Application for Consideration of Independent Prescribing Rights

Pharmacist Prescriber Scope of Practice  October 2010
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**APPENDICES**
The Pharmacy Council of New Zealand (the Council) is the regulatory authority for the profession of pharmacy. The Council implements the requirements set out in the Health Practitioner’s Competence Assurance Act 2003 (HPCAA). The principal purpose of this Act is to protect the health and safety of members of the public by providing for mechanisms to ensure that health practitioners are competent and fit to practise their professions.

These mechanisms include:

- specifying scopes of practice
- prescribing qualifications for each scope of practice
- accrediting the prescribed qualifications
- accrediting and monitoring the educational institution providing the prescribed qualifications
- registration of pharmacists and intern pharmacists and authorisation of scopes of practice
- issuing of annual practising certificates
- reviewing and promoting the competence of pharmacists
- creating pathways to identify and manage cases of pharmacists who may be unable to perform professionally.

The Council proposes to set the requirements for a new scope of practice - the Pharmacist Prescriber Scope of Practice. In this scope, suitably qualified and experienced pharmacists will work in a collaborative team environment with other healthcare professionals to provide medicines related healthcare services which result in tangible health benefits for patients. This new scope of practice will enable pharmacists to provide an individualised model of medicines management to patients within their healthcare team across a range of practice settings.

In this type of collaborative pharmacy practice the Pharmacist Prescriber can write a prescription for a patient in their care to initiate, modify or discontinue medicine therapy; and maintain medicine therapy originally initiated by a medical prescriber.

The Pharmacist Prescriber can also provide a wide range of assessment and treatment interventions which includes, but is not limited to:

- ordering and interpreting investigation including laboratory and related tests
- assessing and monitoring the patient’s response to medicine therapy
- providing education and advice to a patient on their medicine therapy.

One of the main enablers for this model of collaborative pharmacy practice would be the development of systems to ensure patient safety. These can be broadly categorised into systems that would ensure:

- the availability of a legislative framework
- practitioner competence
- clinical governance and monitoring of the practitioner’s clinical practice.

The Government is responsible for the development of a legislative framework (the Medicines Act 1981) that will enable these pharmacists to initiate and modify a patient’s medicine therapy i.e. prescribe prescription medicines. The Council is responsible for the development of systems related to the pharmacist’s competence (through the HPCAA). Healthcare organisations such as District Health Boards (DHBs) and Primary Health Organisations (PHOs) employing Pharmacist Prescribers may wish to develop systems to ensure governance/audits are undertaken and the clinical practice of Pharmacist Prescribers is monitored (e.g. credentialing).

The availability of a legislative framework

The New Zealand Government requires the regulatory body of a health profession to submit an application to the Ministry of Health for designated prescribing rights. The Ministry will assess the application, and pending a successful outcome, a legislative framework (under the Medicines Act 1981, Medicines Regulations 1984, Misuse of Drugs Act 1975 and Misuse of Drugs Regulations 1977 would be made available.

Practitioner competence

This application for designated prescribing rights for pharmacists (i.e. independent prescribing authority) outlines the proposed mechanisms for ensuring practitioner competence\(^1\).

Clinical governance and monitoring of the practitioner’s practice

Healthcare organisations employing Pharmacist Prescribers may decide to develop and implement systems for governance and monitoring of clinical practice of these pharmacists.

For a pharmacist to safely and effectively advise on, initiate or modify a patient’s medicine therapy, a collaborative relationship with other members of the healthcare team and the support of peer professionals are both essential.

Prior to submitting this application, the Pharmacy Council consulted widely with stakeholders. It is confident that the proposed mechanisms to ensure that a pharmacist is fit and competent to practise as a Pharmacist Prescriber are robust, practical and necessary to protect the health and safety of members of the public.

\(^1\) The term ‘independent’ does not mean prescribing in isolation, it is the legal description of the prescribing authority available in New Zealand
1.1 This application is made by the Council and is based on the form to assess applications for independent prescribing authority used by the (now disestablished) New Prescribers Advisory Committee (NPAC).

1.2 The Council, established under the HPCAA, has a duty to protect the public and promote good pharmacist practice. It is responsible for the registration of pharmacists, the setting of standards for pharmacists’ education, scopes of practice and conduct.

1.3 Section 117 of the HPCAA sets out the status and capacity of regulatory authorities. It states that:

(1) Every authority appointed by or under this Act is a body corporate with perpetual succession, and has and may exercise all the rights, powers and privileges, and may incur all the liabilities and obligations, of a natural person of full age and capacity.

(2) Each authority may exercise its rights and powers, and may incur liabilities or obligations, only for the purpose of exercising its functions.

(3) For the purposes of the exercise or performance of the powers, duties, and functions of an authority, the persons who for the time being are the members of the authority are to be taken to be the authority.

(4) All decisions relating to the powers, duties, and functions of an authority are to be made—

(a) by the authority in accordance with Schedule 3; or

(b) by a committee or person authorised to make the decision concerned under a delegation given under clause 17 or clause 19 of Schedule 3.

1.4 Section 118 of the HPCAA sets out the functions of regulatory authorities. It states: The functions of each authority appointed in respect of a health profession are as follows:

(a) to prescribe the qualifications required for scopes of practice within the profession, and, for that purpose, to accredit and monitor educational institutions and degrees, course of studies, or programmes

(b) to authorise the registration of health practitioners under this Act, and to maintain registers
(c) to consider applications for annual practising certificates

(d) to review and promote the competence of health practitioners

(e) to recognise, accredit, and set programmes to ensure the ongoing competence of health practitioners

(f) to receive and act on information from health practitioners, employers, and the Health and Disability Commissioner about the competence of health practitioners

(g) to notify employers, the Accident Compensation Corporation, the Director-General of Health, and the Health and Disability Commissioner that the practice of a health practitioner may pose the risk of harm to the public

(h) to consider the cases of health practitioners who may be unable to perform the functions required for the practice of the profession

(i) to set standards of clinical competence, cultural competence, and ethical conduct to be observed by health practitioners of the profession

(j) to liaise with other authorities appointed under this Act about matters of common interest

(k) to promote education and training in the profession

(l) to promote public awareness of the responsibilities of the authority

(m) to exercise and perform any other functions, powers, and duties that are conferred or imposed on it by or under this Act or any other enactment.
SECTION 2 NAME AND DESCRIPTION OF THE PROPOSING BODY

2.1 The Council is the proposing body, with the support of the Pharmaceutical Society of New Zealand (PSNZ) (Inc), the New Zealand Hospital Pharmacists Association (NZHPA) and the Clinical Pharmacists Advisory Association (CAPA).

2.2 The Pharmaceutical Society of New Zealand Inc is the professional association representing over 3,000 pharmacists from all sectors of pharmacy practice. It provides pharmacists with professional support and representation, training for continuing professional development, and assists them to deliver the best pharmaceutical practice and professional services in relation to medicines.

2.3 The New Zealand Hospital Pharmacists Association is the professional association representing hospital pharmacists. NZHPA is an advocate for pharmacists, and is concerned with clinical and professional aspects of the profession. It has led many of New Zealand's most innovative approaches to pharmacy practice and actively supports the development of new opportunities to enable pharmacists to specialise in ward and team based clinical pharmacy, therapeutic drug monitoring, medicines information, and drug utilisation evaluation. Some of these services have subsequently extended to community practice. The mission statement of NZHPA is “Supporting innovation in the practice of pharmacy and promoting effective medicines management”. The Association provides considerable support for its members through annual conferences, special interest group (SIG) meetings, newsletters, and awards and grants to support research and education. SIGs have been set up within the framework of the NZHPA, and each group usually has an annual gathering where topics of interest are discussed. The following SIGs operate:

- Drug Information and Clinical Pharmacy
- Management
- Compounding, Nutrition and Oncology
- Pharmacists in Mental Health
- Hospital Pharmacy technicians

2.4 The Clinical Advisory Pharmacists Association (CAPA) is a professional association formed to create, lead and support a sustainable future for pharmacists in specialist clinical practices.
SECTION 3  SHORT DESCRIPTION OF APPLICATION

3.1  What Pharmacists Do
(Refer to Appendix 1 for a detailed background to Pharmacy Practice in New Zealand)

3.1.1  Pharmacists are registered health professionals. The profession of pharmacy provides a number of health services that form part of the broad scope of practice of a pharmacist.

3.1.2  The practice of pharmacy includes custody, preparation and dispensing of medicines and pharmaceutical products; the provision of advice on health and well being, including health screening; and the selection and provision of non-prescription medicine therapies and therapeutic aids.

3.1.3  The pharmacist acts as a medicines manager, ensuring safe and quality use of medicines and optimising health outcomes by contributing to the selection, prescribing, monitoring and evaluation of the medicine therapy.

3.1.4  The pharmacist researches information and provides evidence-based advice and recommendations on medicines and medicine-related health problems to patients, carers and other healthcare professionals. The pharmacist is an integral part of the healthcare team.

3.1.5  The pharmacist currently has the ability to “prescribe” some pharmacist-only medicines which have previously been prescription medicines. However, this is a limited pool of medicines for minor ailments in primary health care.

3.2  Purpose of Application - Pharmacists as Designated Prescribers

3.2.1  The Council has specified the requirements for a new scope of practice - the Pharmacist Prescriber Scope of Practice.

3.2.2  Pharmacists registered in this scope will be known as Pharmacist Prescribers.

3.2.3  The Council’s application seeks approval for pharmacists registered in this scope to hold designated prescriber status (independent prescribing authority) as described in the Medicines Act 1981. ²

3.2.4  This application seeks to permit appropriately trained and qualified pharmacists who practise in a collaborative health team environment to be able to prescribe any medicine (except for the listed exclusions) for any condition within their competence.

² The term ‘independent’ does not mean prescribing in isolation, it is the legal description of the prescribing authority available in New Zealand
3.2.5 The practice boundaries are defined in the proposed scope definition in section 5 of the application.

3.3 Components of a Collaborative Health Team Environment

3.3.1 In a collaborative health team environment the patient is the focus and beneficiary of the collaboration, and members of the patient’s healthcare team (doctors, nurses, specialists, midwives, dietitians) cooperate in sharing patient information. This includes diagnosis, test results, medication history, treatment plans and progress notes etc and enables the pharmacist to make informed decisions about the patient's treatment and care.

3.3.2 The pharmacist is an established and integral member of a multidisciplinary healthcare team.

3.3.3 The pharmacist plays an active part in the decision making process with respect to initiating or changing a patient’s medicine and his/her decisions and recommendations directly affect the individual patient's medicine therapy.

3.3.4 The pharmacist holds mutual concern for the well being of the patient; is aware of, contributes to and shares the treatment goals set by the team and the patient, and has the unique skills and knowledge to allow him/her to contribute equally to achieve these.

3.3.5 The pharmacist has direct and up-to-date access to relevant and proportionate information about a patient’s medical history and medicines.

3.3.6 The pharmacist does not need to seek a separate patient consent in order to gain direct access to the patient’s medical records.

3.3.7 The pharmacist ensures that he/she has all relevant information needed for prescribing decisions.

3.3.8 The pharmacist communicates prescribing decisions to other healthcare professionals caring for the same patient and updates the patient’s relevant medical record in a timely manner.

3.4 Key Points - A Pharmacist Prescriber

- is an established member of the multidisciplinary health care team of the patient
- has an active part in the decision making process with respect to initiating or changing a patient’s medicine and his or her decisions and recommendations can directly affect the individual patient’s medicine therapy
• can prescribe medicines for the purpose of optimising medicines related health outcomes of the patient

• works in a collaborative health team environment (as defined above) and is responsible and accountable for communicating medicine changes and decisions to the patient’s doctor and healthcare team

• is most likely to be based in a hospital (wards and clinics), a rest home, a medical practice (via IPA and PHO contracts), a hospice or in a secondary/primary interface liaison role³.

• has met the registration requirements set by the Council for this scope of practice, which includes additional education and training and a period of learning in practice under the supervision of a designated medical practitioner

• must meet the ongoing competency requirements set by the Council for this scope of practice and any credentialing requirements of the employing organisation

• **will not** be based or prescribing in a community pharmacy

• **will not** be a community pharmacy owner

• **will not** dispense prescriptions written by him or herself

• **will not** be the primary diagnostician

• **will not** replace the role of a medical doctor.

3.5 The prescribing parameter for the scope of practice is specified in section 5 of the application.

3.6 The classes of medicines that can be prescribed, including exclusions are specified in section 6 of the application.

3.7 The justification, risks and benefits of this scope of practice is presented in section 7 of the application.

3.8 The prescribing competency framework, curriculum, prescribed qualifications and accreditation standards for the qualification for the scope of practice is specified in section 8 of the application.

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³ Pharmacists working in these areas make up 16% (474) of the pharmacy workforce
3.9 The registration, maintenance of ongoing competency and recertification requirements for this scope are specified in section 9 of the application.

3.10 The consultation and submissions analysis is discussed in section 10 of the application.

3.11 Appendices referred to are included in this document.
## SECTION 4 PRINCIPAL CONTACTS OF THE REGISTRATION BODY

The contacts for this submission and all matters relating to the Pharmacy Council of New Zealand are:

<table>
<thead>
<tr>
<th>For General Council Matters Contact:</th>
<th>For Specific Details Relating to the Application Contact:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bronwyn Clark</td>
<td>Sandy Bhawan</td>
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<td>Chief Executive and Registrar</td>
<td>Competence Projects Manager</td>
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INTRODUCTION

To assist with the understanding of the scope of practice of Pharmacist Prescribers in New Zealand this document refers to attached “exemplars”. These exemplars in Appendix 2 are profiles of four New Zealand registered pharmacists who have supported the Council’s proposal from its inception. These exemplars highlight the calibre and experience of pharmacists likely to be registered in this scope; the practice settings; the makeup and relationships with their respective collaborative health team environments; and how they intend to utilise an independent prescribing authority in their current roles for the benefit of their patients. Council is also aware of other pharmacists working in similar ways in other areas such as Mental Health and with Māori populations. These pharmacists have indicated to Council that the ability to prescribe would enhance their effectiveness in optimising medicines use and medicines related health outcomes for their patients.

Council research shows that Pharmacist Prescribers are most likely to be based in:

- hospital (wards and clinics)
- medical practice (via IPA and PHO contracts)
- secondary/primary interface liaison roles (via DHB contracts)
- rest homes
- hospices.

The Council workforce data as at 30 June 2010 shows that this cohort of pharmacists currently makes up 16% (474 pharmacists) of the workforce. While it is likely that a number of these pharmacists will be in the first group eligible to register as Pharmacist Prescribers, it is not expected that all will want, or be eligible, to pursue registration.

Typically most pharmacists in this cohort have more than five years post registration practice experience, hold post graduate qualifications in clinical pharmacy, work in a collaborative health team environment and would be considered as expert or specialist practitioners. It is envisaged that they would be offered a qualification pathway that is based on an assessment and recognition of their prior learning and experience. Previous estimates have shown that the number of eligible pharmacists in this cohort is less than 300. The reality is that the number of pharmacists in independent prescribing roles in the first few years of implementation will be low and therefore an independent prescribing authority will not be ‘rolled out’ to all pharmacists.

From the exemplars in Appendix 2 it is evident that extending independent prescribing authority to Pharmacist Prescribers for specified conditions only would place significant limitations on the scope of practice of a Pharmacist Prescriber.

As a pharmacist’s scope of practice spans over a vast range of patient groups, either the lists of conditions and medicines would need to be extensive or certain groups of patients be excluded.
In addition, a limited formulary and a list of conditions would need updating regularly, to support ongoing best practice. This would require lengthy administrative and legislative processes and is unlikely to be responsive to the needs of patients or developments in clinical care.

Therefore the Council is seeking approval for appropriately trained and qualified pharmacists who are practising in a collaborative health team environment to be able to prescribe any medicine (except for the listed exclusions) for any condition, within their competence. Due to the nature of a pharmacist’s education, training, and scope of practice, this model of prescribing by pharmacists has already gained approval in the United Kingdom and in some state and provincial jurisdictions in the USA and Canada. Further detailed information on the international experience and context of pharmacist prescribing can be accessed in Appendix 1.

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4 This same principle currently applies to optometrists, nurse practitioners, medical practitioners, dentists and midwives as prescribers.
SECTION 5 PRESCRIBING PARAMETERS

Under the HPCAA the Council must publish a description of the contents of the profession in terms of one or more scopes of practice in the Gazette. The Council has consulted widely and received valuable feedback regarding the proposed scope of practice definition for a Pharmacist Prescriber. Consequently the definition has been revised and is described in 5.2. Pending the outcome of this application, the definition will be published in the Gazette.

An earlier reference has been made concerning the limitations of approaches that could define a scope of practice by conditions for which a pharmacist could prescribe. For this reason the prescribing parameters of a Pharmacist Prescriber cannot be prescriptively confined to patient/age groups or disease states.

The following are points of clarification regarding the proposed scope of practice definition in response to the submissions received.

5.1 Points of clarification regarding a Pharmacists Prescriber’s scope of practice

5.1.1 Prescribing scope with respect to diagnosis and initiation of therapy

- The Pharmacist Prescriber will not be the primary diagnostician but will have the diagnostic skills and reasoning to assess whether the patient requires treatment to be modified or continued (refer to the exemplars in Appendix 2).

- The majority of prescribing decisions made by Pharmacist Prescribers, will be to continue and/or modify therapy (refer to the exemplars in Appendix 2).

- There will be some instances when a Pharmacist Prescriber will initiate therapy but will have the clinical assessment and monitoring skills required to do this in the context of optimising medicines related health outcomes within the confines of a confirmed diagnosis and a collaborative health team environment (refer to the exemplars).

- This practice already applies to other designated prescribers. For example, the optometrist is an independent prescriber who refers the patient to the ophthalmologist to initiate a treatment for glaucoma. In the same way, a Pharmacist Prescriber would refer the patient to their GP or Specialist when further diagnostic investigations were required before treatment would be initiated. The Pharmacist Prescriber and the collaborative health team would have agreed and set these boundaries for referrals.

- The current undergraduate training for pharmacists provides a foundation level of experience in diagnostic and clinical assessment skills.

- The diagnostic and physical assessment skills will be an integral part of the required post graduate diploma prescribing qualification and pharmacists will be taught these skills by their appropriate medical and nursing colleagues (as in the UK).
• Under the current legislative framework the Pharmacist Prescriber will hold an independent prescribing authority which will allow them to initiate therapy, and they will be working in a collaborative health team environment (similar to the nurse prescribers in NZ).

5.1.2 Communication of prescribing decisions and maintenance of clinical records

• The Pharmacist Prescriber will be obliged to communicate their prescribing decisions to ensure continuity of care. It is implicit in their role. The communication of prescribing decisions made by Pharmacist Prescribers to other health professionals caring for the patient is pivotal to the safety and success of the Pharmacist Prescriber role.

• The great majority of pharmacists working in collaborative health team environments already have direct and full access to clinical records, contribute to these records and utilise existing systems to communicate their advice and recommendations to other health care professionals caring for that patient. As Pharmacist Prescribers they must have access to these records and will be required to document their consultation and decisions.

• Under the current healthcare system models, patients have the right to go to any health practitioner. The Council is confident that the practice of Pharmacist Prescribers will not further fragment the health system but may build bridges between healthcare providers.

• The exemplars (in Appendix 2) demonstrate the current communication and clinical record keeping practices of pharmacists currently working in collaborative health team environments.

5.1.3 Perceived financial conflict of interest - Pharmacist Prescribers being able to dispense prescriptions written by themselves

• The Council will direct that Pharmacist Prescribers must separate the activities of dispensing and prescribing and not dispense prescriptions written by them.

• In addition, the Council does not support Pharmacist Prescribers holding a vested interest in a pharmacy business. The Pharmacist Prescriber must not have any pecuniary interest associated with the dispensing activity. (Note: this is also prescribed in the s42C of the Medicines Act 1981).

• Council acknowledges that this stance may effectively exclude pharmacists who own or are employed in a community pharmacy from registering in this scope, thereby restricting the scope to small numbers of the pharmacy workforce.
• Council acknowledges that the greatest impact of this decision will be for pharmacists in rural community pharmacy practice but is confident that there may be different pathways to enable them to prescribe in the context of their practice e.g. under Standing Orders (as nurses do) or under the proposed collaborative prescribing models as anticipated in the Medicines Amendment Bill in 2011.

• Council has revised the scope definition to reflect this.
5.2 Proposed Pharmacist Prescriber Scope of Practice Definition for Gazette notice

Pharmacist Prescribers have additional qualifications, experience in clinical pharmacy practice and work in a collaborative health team environment with other healthcare professionals (primarily with doctors and nurses) to optimise medicines-related health outcomes for individuals and populations.\(^5\) They work in partnership with the patient, his/her family/whanau, caregivers, and healthcare team.

In this environment members of the collaborative health team cooperate in sharing relevant patient information and treatment goals. This enables the Pharmacist Prescriber to apply their unique knowledge, understanding and skills to provide individualised medicines management services, including the prescribing of medicines, to patients across a range of healthcare settings and models.

Pharmacist Prescribers can write a prescription for a patient in their care to initiate or modify therapy\(^6\). This includes discontinuation or maintenance of therapy originally initiated by another prescriber, depending on the identified clinical needs of the patient.

The Pharmacist Prescriber can also provide a wide range of assessment and treatment interventions which includes, but is not limited to:

- ordering and interpreting investigation including laboratory and related tests
- assessing and monitoring the patient’s response to medicine therapy
- the provision of education and advice to a patient on their medicine therapy.

The Pharmacist Prescriber has up-to-date clinical, pharmacological and pharmaceutical knowledge and understanding relevant to their area of prescribing practice. They are responsible and accountable for the care they provide. The Pharmacist Prescriber must prescribe within the limits of their professional expertise, competence (clinical and cultural) and ethical codes of practice.

Pharmacist Prescribers must ensure a separation of prescribing and dispensing and must not dispense prescriptions written by them.\(^7\)

Pharmacist Prescribers are registered pharmacists who have met the registration and competence requirements as specified by the Pharmacy Council of New Zealand.

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\(^5\) Components of a collaborative health team environment are defined in 3.3.

\(^6\) The Pharmacist Prescriber will not be the primary diagnostician.

\(^7\) The revised definition no longer includes the following “In exceptional circumstances where a Pharmacist Prescriber is both prescribing and dispensing a patient’s medication, a second suitably competent person must be involved in the checking process.” In addition, the Council does not support Pharmacist Prescribers holding a vested interest in a pharmacy business. The Pharmacist Prescriber must not have any pecuniary interest associated with the dispensing activity.
SECTION 6 CLASSES OF MEDICINES

6.1 It is expected that prescriptions generated by Pharmacist Prescribers will be funded on the pharmaceutical schedule. In the absence of access to funding, the benefits of a pharmacist prescribing to patients would be limited, if not redundant.

6.2 The background information included in the 2010 consultation document (Appendix 1) highlights that prescribing by pharmacists can be a dynamic process. This process is uniquely defined by the clinical needs of individual patients, the competencies of the individual pharmacists, the availability of information to support prescribing decisions, the relationships and degree of collaboration of the pharmacist with other members of the patient’s health care team, and the pharmacist’s practice within prescribed codes of ethics and standards of practice.

6.3 Pharmacists receive more training, knowledge, and have a wider and more in-depth knowledge of medicines therapy than any other health professional. Pharmacists are referred to as the medicines therapy experts by members of the healthcare team. On completion of their initial qualifications, pharmacists possess unique knowledge and skills about medicines therapy. They are the health professionals that are accessed by patients for all of their medicines therapy, regardless of the original prescriber. Added to this is the diversity of environments and situations within which pharmacists practise, the diversity of the disease states that pharmacists are involved in treating and the diversity of the patient’s needs.

6.4 For these reasons, the Council believes prescribing by Pharmacist Prescribers should not be defined by restricted or pre-defined lists of diseases or medicines. Medicines therapy is constantly evolving and the introduction of new medicines, new therapies and new medicines related problems would inevitably make timely maintenance of such lists impractical.

6.5 The Council therefore proposes that, with the exception of the identified exclusions, the medicines a Pharmacist Prescriber is able to prescribe be determined by the environment within which they will be practising and the pharmacist’s competence.

6.6 This will be determined by the nature of the breadth of patients under their care and/or the focus of their clinical practice.

6.7 Where the collaborative health team environment of the Pharmacist Prescriber is broad, with respect to the type of patients under their care or the practice focus (e.g. general practice), the pharmacist within this practice environment will be able to prescribe the same range of medicines as a medical practitioner in the team.
6.8 Where the collaborative health team environment of the Pharmacist Prescriber is narrow, with respect to the type of patients under their care or the practice focus, (e.g. renal, oncology, diabetes), the pharmacist, within this practice environment, will be able to prescribe the same range of medicines as a medical practitioner in the team.

6.9 This proposal recognises the undergraduate training of pharmacists, which provides pharmacists with an in-depth knowledge of the full range of medicines. It acknowledges that this foundation knowledge will not disappear when they register as Pharmacist Prescribers.

6.10 This proposal is the same as for other current prescribers. Current prescribers can legally prescribe any medicine, but in reality they only prescribe within their scope of practice and expertise (e.g. Care of the Elderly, Neonatal Medicine).

6.11 Under this proposal a Pharmacist Prescriber will be able to prescribe controlled drugs and for off label/unapproved indications in their respective collaborative health team environment as determined by patient need. As with all prescribing decisions, the pharmacist must meet their obligations under the Code of Health and Disability Services Consumer’s Rights.

6.12 The exemplars (in Appendix 2) illustrate how this could work in practice.

**Medicines identified for exclusions**

The Council has identified medicine exclusions in the context of patient safety and consequently accepts that there are some medicines where patient safety could be compromised if Pharmacist Prescribers were permitted to prescribe them, (e.g. agents used in general anaesthesia). In addition, the proposed exclusions recognise the education and training of pharmacists in medicines therapy and ensure that consumer accessibility and benefits are not hindered by medicines being excluded.

6.13 **Controlled Drugs**

In the consultation feedback, two respondents raised the issue of adding controlled drugs to the proposed exclusion list. Council acknowledges the concerns expressed by these parties who stated that Pharmacist Prescribers should not be able to prescribed controlled opioids, *because of their value in the illicit drug market, the danger they pose to human life and the concern and debate in the medical community as to the appropriateness of the prescription of controlled drugs such as narcotic for cancer and post operative pain*. The Council however has identified clear situations where Pharmacist Prescribers should have access to controlled opioids, (e.g. Palliative Care, Pain Management Clinics, Surgical/Post Operative recovery, Methadone

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8 A General Practitioner and the New Zealand Society of Anaesthetists
clinics), and therefore proposes that excluding controlled drugs as a class may not be in the best interest of patients. Instead it may be preferable for those assessing the application to think of restrictions around controlled drugs in terms of what a Pharmacist Prescriber would not prescribe.

6.14 Medicines restricted under section 23 of the Medicines Act or Regulation 22 of the Misuse of Drugs Regulations that require specialist initiation

The Council initially proposed that Pharmacist Prescribers should not be able to prescribe medicines restricted under section 23 of the Medicines Act or Regulation 22 of the Misuse of Drugs Regulations that require specialist initiation.

However, a substantial number of submissions asked Council to reconsider this exclusion for reasons of patient benefit and continuity of patient care. Respondents stated that while it would be reasonable to restrict Pharmacist Prescribers from initiating therapy with medicines under these sections, it would be unreasonable to restrict pharmacists from prescribing them for the purpose of modification and continuation of therapy. Such exclusion could restrict patient benefits and continuity of care.

Therefore the Council now proposes that Pharmacist Prescribers should be able to prescribe specialist initiated medicines (e.g. clozapine) for the purpose of modification and continuation of therapy within their collaborative health team environment.

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<th>Exclusion 1</th>
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Council proposes the following exclusions for Pharmacist Prescribers:

*Initiating* medicines restricted under section 23 of the Medicines Act or Regulation 22 of the Misuse of Drugs Regulations that require specialist initiation, (e.g. thalidomide, methylphenidate and clozapine).

Pharmacist Prescribers should not be excluded from prescribing medicines restricted under this section for the purpose of modification and continuation of therapy within their collaborative health team environment.
6.15 Prescribe unapproved/unregistered medicines restricted by sections 20 and 24 of the Medicines Act

The Council initially proposed that Pharmacist Prescribers should not be able to prescribe unapproved/unregistered medicines restricted by sections 20 and 24 of the Medicines Act. Council acknowledges and agrees with the intent of these provisions for patient safety. However a number of consultation submissions highlighted that in New Zealand an increasing number of routinely used medicines are unregistered and have to be distributed under the provisions of Section 29. The majority of these are not registered because of low use rather than because they are new to practice and there is limited experience.

Therefore any exclusion made in reference to these sections of the Medicines Act needs to be able to distinguish between:
   a. Medicines that are new to practice with which there is limited clinical experience and
   b. Medicines with established historical use which are not currently licensed due to low use in New Zealand.

The feedback from the consultation indicates that excluding the ability of Pharmacist Prescribers to prescribe medicines described in (b) would be unnecessarily restrictive and counterproductive to continuity of patient care. Pharmacist Prescribers should be able to prescribe medicines restricted by sections 20 and 24 of the Medicines Act that have an established historical use but are unapproved/unregistered due to low use in New Zealand. The prescribing of these medicines must be determined by the collaborative health team environment.

Exclusion 2
Council proposes the following exclusions for Pharmacist Prescribers:

Prescribing of medicines restricted by sections 20 and 24 of the Medicines Act which are new to practice with which there is limited clinical experience.

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9 Section 29 of the Medicines Act provides the mechanism for, not the restriction of, the prescribing/supply of unregistered medicines. Note that Section 29 permits only medical practitioners to prescribe/supply unregistered medicines i.e. those that don’t have ministerial consent to distribute.

10 Refer to Appendix 8, analysis 3, question 3

11 Examples of these include melatonin, occuvite, thiamine injection, phenobarbitone injection, aspirin suppositories, Milk of Magnesium Tabs, metoclopramide liquid, Slow Sodium tablets 600mg, Timolol 0.5% Unit Dose preservative free (Timoptol), Urokinase (for unblocking catheters).
6.16 Agents used in Anaesthesia

The Council proposed that Pharmacist Prescribers should not be able to prescribe medicines classed under the therapeutic group of general anaesthetics. Feedback received from the consultation supported this exclusion but has directed Council to be more specific. The basis for this exclusion is patient safety as the practice of anaesthesia is not within the scope of practice of a Pharmacist Prescriber.

Exclusion 3

Council proposes the following exclusions for Pharmacist Prescribers:

Prescribing of medicines that fall within the class of Neuromuscular Blockers (depolarising and non-depolarising), Anaesthetic Inhalants and Anaesthetic Induction medicines.
SECTION 7 JUSTIFICATION, RISKS AND BENEFITS

7.1 Consumer benefits and accessibility

7.1.1 Why should pharmacists have an independent prescribing role?

It is important to understand how and what a pharmacist is trained to do, how many pharmacists get an opportunity to practice at the level to which their training could allow, how they currently influence the quality of prescribing and how the independent prescribing role would enhance their ability to further influence the quality of prescribing.

7.1.2 What are pharmacists trained to do?

It takes a minimum of 5 years to train as a pharmacist. This training includes learning: how the body handles medicines (pharmacodynamics); how medicines work in the body (pharmacology); how medicines are handled in the body (pharmacokinetics); medicine preparation and formulation; how medicines are used to prevent and treat illness; how medicines can relieve symptoms or assist in disease diagnosis.

Pharmacists are medicine experts and are a regulated health professional group who receive the level of training that enables them to contribute to the safe and effective use of medicines and the delivery of pharmaceutical care by the integration of relevant elements of pharmacy practice, pharmacotherapy and pharmaceutical sciences.

However, for the majority of pharmacists, the models of healthcare focus predominantly on the role of the pharmacist in the supply and distribution of medicines (i.e. as a dispenser of medicines). 75% of pharmacists in New Zealand practise in community pharmacy and their livelihood are dependent on the volume of dispensing and the retail aspect of the pharmacy business. Some community pharmacists have been successful in obtaining contracts from their DHBs to provide Medicines Use Reviews (MUR) for individual patients. This has gone some way towards utilising the skills of the pharmacist to optimise the use of medicines and medicines related health outcomes for patients. However, the provision of this and other services in the DHBNZ National Framework for Pharmacist services is not available to patients at a national level.

Health Workforce New Zealand recently approved 15 community pharmacies to provide anticoagulation monitoring and dose adjustments for individual patients. This too goes some

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12 75% is equivalent to 2614 pharmacists. Pharmacy Council of NZ Workforce Data as at 30 June 2010

13 DHBNZ National Framework for Pharmacist Services
way towards recognising and matching the skills of the pharmacist to the role they play in the patient’s medicines related health outcomes.

Overall the funding systems for pharmacy practice do not recognise the full potential of what a pharmacist is trained to provide, nor do they recognise the value they can add to the optimal use of medicines. Hence, while some pharmacists are able to use the skills they have been trained for, overall there is a mismatch of skills and the role of the pharmacist in the New Zealand Healthcare system. **As a result of this mismatch, the independent prescribing role for pharmacists will be for a small number of pharmacists who are in practice settings that recognise the value and unique contribution pharmacists can bring towards optimising medicines use and medicine related health outcomes for patients.** These pharmacists are equipped and supported to manage the independent prescribing role and processes and are likely to be based in hospitals, medical practices (via PHO and IPA contracts), rest homes, hospices and in secondary/primary interface liaison roles.

Under the current models of primary health care the community pharmacist would not have a role as an independent prescriber. It is likely that community pharmacists would have a role in other models of prescribing such as collaborative/supplementary prescribing or prescribing under Patient Group or Patient Specific Directions (PGD or PSD) as in the UK. An example of prescribing under PGD in New Zealand would be the prescribing of anticoagulants by community pharmacists participating in the anticoagulant monitoring scheme funded by Health Workforce New Zealand mentioned previously.

**7.1.3 How do pharmacists currently influence the quality of prescribing?**

Pharmacists already play a critical role in ensuring that quality prescribing results in the optimal use and medicines related health outcomes for their patient. Depending on the individual practice and practice setting this can range from prescription interventions to a comprehensive medicines review for individual patients. This continuum of roles is described by the Council’s Medicines Management Framework in Appendix 3. For some pharmacists, their role in ensuring quality of prescribing expands to include the provision of prescribing education, training and support to other healthcare professionals - in particular to medical, nursing and midwifery staff. Pharmacists also contribute to medicines use policies within healthcare organisations (e.g. antibiotic use policies, preferred medicines lists or formulary for use in DHBs and PHOs).

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14 Local agreements covering a variety of situations where local doctors and pharmacist agree that the pharmacist may facilitate the supply of medicines that are either normally available on prescription only or are subsidised only if prescribed by a doctor participating in the local scheme. This could be directed to groups of patients (PGD) or specific patients (PSD).

At the patient level, pharmacists significantly influence the quality of prescribing by reviewing what has been prescribed and providing advice, education and support to the patient. The undergraduate training and preregistration training requirements are designed to ensure that all pharmacists have the ability and skills to work in this manner regardless of their practice setting. The pharmacist exemplars in Appendix 2 illustrate this well.

- **Reviewing medicines therapy of an individual patient**

  While all pharmacists are trained to review a patient’s total medicine therapy, under the current primary healthcare model pharmacists cannot access relevant patient information required for such a review, nor do the current funding arrangements for pharmacy nationally recognise the value of these reviews. Therefore pharmacists do not routinely undertake such a comprehensive medicines review of a patient’s medicine therapy in community pharmacy settings. However medicines therapy reviews are undertaken by hospital pharmacists, pharmacists working in rest homes, hospices and those contracted by PHOs/IPAs to provide these reviews for specified patients.

  Pharmacists who do have access to the patient and their medical records obtain a patient history and often interview individual patients or their care givers and/or other health professional to obtain a history of medicines and other therapies, if necessary. Pharmacists are able to review the medicine therapy of individual patients by interpreting their medical history and medicine records; checking the dosages and methods of administration for each medicine, assessing the effectiveness of the total medicine therapy taking into account efficacy and patient factors that may affect outcomes. They play an active role in identifying adverse drug reactions and reporting these. Following such a review, the pharmacist identifies and recommends necessary changes to medicines (e.g. contraindications, interactions, incompatibilities, best practice guidelines); recommends the optimal medicine, dose form and method of administration suitable; and on request monitors the medicine therapy of individual patients. Pharmacists maintain patient records, update patient information and document the outcomes of the review including the clinical decisions and recommendations made. Pharmacists discuss and communicate their recommendations to the prescribers (mostly doctors, but can include others e.g. midwives, nurse practitioners, optometrists, dentists) who are responsible for the implementation of the recommendations made. The recommendations are also discussed with the patient. The time it takes to implement recommendations depends on a number of factors including the availability of the prescriber and/or, in the case of primary care, the next scheduled appointment with the patient. Currently pharmacists cannot implement these recommendations as they do not yet have the authority to prescribe.

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• Provision of advice and information to patients on their prescribed medicines

Pharmacists currently contribute to the quality use of the medicine prescribed by:
- Ensuring that the right patient receives/has the correct medicine
- Ascertaining the patient’s understanding of the medicine
- Providing information and advice about the medicine to the patient
- Demonstrating the correct method of administering medicines where applicable (e.g. inhaler, eye drops)
- Checking the patient’s understanding of the advice and information provided and, on request, informing and advising the patient about their condition.

Any changes required on the prescription to optimise the use of the prescribed medicine with respect to dosage, device type, quantity or formulation requires approval from the original prescriber.

Pharmacists in non-prescribing roles already have the skills required to play a key role in the optimal use of medicines at the patient level. Published literature supports the influence of pharmacists in improving the quality of prescribing, resulting in optimal use of medicines and medicines related health outcomes.17

• Reducing prescribing errors

Medication errors are one of the most prevalent forms of medical error, and prescribing errors are the most important source of medication errors.18 Poor prescribing is probably the most common cause of preventable medication errors in hospitals, and many of these events involve junior doctors who have recently graduated. Prescribing is a complex skill that depends on sound knowledge of medicines, an understanding of the principles of clinical pharmacology, the ability to make judgments concerning risks and benefits and, ideally, experience.19 It is therefore not surprising that errors occur.


A recently published systematic review looking at the prevalence, incidence and nature of prescribing errors in hospital inpatients reported that prescribing errors were a common occurrence, affecting 7% of medication orders, 2% of patient days and 50% of hospital admissions. The limitations of the study included variability in the reporting rates of prescribing errors due to variations in the definition of an error; the methods used to collect error data; and the setting of the study. The authors indicated further research would be required to address the wide disparity of these variables. Nonetheless it can be concluded that prescribing errors are a common occurrence and have significant implications for patient safety and utilisation of healthcare resources.

Barber et al (footnote 18) comment that “Pharmacists often intervene to prevent prescribing errors and, increasingly, write discharge prescriptions for the less than adequately trained junior doctors and yet they have not been legally able to prescribe.”

A study showed that hospital pharmacists detect errors in around 1.5% of prescription items written and in a 550 bed hospital which can generate 10,000 prescription items a week, 150 prescribing errors would occur over the period. Statistical regression modeling showed that the experience of the pharmacists, and the time they spend on the ward, are two significant predictors of an increased error detection rate with the type of ward being the only other predictor. A great majority of the prescription interventions a pharmacist makes are in relation to prescribing errors such as incorrect dosage, incorrect medicine, drug-drug interactions, inappropriate compliance, adverse effects, duplicate therapy, and inappropriate dosage formulation etc. These interventions can occur at the time of reviewing a medicines therapy of a patient or when prescriptions are presented for dispensing.

In December 2009 the UK General Medical Council published research showing that nearly 1 in 10 hospital prescriptions contains an error. In response to this research the Royal Pharmaceutical Society of Great Britain released the following statement: “This research will be of no surprise to pharmacists and highlights the vital role they play in ensuring patient safety. Pharmacists spot and correct prescribing errors on a daily basis. Medicines are becoming increasingly complex, and the average number prescribed to patients is increasing. It’s difficult for doctors to keep up with all the new developments, which makes the inclusion of the pharmacist in the clinical team even more important. Pharmacists should be directly involved in prescribing decisions, rather than acting as a safety net and detecting errors after the prescription has been written.”

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21 Study cited in reference 18

22 http://www.gmc-uk.org/about/research/research_commissioned_4.asp
Pharmacists are already playing a key role in improving the quality of prescribing by preventing and reducing prescribing errors. The Council’s proposed scope envisages that the independent prescribing roles of pharmacists would provide a more proactive approach to the prevention and reduction of prescribing errors, resulting in improved patient safety, optimal use of medicines and medicines related health outcomes for patients and a reduction in medicines related morbidities including medicines related hospital admissions and readmissions.

It must be noted that a pharmacist who dispenses the medicines prescribed by a Pharmacist Prescriber will continue to undertake the tasks described above.

7.1.4 Can pharmacists in independent prescribing roles further enhance the quality of prescribing?

The accounts above provide the context for Council’s application for an independent prescribing authority for pharmacists registered in the Pharmacist Prescriber scope of practice. Council’s proposal builds on the existing knowledge, skills and practice of a pharmacist, making it apparent that an independent prescribing authority would be a natural and logical extension of their practice.

The following extract from Barber et al (footnote 18) provides a practical picture of the Council’s Pharmacist Prescriber scope of practice proposal:

Prescribing will change. Medicines offer so much help, can deliver so much harm, and are the most expensive element in health care, after staff costs. Medicines are too important for the status quo to continue – we will have to work differently. The role of the doctor will change. The doctor instead of deciding what should be done and delivering it her/himself, will define the ethos and the ends of treatment, and use others to deliver them. The diagnosis and the direction of treatment will be agreed between the doctor and the patient, and then handed over to others, generally pharmacists, to choose the best medicine and dose in response to its effects on the patient. The routine, technical/pharmacological tasks in prescribing will, in the way of all developing technologies, be taken over by specialists such as the pharmacist, and by improved technology. The doctor will still require skills for the solution of the more difficult problems in prescribing particularly in hospitals, but not for routine prescribing. Pharmacists and nurses who prescribe for patients will work more in therapeutic partnership with the patient – agreeing the end point of knowledge and using their knowledge of medicines to deliver it.”

As mentioned earlier, pharmacists eligible to register in the Pharmacist Prescriber scope of practice will be those who are already an active part of the decision making process with respect to initiating or changing a patient’s medicine where his/her decisions and recommendations can directly affect the individual patient’s medicine therapy. These pharmacists are already making a significant contribution in influencing the quality of prescribing and ensuring that prescribing decisions result in the optimal use of medicines and medicines related health outcomes for the patient. For these pharmacists the ability to prescribe will add to
the clinical tools they already hold and would be a natural extension to their practice. More importantly they would be able to further enhance the quality of prescribing by ensuring that the patient receives optimal medicines related health outcomes in a timely and effective manner.  

7.1.5 What evidence is there to support this?

In addition to the exemplars in Appendix 2 which illustrate how patients in New Zealand could benefit from pharmacists in independent prescribing roles, there is mounting evidence internationally of patient benefits, organisational benefits and improved efficiencies in the healthcare system resulting from the independent prescribing role of pharmacists.

The results of a study evaluating nurse and pharmacist independent prescribers (ENIP) in the UK is due to be published soon, and there is a growing body of evidence showing examples of the impact and patient benefits of utilising non-medical prescribers (including pharmacists) in clinical care pathways. These examples are summarised in the Table 1.

<table>
<thead>
<tr>
<th>TABLE 1</th>
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<tbody>
<tr>
<td><strong>Care Pathway</strong></td>
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<tr>
<td>Staying Healthy</td>
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<td>Planned Care</td>
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<tr>
<th><strong>Long Term Conditions</strong></th>
<th><strong>Difficile</strong>, and reduce length of stay.</th>
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<tbody>
<tr>
<td>Nutrition nurses and pharmacists as prescribers</td>
<td>▶ Take responsibility for Total Parenteral Nutrition and fluid support, and will also prescribe prophylactic treatments.</td>
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<tr>
<th><strong>Stroke</strong></th>
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<tbody>
<tr>
<td>Pharmacists prescribing within a stroke team, initiate treatment and support admission and discharge processes on a stroke unit</td>
<td>▶ Faster access to treatment so that medication can commence immediately following diagnosis, in line with NICE guidance.</td>
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<tr>
<th><strong>Diabetic, Respiratory, Dermatology, Rheumatology</strong></th>
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<tbody>
<tr>
<td>Practice nurses and pharmacist prescribing for diabetes services, hypertension and hyperlipidaemia</td>
<td>▶ Reduce GP waiting times, improve patient access to services, increase prescription review and reduce drug wastage. All patients are monitored in line with the national diabetes guidance.</td>
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<tr>
<th><strong>Nurse and Pharmacist Prescribers for renal patients</strong></th>
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<tbody>
<tr>
<td></td>
<td>▶ Reduce doctor’s hours to meet EWTD (European Working Time Directive), identify medication errors, and save costs by reducing drug wastage.</td>
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<tr>
<th><strong>Cardiovascular</strong></th>
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<tbody>
<tr>
<td>Community heart failure nurse or pharmacist specialists</td>
<td>▶ Initiate and titrate medication, provide faster access to treatment, reducing consultant input and readmission to hospital.</td>
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<tr>
<th><strong>Pharmacist Prescribers in cardiovascular or heart failure clinics</strong></th>
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<tbody>
<tr>
<td></td>
<td>▶ Optimise treatment to increase quality of life, improve QOF (Quality and Outcomes Framework) target achievement and reduce admissions. ▶ Locality reinvestment of freed up resources has paid for additional pharmacist time to run medication reviews and hypertension clinics using their prescribing skills.</td>
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<tr>
<th><strong>Pain Management</strong></th>
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<tbody>
<tr>
<td>Community chronic pain services include Pharmacist Prescribers</td>
<td>▶ This improves the quality of care by optimising medication management more quickly and avoiding use of a pain management consultant or further GP time.</td>
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<th><strong>Other</strong></th>
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<tr>
<td></td>
<td>▶ Allow consultants, senior registrars or GPs</td>
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<tr>
<th><strong>Pharmacist-led clinics monitor treatment for stable patients with long term conditions e.g. anticoagulant and cardiovascular clinics</strong></th>
<th>to concentrate on unstable and complex patients.</th>
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</thead>
<tbody>
<tr>
<td><strong>Pharmacist Prescribers in HIV clinics</strong></td>
<td>► Increase service capacity and allow medical staff to focus on newly diagnosed, acutely unwell or unstable patients who require more intensive input.</td>
</tr>
<tr>
<td><strong>Intermediate care nurse practitioners and Pharmacist Prescribers (acute or PCT-led) offer a one-stop clinic</strong></td>
<td>► Reduce doctors’ hours to meet EWTD, adhere to local and national guidance, identify medication errors and save drug wastage costs.</td>
</tr>
</tbody>
</table>
| **Acute Care** | **A&E nurse and Pharmacist Prescribers**

► Increase the throughput for treating minor illness cases to improve four hour waiting targets, and can discharge patients. Both allow doctors to concentrate on more complex cases. |
| **Nurse practitioners and pharmacists involved in unscheduled care** | ► Prevent unnecessary hospital admission through work in nursing homes, palliative care and out-of-hours services. |
| **Mental Health** | **Nurse and Pharmacist Prescribers in nursing homes and mental health services**

► Optimise prescribing and reduce drug wastage. |
| **Pharmacist Prescribers in a personality disorder unit rationalise prescribing in agreement with the GP, psychiatrist and patient** | ► Allow implementation of a care plan supporting the patient to optimize or withdraw medication. |
| **Nurse and Pharmacist Prescribers in drug dependence** | ► Ensure accurate titration of maintenance doses, timely reviews and individualised detoxification regimes. |
| **End of Life** | **A pharmacist chemotherapy consent clinic**

► Avoid drug wastage which saves costs, and prevents drug errors. This helps to reduce the time to diagnosis and treatment, and meet targets within the NHS Cancer Plan. |
The examples above provide evidence of patient benefits, organisational benefits and efficiencies in healthcare systems resulting from pharmacists in independent prescribing roles. This evidence mirrors the opportunities and possibilities of the proposed scope identified by the key health sector leaders in New Zealand at the Council hosted meeting in November 2009. The full report of this meeting is attached in Appendix 4.

The following are the views and feedback from key stakeholders regarding the opportunities and possibilities of the proposed scope of practice for New Zealand.

Opportunities and possibilities related to improved healthcare outcomes for patients

- Enhancement of inpatient care – timeliness (quality of care)
- Increased access for patients – education
- Transfer of monitoring
- Working with rural GPs – improves access for rural patients to collaborative healthcare
- Improves access – e.g. in facilities with limited GP medicines input
- Another level of patient care, focused on medicines
- Increase patient choice
- Increased access to care
- Prescribing closer to point of care – ensures continuity – quicker
- Better sooner, more convenient healthcare
- Potentially avoid hospitalisations
- High needs/meeting inequalities – Māori health needs
- Reducing risk across the primary/secondary interface (50% of medication related errors occur here)
- Possible improved health outcomes “ultimate aim”
Opportunities and possibilities related to improving efficiencies of the healthcare system

- Improved process
- Targeted access
- Niche practice is an opportunity
- Targeted specialist e.g. x number train in cardiovascular disease
- More efficient
- Clearly defined safe distribution (supply) and quality use of medicines (clinical)
- Timeliness of interventions
- Different model of care
- Better quality of care
- Pharmacist led clinics – access /improved healthcare outcomes
- Take care out of hospitals
- Improved interaction between primary and secondary care
- Addresses workforce issues
- Economies on use of medicines (e.g. cessation of therapy when no longer required)
- Greater focus on quality use of medicines

Opportunities and possibilities related to improving collaboration and professional strengths

- Ongoing education between health professionals is beneficial
- Learning opportunities for multi-disciplinary team
- Improving collaboration
- Knowledge component input
- Better use of skills
- Increased career satisfaction
- Opportunity for truly collaborative team
- Freedom for pharmacists to adjust current regime
- Promulgation of clinical pharmacology
- Pharmacist Prescriber takes responsibility for their recommendation
- Elevate pharmacy profession - reactive to proactive input
- Advancement of Pharmacy as a career
7.1.6 Contribution of Pharmacist Prescribers towards achieving National Health Objectives and Priorities

In addition, pharmacists in independent prescribing roles practising in a collaborative health team environment have the potential to contribute significantly towards the following population health objectives of the New Zealand Health Strategy:

- reduce smoking
- improve nutrition
- increase the level of physical activity
- minimise harm caused by alcohol, illicit and other drug use to both individuals and the community
- reduce the incidence and impact of cancer
- reduce the incidence and impact of cardiovascular disease
- reduce the incidence and impact of diabetes
- improve the health status of people with severe mental illness
- ensure access to appropriate child health care services including well child and family health care, and immunisation.

Pharmacists in these roles can be utilised to contribute towards the following priority objectives to reduce health inequalities of the New Zealand Health Strategy:

- Ensure accessible and appropriate services for people from lower socioeconomic groups.
- Ensure accessible and appropriate services for Māori.
- Ensure accessible and appropriate services for Pacific peoples.
Depending on the practice environment there is a potential for Pharmacist Prescribers to contribute towards achieving the objectives of the following *health and disability strategies* in New Zealand:

- He Korowai Oranga: Māori Health Strategy (November 2002)
- Health of Older People Strategy (April 2002)
- Medicines New Zealand Strategy (Dec 2007) and Actioning Medicines New Zealand
- National Drug Policy (March 2007)
- New Zealand Cancer Control Strategy (August 2003)
- New Zealand Health Information Strategy (August 2005)
- New Zealand Palliative Care Strategy
- Pacific Health and Disability Action Plan
- Primary Health Care Strategy (February 2001)

### 7.2 Communal harm

The Council acknowledges that in the absence of adequate patient safety and system and regulatory controls, adding to the pool of existing prescribers has the potential to result in individual and communal patient harm.

The influence of pharmacists on the quality of prescribing has been described earlier and there is evidence that the involvement of pharmacists in the optimal use of medicines can result in communal benefits rather than harm. For example, pharmacists in hospital settings review antibiotic therapy, choice, duration and route of administration on a regular basis which contributes towards minimising antibiotic resistance.\(^{26}\)\(^{27}\)

The possible communal harm resulting from the prescribing of medicines with a potential for abuse and misuse is also a valid patient safety concern. The Council’s mandate is to ensure patient safety and Council would not support any prescribing proposal that contributed to the abuse and misuse of medicines. The Council is confident that the risks of communal harm


\(^{27}\) Bond C.A and Raehl; C.L., Clinical and economic outcomes of pharmacist-managed antimicrobial prophylaxis in surgical patients, *Am J Health-Syst Pharm*. 2007;64(18):1935-1942
resulting from the wider use of medicines with a potential for misuse and abuse are mitigated by requiring the collaborative health team to determine the medicines a Pharmacist Prescriber can prescribe. In addition, the Council’s registration requirements ask for a submission of a practice plan which includes a description of the independent prescribing role of the pharmacist signed off by the clinical leader or equivalent.

Council firmly believes that the same controls (e.g. through Medicines Control, Microbiology for antibiotic resistance patterns) used to monitor communal harm resulting from the prescribing of other prescribers must be applied to Pharmacist Prescribers.

7.3 Relationships with other providers and systems for communication with other providers

Section 3 of the application sets out the components of the collaborative health team environment within which pharmacists in independent prescribing roles will be practising. Combined with the knowledge, skills and attributes of pharmacists, the Council is confident that Pharmacist Prescribers in such an environment will not further fragment patient care but have the potential to minimise any fragmentation by strengthening the continuum of care for patients across the range of healthcare providers.

The pharmacist will hold independent prescribing authority in a collaborative health team environment. This environment must have the following components of collaboration:

- The patient is the focus and beneficiary of the collaboration, and members of the patient’s healthcare team (doctors, nurses, specialists, midwives, dietitians) cooperate in sharing patient information. This includes diagnosis, test results, medication history, treatment plans and progress notes etc and enables the pharmacist to make informed decisions about the patient’s treatment and care.

- The pharmacist is an established and integral member of a multidisciplinary healthcare team.

- The pharmacist plays an active part in the decision making process with respect to initiating or changing a patient’s medicine and his/her decisions and recommendations directly affect the individual patient’s medicine therapy.

- The pharmacist holds mutual concern for the well being of the patient; is aware of, contributes to and shares the treatment goals set by the team and the patient, and has the unique skills and knowledge to allow him/her to contribute equally to achieve these.

- The pharmacist has direct and up-to-date access to relevant and proportionate information about a patient’s medical history and medicines.
• The pharmacist does not need to seek a separate patient consent in order to gain direct access to the patient’s medical records.

• The pharmacist ensures that he/she has all relevant information needed for prescribing decisions.

• The pharmacist communicates prescribing decisions to other healthcare professionals caring for the same patient and updates the patient’s relevant medical record in a timely manner.

The Council is confident that such an environment will mitigate risks relating to relationships with other providers and systems for communication with other providers. In fact, one of the opportunities of this scope, as identified at the key stakeholders meeting, is the potential to improve collaboration and professional strengths.

The exemplars in Appendix 2 and profiles of Pharmacist Prescribers in the UK in Appendix 5 both outline the nature of the management of relationships and communication of decisions.

**Economic Evaluation**

The application process asks the Council to provide comment on the implications of the independent prescribing role of a pharmacist for the pharmacy and diagnostics budget; implications for remuneration; and compliance costs including safe handling procedures and data management.

**7.4 Implications for the pharmacy and diagnostics budget**

There is a significant volume of published literature that supports the positive clinical and economic outcomes of non-prescribing pharmacist-managed medicines therapy in hospitals.\(^{28}\) More recently, similar evidence has been found for pharmacist-managed medicines therapy in the primary care setting.\(^{29}\)

In these studies, the evidence already strongly suggests that involving non-prescribing pharmacists in managing medicines therapy, results in a significantly positive effect on clinical outcomes (as impacts the patient) and economic outcomes (as impacts the funders). Therefore it would be reasonable to assume that the extension of prescribing rights to this group of health professionals could potentially result in a more positive impact on clinical and economic outcomes. This certainly has been shown to be the case in some of the examples in Table 1.

\(^{28}\) Refers to footnote 26 and 27

The implication on the pharmacy and diagnostics budget, although difficult to quantify, will be apparent, provided accurate evaluation and monitoring mechanisms are in place. It is highly likely that pharmacists in independent prescribing roles will increase the reviewing and monitoring of individual patient’s medicine therapy which could be associated with an increase /decrease in pharmacy costs in the short term. Any increases in cost however could be offset by cost savings from prevention/reduction of a medicine related admission, (e.g. by preventing a drug-drug or drug-disease interaction), or from a reduced length of hospital stay, (e.g. patient warfarinised adequately leading to earlier discharge).

As mentioned earlier, Pharmacist Prescribers will not be the primary diagnostician and therefore the impact on the diagnostics budget is expected to be minimal. Pharmacist Prescribers will however be able to order investigations including laboratory and related tests for the purposes of assessing and monitoring the patient’s response to medicine therapy. Again while this may have an impact on diagnostic budgets, the costs incurred could be offset by preventing/reducing medicines related admissions, reducing length of stay in hospitals and improving the quality of life of patients by optimising their medicines related health outcomes.

7.5 Implications for remuneration

7.5.1 Cost of training

There will be training costs involved for pharmacists wishing to register as a Pharmacist Prescriber. An undergraduate qualification requires investment in a 4 year degree and a one year internship. Under the current proposal it would take a prospective pharmacy student a further 4 years of post graduate study before they could be in an independent prescribing role. A post graduate diploma consists of 120 points of which 30 points (one paper) will be the prescribing practicum. This will have implications for remuneration as the years of training required are a significant undertaking on the part of the pharmacist. Council would anticipate remuneration mechanisms and cost savings made by pharmacists in independent prescribing roles would be reinvested into the continuing professional development of Pharmacist Prescribers.
7.5.2 Remuneration for Pharmacists

Remuneration currently for pharmacists varies, depending on experience, level of responsibility and where in New Zealand they work. For example, a charge pharmacist running a pharmacy and managing staff can expect to earn more than a staff pharmacist with no managerial responsibilities. Pharmacies in rural areas that have difficulty recruiting pharmacists may offer larger salaries.

- Interns (pharmacists who are completing their year of work experience after graduation) earn between $29,500 and $35,500 a year.
- Newly qualified pharmacists usually earn $50,000 or more.
- Experienced pharmacists can earn up to $80,000.
- Locums (pharmacists who fill in for full-time pharmacists when they are away) earn between $30 and $40 an hour.

Source: The Pharmacy Guild of New Zealand.

According to the 2006 Census, pharmacists earned an average of $49,300 a year and worked an average of 35 hours per week. This includes full and part-time workers.

This information is provided as a guide only

While Council cannot quantify a figure for remuneration the following advertisement gives an idea of what is offered internationally for pharmacists in prescribing roles.

A recent publication of the UK Pharmaceutical Journal advertised a position for a Specialist Clinical Pharmacist Band 8A (in Oncology/Haematology, NHS Tayside) and offered an annual salary range of £38,851 - £46,621 (sterling pounds). Band 8A is the level at which would pharmacists in independent prescribing roles are expected to be in. The position also had the opportunity to develop a non-medical prescribing role as an independent prescriber, with full financial and academic support provided.

Taking into consideration the variation in currency exchange rates, this UK remuneration figure gives an approximate salary range in NZD of $75,000 - $98,500 for a pharmacist in this role.

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http://www.careers.govt.nz/default.aspx?id0=60103&id1=J80381

The Pharmaceutical Journal, August 2010 (Vol 285), page 172
7.6 Compliance costs

The following are the anticipated compliance costs for a pharmacist seeking registration as a Pharmacist Prescriber.

7.6.1 Training Costs

Most pharmacists pursuing registration as a Pharmacist Prescriber are likely to complete the post graduate diploma level qualification on a part-time basis over 2 years. It is likely that they would be in full time employment whilst completing the qualification. While the course fees will be set by the University the Council strongly believes that there needs to be a mechanism to support the funding and training of Pharmacist Prescribers to sustain the benefits of the proposed scope. Unlike the nursing and medical profession, pharmacists have not been recipients of any funding from the Government for their ongoing continuing professional development of post graduate training. In the absence of external funding and support for training costs, pharmacists will be expected to pay for the cost of the training.

There will also be a cost associated with any recognition or prior learning and assessment processes put in place.

7.6.2 Registration Costs

The current annual cost of a practising certificate in the Pharmacist scope of practice is $506 (incl. GST). While Council has not yet set the registration fees of this scope it is likely to be similar if not more than the registration fees for the Pharmacist scope of practice. The registration fees will be determined by the operational costs put in place to assess and administer registration processes required for the scope of practice.

7.6.3 Recertification Costs

Costs are likely where mandatory participation in recertification programmes relevant to the scope of practice is required. The current recertification programme costs to pharmacists are determined by the provider of the recertification programme.

7.6.4 Safe Handling Procedures and Data Management

Council is unclear as to what costs these are referring to in the application form. Pharmacist Prescribers will generally continue to work in their current area/location of practice and will have prescribing authority as an additional tool to utilise for the purpose of optimising medicines use and medicines related health outcomes for patients. They will utilise existing data management systems to contribute to clinical records and document their prescribing decisions. Depending on the practice area some additional training may be required in safe handling procedures e.g. chemotherapy outpatient clinics, HIV outpatient clinics, Hepatitis B clinics.
SECTION 8 COMPETENCIES AND EDUCATION

In determining the competencies, additional education and training requirement for Pharmacist Prescribers due consideration and recognition has been given to the pharmacy undergraduate degree course; preregistration requirements as well the context and scope of the prescribing activity that will be carried out by the Pharmacist Prescriber. Please also refer to the relevant sections of the consultation document in appendix 1 which provides a detailed background.

8.1 Undergraduate Pharmacy Training

The detailed information on the undergraduate degree course can be found in the background to the consultation document (appendix 1). In summary it can be stated that the current undergraduate Bachelor of Pharmacy (BPharm) programmes offered by the Schools of Pharmacy at Otago and Auckland universities provide pharmacy students with an excellent and extensive foundation in pharmacology, pharmacodynamics, pharmacokinetics, therapeutics, pharmaceutical sciences and social aspects of pharmacy. For example the fourth (final) year students at both Schools of Pharmacy undertake several integrated pharmcotherapeutic module as described below. Both of these degrees hold full accreditation with the Australian Pharmacy Council (APC).

8.1.1 Description of an Integrated Module

These modules in the fourth year consists of a comprehensive two-week module in each of the core therapeutic areas (e.g. respiratory, cardiovascular, endocrine, renal, dermatology, infectious diseases, cancer/palliative disease, neurology, psychiatry, care of the elderly and paediatrics). Each module is structured and consists of:

- an introductory overview lecture which includes clinical and pharmaceutical aspects;
- self assessment questions which are largely for revision;
- work-up of clinical cases;
- a pharmaceutical care plan workshop which consists of presentations and critique of care plans for individual clinical cases;
- dispensing and pharmaceutical lab which would consist of dispensing medicines and counselling for the same clinical cases;
- patient-oriented lecture given by patients or patient advocates and
- a summary interactive lecture usually given by a medical consultant and an exit test.

At the completion of the degree, students have a high level of knowledge and skills in the selection and use of medicines to prevent or treat illness, relieve symptoms, or assist in the diagnosis of disease.

A full course prescription for the BPharm undergraduate degree is available from the University of Otago and Auckland websites; [http://pharmacy.otago.ac.nz/](http://pharmacy.otago.ac.nz/) and [http://www.fmhs.auckland.ac.nz/sop/](http://www.fmhs.auckland.ac.nz/sop/) respectively.
8.2 Intern Pharmacist Scope of Practice

The training of a pharmacist continues after graduation with a BPharm degree. The Pharmacy Council of New Zealand has a separate Intern Pharmacist scope of practice and registration in this scope is required before a BPharm graduate can commence the internship year under the supervision of a trained and approved registered practising pharmacist. Internships are mostly undertaken in community and hospital pharmacies with some provisions being available for split-site internships. The internship year allows for further development and consolidation of the intern pharmacist’s skills in optimising the use of medicines through supervised practice, experience and completing the training and assessment requirements of an accredited Intern Training Programme (ITP). The Intern Pharmacist scope of practice describes all the services which every intern pharmacist must demonstrate competence in prior to registration as a Pharmacist.  

An intern pharmacist is invited to register in the Pharmacist scope of practice once they meet competence, as assessed by the Pharmacy Council in all seven (7) competence areas detailed in Table 2.

### TABLE 2  Competence Standards for the Pharmacist scope of practice

<table>
<thead>
<tr>
<th>Competence Standard</th>
<th>Functional Area Description</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>1 Practise Pharmacy in a Professional and Culturally Competent Manner</strong></td>
<td>This standard outlines these responsibilities which apply to all pharmacists, regardless of their pharmacy practice. Cultural competence is the ability to interact respectfully and effectively with persons from a background that is different from one’s own. It goes beyond an awareness of or sensitivity to another culture to include the ability to use that knowledge in cross-cultural situations, and includes the development and implementation of processes, procedures and practices that support the delivery of culturally competent (appropriate) services. Clinical competence, as expected of a pharmacist, is the application of knowledge and skills to ensure the safe and quality use of medicines to optimise health outcomes. Ethical conduct, as described in the Pharmacy Council Code of</td>
</tr>
</tbody>
</table>

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| 2 Contribute to the Quality Use of Medicines | Ethics, is the expression of those principles and values that underpin the pharmacy profession. | This competence standard covers the role of the pharmacist in promoting the quality use of medicines within an environment of professional pharmaceutical care. The Pharmacist’s role includes selecting, recommending, monitoring and evaluating medicine therapy as part of a health care team. Rational medicine use refers to the evidence-based selection, monitoring and evaluation of medicine therapy in order to optimise health outcomes. |
| 3 Provide Primary Health Care | This competence standard concerns the role of the pharmacist in encouraging and assisting people to take responsibility for their own health. Primary health incorporates holistic care of patients including attention to lifestyle, diet, health promotion, illness prevention, referral and the supply of non-prescription medicines, therapies, diagnostic and therapeutic aids. This involves the pharmacist in treatment, referral and education. |
| 4 Apply Management and Organisation Skills | This competence standard covers the organisation and management skills common to all pharmacists. It encompasses the ability to deal with contingencies in the workplace as well as routine work. |
| 5 Research and Provide Information | This competence standard covers the role of the pharmacist in providing health-related information to other health professionals, patients and the public. The pharmacist’s role includes finding, interpreting, evaluating, compiling, summarising, generating and disseminating information, for the purpose of optimising medicine related health outcomes. The research component of this standard applies to both applied and practice-based research covering medicines and all areas within pharmacy and health. This includes science, social, cultural, economic and management factors in the health field. |
| 6 Dispense Medicines | This competence standard covers the supply of Prescription Medicines and Pharmacist Only Medicines, including extemporaneously compounded products. The dispensing process includes all actions and responsibilities of the pharmacist from |
8.3 Prescribing Competency Framework for Pharmacist Prescribers

The Council has developed a prescribing competency framework to align with the Pharmacist Prescriber’s scope and context of practice. The competency framework reflects that prescribing is more than putting “pen to paper” i.e. not just an administrative task of generating a prescription. In fact the generation of a prescription is often part of the final steps in the prescribing process. The prescribing process is complex and is underpinned by knowledge, experience, and a commitment to continuing professional development which includes reflection and feedback. In the case of the Council’s proposal the independent prescribing role of a Pharmacist Prescriber must be within a collaborative health team environment as described previously. The prescribing competency framework has been informed in this way and this is conceptualised by the model below.

Pharmacy Council of New Zealand Pharmacist Prescriber Competency Model

Four Components of Prescribing - Ian Coombes, PhD Thesis 2008, University of Queensland, Australia

Underpinned by experience and knowledge base (initial) and ongoing competence through reflection and feedback

Practice supported by a Collaborative Health Team Environment
The four components of prescribing described by Coombes is described in the following way:

<table>
<thead>
<tr>
<th>Four Components of Prescribing</th>
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<tbody>
<tr>
<td><strong>Four Components of Prescribing</strong></td>
<td>(Coombes ID, 2008 PhD thesis, University of Queensland)</td>
</tr>
<tr>
<td>1) <strong>Information gathering</strong></td>
<td>2) <strong>Clinical decision making</strong></td>
</tr>
<tr>
<td>• Medication history, ADRs, medicine taking behaviour, adherence</td>
<td>• Diagnosis</td>
</tr>
<tr>
<td>• Presenting complaints, history of presenting complaint</td>
<td>• Consider ideal therapy</td>
</tr>
<tr>
<td>• Current problems</td>
<td>• Balance risks and benefits of drug-drug, drug-patient, drug-disease actual/potential problems</td>
</tr>
<tr>
<td>• Relevant signs symptoms</td>
<td>• Consider economical/availability of therapeutic options</td>
</tr>
<tr>
<td>• Pathology results</td>
<td>• Select drug, form, route, dose, frequency, duration</td>
</tr>
<tr>
<td>• Guidelines, protocols, pathways</td>
<td></td>
</tr>
</tbody>
</table>

3) **Communicate decision as an instruction to: (generate order)**
- Other medical staff/prescribers to continue and monitor (including discharge)
- Nursing staff to administer or supply
- Pharmacy staff to review and dispense or arrange supply

4) **Monitor and review:**
- Review control of signs and symptoms
- Review adherence
- Review patients outcomes
- Consider need for therapy to be tailored to patient, continued or ceased
- Reflection by prescriber and peer feedback

Council’s approach and recognition of the prescribing process in this way has resulted in a prescribing competency framework for Pharmacist Prescribers that would appear to be more robust and explicit in the competencies required compared to the competency frameworks for other prescribers in New Zealand. Of notable interest to the Council is the absence of a requirement to demonstrate competence against specific prescribing competencies for the current authorised prescribers (medical practitioners, dentists and registered midwives) prior to their registration.

The proposed competency framework is attached as Appendix 6. The framework has been based on, adapted and certain sections reproduced with kind permission from the UK National Prescribing Centre (NPC) Maintaining Competency in Prescribing – an outline framework to help Pharmacist Prescribers (second edition Oct 2006).
8.3.1 Purpose of the Competency Framework

- Ensure that Pharmacist Prescribers possess all relevant competencies to undertake prescribing in their scopes of practice

- Assist in the development of education and training and development of pharmacists e.g. inform development of initial curriculum; assist providers in identifying learning outcomes; use as a self-assessment tool to evaluate their own level of competency; assist employers and Pharmacist Prescribers to identify ongoing training and development needs

- Assist the individual Pharmacist Prescriber to facilitate their CPD e.g. a tool for Pharmacist Prescribers to use to assess their own prescribing practice.

8.3.2 The structure of the prescribing competency framework

The competency framework consists of EIGHT competence standards. These standards are grouped into three areas, with three or two competencies in each area.

Figure 1 illustrates the basic structure of the competency framework.

- The three areas of competency in the framework are:
  - The Consultation – consisting of three competence standards
  - Prescribing Effectively – consisting of three competence standards
  - Prescribing in Context – consisting of two competence standards

- The framework therefore consists of EIGHT competence standards.

- Each of the EIGHT competence standards
  - is described as PP 1 - PP 8 where PP is an acronym for Pharmacist Prescriber
  - has an overarching statement which gives an overview of the competence standard and the expectations of the Pharmacist Prescriber
  - has a number of elements e.g. PP 1.1 which consists of a number of statements e.g. PP 1.1.1 which describes the activities Pharmacist Prescribers will be demonstrating both in initial training and in their practice on an ongoing basis. Some include evidence examples to give an indication of how competency could be demonstrated for these activities
Figure 1

Basic Structure of the Competency Framework

THE CONSULTATION (competency area)

1. Demonstrate clinical and pharmaceutical knowledge
2. Establish options for the patient
3. Communicate with patients

PP 2
Establish Options for the Patient

Overarching Statement
This competence standard describes the ability of the pharmacist prescriber to understand a diagnosis, undertake patient assessments, generate treatment options for the patient and follow up effectiveness of agreed treatment options.

Elements

PP 2.1 Undertake patient assessment
PP 2.2 Generate treatment options
PP 2.3 Monitor treatment and make necessary changes to treatment plan

PRESCRIBING EFFECTIVELY (competency area)

4. Prescribe safely
5. Prescribe professionally
6. Maintain quality of prescribing practice

PRESCRIBING IN CONTEXT (competency area)

7. Work within the context of the New Zealand Healthcare System
8. Work in collaboration – the collaborative health team environment and individual context
8.4 Curriculum

The Prescribing Competency framework has been used to inform the qualification curriculum of Pharmacist Prescribers. The curriculum outline including the indicative content is part of Appendix 7. The curriculum has been based on, adapted and certain sections reproduced with kind permission from the Royal Pharmaceutical Society publication of *Appendix C Outline curriculum for programmes to prepare Pharmacist Prescriber part of The Accreditation of pharmacist independent prescribing course Manual (2nd edn, an 2009, revised Apr 2009)*

In particular the curriculum recognises

- The undergraduate training of pharmacists does provide for an excellent and extensive foundation in pharmacology, pharmacodynamics, pharmacokinetics, therapeutics, pharmaceutical sciences and social aspects of pharmacy.
- The undergraduate training of pharmacists does provide a foundation level of experience in diagnostic and clinical decision making and patient assessment skills.
- In the majority of prescribing decisions made by Pharmacist Prescribers it will be to continue and modify therapy.
- The Pharmacist Prescriber will not be the primary diagnostician but will need to have acquired the necessary diagnostic and clinical reasoning and assessment skills to assess the patients more from the sense of whether the patient requires treatment to be modified or continued.
- There will be some instances when a Pharmacist Prescriber will initiate therapy but that they will have the diagnostic, clinical decision making and patient assessment and monitoring skills required to do this in the context of optimising medicines related health outcomes within the confines of a confirmed diagnosis and a collaborative health team environment (refer to the exemplars in Appendix 2).
- The diagnostic, clinical decision making and patient assessment skills is to be an integral part of the qualification and that pharmacists will be taught these skills by the appropriate medical and nursing colleagues (as in the UK).
- A prescribing practicum (i.e. period of learning in practice) under the supervision of a designated medical practitioner (DMP) is required to provide opportunities for the application and assessment of a Pharmacist Prescriber’s competence in diagnostic, clinical decision making and patient assessment skills and application of clinical pharmacotherapeutic concepts to prescribing.

8.4.1 Learning Outcomes of the Curriculum

Following successful completion of the qualification, Pharmacist Prescribers will be able to:

1. optimise medicines related health outcomes for individual patients in a collaborative health team environment (as defined earlier)
2. understand the responsibilities that the role of Pharmacist Prescriber entails, be aware of their own limitations and work within the limits of their professional competence – knowing when and how to refer / consult / seek guidance from another member of the interprofessional health care team

3. develop and maintain effective relationships, and communicate effectively, with patients, carers, other prescribers and members of the inter-professional health care team

4. describe the pathophysiology of the condition being treated and recognise the signs and symptoms of illness, take an accurate history and carry out a relevant clinical assessment where necessary

5. use common diagnostic aids e.g. stethoscope, sphygmomanometer

6. able to use diagnostic aids relevant to area of practice in which the pharmacist intends to prescribe, including monitoring response to therapy

7. apply clinical assessment skills to:
   - inform a working/confirmed diagnosis
   - formulate a treatment plan
   - the prescribing of one or more medicines if appropriate
   - conduct a checking process to ensure patient safety.
   - monitor response to therapy, review the working/differential diagnosis and modify treatment or refer / consult / seek guidance as appropriate

8. demonstrate a shared approach to decision making by assessing patients' needs for medicines, taking account of their wishes and values and those of their carers when making prescribing decisions

9. identify and assess sources of information, advice and decision support and demonstrate how they will use them in patient care taking into account evidence based practice and national/local guidelines where they exist.

10. recognise, evaluate and respond to influences on prescribing practice at individual, local and national levels

11. prescribe safely, appropriately and with cost awareness

12. work within a prescribing partnership

13. maintain accurate, effective and timely records of the consultation and ensure that other prescribers and members of the interprofessional healthcare team are appropriately informed

14. demonstrate an understanding of the public health issues related to medicines use

15. demonstrate an understanding of the legal, ethical and professional framework for accountability and responsibility in relation to prescribing

16. work within clinical governance frameworks that include audit of prescribing practice and personal development

17. participate regularly in continuing professional development (CPD) and maintain a record of their CPD activity
8.5 Prescribed Qualification for the Pharmacist Prescriber scope of practice

To achieve the depth of knowledge, skills, attributes and clinical experience required articulated in the curriculum the Pharmacy Council has determined that a University based Post Graduate Diploma level qualification in pharmacy will be required as the prescribed qualification for registration in the Pharmacist Prescriber scope of practice. The qualification must have a competence basis.

8.5.1 Essential Components of the Diploma

The diploma will be equivalent to 1200hrs of study and include 300hrs dedicated to the prescribing practicum (i.e. a period of learning in practice) leaving 900hrs of study dedicated to delivering the other components of the curriculum.

8.5.2 Essential Components of the Prescribing Practicum

The prescribing practicum must allow for 20 x 7.5 hr days (i.e. 150 hours out of the 300hours) under the supervision of a Designated Medical Practitioner (DMP) in the intended collaborative health team environment of a Pharmacist Prescriber’s practice.

8.5.3 Accreditation of the Qualification

Both the Otago and Auckland University Schools of Pharmacy have expressed an interest in providing the post graduate diploma level qualification including the prescribing practicum. The accreditation and monitoring of the undergraduate programmes of both schools is carried out by the Accreditation Committee of the Australian Pharmacy Council (APC). The Pharmacy Council of New Zealand is a voting member of the APC and is also represented on the Accreditation Committee of the APC.

In accordance with s12 (2a) and (4) of the HPCAA 2003 the Council will accredit and monitor qualification(s) against the Council developed Accreditation Standards for the Prescribed Qualification: Pharmacist Prescriber Scope of Practice.

A copy of the accreditation standards is attached as appendix 7.
8.6 Education, Training and Registration Pathway for Future Pharmacist Prescribers

Figure 2 presents the education, training and registration pathway for future Pharmacist Prescribers. The Council is confident that an education and training pathway that spans over a minimum of 8 years will contribute significantly towards the governance and safeguards necessary for pharmacists to hold an independent prescribing role in the New Zealand healthcare system.

**FIGURE 2**
8.7 Education, Training and Registration of Pharmacist Prescribers under the Recognition of Prior Learning and Experience (RPLE) Pathway

Feedback from Council’s consultation on the scope strongly indicated a need for an education and training pathway that recognised the prior learning and experience of pharmacists practising in a collaborative health team environment who wish to pursue registration in the Pharmacist Prescriber scope of practice. This cohort of pharmacists are typically holders of (or pharmacists in the process of completing) a post graduate Diploma or Masters level qualification in clinical pharmacy, and these people have post registration experience in the vicinity of 5-10 years and are practising in collaborative health team environments in areas of specialty or general practice.

Separate but possible cohorts of pharmacists also in this group are those who have been trained, registered and have practised as independent prescribers outside of New Zealand. These pharmacists would predominantly come to New Zealand from the UK, Canada and the USA. They would still have to meet the registration requirements of the Pharmacist scope of practice before they can be considered for registration in the Pharmacist Prescriber scope of practice.

It is implicit that Council offers an alternative education and training pathway to these groups of pharmacists which recognise their prior learning and experience in the context of the Pharmacist Prescriber scope of practice. The pathway is likely to be a University based portfolio assessment offered through the Otago and Auckland University Schools of Pharmacy.

The assessment process will recognise the prior learning and experience of the pharmacist, identify the gaps and offer an abbreviated form of the proposed qualification. At a minimum the Council will require these pharmacists to undertake selected parts of the qualification to address the identified gaps, meet the legal and ethical competencies of the course, as well as undertake the prescribing practicum component of the qualification and any summative assessments prescribed.
SECTION 9 ONGOING COMPETENCE AND MONITORING

9.1 Registration Requirements

The Council has determined the following registration requirements for a Pharmacist Prescriber. An applicant must satisfy all the requirements before they can be registered in the scope of practice of a Pharmacist Prescriber.

**To register as a Pharmacist Prescriber, the pharmacist:**

- **a.** must hold an Annual Practising Certificate in the Pharmacist scope of practice;
- **b.** declare that competence standards 1, 2, 4 and 5 (from the Pharmacist scope of practice) forms part of their current practice;
- **c.** must have at least three (3) years of recent, appropriate and relevant post registration experience working in a collaborative health team environment
- **d.** must have completed a Council accredited course of education and training; and
- **e.** must have evidence to identify and support that their prescribing practice occurs in a collaborative health team environment

Each of the above requirements is explained below and also includes changes in response to the feedback received from the consultation.

9.1.1 Requirement a) must hold an Annual Practising Certificate in the Pharmacist scope of practice

A pharmacist is registered and is on the practising register of the Pharmacy Council of New Zealand. This indicates that they are competent and fit to practise in the Pharmacist scope of practice and they hold a current annual practising certificate.

9.1.2 Requirement b) declare that competence standards 1, 2, 4 and 5 (from the Pharmacist scope of practice) forms part of their current practice

A declaration that these standards from the Pharmacist scope of practice forms part of their current practice will be required. This is a minimum requirement. The competence standards are described below:

**Competence Standard 1**

**Practise Pharmacy in a Professional and Culturally Competent Manner**

This standard outlines these responsibilities which apply to all pharmacists, regardless of their pharmacy practice.

Cultural competence is the ability to interact respectfully and effectively with persons from a
background that is different from one’s own. It goes beyond an awareness of or sensitivity to another culture to include the ability to use that knowledge in cross-cultural situations, and includes the development and implementation of processes, procedures and practices that support the delivery of culturally competent (appropriate) services.

Clinical competence, as expected of a pharmacist, is the application of knowledge and skills to ensure the safe and quality use of medicines to optimise health outcomes.

Ethical conduct, as described in the Pharmacy Council Code of Ethics, is the expression of those principles and values that underpin the pharmacy profession.

Competence Standard 2
Contribute to the Quality Use of Medicines

This competence standard covers the role of the pharmacist in promoting the quality use of medicines within an environment of professional pharmaceutical care. The Pharmacist’s role includes selecting, recommending, monitoring and evaluating medicine therapy as part of a health care team. Rational medicine use refers to the evidence-based selection, monitoring and evaluation of medicine therapy in order to optimise health outcomes.

Competence Standard 4
Apply Management and Organisation Skills

This competence standard covers the organisation and management skills common to all pharmacists. It encompasses the ability to deal with contingencies in the workplace as well as routine work.

Competence Standard 5
Research and Provide Information

This competence standard covers the role of the pharmacist in providing health-related information to other health professionals, patients and the public. The pharmacist’s role includes finding, interpreting, evaluating, compiling, summarising, generating and disseminating information, for the purpose of optimising medicine related health outcomes.

The research component of this standard applies to both applied and practice-based research covering medicines and all areas within pharmacy and health. This includes science, social, cultural, economic and management factors in the health field.
9.1.3 Requirement c) must have at least three (3) years of recent, appropriate and relevant post registration experience working in a collaborative health team environment

Council’s intent for this requirement is to give paramount importance to recent, lengthy and pertinent experience in the area in which the pharmacist would be practising as a Pharmacist Prescriber. Based on the feedback from the submissions Council has revised this requirement to ensure the intent is clear.

9.1.4 Requirement d) must have completed a Council accredited course of education and training

This requirement is to ensure that a pharmacist has completed the education and training requirements of the qualification prescribed and ensure that only qualification(s) accredited by the Council (against its prescribed accreditation standards) will be the recognised course of education and training.

9.1.5 Requirement e) must have evidence to identify and support that their prescribing practice occurs in a collaborative health team environment

This requirement is to ensure that the Pharmacist Prescriber would continue to practise in a collaborative health team environment after registration in the scope.

Council received several requests from respondents asking to clarify what this evidence is and how this will be assessed and determined. The Council acknowledges the concerns expressed and welcomes the useful suggestions made to clarify this requirement. Council has responded to these requests in the following manner:

- Council proposes that the Pharmacist Prescriber must provide as part of this evidence an agreed “practice plan” which is endorsed by the clinical leader of the collaborative health team.
  a) The practice plan should provide information on the scope of practice, type of patients and areas of prescribing expected from the Pharmacist Prescriber.
  b) The practice plan should document the nature of access to patient health information. This access should be direct and immediately available to the pharmacist and they should not need to request access.
  c) The patient health information should include history and physical examination and essential diagnostics.
  d) The practice plan could also include evaluation and peer review plans for assuring the quality of prescribing and self-reviews.
A further issue raised in relation to this requirement was to define what mechanisms Council will put in place to manage the Pharmacist Prescribers when their collaborative health team environments change. To this Council has responded in the following manner:

- Council shares the potential patient safety concerns brought about when a Pharmacist Prescriber moves and/or has changes made to their current collaborative health team environment.
- Currently pharmacist’s can move practice environments within the Annual Practising Certificate (APC) year, without notifying Council, but are required to undertake a ‘practice review’ if they do so. A practice review is a reflection exercise against the competence standards and it identifies the areas where further learning is required and is declared at the time of APC renewal. There are additional recertification requirements for pharmacists who move practice environments.
- Council is confident that this concern can be addressed through a similar recertification mechanism and APC renewal process offered under the HPCAA 2003.
- Council envisages developing guidance for Pharmacist Prescribers who move or have changes made to their collaborative health team environment within the APC year.
- Further to this, part 3 of the HPCAA also offers mechanisms relating to the competence and fitness to practise concerns for pharmacists.
- The Council is confident that these already available mechanisms will mitigate risks to patient safety concerns expressed.
- In view of these concerns expressed from respondents Council would like to draw attention that regulatory authorities of other prescribers do not have a requirement for practitioners to notify them when changing practice environments with respect to their prescribing practice. For example a dentist, doctor or a midwife can provide locum services between primary and secondary environments without having to notify their regulatory authority. This assumes an element of professional judgment required on the part of the practitioner who has the responsibility to always practise within their competence.

9.2 Public Register

As is currently available for the Intern and Pharmacist scopes of practice, a public register of pharmacists registered in the scope of practice of a Pharmacist Prescriber will be available.

Currently the following pharmacist information is available on public register:

- Name of Pharmacist
- District
- Qualification for Registration
- Scope of Practice
- Practising Certificate (issue and expiry date)
o Conditions on practice

Pharmacist Prescribers will be issued with an annual practising certificate in the scope of practice of a Pharmacist Prescriber. This can be displayed or noted by the employer and this information will be available online.

9.3 Auditing/Monitoring of Individual Pharmacist Prescribers (Recertification Proposal)

Please also refer to Appendix 1 for background to this determination.

Council will utilise the recertification mechanism available under the HPCAA to set, audit and monitor the ongoing competence requirements of individual Pharmacist Prescribers.

Participation in continuing professional development (CPD) is mandatory and recertification requirements are based on the CPD undertaken.

CPD for prescribers nationally and internationally recognises that prescribing is an inherent part of their practice and therefore does not require specific mandatory CPD activities for prescribing activity only. Therefore in line with international and national practice Council proposes that: Pharmacist Prescribers must meet the mandatory recertification requirements for the Pharmacist Scope of practice and undertake their CPD according to Council (to be) developed guidelines. These guidelines will require CPD to reflect their practice as prescribers. They would be expected to use the prescribing competency framework to identify their ongoing CPD learning needs. In developing these guidelines Council will look at other models for prescribers in New Zealand to assess ongoing competency e.g. nursing, medical.

The guidelines will direct that CPD activities of Pharmacist Prescribers must be multidisciplinary and include a combination of clinical audits, peer reviews and a learning portfolio.
9.4 Reaccreditation/Recertification

To further inform the above processes the Council proposes an annual recertification audit of Pharmacist Prescribers.

In addition the Council may also require an updated practice plan of the Pharmacist Prescriber at APC renewal (developed like a portfolio) if this is deemed necessary.

The Council may also recognise a credentialing system conducted by employer organisations such as DHBs and PHOs.

9.5 Disciplinary procedures/complaints

The HPCAA allows for a number of referral points for a complaint or notification and a variety of processes that the complaint or notification may follow.

The Council’s decision-making with regards to complaints or notifications received is viewed in the context of the entire HPCAA process. The HPCAA separates competence and fitness to practise from discipline and penalties imposed. It is the role of the Council to deal with competence and fitness to practise and it is the role of Health Practitioners Disciplinary Tribunal (HPDT) to deal with discipline and penalties. Any time a complaint or a notification involves a consumer the Council is obliged to forward it to the Health and Disability Commissioner. If the Commissioner decides that a complaint raises issues about a pharmacist’s competence, professional conduct, or his or her fitness to practice then he/she may refer the complaint to the Pharmacy Council.

The Council would handle complaints or notifications regarding Pharmacist Prescribers using the established existing processes in place.

The Council has recently reviewed and revised the Code of Ethics for Pharmacists and intends to issue guidance/obligations based on the principles of this Code relevant to the practice of Pharmacist Prescribers.

9.6 Evidence of independent prescribing review.

Council would look to undertake an independent prescribing review of Pharmacist Prescribers using organisations with ‘neutral’ authority e.g. BPAC\textsuperscript{33} or IPAC\textsuperscript{34}, Medicines Review Committees or equivalent in DHBs and National Prescribing Centre (Australia)

\textsuperscript{33} BPAC – Best Practice Advocacy Centre

\textsuperscript{34} IPAC – Independent Practitioners Association Council
Council would also utilise the protected quality assurance provisions of HPCA Act to review prescribing practice initiatives, both independently and with other interprofessional prescribers.
10.1 Consultation Document

The background section of the consultation document provides the context for the practice of pharmacist’s prescribers in New Zealand and the determinations made by the Council regarding registration in this scope of practice. This is attached as appendix 1 and has been referred to throughout the application.

10.2 Submissions Analysis

A summary of the results of the submissions and the submissions analysis report of the consultation feedback are attached as appendix 8. The report also details who was advised of the consultation and those that responded. Respondents who gave permission to have their comments included in the application are included and can be identified. **Please note that this report is confidential.**

Consumer and Māori groups were offered an additional opportunity to provide feedback on the consultation document after the consultation period closed. These organisations were contacted by phone, sent a cover letter and the consultation documents. A number of them were unable to provide feedback a second time within the allocated time frame. Council believes it has been reasonable in its efforts to obtain feedback from these groups and their inability to respond cannot be taken as lack of consultation with these groups. The list of groups contacted and responses received is attached as appendix 9.

10.3 Council responses to the submissions received

The submissions analysis looked at the feedback received in a number of ways to ensure that Council was able to respond in a meaningful way. The analysis also groups the issues for each of the questions asked in the consultation. Council has considered these issues and responded accordingly and a reference to how the application has been amended to reflect feedback received has been made throughout the relevant sections of the application. Post consultation drafts of the Prescribing Competency Framework (with tracked changes), and Accreditation Standards including the Curriculum reflect the Councils’ response to the submissions received.

The significant changes made to the proposal as a result of the submissions is summarised here:

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35 Published in the Pharmacy Council of New Zealand Newsletter September 2010
10.3.1 Scope of Practice Definition

The independent pharmacist prescribing role cannot occur in a community pharmacy or by a pharmacy owner.

The Council will direct that Pharmacist Prescribers must separate the activities of dispensing and prescribing and not dispense prescriptions written by them.

The Council does not support Pharmacist Prescribers having a vested interest in a pharmacy business – the Pharmacist Prescriber must not have any pecuniary interest associated with the dispensing activity (n.b. *This is also prescribed in the s42C of the Medicines Act 1981*). The Council acknowledges that this stance may effectively exclude pharmacists who own, or are employed, in a community pharmacy from registering in this scope. In making this decision the Council recognises that the greatest impact of this decision is likely to be for pharmacists in rural community pharmacy practice. However the Council is confident that there may be different pathways to enable them to prescribe in the context of their practice e.g. under Standing Orders (like nurses do) or under the proposed collaborative prescribing models as anticipated in the Medicines Amendment Bill in 2011.

The Council has revised the scope definition to reflect this decision.

*Initiation of therapy will be for the purpose of optimising medicines related health outcomes for the patient, the Pharmacist Prescriber will not be the primary diagnostician.*

The Council has included four pharmacist exemplars in the application to illustrate the scope of prescribing activity by Pharmacist Prescribers. The Council has drawn attention to the fact that the diagnostic and physical assessment skills will be an integral part of the post graduate diploma level qualification and that pharmacists will be taught these skills by the appropriate medical and nursing colleagues (as in the UK). The Council reiterates that the initiation of therapy will be for the purpose of optimising medicines related health outcomes for the patient and that the Pharmacist Prescriber will not be the primary diagnostician.

*Strengthening the definition of a collaborative health team environment*

Council has added to this definition to make it more robust and definitive, Section 3 of the application defines the components of this type of environment. The Prescribing Competency Framework and registration requirements have also been amended to reflect this.

*Communication of prescribing decisions and maintenance of clinical records*

Council has addressed issues relating to this by illustrating how pharmacists currently communicate their decisions and recommendations and maintains records; strengthening the definition of a collaborative health team environment and amending the learning outcomes and
assessments in the qualification. Council has also included a range statement to the prescribing competency PP 4.4.1 relating to this.

10.3.2 Changes to proposed exclusions

Section 6 of the application states the changes made to the proposed exclusions in response to the submissions received.

10.3.3 Recognition of Prior Learning and Experience Qualification Pathway

Council has clarified that recognition of prior learning and experience assessment pathway will be offered to eligible pharmacists.

10.3.4 Education and Qualification and Registration Pathway for future Pharmacist Prescribers

Council has considered the wide ranging views on the length of the education and training requirements proposed. It firmly believes that for pharmacists to hold an independent prescribing role the proposed length of training and supervised practice requirements are necessary to protect the health and safety of members of the public. It acknowledges that while in the UK the independent Pharmacist Prescriber course is shorter in duration it is reflective of pharmacy practice in the UK as well as the governmental and organisational support provided to the continuing professional development and role of pharmacists in the NHS.

10.3.5 Clarification of registration requirements

The changes made to these have been referenced in section 9 of the application.
## APPENDICES

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