, including de-blistering of medicines.**

Criteria The basic requirements are:

5.43.1 The pharmacy manager shall ensure that all staff involved in the automated packaging process are appropriately qualified as required by the Medicines Regulations and have received appropriate training.

5.43.2 The pharmacy manager shall ensure that procedures related to health, hygiene practices and clothing are established.

5.43.3 The charge pharmacist shall ensure that these procedures are followed.

GUIDANCE

G 5.44.2 A clearly defined list of medicines not suitable for packing in the automated device should be appended to the automated device SOP. This list should be current. For example beta-lactam antibiotics are unsuitable for use in an automated device to avoid cross-contamination.

G 5.44.3 Mixing batches of medicines when refilling the canisters should be avoided.

G 5.44.4 A pharmacist should perform this check wherever possible.

G 5.46 Each part of the automated device shall be maintained in a good and hygienic condition, with particular attention paid to the areas where dust and particulate matter collect. Care should be taken to ensure that any residual product or labels are removed.

G 5.46.1 These schedules should adhere to the manufacturer's specifications including frequency, cleaning instruction and the cleaning material used.

G 5.47.1 This may include but is not limited to:

(a) Checking against the original prescription;

(b) Checking against the prescriber-signed medication chart.

FILLING THE RESERVOIRS/CANISTERS WITH MEDICINES

Standard 5.44 There shall be a fully documented systematic process for filling the medicine reservoirs/canisters to avoid any chance of incorrect filling.

Criteria The basic requirements are:

5.44.1 This system shall be validated.

5.44.2 There shall be a system for identifying medicines not suitable for processing through the automated device.

5.44.3 A record shall be made of the batch number and expiry date of the medicine, identification of the person filling the canister and the date of filling.

5.44.4 Before an exceptions tray is loaded into the automated device for packing, the medicines shall be checked for accuracy.

DE-BLISTERING OF MEDICINES FOR AUTOMATED PACKING AND DISPENSING

Standard 5.45 A documented and systematic procedure shall be followed when medicines are removed from their original strip packaging.

Criterion **5.45.1** The criteria of 5.39 shall be met.

CLEANING THE AUTOMATED DEVICE

Standard 5.46 The device shall be maintained in a clean and hygienic condition.

Criteria The basic requirements are:

5.46.1 There shall be written procedures and schedules available for cleaning for all parts of the automated device.

5.46.2 The cleaning shall be documented including the identity of the person, the date and the time.

CHECKING THE FINISHED PRODUCT

Standard 5.47 The pharmacist shall be responsible for checking the contents and label of every packed medicine prior to supply to a consumer.

Criteria The basic requirements are:

5.47.1 This check shall be made against the appropriate authorisation following the normal checking procedure for dispensed medicines within the pharmacy.

5.47.2 This checking process shall be documented and retained on the pharmacy premises.

5.47.3 Each medicine container will be appropriately labelled as listed in 5.40.1.

5.47.4 If medicines are placed in individual sachets, each sachet shall be labelled in accordance with 5.40.2 and there shall be a 'header' label for the entire dose pack that is labelled in accordance with 5.40.1.

5.47.5 There shall be a documented process for handling rejected packs, following GMP principles.

GUIDANCE

G 5.48 A pharmacy can only contract compliance packaging, dose packaging, or unit dose packaging of medicines from a facility with a licence to pack medicines. This is a separate licence from a licence to operate a pharmacy.

G 5.48.3 Labels should include all details listed in 5.40.

5.47.6 Completed packs awaiting supply to consumers shall be stored in appropriate areas to protect from heat and light and avoid contamination.

CONTRACT COMPOUNDING, PACKING AND ANALYSIS

PRINCIPLE

If a service provider contracts the services of an outside supplier of extemporaneously compounded medicines, licensed packing facility, or of a control laboratory, it is the responsibility of the service provider to be assured of the competence of that supplier or laboratory.

Standard 5.48 **The service provider shall have a contract with the contracted provider of the service that clarifies and defines the division of responsibilities between the two parties.**

Criteria The basic requirements are:

5.48.1 The service provider shall obtain written assurance that any control laboratory used has appropriate accreditation.

5.48.2 Before dispensing, the service provider shall ensure that the labelled product supplied correlates with the original request.

5.48.3 The service provider shall label the product appropriately before it is sold or supplied to a consumer. This includes dose packed medicines supplied from a licensed packing facility.

GUIDANCE

G 6.1.1 This may be achieved by, but is not limited to, consideration of the following:

(a) What might go wrong?

(b) What is the likelihood (probability) it will go wrong?

(c) What are the consequences (severity)?

(d) The risks include medication errors and microbiological contamination and risks related to facilities, equipment, staff, training, environment and microbiological contamination.

G 6.1.2 Risk assessment tool

To meet the criteria of 6.1.2, the use of a risk assessment tool is recommended. A suggested risk assessment tool is set out in figure 1.

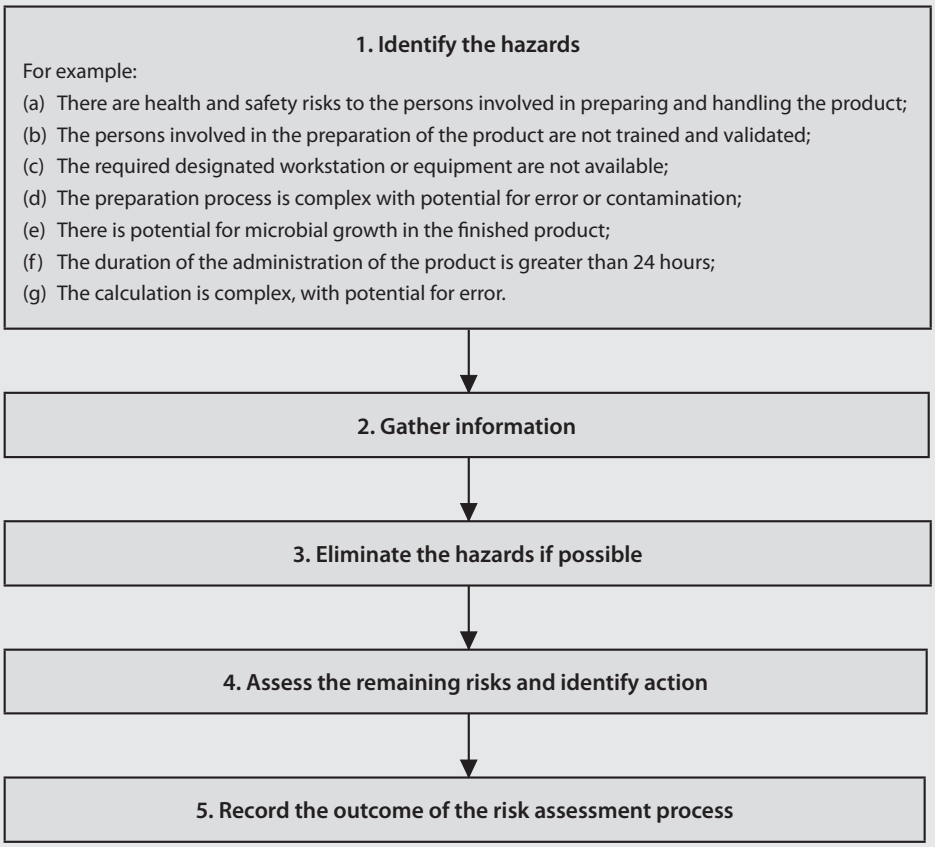

Figure 1 – Risk assessment flow chart

6 ASEPTIC DISPENSING OF STERILE PRODUCTS IN COMMUNITY PHARMACIES

Outcome 6 Consumers receive aseptically prepared products, dispensed by community pharmacists pursuant to a prescription from a designated prescriber, in accordance with standards and guidelines.

INTERPRETATION

Section 6 is applicable to a community pharmacy that undertakes small scale aseptic dispensing using a still air box, isolator, laminar flow unit, or other validated device.

This section replaces Annex 1 of the *New Zealand Code of good manufacturing practice for manufacture and distribution of therapeutic goods, Part 3: Compounding and dispensing 1993 (Code of GMP).*

RISK MANAGEMENT

Standard 6.1 **Before undertaking any aseptic dispensing a risk assessment shall be undertaken.**

Criteria The basic requirements are:

6.1.1 The risk potential for negative health outcomes when conducting aseptic dispensing shall be assessed prior to commencing aseptic dispensing for the first time.

6.1.2 The risk potential of failures, such as quality defects, varies with different types of products and shall be assessed for every new product compounded.

STAFF AND TRAINING

Standard 6.2 **The organisation shall ensure that appropriate training is provided for all qualified staff undertaking aseptic dispensing.**

Criteria The basic requirements are:

6.2.1 There shall be sufficient competent staff to carry out all the tasks required for aseptic dispensing.

6.2.2 Before undertaking aseptic dispensing, all staff shall receive training in the appropriate skills and knowledge. The training shall be documented.

6.2.3 All staff shall receive training that will provide them with:

(a) An appropriate knowledge of quality assurance processes;

(b) Competence in the necessary aseptic manipulative skills;

(c) Knowledge of pharmaceutical microbiology;

(d) A working knowledge of the products and services provided.

6.2.4 The competence of the staff shall be assessed annually and revision or retraining provided if necessary.

6.2.5 A designated trainer or an accredited provider shall undertake assessment of the competence of the staff.

GUIDANCE

G 6.2.6 Re-evaluation could include peer evaluation or a broth test.

G 6.3.2 Guidance considerations to achieve these criteria include:

(a) Sinks or hand-washing facilities should not be adjacent to the workstation or preparation areas to prevent aerosol or liquid sprays impinging on the materials being processed;

(b) Air flow from windows or doors or air conditioning units is likely to create turbulent air flow within the dedicated area;

(c) Storage areas may result in excessive particles being introduced into the designated device.

G 6.3.3 Staff who are not necessary to the dispensing process may introduce contamination and turbulent airflow into the dedicated area.

G 6.3.7 An additional non-shedding cover may be used for long periods of storage.

G 6.3.13 Considerations to achieve this criterion include:

(a) All 'sharps' (for example, glass ampoules, vials, or needles) should be disposed of safely;

(b) Paper rubbish, unused medication and all 'non-sharps' equipment should be disposed of appropriately.

6.2.6 Staff who have been absent from the aseptic dispensing process for 6 months or more shall have their technique re-evaluated before commencing aseptic dispensing.

6.2.7 All infections and skin lesions shall be assessed to determine whether the operator can safely dispense aseptic products.

FACILITIES AND EQUIPMENT

Standard 6.3 **Aseptic dispensing shall be carried out using equipment that is fit for purpose and from facilities that are appropriate, accessible, safe and fit for purpose.**

Criteria The basic requirements are:

6.3.1 All aseptic dispensing shall be carried out in a still air box (SAB), isolator, laminar flow unit, or other validated device.

6.3.2 The device shall be located in a dedicated area which is separate from the main pharmacy dispensing areas and areas of high traffic. It shall be separate from such environments as wet areas, air flow, carpets, or storage areas.

6.3.3 Only staff who are actively involved in the aseptic process shall be allowed access to the dedicated area during aseptic dispensing.

6.3.4 The dedicated area shall have sufficient space to allow the decontamination and transfer of equipment into the device.

6.3.5 The device shall be able to be easily cleaned and disinfected.

6.3.6 All surfaces shall be smooth and impervious.

6.3.7 The device shall be cleaned regularly even when not in frequent use. The device shall be closed when not in use.

6.3.8 The isolator, laminar flow unit or other validated device shall be used in accordance with any operating instructions.

6.3.9 All equipment used in aseptic dispensing shall be purchased from reputable companies and shall be fit for purpose. Syringes, filters and needles shall be sterile and in date.

6.3.10 Sterile components or equipment shall be stored so as to minimise any increase in the bioburden on the surface of the primary packaging.

6.3.11 Sterile components shall not be used beyond one working session.

6.3.12 Any unused sterile components shall be discarded according to in-house procedures.

6.3.13 All used equipment and rubbish shall be discarded as appropriate.

GUIDANCE

G 6.4.1 Masks prevent vapour droplets spraying onto equipment during aseptic dispensing processes.

G 6.4.2 Guidance considerations to achieve this criterion include:

(a) Armlets which cover wrist to elbow may be used;

(b) Short sleeves should be worn for comfort.

G 6.4.5 Guidance considerations to achieve this criterion include:

(a) Eye wear such as glasses should be routinely cleaned and free from visible contamination;

(b) If jewellery items cannot be removed, suitable coverings should be used (for example, paper tape).

G 6.4.7 Guidance considerations to achieve these criteria include:

(a) Suitable anti-bacterial agents include chlorhexidine 4% hand scrub or povidone iodine 7.5% hand scrub;

(b) Alternatives to hand washing (for example, the use of anti-bacterial alcohol-based solutions) should be validated before use;

(c) Scrub brushes should not be used as they can cause skin damage.

G 6.4.8 Disinfection of contaminated gloves may be accomplished by applying 70% alcohol to all contact surface areas of the gloves and allowing to dry thoroughly (usually 2 minutes).

CLOTHING

Standard 6.4 **Service providers undertaking aseptic dispensing shall wear clothing that minimises the risks of contaminating the workstation or preparation areas and the dispensed product.**

Criteria The basic requirements are:

6.4.1 Staff who are actively involved in the aseptic dispensing process shall wear head coverings (to totally cover the hair) and masks.

6.4.2 A non-shedding gown or apron shall be worn to cover the critical area of the operator's body.

6.4.3 Powder-free gloves that have been disinfected prior to use or are sterile shall be worn.

6.4.4 Garments that create particles shall not be worn (for example, woollen jumpers or jerseys).

6.4.5 All visible jewellery shall be removed if possible including wrist watches, bracelets and rings.

6.4.6 Cosmetics, nail polish and false nails shall not be worn.

6.4.7 Hand hygiene shall be carried out in the following manner:

(a) Wash the hands, nails and arms to the elbows using an anti-bacterial scrub and water for a minimum of 2 minutes;

(b) Dry hands and forearms using a non-linting cloth.

6.4.8 Gloves shall be disinfected when removed from the work device or otherwise contaminated.

6.4.9 Gloves shall be inspected for punctures or tears and replaced immediately if punctured or torn. Products that have been compounded during the time when gloves could have been punctured shall be discarded as they may have been contaminated.

6.4.10 A new head covering, mask, gown and gloves shall be used for each session of aseptic dispensing.

GUIDANCE

G 6.5.1 Guidance considerations to achieve this criterion include:

(a) Cleaning and disinfecting agents should be free from viable microorganisms. A disinfectant of 70% alcohol should have a defined expiry date;

(b) If there is visible soiling, the device should be washed with detergent and water. Dry dusting is not acceptable.

G. 6.5.3 Spores are more effectively removed by including a wiping stage in the surface disinfecting procedure.

G 6.6.3 Guidance considerations to achieve a completed batch record include:

(a) Name of the product;

(b) A description of the pharmaceutical form and strength of the product;

(c) A list of the ingredients together with supplier, batch number and quantity of each required;

(d) The number of items prepared and the total quantity prepared;

(e) A unique number to identify the product;

(f) A step-by-step description of the compounding procedure;

(g) Date of preparation and time if applicable;

(h) Expiry date and time (if applicable) of product;

(i) A list of packaging materials used;

(j) Storage conditions for the finished product;

(k) Signature or initials of person performing initial, pre-process checks;

(l) Signature or initials of person undertaking the preparation and any in-process visual checking quality assurance procedures;

(m) A record of the label used on the product;

(n) A 'comments' section for recording of any unusual occurrence or observations;

(o) Signature or initials of the person who is responsible for the final release of the product(s).

CLEANING

Standard 6.5 **The preparation areas and device shall be cleaned in a manner that minimises the risk of contamination of the environment and dispensed product.**

Criteria The basic requirements are:

6.5.1 The device shall be cleaned before the commencement of any aseptic dispensing session.

6.5.2 The device shall be disinfected in the following manner:

(a) Still air box (SAB)

Spray all the inside surfaces and the lid with 70% alcohol.

Use wipes impregnated with 70% alcohol to disinfect each surface of the designated workstation. Use long, overlapping strokes in the following order: base, ceiling, back, sides, front, base and lid.

Replace the lid and let the alcohol dry for 2 minutes.

(b) Other devices

According to validated standard operating procedures.

6.5.3 The decontamination shall be a two-step process (one of which is a spray and wipe procedure and the other may be a spray or wipe-only procedure). After each step a drying period of no less than 2 minutes is required.

6.5.4 The device workstation shall be disinfected at the end of the dispensing process.

DOCUMENTATION

Standard 6.6 **Documentation shall be site specific, traceable, unambiguous, complete and easy to read.**

Criteria The basic requirements are:

6.6.1 Individual batch records shall be reproduced from master batch documents.

6.6.2 The batch record shall be sufficiently detailed to allow traceability of starting materials and components to establish an audit trail for the completed product.

6.6.3 Documentation relating to batch preparation and repacking shall be retained for a minimum of 3 years after the expiry date of the preparation.

6.6.4 The batch record shall be signed or initialled by the person who checked the calculations.

6.6.5 All master batch documents shall be regularly reviewed, at intervals of not more than 2 years.

6.6.6 Operation, cleaning, maintenance and fault logs shall be kept for the designated area and devices.

6.6.7 A record shall be maintained of errors, near-misses and of investigations undertaken.

GUIDANCE

G 6.6.4 Where practicable the calculation should be checked by a different pharmacist to the operator dispensing.

G 6.7.2 Guidance considerations to achieve this criterion include:

(a) Aseptic dispensing comprises aseptic process and aseptic technique;

(b) The key elements of the aseptic process include:

- (i) Entry of staff into the processing area
- (ii) Completing all documentation for each product including batch records, labels, and so on
- (iii) Maintaining the integrity of the aseptic processing area, and the care of the device and its dedicated area
- (iv) Handling and preparation of starting materials, especially the decontamination process
- (v) Transfer of the starting materials into the dedicated area and device
- (vi) Standard aseptic techniques such as 'no-touch' of the critical surfaces, correct positioning of materials in the device, and disinfection of gloves if in use for greater than 30 minutes
- (vii) Segregation and flow of materials to ensure no accidental cross-contamination of starting materials or end products
- (viii) No removal of the gloved hands from the workstation except in exceptional circumstances. Subsequent decontamination of gloved hands if removed
- (ix) Performance and recording of in-process checks
- (x) Removal of product and waste materials from the processing area
- (xi) Preparations failing to meet the required standard are investigated and acted upon;

(c) Examples of good aseptic technique include:

- (i) Syringes or needles packed in strips should be separated before decontamination and transferred into the critical work zone to reduce the potential for particle dispersion
- (ii) The spray and wipe technique (see 6.5.2) should be used
- (iii) When the transfer process has been completed the materials should be allowed to dry before proceeding with the dispensing process (usually 2 minutes). The lid of the SAB should be closed at this stage
- (iv) Keep the critical work zone uncluttered and free from waste
- (v) Avoid reaching over the critical work zone to access equipment or dispose of waste. Arms should not cross-over in front of the operator's body
- (vi) Swab the surfaces of rubber bungs of vials and the necks of ampoules with sterile 70% alcohol impregnated wipes and allow to dry before proceeding (usually 2 minutes)
- (vii) Use a strict 'no-touch' technique to avoid any contact with any surface which is in contact with the sterile fluid path
- (viii) Peel open overwrapped items. Do not tear paper wrappers
- (ix) Use closed systems wherever possible
- (x) Where ampoules are used make one withdrawal, use immediately after opening and discard any remainder
- (xi) When withdrawing from glass or plastic ampoules use a sterile filter needle (5 micron) to remove glass or plastic particles
- (xii) When using vials avoid creating aerosols by using pressure equalisation within the syringe
- (xiii) Use the appropriate gauge of needle that will minimise damage to rubber bungs while still maintaining an acceptable flow rate
- (xiv) Clean up all drips or spillage of product immediately.

G 6.9.2 USP *Revised general chapter 797* standard for high risk compounded sterile products prepared in an

ASEPTIC PROCESSES

Standard 6.7 **A system of written standard operating procedures (SOPs) shall be maintained to control all facets of aseptic dispensing.**

Criteria The basic requirements are:

6.7.1 A comprehensive documentation system shall be prepared and maintained by a competent staff member.

6.7.2 All key elements and manipulative steps in the aseptic dispensing process shall be controlled by a written SOP to facilitate the consistent production of a product of the required quality.

6.7.3 All documents shall be clear, standardised and detailed.

6.7.4 All documents shall be regularly reviewed at defined intervals of not more than 2 years. Superseded documents shall be clearly identified as such.

CHECKING OF PRODUCT FOR RELEASE

Standard 6.8 **There shall be a defined step where the finished product is visually examined, compared with its specifications and released or rejected.**

Criteria The basic requirements are:

6.8.1 A SOP shall include the final checking of the product(s) for release.

6.8.2 A visual inspection of the final product(s) for particulate matter and degradation such as precipitation shall be carried out, as well as the appropriate documentation checks.

6.8.3 A close examination shall be made of the product before its distribution and use to ensure that the quality of the product has not been compromised.

STORAGE AND EXPIRY DATING

Standard 6.9 **Aseptically prepared products shall be assigned an appropriate expiry date and stored appropriately.**

Criteria The basic requirements are:

6.9.1 Products shall be stored under refrigeration, normally 2 – 8°C, unless it would be detrimental to the product to do so.

6.9.2 Expiry dates shall be assigned to all aseptic products according to known standards or literature.

GUIDANCE

unapproved device such as a SAB recommends a maximum end of use expiry period of 3 days if stored between 2 and 8°C.

G 6.10.2 Guidance considerations to achieve this criterion include:

(a) Labels should not obscure the graduations marked on the syringe barrel;

(b) In addition to the criteria on 5.24.1, the main body of the label should include the total volume and the infusion period.

G 6.11.1 Double covering should allow visual inspection of contents plus protection from light.

G 6.12.2 Guidance considerations to achieve this criterion include:

(a) In addition to inspection of the dedicated areas and devices, detailed examination of all documentation, quality control methods, validation and training should be undertaken;

(b) Any observations made should be recorded along with any proposals and the time frame for corrective action.

G 6.12.4 Samples may be obtained from unused product(s) or from extra, specially prepared samples that have been made according to and at the same time as the process being examined.

LABELLING AND PACKAGING

Standard 6.10 **Labels that accurately describe the aseptically dispensed product shall be attached to the container.**

Criteria The basic requirements are:

6.10.1 The requirements of 5.24.1 shall be met.

6.10.2 Labelling shall immediately follow filling and closing of the syringe in the aseptic procedure.

Standard 6.11 **The packaging shall ensure the integrity of the product and maintain asepsis.**

Criteria The basic requirements are:

6.11.1 The packaging shall provide protection from gross contamination and where necessary protection from light.

6.11.2 The syringe(s) shall be packaged to prevent the relative movement of components such as the syringe barrel or syringe caps becoming dislodged during transport and storage.

AUDITS AND QUALITY ASSURANCE

Standard 6.12 **There shall be a quality management scheme in place to facilitate the safety, quality and efficacy of aseptically dispensed products.**

Criteria The basic requirements are:

6.12.1 Internal audits shall be carried out in addition to external audits by the regulatory authority.

6.12.2 Regular monitoring, on a planned basis, of the process and the finished product shall be undertaken as an essential part of the quality assurance of all aseptic dispensing in community pharmacies.

6.12.3 Operator training and performance shall be monitored by peer observation or an annual broth validation.

6.12.4 There shall be a planned programme of microbiological analysis of the finished product as appropriate.

DISPENSING INCIDENTS AND RECALLS

Standard 6.13 **There shall be a system for capturing, investigating and documenting errors, near-misses, defects, complaints and recalls.**

Criteria The basic requirements are:

6.13.1 Written procedures documenting incidents such as errors, near-misses, defects, complaints, or other signals indicating quality problems shall be in place.

6.13.2 Subsequent investigations of these incidents and any remedial action taken shall be documented.

6.13.3 A process is available to track and recall any dispensed product.

GUIDANCE

7 ASEPTIC DISPENSING OF STERILE PRODUCTS IN HOSPITAL PHARMACIES

INTERPRETATION

This section replaces Annex 1 of the *New Zealand Code of good manufacturing practice for manufacture and distribution of therapeutic goods, Part 3: Compounding and dispensing 1993 (Code of GMP).*

The Pharmaceutical Inspection Co-operation Scheme (PIC/S) has given permission for Standards New Zealand to adopt Annex 1 of the PIC/S *Guide to good practices for the preparation of medicinal products in healthcare establishments* (PE 010-3) as the New Zealand Standard for the aseptic dispensing of sterile products in hospital pharmacies. Annex 1 is titled *Guidelines on the standards required for the sterile preparation of medicinal products*. A pdf copy of the PIC/S guide is available at http://www.picscheme.org/.

For the purpose of these standards and guidelines, the words 'should' and 'shall' appearing in Annex 1 of the PIC/S guide mean 'must' and the activities, descriptions or specifications accompanied by the word 'should' or 'shall' are to be read as mandatory, unless the provider of the aseptic dispensing is able to demonstrate that the activity, description or specification is inapplicable or can be replaced by an alternative which shall be demonstrated to provide at least an equivalent level of quality assurance.

The Standards and guidelines for the aseptic dispensing of sterile products in hospital pharmacies are applicable to the scale of compounding likely to be undertaken in a hospital pharmacy.

NOTES

APPENDIX A

DEFINITIONS AND ABBREVIATIONS (Normative)

DEFINITIONS

For the purposes of this Standard the following definitions shall apply:

Access — Ability of a consumer or potential consumer to obtain a service when needed within an appropriate time

Accountability — Where an organisation has to account for, or is liable for fulfilling an action whether or not that action is carried out by that organisation

Adverse drug reaction — Intolerances to medications administered in their usual doses

Adverse event — Events with negative or unfavourable reactions or results that are unintended, unexpected, or unplanned

Allergies — A damaging immune response by the body to a substance to which it has become hypersensitive

Appropriate equipment — Dedicated devices or apparatus with established capacity to be used in the dispensing, compounding, repackaging and batch preparation of medicines to assist in the production of quality pharmaceutical products with required results

Aseptic dispensing — The preparation of a medicine that is appropriate for issue or administration to a consumer, by a method of handling sterile material that employs techniques which minimise the risk of microbial contamination

Assessment — A systematic and ongoing process for the collection and analysis of information that describes the needs of the consumer in order to:

(a) Determine eligibility for a service; or

(b) Develop and review individual service delivery plans when the consumer enters the service

The assessment process shall meet current standards for assessment and shall include input from the consumer, family/whānau, or other health carers or representatives where appropriate

Authority — The proper powers to carry out an action, whether granted directly or delegated

Automated device — The use of a computerised robotic machine to automatically pack and label medicines into containers either individually or together in specific doses

Batch — A specific quantity of material produced in a process or series of processes, prepared in advance of use, that is expected to be standardised within specified limits

Batch number	A unique combination of numbers and/or letters which specifically identify a batch or lot and from which the production and distribution history can be determined
Batch record	A copy of a master batch document used for each batch of a preparation, or the record kept of an individual compounding or repackaging where a master batch document is not used. See 5.16.1 for requirements
Broth test	Used to validate the procedures used during aseptic dispensing and an operator's ability to maintain the sterility of materials during the preparation of aseptically dispensed products. The procedure tests the operator's ability to prevent microbial contamination of sterile materials during a variety of reconstitution and transfer manipulations
Calibration	The set of operations which establish, under specified conditions, the relationship between values indicated by a measuring instrument or measuring system, or values represented by a material measure, and the corresponding known values of a reference standard
Capsule powder blend	The appropriately mixed and compounded combination of powdered starting materials, expected to be homogeneous within specified limits, prior to encapsulation
Clinical pharmacy	That area of pharmacy concerned with the science and practice of rational medication use, in which practitioners provide patient care that optimises medication therapy and promotes health, wellness, and disease prevention. It blends a caring orientation with specialised therapeutic knowledge, experience, and judgement for the purpose of ensuring optimal patient outcomes
Charge pharmacist	The pharmacist who is present in the pharmacy or other place and at any particular time is responsible for overall control of the provision of pharmacy services from that place
Communicable disease	As defined in the Health Act and referred to in Medicines Regulation 27. It includes infectious diseases
Community pharmacy	A licensed premise (under the Medicines Act) located in the community that is not a hospital pharmacy, wholesaler, packer, or manufacturer from which pharmacy services are provided
Compliance packaging	A pack that is prepared for a specific consumer containing their medication in separate dose compartments depending on the day and time that the consumer is to take their medication. There may be one or more tablets/capsules in each compartment. The preparation of compliance packs is an extension of the dispensing process
Compounding	All operations involved in the preparation of a pharmaceutical product, from receipt of materials, through processing, labelling, and packaging to its completion as a finished product, excluding manufacturing

Consumer	A person who uses/receives a health or disability service. For the purposes of this Standard 'consumer' has been used in place of the more commonly used term 'patient' found in the Pharmacy Council of New Zealand's publications
Critical work zone	That part of the designated workstation where aseptic manipulation is carried out. Particulate and microbiological contamination should be reduced to levels appropriate to the intended use
Culturally competent	The ability to interact respectfully and effectively with persons from a background different from one's own. Cultural competence goes beyond an awareness of or sensitivity to another culture, to include the ability to use that knowledge in cross-cultural situations
Culture	Culture includes but is not limited to age or generation; gender; sexual orientation; occupation and socio-economic status; ethnic origin or migrant experience; religious or spiritual belief; and disability
Cytotoxic medicine	A medicine that is detrimental to cells within the body, particularly those that reproduce rapidly. The term usually denotes a medicine used to treat cancer
Cytotoxic waste	Discarded items such as residual cytotoxic drug, gowns, gloves, masks, intravenous (IV) tubing, empty bags, empty drug vials, needles and syringes, and other items generated while preparing and administering cytotoxic drugs. Such waste will be contaminated with the cytotoxic medicine
De-blistering of medicines	The process of removal of medicines from their original, proprietary foil strip packaging for use later in compliance packaging or for addition to automated dispensing reservoirs
Decontamination	The process of reduction of the number of viable microorganisms in or on an inanimate object, by the action of an approved agent, to a level judged to be appropriate for a specified, defined purpose
Device (in relation to section 6)	The unit used to separate the specific area used for aseptic dispensing from the clean room or dispensary. Commonly in a community pharmacy a still air box is used. Depending on the scale of aseptic preparation and the products prepared, laminar flow units, biohazard safety cabinets, or other forms of isolators may be used
Disability	A functional limitation or impairment. This can include a physical, visual, hearing, intellectual or cognitive impairment and can be of a temporary or permanent nature
Discrimination	Discrimination is an act or belief that results in the systematic unfair treatment of a person or a group because they are different
Disinfection	The inactivation of non-sporing organisms using either heat or moist heat or by chemical means

Dispensary	That area of a pharmacy where medicines are dispensed, compounded, or repackaged
Dispensing	In relation to a medicine has the meaning given in the Medicines Act and includes, without limitation: (a) The preparation of that medicine for sale to the public (whether in response to the issue of a prescription or a request by an individual to be supplied with the medicine); and (b) The packaging, labelling, recording, and delivery of that medicine. The preparation of compliance packs is an extension of the dispensing process
Dispensing error	An error detected and reported after the medication has been consumed by the patient or the medication has left the pharmacy
Dose pack	A container in which a preselected dose or dose regimen of medication is placed
Entry	The point at which the consumer attends the first appointment or consultation or receives the first episode of service delivery
Evaluation	A formal process for determining the extent to which the planned or desired consequences of an action are attained
Event reporting	Includes the recording/reporting of: (a) Accidents and incidents; (b) Adverse clinical events; (c) Complaints and suggestions; (d) Infections/notifiable diseases; (e) Other events as indicated by statute, regulation or professional practice standards; (f) Near misses
Evidence-based guideline	Has the following characteristics: (a) Is the opinion of experts based on robust researched evidence with the levels of robustness explicitly stated; (b) Is a tool for transferring population-based research findings into a guide for clinical practice; (c) Follows a clear format and process which are described within the guideline so they can be readily replicated; (d) Can include an algorithm or flow chart to provide easy-to-follow steps that reflect the recommendations outlined in detail within the guideline
Evidence-based practice	The conscientious, explicit, and judicious use of current best evidence that takes into account the needs and circumstances of each consumer. Evidence-based practice is also applicable to decisions about the planning and provision of services. Evidence encompasses a range of qualitative and quantitative methodologies including indigenous methodologies and consumer experiences

Extemporaneously compounded medicine	A medicine compounded to suit the needs of a particular consumer
External audit	An audit undertaken by persons who are not managerially accountable within the organisation and are independent of any service provision
Family/whānau	The family or an extended family/group of people who are important to the person who is receiving the service
Finished product	A pharmaceutical product that has undergone all stages of production, including packaging in its final container
Good manufacturing practice (GMP)	That part of quality assurance which ensures that products are consistently produced and controlled to the quality standards appropriate to their intended use
Good practice	The current accepted range of safe and reasonable actions that result in efficient and effective use of available resources to achieve quality outcomes, and minimise risk for the consumer
Governance	Taking responsibility for the overall direction of the organisation, including the development of policy, which determines the purpose and goals of the service
Guideline	Recommendations based on consensus agreement, expert opinion, or experience. Some forms of evidence may also be included. The guideline provides the recommended approach but not the practical 'how to' details specified in a protocol or pathway
Hand hygiene	A general term that applies to either hand-washing, antiseptic handwash, antiseptic handrub, or surgical hand antisepsis.
Hospital pharmacy	A licensed premise within a hospital (either public or private) providing pharmacy services
Infection	Condition in a host resulting from the presence, invasion, and damage by microorganisms
Informed consent	As in the Code of health and disability services consumers' rights 1996, informed consent is a process rather than a one-off event, involving effective communication, full information, and freely given, competent consent (rights 5, 6, and 7 respectively)
Interdisciplinary team	A group of healthcare practitioners with diverse training and backgrounds who work together as an identified unit or system
Internal audit	An audit undertaken by staff members who are a part of the management or organisational structure of the pharmacy

Isolator	A containment device that uses barrier technology for the enclosure of a controlled workspace. Transfer devices or hatches allow transfer of material into and out of the isolator
Laminar flow unit	A work zone or cabinet in which the airflow moves in a unidirectional and uniform manner. The flow is regulated and validated on a regular basis
Loose powder blend	A blend of ingredients made up of starting material powders intended for consumption as a powder dose
Management	People responsible for implementing the policy determined by the governing body and coordinating the day-to-day service activities, which achieve the purpose and goals of the organisation
Manufacturing	The industrial preparation of marketed products
Master batch document	A standard template populated for frequently prepared (either compounded or repackaged) products
Master document	A standard template designed to record frequently undertaken activities including validations, calibrations, cleaning, maintenance, and other monitoring procedures
Medicine	As defined in the Medicines Act
Medicine management services	A range of patient-centred services that improve medicines-related health outcomes.
Medicine reconciliation	The process of collecting, comparing, and communicating the most accurate list possible of all medicines a consumer is taking, together with details of any allergies and/or adverse drug reactions with the goal of providing correct medicines for a given time period at all transition points. Examples include admission, transfer, and discharge from a hospital or other inpatient care facility
Medicines use review	A structured and systematic, consultation-based service undertaken by an accredited pharmacist. MUR aims to improve the patient's understanding of their medicines-related health outcomes by identifying access, adherence, and day-to-day management issues a patient has with their medicines and setting goals with the patient during the checking process to resolve these issues.
National health index (NHI) unique identifier	An alpha-numeric code designed to uniquely identify individuals within the health system in New Zealand. For the purposes of health informatics, the NHI allows easy electronic matching between varying data sets in the health sector
Near miss	Any error that was detected during the checking process up to and including the point at which the medication was handed over to the patient or patient's representative

Open disclosure	A timely and transparent approach to communicating with, and supporting consumers when things go wrong. This includes a factual explanation of what happened, an apology, and actions that deal with the actual and potential consequences. An important aspect of open disclosure is explaining to consumers how the incident has been reviewed and what systems will be put in place to make sure similar incidents will not happen again
Operational plan	A plan that provides information on how the strategic plan will be accomplished
Organisation	The legal entity responsible and accountable for the delivery of services to the consumer
Packing	The processes and operations, including filling and labelling, which a pharmaceutical product has to undergo in order to become a finished product
Packaging material	Any material employed in the packaging of a starting material, an intermediate or finished product, including dispensed products
Pharmaceutical product	Any medicine or similar product compounded in, or supplied by a licensed pharmacy
Pharmacist	A health practitioner who is, or is deemed to be, registered with the Pharmacy Council of New Zealand in the scope of practice of a pharmacist. In this Standard the term pharmacist refers to a practising pharmacist who holds a current annual practising certificate
Pharmacy	A licensed premise for the sale, dispensing, compounding, repackaging, batch preparation and distribution of pharmaceutical products and provision of pharmacy practice
Pharmacy Council of New Zealand	The statutory body constituted under the Health Practitioners Competence Assurance Act for maintaining self-regulation of the pharmacy profession. The primary role of the Council is to promote and protect the public interest by ensuring that pharmacists are safe and competent to practise
Pharmacy manager	A responsible person which includes any or all of the following: (a) Pharmacist(s) who own the majority share capital of the pharmacy; (b) Pharmacist(s) who are permanent managers; (c) Pharmacist(s) who manage the dispensary
Pharmacy practice	Pharmacy practice embraces a diverse range of medicines-related services and initiatives designed to optimise the benefits and use of medicines
Policy	A services plan or course of action intended to influence and determine decisions, actions, and other matters
Potable	Water fit to drink, being free from pollution, harmful organisms, and impurities

Procedure	Written instructions conveying the approved and recommended steps for a particular act or sequence of acts
Protective clothing	Clothing which prevents cross-contamination from a pharmaceutical product and the person. This typically may include gloves, eye protection, apron/gown, masks, and ventilation devices
Qualified staff	In relation to section 5 and 6 of NZS 8134.7 are the persons listed in Medicines Regulations 42(1), noting the restrictions in regulations 42(1A) and 63
Quality assurance	A wide-ranging concept covering all matters which individually or collectively influence the quality of a product
Recall	A formal process for retrieving products that have been sold/dispensed when a quality/safety issue has been discovered
Repackaging	The transfer of a medicine from one container to another as a batch operation
Repackaged unit	A labelled container that has been filled from a proprietary product container
Risk management	The culture, processes, and structures that are directed towards realising potential opportunities while managing adverse effects (AS/NZS ISO 31000
Safety	Being safe and free from abuse, exploitation, danger, risk, harm, or injury. *Cultural safety* The provision of a service to a person or family from another culture that meets the needs of that culture, as determined by that person or family *Safe environment* The environment is free from physical hazards including structures, fittings, as well as harmful compounds and toxic substances A service also provides a safe environment through a respectful and strength-based approach that places consumers first *Organisational safety* Risks within the organisation that have the potential to compromise safety are identified, monitored, evaluated, recorded in a risk register, and managed to acceptable levels
Service	The provision of assessment, treatment, care, support, teaching, research, promotion of independence, and other inputs provided to the consumer by the organisation
Service delivery	The act of service provision by the organisation or service provider to the consumer

Service delivery planning	The documentation describing the assessment, planning, implementation, evaluation, review, and exit processes of service delivery
Service provider	An individual who is responsible for performing the service either independently, or on behalf of an organisation. This includes the provision of direct and indirect care or a support service to the consumer
Standard operating procedures (SOP)	Detailed documents which describe the operations to be carried out, the precautions to be taken and the measures applied that are directly or indirectly related to the preparation and supply of the product. They give directions for performing certain operations (such as dispensing, cleaning, and equipment operation) to ensure that they are performed to a consistent standard
Starting material	A substance, used in the preparation of a pharmaceutical product, excluding packaging material
Still air box (SAB)	The SAB was developed from a concept of transparent screens of glass or Perspex used to give some protection against falling organisms, and contamination by the operator. For maximum protection the aseptic area should be completely enclosed with only a hatch for the introduction of materials and apparatus. The SAB used in aseptic compounding in New Zealand is a unique apparatus
Unit dose pack	A single dose of medication within a single compartment containing the proper identification
Validation	The accumulation of documentary evidence to show that any system, procedure, equipment, material, activity, or process will consistently perform as expected to a predetermined specification or acceptance criteria

ABBREVIATIONS

The following abbreviations are used in this document:

CARM	Centre for Adverse Reaction Monitoring
GMP	Good manufacturing practice
GP	General practitioner
IMMP	Intensive Medicines Monitoring Programme
MUR	Medicines use review
NHI	National Health Index
SAB	Still air box
SOPs	Standard operating procedures

NOTES

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